INTERNATIONAL DEVELOPMENT IN PRACTICE

Comprehensive Diagnostic Tool

Annex to the QI Toolkit

Martin Kellermann

WORLD BANK GROUP

PTB Physikalisch-Technische Bundesanstalt
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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

BIPM	International Bureau of Weights and Measures
CEO	chief executive officer
CGPM	General Conference on Weights and Measures
CIPM	International Committee for Weights and Measures
CMCs	calibration and measurement capabilities
DI	designated institute
EU	European Union
FSC	Forest Stewardship Council
GSP	good standardization practice
HACCP	hazard analysis and critical control points
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
IECEE	IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components
IECEx	IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
IT	information technology
MRA	Mutual Recognition Arrangement (CIPM or IAF)
MSC	Marine Stewardship Council
NAB	national accreditation body
NMI	national metrology institute
NQP	national quality policy
NSB	national standards body
OIML	International Organization of Legal Metrology
QI	quality infrastructure
RAB	regional accreditation body
RIA	regulatory impact assessment
RLMO	regional legal metrology organization
RMO	regional metrology organization
SDO	standards development organization
SI	International System of Units

SMEs	small and medium enterprises
TBT	Agreement on Technical Barriers to Trade (WTO) Agreement
UNECE	United Nations Economic Commission for Europe
WTO	World Trade Organization

1

Comprehensive QI Assessment

1.1 INTRODUCTION

This annex contains the methodology for a comprehensive assessment of a country's quality infrastructure (QI) based on the detailed description thereof in modules 3–8 of *Ensuring Quality to Gain Access to Global Markets: A Reform Toolkit* (henceforth, QI Toolkit). Hence, the comprehensive assessment should not be conducted without having carefully studied modules 3–8 of the QI Toolkit.

Nevertheless, to evaluate the QI of a country with this Comprehensive Diagnostic Tool will require the involvement of knowledgeable experts, the full support of the country to be assessed, and quite a long time—at least a few weeks in the field. The outcome of such an evaluation will be a detailed report on the status and efficacy of the QI of a country (see also module 9, section 9.2, of the QI Toolkit).

The Comprehensive Diagnostic Tool has a companion—the Rapid Diagnostic Tool (see module 9, section 9.1, of the QI Toolkit)—that allows for a much quicker but less detailed assessment of a country's QI. The Rapid Diagnostic Tool can be used for a quick assessment that would enable a better decision to be made regarding the need for a more detailed assessment, which would be much more resource-intensive.

The QI Toolkit, as well as the Rapid Diagnostic Tool, can be downloaded from the World Bank website (http://www.worldbank.org/qi) and the National Metrology Institute of Germany (PTB) website (https://www.ptb.de/qitoolkit).

1.2 COMPREHENSIVE DIAGNOSTIC TOOL

1.2.1 Elements of the Comprehensive Diagnostic Tool

The Comprehensive Diagnostic Tool provides information on the evaluation of the QI in a number of important elements:

- National policy 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 this annex, available on the World Bank website (http://www.worldbank.org/qi), as well as on the PTB website (https://www.ptb.de/qitoolkit).

1.2.2 Approach of the Comprehensive Diagnostic Tool

The Comprehensive Diagnostic Tool follows a specific logic, starting from the policy and legal environment before dealing 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 national quality policy, that clarifies the interdependence between the fundamentals, QI services, technical regulations, and the market. It should also be related to the broader trade or export development policies. Furthermore, the coordination between (a) the fundamentals and QI services, and (b) the technical regulation (the mandatory manifestation of the QI) is provided for in what is generally known as a 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

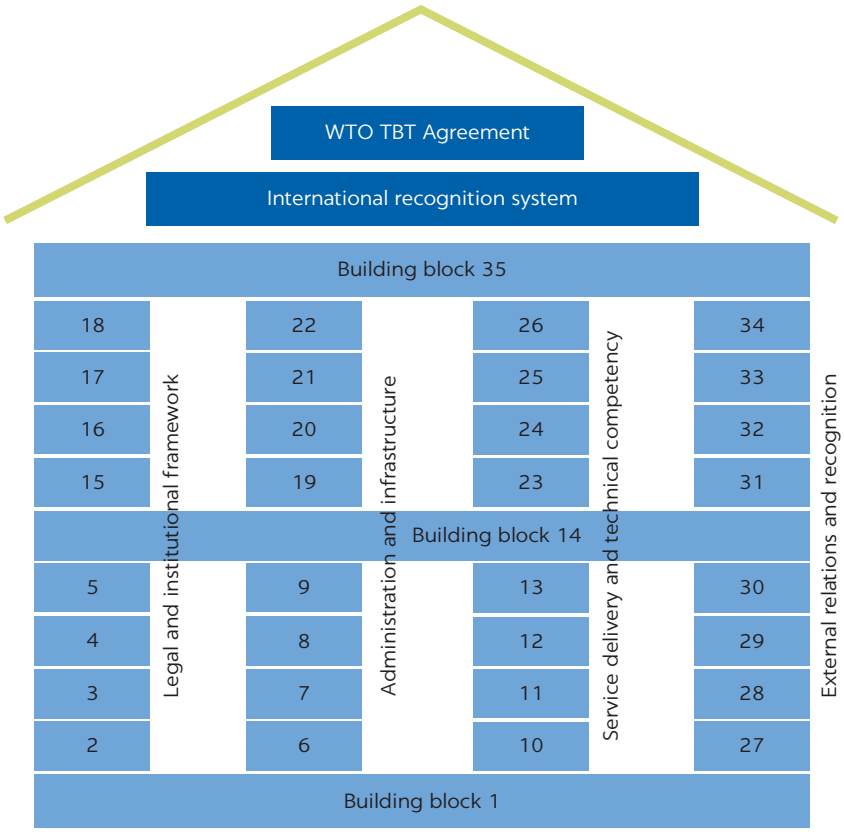
Each of these pillars consists of building blocks that have to be in place for the QI element to function optimally and to comply with international good practices and requirements. Some of the building blocks for each of the QI elements would be similar, but there will also be quite a few differences. Such an approach can be illustrated as being a "building" (figure 1.1).

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

FIGURE 1.1

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.

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 (a) the *basic QI* (relevant for a low- or middle-income country approach); (b) an *advanced QI* (relevant for an economywide approach); or (c) ultimately as a *mature or innovative QI* (relevant for a high-income economy or world-class approach). If there is virtually no QI established, then a *rudimentary* state exists, which is a major challenge for the country irrespective of its development status (see also module 2, section 2.2.2, of the QI Toolkit). The country's development status is not equally relevant for all the QI elements; it is more relevant for those of a more technical nature, such as metrology. 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 that is 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 color-coded "bricks" (figure 1.2), a radar-type diagram (figure 1.3) for the individual elements, or a dashboard illustration for the QI collectively (figure 1.4), supported by extensive narrative.

For each of the building blocks, the comprehensive diagnostic

- Provides details about the best practices against which the building block should be compared, under the heading "What is meant";
- 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

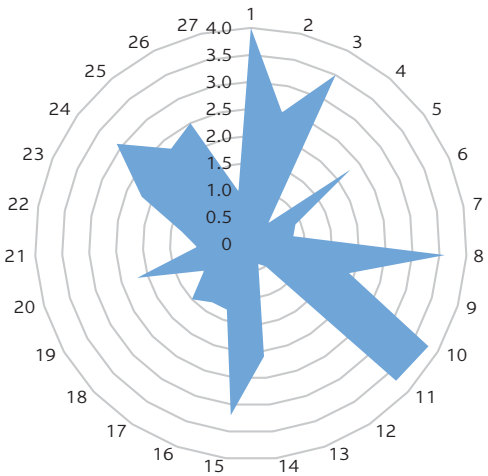
FIGURE 1.2

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.

FIGURE 1.3

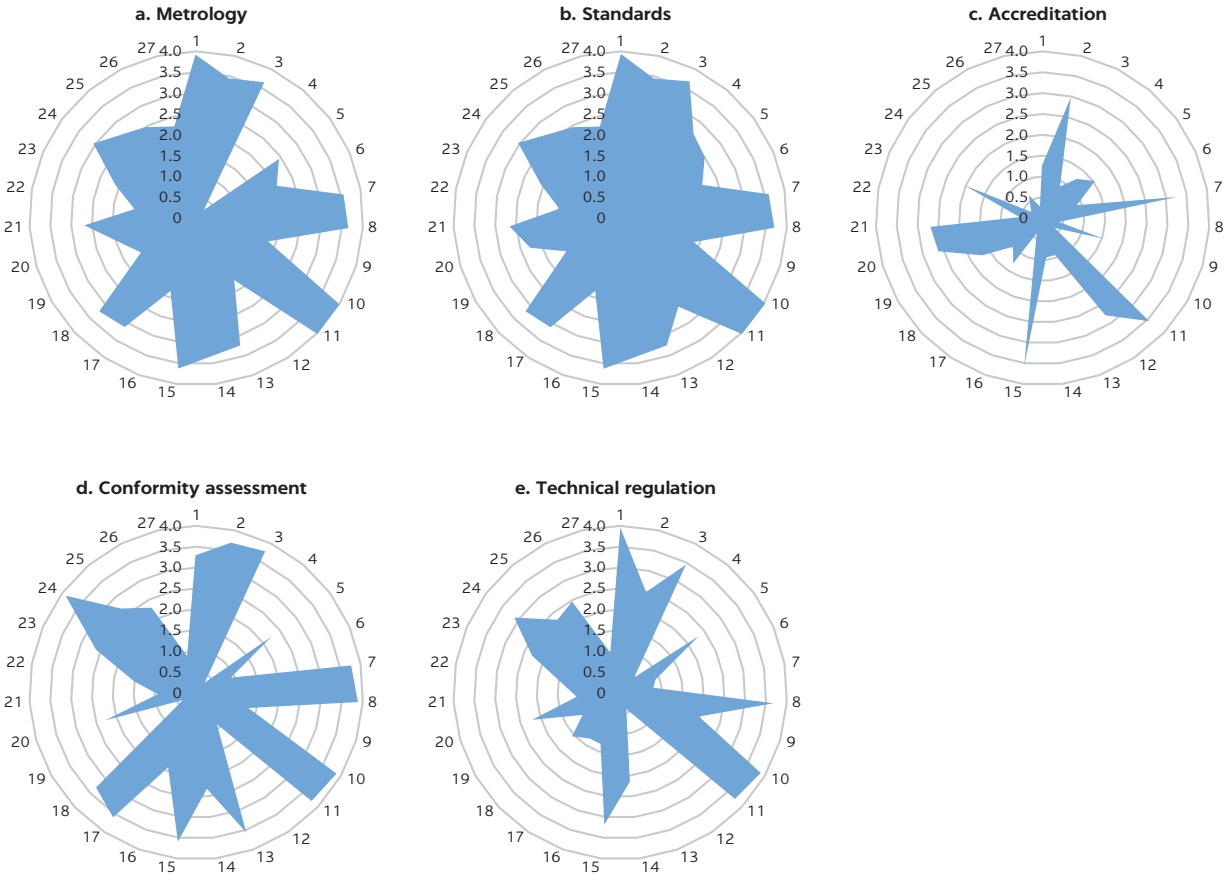
Radar diagram of QI entity's implementation status (conceptual)



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).

FIGURE 1.4

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).

"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.

To depict the "building" (figure 1.2) or construct a radar diagram (figure 1.3), 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 the expert's experience, as well as 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 in module 9, section 9.1, of the QI Toolkit) can provide some guidance in this respect.

Once the percentages are determined, it is fairly easy to construct a radar diagram (figure 1.3). To depict the "building" will take an additional step. The percentages can be grouped into four categories, such as the following:

- *More than 75.1 percent:* Implemented
- *50.1–75 percent:* Mostly implemented

- *25.1–50 percent:* Partially implemented
- *0–25 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 1.2). It helps if the colors are chosen to coincide with a color scheme that can be psychologically understood by the potential readers.

1.3 The need for expert knowledge

The comprehensive evaluation criteria contained in this annex do not negate the necessity of expert knowledge when conducting a comprehensive evaluation of a country's QI. The criteria are, to a large extent, guidelines that endeavor to ensure that all the important issues are included in such an evaluation. It is especially the difference between the country's QI and (a) its compliance with stated or formal criteria; and (b) criteria for competent, effective, and efficient working structures that are important to highlight during such an evaluation. The former can be provided on paper as a checklist to be ticked off, but the latter depends on the judgment, and hence experience, of the evaluator, as well as quantitative evidence. These are not easy to encompass in a publication such as this.

2

National Policy and Legal Environment

Two cross-cutting issues that have a distinct influence on the quality infrastructure (QI) landscape in a country are the policy environment regarding the QI and the technical regulation regime. These are most commonly contained in a national quality policy and a technical regulation framework.

2.1 QUALITY POLICY

2.1.1 Benchmark and significance

The national quality policy (NQP) provides the policy framework, endorsed at the highest political level, of the way in which the country wishes to establish and maintain its QI. The policy has to clearly address the organizational structures, responsibilities, and coordination among the entities of the QI. It should provide guidance regarding governmental responsibilities in relation to those of the private sector. It should provide the connection between other government policies and the need for an effective and efficient QI. For a detailed discussion of quality policy, see module 10 of the QI Toolkit.

2.1.2 Classification, best practices, and implementation strategy

What is meant

Major

A quality policy gives meaning to the establishment and maintenance of a quality infrastructure and generally consists of the following:

- Policy objectives
- The quality infrastructure (QI)
- Education and training
- Role of all the stakeholders
- International and regional liaisons
- Financing the QI
- Legal framework for the QI
- Implementation plan

How can it be demonstrated?

The NQP should be a formal document approved by the cabinet or parliament as relevant for implementation. It should be publicly available—that is, on the relevant ministry website or in hard copy. The activities, business plans, and budgets of the QI entities should be aligned with the NQP to ensure its implementation. The NQP should be accompanied by an implementation plan and a concomitant budget with detailed responsibilities for actions and outcomes.

Existing information/reporting/monitoring

- Relevant ministry (for example, Trade and Industry) website
- QI websites
- Annual reports of the QI entities
- Reports of a coordinating committee responsible for implementation of the NQP

2.2 TECHNICAL REGULATION FRAMEWORK

2.2.1 Benchmark and significance

A technical regulation framework details the way in which a country wishes to implement technical regulations in accordance with the requirements of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement), and in an effective and efficient way that is acceptable to major trading partners. Without such a technical regulation framework, the technical regulation regime as practiced by the various authorities is frequently fragmented, gaps and overlaps in responsibilities abound, compliance with the WTO TBT Agreement is debatable, the efficacy of technical regulations is suboptimal, the transaction costs for suppliers are high, and unnecessary, restrictive trade measures are commonplace. For a detailed discussion of the technical regulation framework, see module 7, section 7.9.3, of the QI Toolkit.

2.2.2 Classification, best practices, and implementation strategy

What is meant

Major	A technical regulation framework provides definitive guidance to all authorities that are developing and implementing technical regulations to ensure a common approach throughout that is in full compliance with the WTO TBT Agreement requirements. It generally consists of the following: • Regulatory impact assessment (RIA) • Use of standards in determining technical requirements • Conformity assessment modalities • Technical regulation authorities and their responsibilities • Imposition of sanctions • Coordination mechanisms

How can it be demonstrated?

The technical regulation framework should be a legally enforceable approach (under law, regulation, or decree) approved by the cabinet, parliament, or head of state, as relevant for implementation. It should be publicly available—that is,

on the relevant ministry website or in hard copy. The activities, business plans, and budgets of the regulatory authorities at all levels of government should be aligned with the technical regulation framework to ensure its implementation.

Existing information/reporting/monitoring

- Official list of legislations
- Relevant ministry (for example, Trade and Industry) website
- Annual reports of the regulatory authorities
- Reports of a coordinating office responsible for implementation of the technical regulation framework

3

Standards

3.1 INTRODUCTION

Standardization has a long history. In more recent times, good standardization practices from a free-trade perspective have been codified in the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement) and in the decisions of its Committee on Technical Barriers to Trade (TBT Committee). To provide guidance on the development of international standards, this committee drew up a set of principles: (a) transparency, (b) openness, (c) impartiality and consensus, (d) effectiveness and relevance, (e) coherence, and (f) development dimension (WTO 2000). Organizations, such as the International Organization for Standardization (ISO) have added three more to this mix (ISO 2010): (g) stakeholder engagement, (h) due process, and (i) national implementation.

Although these nine principles were established for international standardization, they are as relevant for regional and national standardization, and they form the basis of good standardization practice (GSP) (see module 3, section 3.4, of the QI Toolkit). Other definitive documents providing guidance on standardization practices are the "ISO/IEC Directives, Parts 1 and 2: Procedures for Technical Work" (ISO 2017) and "ISO/IEC Guide 59: Code of Good Practice for Standardization" (ISO and IEC 1994).

The level of maturity of the country's trade, technical regulation regime, industrial development, and other factors influences the maturity demanded of the national standards body (NSB). A four-level breakdown is shown in table 3.1. These maturity levels have to be taken into consideration when a comprehensive diagnostic evaluation of standardization is conducted, thereby influencing the qualitative and especially the quantitative outcome of the application of the various quality infrastructure (QI) building blocks. The building blocks of the NSB relating to the four pillars are listed in table 3.2.

To depict the pillars and building blocks in a graphical way that would indicate the state of standardization in a country at a glance, they can be put together as shown in figure 3.1. For a complete description of the construction, interpretation, and use of this graphic or of the matching radar diagram, see the earlier discussion in section 1: Comprehensive QI Assessment.

TABLE 3.1 Maturity levels of a country's national standards body, by factor

FACTOR	RUDIMENTARY (LITTLE QI IN PLACE)	BASIC (LOW- TO MIDDLE-INCOME COUNTRY APPROACH)	ADVANCED (ECONOMYWIDE APPROACH, SECTORAL APPROACH)	MATURE (INNOVATIVE, CUTTING-EDGE TECHNOLOGY)
International liaison and membership	None	Correspondent member of ISO Involved in affiliate country program of IEC	Member of ISO Associate member of IEC Member of CAC	Member of ISO and IEC Member of CAC and ITU
National technical committees (TCs)	None	A few TCs for nationally important products and services	A number of TCs for nationally important products and services	A large number of TCs relevant for the country's needs
Mirror committees for international or regional standardization	None	None	A small number for strategically important products and services	A number determined by the strategic importance of the national industry
Participation in international TCs	None	None	A few based on strategically important products or services for the country	A number based on the strategic influence the country wishes to have in international standardization
Standards development organizations (SDOs)	None	None	One or two SDOs, as relevant	Number of SDOs, as relevant
Standards information service	Rudimentary, at government department level	Rudimentary	Fully electronic access to national standards	Fully electronic access and sales for standards
Human resources	No training	Training on the job	Training on the job Training courses for TC chairpersons and secretariats	Training on the job Training courses for TC chairpersons and secretariats
Demand orientation	None	Demand surveys, mostly through projects	Demand surveys Stakeholder participation and consultative mechanism	Strong instruments and constructs to ensure demand orientation

Note: CAC = Codex Alimentarius Commission; IEC = International Electrotechnical Commission; ISO = International Organization for Standardization; ITU = International Telecommunication Union.

TABLE 3.2 Pillars and building blocks of the national standards body

PILLAR	BUILDING BLOCK NO.	BUILDING BLOCK DESCRIPTION
1: Legal and institutional framework	1	Standards strategy
	2	Legal entity
	3	Autonomy
	4	Legal standing of national standards
	5	Governance
	6	Financial sustainability
2: Administration and infrastructure	7	Chief executive officer
	8	Organizational structure • Standards development and editing unit • Standards information unit • Public relations unit
	9	Management and personnel
	10	Premises
	11	Equipment
3: Service delivery and technical competency	12	Standard for a standard[a]
	13	Technical committees
	14	New project approvals and work program

continued

TABLE 3.2 *continued*

PILLAR	BUILDING BLOCK NO.	BUILDING BLOCK DESCRIPTION
	15	Committee process
	16	Relevance of standards
	17	Coherence of standards
	18	Public inquiry
	19	National standards
	20	National adoptions
	21	Standards information
4: External relations and recognition	22	WTO TBT Inquiry Point[b]
	23	Training system
	24	Liaison with international organizations
	25	Liaison with regional organizations
	26	Coordination within the QI
	27	Standards development organizations (SDOs)
	28	Engagement with stakeholders

Note: QI = quality infrastructure.
a. "Standard for a standard" refers to the publication of all formal processes to be followed in the national standards development as a collective "standard for a standard" that is freely available to any interested party and can form the basis for the training of technical committee chairpersons and secretariats (see module 3, section 3.2.3, of the QI Toolkit).
b. The World Trade Organization (WTO) Technical Barriers to Trade (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.

3.2 PILLAR 1: LEGAL AND INSTITUTIONAL FRAMEWORK

3.2.1 Benchmark and significance

The NSB must be an identifiable legal entity operating within an agreed-upon policy framework of the government. That is, the NSB should be recognized by the government as the pinnacle NSB mandated to represent the country in international organizations. Its mandate should include a clear and unambiguous statement regarding the development and publication of the national standards. Without such legal and policy backup, the NSB cannot fulfil its fundamental responsibility, namely, the development and publication of national standards.

Regarding its governance, the NSB should follow a more open and transparent model, with stakeholders having a meaningful influence on strategy, rather than a top-down system controlled by public servants. The latter will stifle innovation and render the NSB less able to serve one of its main stakeholder groups—industry—effectively.

3.2.2 Standards strategy (building block no. 1)

What is meant

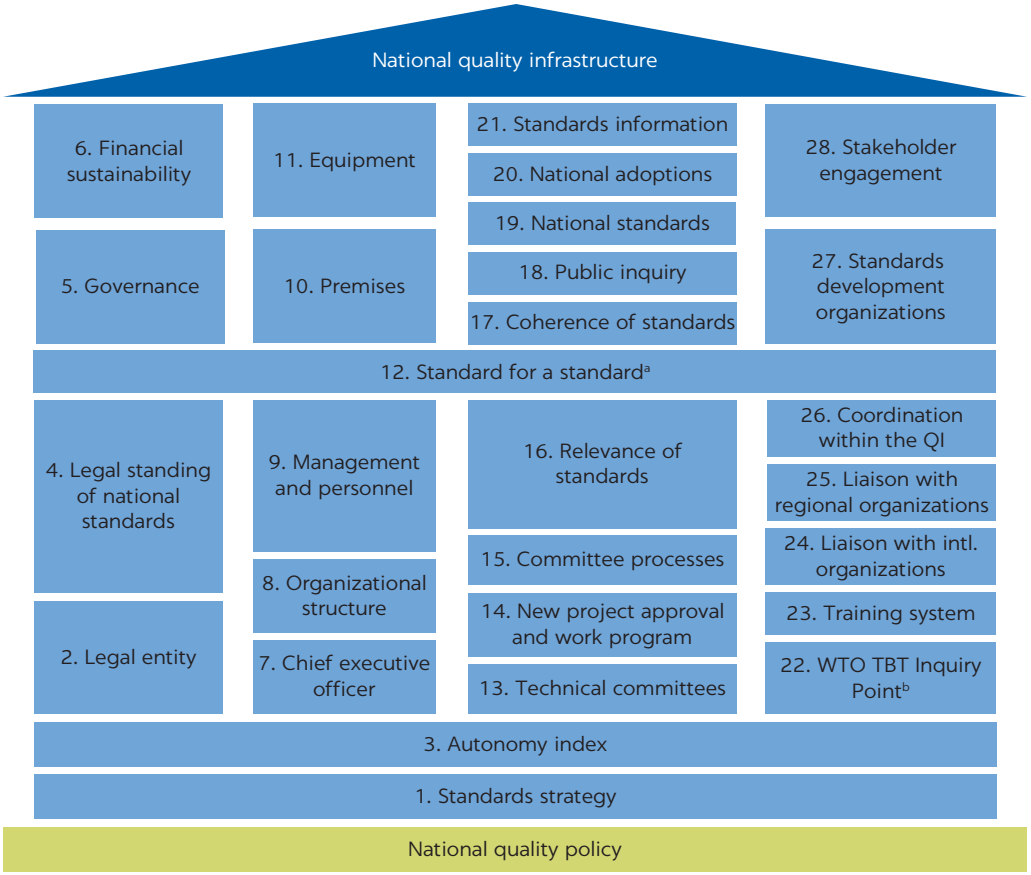
Major

Following on from the quality policy (see subsection 2.1), a standards strategy gives meaning to the implementation of the quality policy regarding standards development, publication, and information.
The standards strategy is about

- Making the right choices regarding the products to offer and the customers to focus on;
- Getting stakeholder support for the NSB; and
- Building capacity in the NSB to fulfill its role in the most innovative, effective, and efficient way.

FIGURE 3.1

House of standardization for a national quality infrastructure



Note: QI = quality infrastructure. The four "pillars" of the QI—represented by the blue columns containing the "building block" numbers—are as follows (left to right): "legal and institutional framework," "administration and infrastructure," "service delivery and technical competency," and "external relations and recognition."
a. "Standard for a standard" refers to the publication of all formal processes to be followed in the national standards development as a collective "standard for a standard" that is freely available to any interested party and can form the basis for the training of technical committee chairpersons and secretariats (see module 3, section 3.2.3, of the QI Toolkit).
b. The World Trade Organization (WTO) Technical Barriers to Trade (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.

How can it be demonstrated?

The standards strategy can be seen as an intended plan to set a pattern, create a unique position, follow a specific perspective, or implement a specific tactic—all to enable the NSB to make a difference to a critical mass of the right customers and to connect its purpose with those of its customers and external stakeholders (Minzberg, Ahlstrand, and Lampel 1998).

The standards strategy should be a formal document approved at least by the NSB board or council, and in some countries even by the minister or cabinet, depending on national custom and practice. It should be publicly available—that is, on the NSB website or in hard copy. The activities, business plans, and budgets of the NSB should be aligned with the standards strategy to ensure its implementation.

Existing information/reporting/monitoring

- NSB board or council papers
- NSB website

- Relevant ministry (for example, Trade and Industry) website
- Annual reports of the NSB

3.2.3 Legal entity (building block no. 2)

What is meant

Fundamental	The NSB shall be a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for its standards development and publication activities. The NSB may be a governmental department, an institution of public law (such as a statutory body), a not-for-profit private company, or a for-profit private company.

How can it be demonstrated?

The NSB shall be established by legislation or articles of incorporation as relevant. Legislation may be a Standards Act or a similar law. Articles of incorporation are required for the NSB to be registered as a private company in terms of company legislation. The legislation or articles of incorporation must define, at a minimum, (a) the NSB's governance, financial provisions, and responsibilities and functions; and (b) the development, publication, and legal standing of national standards (if the NSB is a governmental body). The responsibilities should include representing the country in international standards forums.

If the NSB is a private company, then a formal agreement must exist between the NSB and the government in which the NSB is given the mandate to operate as the NSB, to develop and publish national standards, and to represent the country at the international level regarding standardization. In this case, the legal standing of national standards must additionally be defined in a legally defensible way.

To ensure that the responsibilities and functions of the NSB remain relevant in a changing international and regional standards environment, the legislation or articles of incorporation should be reviewed and modernized every five to eight years. The same applies to the formal agreement between the government and the NSB as a private company. Failure to do so could hinder the NSB in playing its national, regional, or international roles effectively and efficiently in the medium to long term.

Existing information/reporting/monitoring

- Standards Act, decree, regulation, or similar law
- Articles of incorporation as a private company
- NSB's website and annual reports

3.2.4 Autonomy (building block no. 3)

What is meant

Major	It is good practice for an NSB to move toward a market-economy model of increased institutional autonomy, as opposed to being fully controlled by government. This model gives it the management responsibility and freedom to operate effectively in the marketplace (Racine 2011).

How can it be demonstrated?

There are generally nine elements that can be considered to determine a legal autonomy index of the NSB. This is not an absolute number but a good indicator. Does the NSB have the autonomy and the authority to

- Adopt and revoke standards;
- Determine the positions and staffing of its workforce;
- Determine the salaries of its workforce;
- Select its workforce;
- Create new administrative divisions;
- Determine its own budget;
- Determine the fees of standards publications;
- Offer new services or initiate new activities; and
- Solicit membership in international or regional standardization organizations and sign international agreements?

Existing information/reporting/monitoring

- Standards Act, decree, regulation, or similar law
- Articles of incorporation as a private company
- NSB council or board policy papers
- NSB's website and annual reports
- Government regulations regarding rules of employment (if the NSB is a governmental body or a body of public law)

3.2.5 Legal standing of national standards (building block no. 4)

What is meant

Major	National standards can be the basis of technical regulation or can be referenced directly in the same; they can form part of contractual obligations between the purchaser and supplier; and they can be indicators of good practice in court proceedings. Therefore, it is good practice to provide them with authoritative standing within the legal system of the country, even though they are considered to be voluntary in their application in the WTO TBT Agreement context.

How can it be demonstrated?

In the Standards Act or a similar law, national standards are given standing within the legal system of the country, and normative-type documents published by other entities should not enjoy this privilege. In some countries, this means approved national standards have to be listed in the official government journal or gazette at least by number and title. The same applies to revised or withdrawn national standards. Furthermore, regulatory authorities must be given the mandate to reference national standards by number and title in legislation (typically in technical regulations, sanitary and phytosanitary [SPS] measures, and the like) without having to replicate the complete text of the standard. This mandate confers legislative legitimacy on the national standard.

Existing information/reporting/monitoring

- Standards Act, decree, regulation, or similar law
- Formal agreement between the NSB and government
- Official government journal, gazette, or similar publication

3.2.6 Governance (building block no. 5)

What is meant

Fundamental	The NSB should have a board or council in charge of strategy approval and overall fiduciary responsibilities, whether the board or council is appointed by a relevant minister or by shareholders (in the latter case, if the NSB is a private company).

Major	Good governance models suggest that the members of the board or council should be individuals with specific knowledge regarding standardization and market realities.

How can it be demonstrated?

The actual composition of the council or board must be considered. The number of members, as well as the balance between industrialists, academia, and public servants is important. The more-progressive NSBs have more industrialists than public servants on their councils or boards. The industrialists are appointed in their individual capacities and not as representatives of business or industry associations. Lower-level functionaries of business or industrial associations are not the greatest representatives of those associations to include on a council or board.

The members of a council or board, however appointed, should be selected for their knowledge, experience, or qualifications relating to the functions of the NSB, particularly regarding business management, finance, marketing, local and international standardization, and technical infrastructure matters (ISO and UNIDO 2008). The council or board should include 12–15 members. Depending on the custom and practice of the country, good governance principles suggest that the chief executive officer (CEO) of the NSB should be a full member of the council or board. Whatever the case, the CEO should only be an ordinary member of the council or board (that is, he or she is not allowed to hold the position of chair or vice-chair) to ensure proper oversight of the NSB by the council or board.

The council or board should have the mandate or authority to (a) approve the business, standards, and marketing strategies of the NSB; (b) appoint the CEO and consider his or her performance; (c) oversee the financial integrity of the NSB; (d) approve the budget and monitor performance of the NSB against the budget; (e) approve the organizational structure; (f) establish the standards approvals committee; and (g) hear final appeals against approved standards.

Existing information/reporting/monitoring

- Standards Act, decree, regulation, or similar law
- Articles of incorporation as a private company
- NSB council or board policy papers
- NSB's website and annual reports
- Government regulations regarding public entities
- NSB council or board committee structures

3.2.7 Financial sustainability (building block no. 6)

What is meant

Fundamental	The finances for the NSB can be provided from government sources, membership fees, sales of standards and information, financial support from industry and other stakeholders, and profits generated by conformity assessment services (ISO 2010). Whatever the source of funding, there should be assurances that it would be adequate also in the medium to long term.

How can it be demonstrated?

For most NSBs, especially in low- and middle-income countries, sales of standards are nowhere near sufficient to cover the cost of standards development and publication. Therefore, for government-type NSBs (see section 3.2.3), the

bulk of the finances will probably be provided through government budgets. For private sector NSBs, profits from conformity assessment services are frequently the major source of funding. Care should be taken that the provision of finances does not unduly influence the decisions on the development of standards as determined by demand of the broader stakeholders.

The NSB's overall financial situation of the past three to five years would be a good indication of its financial sustainability. The situation should show a positive trend over the years under review. The income generated from standards sales would be a further indicator that should show a positive trend. A formal government commitment to support the NSB in its standards development, publication, and information activities, as well as specific financial support for its international and regional liaison activities, are positive indicators of the NSB's financial sustainability.

Existing information/reporting/monitoring

- National quality policy
- Annual government budget allocations
- Annual reports of the NSB
- Monthly and annual financial statements of the NSB
- Monthly figures for standards sales

3.3 PILLAR 2: ADMINISTRATION AND INFRASTRUCTURE

3.3.1 Benchmark and significance

Form follows function, and the organizational structure of the NSB should be conducive to providing the full complement of standardization services effectively and efficiently according to the needs of its stakeholders. Good governance principles require the NSB to have a proper management executive, and the standards value chain indicates that the NSB should have divisions dedicated to the development of standards; editing and publication of the same; and a standards information service ably supported by the necessary corporate services, such as finance, human resources, training, and facility services. If the NSB also provides conformity assessment services, then the organizational structure should ensure that standards development is independent from other business influences.

3.3.2 Chief executive officer (building block no. 7)

What is meant

Fundamental	The chief executive officer (here referred to as the CEO, whatever the actual title) is responsible for leading the development and execution of the NSB's long-term strategy with a view to fulfilling its reason for existence. The CEO acts as a direct liaison between the board or council and management of the NSB and communicates to the board or council on behalf of NSB management. The public face of the NSB is the CEO rather than the chair of the board or council. The CEO could be a full member of the board or council, depending on the custom and practice of the country; but whatever the case, the CEO should only be an ordinary member of the council or board (that is, he or she is not allowed to hold the position of chair or vice-chair) to ensure proper oversight of the NSB by the council or board.

Minor	Depending on the legislation, custom, and practice relevant to the NSB, the CEO may be appointed by the relevant minister or the board or council. Recent tendencies suggest that the CEO should be appointed for only a limited period, typically five years. He or she can be reappointed if relevant key performance indicators are more than fulfilled.

How can it be demonstrated?

There is no standardized list of an NSB CEO's major functions and responsibilities, but the typical functions include the following:

- Supports operations and administration of the board or council by advising and informing its members, interfacing between the board or council and the staff, and supporting the board or council's evaluation of management executives
- Oversees the design, marketing, promotion, delivery, and quality of programs, products, and services regarding standardization
- Recommends the annual budget for board or council approval and prudently manages the NSB's resources within those budget guidelines according to current laws and regulations
- Effectively manages the human resources of the NSB according to authorized personnel policies and procedures that fully conform with current laws and regulations
- Ensures that the NSB and its mission, programs, products, and services are consistently presented with strong, positive images to relevant stakeholders
- Oversees fundraising planning and implementation, including identifying resource requirements, researching funding sources, and establishing strategies to approach funders

Existing information/reporting/monitoring

- Relevant legislation (Standards Act or similar law) or articles of incorporation
- Official ministerial decisions
- Board or council decisions and minutes
- Official CEO job description
- Agreed-upon CEO key performance indicators

3.3.3 Organizational structure (building block no. 8)

What is meant

Major	The standards value chain has a number of distinct elements: (a) standards development; (b) editing, approval, and publication; and (c) standards information. It therefore follows that the organizational structure of an NSB should have divisions that optimally support this standards value chain.
Major	Furthermore, because standards services are seldom self-sufficient in low- and middle-income countries and have to be funded by government, the organizational structure should facilitate the determination of these finances.
Major	The funding of the development and publication of standards by the state or another stakeholder should not negatively affect the independence of the NSB in making appropriate decisions regarding the choice of standards to be developed in accordance with appropriate demand assessments.

How can it be demonstrated?

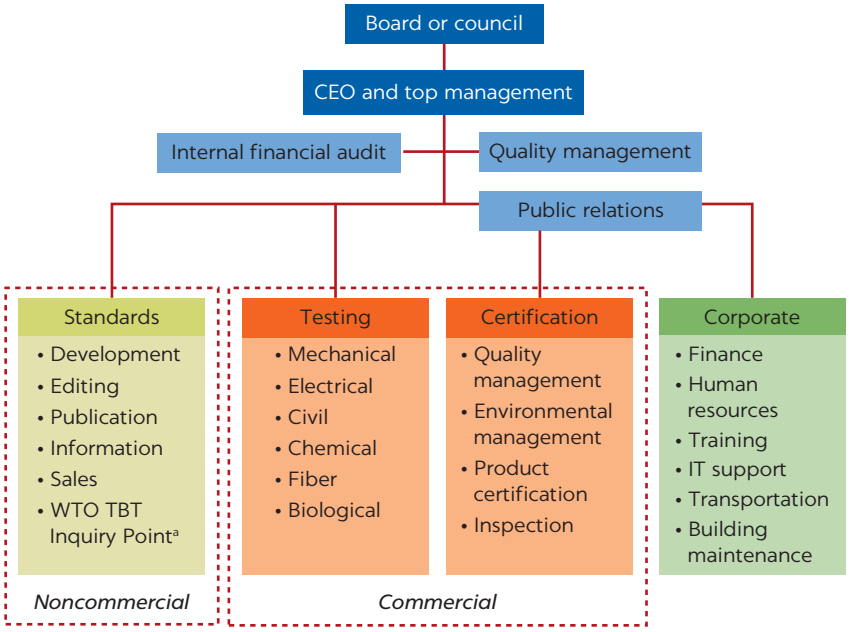
A typical organizational structure of an NSB that also provides conformity assessment services is shown in figure 3.2. This would be the case for the vast majority of ISO members that are low- or middle-income countries. Another possibility could be that the organization serving as the NSB is also the national accreditation body, in which case the conformity assessment departments would be replaced by the necessary accreditation departments. In a few instances, the NSB would only be responsible for the development and publication of national standards, in which case the standards divisions and support divisions would be the only relevant ones.

A clean structure (figure 3.2) will enable clear identification of the finances for the standards activities for the common good, which may have to be funded by government in most low- and middle-income countries. Conformity assessment services that can be considered commercial should be fully paid for by the customers. The corporate services are overhead, and these can be allocated to the other divisions in an equitable manner.

As for the organizational structure within the standards department, it is important that the editing division be completely separated from standards development divisions because editing is the final quality control on the integrity of draft standards before they are approved. Standards development can consist of a number of sectoral divisions, depending on the number of technical committees that have to be managed. In smaller NSBs, standards information, sales, and the WTO TBT Inquiry Point are frequently combined. The inclination to attach the TBT Inquiry Point to the office of the CEO (because it supposedly

FIGURE 3.2

Typical NSB organizational structure in a low- or middle-income country



Note: CEO = chief executive officer; IT = information technology.

a. The World Trade Organization (WTO) Technical Barriers to Trade (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.

deals with high-level foreign entities) is counterproductive; it should remain close to the standards information center.

Existing information/reporting/monitoring

- Approved organizational structure
- Board or council decisions
- Ministerial decisions
- Financial system documentation

3.3.4 Management and personnel (building block no. 9)

What is meant

Major	Standards development, publication, and information are largely people-based activities operating within formal processes supported by an effective information technology (IT) system. Management and personnel must therefore have the appropriate skill sets assured by appropriate training, qualifications, and experience. These would include management and technical knowledge, project management skills, and language proficiency as required by the various activities of the standards value chain.

How can it be demonstrated?

In the first place, the NSB should operate with an organizational structure approved by either the board or council or the relevant minister. For each of the positions, the skill set (qualifications, training, and experience) should be clearly and formally stated. The ratio between technical and administrative staff is a good indicator of efficacy, with administrative staff being no more than 20 percent of the total a good guideline.

Second, there should be few staff vacancies on either the management or technical levels; more than 95 percent of those positions should remain filled. Anything less indicates that the NSB cannot operate effectively or efficiently. Staffing challenges often include a lack of skilled people in the country, but even more so, inadequate remuneration (resulting in the departure of trained staff for more lucrative offers elsewhere).

Existing information/reporting/monitoring

- Approved organizational structure
- Actual staffing levels
- Staff turnover figures

3.3.5 Premises (building block no. 10)

What is meant

Minor	As a premier QI organization, the NSB should occupy premises appropriate to its status, and the premises should facilitate optimum service delivery. The premises should be situated in an area accessible to its customers. Environmental disturbances and challenges should be kept to a minimum.

How can it be demonstrated?

In the first place, the premises of the NSB should create the feeling of professionalism and be inviting; occupying a run-down, dirty government building is not a good idea. In the same vein, the premises should not be so pretentious

that customers get an impression of money spent unnecessarily on wasted space and gimmicks. Access to the premises should be relatively easy; that is, having them in the middle of the city with congested traffic conditions is not a good idea, nor is locating them on the city's outskirts far from everything and everybody. Poor siting will make it difficult for customers to reach the NSB and be a disincentive for members of technical committees to attend meetings.

Over and above the necessary office space for the staff, the premises should have a number of meeting rooms of appropriate size and IT support for holding technical committee meetings. The standards information center should be easily accessible from the main entrance, preferably directly. It should also be given special attention because it is often the first encounter that customers will have with the NSB. As such, it should exude an aura of professionalism and modern design as an information center. It should have ample space for customers to browse through standards, and standards sales should be adjacent to it, making the whole experience of obtaining standards information and purchasing standards a pleasurable one.

Existing information/reporting/monitoring

- Consideration of the NSB premises in relation to design, access, and maintenance
- Review of technical committee meeting rooms and facilities
- Review of the standards information center

3.3.6 Equipment (building block no. 11)

What is meant

Major	The development of standards has become totally reliant on electronic media. The NSB should therefore have a modern IT system and good connectivity to the Internet. Technical committee rooms and the standards information center should be appropriately equipped (for example, with digital projection, monitors, and so on). Staff should have access to computers and a workable intranet system.

How can it be demonstrated?

The Internet connection of the NSB should be of a high quality. Communications between the NSB and its peers elsewhere in the world and with regional and international standards organizations are totally electronic; that is, fast download bit rates and uncapped data are required. Staff members, especially those involved in standards development and information, should have computers linked to an efficient intranet system.

In the standards information center, an adequate number of monitors should be provided on which customers can browse through national, regional, and international standards without NSB staff having to print anything. A print-on-demand system should be available to print the standards that customers wish to purchase while they wait a few minutes.

Existing information/reporting/monitoring

- Consideration of the NSB intranet system and its connectivity to the Internet in relation to access and maintenance
- Review of availability of IT equipment and services to relevant staff
- Review of the standards information center's IT equipment and maintenance

3.4 PILLAR 3: SERVICE DELIVERY AND TECHNICAL COMPETENCY

3.4.1 Benchmark and significance

No international standards have been published that standards bodies can use for evaluating their own competence, as is the case for metrology institutions (for example, in ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories") or for accreditation bodies (for example, in ISO/IEC 17011, "Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies"). Hence, no international peer recognition systems exist for standards bodies as they do for metrology (the International Bureau of Weights and Measures [BIPM] and International Organization of Legal Metrology [OIML]) and for accreditation (the International Laboratory Accreditation Cooperation [ILAC] and International Accreditation Forum [IAF]).

There are, however, internationally agreed-upon principles that form the basis of good standardization practice (GSP) that standards bodies can and must aspire to. GSP includes the methods or techniques that (a) have been generally accepted as superior to any alternatives because they produce results superior to those achieved by other means, and (b) have become a standard way of doing things regarding the development and publication of standards and related information systems.

Six of these principles have been codified in the WTO TBT Agreement and in decisions of its Committee on Technical Barriers to Trade (WTO 2000), as discussed further in module 3, section 3.4, of the QI Toolkit: transparency; openness; impartiality and consensus; effectiveness and relevance; coherence; and development dimension. Organizations, such as the ISO, added three more to this list (ISO 2010): stakeholder engagement, due process, and national implementation.

Although these nine principles were established for international standardization, they are just as relevant for regional and national standardization. Other definitive documents include the ISO/IEC Directives, Parts 1 and 2 (ISO 2017), and "ISO/IEC Guide 59: Code of Good Practice for Standardization" (ISO and IEC 1994). The former guide the international standards development process, but they can likewise be made applicable to regional or national standards bodies.

A few of the high-income economies are "standards makers" at the international level. Low- and middle-income countries, on the other hand, are invariably "standards takers"; that is, they adopt international standards rather than developing indigenous standards from basics. This has a marked influence on the format of their national standards: namely, 80–90 percent of their national standards would be adoptions of international standards. The standards development process should be shaped accordingly.

3.4.2 Standard for a standard (building block no. 12)

What is meant

Major	The standards development and publication process must be open and transparent. The process must be publicly known, and the NSB must abide by it.

How can it be demonstrated?

The best-practice model to make the standards development and publication process publicly known is to develop, approve, and publish a "standard for a standard." This normative document will include the principles for the complete standards development process—from approval of a new work item, the technical committee stages, and public inquiry to the editing, approval, and final publication of the standard, including regular review of the standard over time. It should also include a process to appeal the publication of specific standards. The process must be based on the internationally agreed-upon standards development value chain, as provided for in the ISO/IEC Directives, Parts 1 and 2 (ISO 2017), and as transcribed for the national situation. The "standard for a standard" should be made available free of charge to any interested party.

The "standard for a standard," which primarily contains the principles of the standards development process, must be supported by NSB internal procedures and work instruction-type documents aligned with the "standard for a standard" that guide the activities of the whole standards department. These should be part and parcel of the quality management system operated by the NSB and subject to documentation control—for example, as provided for in ISO 9001 ("Quality Management Systems—Requirements").

Existing information/reporting/monitoring

- Standards catalog
- Quality management system documentation

3.4.3 Technical committees (building block no. 13)

What is meant

Fundamental	Standards are developed by technical committees (including subcommittees and working groups) as established by the NSB, yet they are representative of interested parties coming from the broader stakeholder group of the NSB. Interested parties could include ministries, public authorities, business, industry, consumers, academia, and civil society.
Fundamental	Membership of technical committees should be open to all but should be balanced; that is, no interested party should be able to dominate.

How can it be demonstrated?

When establishing a technical committee, the NSB should map its stakeholders for that committee. Thereafter, the NSB should communicate directly with possible interested parties, inviting them to participate. At the same time, the NSB should publicly announce the same on its website, for example, to ensure that unidentified interested parties can also be reached. The NSB should make a special effort to involve consumer groups and civil society because these stakeholders do not always have the people resources to participate.

The invitation should require the interested party to nominate a specific member and provide contact details. The establishment of the technical committee is approved by the NSB executive management or the board or council, as relevant. The NSB should try to achieve a reasonable balance of interested parties on the technical committee.

The NSB should retain the secretariat of the technical committee because this facilitates project management and compliance with the WTO TBT Agreement requirements to make known the overall work program of standards

development once every six months. It is good practice to select the chair from among the participants, either by the technical committee's participants themselves or by the NSB. The tenure of the chair could be limited (for example, to three to five years) to give the NSB an elegant way to replace the chair if he or she is not performing appropriately.

The scope of each technical committee should be such that it can develop a meaningful number of standards. Where the NSB also participates in international or regional technical committees, it is useful to align the scope of the national committee with that of its regional or international counterpart—that is, establishing it as a "mirror committee." In this way, national positions regarding the regional or international standard can be developed and brought to the attention of the regional or international committee. Such a construct also facilitates the voting process for regional and international standards.

Existing information/reporting/monitoring

- Formal procedures for establishing technical committees
- List of technical committees, their scopes, secretariats, and chairs
- Membership lists of technical committees
- Annual evaluation of the performance of chairs and secretariats

3.4.4 New project approval and work program (building block no. 14)

What is meant

Major	Requests for the development of a new standard could come from many sources. The NSB must evaluate the request for relevance and add it to its work program, if appropriate and if resources are available.
Fundamental	The work program must be made known publicly every six months in a manner compliant with WTO TBT Agreement requirements.

How can it be demonstrated?

The NSB should follow a formal procedure for evaluating requests for the development of a standard. This process should be ongoing, not conducted only once a year or every six months. The procedure should include elements, such as the following:

- Determination of the standard's net value to the country
- Determination of whether development of the standard can be allocated to a current technical committee or whether a new technical committee must be established
- Availability of resources (for example, budget, human resources, and so on)
- Availability of international or regional standards that could be adopted or form the basis of the national standard
- The priority of the work
- Risks to be managed that could work against successful completion of the standard's development

At least once every six months, the standardizing body must publish a work program containing its name and address, the standards it is currently preparing, and the standards it has adopted in the preceding period—all as required by the WTO TBT Agreement. A standard is under preparation from the moment a decision has been made to develop a standard until the time that standard has been approved. The work program shall, for each standard, indicate the classification

relevant to the subject matter, the stage attained in the standard's development, and the references of any international standards taken as a basis. Best practice is to publish the work program on the NSB website, but its existence must be notified to the ISO.

Existing information/reporting/monitoring

- Formal procedure for new project approvals
- New project evaluation documentation
- NSB website
- Formal notification to the ISO Central Secretariat

3.4.5 Committee processes (building block no. 15)

What is meant

Major	The technical committee should meet at appropriate intervals to facilitate regular attendance by all interested parties. Meeting documents must be circulated well in advance of the meeting to enable members to prepare themselves. Discussions should focus on the technical content of draft standards and less on editorial matters. All members should be given ample opportunity to participate actively.
Fundamental	Decisions should be reached by consensus.
Minor	The technical committee should develop a business plan and update it annually to guide its activities.

How can it be demonstrated?

Appropriate intervals for the meetings of technical committees could be anything from once a month to once every three months, depending on the circumstances and urgency of completing the work. Meetings scheduled weekly are counterproductive because business and industry representatives will be unlikely to attend so often owing to work pressures, and the same is true for interested parties stationed far away from the meeting venue.

Working documents, minutes, and agendas for technical committee meetings should be circulated at least two weeks beforehand. Minutes of meetings should be available within a week after the meeting. Discussions at the meeting should focus on technical issues and less on editorial matters or even on trying to translate an international standard into the local language. Translations should be provided by the NSB beforehand.

Reaching decisions by consensus is important, and application of the ISO definition of a consensus in "ISO/IEC Guide 2 Standardization and Related Activities—General Vocabulary" (ISO and IEC 2004) should be the guideline. Although voting (with appropriate criteria) is used at the regional and international levels as a measure of consensus, it may not be a good idea at the national level. The arguments as to who is eligible to vote can render such a process problematic. At the regional and international levels, the matter is less problematic because only member countries are eligible to vote.

The use of modern IT equipment (for example, computers and digital projection) during the meeting is a useful mechanism to capture decisions for all members to see as the meeting progresses, and at the end of the meeting the updated working document can be distributed immediately.

Existing information/reporting/monitoring

- Standard for a standard
- Formal technical committee meeting procedures

- Technical committee business plans
- Schedules of technical committee meetings
- Working documentation of technical committees and their circulation
- Minutes of technical committee meetings

3.4.6 Relevance of standards (building block no. 16)

What is meant

Fundamental	Standards must facilitate trade, prevent unnecessary trade barriers, not distort the market, respond to regulatory and market demands, and take technological development into account.

How can it be demonstrated?

To address all of these requirements, standards should be as follows:

- *Based on performance criteria 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.
- *Developed with consideration of the latest technology*, even though standards are mostly based on proven technology.
- *Meet demonstrable market or regulatory demands.* If not, then the standard will not be used, and the resources spent in developing the standard would have been wasted. Hence, such demonstrable demands should feature strongly in the decision making of whether to develop the standard.
- *Reviewed at least once every five years, in accordance with GSP for published standards.* For some technologies that develop quickly, even five years may be too long an interval between reviews. 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. If nothing has changed, then the standard is reaffirmed. If things have changed, then the standard could be amended, revised, or sometimes even withdrawn if it is no longer in use.
- *Developed with meaningful liaison with international and regional standards organizations.* 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. For low- and middle-income countries, 60–80 percent adopted standards is a good target.

Existing information/reporting/monitoring

- Standard strategy
- Standard for a standard
- New work-item approval criteria
- Internal standards development procedures
- Percentage of national standards based on international standards
- Percentage of standards more than five years old
- List of standards not reviewed within five years

3.4.7 Coherence of standards (building block no. 17)

What is meant

Major	The body of standards should not have any overlaps in scope between standards, nor should the same commodity or service be dealt with in two or more standards with the possibility of differences in requirements.

How can it be demonstrated?

The NSB should ensure that its technical committees, especially those that have scopes that could overlap, do not develop standards with conflicting requirements. 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, then both may end up including safety requirements in their respective standards that may differ.

Second, if the NSB has "recognized" a number of standards development organizations (SDOs) (see building block no. 27), 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 one hand, and another by the NSB technical committee on potable water, on the other hand.

Existing information/reporting/monitoring

- Standards strategy
- Standard for a standard
- Scopes of technical committees of NSB and SDOs
- Editing manual

3.4.8 Public inquiry (building block no. 18)

What is meant

Fundamental	Once the technical committee has completed work and reached a consensus on the draft standard, the standard must be circulated for public comment for 60 days in accordance with the WTO TBT Agreement.

How can it be demonstrated?

The draft standard, as completed by the technical committee, may be edited before it is circulated for public comment, although this is not a must. The draft standard can be circulated to specified interested parties, but it should also be made available on the NSB website as a general notice and, if relevant, maybe also to the sectoral press of the country (for example, an engineering weekly, monthly food-related magazine, business association magazine, and so on). On the NSB website, the number, title, and scope of the draft standard should be listed, as well as a contact point where it can be obtained (for which a fee may be charged).

Interested parties should be asked to provide comments on the draft standard, and they should be given 60 days to do so. All the comments should be collated by the NSB and submitted to the relevant technical committee for consideration and decision. The technical committee may invite specific interested parties to a meeting to explain their comments further if of a substantive nature. Interested parties should be given formal feedback as to whether their comments had been accepted.

Existing information/reporting/monitoring

- Standard for a standard
- Internal standards development procedures

- Records of public comment periods
- NSB website
- Records of collated comments
- Technical committee records and minutes
- Formal feedback to interested parties on comments

3.4.9 National standards (building block no. 19)

What is meant

Major	The final draft standard should be edited to ensure its compliance with stated norms.
Fundamental	Once approved or adopted, the standard needs to be published promptly.
Major	Published standards should be reviewed at least every five years to ensure their continued relevance.

How can it be demonstrated?

Final draft standards, which include relevant comments from the public inquiry (see building block no. 18), need to be edited by an editing division independent from the technical committee and secretariat. Editing ensures that the standard follows the agreed-upon format, that the language is understandable, and that references and cross-references are correct. It is the final quality control step in the standards development process.

After editing, the final draft standard needs to be approved promptly, whether by the NSB board or council or by a standards approvals committee. The latter can be established by the board or council as one of its committees, or it may be established by legislation or articles of incorporation of the NSB. The board, council, or standards approvals committee should ensure that all appropriate steps in the standard's development have been fulfilled, and it is the final arbiter in the case of an appeal against the final draft standard. The standard should not be approved by the technical committee.

Once approved, the standard should be promptly made available to customers. This means the standard should be taken up in the standards catalog, made known on the NSB website, and offered for sale. Standards may be sold in hard copy or electronically. Electronic copies are replacing hard-copy sales, even though hard-copy sales are still required for customers with limited access to the Internet. Failure to provide for Internet sales will harm sales figures.

The approved standards should be reviewed at least once every five years to ensure their continued relevance (see building block no. 16). Hence, all newly approved standards should be placed on lists of a formal review program. Reviewed standards should be reaffirmed if still relevant, amended or revised if need be, or withdrawn if no longer relevant or needed. Their status after review should be indicated in the standard and catalog.

Existing information/reporting/monitoring

- Board or council minutes
- Standards approvals committee minutes
- Standards sales information and records
- Standards catalog
- Analysis of average age of standards
- List of standards older than five years

3.4.10 National adoptions (building block no. 20)

What is meant

Fundamental	Where international standards exist or their completion is imminent, the standards body shall use them, or the relevant parts of them, as a basis for the standards it develops, except where such international standards or relevant parts would be ineffective or inappropriate—for instance, because of an insufficient level of protection, fundamental climatic or geographical factors, or fundamental technological problems (WTO 1995).

How can it be demonstrated?

NSBs should ensure that the national standards developed in their technical committees are based on international standards in the first place. The best practice would be to adopt them without change. If changes are necessary, then there should be good reasons for doing so, because changes could be interpreted as an unnecessary trade barrier. "ISO/IEC Guide 21: Regional or National Adoption of International Standards and Other International Deliverables" should be used in identifying the extent to which standards are based on international standards, as follows (ISO and IEC 2005):

- *Identical,* which includes a direct translation but no editorial, structural, or technical changes
- *Modified,* which may include editorial changes but no structural or technical deviations, provided that the editorial changes are clearly indicated in the text of the standard
- *Not equivalent,* which includes editorial changes and technical deviations, even though the international standard may have served as the basis for the national standard

For most low- and middle-income countries, 80–90 percent of national standards have involved adoption of international standards. The remainder would be indigenous standards for which (a) no equivalent international standards exist, or (b) adoption of international standards would be totally inappropriate.

Existing information/reporting/monitoring

- Number and percentage of international standards adopted as national standards
- Standard for a standard
- Internal NSB procedures

3.4.11 Standards information (building block no. 21)

What is meant

Major	The NSB must provide information on national, regional, and international standards to interested parties in the most efficient way.

How can it be demonstrated?

In the first place, the NSB standards information center should be fitted with adequate IT equipment such that interested parties can browse through national, regional, and international standards before having to make a purchase or just for obtaining information. It should be staffed with knowledgeable standards information officers who can assist interested parties. Purchase of chosen

standards should be possible, and these should be provided by a modern print-on-demand system, which is more efficient than printing thousands of standards in hard copy when they are approved.

Second, the NSB should operate an Internet-based information service through which interested parties can access information and also purchase standards online. Failure to provide such a service will cost the NSB dearly because would-be purchasers will go elsewhere. In all cases, the necessary measures to protect the copyright of standards must be in place.

Existing information/reporting/monitoring

- Extent of the standards information and sales services
- Standards sales figures
- Copyright protection measures

3.5 PILLAR 4: EXTERNAL RELATIONS AND RECOGNITION

3.5.1 Benchmark and significance

Standards have become totally internationalized, with only a few countries recognized as "standards makers." Even though most low- and middle-income countries are "standards takers," it is still important that their NSBs have a strategic presence in regional and international standards development to represent national interests and to serve as a conduit of timely information for local industry and government on future technological and market developments.

3.5.2 WTO TBT Inquiry Point (building block no. 22)

What is meant

Fundamental	The WTO TBT Inquiry Point must, on request, be able to provide information to WTO member states with regard to standards, technical regulations, conformity assessment services, and regional or international memberships related to these.
Minor	The WTO TBT Inquiry Point may provide additional services related to an early warning system for exporters, providing information on imminent technical regulations to be implemented by trading partners.

How can it be demonstrated?

The national WTO TBT Inquiry Point—whether or not the NSB is designated as such (as is the case for more than 80 percent of WTO members)—must be able to provide the following information on request:[1]

- National standards: published and under development
- Technical regulations: implemented and under development
- Membership of regional structures
- Conformity assessment systems in the country
- Conformity assessment recognition agreements

In the past, some national WTO TBT Inquiry Points provided additional services for the common good, such as the following "export alert" type of information:

- Continuous analysis of the notifications of WTO member states, especially regarding new technical regulations that could be of interest to local industry and authorities

- Dissemination of such information to interested parties, which could have registered their interests beforehand
- Collation of comments on notified technical regulations for use by country representatives at WTO TBT Agreement Technical Committee discussions

The first two of these additional services are now accessible through the e-ping service (http://www.epingalert.org)—provided by the WTO, the International Trade Centre (ITC), and the United Nations—that analyzes notifications of WTO member states. NSBs should direct their stakeholders accordingly, but the NSB can still make a useful contribution by soliciting comments on notifications important to the country for the country representatives in Geneva at the WTO TBT Agreement Technical Committee.

Existing information/reporting/monitoring

- Extent of services provided by the national WTO TBT Inquiry Point
- Records of inquiries submitted over time
- Website of the NSB
- Database of the NSB regarding WTO TBT notifications

3.5.3 Training system (building block no. 23)

What is meant

Major	To ensure consistently high quality in standards development, the NSB must provide appropriate training for technical committee chairs, secretariats, and standards information personnel.

How can it be demonstrated?

Standards development, publication, and information are people-based activities. The NSB must therefore provide for the training of newly appointed technical committee chairs and secretariats, as well as annual refresher courses. The same applies to standards information center personnel. The training can be provided initially through ISO programs, but the NSB should make these part and parcel of its own training department activities.

Existing information/reporting/monitoring

- Training programs
- Training records

3.5.4 Liaison with international organizations (building block no. 24)

What is meant

Major	The most relevant international standardization organizations from the NSB's perspective would be the ISO, International Electrotechnical Commission (IEC), International Telecommunications Union (ITU), Codex Alimentarius Commission (CAC), International Plant Protection Convention (IPPC), and World Organisation for Animal Health (OIE). The IEC, ISO, and CAC are the most important because their standards would constitute the bulk of national adoptions. Hence, the NSB should be a member of these at a level appropriate to the country's involvement in international trade.

How can it be demonstrated?

In the first instance, the NSB's actual membership level within the ISO—and, if the NSB is also on the IEC National Committee, its level of membership in the IEC—is important. Depending on the needs and resources of the country, these could be as a member body in the ISO or as a full member in the IEC.

Lower membership levels have access to working documents but limited voting rights in the technical work; no eligibility for technical committee managerial functions; and, at the lowest level, only limited rights to adopt international standards as national standards (ISO 2015). Lower membership levels are acceptable in countries where resources are limited or where standardization needs are less strategic. However, if the country needs to adopt and publish large numbers of international standards as national standards, then the highest level of ISO or IEC membership is indicated.

Second, the NSB should be involved in the technical work of the ISO and IEC, as determined by the needs of the country. Membership can be as a participating member (P-member) or as an observer member (O-member). The number of international technical committees and subcommittees of which the NSB is a P-member or O-member is a useful indicator. More important, though, is the voting performance of the NSB in the case of P-membership. Not only should the NSB's voting performance on final draft international standards be higher than 95 percent, but appropriate comments as developed in mirror committees (see building block no. 13) should have been submitted as well.

Ultimately, the NSB should be actively involved in the international technical committees of strategic importance to the country; for example, national delegations led by the NSB should attend international technical committee meetings on a regular basis. It is not useful from a strategy perspective to be a P-member of 100 committees but not to attend any of their meetings. It is far more beneficial for the country to attend a small number of strategically important international technical committees that are involved in developing international standards for commodities the country's trade depends on. This number can be increased over time as resources become more readily available. Even though the country may be a low- or middle-income country operating as a "standards taker" rather than a "standards maker," it can still influence international standards, but then it has to be present at technical committee meetings.

Existing information/reporting/monitoring

- Standards strategy and its implementation plans
- ISO and IEC membership data
- ISO and IEC technical committee data
- Annual reports of the NSB
- Business plans and minutes of the NSB technical and mirror committees
- Formal communication records of the NSB with the ISO and IEC

3.5.5 Liaison with regional organizations (building block no. 25)

What is meant

Major	If the country is a member of a regional construct, then the NSB will be required to participate actively in regional standardization activities if these are part of the regional agreements. This means also participating in technical committees at the regional level.

How can it be demonstrated?

Regional standardization organizations are sometimes the outcome of trade agreements leading to regional common markets; in other cases, they are based on cooperation objectives between NSBs from a geographic region. In the former, NSBs are members by default, having to represent their respective countries in the regional standardization organization. In the latter, membership is by choice.

Some regional standardization organizations are entities with full-time staff and premises; others are liaison-type committees with only a secretariat. Some, but not all, of the regional organizations develop and publish regional standards (for example, for use in harmonized technical regulations). Some are forums where a regional approach to international standardization is discussed and agreed to; others identify international or harmonized standards that should be adopted by member countries as national standards; and some only coordinate standards development activities across the region. There is no model that is superior to others (Kellermann and Keller 2014).

Regional standardization organizations include the Arab Industrial Development and Mining Organization (AIDMO); African Organization for Standardization (ARSO); Association of Southeast Asian Nations (ASEAN) Consultative Committee on Standards and Quality (ACCSQ); European Committee for Standardization (CEN); European Committee for Electrotechnical Standardization (CENELEC); EuroAsian Interstate Council for Standardization, Metrology and Certification (EASC); Pacific Area Standards Congress (PASC); Pan American Standards Commission (COPANT); and South Asian Regional Standards Organization (SARSO). In some of these, there are subregional standardization organizations, such as the East African Standards Committee (EASC); Southern African Development Community (SADC) Cooperation in Standards (SADCSTAN), as well as others precisely aligned with the various common markets that are developing on the African continent; and the Caribbean Community (CARICOM) Regional Organization for Standards and Quality (CROSQ).

The membership of the country in any regional construct will be indicative as to whether the NSB will be or should become a member of a regional standards organization. The role and responsibilities of the NSB within the regional standards organization will be spelled out in relevant regional treaties, protocols, agreements, or in some cases even regional legislation. If relevant, then the NSB will have to establish mirror committees for regional standards development and must participate actively in the same. In some regional trade agreements, member countries are obliged to adopt regional standards within a given time once they have been approved and to withdraw their own. They are also obliged to stop the development of a national standard once the development of the regional standard of similar scope is under way. NSBs are obliged to provide information on their regional standards and are able to market them.

Existing information/reporting/monitoring

- Regional membership status of the country
- Relevant regional treaties, protocols, agreements, or legislation
- Catalog of regional standards adopted by the NSB
- Annual reports of the NSB
- NSB internal reports of regional standards body meetings

3.5.6 Coordination within the QI (building block no. 26)

What is meant

Major	Coordination among the fundamental QI organizations (the NSB, NMI, and NAB) is important to ensure that their responsibilities and activities provide a unified basis for calibration and conformity assessment service providers and the market surveillance activities of regulatory authorities.

How can it be demonstrated?

Coordination within the QI is important, especially among the NSB, the national metrology institute (NMI), and the national accreditation body (NAB) as the three pinnacle QI organizations. This coordination, to ensure that there are no overlaps or gaps in their service delivery or activities, can be realized formally or informally.

If the NSB, NMI, and NAB are governmental organizations, then their line ministries are in a good position to ensure such coordination, especially to ensure that the three are implementing the quality policy measures. Otherwise, a quality council or similar construct would be able to do the same. A third alternative is for the CEOs of the NSB, NMI, and NAB to have a formal coordination meeting at regular intervals. A technical regulation coordination office (whatever its name) coordinates the activities of the regulatory authorities with the QI regarding the development and implementation of technical regulations, ensuring that costly overlaps and gaps in service delivery are kept to a minimum.

Existing information/reporting/monitoring

- Line ministry policies, pronouncements, and documentation
- Quality council (or similar body) documentation and minutes of meetings
- Technical regulation coordination office mandate and pronouncements

3.5.7 Standards development organizations (building block no. 27)

What is meant

Major	It is not always only the NSB that develops national standards in the country. Other standards development organizations (SDOs), such as ministries, professional societies, and the like, might also be active. The NSB should recognize such entities and ensure that they comply with the international and regional obligations as defined in the WTO TBT Agreement, for example.

How can it be demonstrated?

SDOs are standards development organizations other than the NSB in the country. These could be engineering associations, government departments, or utilities—that is, any official organization that can provide the infrastructure for developing standards in compliance with the same procedures the NSB uses. SDOs are a useful mechanism to spread the load of standards development and to obtain additional funding for the work, leading to both an enhanced work program and a quicker time to market for relevant standards.

It is good practice for the NSB to register such SDOs after ensuring that they comply with Annex 3 of the WTO TBT Agreement; the ISO/IEC Directives (ISO 2017); and any national "standard for a standard" (see building block no. 12). The standards that are developed by SDOs are then published by the

NSB as national standards. By registering SDOs and coordinating the standards development work programs of the NSB and all SDOs, the NSB also ensures compliance with a fundamental GSP: ensuring that there are no overlaps in national standards that would lead to chaos in the marketplace or in technical regulation.

If the NSB is a governmental-type organization (see building block no. 2), then it should be mandated by its legislation (for example, a Standards Act or similar law) to register SDOs. Without such a mandate, it may be difficult to do so, depending on the legislative framework of the country. If the NSB is a private company, then its articles of incorporation should provide it with such a mandate. If such a mandate exists, then the NSB should have a formal process and procedures by which it registers SDOs, coordinates the standards development work programs, and ensures that the SDO remains compliant in all respects. Obviously, the NSB should also be able to rescind any organization's SDO status if it fails to comply continuously with stated requirements and to make the rescinding known publicly. Such a system, over and above being good practice, also facilitates a country's compliance with WTO TBT Agreement requirements regarding standardization principles.

Existing information/reporting/monitoring

- NSB legislation or articles of incorporation
- Formal NSB procedures for registering SDOs
- Official registration documentation of SDOs
- Work programs of the NSB and SDOs
- Annual reports of the NSB
- Standards catalog of the NSB
- Minutes of quality council or CEO coordination meetings

3.5.8 Stakeholder engagement (building block no. 28)

What is meant

Fundamental	Stakeholders play an important role in the development and implementation of national, regional, and international standards. The NSB must identify its stakeholders, communicate clearly with them, and gain their support and participation in the development and implementation of national, regional, or international standards.

How can it be demonstrated?

The NSB should map its stakeholder environment, including sectors such as

- *Governance,* such as QI organization boards or councils, regulatory authorities, NSB line ministry and other ministries, and so on;
- *Beneficiaries,* such as industry, traders, importers, society, and so on; and
- *Influencers,* such as business associations, media, nongovernmental organizations (NGOs), trade unions, and so on.

Thereafter, the NSB should follow a deliberate and continuous approach to stakeholder engagement that is properly planned, conveys a clear message, and asks stakeholders their opinions and then acts upon them. The central theme of the message should be the importance of standards for socioeconomic development and the role the NSB plays in developing the standards appropriate for the country. This message would be in the form of a formal communication plan or a similar strategy.

The governance of the NSB is vested in its board or council, but these should be individuals with specific strengths rather than a collection of representatives from all stakeholder groups (see subsection 3.2.1). Hence, it is useful for the NSB to establish a quality forum or similar open stakeholder meeting in which all stakeholders can participate freely and whereby the NSB can gain an understanding of the needs of its broader stakeholder groups. In addition, it is important for senior NSB management to commit energy and time to building high-level relationships that engender trust and to seeking out networking opportunities.

Existing information/reporting/monitoring

- Standards strategy and its implementation
- Communication strategy or plan and its implementation
- Minutes of a quality forum or similar open stakeholder meeting
- Key performance indicators of senior management
- Stakeholder mapping results

NOTE

1. The WTO TBT Inquiry Point, under the TBT Agreement, 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.

STANDARDS REFERENCED IN SECTION 3

Note: The most recent revision of these international standards should be obtained from the ISO or IEC, as relevant. Details regarding the private standards referenced in the text should be obtained from the relevant organizations.

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). 2004. "ISO/IEC 17011: Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies." Ref. no. ISO/IEC 17011:2004(E), ISO, Geneva.

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ISO and UNIDO (International Organization for Standardization and United Nations Industrial Development Organization). 2008. *Fast Forward: National Standards Bodies in Developing Countries*. 2nd ed. Geneva: ISO.

Kellermann, Martin, and Daniel Paul Keller. 2014. "Leveraging the Impact of Business Environment Reform: The Contribution of Quality Infrastructure—Lessons from Practice." Working paper, Business Environment Working Group of the Donor Committee for Enterprise Development (DCED) and United Nations Industrial Development Organization (UNIDO), Vienna.

Minzberg, H., B. Ahlstrand, and J. Lampel. 1998. *Strategy Safari: The Complete Guide through the Wilds of Strategic Management*. Edinburgh: Pearson Education, Prentice Hall.

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WTO (World Trade Organization). 1995. "Agreement on Technical Barriers to Trade." Treaty document, WTO, Geneva.

———. 2000. "Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement." Annex 4 of Document G/TBT/9, "Second Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade," Committee on Technical Barriers to Trade, WTO, Geneva.

4

Metrology

4.1 INTRODUCTION

In everyday life, metrology is hardly ostentatious, but its calm surface covers depths of knowledge that only a few are familiar with but that most use without thinking twice—confident that they are sharing a common perception of what is meant by expressions, such as meter, kilogram, and liter, for example, or confident that cell phones will connect, Global Positioning System (GPS) instruments will take us to the right address, and pilots will land aircraft safely. This *confidence* is vital in enabling metrology to link human activities together across geographic and professional boundaries.

Just as important is the *accuracy* of measurements—from the everyday use of weights and measures to the absolute cutting edge of technology, from the liter of fuel purchased to the accuracy of time measurement gaining or losing a second in millions of years. Accuracy of measurement has massive resource implications. It is therefore important to differentiate between the metrology needs of a low- or middle-income country and those of a country involved in fundamental research to transpose the definition of a measurement standard based on the laws of physics (see module 4 of the QI Toolkit) into measuring equipment for the same. This differentiation can be expressed as shown in table 4.1.

Any evaluation of the metrology system of the country is therefore heavily dependent on its level of development and the demands of the stakeholders. The establishment of a national metrology institute (NMI) as one of the fundamental organizations of the quality infrastructure (QI) is important, but even more important is the level of technology the NMI must operate to balance resource constraints with the country's needs. An evaluation of the metrology system of the country is therefore incomplete without knowledge of the actual demands of industry, authorities, and society.

Metrology is normally separated into three categories with different levels of complexity and accuracy but with known interdependencies (see module 3 of the QI Toolkit):

- *Scientific metrology*, which concerns the organization, development, and maintenance of measurement standards

TABLE 4.1 Maturity levels of a national metrology institute

NMI CHARACTERISTIC	RUDIMENTARY (LITTLE OR NO METROLOGY)	BASIC (LOW- TO MIDDLE-INCOME COUNTRY APPROACH)	ADVANCED (ECONOMYWIDE APPROACH, SECTORAL APPROACH)	MATURE (INNOVATIVE, CUTTING-EDGE TECHNOLOGY)
NMI laboratory infrastructure	No NMI; legal metrology department is only entity	A number of "basic basket" laboratories (including the appropriate accuracy levels)	Laboratories (including the CMCs) defined through economywide surveys Laboratories (including the CMCs) defined through sectoral international benchmark	High-level laboratories for innovative sector
International recognition	None	Through accreditation or CMC declarations	Through CMC declarations (or accreditation)	Through CMC declarations
Membership	None	Active RMO member	Active RMO member BIPM membership OIML membership	Active RMO member BIPM membership OIML membership Active in BIPM committees
Services	Calibration services	Calibration services	Calibration services Reference materials Intercomparisons Proficiency tests	Calibration services Reference materials Intercomparisons Proficiency tests Metrological consultancy Research
Secondary laboratories	None	None to some secondary calibration laboratories	Several calibration laboratories Loose network of calibration laboratories	Strong network of calibration laboratories coordinated by the NMI
Human resources	Training on the job	Training on the job	Training on the job Training courses in metrology	Training on the job Training courses in metrology Metrologist as a professional profile
Demand orientation	Not really	Demand surveys, mostly through projects	Demand surveys Stakeholder participation and consultative mechanism	Strong instruments and constructs to ensure demand orientation

Note: BIPM = International Bureau for Weights and Measures; CMC = calibration and measurement capability; NMI = national metrology institute; OIML = International Organization of Legal Metrology; RMO = regional metrology organization. The point of departure of the table is the NMI. It is possible, however, that a country may have only a weak NMI, whereas there may be independent calibration laboratories that deliver appropriate services, with their measurement standards traceable to other countries' measurement standards. If this is the case, then the table should be adjusted in an appropriate manner by the experts conducting the evaluation.

- *Industrial metrology,* which concerns the adequate functioning of measuring instruments used in industry, production, and testing processes
- *Legal metrology,* which concerns the accuracy of measurements where these influence the transparency of economical transactions, health, safety, and compliance with legislation.

Legal metrology is covered in section 11: Legal Metrology. The building blocks of the NMI relating to the four pillars are listed in table 4.2.

To depict the pillars and building blocks in a graphical way that would indicate the state of metrology in a country at a glance, they can be put together as shown in figure 4.1. For a complete description of the construction, interpretation, and use of this graphic or of the matching radar diagram, see section 1: Comprehensive QI Assessment.

TABLE 4.2 Pillars and building blocks of the national metrology institute (NMI)

	BUILDING BLOCK	
PILLAR	**NO.**	**DESCRIPTION**
1: Legal and institutional framework	1	Metrology strategy
	2	Legal entity
	3	Autonomy
	4	Legal standing of national measurement standards
	5	Governance
	6	Financial sustainability
2: Administration and infrastructure	7	Chief executive officer
	8	Organizational structure
	9	Management and personnel
	10	Premises
	11	Equipment
	12	Quality system documentation
3: Service delivery and technical competency	13	Metrologists
	14	Interlaboratory and key comparisons
	15	Calibration and measurement capability
	16	Calibration service
4: External relations and recognition	17	Training system
	18	Liaison with regional organizations
	19	Liaison with international organizations
	20	Coordination within the QI
	21	Designated institutes
	22	Stakeholder engagement

Note: QI = quality infrastructure.

4.2 PILLAR 1: LEGAL AND INSTITUTIONAL FRAMEWORK

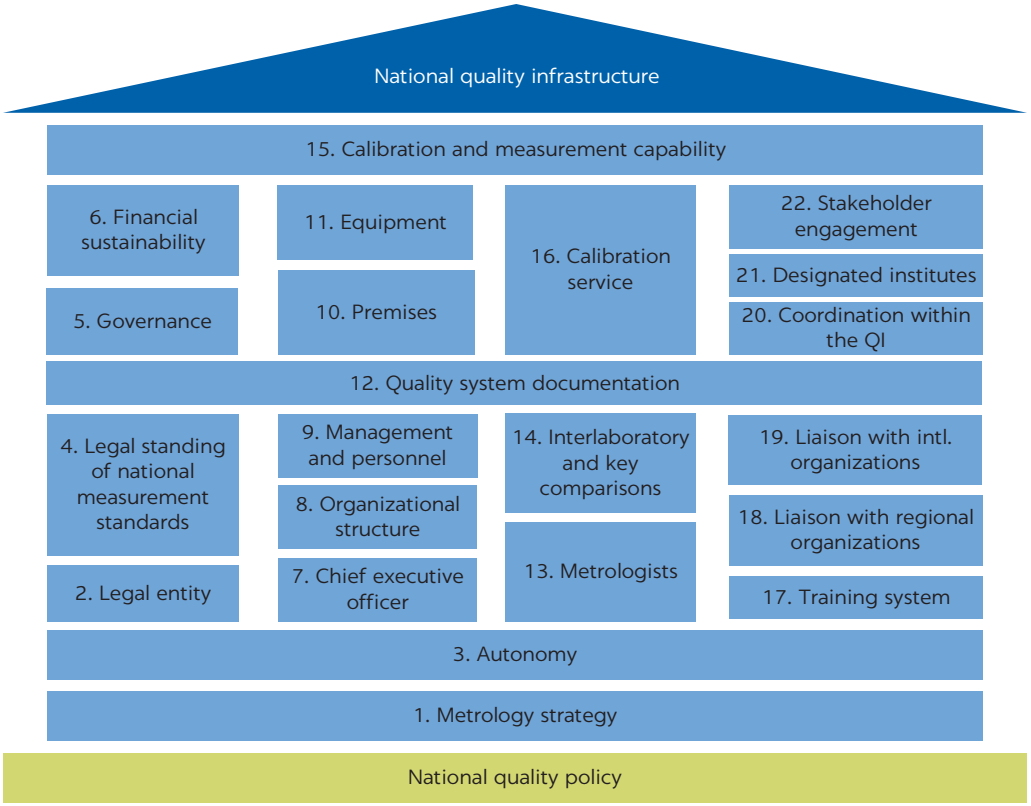
4.2.1 Benchmark and significance

The NMI must be an identifiable legal entity operating within an agreed-upon policy framework of the government. Its mandate should include a clear and unambiguous statement regarding the establishment and maintenance of the national measurement standards. Without such policy and legal backup, the NMI may find it difficult to carry out its fundamental responsibilities, namely, the realization of the definitions of the national measurement units and the diffusion of accurate and trustworthy measurements through traceability chains within the country.

Regarding its governance, the NMI should follow a more open and transparent model, with stakeholders having a meaningful influence on strategy, rather than a top-down system controlled by public servants. The latter will stifle innovation and render the NMI less able to serve its main stakeholder groups effectively. The stakeholders also play an important part in determining the level of accuracy that a national measurement standard should have in order to meet stated needs.

FIGURE 4.1

House of metrology for a national quality infrastructure



Note: QI = quality infrastructure. The four "pillars" of the QI—represented by the blue columns containing the "building block" numbers—are as follows (left to right): "legal and institutional framework," "administration and infrastructure," "service delivery and technical competency," and "external relations and recognition."

4.2.2 Metrology strategy (building block no. 1)

What is meant

Major

Following on from the quality policy (see subsection 2.1: Quality Policy), a metrology strategy gives meaning to the implementation of the quality policy regarding the establishment and maintenance of national measurement standards and the diffusion of accurate and trustworthy measurements in the country. The metrology strategy is about

- Making the right choices regarding the metrology services to offer and the customers to focus on;
- Getting stakeholder support for the NMI; and
- Building capacity in the NMI to fulfill its part in the most innovative, effective, and efficient way.

How can it be demonstrated?

The metrology strategy can be seen as an intended plan to set a pattern, create a unique position, follow a specific perspective, and implement a specific tactic—all to enable the NMI to make a difference to a critical mass of the right customers and to connect its purpose with those of its customers and external stakeholders (Minzberg, Ahlstrand, and Lampel 1998).

The metrology strategy should be a formal document approved at least by the NMI board or council, and in some countries even by the minister or cabinet, depending on national custom and practice. It should be publicly available—that is, on the NMI website or in hard copy. The activities, business plans, and budgets of the NMI should be aligned with the metrology strategy to ensure its implementation.

Existing information/reporting/monitoring

- NMI board or council papers
- NMI website
- Relevant ministry (for example, Trade and Industry) website
- Annual reports of the NMI
- Available metrology services

4.2.3 Legal entity (building block no. 2)

What is meant

Fundamental	The NMI shall be a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for the establishment and maintenance of national measurement standards and for the diffusion of accurate and trustworthy measurements within the country. The NMI is often a governmental department or an institution of public law (such as a statutory body), although private sector institutions are also possible. It may be an independent institution, but it can also be combined with the legal metrology department or with the national standards body (NSB).

How can it be demonstrated?

The NMI should be established by a legislative instrument, such as a Metrology Act or a similar law. The legislative instrument must define, at a minimum, the NMI's governance, financial provisions, responsibilities, and functions, as well as the establishment and maintenance of national measurement standards. The NMI's responsibilities should include representing the country in regional and international metrology forums.

To ensure that the responsibilities and functions of the NMI remain relevant in a changing international and regional metrology environment, the legislative instrument should be reviewed and modernized at regular intervals, typically five to eight years. Failure to do so could hinder the NMI in achieving its mandate at the national, regional, or international level in the medium to long term.

Existing information/reporting/monitoring

- Metrology Act, decree, regulation, or similar law
- NMI's website and annual reports

4.2.4 Autonomy (building block no. 3)

What is meant

Major	It is good practice for an NMI to move toward a market-economy model of increased institutional autonomy, as opposed to being fully controlled by the government. This gives it the management responsibility and freedom to operate effectively in the marketplace (Racine 2011).

How can it be demonstrated?

There are generally nine elements that can be considered to determine a legal autonomy index of the NMI. This is not an absolute number but a good indicator. Does the NMI have the autonomy and the authority to

- Decide which measurement standards are considered to be the national standards;
- Officially designate other institutions to be custodians of national measurement standards;
- Determine the positions and staffing of its workforce;
- Determine the salaries of its workforce;
- Select its workforce;
- Determine its own budget and income;
- Create new administrative divisions;
- Offer new services or initiate new activities; and
- Solicit membership in international or regional metrology organizations and sign international agreements?

Existing information/reporting/monitoring

- Metrology Act, decree, regulation, or similar law
- NMI council or board policy papers
- NMI's website and annual reports
- Government regulations regarding rules of employment (if the NMI is a governmental or public body)

4.2.5 Legal standing of national measurement standards (building block no. 4)

What is meant

Fundamental	National measurement standards (for example, for physical equipment and methods in the case of metrology in chemistry) are the basis of all metrology activities in the country, be they market-related or required by legislation or regulation. Therefore, it is good practice to provide them with authoritative standing within the country's legal system.

How can it be demonstrated?

National measurement standards should be given standing in principle within the country's legal system in terms of a Metrology Act or a similar law. Thereafter, once a specific national measurement standard is established and its metrological quantities defined, its existence should be made known publicly through a government gazette or similar publication in a way that uniquely identifies the specific instrument. Legally, the national measurement standards should be designated the highest-accuracy instruments of the country's legal metrology system and the links to the international system of measurements.

Existing information/reporting/monitoring

- Metrology Act, decree, regulation, or a similar law
- Formal agreement between the NMI and the government
- Official government journal or gazette or similar publication

4.2.6 Governance (building block no. 5)

What is meant

Fundamental	The NMI should have a board or council in charge of strategy approval and overall fiduciary responsibilities, whether the board or council is appointed by a relevant minister, general meeting, or shareholders.
Major	Good governance models suggest that the members of the board or council should be individuals with specific knowledge regarding metrology and market realities.

How can it be demonstrated?

The actual composition of the council or board must be considered. The number of members, as well as the balance between private sector members, public servants, and even academia, is important. The more-progressive NMIs have more private sector representatives than public servants on their councils or boards. Council or board members should be appointed in their individual capacities and not as representatives of business or industry associations or specific public institutions.

The members of a council or board, however appointed, should be selected for their knowledge, experience, or qualifications relating to the NMI's functions, particularly including local and international metrology and technical infrastructure matters, as well as business management and finance. The council or board should include 12–15 members. Depending on the custom and practice of the country, good governance principles suggest that the CEO of the NMI should be a full member of the council or board. Whatever the case, the CEO should only be an ordinary member of the council or board (that is, not allowed to hold the position of chair or vice-chair) to ensure proper oversight of the NMI by the council or board.

The council or board should have the mandate or authority to (a) approve the business strategies of the NMI, (b) appoint the CEO and consider his or her performance, (c) oversee the financial integrity of the NMI, (d) approve the budget and monitor performance of the NMI against the budget, and (e) approve the NMI's organizational structure.

Existing information/reporting/monitoring

- Metrology Act, decree, regulation, or similar law
- NMI council or board policy papers
- NMI's website and annual reports
- Government regulations regarding public entities
- NMI council or board committee structures

4.2.7 Financial sustainability (building block no. 6)

What is meant

Fundamental	The finances for the NMI can be provided from government sources, from financial support from industry and other stakeholders, and from income generated by metrological services. Whatever the source of funding, there should be assurances that it would be adequate also in the medium to long term.

How can it be demonstrated?

Most NMIs are largely dependent on government funding because they provide a service for the public good for which a specific paying customer cannot be identified. This funding would broadly include the budget for new laboratories

or the upgrading of older ones and the budget to maintain the laboratory's capacity and recognition costs (for example, memberships, active participation in regional and international activities, intercomparisons, training, environmental controls, and so on).

The NMI will also gain some income for metrological services, such as calibrations, provision of reference materials, consultancy to calibration laboratories, training of metrologists, running proficiency testing schemes, and the like. The NMI's finances should not become totally dependent on services rendered because this may lead to an undue focus on income-generating activities with a concomitant neglect of its fundamental responsibilities, or it may lead to unfair competition with private sector calibration laboratories.

The NMI's overall financial situation of the past three to five years would be a good indication of its financial sustainability. The situation regarding both government funding and income from services rendered should show a positive trend over the years under review. The demand for the NMI's primary metrological services would be a further indicator that should show a positive trend. A formal government commitment to support the NMI in carrying out its responsibilities regarding the establishment and maintenance of national measurement standards, as well as specific financial support for its international and regional liaison activities, are positive indicators of the NMI's financial sustainability.

Existing information/reporting/monitoring

- National quality policy
- Annual government budget allocations
- Annual reports of the NMI
- Monthly and annual financial statements of the NMI

4.3 PILLAR 2: ADMINISTRATION AND INFRASTRUCTURE

4.3.1 Benchmark and significance

Form follows function, and the NMI's organizational structure should be conducive to providing the full complement of metrology services effectively and efficiently according to the needs of its stakeholders. Good governance principles require the NMI to have a proper management executive, and the subject fields of metrology indicate that the NMI should have divisions dedicated to the development and maintenance of national standards in these fields, as well as the wherewithal to serve the calibration environment in the public and private sector and society, ably supported by the necessary corporate services, such as finance, human resources, training, and facility services.

Much more so than for standardization and accreditation, facilities are a vital factor in the success or otherwise of metrology. Without laboratory space and environmental controls appropriate for the specific metrology fields and the accuracy levels the NMI is engaged in, calibration and measurement capabilities (CMCs) cannot be established and metrology services to the country are compromised.

4.3.2 Chief executive officer (building block no. 7)

What is meant

Major	The chief executive officer (here referred to as the CEO, whatever the actual title) is responsible for leading the development and execution of the NMI's long-term strategy with a view to fulfilling its reason for existence. The CEO acts as a direct liaison between the board or council and management of the NMI and communicates to the board or council on behalf of NMI management. The CEO—rather than the chair of the board or council—is the public face of the NMI.
Minor	Depending on the legislation, custom, and practice relevant to the NMI, the CEO may be appointed by the relevant minister or the board or council. Recent tendencies suggest that the CEO should be appointed for a limited period only, typically five years. He or she can be reappointed if relevant key performance indicators are more than fulfilled.

How can it be demonstrated?

There is no standardized list of the major functions and responsibilities carried out by an NMI's CEO, but the following list includes the typical functions:

- Supports operations and administration of the board or council by advising and informing its members, interfacing between board or council and NMI staff, and supporting the board or council's evaluation of management executives
- Oversees the design, marketing, promotion, delivery, and quality of metrology-related programs, products, and services
- Recommends the annual budget for board or council approval and prudently manages the NMI's resources within those budget guidelines according to current laws and regulations
- Effectively manages the human resources of the NMI according to authorized personnel policies and procedures that fully conform with current laws and regulations
- Ensures that the NMI and its mission, programs, products, and services are consistently presented using strong, positive images to relevant stakeholders
- Oversees fundraising planning and implementation, including identifying resource requirements, researching funding sources, and establishing strategies to approach funders
- Represents the NMI regionally and internationally
- Identifies and proposes the development of new areas in the NMI

Existing information/reporting/monitoring

- Relevant legislation (Metrology Act or similar law)
- Official ministerial decisions
- Board or council decisions and minutes
- Official CEO job description
- Agreed-upon CEO key performance indicators

4.3.3 Organizational structure (building block no. 8)

What is meant

Major	Metrology consists of a number of major subject fields in two major groups: physical metrology, and chemical and biological metrology. It therefore follows that an NMI's organizational structure should have divisions that optimally support these groups and their subject fields.

How can it be demonstrated?

Physical metrology has long dominated the metrology world. The physical metrology subject fields are therefore fairly well developed, and the best accuracy levels are extremely high—that is, at the forefront of technology. Typical subject fields include (a) mass and related quantities; (b) electricity and magnetism; (c) length; (d) time and frequency; (e) thermometry; (f) photometry and radiometry; (g) flow; and (h) acoustics, ultrasound, and vibration (see module 4 of the QI Toolkit).

Metrology in chemistry and biology has risen to prominence over the past two decades as international travel has become commonplace, as has the cross-border transporting of livestock and agricultural products. Just as important are issues like new industrial development (for example, biotechnology, nanomaterials, and so on), as well as those that impinge on quality of life (for example, health care, the environment, food quality, and so on). In all of these matters, chemical and biological measurements play a vital role. The chemical and biological subject fields are still developing, but the following can already be identified: (a) certified reference materials, (b) reference measurement methods, (c) organic chemistry, (d) inorganic chemistry, (e) cell and nucleic analysis, (f) microbial analysis, (g) protein analysis, and (h) electrochemical analysis. These fields will develop further as chemical and biological metrology matures.

Each of the metrology fields is technology-intensive. The NMI's organizational structure should take cognizance of these realities and should support the technologies in question. Other areas or issues to consider in the organizational structure include the following:

- Service delivery regarding calibration, intercomparisons, metrology advice, and certified reference materials
- Support functions, such as human resources and finance
- The NMI's training and development responsibility for the common good relating to the country's metrology infrastructure, such as calibration and high-technology research laboratories
- The major importance of a technical division that can ensure the maintenance of environmental controls and measurement equipment
- The increasing importance of a technical division as the NMI moves from the *advanced* to the *mature* level (see table 4.1) for the development of new high-technology, high-accuracy measuring equipment.

Existing information/reporting/monitoring

- Approved organizational structure
- Board or council decisions
- Ministerial decisions
- Financial system documentation

4.3.4 Management and personnel (building block no. 9)

What is meant

Major	The science of measurement is a people-based activity operating within a high-level technical environment. The management and personnel must therefore have the appropriate skill sets assured by appropriate training, qualifications, and experience. These would include management and technical knowledge as required by the various activities within the metrology fields.

How can it be demonstrated?

In the first place, the NMI should operate with an organizational structure approved by either the board or council or the relevant minister. For each of the positions, the skill set (qualifications, training, and experience) should be clearly and formally stated. The ratio between technical and administrative staff is a good indicator of efficacy, with a good guideline being that administrative staff make up no more than 20 percent of the total.

Second, there should be few staff vacancies on either the management or technical levels; more than 95 percent of those positions should remain filled. Anything less indicates that the NMI cannot operate effectively or efficiently. Staffing challenges often include a lack of skilled people in the country, but even more so, inadequate remuneration resulting in the departure of trained staff for more lucrative offers elsewhere.

Existing information/reporting/monitoring

- Approved organizational structure
- Actual staffing levels
- Staff turnover figures

4.3.5 Premises (building block no. 10)

What is meant

Fundamental	Metrology is a highly technical endeavor. Each of the metrology fields has specific requirements regarding the laboratory space it needs to operate with the required accuracy.

How can it be demonstrated?

Each of the metrology fields has specific requirements regarding the laboratory space within which it can operate with the required accuracy. These requirements include environmental controls, such as temperature and humidity, lighting levels, and many more. Freedom from vibrations may indicate premises far removed from heavy traffic lanes, train lines, or airport flight paths. Requirements may also include controlled access to the laboratories.

The requirements also depend on the level of measurement accuracy needed—requirements are far too numerous and technology-specific to list here. The requirements must be obtained from experts in each of the metrology fields and in accordance with the accuracy requirements demanded by the country.

Some equipment submitted for calibration is large and heavy, such as weights for calibrating weighbridges, and ease of access for such equipment must be considered. Appropriate office space for staff outside of the laboratories also needs to be provided, as well as meeting rooms for individual customer discussions and meetings of metrology technical committees.

Existing information/reporting/monitoring

- Consideration of the NMI premises in relation to design, environmental controls, access, and maintenance
- Review of laboratories and environmental controls
- Review of office space and meeting rooms
- Technical requirements as advised by experts in specific metrology fields

4.3.6 Equipment (building block no. 11)

What is meant

Fundamental	The NMI is the custodian of the national measuring standard, in principle the one with the highest accuracy level in the country and traceable to the International System of Units (SI). The type of equipment and its accuracy class are fundamental aspects that need to be aligned with the country's demonstrable needs.

How can it be demonstrated?

The national measurement standard for a specific metrology entity should in theory be the one with the highest accuracy in the country, and its accuracy class should be related to the demands of the users with the highest level of technology. It is therefore important that the NMI understand and know the demands of the stakeholders (see table 4.1). With this knowledge, the type and accuracy class of equipment to serve as the national measurement standard can be obtained.

The national measurement standard could be established from the definition of the measurement unit, in which case intercomparisons with similar measurement standards of other NMIs would be indicated to ensure the standard's degree of conformance to the SI definition. This is a technologically advanced and costly option. For many economies, the purchase of a high-level measurement standard, traceably calibrated to a primary standard of an advanced NMI, would be fine.

Thereafter, the NMI will also require a variety of reference standards that can be used to calibrate given measuring equipment at high accuracy levels. The reference standards should be traceably calibrated to the national measurement standards. For each type of measuring equipment, appropriate maintenance measures need to be in place.

The maturity level of the NMI (see table 4.1) will have a marked influence on the type and accuracy class of the measuring equipment used. The spectrum is extreme and is not listed here; expert knowledge for each metrology field will need to be obtained to provide a meaningful evaluation. Such an evaluation is important owing to the high cost of equipment.

Existing information/reporting/monitoring

- Consideration of the NMI's metrology fields of activity
- Demonstrable metrology needs of the country
- Review of national measurement standards
- Review of working reference measurement standards
- Review of maintenance measures for all measuring equipment
- Calibration certificates of national measurement standards (if applicable)

4.3.7 Quality system documentation (building block no. 12)

What is meant

Major	In presenting its CMCs or applying for accreditation, the NMI must demonstrate its compliance with an approved quality system. The quality system must be formalized in quality system documentation.

How can it be demonstrated?

In establishing its calibration and measurement capabilities (CMCs), the NMI will have to ensure that its workflow is optimized. Good practice suggests that this workflow be formalized in quality system documentation. If the NMI is still at the *basic* maturity level (see table 4.1)—that is, just starting—then this is important, because its recognition will hinge on being accredited to ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories") rather than being accepted internationally through declaring its CMCs.

Accreditation to ISO/IEC 17025 presupposes a quality management system, the implementation of which is facilitated by complete quality system documentation. Even for *mature* NMIs, formalizing their workflow in proper quality system documentation is essential to have their CMCs recognized (see table 4.1). The NMI's credentials as a technically competent organization have to be earned, and it is a long journey before the International Bureau of Weights and Measures (BIPM) will accept the NMI's declared CMCs.

Existing information/reporting/monitoring

- Consideration of the NMI's formal quality system and its compliance with known international standards, such as ISO/IEC 17025
- Accreditation certificate or CMCs in the Key Comparison Database (KCDB) of the International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA), which is maintained by the BIPM

4.4 PILLAR 3: SERVICE DELIVERY AND TECHNICAL COMPETENCY

4.4.1 Benchmark and significance

ISO/IEC 17025 is generally used for the evaluation of calibration laboratories for accreditation. Although the standard was not specifically developed for NMIs, the journey for a newly established NMI to be internationally recognized seldom bypasses accreditation to ISO/IEC 17025 as a first step (see table 4.1). Once the NMI has reached the *advanced* maturity level, accreditation could be replaced by admission to the International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (CIPM MRA) combined with the declared and approved CMCs.

The 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 CIPM MRA are the internationally recognized (peer-reviewed and approved) CMCs of the participating institutes. Approved CMCs and supporting technical data are publicly available from the CIPM MRA database, the KCDB.

4.4.2 Metrologists (building block no. 13)

What is meant

Fundamental	Metrology is a highly technical endeavor. The people practicing metrology have to be highly trained and experienced to do justice to the technological level required. The more advanced the NMI, the more highly trained and skilled the practitioners need to be.

How can it be demonstrated?

Metrologists come from various disciplines, including physics, engineering, chemistry, biology, and many more. Over and above the basic education at a university or technical college, important elements in developing metrologists include further training and gaining experience in advanced NMIs of high-income countries. Ultimately, once the NMI moves into the *advanced* maturity level (table 4.1), research activities will foster even greater expertise, and the expertise of relevant metrologists will be acknowledged by their peers.

For a newly established NMI, employing metrologists who take more of a practical approach than a theoretical one may be an effective way to start. The same applies to the personnel responsible for the maintenance of measuring equipment or environmental controls. Ultimately, proficiency in engineering design (mechanical, electronic, electrical, or chemical) may be required to design and manufacture measuring equipment at the highest technological level. Most measuring equipment relies heavily on electronics; hence, electronic specialists and technicians are important members of the NMI.

Existing information/reporting/monitoring

- Approved organizational structure
- Formal job descriptions
- Personnel records regarding education, training, and experience
- Annual training plans and concomitant records

4.4.3 Interlaboratory and key comparisons (building block no. 14)

What is meant

Fundamental	Interlaboratory or key comparisons provide information regarding the NMI's ability to deliver accurate measurement results. They are important for accreditation and are the foundation of establishing the CMCs.

How can it be demonstrated?

Participation in interlaboratory comparisons provides independent verification of an NMI's measurement capability and shows a commitment to maintenance and improvement of performance. For an NMI at the *basic* maturity level (see table 4.1), such participation is a prerequisite for accreditation. At this level, the interlaboratory comparisons can still be a low-key affair, overseen by an *advanced* or *mature* NMI acting as lead laboratory and involving a smaller number of NMIs.

Once the establishment of CMCs is being contemplated, interlaboratory comparisons move to a higher level, as defined by the BIPM, and are known as key comparisons. The BIPM key comparisons are of two types (see section 4.11.1 in module 4 of the QI Toolkit):

- *CIPM key comparisons*, of international scope, are carried out by those participants having the highest 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.
- *Regional metrology organization (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.

Existing information/reporting/monitoring
- Key Comparison Database (KCDB) of the CIPM MRA maintained by the BIPM
- Interlaboratory comparison reports of the NMI
- Results of key comparisons of RMOs
- Results of key comparisons of the BIPM and Consultative Committees of the CIPM

4.4.4 Calibration and measurement capability (CMC) (building block no. 15)

What is meant

Fundamental	International recognition of the NMI can be achieved through the CIPM MRA, which is underpinned by the listing of the CMCs in the KCDB maintained by the BIPM for General Conference on Weights and Measures (CGPM) members and associate members.
Major	Alternatively, the NMI can achieve a measure of international recognition through accreditation to ISO/IEC 17025 should listing of its CMCs not yet be feasible.

How can it be demonstrated?

The outcomes of the CIPM MRA are the internationally recognized (peer-reviewed and approved) CMCs of the participating NMIs. Approved CMCs are publicly available in the CIPM MRA database, the KCDB. The fundamental elements that lead to the approval of an NMI's CMCs include the following:

- Country status as a signatory of the Metre Convention or as an associate member and economy of the CGPM
- Participation by the NMI in reviewed and approved scientific comparisons
- Operation by the NMI of an appropriate and approved quality management system
- International peer review (regional and interregional) of claimed calibration and measurement capabilities

The last three elements are normally organized through a BIPM-recognized RMO. For an NMI that cannot yet participate in the establishment of CMCs, accreditation to ISO/IEC 17025 could be a way to gain a measure of international recognition in the meantime. The accreditation organization, however, needs to be an internationally recognized one.

Existing information/reporting/monitoring

- Key Comparison Database (KCDB) of the CIPM MRA maintained by the BIPM
- Accreditation records of the relevant accreditation body

4.4.5 Calibration service (building block no. 16)

What is meant

Major	The metrological values of the national measurement standards need to be diffused to industry, society, and authorities. This is achieved through the traceability chain of calibration, starting with the NMI.

How can it be demonstrated?

A traceability chain is an unbroken chain of comparisons to make it certain that a measurement result is related to references at a higher level, ending in the final level of the national measurement standard. The basic tool in ensuring this traceability is measuring standard calibration, from the national measurement standard through reference standards to industrial standards and their measurements.

In a low- or middle-income economy, with the NMI still at the *basic* maturity level (see table 4.1), the NMI provides such a calibration service to industry. As the economy develops and the NMI with it, this function should be taken up by calibration laboratories, in both the public and private sectors, whose reference and working standards are traceably calibrated to the national measurement standard by the NMI; that is, the NMI calibrates the working standards. In fact, the NMI should promote and support the creation of such secondary metrology laboratories, which is a challenge if the NMI's income is too dependent on calibration services.

Ultimately, the NMI is the pinnacle of a whole system of metrology and calibration laboratories providing the relevant calibration services to industry, authorities, and society. The accreditation of such service providers to ISO/IEC 17025 is an important element in preserving the confidence in the national metrology system.

Existing information/reporting/monitoring

- Network of calibration laboratories
- Calibration laboratory associations
- Accreditation records of calibration laboratories
- Records of the accreditation organization regarding calibration laboratories
- Collaboration between the NMI, calibration laboratories, and technical working groups

4.5 PILLAR 4: EXTERNAL RELATIONS AND RECOGNITION

4.5.1 Benchmark and significance

International recognition of the country's CMCs and their listing in the KCDB maintained by the BIPM are of paramount importance for the country's metrology system. Such recognition has to be obtained through RMOs. The NMI's liaison with RMOs is therefore an important fundamental necessity; liaison with international organizations can follow thereafter. The recognition based on

CMCs, however, is only possible for signatories to the Metre Convention or for associate members and economies of the CGPM under the Metre Convention. Otherwise, accreditation is currently the only way to achieve a measure of international recognition.

4.5.2 Training system (building block no. 17)

What is meant

Major	Trained and skilled metrologists are a vital component of an effective and efficient national metrology system. Training mechanisms provided by the NMI to develop such metrologists are important.

How can it be demonstrated?

In parallel with the high demands on the technical side, high demands are placed on appropriately educated, trained, and experienced metrologists and technical staff. The NMI must therefore provide for the training of its own staff, a requirement that increases with the development of a whole calibration laboratory network. Initial training programs can be initiated by technical cooperation programs but eventually must be provided by the NMI in collaboration with tertiary technical education institutions.

Issues that should be considered in training programs include the following:

- Higher-level training of specialist metrologists at NMIs that have higher-level metrology in place
- New developments and new metrology sectors the NMI is getting involved in
- Training programs for metrologists of secondary laboratories

Existing information/reporting/monitoring

- Training programs
- Training records

4.5.3 Liaison with regional organizations (building block no. 18)

What is meant

Fundamental	International recognition of the technical capability of an NMI, and hence of a country, is gained through RMOs recognized by the BIPM or through accreditation. Active membership of the NMI in the relevant RMO is therefore an imperative.
Major	If the country is a member of a regional construct, then the NMI will be required to participate actively in regional metrology activities if these are part of the regional agreements. This means also participating in technical committees at the regional level.
Major	Membership in an RMO affords NMI staff the opportunity to learn from other member NMIs and through participation in working groups of the RMO.

How can it be demonstrated?

International recognition of an NMI, and hence of the country, is based on the declaration of its CMCs and their inclusion in the KCDB kept by the BIPM. The regional key comparisons on which the determinations of CMCs are based are arranged through RMOs recognized by the BIPM, and RMOs also carry out other actions to enhance the mutual confidence and validity of calibration and measurement certificates issued by participating NMIs. (*Note:* For NMIs of countries that are not yet signatories to the Metre Convention or associate

members and economies of the CGPM under the Metre Convention, this route is not possible, but they may gain a measure of recognition through accreditation.)

It is therefore of paramount importance that the NMI be an active member of the relevant RMO when contemplating membership in international metrology organizations (see building block no. 19). Unfortunately, not all countries are covered yet by recognized RMOs, and NMIs in such countries find it difficult to gain international recognition. In such cases, the country should make every endeavor to have an RMO established and recognized by the BIPM in its region.

At the time of writing (January 2019), six RMOs are recognized within the framework of the CIPM MRA:[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)

Existing information/reporting/monitoring

- Membership of the NMI in the recognized RMOs
- Reports of the NMI's participation in RMO activities
- Regional trade agreement membership status of the country
- Relevant regional treaties, protocols, agreements, or legislation
- Annual reports of the NMI
- NMI internal reports of RMO meetings attended

4.5.4 Liaison with international organizations (building block no. 19)

What is meant

Major | The two relevant international metrology organizations would be the BIPM and the International Organization of Legal Metrology (OIML). Hence, once the NMI moves from a basic to an advanced level (see table 4.1), the NMI should pursue membership in both organizations if its responsibilities include legal metrology.

How can it be demonstrated?

The BIPM is the international intergovernmental organization set up by the Metre Convention through which member states act together on matters related to measurement science and measurement standards. Membership can be at two levels, depending on whether the country has signed the Metre Convention (established in 1875), under which the current International System of Units (SI) was established in 1960. If the country is a signatory, then the country is a member (and the NMI can represent it); if not, then the country can become an associate member.

As a signatory, the country participates actively in the various committees under the Metre Convention, starting with the CGPM, which is the highest policy-making organ under the Metre Convention, meeting every four years. The CIPM consists of 18 representatives from the CGPM, and it oversees the BIPM, provides for the chairs of technical committees, and is responsible for cooperation with other international QI organizations. A number of consultative committees accountable to the CIPM have been established, dealing with

specific metrology issues. Participation in the CGPM should be a given for the country (there is also an annual NMI directors' meeting); however, only specific individuals are invited to the CIPM. And active participation in the consultative committees will depend on the metrology policy or strategy of the country.

As an associate member and economy, an NMI can participate in the CIPM MRA. This allows the country to register its CMCs on the KCDB managed by the BIPM, thereby achieving international recognition for its metrology capabilities.

The OIML is discussed in section 11: Legal Metrology.

Existing information/reporting/monitoring

- Metrology strategy and its implementation plans
- BIPM membership data
- BIPM technical committee data
- Annual reports of the NMI
- Business plans and minutes of the NMI technical and mirror committees
- Formal communication records of the NMI with the BIPM and OIML

4.5.5 Coordination within the QI (building block no. 20)

What is meant

Major	Coordination among the fundamental QI organizations (the NSB, NMI, and national accreditation body [NAB]) is important to ensure that their responsibilities and activities provide a unified basis for the calibration and conformity assessment service providers and the market surveillance activities of regulatory authorities. The same applies to the legal metrology organizations.
Minor	NMI staff should participate actively in NSB, NAB, and legal metrology technical committees and ensure there is an exchange of information and liaison between the NMI, NAB, and legal metrology regarding the metrology needs of accredited entities.

How can it be demonstrated?

Coordination within the QI is important, especially among the NSB, the NMI, and the NAB, as the three pinnacle QI organizations. The coordination—to ensure that there are no overlaps or gaps in their service delivery or activities—can be realized formally or informally. If the NSB, NMI, and NAB are governmental organizations, then their line ministries are in a good position to ensure such coordination, especially to ensure that the three are implementing the quality policy measures. Otherwise, a quality council or similar construct would be able to do the same. A third alternative is for the CEOs to have a formal coordination meeting at regular intervals. A technical regulation coordination office (whatever its name) coordinates the activities of the regulatory authorities with the QI regarding the development and implementation of technical regulations, ensuring that costly overlaps and gaps in service delivery are kept to a minimum.

NMI staff should participate in standardization technical committees, act as technical evaluators for the accreditation body, and participate in the technical committee dealing with metrology questions of the accreditation body. Furthermore, an exchange should be fostered between metrologists and the accreditation body regarding the traceability and intercomparison needs that are identified through the existing accredited calibration, clinical, and testing laboratories.

Existing information/reporting/monitoring

- Line ministry policies, pronouncements, and documentation
- Quality council (or similar body) documentation and minutes of meetings
- Technical regulation coordination office mandate and pronouncements
- NSB and NAB technical committee membership
- NAB assessment team membership
- Liaison meeting reports and minutes

4.5.6 Designated institutes (DIs) (building block no. 21)

What is meant

Major

It is not always only the NMI that establishes and maintains national measurement standards in the country. Designated institutes (DIs) might also be involved. This is often the case for technologies that are not covered by the NMI, such as nuclear technology, metrology in chemistry, and so on. The NMI recognizes such entities and ensures that they comply with the relevant requirements.

How can it be demonstrated?

In many countries, the NMI shares its responsibilities with one or more designated institutes (DIs), which, like the NMI, operate at the top of the national metrology system. DIs play a crucial role in complementing the NMI's fields of activity at the national reference level and bring expertise in metrological areas not covered by the NMI, thus using the available national resources efficiently. Typical areas would be nuclear technology-related metrology, metrology in chemistry, and the like.

Institutes should only be designated if they have appropriate metrological experience and scientific expertise *and* meet all of the following conditions:

- Hold (or will hold) and maintain national measurement standards
- Will deliver metrological traceability through the provision of calibration services or reference materials in a well-defined metrology area and on an equal basis to all customers
- Will act similarly to the NMI within a limited and well-defined area of metrology, as well as understand and accept the obligations of participation in the CIPM MRA
- Will be appropriately resourced and sufficiently stable for their role within the national measurement system and as DIs within the CIPM MRA

The designation must be done by the authorized body of the state, that is (a) the responsible ministry or authority within the government, or (b) the NMI, if authorized to do so by its government.

Performance of the DI with respect to the CIPM MRA should be monitored by the NMI.

Existing information/reporting/monitoring

- NMI legislation
- Formal procedures for designating institutes
- Official designation documentation of DIs
- BIPM records of the NMIs and DIs
- Work programs of the NMI and DIs
- Annual reports of the NMI

4.5.7 Stakeholder engagement (building block no. 22)

What is meant

Fundamental	Stakeholders play an important role in determining choices regarding the establishment of national measurement standards and their accuracy levels. The NMI must identify its stakeholders, communicate clearly with them, and gain their support and participation in the development and implementation of national metrology standards, as well as the resulting national metrology system that diffuses these standards into industry, authorities, and society through calibration chains.

How can it be demonstrated?

The NMI should map its stakeholder environment, including sectors such as

- *Governance,* such as QI organization boards or councils, regulatory authorities, the NMI line ministry and other ministries, and so on;
- *Beneficiaries,* such as industry, laboratories, business, society, consumers, academia, and so on; and
- *Influencers,* such as business associations, media, nongovernmental organizations (NGOs), trade unions, and so on.

Thereafter, the NMI should follow a deliberate and continuous approach to stakeholder engagement that is properly planned, conveys a clear message, and asks stakeholders their opinions and then acts upon them. This approach would be in the form of a formal communication plan or a similar strategy.

The governance of the NMI is vested in its board or council, but these should be individuals with specific strengths rather than a collection of representatives from stakeholder groups (see building block no. 5). Hence, it is useful for the NMI to establish a metrology forum or a similar meeting in which all stakeholders can participate freely and whereby the NMI can gain an understanding of the needs of its broader stakeholder groups. In addition, it is important for senior NMI management to commit energy and time to building high-level relationships that engender trust and to seeking out networking opportunities and even joint research projects with industry and academia.

Existing information/reporting/monitoring

- Metrology strategy and its implementation
- Communication strategy or plan and its implementation
- Minutes of a metrology forum or similar open stakeholder meeting
- Key performance indicators of senior management
- Stakeholder mapping results

NOTE

1. The list of the recognized RMOs can be found on the BIPM website: https://www.bipm.org/en/worldwide-metrology/regional/.

REFERENCES

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5

Accreditation

5.1 INTRODUCTION

Accreditation is the youngest of the three fundamentals of the quality infrastructure (QI). It rose to prominence only after World War II and initially only in some parts of the world, such as Australia and New Zealand. It is now a well-respected and mature service in the QI worldwide, taking its place alongside the other two fundamentals: standards and metrology. Within the context of QI and at its most basic level, accreditation is seen as the independent attestation of the technical competency of a QI service provider. And herein lies its difference from certification, which is an attestation of compliance with set requirements.

In a well-organized QI, calibration laboratories, inspection bodies, testing laboratories, certification bodies (product, system, and person), and QI personnel training institutions are accredited, thereby assuring their customers and authorities alike that they are competent. In addition, by being accredited by an internationally recognized accreditation body, the outcomes of services provided by such QI service providers (such as reports and certificates) gain the possibility of being recognized at the international level as well.

Accreditation has therefore become an important element in opening markets to products and services, whether locally or in the export markets. Likewise, it is becoming a prerequisite for the acceptance of conformity assessment service providers by regulatory authorities for the implementation of technical regulations. On the other hand, if the regulatory authorities do not use accreditation in this way, the uptake of accreditation services may well be on the low side.

Accreditation is not as reliant as metrology on high-level technology equipment; it is primarily a people-based service, like standardization. Competent assessors are required for each sector-specific accreditation service because, in the final analysis, accreditation is based on their judgment call regarding the technical competency of the QI service provider. The accreditation body is seldom in the position to employ all of these assessors permanently; hence a system to manage a pool of external assessors is a necessity.

Accreditation is a service that can fairly easily be provided at the regional level wherever the domestic accreditation market is too small to warrant the establishment of a national accreditation body (NAB). There are, however, also

TABLE 5.1 Pillars and building blocks of accreditation

PILLAR	BUILDING BLOCK	
	NO.	DESCRIPTION
1: Legal and institutional framework	1	Accreditation strategy
	2	Legal entity
	3	Autonomy
	4	Legal standing of accreditation
	5	Governance
	6	Financial sustainability
2: Administration and infrastructure	7	Chief executive officer
	8	Organizational structure
	9	Management and personnel
	10	Premises
	11	Equipment
3: Service delivery and technical competence	12	Lead assessors
	13	Assessors and technical experts
	14	Specialist technical committees
	15	Quality system documentation
	16	Assessment process
	17	Approval process
	18	Accreditation and follow-up
4: External relations and recognition	19	Training system
	20	Liaison with regional organizations
	21	Liaison with international organizations
	22	International recognition
	23	Coordination within the QI

Note: QI = quality infrastructure.

challenges, such as logistics and language, that have to be taken care of in a regional context. Whichever way accreditation services are provided, it is important that they be independent from any QI service provider; hence, conflicts of interest have to be carefully considered. Conflicts of interest arise when the accreditation services are provided by an organization that also offers conformity assessment and calibration services.

The building blocks of accreditation relating to the four pillars are listed in table 5.1.

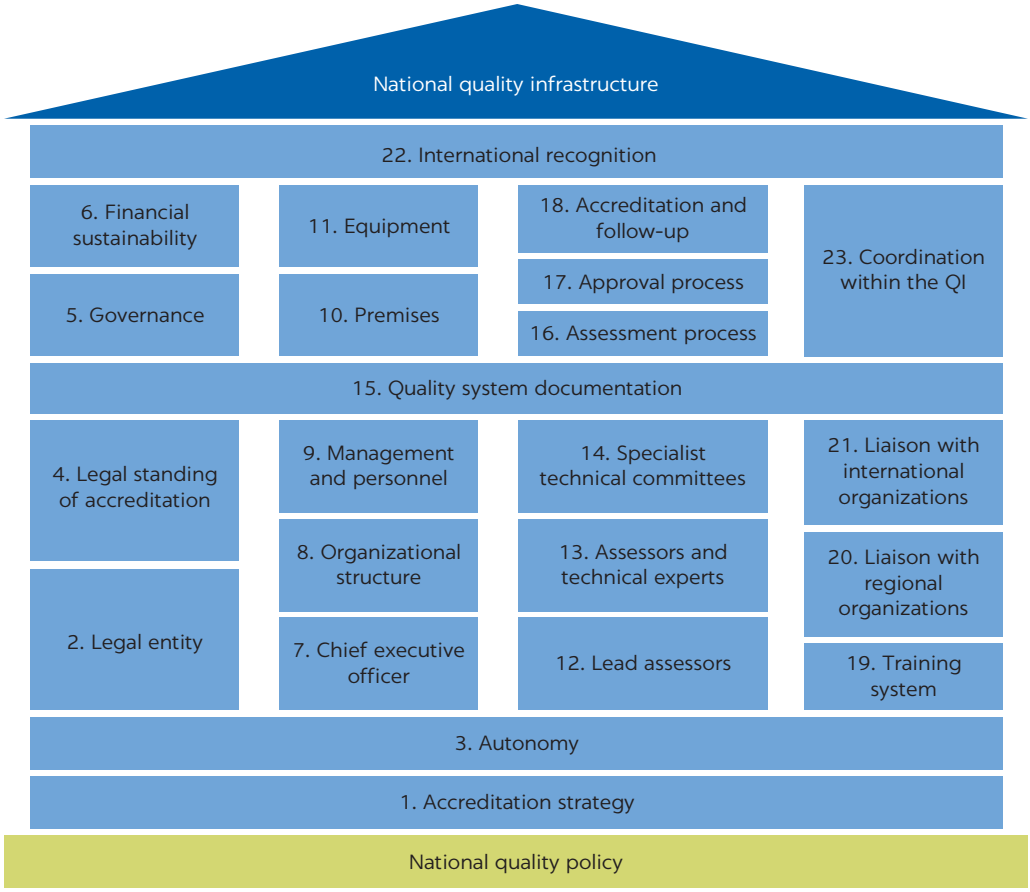
To depict the pillars and building blocks in a graphical way that would indicate the state of accreditation in a country at a glance, they can be put together as shown in figure 5.1. For a complete description of the construction, interpretation, and use of this graphic or of the matching radar diagram, see section 1: Comprehensive QI Assessment.

5.2 LEGAL AND INSTITUTIONAL FRAMEWORK

5.2.1 Benchmark and significance

The NAB must be an identifiable legal entity operating within an agreed-upon policy framework of the government. Its mandate should include a clear and unambiguous statement regarding the establishment and maintenance of the

FIGURE 5.1
House of accreditation for a national quality infrastructure



Note: QI = quality infrastructure. The four "pillars" of the QI—represented by the blue columns containing the "building block" numbers—are as follows (left to right): "legal and institutional framework," "administration and infrastructure," "service delivery and technical competency," and "external relations and recognition."

national accreditation system. Without such policy and legal backup, the NAB may find it difficult to carry out its fundamental responsibilities, namely, the independent attestation of the technical competency of service providers for (a) the implementation of technical regulations, and (b) the demands of the market within the country.

Regarding its governance, the NAB should follow a more open and transparent model, with stakeholders having a meaningful influence on strategy, rather than a top-down system controlled by public servants. The latter is, in any case, problematic regarding the recognition of the NAB by the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF), in that the NAB has to prove its independence from political influences.

International recognition is obtained, in theory, through recognition by either ILAC or the IAF; signing of their multilateral recognition agreements; or arrangements after a successful peer evaluation process based on ISO/IEC 17011 ("Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies"). In practice, recognition is also dependent on the custom and practice of specific countries, especially because

regulatory authorities are sometimes reluctant to accept ILAC or IAF recognition at face value. Because of the increase of accreditation bodies worldwide, many peer reviews are now arranged through recognized regional cooperation bodies or groups (not to be confused with regional accreditation bodies providing an accreditation service) rather than by ILAC and the IAF themselves.[1] Liaison with such regional groupings is therefore an important fundamental necessity where these exist; liaison with the international organizations can follow thereafter.

The benchmarks for a regional accreditation body (RAB) are essentially the same as for an NAB. In some instances, RABs cooperate with national accreditation focal points to facilitate the training and registering of local assessors and to act as a liaison between the entity wishing to be accredited and the RAB. For a comprehensive discussion of RABs and NABs, see module 5 of the QI Toolkit.

5.2.2 Accreditation strategy (building block no. 1)

What is meant

Major	Following on from the quality policy (see subsection 2.1: Quality Policy), an accreditation strategy gives meaning to the implementation of the quality policy regarding the establishment of an internationally recognized accreditation system. The accreditation strategy is about • Making the right choices on accreditation bodies in the country or at a regional level; • Using accreditation to designate conformity assessment service providers for the implementation of technical regulations; • Using accreditation as a measure of the quality of conformity assessment services in the market for nonregulated areas; and • Building capacity in the NAB or RAB to fulfill its part in the most innovative, effective, and efficient way.

How can it be demonstrated?

The accreditation strategy can be seen as an intended plan to set a pattern, create a unique position, follow a specific perspective, and implement a specific tactic—all to enable the NAB or RAB to make a difference to a critical mass of the right customers and to connect its purpose with those of its customers and external stakeholders (Minzberg, Ahlstrand, and Lampel 1998).

The accreditation strategy should be a formal document approved at least by the relevant ministry in the absence of the NAB or RAB board or council, and in some countries even by the cabinet, depending on national custom and practice. It should be publicly available—that is, on the NAB or RAB website or in hard copy. The activities, business plans, and budgets of the NAB or RAB should be aligned with the accreditation strategy to ensure its implementation.

Existing information/reporting/monitoring

- NAB or RAB board or council papers
- NAB or RAB website
- Relevant ministry (for example, Trade and Industry) website
- Annual reports of the NAB or RAB

5.2.3 Legal entity (building block no. 2)

What is meant

Fundamental	The NAB or RAB shall be a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for the establishment and maintenance of the country's accreditation system. The NAB or RAB can be a governmental department or an institution of public law (such as a statutory body) or a private sector organization with a specific conferred regulatory mandate. It should be an independent institution, but it may be combined with the national standards body (NSB) if no conflicts of interest exist.

How can it be demonstrated?

The NAB or RAB shall be established by legislation or articles of incorporation, as relevant. Legislation may be an Accreditation Act or a similar law. Articles of incorporation are required for the NAB or RAB to be registered as a private company in terms of company legislation. The legislation or articles of incorporation must define the governance, financial provisions, and responsibilities and functions of the NAB or RAB, including its functions in representing the country or region in international accreditation forums. An important element that needs to be defined is the use of accreditation as one of the preconditions for designating QI service providers for regulatory purposes. Such QI services may be required in technical regulation implementation (such as health and safety systems, environmental controls, transportation, and building and construction); in legal metrology; and in the imposition of legal proceedings based on measurement and testing.

If the NAB or RAB is a private company, then a formal agreement should exist between the NAB or RAB and the government in which the NAB or RAB is given the mandate to operate as the NAB. In addition, it may be necessary for the government, depending on the country's legal system, to confer specified regulatory mandates to the NAB or RAB concerning the role that accreditation plays for defined regulatory purposes.

To ensure that the responsibilities and functions of the NAB or RAB remain relevant in a changing international and regional accreditation environment, the legislation or articles of incorporation should be reviewed and modernized every five to eight years. The same applies to the formal agreement between the government and the NAB or RAB as a private company. Failure to do so could hinder the NAB or RAB in playing its national, regional, or international roles effectively and efficiently in the medium to long term.

There is no international requirement that a country may have only one accreditation body, although it is seen as good practice. Hence, in some countries, multiple accreditation bodies have been established for specific sectors. In smaller economies, this is an expensive option because every accreditation body has to gain international recognition on its own. It could also lead to chaos in the market because different regulatory authorities might use different specific accreditation bodies, whereas some conformity assessment service providers operate across the whole market. Theoretically, such service providers now need accreditation from two different accreditation organizations for the service they provide. Many countries faced with this dilemma are therefore merging their accreditation bodies into a single NAB.

Existing information/reporting/monitoring

- Accreditation Act, decree, regulation, or similar law, if relevant
- Articles of incorporation, if relevant
- Formal agreements between the government and the NAB or RAB
- NAB or RAB website and annual reports

5.2.4 Autonomy (building block no. 3)

What is meant

Major	It is good practice for an NAB or RAB to move toward a market-economy model of increased institutional autonomy, as opposed to being fully controlled by government. The latter is a challenge in any case, owing to international recognition criteria. Autonomy gives the management responsibility and freedom to operate effectively in the marketplace (Racine 2011). The NAB must be free from undue influences, political or financial, that would compromise its impartiality in making accreditation decisions.

How can it be demonstrated?

There are generally nine elements that can be considered to determine a legal autonomy index of the NAB or RAB. This is not an absolute number but a good indicator. Does the NAB or RAB have the autonomy and the authority to

- Grant and revoke accreditation;
- Determine the positions and staffing of its workforce;
- Determine the salaries of its workforce;
- Select the workforce;
- Set accreditation fees;
- Determine its own budget;
- Create new administrative divisions;
- Offer new service or initiate new activities; and
- Solicit membership in international accreditation organizations and sign international agreements?

Some of these elements are fundamental regarding the international recognition of the NAB or RAB based on compliance with ISO/IEC 17011. It is especially the authority of the NAB or RAB in granting and revoking accreditation that needs to be demonstrably free from political interference and from financial incentives related to remuneration or budget.

Existing information/reporting/monitoring

- Accreditation Act, decree, regulation, or similar law, if relevant
- Articles of incorporation, if relevant
- NAB or RAB council or board policy papers
- NAB or RAB website and annual reports
- Government regulations regarding rules of employment (if the NAB is a governmental or public body)

5.2.5 Legal standing of accreditation (building block no. 4)

What is meant

Major	The role of accreditation—especially in the realm of technical regulation or implementation of other legislative instruments based on the outcome of QI service delivery—should be clearly articulated in relevant legislation.

How can it be demonstrated?

QI services, such as test reports, certificates, and the like for conformity with technical regulations or other types of legislative instruments, are progressively being provided by service providers independent of the regulatory authorities. Hence, the technical competency of such service providers needs to be demonstrated. Accreditation has become the method of choice in this regard. It is therefore important that its role is given legal standing in the form of appropriate legislation.

Existing information/reporting/monitoring

- Accreditation Act, decree, regulation, or similar law, if relevant
- Formal government mandate of the NAB or RAB

5.2.6 Governance (building block no. 5)

What is meant

Fundamental	The NAB or RAB should have a board or council in charge of strategy approval and overall fiduciary responsibilities, whether the board or council is appointed by a relevant minister or by shareholders.
Major	Good governance models suggest that the members of the board or council should be individuals with specific knowledge regarding accreditation and market realities.

How can it be demonstrated?

The actual composition of the council or board must be considered. The number of members, as well as the balance between private sector members and public servants, is important. The more-progressive NABs have more private sector representatives than public servants on their councils or boards. Council or board members should be appointed in their individual capacities and not as representatives of business or industry associations or specific public institutions.

The members of a council or board, however appointed, should be selected for their knowledge, experience, or qualifications relating to the functions of the NAB, particularly including local and international metrology and technical infrastructure matters, as well as business management and finance. The council or board should not be larger than 15 members. Good governance principles suggest that the chief executive officer (CEO) of the NAB should be a full member of the council or board but should not be allowed to hold a leadership position on the council or board (for example, chair, vice-chair, or secretary).

The council or board should have the mandate or authority to (a) approve the business strategies of the NAB; (b) appoint the CEO and consider his or her performance (with appropriate firewalls to ensure that the accreditation decisions are not compromised by issues, such as number of accreditations within a given time frame); (c) oversee the financial integrity of the NAB or RAB; (d) approve the budget and monitor performance of the NAB against the budget; and (e) approve the organizational structure.

Existing information/reporting/monitoring

- Accreditation Act, decree, regulation, or similar law
- Articles of incorporation, if relevant
- NAB or RAB council or board policy papers

- NAB or RAB website and annual reports
- Government regulations regarding public entities
- NAB or RAB council or board committee structures

5.2.7 Financial sustainability (building block no. 6)

What is meant

Fundamental	The finances for the NAB can be provided from government sources, financial support from industry and other stakeholders, and income generated by accreditation services. Whatever the source of funding, there should be assurances that it would be adequate also in the medium to long term.

How can it be demonstrated?

The NAB or RAB will require major government funding during its first few years of operation, before it has gained international recognition. Once the NAB or RAB has international recognition, its accreditation services will be more marketable. It has been shown that once an NAB or RAB has gained 200–250 accredited organizations on its books, then the income from accreditation can cover costs. Government support is then only required to maintain international liaison activities, such as ILAC and IAF membership and active participation in their committees.

This picture is complicated when the NAB or RAB has been given a government mandate to accredit QI organizations that operate within the regulatory domain (that is, when the government forces accreditation on such QI organizations). In such cases, market forces regarding fees are often set aside, and the NAB or RAB cannot market its services at market-related prices but have to charge lower fees as prescribed by the authorities.

The overall financial situation of the NAB or RAB of the past three to five years would be a good indication of the financial sustainability of the institution. The situation should show a positive trend over the years under review. The income generated from accreditation services would be a further indicator that should show a positive trend. A formal government commitment to support the NAB or RAB in carrying out its responsibilities regarding accreditation, as well as specific financial support for its international and regional liaison activities, are positive indicators of the NAB's or RAB's financial sustainability.

Existing information/reporting/monitoring

- Accreditation strategy
- Annual NAB or RAB business plans
- Annual government budget allocations
- Annual reports of the NAB or RAB
- Monthly and annual financial statements of the NAB or RAB

5.3 ADMINISTRATION AND INFRASTRUCTURE

5.3.1 Benchmark and significance

The organizational structure of the NAB or RAB must be conducive to providing the full complement of accreditation services that its stakeholders require. Good governance principles require the NAB or RAB to have a proper management

executive, and the subject fields of accreditation suggest that the NAB or RAB should have divisions dedicated to accreditation services in these fields.

Over and above these general guidelines, the NAB or RAB has to comply with the requirements of ISO/IEC 17011 relating to organizational structures. These include an accreditation approvals committee; an advisory committee; technical committees related to the fields of accreditation; and the administrative systems to manage a vast pool of external assessors, management system documentation, and accreditation information.

The demand for premises relates mostly to appropriate office space, meeting rooms, and information technology (IT) infrastructure. The NAB or RAB would not experience as much people traffic as the NSB or national metrology institute (NMI) would.

5.3.2 Chief executive officer (building block no. 7)

What is meant

Major	The chief executive officer (here referred to as the CEO, whatever the actual title) is responsible for leading the development and execution of the NAB or RAB's strategy and overall management. The CEO acts as a direct liaison between the board or council and management of the NAB or RAB and communicates to the board or council on behalf of NAB or RAB management. The CEO—rather than the chair of the board or council—is the public face of the NAB or RAB.
Minor	Depending on the legislation, custom, and practice relevant to the NAB or RAB, the CEO may be appointed by the relevant minister or the board or council. Recent tendencies suggest that the CEO should be appointed for only a limited period, typically five years. He or she can be reappointed if relevant key performance indicators are fulfilled.

How can it be demonstrated?

There is no standardized list of the major functions and responsibilities carried out by an NAB's or RAB's CEO, but the following list includes the typical functions:

- Supports operations and administration of the board or council by advising and informing its members, interfacing between board or council and staff, and supporting the board or council's evaluation of management executives
- Oversees the design, marketing, promotion, delivery, and quality of accreditation programs, products, and services
- Recommends the annual budget for board or council approval and prudently manages the NAB or RAB's resources within those budget guidelines according to current laws and regulations
- Effectively manages the human resources of the NAB or RAB according to authorized personnel policies and procedures that fully conform with current laws and regulations
- Ensures that the NAB or RAB and its mission, programs, products, and services are consistently presented using strong, positive images to relevant stakeholders
- Oversees fundraising planning and implementation, including identifying resource requirements, researching funding sources, and establishing strategies to approach funders
- Represents the NAB or RAB and has the right to sign legal documents

Existing information/reporting/monitoring

- Relevant legislation (Accreditation Act or similar law), if relevant
- Articles of incorporation, if relevant
- Official ministerial decisions
- Board or council decisions and minutes
- Official CEO job description
- Agreed CEO key performance indicators

5.3.3 Organizational structure (building block no. 8)

What is meant

Major	Accreditation consists of a number of subject fields. It therefore follows that the organizational structure of an NAB or RAB should have divisions that optimally support these groups and their subject fields. In addition, an accreditation approvals committee is a requirement and an advisory committee is a strong recommendation.

How can it be demonstrated?

Good management practice suggests that the organizational structure of the NAB or RAB should take cognizance of these various scopes of accreditation. That is, the NAB or RAB should have divisions that are specifically responsible for those scopes in which it provides services. (For a list of scopes, see module 5 of the QI Toolkit.) Such a structure would also facilitate the international recognition that is generally arranged in line with these international standards.

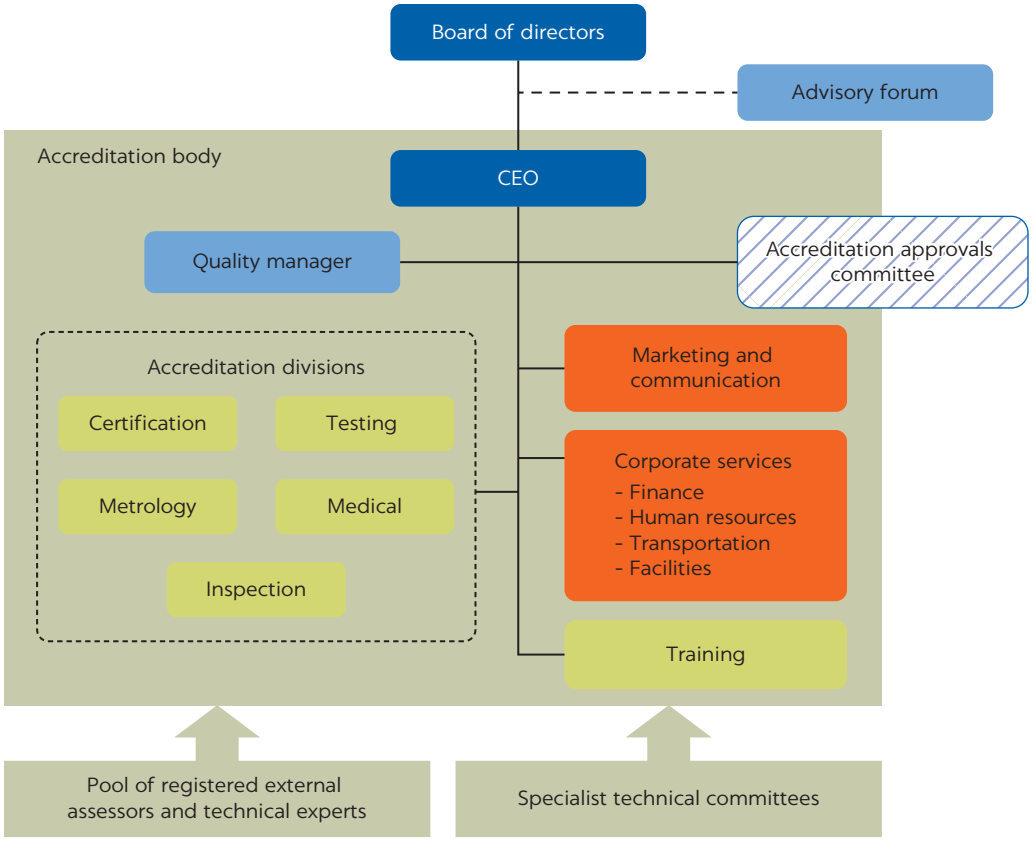
Other important organizational structure elements include the following (figure 5.2):

- *External assessors and technical experts.* The NAB or RAB seldom employs all the assessors and technical experts required as full-time staff and has to depend on a vast pool of external assessors and technical experts. These have to be managed, and the appropriate element within the NAB or RAB organizational structure has to be established.
- *Accreditation approvals committee.* The accreditation decision must be made by an accreditation approvals committee totally independent of the assessment teams. Such an accreditation approvals committee has to be established within the organizational structure, with NAB or RAB staff, as well as outside experts as its members.
- *Advisory forum.* An accreditation advisory forum is a useful forum in which stakeholders can provide the NAB or RAB with information on future requirements, market developments, and the like, with which the NAB or RAB strategy and business plans can be enriched.
- *Training division.* An internal training division is a useful organizational construct because the training of assessors and experts in the various accreditation scopes is an ongoing activity.

Existing information/reporting/monitoring

- Approved organizational structure
- Board or Council decisions
- Ministerial decisions
- Financial system documentation

FIGURE 5.2
Typical organizational structure of a national or regional accreditation body



Based on ISO/IEC 17011, "Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies."

5.3.4 Management and personnel (building block no. 9)

What is meant

Major	Accreditation is a people-based activity operating within specified scopes. The management and personnel must therefore have the appropriate skill sets assured by appropriate training, qualifications, and experience. These would include management and technical knowledge as required by the various activities within the accreditation scopes.

How can it be demonstrated?

In the first place, the NAB or RAB should operate with an organizational structure approved by either the board or council or the relevant minister. For each of the positions, the skill set (qualifications, training, and experience) should be clearly and formally stated. The ratio between technical and administrative staff will depend largely on the way in which the NAB or RAB uses external assessors and experts, but the percentage of administrative staff dedicated solely to internal activities should not be more than 20 percent.

Second, there should be few staff vacancies on either the management or technical levels; more than 95 percent of those positions should remain filled. Anything less indicates that the NAB or RAB cannot operate effectively or efficiently. Staffing challenges often include a lack of skilled people in the country, but even more so, inadequate remuneration resulting in the departure of trained staff for more lucrative offers elsewhere.

Existing information/reporting/monitoring

- Approved organizational structure
- Actual staffing levels
- Staff turnover figures

5.3.5 Premises (building block no. 10)

What is meant

Major	Accreditation is a people-based activity; hence laboratory-type space for highly technical equipment is not required. The premises should be appropriate for staff, meeting rooms, and IT equipment. The confidentiality of the information must be ensured.

How can it be demonstrated?

Office space conducive to a positive working environment is necessary for the staff of the NAB or RAB. Meeting rooms where clients can be received and committee rooms for technical committee meetings and training are important as well. Space for storing and ease of retrieval of the records of assessments and accreditation is essential, and the security of these records needs to be ensured. The location of the NAB or RAB offices should not be underestimated; in particular, it should not create a perception that the impartiality of the NAB or RAB could be compromised, such as by sharing accommodation with a conformity assessment service provider.

Existing information/reporting/monitoring

- Review of office space and meeting rooms
- Location of the NAB or RAB in relation to other QI entities

5.3.6 Equipment (building block no. 11)

What is meant

Major	Equipment requirements for the NAB or RAB are fulfilled by an effective, efficient, and secure IT system.

How can it be demonstrated?

An efficient and effective IT system that can handle the quality management system documentation and the assessment and accreditation records is important. Its access control should be such that the integrity of all records can be ensured at all times.

Existing information/reporting/monitoring

- Consideration of the effectiveness and efficiency of the IT system
- Consideration of the access control of the IT system

5.4 PILLAR 3: SERVICE DELIVERY AND TECHNICAL COMPETENCY

5.4.1 Benchmark and significance

International recognition is a nonnegotiable fundamental for the NAB or RAB for its trade-related areas of activity; it is also good practice for the other areas,

such as medical laboratories and so on. Without such international recognition, the NAB's or RAB's services will largely be inconsequential. International recognition is achieved by becoming a signatory of the ILAC and IAF multilateral recognition arrangements or agreements, respectively. Achieving signatory status is based on the positive outcome of peer reviews of the NAB or RAB by either ILAC or the IAF directly or through a regional coordination body or group recognized by them.

The assessment of an organization is conducted by a team led by a team leader and comprising relevant assessors and technical experts. All of these must be appropriately trained and experienced. The accreditation is granted by an independent accreditation approvals committee to further safeguard the integrity of the accreditation process.

5.4.2 Lead assessors (building block no. 12)

What is meant

Fundamental	An assessment for accreditation is conducted by teams led by a registered lead assessor, supported by the appropriate assessors and technical experts. Such lead assessors are selected, trained, and registered for specific accreditation scopes.

How can it be demonstrated?

Accreditation includes scopes as defined in relevant International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) standards, such as for

- *Calibration and testing laboratories*: ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories";
- *Medical laboratories:* ISO 15189, "Medical Laboratories—Requirements for Quality and Competence";
- *Product certification:* ISO/IEC 17065, "Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services";
- *Quality management certification:* ISO/IEC 17021, "Conformity Assessment—Requirements for Bodies Providing Audit and Certification of Management Systems";
- *Inspection organizations:* ISO/IEC 17020, "Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection"; and
- *Personnel certification:* ISO/IEC 17024, "Conformity Assessment—General Requirements for Bodies Operating Certification of Persons."

Other standards that are used include fields, such as Principles of Good Laboratory Practice (GLP), Good Manufacturing Practices (GMP), and many more (as described in module 5 of the QI Toolkit).

The teams assessing organizations in terms of any of the scopes will be led by a lead assessor who is knowledgeable about the specific scope. The NAB or RAB must ensure that the lead assessors are appropriately selected, trained in the accreditation procedures, and registered in the database of the NAB or RAB as lead assessors. The NAB or RAB has to continuously ensure that assessment teams are led by the appropriate lead assessor, such as one who has been registered for the specific accreditation scope.

Existing information/reporting/monitoring

- Lead assessor database of the NAB or RAB
- Formal job description of lead assessors
- Personnel records regarding education, training, and experience of lead assessors
- Annual training plans and concomitant records of lead assessors
- Assessment reports

5.4.3 Assessors and technical experts (building block no. 13)

What is meant

Fundamental	The lead assessor of a team conducting an assessment is supported by registered assessors and technical experts who are trained and experienced regarding the specific scope and technology of the organization being assessed.

How can it be demonstrated?

Within the general scope of accreditation (see building block no. 8), the organization being assessed will provide specific services related to testing, inspection, or certification, for example. Accreditation is an attestation of the technical competency of such an organization; hence, during the assessment, a judgment call has to be made regarding the organization's competency. This can only be done by assessors and technical experts who are well versed in the specific technology or service and knowledgeable regarding assessment practices.

The NAB or RAB has to maintain a registry of the assessors and technical experts it has selected and trained, together with their experience and assessment records. The NAB or RAB has to ensure that only appropriately registered assessors and technical experts are used on all of its assessment teams.

Existing information/reporting/monitoring

- Assessor and technical expert database of the NAB or RAB
- Formal job descriptions of assessors and technical experts
- Personnel records regarding education, training, and experience of assessors and technical experts
- Annual training plans and concomitant records of assessors and technical experts
- Assessment reports

5.4.4 Specialist technical committees (building block no. 14)

What is meant

Fundamental	The NAB or RAB needs input from interested parties regarding accreditation processes and assessor training within each accreditation scope. This can be provided through specialist technical committees or working groups.

How can it be demonstrated?

It is good practice for the NAB or RAB to establish specialist technical committees or working groups to provide it with recommendations regarding the various scopes of accreditation services provided by the NAB or RAB. These committees do not have a governance function but are representing interested parties as experts in their specific fields.

Existing information/reporting/monitoring

- List of working groups
- Working group minutes, decisions, and recommendations
- NAB or RAB responses to working group recommendations

5.4.5 Quality system documentation (building block no. 15)

What is meant

Fundamental	The NAB or RAB must provide for an open and transparent system of applications, requirements, assessments, and approval processes regarding accreditation, including the publicly available information on accredited organizations, all of which must be compliant with ISO/IEC 17011 and the interpretation documents of ILAC and the IAF.

How can it be demonstrated?

The NAB or RAB must have a formal quality management system that complies with the requirements of ISO/IEC 17011 and the relevant interpretation documents of ILAC and the IAF. This system entails policies, procedures, work instructions, and records. Over and above the internal use of such documentation to ensure the continued compliance of the NAB's or RAB's activities, ISO/IEC 17011 also requires that the accreditation process-related quality management documentation be publicly available. The publication of such documentation on the official website of the NAB or RAB is the most efficient way of doing so. Documentation control is an important part of such a system to ensure that users always have immediate access to the latest revisions thereof.

Existing information/reporting/monitoring

- The NAB or RAB quality system and its compliance with ISO/IEC 17011
- Quality system documentation and its revision control system
- Official website of the NAB or RAB

5.4.6 Assessment process (building block no. 16)

What is meant

Fundamental	The assessment process initiated with an application contains distinct steps that include documentation review, preassessment, assessment team selection, on-site assessment, and closing out of nonconformities before an accreditation decision can be made.

How can it be demonstrated?

The assessment process has been largely standardized internationally. It starts with the application for accreditation by an organization providing information on the application form. The NAB or RAB continues with the evaluation of the applicant's quality management documentation, highlighting areas that need attention. Thereafter, a preassessment may be conducted, depending on the circumstances and scope of accreditation, during which major nonconformities are highlighted and a decision is made on whether a full assessment could lead to a positive outcome.

The assessment team is thereafter selected with an appropriate lead assessor and technical assessors. The team conducts a full on-site assessment to determine compliance with the relevant standard. Nonconformities are identified, and the organization is given a specified time frame in which to resolve them,

after which they are reassessed. The team compiles a full report with a recommendation of accreditation. The report is submitted to an accreditation approvals committee for consideration.

Existing information/reporting/monitoring

- Quality system documentation
- Assessment applications
- Preassessment reports
- Assessment reports

5.4.7 Approval process (building block no. 17)

What is meant

Fundamental	The assessment report recommending accreditation is considered for a decision on whether to grant accreditation by an accreditation approvals committee that is totally independent from the assessment team. The same process applies to revoking accreditation.

How can it be demonstrated?

The NAB or RAB has to establish an accreditation approvals committee to consider reports of the assessment teams with the view to granting accreditation. This committee must be totally independent of the assessment team; that is, none of the assessment team members may be a member of the approvals committee. In larger NABs or RABs, the approvals committee will consist of senior management, but it is also useful to bring in outside expertise as relevant.

Existing information/reporting/monitoring

- Quality system documentation
- Assessment reports
- Accreditation approvals committee minutes and decisions

5.4.8 Accreditation and follow-up (building block no. 18)

What is meant

Fundamental	An accreditation certificate is issued, carefully detailing the scope of accreditation. The details of the accredited company are published in the publicly available database of the NAB or RAB, and the company is placed on the postaccreditation surveillance and reassessment roster.

How can it be demonstrated?

If the accreditation approvals committee approves the recommendation of the assessment team to accredit the organization, then an accreditation certificate is issued, generally for a period of three years. The certificate includes a full description of the scope of the accreditation, not only in general terms but also in details of specific tests and certification services of the accredited organization. The accredited organization is then placed on the surveillance and reassessment roster of the NAB or RAB. Surveillance visits usually take place every six months, during which selected elements are audited. After three years, the complete assessment is repeated before a three-year extension to the accreditation certificate is granted.

Existing information/reporting/monitoring

- Quality system documentation
- Database of accredited organizations
- Surveillance reports
- Reassessment reports
- Reissuance of accreditation certificate records

5.5 PILLAR 4: EXTERNAL RELATIONS AND RECOGNITION

5.5.1 Benchmark and significance

Whereas the extent of the services offered by the accreditation body depends on the needs of the market and regulatory authorities, requirements for international recognition are independent of its size; they are basically the same for all. International recognition of the accreditation body is based on its competency and impartiality, and this is determined by a system of peer reviews against the requirements of ISO/IEC 17011.

The bulk of international recognition is provided through the mutual or multilateral recognition agreements or arrangements of ILAC (for test and calibration laboratories, medical test laboratories, and inspection bodies) and the IAF (for product and management system certification bodies, as well as certification of persons), but some sector-specific arrangements are also in place, such as for suppliers of automotive parts, private sector food certification, and so on.

5.5.2 Training system (building block no. 19)

What is meant

Fundamental	The NAB or RAB has to train its lead assessors, assessors, and technical experts and maintain a register of their education, training, and technical and assessment experience.

How can it be demonstrated?

Lead and technical assessors are selected for their education levels and industrial or technical experience. They then have to be trained in accreditation skills, including knowledge regarding the formal quality management system of the NAB or RAB. Thereafter, their performance on actual assessments is reviewed by a registered senior lead assessor and technical assessors, leading to their registration by the NAB or RAB. It is good practice for the NAB or RAB to provide the training in-house; otherwise, it has to contracted from foreign institutions at high cost. This training should also be provided to quality managers of entities that wish to be accredited.

Existing information/reporting/monitoring

- Training programs for lead and technical assessors
- Database of lead and technical assessors and their personnel records

5.5.3 Liaison with regional organizations (building block no. 20)

What is meant

Fundamental	International recognition of the capability of an NAB or RAB is increasingly organized through regional cooperation bodies or groups. Liaison and active participation in such bodies is therefore an imperative.

Major	If the country is a member of a regional trade bloc, then the NAB or RAB will be required to participate actively in regional accreditation activities if these are part of the regional agreements. This means also participating in technical committees at the regional level.

How can it be demonstrated?

At the regional level, three types of organizational constructs related to accreditation have developed over the past few decades that should not be confused:

- *Regional cooperation bodies or groups.* Because of the increase of accreditation bodies worldwide, many peer reviews for international recognition are now arranged through recognized regional cooperation bodies or groups rather than by ILAC and the IAF themselves. Liaison by accreditation bodies with such cooperation bodies or groups is therefore an important fundamental necessity. The situation regarding recognition of such regional cooperation bodies or groups by ILAC and IAF is fluid, and the latest information regarding the status of such bodies needs to be obtained from the ILAC and IAF websites.
- *Regional accreditation committees or forums.* Various regional accreditation constructs (committees, forums, and so on) have also been established as the outcome of trade agreements leading to regional common markets. In many cases, NAB or RABs are members by default, having to represent their countries in these regional constructs. Some regional accreditation constructs 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. There is no one model that is superior to others (Kellermann and Keller 2014).
- *Regional accreditation service entities.* RABs providing accreditation services to smaller countries in the region covered by the relevant trade agreements are being established and are slowly gaining recognition through ILAC and the IAF. 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. In the initial stages, they may be funded by the member states of the region. A country without an NAB can enter into a formal agreement with such an RAB to act as the de facto or in some cases even the de jure NAB. In some regions, member states establish accreditation focal points to act as a liaison between the RAB and entities wishing to be accredited, as well as to play a role in the training and registering of local assessors to be used by the RAB.

Existing information/reporting/monitoring

- Membership of the NAB or RAB in the recognized regional coordination body or group
- Reports of NAB or RAB participation in the regional activities
- Regional trade agreement membership status of the country
- Relevant regional treaties, protocols, agreements, or legislation
- Annual reports of the NAB or RAB
- NAB or RAB internal reports of regional accreditation activities and meetings

5.5.4 Liaison with international organizations (building block no. 21)

What is meant

Fundamental	The two relevant international organizations from an accreditation perspective would be ILAC and the IAF, because they manage the general multilateral recognition agreements or arrangements at the international level. Membership is differentiated between associate members and full members as signatories of the recognition agreements or arrangements.
Major	Becoming a signatory to the recognition agreement or arrangement is a peer evaluation process that includes a preevaluation and a final evaluation of the NAB or RAB against the requirements of ISO/IEC 17011 and the relevant interpretation documents of ILAC and the IAF, respectively. Twinning with a signatory accreditation body is a major advantage in this process.

How can it be demonstrated?

ILAC provides for the mutual recognition arrangement concerning accreditation of testing and calibration laboratories, medical laboratories, and inspection bodies. The IAF provides for the multilateral recognition arrangements concerning accreditation of management system and product certification bodies and personnel certification bodies.

An accreditation body can become an associate member as a precursor to becoming a full member as a signatory to the recognition agreement or arrangements. Signatory status is only achieved once a peer review has been conducted that results in a positive outcome based on the requirements of ISO/IEC 17011 and the related interpretation documents of ILAC and the IAF. Signatory status means that the output of accredited organizations in the country or region—for example, test reports, calibration certificates, and product and management system certificates—are recognized by accreditation bodies that are also signatories and are more readily recognized in markets and regulation of those countries whose accreditation bodies are also signatories.

A number of sector-specific accreditation and recognition schemes are managed by organizations other than ILAC and the IAF. Examples include the following, among many others (as further discussed in module 5, section 5.5.3, of the QI Toolkit):

- *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 (IECBx); and Quality Assessment System for Electronic Components (IECQ) schemes, managed by the IEC
- *Legal metrology equipment:* Mutual Acceptance Arrangements managed by the International Organization for Legal Metrology (OIML)

These schemes are not included in this Comprehensive Diagnostic Tool and, if needed, will require a separate evaluation of the needs of the country related to the specific sector.

Existing information/reporting/monitoring

- Accreditation strategy and its implementation plans
- ILAC and IAF membership data
- ILAC and IAF technical committee data
- Annual reports of the NAB or RAB
- Business plans and minutes of the NAB or RAB technical committees
- Formal communication records of the NAB or RAB with ILAC and the IAF
- Twinning agreement with a signatory NAB or RAB

5.5.5 International recognition (building block no. 22)

What is meant

Fundamental	International recognition is afforded to the NAB or RAB once it becomes a signatory to the multilateral recognition agreement or arrangement of ILAC and the IAF, respectively. To become a signatory entails a peer review against the requirements of ISO/IEC 17011 and relevant ILAC and IAF interpretation documents.

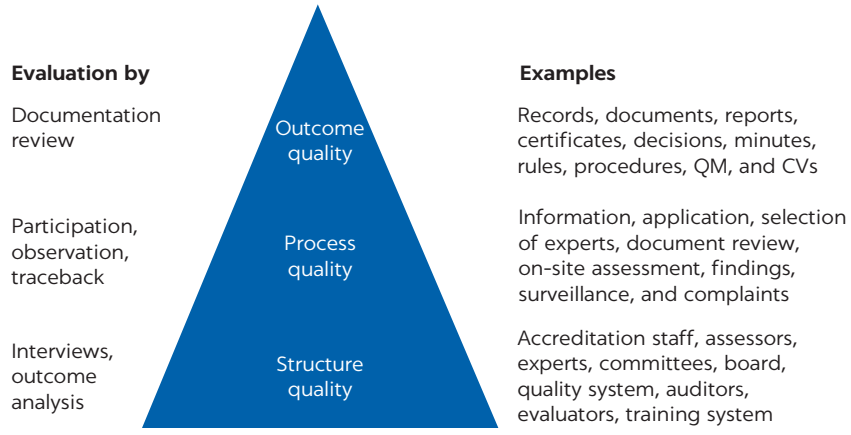
How can it be demonstrated?

The precursor of becoming a signatory of the ILAC and IAF recognition agreements and arrangements is a peer review against the requirements of ISO/IEC 17011 and the interpretation documents of ILAC and the IAF, respectively. The peer reviews of ILAC and the IAF are largely standardized, and are conducted on three levels (figure 5.3). The NAB or RAB has to formally apply, after which a peer review team will be selected by the regional cooperation body or group if relevant, or by ILAC or the IAF if a recognized group or body does not exist for the specific region, to conduct the peer review.

Becoming a signatory is a long journey; it takes quite a few years. 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. This is not so easy, because most organizations that wish to be accredited prefer to be accredited by an internationally recognized accreditation body. A newly

FIGURE 5.3

Evaluation pyramid for compliance with ISO/IEC 17011



Source: UNIDO 2011. ©United Nations Industrial Development Organization (UNIDO). Reproduced with permission from UNIDO; further permission required for reuse.
Note: ISO/IEC 17011 = "Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies." QM = quality management. CVs = curricula vitae.

established NAB or RAB is therefore at a market disadvantage because it lacks this recognition. Such an NAB or RAB will find it beneficial to enter into a twinning arrangement with a signatory NAB or RAB that would help the fledgling NAB or RAB negotiate the vagaries of the peer reviews and would provide a mechanism whereby the organizations it accredits will receive a joint accreditation certificate giving them the recognition they require. Once the NAB or RAB has attained signatory status, then all joint accreditation certificates are transferred to it.

Existing information/reporting/monitoring

- Formal application for signatory status
- Time schedule for peer review program
- Peer review reports
- ILAC and IAF website information on signatory status

5.5.6 Coordination within the QI (building block no. 23)

What is meant

Major	Coordination among the fundamental QI organizations (NSB, NMI, and NAB) is important to ensure that their responsibilities and activities provide a unified basis for calibration and conformity assessment service providers and market surveillance activities of regulatory authorities.

How can it be demonstrated?

Coordination within the QI is important, especially among the NSB, the NMI, and the NAB (or RAB), as the three pinnacle QI organizations. The coordination—which is important to ensure that there are no overlaps or gaps in their service delivery or activities—can be achieved formally or informally. If the NSB, NMI, and NAB (or RAB) are governmental organizations, then their line ministries are in a good position to ensure such coordination, especially that the three are implementing the quality policy measures. Otherwise a quality council or similar body would be able to do the same. A third alternative is for the CEOs to have a formal coordination meeting at regular intervals. A technical regulation coordination office (whatever its name) coordinates the activities of the regulatory authorities with the QI on the development and implementation of technical regulations, ensuring that costly overlaps and gaps in service delivery are kept to a minimum.

Existing information/reporting/monitoring

- Line ministry policies, pronouncements, documentation, and regulations
- Quality council (or similar body) documentation and minutes of meetings
- Technical regulation coordination office mandate and pronouncements

NOTE

1. RABs provide accreditation services to the member states of the region. Each one is an accreditation body proper. In contrast, ILAC and the IAF devised the nomenclature of regional cooperation bodies or groups to denote regional accreditation constructs that are similar in nature to the international accreditation organizations, namely, ILAC and the IAF. These bodies or groups do not provide accreditation services, and their main responsibility is to coordinate accreditation activities within the region.

STANDARDS REFERENCED IN SECTION 5

Note: The most recent revision of these international standards should be obtained from the ISO or IEC, as relevant. Details regarding the private standards referenced in the text should be obtained from the relevant organizations.

ISO (International Organization for Standardization). 2012. "ISO 15189: Medical Laboratories—Requirements for Quality and Competence." 3rd ed. Ref. no. ISO 15189:2012(E), ISO, Geneva.

ISO and IEC (International Organization for Standardization and International Electrotechnical Commission). 2012. "ISO/IEC 17020: Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection." Ref. no. ISO/IEC 17020:2012(E), ISO, Geneva.

———. 2012. "ISO/IEC 17024: Conformity Assessment—General Requirements for Bodies Operating Certification of Persons." 2nd ed. Ref. no. ISO/IEC 17024:2012(E), ISO, Geneva.

———. 2012. "ISO/IEC 17065: Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services." Ref. no. ISO/IEC 17065:2012(E), ISO, Geneva.

———. 2015. "ISO/IEC 17021-1 Conformity Assessment—Requirements for Bodies Providing Audit and Certification of Management Systems—Part 1: Requirements." Ref. no. ISO/IEC 17021-1:2015(E). Geneva: ISO.

———. 2017. "ISO/IEC 17011: Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies." 2nd ed. Ref. no. ISO/IEC17011:2017(E), ISO, Geneva.

———. 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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Kellermann, Martin, and Daniel Paul Keller. 2014. "Leveraging the Impact of Business Environment Reform: The Contribution of Quality Infrastructure—Lessons from Practice." Working paper, Business Environment Working Group of the Donor Committee for Enterprise Development (DCED) and United Nations Industrial Development Organization (UNIDO), Vienna.

Minzberg, H., B. Ahlstrand, and J. Lampel. 1998. *Strategy Safari: The Complete Guide through the Wilds of Strategic Management*. Edinburgh: Pearson Education, Prentice Hall.

Racine, Jean-Louis, ed. 2011. *Harnessing Quality for Global Competitiveness in Eastern Europe and Central Asia*. Washington, DC: World Bank.

UNIDO (United Nations Industrial Development Organization). 2011. "Reference Manual for Quality Infrastructure Building Blocks." UNIDO, Vienna.

6

Inspection

6.1 INTRODUCTION

Inspection is defined in ISO 17000 ("Conformity Assessment—Vocabulary and General Principles") as the examination of a product design, a product, a process, or installation to determine its conformity with specific requirements or, on the basis of professional judgment, with general requirements. Inspection activities can overlap with testing and certification activities where these activities have common characteristics. However, an important difference is that many types of inspection involve professional judgment to determine acceptability against general requirements, for which reason the inspection body needs the necessary competence to perform the task.

In *regulatory work*, inspection may cover product compliance with technical regulation requirements before being made available for marketing. In this case, inspection activities often lead to testing and a certificate of compliance. Inspection also includes postmarket surveillance in the case of products already in the market and regular examination of installations for safety purposes. Inspections of the latter are applied to motor vehicles, cranes and lifting gear, boilers and pressure vessels, and electrical installations. Probably the most common form of regulatory inspection takes place in the area of food safety and food outlet hygiene.

In the *manufacturing sector*, inspection is an essential tool in quality control. It applies not only to the inspection of the completed product but also to the physical examination of in-process products to assess their fitness to proceed to the next manufacturing step. Inspection is used in the *services sector* as well, to establish conformity with service procedures and fulfillment of critical service requirements.

In the *manufacture of complex products or assemblies*, it is not uncommon for the customer to either participate in the multiproduction inspection process or engage a competent third-party inspection body to represent its interests. The same applies if a nonconforming product may have catastrophic consequences for the customer. In such cases (for example, aircraft manufacture, shipbuilding, and the like), the customer will pay great attention to the inspection systems employed by the manufacturer. A government may decide that certain products

are of high value, and it wishes to bolster or maintain its image in export markets as a prime manufacturing country. It then institutes inspection systems for such products before they may be exported.

Inspection bodies carry out assessments on behalf of private clients, their parent organizations, or authorities to provide information about the conformity of inspected items with regulations, standards, specifications, inspection requirements, or contracts. Inspection parameters include matters of quantity, quality, safety, fitness for purpose, and continued safety compliance of installations or systems in operation.

This multiplicity of inspections is taken into consideration in ISO/IEC 17020 ("Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection"), the international standard for inspection bodies. The standard defines three types of inspection bodies differentiated by the extent of formal separation from possible sources of influence (as further discussed in module 6, section 6.2, of the QI Toolkit):

- *Type A:* Third-party inspection bodies not directly linked to the organization involved with the design, manufacture, use, or maintenance of items under 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

(*Note:* This Comprehensive Diagnostic Tool considers only Type A and, to a lesser extent, Type C inspection services—that is, independent inspection services in both the regulatory and nonregulatory fields. It does not address Type B inspection services, such as in-house inspection services of manufacturers, and so on.)

Considering the multiplicity of inspection services, evaluating the needs of a country with respect to inspection is complex, and many facets need to be taken into consideration. Hence, it is useful to differentiate between basic, advanced, and mature inspection systems, depending on the maturity levels of the quality infrastructure (QI) in a country (table 6.1).

These have to be considered in relation to the needs of manufacturers, regulatory authorities, and the marketplace; in other words, the evaluation becomes a multifaceted exercise. In low- and middle-income countries, governments may be the sole user of inspection services, especially in the regulatory domain, whereas in high-income economies, commercial inspection activities have an impact across all sectors and are not only concerned with safety but also with customer satisfaction and the quality of manufactured goods and services.

The diagnostic tool concerning inspection consists of two subsections: the first dealing with the inspection sector as a whole, and the second with the evaluation of an individual inspection body. The former (on the inspection sector) deals primarily with the policy environment of the country, taking into consideration both the public and the private sectors; its building blocks are listed in table 6.2). The pillars and building blocks for the latter (evaluating a specific inspection body) are listed in table 6.3.

TABLE 6.1 Maturity levels of a country's inspection services, by characteristic

CHARACTERISTIC	RUDIMENTARY (LITTLE IS IN PLACE)	BASIC (LOW- TO MIDDLE-INCOME COUNTRY APPROACH)	ADVANCED (ECONOMYWIDE APPROACH, SECTORAL APPROACH)	MATURE (TOTALLY FREE-MARKET APPROACH)
Inspection body infrastructure	A few public sector inspection bodies	A few public sector inspection bodies	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
Recognition	Through legislation	By government appointment	Through government appointment, designation, and accreditation	Through government appointment, designation, and accreditation
Establishment	Public sector inspection bodies	Public sector inspection bodies	Mix of public and private sector inspection bodies	Wide range of public and private sector inspection services
Services	A small number of regulatory inspections	Selected regulatory inspection	Regulatory inspection, with nonregulatory inspection services emerging	Wide range of inspection services, both regulatory and nonregulatory
Human resources	Training on the job	Training on the job	Training on the job Training courses in inspection	Training on the job Training courses in inspection Inspectors as a professional profile
Demand orientation	No demand orientation	Demand surveys, mostly through projects	Demand surveys Stakeholder participation and consultative mechanism	Free-market instruments and constructs to ensure demand orientation

TABLE 6.2 Building blocks of a country's inspection sector

	BUILDING BLOCK	
PILLAR	NO.	DESCRIPTION
1: Legal and institutional framework, inspection services sector	1	Inspection services strategy
	2	Designated inspection bodies
	3	National inspection bodies for regional markets

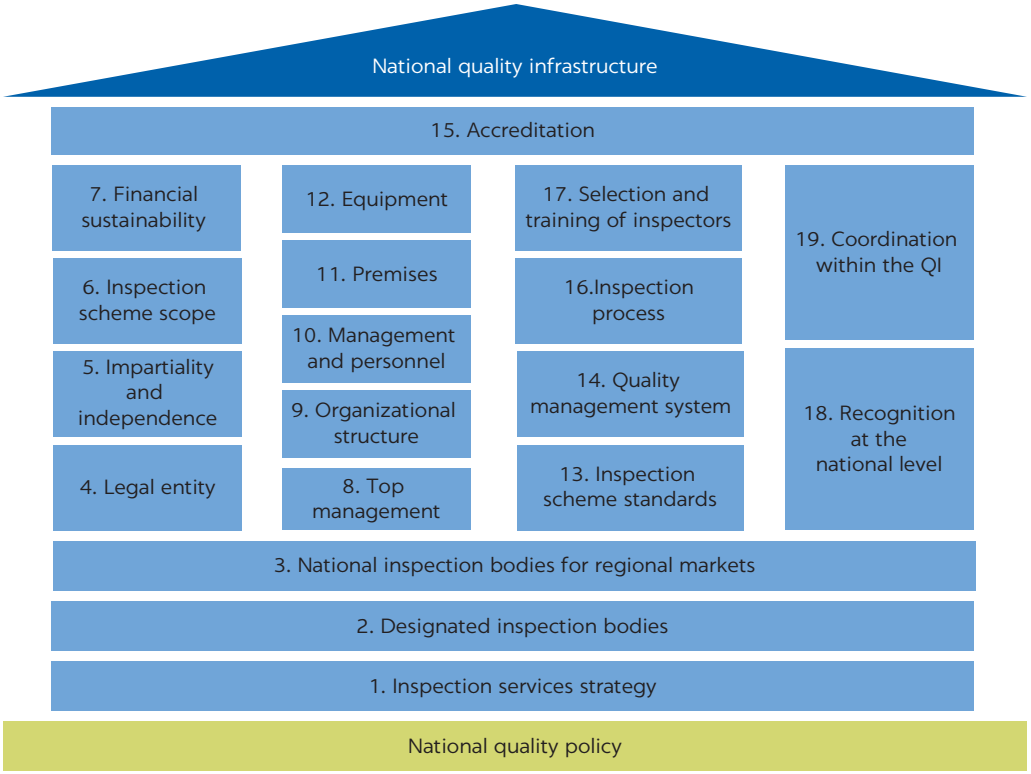
TABLE 6.3 Pillars and building blocks of an inspection body

	BUILDING BLOCK	
PILLAR	NO.	DESCRIPTION
1: Legal and institutional framework, individual inspection body	4	Legal entity
	5	Impartiality and independence
	6	Inspection scheme scope(s)
	7	Financial sustainability
2: Administration and infrastructure	8	Top management
	9	Organizational structure
	10	Management and personnel
	11	Premises
	12	Equipment
3: Service delivery and technical competency	13	Inspection scheme standards
	14	Quality management system
	15	Accreditation
	16	Inspection process
	17	Selection and training of inspectors
4: External relations and recognition	18	Recognition at the national level
	19	Coordination within the QI

Note: QI = quality infrastructure.

FIGURE 6.1

House of inspection for a national quality infrastructure



Note: QI = quality infrastructure. The four "pillars" of the QI—represented by the blue columns containing the "building block" numbers—are as follows (left to right): "legal and institutional framework," "administration and infrastructure," "service delivery and technical competency," and "external relations and recognition."

To depict the pillars and building blocks in a graphical way that would indicate the state of inspection in a country at a glance, they can be put together as shown in figure 6.1. For a complete description of the construction, interpretation, and use of this graphic or of the matching radar diagram, see section 1: Comprehensive QI Assessment.

Inspection bodies gain a certain level of recognition once accredited. In many countries, however, accreditation alone is not enough; regulatory authorities would designate inspection bodies once they are accredited before they may provide inspection services in the regulated domain. For inspection bodies operating in the nonregulated domain, accreditation can be seen as the first step; thereafter, responsiveness, price, and so on would determine their acceptance by the market. These postaccreditation realities need to be factored into the evaluation as additional elements to the building blocks depicted in figure 6.1, where appropriate.

6.2 PILLAR 1: LEGAL AND INSTITUTIONAL FRAMEWORK, INSPECTION SERVICES SECTOR

6.2.1 Benchmark and significance

With the immense scope of inspection types, the wide variety of users of inspection services, and the importance of inspection in both the regulatory and nonregulatory domains, it is important that the government has a clear vision and

strategy of the use of inspection, especially in the regulatory domain. This strategy needs to clearly indicate the responsibilities of inspection bodies and the government's intentions to use only technically competent inspection bodies for work in the public domain.

6.2.2 Inspection services strategy (building block no. 1)

What is meant

Major

Following on from the quality policy (see module 10 of the QI Toolkit), an inspection services strategy gives meaning to the implementation of the quality policy regarding the establishment of technically competent inspection bodies in both the public and private sectors. The inspection services strategy is about

- Making the right choices regarding the overall approach to the use of inspection bodies in the country;
- Providing technically competent inspection services within the public sector;
- Getting the mix right between public and private sector inspection bodies;
- Using accreditation (to ISO/IEC 17020) to demonstrate the technical capability of inspection bodies in both the public and private sectors;
- Designating the private sector inspection bodies providing services in the regulatory domain;
- Using inspection services in government purchases; and
- Building capacity in inspection bodies, especially the training of inspectors, to provide required inspection services in the most innovative, effective, and efficient way.

How can it be demonstrated?

The inspection services strategy can be seen as an intended plan to set a pattern, create a unique position, follow a specific perspective, and implement a specific tactic—all to enable the government and the private sector collectively to make a difference to a critical mass of the right customers and to connect their purposes with those of their customers and external stakeholders (Minzberg, Ahlstrand, and Lampel 1998).

The strategy should take cognizance of the country's demonstrated demands for inspection services in important sectors (for example, the regulatory domain for products and services, private sector demands, and so on). Although the government usually takes the initiative to establish inspection services in the regulatory domain, the outsourcing of such inspection services to accredited and designated commercial inspection bodies is a growing trend. The mechanism of designating inspection bodies for technical regulation implementation should therefore be detailed. Priority development sectors should be identified, and government support for the development of inspection bodies by the private sector should be provided for, where relevant.

Technical capability is of paramount importance for establishing trust in the work of inspection bodies. Therefore, accreditation to ISO/IEC 17020 should be a prerequisite for both public and private sector inspection bodies before they begin working in the regulatory domain. The training of inspectors is likewise an important element because inspection frequently relies on the professional judgment of inspectors in determining whether a product, installation, or service meets regulatory requirements.

The inspection services strategy should be a formal document approved at least by the relevant ministry, and in some countries by the cabinet, because it will be cross-cutting with respect to ministries in its implementation. The inspection services strategy should be publicly available—that is, on the relevant ministry website or in hard copy. The activities, business plans, and budgets of the relevant ministry regarding a public inspection body should be aligned with the strategy. The private sector will make its own business plans, depending on the space it is given in the strategy.

Existing information/reporting/monitoring

- Relevant government policies, strategies, and implementation plans
- Review of the extent of the public sector inspection body's capacity and capabilities
- Government purchasing documentation
- Relevant ministry (for example, Trade and Industry, Science and Technology, Health, Agriculture, or others) websites

6.2.3 Designated inspection bodies (building block no. 2)

What is meant

Major	Inspection bodies mandated to provide inspection services in the regulatory domain should be designated by the relevant authorities based on their technical competence (that is, accreditation) and their legal liability in the country.

How can it be demonstrated?

Public sector inspection bodies are usually given their mandate in terms of legislation. However, a noticeable trend is for governments to shift the inspection workload to private sector inspection bodies. To legalize such a shift, private sector inspection bodies need to be designated in terms of specific legislative mandates.

Designation is a formal, legal recognition of a private sector inspection body by the relevant authority to provide specified inspection functions in the regulatory domain. Designation only follows once certain requirements have been met. These include a demonstration of the inspection body's technical competency (that is, accreditation to ISO/IEC 17020) and compliance with requirements that accreditation does not address, such as legal liability in the country, up-to-date income tax returns, and so on.

Existing information/reporting/monitoring

- Accreditation Act, decree, regulation, or similar law, if relevant
- Relevant legislative instruments of ministries
- Accreditation body lists of accredited inspection bodies
- Official lists of designated inspection bodies for the regulatory domain

6.2.4 National inspection bodies for the regional markets (building block no. 3)

What is meant

Major	Inspection bodies providing inspection services in the context of a regional common market are recognized by the relevant authorities and the regional market.

How can it be demonstrated?

Within regional common markets, regulatory inspections play a significant role in facilitating intraregional trade. Products subject to technical regulations that are inspected and released for marketing in one member state should be able to be marketed in the other member states without further inspection. This presupposes that the work of inspection bodies of one member state is acceptable to the others.

A regional system of recognizing and designating such inspection bodies is required to ensure the legitimacy of the system as a multilateral recognition arrangement. Accreditation of the inspection bodies to ISO/IEC 17020 and the "notification" of designated inspection bodies to all member states by the government of the country in which the inspection body is legally registered are necessary preconditions for such a recognition arrangement.

Existing information/reporting/monitoring

- Government export policies and strategies
- Recognition agreements between the government and regional common market authorities
- Records of notification of designated inspection bodies within the regional common market

6.3 PILLAR 1: LEGAL AND INSTITUTIONAL FRAMEWORK, INDIVIDUAL INSPECTION BODIES

6.3.1 Benchmark and significance

Inspection bodies are either fully independent, able to provide third-party inspection services (Type A), or part of a larger organization providing first- and second-party inspection services (Types B and C). To be recognized, inspection bodies have to demonstrate their competency; that is, they will need to be accredited. Hence, it is important that the inspection body clearly define the scope of its inspection schemes because accreditation will be ascribed accordingly.[1]

The inspection body's financial sustainability is an important parameter. Public sector inspection bodies should be assured of appropriate government funding, and commercial inspection bodies operating in the regulatory domain should be allowed to charge fees that will facilitate their financial sustainability.

6.3.2 Legal entity (building block no. 4)

What is meant

Major	An inspection body shall be a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for the outcome of its inspection services. Inspection bodies may be a public or a private sector entity.

How can it be demonstrated?

The individual inspection body shall be established by legislation or articles of incorporation, depending on whether it is a public or private sector entity. A governmental inspection body can also be deemed to be a legal entity on the basis of its governmental status. The legislation or articles of incorporation must define the governance, financial provisions, and responsibilities and

functions of the inspection body. The ability to demonstrate its legal entity status is a prerequisite for accreditation.

Existing information/reporting/monitoring

- Relevant legislative instruments of ministries
- Relevant articles of incorporation

6.3.3 Impartiality and independence (building block no. 5)

What is meant

Fundamental	The inspection body is responsible for ensuring that inspection activities are undertaken impartially and that commercial, financial, or other pressures do not compromise its impartiality.

How can it be demonstrated?

An inspection body may be an independent public or private sector entity, or it may be a part of a greater entity. Each of these will have a different governance structure, depending on the extent of its independence. If operating as an independent inspection body (Type A), then it should not be involved in the design, manufacture, supply, or operation of the item to be inspected. If operating as part of a larger organization (Types B and C), then its inspection activities should be ring-fenced as an identifiable entity within the parent.

Whatever the case, the inspection body must ensure and be able to demonstrate that commercial, financial, or other pressures do not influence the outcome of its inspections. It has to identify the risks to its impartiality, such as ownership, governance, shared resources, payment of commissions, and so on, and it must detail the measures undertaken to minimize the influence of such risks.

Existing information/reporting/monitoring

- Legislative instrument establishing the inspection body, if relevant
- Articles of incorporation, if relevant
- Government decisions or decrees, if relevant
- Official organizational structure
- Annual reports of the inspection body

6.3.4 Inspection scheme scope(s) (building block no. 6)

What is meant

Fundamental	The inspection body has to clearly define the scope of the inspection scheme(s) it offers. These are also the basis of its accreditation.

How can it be demonstrated?

Many inspection schemes are possible—for example, for pressure vessels, lifts and escalators, food safety, roadworthiness of vehicles, occupational safety and health, environmental factors, market surveillance of products falling within the scope of technical regulations, and many more. The inspection body has to define which of these it offers or plans to offer inspection services for. These services should be aligned with the demonstrable needs of its chosen target market or defined extent of regulatory work. The scope will determine the requirements for its initial audit, surveillance audits, and other elements required for its accreditation, as determined by the accreditation body.

Existing information/reporting/monitoring

- Official description of the scope of inspection schemes offered
- Accreditation scopes
- Inspection body business strategy and plans
- Inspection body annual budgets

6.3.5 Financial sustainability (building block no. 7)

What is meant

Fundamental	The finances for the inspection body can be provided from government sources or through payment for services by its clients. However the finances are provided, the inspection body should be financially sustainable, without financial pressures having a deleterious effect on its services.

How can it be demonstrated?

The finances of a governmental inspection body operating in the regulatory domain are usually provided by the state. Pressures on government finances are common; therefore, care should be taken that the necessary finances are ensured for the inspection body to fulfill its mandate effectively over time. The fees of commercial inspection bodies operating in the regulatory domain are often prescribed by the state to protect companies from being exploited by inspection bodies. In this case, care should be taken that the prescribed fees are market-related and do not hamper the inspection bodies from delivering an effective service.

Fees for commercial-type inspection services should be left to market forces, and they should be agreed to between the inspection body and its clients as a normal business transaction. The fees of governmental inspection bodies providing commercial inspection services should not be so low as to distort the market, because this will inhibit the establishment of private sector inspection bodies.

The inspection body's overall financial situation for the past three to five years would be a good indication of its financial sustainability. The situation should show a positive trend over the years under review. A positive trend in the income generated from inspection services would be a further indicator, as would be business plans for future developments.

Existing information/reporting/monitoring

- Annual government budget allocations
- Annual government fee prescriptions in the regulatory inspection domain
- Inspection body business plans
- Annual reports of the inspection body
- Monthly and annual financial statements of the inspection body

6.4 PILLAR 2: ADMINISTRATION AND INFRASTRUCTURE

6.4.1 Benchmark and significance

The inspection body's organizational structure must be conducive to providing the full complement of the inspection schemes included in its scope and subscopes, and as required by its stakeholders or regulatory authorities.

Good governance principles require the inspection body to have a top management, and the subject fields of its inspection schemes suggest that the inspection body should have divisions dedicated to inspection schemes in these fields, if relevant. The confidentiality of inspection information must be ensured in a legally enforceable manner.

Over and above these general guidelines, the inspection body has to comply with the requirements of ISO/IEC 17020 relating to organizational structures and impartiality or any other relevant standards it wishes to be accredited for. The inspection body has to use properly trained inspectors, and it will have to demonstrate that its personnel are free from any undue commercial, financial, and other pressures that might influence their technical judgment.

6.4.2 Top management (building block no. 8)

What is meant

Major	The top management of the inspection body is responsible for the technical management of the inspection body and is accountable for the quality and integrity of its services. Effective communication channels must exist between the top management and personnel, as well as between top management and higher-level management or governance structures.

How can it be demonstrated?

There is no standardized list of the major functions and responsibilities carried out by the top management, but some typical functions include the following:

- Supports operations and administration of the inspection body governance structures by advising and informing its members and by interfacing between governance structures and personnel
- Oversees the development, marketing, promotion, delivery, and quality of inspection services
- Recommends the annual budget for approval and prudently manages the inspection body's resources within those budget guidelines
- Effectively manages the human resources of the inspection body according to authorized personnel policies and procedures
- Ensures that the inspection body and its mission and services are consistently presented using strong, positive images to relevant stakeholders
- Oversees the identification of resource requirements and possible income sources, including ascertaining strategies to approach funders

Existing information/reporting/monitoring

- Governance structure decisions and minutes
- Official top management job descriptions
- Agreed-upon top management key performance indicators

6.4.3 Organizational structure (building block no. 9)

What is meant

Major	A number of inspection schemes covering a vast range of products, processes, and services are possible. It therefore follows that the organizational structure of an inspection body should have divisions that optimally support its scope of inspection schemes, the groupings within it, the modalities of the inspection process, and maintenance of its impartiality.

How can it be demonstrated?

Good management practice suggests that the organizational structure of the inspection body should take cognizance of groupings within its scope of inspection schemes. Other issues to consider include the following:

- The organizational structure must support its impartiality.
- The organizational structure must allow it to manage inspection activities effectively.
- One or more technical managers have the overall responsibility to ensure that inspections are carried out in accordance with stated requirements.
- Professional judgment resources are available for the final decision on the acceptability of the inspected product, process, or service.

These elements are not only important from a good governance perspective but also are necessary to consider for accreditation purposes.

Existing information/reporting/monitoring

- Approved organizational structure
- Governance structure decisions
- Financial system documentation

6.4.4 Management and personnel (building block no. 10)

What is meant

Fundamental	Inspection is largely a people-based activity supported by testing in specific cases. The management and personnel must therefore have the appropriate skill sets assured by appropriate training, qualifications, and experience. These would include management and technical knowledge as required by the various activities within the inspection body's scopes.

How can it be demonstrated?

In the first place, the inspection body should operate with an organizational structure approved by its governance structures. For each of the positions, the skill set (qualifications, training, and experience) should be clearly and formally stated. The administrative staff should not make up more than 20 percent of total staff; the major proportion should be technical staff.

Second, there should be few staff vacancies on either the management or technical levels; more than 95 percent of those positions should remain filled. Anything less indicates that the inspection body cannot operate effectively or efficiently. Staffing challenges often include a lack of skilled people in the country, but even more so, inadequate remuneration resulting in the departure of trained staff for more lucrative offers elsewhere.

Third, technical staff should have the necessary skill set of education, training, and experience to be able to manage and conduct inspections within specified scopes regarding relevant technology; the ways in which the products, processes, and installations are used; and the nonconformities that might occur. The inspection body should have documented procedures for selecting, training, and monitoring their inspectors.

Inspection bodies normally do not subcontract individuals on an ad hoc basis to conduct inspection work, owing to the high demands on the interpretation skills of the inspector. They may have individuals on long-term contracts, but these would have to comply with all the selection and training criteria for inspectors (see building block no. 17). In the case of unforeseen circumstances, such as

an unforeseen overload of work or the incapacity of specific inspectors on staff, the inspection body may use subcontracted inspectors, but the inspection body remains responsible for the integrity of their work.

(*Note:* For testing personnel, see section 7: Testing.)

Existing information/reporting/monitoring

- Approved organizational structure
- Approved criteria for technical staff
- Actual staffing levels
- Staff turnover figures
- Selection, training, and monitoring records of inspectors

6.4.5 Premises (building block no. 11)

What is meant

Major	Appropriate office accommodation for personnel is required. The offices should have meeting rooms where clients can be received, rather than in the offices of personnel, to ensure that information about other companies remains confidential. Storage space for records is essential.

How can it be demonstrated?

Office space conducive to a positive working environment is necessary for the staff of the inspection body. Meeting rooms in which clients can be received rather than in the offices of personnel, especially inspectors, are important to keep information of other clients confidential. Space for storing and ease of retrieval of the records of audits and inspections is essential. The effect of the location of the offices of the inspection body on business should not be underestimated; it should be relatively easily accessible by clients.

Also important is the correct storage of inspection and testing equipment to maintain the equipment's operational ability and calibration status, as well as the correct storage of laboratory testing equipment used in inspection activities. Specialized knowledge is required to determine the suitability of such premises.

(*Note:* The requirements for laboratories for product testing are detailed in section 7: Testing.)

Existing information/reporting/monitoring

- Review of inspection body accommodation in the light of defined requirements

6.4.6 Equipment (building block no. 12)

What is meant

Fundamental	Suitable and adequate facilities and equipment must be available for the inspection body to perform all inspection activities for its inspection schemes in a competent and safe manner.

How can it be demonstrated?

The inspection body must use equipment appropriate for the inspection task. It may own the equipment, or it can be rented, leased, borrowed, or provided by another party, but the inspection body remains responsible to ensure the

equipment is in good working order and calibrated. Inspection equipment that has a significant influence on inspection results should be uniquely identified. Measuring equipment should be properly maintained and calibrated, and reference materials should be traceable to national or international reference materials.

Automated test equipment is increasingly being used in inspection, and special attention needs to be given to the integrity of related computer software, which should be validated and updated continuously. Formal procedures should be in place to ensure the integrity of all inspection equipment, and defective or out-of-calibration equipment should be removed immediately to minimize the inadvertent use of such equipment.

Data protection with regard to inspection results is of paramount importance, and national judicial requirements in this regard have to be followed.

(*Note:* The equipment requirements for product testing are detailed in section 7: Testing.)

Existing information/reporting/monitoring

- Consideration of the effectiveness of the choice and acquisition of inspection equipment
- Consideration of the formal control system over inspection equipment (including maintenance and calibration intervals and records thereof)
- Consideration of the validation and updating mechanisms and records of computer software
- Consideration of the access control of the information technology (IT) system

6.5 PILLAR 3: SERVICE DELIVERY AND TECHNICAL COMPETENCY

6.5.1 Benchmark and significance

Accreditation by an independent and recognized accreditation body is the primary recognition mechanism for inspection bodies (see building block no. 15). This may be accreditation to ISO/IEC 17020 or similar sector-based systems, thereby demonstrating the inspection body's technical competency. All of them require the implementation of a formal quality management system, with internal audit procedures and management review to ensure continuous compliance. With inspection often resulting in a judgment call based on the professional knowledge of the inspector, the appointment, training, and monitoring of appropriately skilled inspectors is of particular significance.

6.5.2 Inspection scheme standards (building block no. 13)

What is meant

Fundamental	The inspection body must have a clear description of the inspection schemes it provides, including their applicability regarding national or international standards.

How can it be demonstrated?

The inspection body should clearly define the scope of its inspection schemes (see also building block no. 6). This should preferably be in terms of published

standards—that is, public or private, or national, regional, or international standards. In the regulatory domain, the regulatory authorities may have published criteria additional to the relevant standards the inspection body has to comply with. All of this information should be made publicly available by the inspection body or the regulatory authority where relevant.

Existing information/reporting/monitoring

- Quality management system documentation
- Inspection body website
- Inspection body marketing material and brochures
- Accreditation records
- Regulatory authority information

6.5.3 Quality management system (building block no. 14)

What is meant

Fundamental	The quality management system must comply with the requirements of the relevant accreditation standard (for example, ISO/IEC 17020) that may be aligned with ISO 9001 or a similar quality management standard.

How can it be demonstrated?

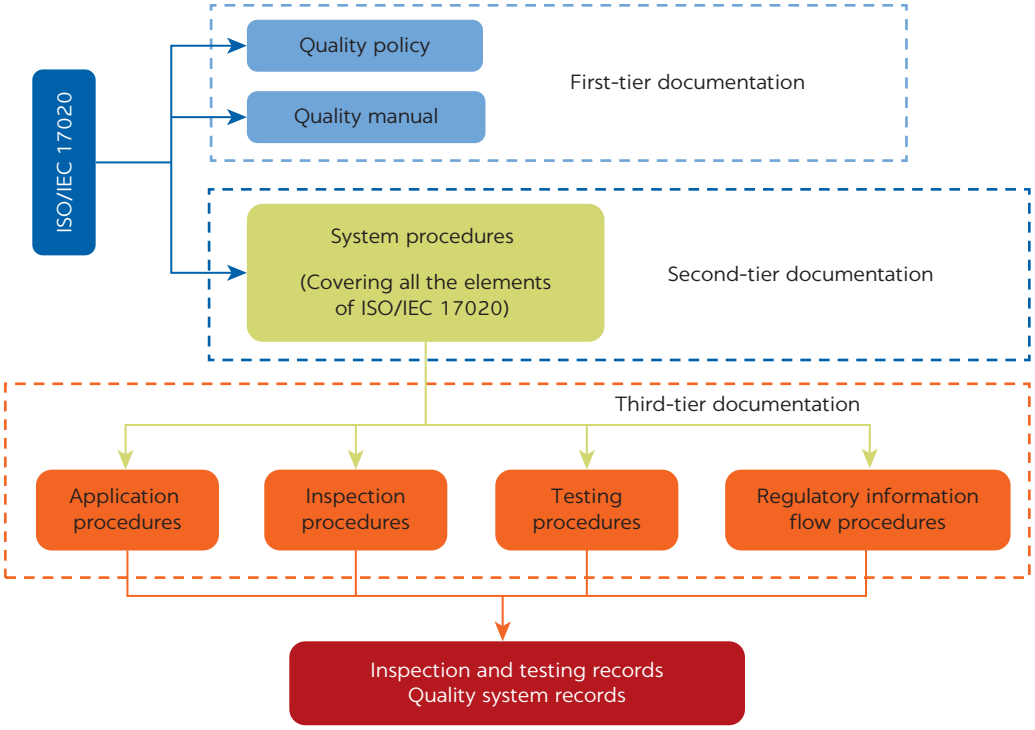
The inspection body has to implement and maintain a formal quality management system. It may be similar to the requirements of ISO 9001 ("Quality Management Systems—Requirements"), or it may be as detailed in the accreditation standard (for example, ISO/IEC 17020). The elements of such a formal quality management system usually include management system documentation, records and their control, management review, internal audits, and corrective action, among others.

The quality management system documentation is generally organized on three tiers, generically known as policy documents, procedures, and work instructions. These are supported by records of the inspections, internal audit records, management review records, and records of nonconformities and others required by the relevant accreditation standard. In the regulatory domain, specific requirements may have been published by the regulatory authority. A typical quality management documentation system for an inspection body is shown in figure 6.2.

The accreditation process usually includes an assessment of the quality management documentation before a preassessment or initial assessment is conducted, to ensure that all the elements of the relevant accreditation standard are addressed. The inspection body normally has six months to rectify any nonconformities identified in the quality management documentation before on-site assessments are considered.

An important element for inspection bodies operating in the regulatory domain is the legal obligation they have to inform relevant authorities regarding their inspection results, especially the uncovering of nonconformities. Specific procedures should be established to properly manage this flow of information, and an appropriate mechanism to also inform the inspected supplier should be in place as well.

FIGURE 6.2
Typical inspection body documentation system



Note: ISO/IEC 17020 = "Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection."

Existing information/reporting/monitoring

- Quality management documentation
- Internal audit results
- Management review records
- Accreditation records

6.5.4 Accreditation (building block no. 15)

What is meant

Major	*Preassessment.* An inspection body may request a preassessment before an initial assessment is conducted to determine whether a formal quality management system is in place.
Fundamental	*Initial assessment.* The initial assessment for accreditation is an on-site visit by a team from the accreditation body to determine whether the quality management system documentation is fully operational and whether the inspection body is competent to conduct the inspection defined in its scope.
Fundamental	*Accreditation.* Once all nonconformities have been cleared, the accreditation body submits the assessment report to its approvals committee for a final decision. Should accreditation be granted, the inspection body receives an accreditation certificate carefully detailing its inspection scheme scopes, and its data are added to the publicly available information of the accreditation body.
Fundamental	*Designation.* Once accredited, commercial inspection bodies operating in the regulatory domain can request designation as such from the regulatory authority.

How can it be demonstrated?

Preassessment. Once the quality system documentation has been assessed, the inspection body may request a preassessment by the accreditation body. The preassessment is usually a one-day visit by the lead assessor of the accreditation body to determine whether a formal quality management system is in place, without determining whether the inspection body is competent to conduct inspection. In some cases, the accreditation body may require a preassessment as a precondition for the initial assessment. Nonconformities detected during the preassessment have to be corrected before an initial assessment can take place.

Initial assessment. The initial assessment is conducted by an accreditation body team consisting of a team leader and technical assessors and experts. The inspection body has to ensure that there are sufficient records to confirm that the system is implemented before the initial assessment; for example, inspections must have been successfully completed. Most accreditation bodies also require a complete internal audit and management review cycle to have been completed.

The inspection body's staff will have to demonstrate to the technical assessors that they are competent to conduct inspections and complete the inspection reports. Any nonconformities identified during the initial assessment usually have to be demonstrably corrected within six months; otherwise the complete initial assessment may need to be repeated.

Accreditation. The assessment report detailing all the findings of the assessment team, evidence of the correction of any nonconformities, and a recommendation for accreditation is submitted to the approvals committee of the accreditation body. If accreditation is granted, then the inspection body receives an accreditation certificate that will detail the scope of its inspection schemes. The accreditation certificate usually has a validity of three to five years, during which follow-up assessments are conducted on an audit basis. An initial assessment is repeated to reissue the accreditation certificate.

Should the follow-up audits reveal nonconformities, the inspection body will be given a specified amount of time to rectify them. Failure to do so will result in the suspension of the accreditation, followed by the withdrawal of the accreditation certificate if no progress is achieved. During suspension, the inspection body may not claim accreditation status.

Designation. In the case of commercial inspection bodies operating in the regulatory domain, accreditation is only the first step to recognition. The inspection body has to approach the relevant regulatory authority with all the additional information required for designation before it can legally provide inspection services for the specific technical regulation. The designation status is automatically lost if accreditation is suspended or withdrawn.

Existing information/reporting/monitoring

- Accreditation application
- Assessment result of the quality management system documentation
- Preassessment record
- Initial assessment reports and records
- List of identified nonconformities
- Records of closeout of nonconformities
- Accreditation certificate

- Public records of accreditation body
- Designation records of the relevant regulatory authorities

6.5.5 Inspection process (building block no. 16)

What is meant

Fundamental	The approach and processes an inspection body follows must comply with the technical inspection requirements for the product, process, or service as stated in standards, technical regulations, or other contractual documents, and they must be in line with the requirements of ISO/IEC 17065 ("Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services") or similar standards used for its accreditation.

How can it be demonstrated?

Most inspection are performed in accordance with methods and procedures stated in standards or technical regulations appropriate for the product, process, or service to be inspected. They can also be contained in contracts or in-house requirements of clients. Where these methods and procedures are not stated, the inspection body has to develop its own fully documented procedures.

The inspection body has to ensure that the work it undertakes is within its expertise and that it has adequate resources to do so. When it uses information from another party in the inspection process, it shall verify the integrity thereof. All inspection observations and results have to be recorded in a timely manner to ensure that important information does not get lost or is distorted. Data transfer and calculations should be given special attention to prevent errors.

The inspection body must ensure that any inspection samples are properly identified to avoid any later confusion. Obviously, the inspection body must ensure that such samples do not deteriorate or are damaged while under its responsibility.

Existing information/reporting/monitoring

- Inspection body's quality management and process documentation
- Standards and technical regulation requirements
- Inspection reports and records
- Inspector(s) records
- Inspection body's website

6.5.6 Selection and training of inspectors (building block no. 17)

What is meant

Fundamental	The personnel responsible for inspections shall have appropriate qualifications, training, and experience, and a satisfactory knowledge of the requirements of the inspections to be carried out.

How can it be demonstrated?

The outcome of inspections is frequently heavily dependent on the personal judgment of the inspector. The inspector should have not only general technical qualifications and experience but also specific knowledge regarding the

- Technology used for the manufacture of the product, the operation of processes, or the delivery of services to be inspected;

- The way in which products will be used, processes operated, and services delivered; and
- Any defects that may occur during the use of the product or in the operation of processes, as well as any deficiencies in the delivery of services.

Inspectors therefore have to be carefully selected, trained, and monitored to ensure their continuous optimum performance. Training normally consists of an induction period, a mentored period, and continuous training to keep pace with developing technologies. Mentoring takes place on-site under the watchful eyes of more-senior inspectors. For some of the regulatory inspection work, approved training programs may be provided by the inspection body association, technical colleges, or regulatory authorities.

Existing information/reporting/monitoring

- Inspection body's quality management and process documentation
- Standards and technical regulation requirements
- Inspector selection, training, and mentoring records

6.6 PILLAR 4: EXTERNAL RELATIONS AND RECOGNITION

6.6.1 Benchmark and significance

The formal recognition of inspection bodies for regulatory work based on their technical competency and their legal liability is important because they are operating as extensions of the government that is ultimately accountable for the outcome of the inspection work, be it concerning safety and health at the workplace, in society, or of the environment. The same applies to inspection services used by industry in the nonregulated domain.

6.6.2 Recognition at the national level (building block no. 18)

What is meant

Major	Recognition at the national level is facilitated by accreditation to the relevant international standard (for example, ISO/IEC 17020). Recognition may be by the market, or it can go a step further in being designated by a governmental authority for specific inspection scheme(s) related to the implementation of regulations.

How can it be demonstrated?

Many governmental inspection bodies operate with a legal mandate not requiring any further recognition. It is good practice, however, if such governmental inspection bodies would also consider accreditation to ISO/IEC 17020. It will not change their legal mandate but would enhance their standing as a technically competent entity. In a regional common market context, accreditation may be indicated even for governmental inspection bodies in order to gain recognition in all member states.

Commercial inspection bodies will do well to gain accreditation to ISO/IEC 17020, even though they may be able to trade on their reputation for some time in the marketplace. Recognition by regulatory authorities through designation is now largely based on such accreditation plus some additional legal requirements not covered by accreditation, such as legal liability in the country, up-to-date tax

returns, and others. Competency assessments by regulatory authorities against own requirements, for example, are slowly being abandoned in lieu of an independent accreditation to ISO/IEC 17020.

Existing information/reporting/monitoring

- Official lists of accredited inspection bodies
- Official lists of regulatory authorities regarding designated inspection bodies

6.6.3 Coordination within the QI (building block no. 19)

What is meant

Minor	Coordination among the inspection bodies of the country is based largely on activities managed through voluntary associations. Coordination of the regulatory work of inspection bodies is managed by the state.

How can it be demonstrated?

A national inspection body association in which membership is voluntary can be helpful in coordinating some elements of inspection activities—for example, lobbying governmental authorities, facilitating discussions on a better understanding of inspection standards, training of inspectors, and so on. Such associations can be important communication forums between ministries responsible for sector-specific technical regulation and the relevant commercial inspection bodies (for example, pressurized equipment inspection bodies, occupational safety and health environmental inspection bodies, roadworthy-vehicle inspection bodies, and so on).

In addition, a technical regulation coordination office (or a similar facility) may enforce coordination of activities between inspection bodies and the regulatory authorities, as well as with the national accreditation body (NAB), national standards body (NSB), and national metrology institute (NMI) regarding the implementation of technical regulations.

Existing information/reporting/monitoring

- Regulatory authority policies, pronouncements, and documentation
- Inspection body associations' documentation and minutes of meetings
- Technical regulation coordination office mandate and pronouncements

NOTE

1. ISO/IEC 17020 defines an inspection scheme as a system to which the same specific requirements, rules, and procedures for carrying out inspection apply.

STANDARDS REFERENCED IN SECTION 6

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7

Testing

7.1 INTRODUCTION

Testing is the determination of one or more characteristics of a product, material, or process in accordance with a specified procedure. Testing, like metrology, is a technology-intensive endeavor. The technical competency of testing laboratories is mostly demonstrated through accreditation to ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories"), although other peer review mechanisms are also used. Testing services are required by both the public and the private sectors for the implementation of technical regulations, by industry for production purposes, by the marketplace for the demonstration of product quality, and for many other purposes. Testing is required in wide-ranging settings, and evaluating the needs of the country is therefore of paramount importance.

In the past, testing for the implementation of technical regulations and sanitary and phytosanitary measures was the sole domain of regulatory authorities. This model is slowly being replaced by a liberalization (subsidiarity concept) of testing, with regulatory authorities designating testing laboratories that are technically competent (that is, accredited) and that can be held legally accountable in the country where the technical regulations are implemented. Such testing services can be provided by both public and private sector laboratories. The designation of testing laboratories is discussed in more detail in module 7 of the QI Toolkit.

Because of the costs of establishing and maintaining testing laboratories, private sector laboratories are slowly increasing, whereas the scope of public sector laboratories is slowly decreasing, even in low- and middle-income countries. Such shifts are closely connected with the liberalization of testing services for regulatory purposes. Establishing sophisticated testing services in low- and middle-income economies remains a major challenge for authorities, and recognition of test results of foreign laboratories is often the only feasible alternative, despite the risks involved owing to the lack of legal accountability of the foreign

laboratories in the country and the possibility of fraudulent certificates being presented by suppliers.

Evaluating a country's needs regarding testing services is complex, and many facets need to be taken into consideration. It is useful to differentiate between basic, advanced, and mature requirements, depending on the maturity levels of the quality infrastructure (QI) in a country (table 7.1).

This part of the Comprehensive Diagnostic Tool consists of two subsections: the first dealing with the testing laboratory sector as a whole, and the second with the evaluation of an individual laboratory. The former (on the testing laboratory sector as a whole) deals primarily with the evaluation of the country's demands, taking into consideration both the public and the private sectors. The basic building blocks for evaluating the testing laboratory sector are listed in table 7.2.

(*Note:* In-house laboratories of manufacturing facilities are not considered in this diagnostic tool unless they provide testing services on request to outside organizations, in which case they should comply with the same criteria as an independent testing laboratory.)

The pillars and building blocks for evaluating a specific testing laboratory are listed in table 7.3. If more than one laboratory in a specific sector have to be evaluated, then the building blocks of table 7.3 should be adjusted as appropriate. It may be possible to provide a common result for all laboratories evaluated, or

TABLE 7.1 Maturity levels of a country's testing services, by characteristic

CHARACTERISTIC	RUDIMENTARY (VERY LITTLE IS IN PLACE)	BASIC (LOW- TO MIDDLE-INCOME COUNTRY APPROACH)	ADVANCED (ECONOMYWIDE APPROACH, SECTORAL APPROACH)	MATURE (INNOVATIVE, CUTTING-EDGE TECHNOLOGY)
Testing laboratory infrastructure	Few or no laboratories established	A few testing laboratories to support • Main exported products; • Important health services; and • Critical technical regulation implementation	Testing services defined through economywide surveys and defined sectoral needs	High-level testing laboratories for innovative sectors
Recognition	None	Through accreditation	Through accreditation and designation	Through accreditation and designation
Establishment	All public sector laboratories	Mostly public sector laboratories	Good mix of public and private sector laboratories	Predominance of private sector laboratories for service delivery, public sector for research and development
Services	A few low-technology testing services offered	Selected testing services	Wide range of testing services	Wide range of testing services and research activities
Human resources	Training on the job	Training on the job	Training on the job Training courses in testing methodologies	Training on the job Training courses in testing methodologies Researchers as a professional profile
Demand orientation	None	Demand surveys, mostly through projects	Demand surveys Stakeholder participation and consultative mechanism	Strong instruments and constructs to ensure demand orientation

TABLE 7.2 Building blocks of a country's testing laboratory sector

PILLAR	BUILDING BLOCK	
	NO.	DESCRIPTION
1: Legal and institutional framework, the laboratory sector	1	Testing services strategy
	2	Designated testing laboratories
	3	Testing laboratories for the export markets
	4	Testing laboratories for the health sector

TABLE 7.3 Pillars and building blocks of a testing laboratory

PILLAR	BUILDING BLOCK	
	NO.	DESCRIPTION
1: Legal and institutional framework, an individual laboratory	5	Legal entity
	6	Governance
	7	Testing scope
	8	Financial sustainability
2: Administration and infrastructure	9	Top management
	10	Organizational structure
	11	Management and personnel
	12	Premises
	13	Equipment
3: Service delivery and technical competency	14	Testing services scope
	15	Quality management system documentation
	16	Proficiency testing
	17	Preassessment
	18	Initial assessment
	19	Accreditation
4: External relations and recognition	20	Recognition at the national level
	21	Recognition at the international level
	22	Coordination within the QI

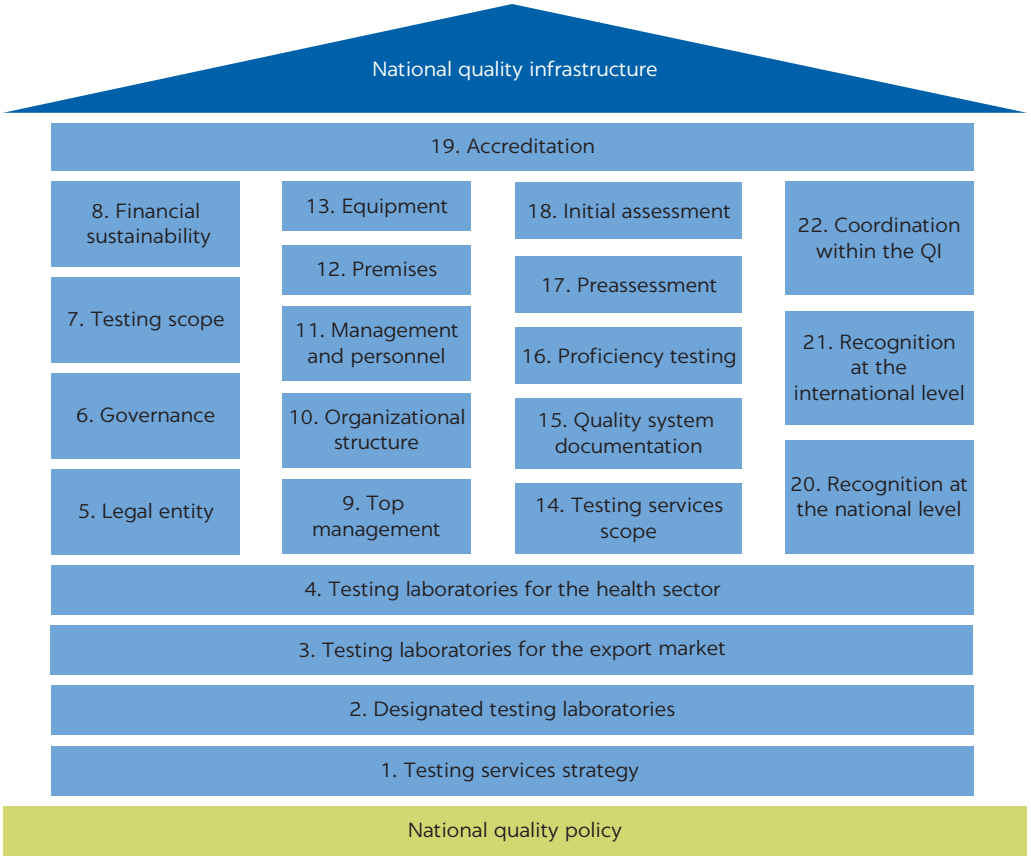
Note: QI = quality infrastructure.

the results have to be shown in tabular form if differences among the laboratories are significant.

To depict the pillars and building blocks in a graphical way that would indicate the state of testing in a country at a glance, they can be put together as shown in figure 7.1. For a complete description of the construction, interpretation, and use of this graphic or of the matching radar diagram, see section 1: Comprehensive QI Assessment.

Testing laboratories gain a certain level of recognition once accredited. In many countries, however, accreditation alone is not enough; regulatory authorities would designate testing laboratories once they are accredited before they may provide testing services in the regulated domain. For testing laboratories operating in the nonregulated domain, accreditation can be seen as the first step; thereafter, responsiveness, price, and so on would determine its acceptance by the market. These postaccreditation realities need to be factored into the evaluation as additional elements to the building blocks depicted in figure 7.1 where appropriate.

FIGURE 7.1
House of testing for a national quality infrastructure



Note: QI = quality infrastructure. The four "pillars" of the QI—represented by the blue columns containing the "building block" numbers—are as follows (left to right): "legal and institutional framework," "administration and infrastructure," "service delivery and technical competency," and "external relations and recognition."

7.2 PILLAR 1: LEGAL AND INSTITUTIONAL FRAMEWORK, THE LABORATORY SECTOR

7.2.1 Benchmark and significance

Testing is the determination of the characteristics of a product, material, or process and, in the QI context, the evaluation thereof against the requirements—such as those established in a standard or a technical regulation. The output of a testing laboratory is a test report or a test certificate.

The scope of testing is immense, encompassing mechanical, electrical, metallurgical, and civil engineering; biological and chemical sciences; food technology; fiber technology; and many other fields. Testing can be of a destructive or a nondestructive nature. It can be mundane, extremely complex, and anything in between. It can involve routine, state-of-the-art, or cutting-edge technology. Establishing testing laboratories can quickly become a "black hole" into which finances can disappear without a trace, and a careful analysis of the real demand of the country is therefore indicated.

A testing laboratory's technical competency is generally demonstrated through accreditation to ISO/IEC 17025 by a recognized accreditation body, and in the case of a medical laboratory, to ISO 15189 ("Medical Laboratories—Requirements for

Quality and Competence"). It can also be recognized in terms of peer evaluation, depending on the recognition system requirements. Interlaboratory comparisons or proficiency testing are important elements in both. Accreditation is generally one of the preconditions for the liberalization of testing services required for the implementation of technical regulations, the other element being the designation of such testing laboratories by the authorities.

7.2.3 Testing services strategy (building block no. 1)

What is meant

Major

Following on from the quality policy (see module 10 of the QI Toolkit), a testing services strategy gives meaning to the implementation of the quality policy regarding the establishment of technically competent testing laboratories in both the public and private sectors. The testing services strategy is about

- Making the right choices regarding the overall approach to the use of testing laboratories in the country;
- Getting the mix right between public and private sector testing laboratories;
- Using accreditation to designate testing laboratories providing services in the regulatory domain; and
- Building capacity in testing laboratories to provide required testing services in the most innovative, effective, and efficient way.

How can it be demonstrated?

The testing laboratories' strategy can be seen as an intended plan to set a pattern, create a unique position, follow a specific perspective, and implement a specific tactic—all to enable the government and the private sector collectively to make a difference to a critical mass of the right customers and to connect their purposes with those of their customers and external stakeholders (Minzberg, Ahlstrand, and Lampel 1998).

The strategy should take cognizance of the demonstrated needs of the country regarding testing services in important sectors (for example, the regulatory domain, main export sectors, health sector, law enforcement, industrial sector, and so on). The strategy should give appropriate space for the private sector to establish laboratories, even for testing services required in regulatory work. The system of designating testing laboratories for technical regulation implementation should be detailed. Priority development sectors should be identified and government support provided for the development of testing laboratories by the private sector.

The testing laboratories strategy should be a formal document approved at least by the relevant ministries and, in most countries, by the cabinet because it will be cross-cutting with respect to ministries in its implementation. The testing laboratories strategy should be publicly available—that is, on the relevant ministry website or in hard copy. The activities, business plans, and budgets of the various ministries regarding public laboratories should be aligned with the testing laboratories strategy. The private sector will make its own business plans depending on the space it is given in the strategy.

Existing information/reporting/monitoring

- Relevant government policies, strategies, and implementation plans
- Review of the extent of government laboratory capacity and capabilities
- Relevant ministry (for example, Trade and Industry, Science and Technology, and so on) websites

7.2.4 Designated testing laboratories (building block no. 2)

What is meant

Major	Testing laboratories mandated to provide testing services in the regulatory domain should be designated by the relevant authorities based on their technical competence (that is, accreditation) and their legal liability in the country.

How can it be demonstrated?

Regarding the laboratory services sector as a whole, an important element that needs to be defined in a legislative instrument is the use of accreditation as one of the preconditions of designating laboratories providing testing services for regulatory purposes. Such testing services may be required in technical regulation implementation, health and safety systems, environmental controls, transportation, building and construction, legal metrology, and the imposition of legal proceedings based on measurement and testing. In addition to their technical competence, designated laboratories should be able to be held legally liable in the country regarding the integrity of their services.

Existing information/reporting/monitoring

- Accreditation Act, decree, regulation, or similar law, if relevant
- Relevant legislative instruments of ministries
- Official lists of designated laboratories for the regulatory domain

7.2.5 Testing laboratories for the export markets (building block no. 3)

What is meant

Major	Testing laboratories to provide testing services for major exported products are recognized by the export market authorities.

How can it be demonstrated?

The export market frequently demands testing and certification of products before they can be legally exported and marketed. A variety of systems exist through which local testing laboratory results are recognized by the authorities in the export markets. Typical examples include the testing of meat and fish products for the European Union (EU); testing of automotive components within the United Nations Economic Commission for Europe (UNECE) 1958 Agreement; safety of electrical products under the International Electrotechnical Commission (IEC) System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE); the IEC System for Certification of Equipment for Use in Explosive Atmospheres (IECEx); the International Organization for Legal Metrology (OIML) Certificate System for Measuring Instruments; and many more.[1] The most relevant of these for the country should be identified, and recognition should be sought and maintained.

Existing information/reporting/monitoring

- Export policies and strategies
- Recognition agreements between the government and export market authorities
- Official lists of recognized laboratories in the export markets
- Lists of recognized testing laboratories of the IEC and OIML schemes, the European Commission, the UNECE 1958 Mutual Recognition Agreement, and so on

7.2.6 Testing laboratories for the health sector (building block no. 4)

What is meant

Major	Medical laboratories to provide testing services for the health sector are technically competent and are recognized by the health authorities.

How can it be demonstrated?

Testing laboratories in the health sector have a vital role to play in providing proper health services to the population. These can be independent medical or pathology laboratories or laboratories attached to hospitals and other health service providers. These medical laboratories should be technically competent and should be designated by the relevant health authorities, such as the Ministry of Health, for example. Technical competency for medical laboratories is determined by accreditation to ISO 15189 by a recognized accreditation body. Thereafter, the medical laboratory is designated by the relevant authority to provide testing services in the health sector.

Existing information/reporting/monitoring

- Legislation regarding medical laboratories
- Ministry of Health (or similar agency) decrees or regulations
- Official lists of designated laboratories in the health sector
- Official lists of accreditation bodies for ISO 15189-accredited laboratories

7.3 PILLAR 1: LEGAL AND INSTITUTIONAL FRAMEWORK, INDIVIDUAL LABORATORIES

7.3.1 Benchmark and significance

When considering individual laboratories, it is important that they clearly define the scope of their services. To be recognized, testing laboratories have to demonstrate their technical competency; that is, they need to be accredited. Their accreditation will be defined in line with their scope.

Their financial sustainability is an important parameter, and especially public laboratories should be given the freedom to determine the pricing of their services in accordance with the market. In other words, the government should not ask them to offer testing services below market prices. Small and medium enterprises (SMEs) that require financial support to have products, materials, and processes tested may be given such support, but it should not be through low pricing of public laboratories' testing services.

7.3.2 Legal entity (building block no. 5)

What is meant

Major	Testing laboratories shall be a legal entities, or defined parts of legal entities, such that they can be held legally responsible for the outcome of their testing services. Testing laboratories can be either public or private sector entities.

How can it be demonstrated?

Individual testing laboratories shall be established by legislation or articles of incorporation, depending on whether they are public or private sector entities. The legislation or articles of incorporation must define the governance, financial provisions, and responsibilities and functions of the testing laboratory. Being able to demonstrate their legal organizational form is a prerequisite for accreditation.

Existing information/reporting/monitoring

- Relevant legislative instruments of ministries
- Relevant articles of incorporation

7.3.3 Governance (building block no. 6)

What is meant

Fundamental	The testing laboratory should have a governance structure in charge of strategy approval and overall fiduciary responsibilities, whether it is appointed by a relevant ministry, by the parent ministry, or by shareholders.
Major	Good governance models suggest that the members of the governance structure should be individuals with specific knowledge regarding testing and market realities.

How can it be demonstrated?

A testing laboratory can be a department or division within a ministry, an independent public sector entity or a part thereof, or a private sector entity. Each of these will have a different governance structure, depending on the extent of its independence. Whatever the case, the governance structure should have the authority to determine the strategy for the testing laboratory, approve the business plans and budget, and exercise overall fiduciary responsibility over the testing laboratory.

Existing information/reporting/monitoring

- Legislative instrument establishing the testing laboratory, if relevant
- Articles of incorporation, if relevant
- Government decisions or decrees, if relevant
- Official organizational structure
- Annual reports of the testing laboratory

7.3.4 Testing scope (building block no. 7)

What is meant

Fundamental	Testing laboratories must be clear regarding the scope of their testing services. The scope should be aligned with demonstrable needs, as determined by a demand survey; it determines resource requirements and forms the basis of the testing laboratory's accreditation.

How can it be demonstrated?

The overall scope of testing services is immense, from very high technology to the mundane, covering a wide spectrum of sectors and technologies. It is virtually

impossible for the testing laboratory, even an institute, to offer testing services that cover the whole spectrum. The testing laboratory has to clearly define the scope of its testing services, and these should be aligned with demonstrable needs of its chosen customer base. The scope will determine laboratory accommodation requirements, environmental controls, the level of scientists and technical staff, proficiency testing, and ultimately accreditation requirements. The defined scope is therefore fundamental regarding everything else that follows.

Existing information/reporting/monitoring

- Official description of the scope of testing services offered
- Accreditation scopes
- Testing laboratory business strategy and plans
- Testing laboratory annual budgets

7.3.5 Financial sustainability (building block no. 8)

What is meant

Fundamental	The finances for establishing the testing laboratory can be provided from government sources or through financial support from industry. Once operational, the testing laboratory should become financially self-sufficient. An exception would be a testing laboratory that is considered a strategic necessity for the country or a sector, even though the amount of business will not cover its costs.

How can it be demonstrated?

Establishing a testing laboratory is an expensive business. Hence, governments are frequently called upon to provide such funding, especially in low- and middle-income countries. Once established, the testing laboratory should be able to become self-sufficient as quickly as possible; government subsidies should not be necessary for its medium- and long-term existence. Income should cover operational costs fully and should provide for the maintenance and renewal of costly testing equipment on a regular basis.

An exception would be a laboratory that is strategically important for the country but for which the amount of testing services cannot cover costs. Such laboratories are the exception and are usually to be found in high-technology sectors. The government should identify such laboratories and provide for their continued existence as long as the strategic need remains valid. It is also quite possible for a producer association to establish a laboratory rather than just one producer doing so—for instance, a sophisticated cement-testing laboratory established by the Cement Producers Association.

SMEs frequently find it difficult to pay for testing services. Hence, many governments wish to support the SME sector by subsidizing testing fees. Such support should not come from providing below-cost testing services by public laboratories because this will negatively affect the laboratories' financial sustainability, distort the market, and constrain the establishment of private sector testing laboratories. Such financial support, if necessary, should be provided directly to the enterprises or to the service.

The overall financial situation of the testing laboratory of the past three to five years would be a good indication of the financial sustainability of the laboratory. The situation should show a positive trend over the years under review.

A positive trend in the income generated from testing services would be a further indicator, as would business plans for future developments.

Existing information/reporting/monitoring

- Annual government budget allocations
- Testing laboratory business plans
- Annual reports of the testing laboratory
- Monthly and annual financial statements of the testing laboratory

7.4 PILLAR 2: ADMINISTRATION AND INFRASTRUCTURE

7.4.1 Benchmark and significance

The organizational structure of the testing laboratory must be conducive to providing the full complement of testing services included in its scope and required by its stakeholders. Good governance principles require the testing laboratory to have a top management, and the subject fields of its testing services suggest that the testing laboratory should have divisions dedicated to testing services in these fields.

Over and above these general guidelines, the testing laboratory has to comply with the requirements relating to the organizational structures of ISO/IEC 17025 or any other relevant standards it wishes to be accredited for. These usually include adequate supervision of testing personnel by persons well versed in the methods and procedures of the defined testing scopes, and the testing laboratory will have to demonstrate that its personnel are free from any undue commercial, financial, and other pressures that might influence their technical judgment.

The demands regarding premises are fundamental to the quality of the laboratory's testing work and are intimately related to the type of testing conducted. The premises must not only comply with stated and strict requirements; environmental controls are very much part and parcel of it as well. These vary widely from the very mundane to extremely sophisticated, depending on the type of testing to be conducted. It is therefore not possible to list details in this diagnostic tool. Knowledgeable experts will have to be consulted on a case-by-case assessment.

7.4.2 Top management (building block no. 9)

What is meant

Major	The top management of the testing laboratory—whether a single person in a small laboratory or a number of people in a larger organization—is responsible for the technical management of the laboratory and is accountable for the quality and integrity of its services. Effective communication channels must exist between the top management and personnel, as well as between top management and higher-level management or governance structures.

How can it be demonstrated?

There is no standardized list of the major functions and responsibilities carried out by the top management, but some typical functions include the following:

- Supports operations and administration of the testing laboratory governance structures by advising and informing its members and interfacing between governance structures and personnel

- Oversees the development, marketing, promotion, delivery, and quality of testing services
- Recommends the annual budget for approval and prudently manages the testing laboratory's resources within those budget guidelines
- Effectively manages the human resources of the testing laboratory according to authorized personnel policies and procedures
- Assures that the testing laboratory and its mission and services are consistently presented using strong, positive images to relevant stakeholders
- Oversees the identification of resource requirements and possible funding sources, including ascertaining strategies to approach funders

Existing information/reporting/monitoring

- Governance structure decisions and minutes
- Official top management job descriptions
- Agreed-upon top management key performance indicators

7.4.3 Organizational structure (building block no. 10)

What is meant

Major	Testing services cover a wide range of subject fields. It therefore follows that a testing laboratory's organizational structure of should have divisions that optimally support its scope of services and groupings within it.

How can it be demonstrated?

Good management practice suggests that the organizational structure of the testing laboratory should take cognizance of groupings within its scope of services. Such a structure would also facilitate the accreditation process. An important element is the appointment of a quality manager who has the defined responsibility and authority for ensuring that the quality management system is implemented and followed at all times. The quality manager must have direct access to top management who make decisions on laboratory policy or resources.

Existing information/reporting/monitoring

- Approved organizational structure
- Governance structure decisions
- Financial system documentation

7.4.4 Management and personnel (building block no. 11)

What is meant

Major	Testing is technology combined with a people-based activity operating within specified scopes. The management and personnel must therefore have the appropriate skill sets assured by appropriate training, qualifications, and experience. These would include management and technical knowledge, as required by the various activities within the testing laboratory's scopes.

How can it be demonstrated?

In the first place, the testing laboratory should operate with an organizational structure approved by its governance structures. For each of the positions, the

skill set (qualifications, training, and experience) should be clearly and formally stated. The administrative staff should not be more than 20 percent of total staff; the major proportion should be technical staff.

Second, there should be few staff vacancies on either the management or technical levels; more than 95 percent of those positions should remain filled. Anything less indicates that the testing laboratory cannot operate effectively or efficiently. Staffing challenges often include a lack of skilled people in the country, but even more so, inadequate remuneration (resulting in the departure of trained staff for more lucrative offers elsewhere).

Third, technical staff should have the necessary skills set of education, training, and experience to be able to conduct testing procedures. In addition, accreditation criteria often require dual signatures on test reports or certificates, with the laboratory manager countersigning the work of the technical staff. This means that the managers should have the appropriate skill sets as well. These criteria are dependent on the testing scope of the laboratory, and detailed expert knowledge is required to evaluate them.

Existing information/reporting/monitoring

- Approved organizational structure
- Approved criteria for technical staff
- Actual staffing levels
- Staff turnover figures

7.4.5 Premises (building block no. 12)

What is meant

Fundamental	The requirements for the laboratory accommodation depend heavily on the type of testing and its equipment. Typical issues that need to be considered include (a) access control to laboratories to ensure that samples are not contaminated and that the confidentiality of test results is ensured; (b) optimized environmental controls; (c) prevention of vibration and dust interference with test results; and (d) facilitation of cleaning operations. Expert advice is required to determine the details for each type of testing.

How can it be demonstrated?

Laboratory accommodation requirements span the gamut from the mundane to the sophisticated. The requirements are very much dependent on the type of testing to be conducted, as follows:

- In most cases, accreditation requirements include access control to ensure that test results remain confidential in third-party laboratories.
- Access control may be required to ensure that samples are not contaminated, hence leading to erroneous results.
- Sensitive equipment, such as chemical balances, require special structures to limit vibrations that can influence results.
- The quality of the air (such as being dust-free) may be an issue for some tests.
- The quality of electricity supply (for example, required voltage) must be available within narrow limits for sensitive electronic equipment.
- Cleanliness requirements may indicate special types of laboratory furniture and floors or wall and ceiling coverings.
- Environmental controls, such as temperature and humidity, must be in place, ranging from the fairly simple to the extremely sophisticated.

The requirements are too numerous to provide a complete list. Hence, expert advice is essential to conduct an appropriate assessment based on the knowledge of the scope of testing to be conducted.

Existing information/reporting/monitoring

- Review of laboratory accommodation in the light of defined requirements

7.4.6 Equipment (building block no. 13)

What is meant

Fundamental	The equipment requirements for the testing scope must be fulfilled in all known respects. New equipment has to be properly commissioned. Proper maintenance and calibration at defined intervals are a necessity to keep test equipment in full working order and at the required accuracy level.

How can it be demonstrated?

For each type of test, appropriate equipment must be provided. This needs to be properly commissioned, including initial calibration, when being installed to ensure that it operates with the required accuracy and repeatability. Thereafter, equipment needs to be properly maintained and recalibrated at intervals defined by the manufacturer or demanded by its accuracy requirements. Maintenance services can be in-house or contracted.

The same applies to calibration services. For some tests, calibration precedes every test, in which case calibration equipment or certified reference materials, as relevant, must always be at hand.

An interlaboratory information technology (IT) system may be indicated to enhance the continuous integrity and quality of testing results. Expert advice needs to be sought for the assessment of the equipment of a testing laboratory based on its defined scope of testing.

Existing information/reporting/monitoring

- Review of laboratory testing and IT equipment in the light of defined requirements

7.5 PILLAR 3: SERVICE DELIVERY AND TECHNICAL COMPETENCY

7.5.1 Benchmark and significance

Accreditation by an independent and recognized accreditation body has virtually replaced all other recognition systems for testing laboratories (see building blocks no. 16 and no. 18). This may be accreditation to the ubiquitous ISO/IEC 17025 in general, ISO 15189 specifically for medical laboratories, or similar sector-based systems, thereby demonstrating the laboratory's technical competency. All of them require the implementation of a formal quality management system; the appointment of appropriately skilled personnel; interlaboratory comparisons to demonstrate the accuracy and repeatability of testing procedures; calibration and maintenance of equipment; and internal audit procedures to ensure continuous compliance.

7.5.2 Testing services scope (building block no. 14)

What is meant

Fundamental	The testing laboratory must have a clear description of the testing services it provides, including their applicability, whether they are performed in-house or on-site, and their level of accuracy.

How can it be demonstrated?

The testing laboratory should clearly define the scope of its testing services. This should preferably be in terms of published standards, whether public or private, or whether national, regional, or international. The applicability of the testing services in various sectors, as well as the typical accuracy of such testing results, are important additions to the general information. This information should be publicly available or at the very least available to interested parties on request.

Existing information/reporting/monitoring

- Quality management system documentation
- Testing laboratory website
- Testing laboratory marketing material and brochures
- Accreditation records

7.5.3 Quality management system documentation (building block no. 15)

What is meant

Fundamental	The quality management system documentation must comply with the requirements of the relevant accreditation standard.

How can it be demonstrated?

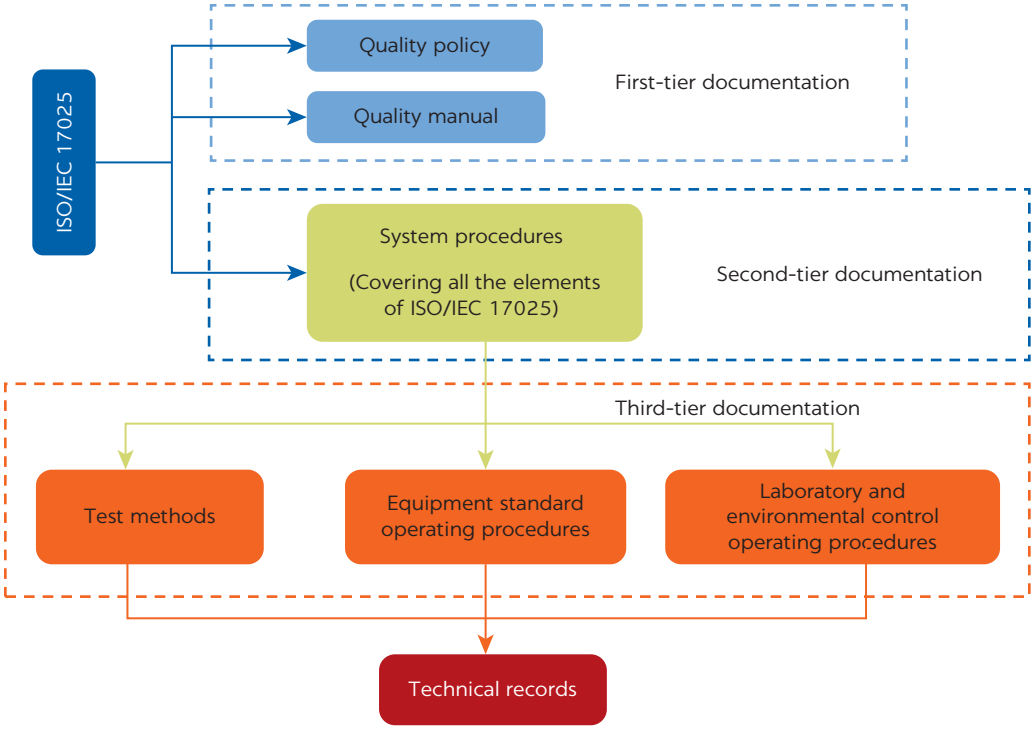
The quality management system documentation is generally organized on three tiers, generically known as policy documents, procedures, and work instructions. These are supported by records of the test reports or certificates, calibration records, internal audit records, management review records, and records of nonconformities and others required by the relevant accreditation standard. A typical quality management documentation system for a laboratory is shown in figure 7.2.

The accreditation process usually includes an assessment of the quality management documentation, before a preassessment or initial assessment is conducted, to ensure that all the elements of the relevant accreditation standard are addressed. The testing laboratory normally has six months to rectify any nonconformities identified in the quality management documentation before on-site assessments are considered.

Existing information/reporting/monitoring

- Quality management documentation
- Internal audit results
- Management review records
- Accreditation records

FIGURE 7.2
Typical testing laboratory documentation system



Note: ISO/IEC 17025 = "General Requirements for the Competence of Testing and Calibration Laboratories."

7.5.4 Proficiency testing (building block no. 16)

What is meant

Major	Proficiency testing is the use of interlaboratory comparisons to assess a laboratory's ability to perform tests and measurements competently. It is frequently the precursor to accreditation.

How can it be demonstrated?

Proficiency testing is defined in ISO/IEC 17043 ("Conformity Assessment—General Requirements for Proficiency Testing") as the use of interlaboratory comparisons to determine a laboratory's ability to perform tests and measurements competently—a benchmarking activity. It is also used to determine performance characteristics of test methods and assignment of values to reference materials.

It is used by laboratories to monitor their performance against laboratories providing similar services. Large multinational companies use it to ensure consistency of performance throughout the corporation, and accreditation bodies use it to complement their other assessment techniques, such as on-site assessment by technical assessors.

A number of organizations all over the world offer proficiency testing programs for laboratories. Some are open only to laboratories in the country or region, whereas others are open to any laboratory on a commercial basis. Some are offered for a narrow range of products or materials, whereas others provide more comprehensive programs.

Proficiency testing programs organized on a domestic level may suffer from an inadequate number of laboratories participating. Large-scale regional or international proficiency testing programs offer some advantages in this respect, but there are also challenges associated with participation, notably with delays in the transportation of samples and difficulties getting them through customs. Proficiency testing providers should also be accredited to ISO/IEC 17043. The choice for the individual laboratory must take all of these practical aspects into consideration.

Existing information/reporting/monitoring

- Proficiency testing participation records
- Interlaboratory comparison results
- List of proficiency testing providers in the country or region
- Accreditation assessment reports

7.5.5 Preassessment (building block no. 17)

What is meant

Major	A testing laboratory may request a preassessment before an initial assessment is conducted to determine whether a formal quality management system is in place.

How can it be demonstrated?

Once the quality system documentation has been established, the testing laboratory may request a preassessment by the accreditation body. The preassessment is usually a one-day visit by the lead assessor of the accreditation body to determine whether a formal quality management system is in place, without determining whether the testing laboratory is competent to conduct the testing. In some cases, the accreditation body may require a preassessment as a precondition for the initial assessment. Nonconformities detected during the preassessment have to be corrected before an initial assessment can take place.

Existing information/reporting/monitoring

- Accreditation application
- Assessment result of the quality management system documentation
- Preassessment record
- Records of the closeout of nonconformities

7.5.6 Initial assessment (building block no. 18)

What is meant

Fundamental	The initial assessment for accreditation is an on-site visit by a team from the accreditation body to determine whether the quality management system documentation is fully operational and whether the testing laboratory is competent to conduct the testing defined in its scope.

How can it be demonstrated?

The initial assessment is conducted by an accreditation body team consisting of a team leader and technical assessors. The testing laboratory has to ensure that there are sufficient records to confirm that the system is implemented before the initial assessment. Most accreditation bodies also require

a complete internal audit and management review cycle to have been completed.

The testing laboratory's staff will have to actually demonstrate to the technical assessors that they are competent to conduct the testing, and the testing laboratory should submit additional proficiency evidence to this effect. Any nonconformities identified during the initial assessment usually have to be demonstrably corrected within a period of six months; otherwise the complete initial assessment may need to be repeated.

Existing information/reporting/monitoring

- Initial assessment reports
- List of identified nonconformities
- Formal acknowledgment by the accreditation body that nonconformities have been closed out

7.5.7 Accreditation (building block no. 19)

What is meant

Fundamental	Once all nonconformities have been cleared, the accreditation body submits the assessment report to its approvals committee for a final decision. Should accreditation be granted, the testing laboratory receives an accreditation certificate carefully detailing its testing scopes, and its data are added to the publicly available information of the accreditation body.

How can it be demonstrated?

The assessment report detailing all the findings of the assessment team, evidence of the correction of any nonconformities, and a recommendation for accreditation is submitted to the approvals committee of the accreditation body. If accreditation is granted, then the testing laboratory receives an accreditation certificate detailing its scope. The accreditation certificate usually has a validity of three to five years, during which follow-up assessments are conducted on an audit basis. An initial assessment is repeated to reissue the accreditation certificate.

Should the follow-up audits reveal nonconformities, the testing laboratory will be given a specified amount of time to rectify them. Failure to do so will result in the suspension of the accreditation, followed by the withdrawal of the accreditation certificate if no progress is achieved. During suspension, the testing laboratory may not claim accreditation status.

Existing information/reporting/monitoring

- Initial assessment reports and records
- Records of closeout of nonconformities
- Accreditation certificate
- Public records of accreditation body

7.6 PILLAR 4: EXTERNAL RELATIONS AND RECOGNITION

7.6.1 Benchmark and significance

Whereas accreditation may be a precondition for the recognition of the competency of a testing laboratory in the nonregulated market, further steps are frequently

necessary in the regulated market. These have to do with the legal accountability of the testing laboratory once it starts providing test services to support the implementation of technical regulations or sanitary and phytosanitary measures.

The technical term for this official recognition by the authorities is "designation" (ISO/IEC 17000, "Conformity Assessment—Vocabulary and General Principles"). Countries may use others—for example, the "notified bodies" of the EU. Many multinational certification schemes have their own mechanisms to recognize testing laboratories providing test services in support of these schemes. Without such recognition, testing laboratories will find it difficult to penetrate these potentially lucrative markets.

7.6.2 Recognition at the national level (building block no. 20)

What is meant

Major	Recognition at the national level may be supported through accreditation to the relevant international standard. Recognition can be by the market, or it can go a step further in being designated by a governmental authority for specific testing services related to the implementation of regulations.

How can it be demonstrated?

Recognition at the national level has developed to the point where accreditation by a recognized accreditation body to the relevant international standard (such as ISO/IEC 17025, ISO 15189, or a similar standard) has overtaken all other types of recognition arrangements in importance, even though it is not the only criterion. Assessments by individual authorities against their own requirements, for example, are slowly being abandoned in lieu of an independent accreditation. Accreditation should be provided by an accreditation body (local or foreign) that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

In the regulated domain, recognition by regulatory authorities through designation is practiced in many countries, and it is usually based on accreditation plus some additional legal requirements not covered by accreditation, such as legal liability in the country, completed tax returns, and so on. Recognition by the market in the nonregulated domain is dependent on service delivery, price, and other factors subject to market forces—accreditation providing a measure of the technical competency of the testing laboratory.

Existing information/reporting/monitoring

- Official lists of accredited testing laboratories
- Official lists of regulatory authorities in respect of designated testing laboratories

7.6.3 Recognition at the international level (building block no. 21)

What is meant

Major	Recognition at the international level can be achieved by various means. Accreditation by an ILAC-recognized accreditation body is a good start. Sectoral arrangements have developed over the years—for example, the IEC schemes for electrotechnical products, the OIML schemes for legal metrology instruments, and the UNECE 1958 Agreement on the testing of automotive components.

How can it be demonstrated?

Accreditation by a recognized accreditation body (to ISO/IEC 17025 and ISO 15189, for example) facilitates the recognition of testing laboratory results by at least the other members of the ILAC Mutual Recognition Arrangement. Such accreditation may also facilitate recognition in countries not yet part of the Arrangement.

Other schemes with an international flavor have also developed over the years:

- The IEC developed a number of schemes, such as the IECEE (electrical and electronic equipment); IECEx (hazardous environments); Quality Assessment System for Electronic Components (IECQ); and System for Certification to Standards Relating to Equipment for Use in Renewable Energy Applications (IECRE). Through all of these schemes, products are tested once, and then the test results are accepted in all countries participating in the schemes as the basis for technical regulation.
- The OIML has a similar scheme for the testing of measuring equipment subject to legal metrology requirements.
- The UNECE 1958 Agreement, with a number of countries outside the United States being signatories, endeavors to do the same for automotive components.
- Food products destined for the EU must be tested by laboratories approved by the relevant European Commission Directorate.

These are not the only schemes operating at the international level, and a careful analysis of the main exports of the country will reveal the need for recognition of testing laboratory results and the concomitant international scheme for achieving the same.

Existing information/reporting/monitoring

- Testing strategy and its implementation plans
- ILAC membership data
- Official data of the IEC and OIML schemes
- Official data of the UNECE 1958 Agreement and its signatory countries
- Other international recognition systems relevant to the country

7.6.4 Coordination within the QI (building block no. 22)

What is meant

Minor	Coordination among the testing laboratories of the country is based largely on activities managed through voluntary associations.

How can it be demonstrated?

A national testing laboratory association in which membership is voluntary can be helpful in coordinating some elements of laboratory activities—for example, lobbying governmental authorities, facilitating precompetitive technology transfer, and so on.

In addition, a technical regulation coordination office (or a similar facility) may enforce coordination of activities between testing laboratories and the regulatory authorities, as well as with the national accreditation body (NAB), national standards body (NSB), and national metrology institute (NMI) with respect to the implementation of technical regulations. Such offices have been

established in many of the Organisation for Economic Co-operation and Development (OECD) countries, for example (Jacobzone, Choi, and Miguet 2007).

Existing information/reporting/monitoring

- Regulatory authority policies, pronouncements, and documentation
- Testing laboratory association documentation and minutes of meetings
- Technical regulation coordination office mandate and pronouncements

NOTE

1. For more about these conformity assessment schemes, see module 5, section 5.5.3, of the QI Toolkit.

STANDARDS REFERENCED IN SECTION 7

ISO (International Organization for Standardization). 2012. "ISO 15189: Medical Laboratories—Requirements for Quality and Competence." 3rd ed. Ref. no. ISO 15189:2012(E), ISO, Geneva.

ISO and IEC (International Organization for Standardization and International Electrotechnical Commission). 2004. "ISO/IEC 17000: Conformity Assessment—Vocabulary and General Principles." Ref. no. ISO/IEC 17000:2004(E), ISO, Geneva.

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Jacobzone, S., C. Choi, and C. Miguet. 2007. "Indicators of Regulatory Management Systems." OECD Working Papers on Public Governance No. 2007/4, Organisation for Economic Co-operation and Development (OECD), Paris.

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8

Product Certification

8.1 INTRODUCTION

Product certification is the mechanism whereby a certification body attests that products (either a batch or the continuous production thereof) have been inspected and tested; the quality controls of production are audited; and the products collectively comply with the specified requirements of a standard or technical regulation. The attestation by the certification body is in the form of a certificate, which is supported by outward demonstration through a product certification mark that the manufacturer or producer affixes to the product after being licensed to do so.

Product certification services and schemes are offered by many certification bodies in both the public and private sectors.[1] In low- and middle-income economies, national standards bodies (NSBs) are often, besides foreign bodies, the only bodies able to provide product certification with any market relevance (provided they do not offer accreditation services). Once the market for product certification has grown, as in high-income economies, private sector certification bodies may become more important from a market perspective. While management system certificates "travel" easily across borders, product certification marks do not: they are mostly recognized and accepted only in the home market of the certification body, but a few operate successfully at the regional or even the international level.

The process underpinning product certification will always include an assessment of the product, whether sampled at the factory, from a consignment, 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 market. Compliance with management systems such as ISO 9001 ("Quality Management Systems—Requirements") or hazard analysis and critical control points (HACCP, which concern food safety), for example, may be required. Once compliance has been demonstrated, the manufacturer will be licensed to affix the product certification mark of the certification body to the product and packaging, thereby signifying compliance of the product with the relevant standard.

Various product certification schemes are described in ISO/IEC 17067 ("Conformity Assessment—Fundamentals of Product Certification and Guidelines for Product Certification Schemes") and are identified by a scheme number that is universally understood, an extract of which is shown in table 8.1.

TABLE 8.1 Product certification schemes

SCHEME	DESCRIPTION
Scheme 1a and 1b	Batch inspection
Scheme 2	Surveillance testing in the market
Scheme 3	Testing of products in the factory
Scheme 4	Type testing plus production control
Scheme 5	Type testing plus quality assurance, including market surveillance

Source: ISO/IEC 17067, "Conformity Assessment—Fundamentals of Product Certification and Guidelines for Product Certification Schemes."
Note: For a detailed description of the product certification schemes, see module 6, section 6.4, of the QI Toolkit.

Some certificates are valid for a limited period (typically a year), after which they can be reissued on review by the certification body. Others have no time limit; as long as the manufacturer continues to meet requirements and pays the annual fees, the certificate stays valid. Obviously, the manufacturer has to pay for product certification. Payments will cover the testing of the product (initial and follow-up testing), initial and surveillance audits of the manufacturing facility, clearance of nonconformities, and an annual license fee.

Although no international system for product certification recognition exists and is unlikely to develop in the future for a variety of reasons, it does have value in local markets, as follows:

- The manufacturer (which may be less well known) wants to add to its reputation, expand its market share, gain access to new markets, improve competitiveness, or promote new products.
- The purchaser (such as an individual, retailer, manufacturer, public procurement organization, importer, supplier, employer, and so on) wishes to have an independent guarantee of the quality of product.
- The product certification mark may be considered reputable evidence by regulatory authorities that the product meets technical regulation requirements (see section 10: Technical Regulation).

Evaluating the needs of a country regarding product certification schemes is complex, and many facets need to be taken into consideration. Hence, it is useful to differentiate between basic, advanced, and mature product certification schemes, depending on the maturity levels of the quality infrastructure (QI) in a country (table 8.2). These have to be considered in relation to the needs of manufacturers, regulatory authorities, and the marketplace; in other words, the evaluation becomes a multifaceted exercise. In low- and middle-income countries, governments may have to initiate the establishment of a national product certification body, but such bodies may eventually be eclipsed by private sector certification bodies as the market for product certification develops.

This section of the Comprehensive Diagnostic Tool consists of two subsections: the first dealing with the product certification sector as a whole, and the second with the evaluation of an individual product certification body. The former (on the product certification sector) deals primarily with the evaluation of the country's needs, taking into consideration both the public and the private sectors. The basic building blocks for evaluating the country's needs regarding product certification are listed in table 8.3.

The pillars and building blocks for evaluating a specific product certification body are listed in table 8.4.

TABLE 8.2 Maturity levels of a country's product certification services, by characteristic

CHARACTERISTIC	RUDIMENTARY (VERY LITTLE IS IN PLACE)	BASIC (LOW- TO MIDDLE-INCOME COUNTRY APPROACH)	ADVANCED (ECONOMYWIDE APPROACH, SECTORAL APPROACH)	MATURE (TOTALLY FREE-MARKET APPROACH)
Certification body infrastructure	No national certification body established	A national certification body to support • Locally manufactured products; and • Critical technical regulation implementation	Product certification scheme services defined through economywide surveys and defined sectoral needs	Product certification schemes determined by free-market principles
Recognition	None	Through accreditation	Through accreditation	Through accreditation
Establishment	None	Public sector certification body Foreign certification bodies?	Mix of public and private sector certification bodies Public sector certification bodies looking after SME sector	Predominance of private sector certification bodies; public sector certification bodies mostly looking after SME sector
Services	None	Selected product certification schemes	Small range of system certification schemes	Wide range of system certification schemes
Human resources	None	Training on the job	Training on the job Training courses in auditing	Training on the job Training courses in auditing methodologies Auditors as a professional profile
Demand orientation	None	Demand surveys, mostly through projects	Demand surveys Stakeholder participation and consultative mechanism	Free-market instruments and constructs to ensure demand orientation

Note: SMEs = small and medium enterprises.

TABLE 8.3 Building blocks for evaluating a country's product certification sector

PILLAR	BUILDING BLOCK NO.	BUILDING BLOCK DESCRIPTION
1: Legal and institutional framework, product certification sector	1	Product certification services strategy
	2	National certification bodies for home and regional markets
	3	Designated certification bodies
	4	Product certification schemes to upgrade SMEs

Note: SMEs = small and medium enterprises.

(*Note:* The inspection and testing of products, which is an integral part of product certification, is not considered in this section of the Comprehensive Diagnostic Tool. They are covered in the relevant diagnostic tools relating to inspection and testing in sections 6 and 7, respectively.)

To depict the pillars and building blocks in a graphical way that would indicate the state of product certification in a country at a glance, they can be put together as shown in figure 8.1. For a complete description of the construction, interpretation, and use of this graphic or of the matching radar diagram, see section 1: Comprehensive QI Assessment.

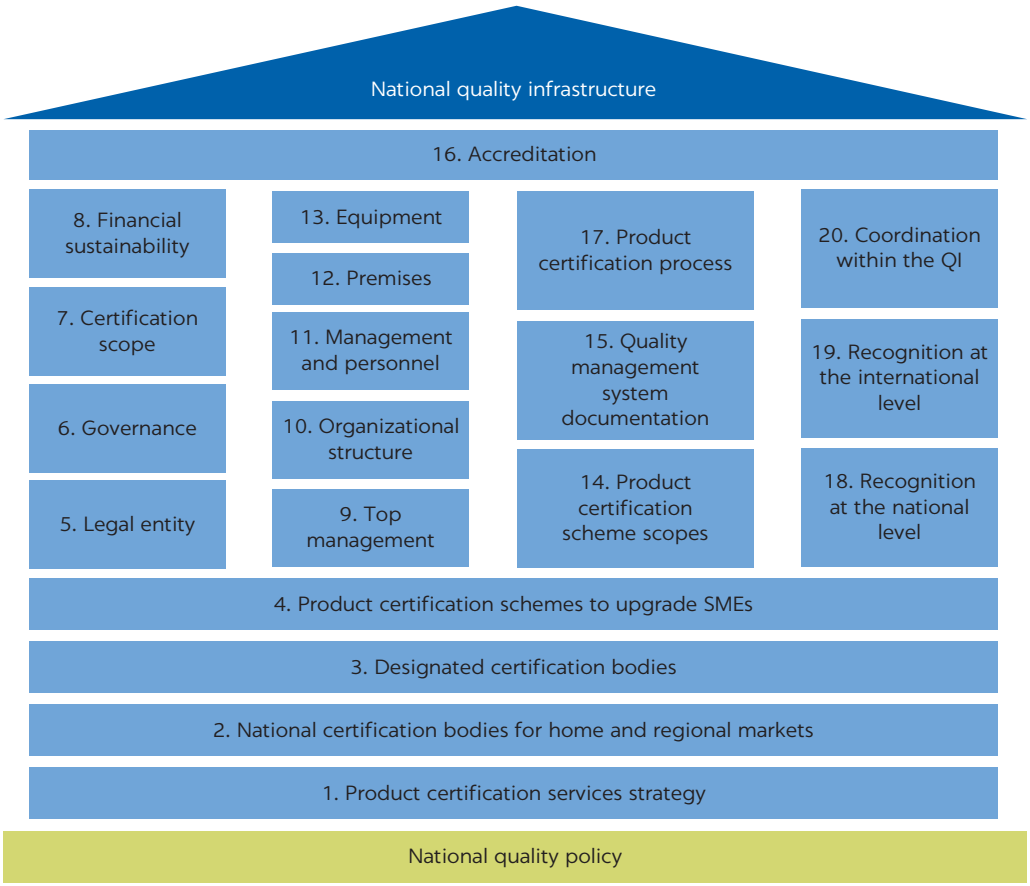
Product certification bodies gain a certain level of recognition once accredited. However, acceptance in the market hinges on a number of additional issues. These could include the use of product certification for regulatory purposes, even though it is now frowned upon as a trade barrier; the image of the product certification mark among consumers; whether manufacturers and suppliers believe product certification will gain them market share; and others. Hence, for certification bodies, accreditation can be seen as an

TABLE 8.4 Pillars and building blocks of a product certification body

PILLAR	BUILDING BLOCK NO.	BUILDING BLOCK DESCRIPTION
1: Legal and institutional framework, individual certification bodies	5	Legal entity
	6	Governance
	7	Certification scope
	8	Financial sustainability
2: Administration and infrastructure	9	Top management
	10	Organizational structure
	11	Management and personnel
	12	Premises
	13	Equipment
3: Service delivery and technical competency	14	Product certification scheme scopes
	15	Quality management system documentation
	16	Accreditation
	17	Product certification process
4: External relations and recognition	18	Recognition at the national level
	19	Recognition at the international level
	20	Coordination within the QI

Note: QI = quality infrastructure.

FIGURE 8.1
House of product certification for a national quality infrastructure



Note: ISO/IEC 17065 = "Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services." The four "pillars" of the QI—represented by the blue columns containing the "building block" numbers—are as follows (left to right): "legal and institutional framework," "administration and infrastructure," "service delivery and technical competency," and "external relations and recognition."

enhancement of their credibility. These market realities need to be factored into the evaluation as additional elements of the building blocks depicted in figure 8.1, where appropriate.

8.2 PILLAR 1: LEGAL AND INSTITUTIONAL FRAMEWORK, PRODUCT CERTIFICATION SECTOR

8.2.1 Benchmark and significance

Product certification is much older than system certification and much more visible to consumers because they use product certification marks to make purchasing decisions when the quality of the product is important and they cannot establish this by themselves.

Product certification is often considered by governments as a vehicle to upgrade the quality of locally manufactured products, especially in the SME sector. Depending on the market relevance of the national product certification mark, less-well-known manufacturers may wish to gain certification for their products to gain market acceptance. Some regulatory authorities consider a product certification mark as "deem to satisfy" evidence of the product's compliance with a technical regulation.[2] In some cases, product certification may help exporters gain access to foreign markets, especially within a regional common market context.

In general, governments in low- and middle-income economies have to take the initiative to establish a product certification body, because it will take a while for its product certification mark to gain market recognition and for the certification body to become financially sustainable. Once the market has developed, private certification bodies offering product certification may be established, although this remains a challenge because of the need for appropriate testing facilities. It is more likely that multinational private sector certification bodies will start operating in the country.

Product certification bodies providing such services, whether public or private sector aligned, should be accredited to ISO/IEC 17065 ("Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services") or similar standards by a recognized accreditation body to ensure their technical competency and to facilitate their recognition for regulatory purposes and in the marketplace.

8.2.2 Product certification services strategy (building block no. 1)

What is meant

Major

Following on from the quality policy (see module 10 of the QI Toolkit), a product certification services strategy gives meaning to the implementation of the quality policy regarding the establishment of technically competent product certification bodies in both the public and private sectors. The product certification services strategy is about

- Making the right choices regarding the overall approach to the use of product certification bodies in the country;
- Getting the mix right between public and private sector certification bodies;
- Using accreditation to designate certification bodies providing services in the regulatory domain;
- Using product certification in government purchases; and
- Building capacity in certification bodies to provide required product certification services in the most innovative, effective, and efficient way.

How can it be demonstrated?

The product certification strategy can be seen as an intended plan to set a pattern, create a unique position, follow a specific perspective, and implement a specific tactic—all to enable the government and the private sector collectively to make a difference to a critical mass of the right customers and to connect their purposes with those of their customers and external stakeholders (Minzberg, Ahlstrand, and Lampel 1998).

The strategy should take cognizance of the state of the art of the QI and the demonstrated needs of the country regarding product certification services in important sectors (for example, local manufacturing, the SME sector, the regulatory domain, and so on). Although, where no certification infrastructure exists, the government usually has to take the initiative to establish a national product certification body, space should be given for the private sector to establish the same in the future, including product certification services required in regulatory work.

The mechanism of designating certification bodies for technical regulation implementation should be detailed. Priority development sectors should be identified, and government support for the development of certification bodies by the private sector should be provided where relevant. This support may include an awareness campaign to raise the demand for certified products and the promotion of testing capacity as a basis.

The product certification strategy should be a formal document approved at least by the relevant ministry, and in some countries by the cabinet, because it will be cross-cutting with respect to ministries in its implementation. The product certification strategy should be publicly available—that is, on the relevant ministry website or in hard copy. The activities, business plans, and budgets of the relevant ministry regarding public certification bodies should be aligned with the strategy. The private sector will make its own business plans, depending on the space it is given in the strategy.

Existing information/reporting/monitoring

- Relevant government policies, strategies, and implementation plans
- Review of the extent of public sector certification body capacity and capabilities
- Government purchasing documentation
- Relevant ministry (for example, Trade and Industry, Science and Technology, Health, Agriculture, and so on) websites

8.2.3 National certification bodies for home and regional markets (building block no. 2)

What is meant

Major	Certification bodies providing product certification services for products for the local market and the regional common market are recognized by the relevant market and its authorities.

How can it be demonstrated?

Governments use product certification as a vehicle to upgrade the quality of locally manufactured products to enable them to compete with imported products. Similarly, governments may use a national product certification scheme as a positive indicator for the supply of products to the state.

Within a regional common market, regulatory authorities frequently recognize product certification as "deem to satisfy" evidence that products comply with technical regulations. Such recognition is based either on regional mutual recognition agreements (MRAs) or through regional legislation. The recognition is invariably based on the appropriate accreditation of the certification body and the harmonization of the relevant product standard.

As for the marketplace, recognition of the product certification marks will depend largely on the public image the certification body is able to establish. However, without a well-established market position in the home market, expanding its recognition to a regional common market will be difficult.

The most relevant of these issues for the local and regional markets should be clearly identified. Thereafter, the appropriate national product certification body and schemes should be established and accredited to ISO/IEC 17065. Every effort should be made to gain market recognition and acceptance of the product certification mark in the home market before the regional common market is targeted.

Private sector certification bodies, especially the multinational product certification bodies, will develop their own strategies and business plans.

Existing information/reporting/monitoring

- Government export policies and strategies
- Recognition agreements between the government and regional common market authorities
- Market intelligence regarding relevant product certification in the regional common market
- Communication and advertising strategies to target the home and regional common markets

8.2.4 Designated certification bodies (building block no. 3)

What is meant

Major	Product certification bodies mandated to provide product certification services in the regulatory domain should be designated by the relevant authorities based on their technical competence (that is, accreditation) and their legal liability in the country.

How can it be demonstrated?

In the product certification services sector as a whole, an important element that needs to be defined in a legislative instrument is the use of accreditation as one of the preconditions for designating certification bodies that provide product certification services for regulatory purposes. Such certification services may be required in technical regulation implementation, occupational health and safety systems, environmental controls, transportation, building and construction, and other areas. In addition to their technical competence, designated certification bodies should be able to be held legally liable in the country regarding the integrity of their services.

Existing information/reporting/monitoring

- Accreditation Act, decree, regulation, or similar law, if relevant
- Relevant legislative instruments of ministries
- Official lists of designated certification bodies for the regulatory domain

8.2.5 Product certification schemes to upgrade SMEs (building block no. 4)

What is meant

Minor	SMEs are supported through government programs to obtain product certification, all to upgrade the quality of their products.

How can it be demonstrated?

In most low- and middle-income countries, SMEs are the most prevalent type of firm in the industrial sector. However, they are seriously challenged to provide high-quality products and services fully compliant with national standards or to compete with larger manufacturers or multinational companies. Governments therefore often implement support programs to facilitate the SMEs' ability to gain certification for their products.

Well-designed support programs consist of training selected SMEs in quality control systems, consultancy support for improving the quality of their products, and some financial payback after a positive outcome of the certification process (for example, 50 percent of the testing, audit, and certification fees). Thereafter, the financial support is partially continued if the SME retains its certification in the years following. Failure by the SME to maintain its certification obviously leads to a cessation of financial support.

Existing information/reporting/monitoring

- Formal documentation of government support programs for the certification of products manufactured by SMEs
- Records of certification bodies
- Records of financial support to SMEs once certification has been granted
- Official lists of certified SMEs by certification bodies

8.3 PILLAR 1: LEGAL AND INSTITUTIONAL FRAMEWORK, INDIVIDUAL PRODUCT CERTIFICATION BODIES

8.3.1 Benchmark and significance

To be recognized, product certification bodies have to demonstrate their competency; that is, they will need to be accredited. Hence, it is important that the certification body clearly define the scope of its product certification schemes because accreditation will be ascribed accordingly.

Their financial sustainability is an important parameter, and especially public certification bodies should be given the freedom to determine the pricing of their services in accordance with the market. In other words, the government should not force them to offer certification services below market prices (see module 6, section 6.4, of the QI Toolkit).

8.3.2 Legal entity (building block no. 5)

What is meant

Major	A certification body shall be a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for the outcome of its certification services. Certification bodies may be either public or private sector entities.

How can it be demonstrated?

The individual certification body shall be established by legislation or articles of incorporation, depending on whether it is a public or private sector entity. The legislation or articles of incorporation must define the governance, financial provisions, and responsibilities and functions of the certification body. Being able to demonstrate its legal entity status is a prerequisite for accreditation.

Existing information/reporting/monitoring

- Relevant legislative instruments of ministries
- Relevant articles of incorporation

8.3.3 Governance (building block no. 6)

What is meant

Fundamental	The certification body should have a governance structure in charge of strategy approval and overall fiduciary responsibilities, whether it is appointed by a relevant minister, by the parent ministry, or by shareholders.
Major	Good governance models suggest that the members of the governance structure should be individuals with specific knowledge regarding product certification and market realities.
Major	The governance structure has to comply with the relevant requirements of ISO/IEC 17065. A committee or similar body separate from management and representative of interested parties oversees the impartiality of the certification body.

How can it be demonstrated?

A certification body may be (a) an independent public or private sector entity, or (b) a part of a greater entity. Each of these will have a different governance structure, depending on the extent of its independence. Whatever the case, the governance structure should have the authority to determine the strategy for the certification body, approve the business plans and budget, and exercise overall fiduciary responsibility over the certification body.

The governance structure has to comply with the requirements of ISO/IEC 17065. Special attention needs to be given, for example, to a committee or similar body that is representative of interested parties but separate from management and governance structures to oversee the impartiality of the certification body.

Existing information/reporting/monitoring

- Legislative instrument establishing the certification body, if relevant
- Articles of incorporation, if relevant
- Government decisions or decrees, if relevant
- Official organizational structure
- Annual reports of the certification body

8.3.4 Certification scope (building block no. 7)

What is meant

Fundamental	The certification body has to clearly define the scope of the certification schemes it offers. These are also the basis of its accreditation.

How can it be demonstrated?

A number of product certification schemes are possible (for examples, see table 8.1). The certification body has to define which of these it offers or plans to offer system certification services for. These should be aligned with the demonstrable needs of its chosen target market. The scope will determine the requirements for its initial auditing processes, testing regimes, surveillance audits, and other elements required in terms of its accreditation as determined by the accreditation body.

Existing information/reporting/monitoring

- Official description of the scope of system certification schemes offered
- Accreditation scopes
- Certification body business strategy and plans
- Certification body annual budgets

8.3.5 Financial sustainability (building block no. 8)

What is meant

Fundamental	The finances for establishing the certification body can be provided from government sources or through financial support from industry. Once operational and accredited, the certification body should become financially self-sufficient. Its financial sustainability has to be demonstrated to the accreditation body.

How can it be demonstrated?

Establishing a certification body will require a fair amount of financing in the initial stages, especially before it is accredited. Before being accredited, it may battle to gain customers because these generally wish to be certified by a recognized certification body. However, once established and accredited, a certification body should become self-sufficient; that is, government or industry subsidies should not be necessary for its medium- to long-term existence. Income should cover all operational costs fully, with surpluses to finance future developments. Private sector certification bodies ultimately have to deliver dividends to their investors.

SMEs frequently find it difficult to pay for certification services. Hence, many governments wish to support the SME sector by subsidizing certification fees. Such support should not be provided by below-cost certification services rendered by public certification bodies because this will negatively affect their financial sustainability, distort the market, and constrain the establishment of private sector certification bodies. Such financial support, if necessary, should be provided directly to the enterprises through programs designed to help SMEs continue their certification over longer periods.

The certification body's overall financial situation of the past three to five years would be a good indication of its financial sustainability. The situation should show a positive trend over the years under review. A positive trend in the income generated from certification services would be a further indicator, as would be business plans for future developments. Such information also has to be presented to the accreditation body during the initial audit (see building block no. 16).

Existing information/reporting/monitoring

- Annual government budget allocations
- Certification body business plans

- Annual reports of the certification body
- Monthly and annual financial statements of the certification body

8.4 PILLAR 2: ADMINISTRATION AND INFRASTRUCTURE

8.4.1 Benchmark and significance

The organizational structure of the product certification body must be conducive to providing the full complement of product certification schemes included in its scope and subscopes and as required by its stakeholders. Good governance principles require the certification body to have a top management, and the subject fields of its certification schemes suggest that the certification body should have divisions dedicated to certification schemes in these fields, if relevant.

Over and above these general guidelines, the certification body must comply with the requirements of ISO/IEC 17065 relating to organizational structures or with any other relevant standards it wishes to be accredited for. These usually include a separation of personnel involved in audits and testing from the certification decision. The certification body has to use registered auditors and lead auditors, and it will have to demonstrate that its personnel are free from any undue commercial, financial, and other pressures that might influence their technical judgment.

8.4.2 Top management (building block no. 9)

What is meant

Major	The top management of the certification body is responsible for the technical management of the certification body and is accountable for the quality and integrity of its services. Effective communication channels must exist between the top management and personnel, as well as between top management and higher-level management or governance structures.

How can it be demonstrated?

There is no standardized list of the major functions and responsibilities carried out by the top management, but some typical functions include the following:

- Supports operations and administration of the certification body governance structures by advising and informing its members and interfacing between governance structures and personnel
- Oversees the development, marketing, promotion, delivery, and quality of certification services
- Recommends the annual budget for approval and prudently manages the certification body resources within those budget guidelines
- Effectively manages the human resources of the certification body according to authorized personnel policies and procedures
- Assures that the certification body and its mission and services are consistently presented using strong, positive images to relevant stakeholders
- Oversees the identification of resource requirements and possible income sources, including ascertaining strategies to approach funders

Existing information/reporting/monitoring

- Governance structure decisions and minutes
- Official top management job descriptions
- Agreed-upon top management key performance indicators

8.4.3 Organizational structure (building block no. 10)

What is meant

Major	A number of product certification schemes covering a vast range of products, processes, and services are possible. It therefore follows that the organizational structure of a certification body should have divisions that optimally support its scope of certification schemes, the groupings within it, and the modalities of the certification process.

How can it be demonstrated?

Good management practice suggests that the organizational structure of the certification body should take cognizance of groupings within its scope of certification schemes. Other issues to consider include the following:

- The certification decision has to be made by a person, or persons, independent from the testing and audit teams.
- Testing could be in-house or subcontracted to an accredited laboratory.
- The pool of external auditors, if relevant, must be appropriately managed.
- The place and participants of the impartiality committee must be determined.
- A quality manager should be appointed who (a) has the defined responsibility and authority for ensuring that the management system related to the quality of certification services is implemented and followed at all times, and (b) has direct access to top management, where decisions are made on certification body policy or resources.

These elements are not only important from a good governance perspective but also are necessary to consider for accreditation purposes.

Existing information/reporting/monitoring

- Approved organizational structure
- Governance structure decisions
- Financial system documentation

8.4.4 Management and personnel (building block no. 11)

What is meant

Major	Product certification is both a people-based activity for auditing and a technical operation with regard to testing. The management and personnel must therefore have the appropriate skill sets assured by appropriate training, qualifications, and experience. These would include management and technical knowledge as required by the various activities within the certification body's scopes. Registered auditors and lead auditors are essential.

How can it be demonstrated?

In the first place, the product certification body should operate with an organizational structure approved by its governance structures. For each of the positions, the skill set (qualifications, training, and experience) should be clearly and formally stated. The administrative staff should not be more than 20 percent of total staff; the major proportion should be technical staff.

Second, there should be few staff vacancies on either the management or technical levels; more than 95 percent of those positions should remain filled. Anything less indicates that the certification body cannot operate

effectively or efficiently. Staffing challenges often include a lack of skilled people in the country, but even more so, inadequate remuneration resulting in the departure of trained staff for more lucrative offers elsewhere.

Third, technical staff should have the necessary skills set of education, training, and experience to be able to manage and conduct audits within specified scopes. Auditors and lead auditors must be registered and their registrations kept up-to-date. This applies to those permanently employed, as well as those subcontracted as required.

(*Note:* For more about the qualifications of testing personnel, see section 7: Testing.)

Existing information/reporting/monitoring

- Approved organizational structure
- Approved criteria for technical staff
- Actual staffing levels
- Staff turnover figures
- Registration records of auditors and lead auditors

8.4.5 Premises (building block no. 12)

What is meant

Major	Appropriate office accommodation for personnel is required. The offices should have meeting rooms where clients can be received, rather than in the offices of personnel, to ensure that information about other companies remains confidential. Storage space for records is essential.

How can it be demonstrated?

Office space conducive to a positive working environment is necessary for the staff of the certification body. Meeting rooms in which clients can be received rather than in the offices of personnel, especially auditors and lead auditors, are important to keep information of other clients confidential. Space for storing and ease of retrieval of the records of audits and certifications is essential. The effect of the location of the offices of the certification body on business should not be underestimated; it should be relatively easily accessible by clients.

(*Note:* The requirements for laboratories for the testing of products are detailed in section 7: Testing.)

Existing information/reporting/monitoring

- Review of certification body accommodation in the light of defined requirements

8.4.6 Equipment (building block no. 13)

What is meant

Major	Equipment requirements for the certification are largely fulfilled by an effective, efficient, and secure information technology (IT) system.

How can it be demonstrated?

An efficient and effective IT system that can handle the quality management system documentation and the audit and certification records is important. Its access control should be such that the integrity of all records can be ensured at all times.

(*Note:* The requirements for equipment for the testing of products are detailed in section 7: Testing.)

Existing information/reporting/monitoring

- Consideration of the effectiveness and efficiency of the IT system
- Consideration of the access control of the IT system

8.5 PILLAR 3: SERVICE DELIVERY AND TECHNICAL COMPETENCY

8.5.1 Benchmark and significance

Accreditation by an independent and recognized accreditor body is the primary recognition mechanism for certification bodies (see building block no. 16). This may be accreditation to ISO/IEC 17065 or similar sector-based systems, thereby demonstrating the certification body's technical competency. All of them require the implementation of a formal quality management system, the appointment of appropriately skilled personnel, and internal audit procedures and management review to ensure continuous compliance.

8.5.2 Product certification scheme scopes (building block no. 14)

What is meant

Fundamental	The certification body must have a clear description of the product certification schemes it provides, including their applicability to national or international standards.

How can it be demonstrated?

The certification body should clearly define the scope of its product certification schemes. This should preferably be in terms of published standards, whether public or private, or whether national, regional, or international standards. The applicability of these certification schemes in various sectors is an important addition to the general information. This information should be publicly available.

Existing information/reporting/monitoring

- Quality management system documentation
- Certification body website
- Certification body marketing material and brochures
- Accreditation records

8.5.3 Quality management system documentation (building block no. 15)

What is meant

Fundamental	The quality management system documentation must comply with the requirements of the relevant accreditation standard.

How can it be demonstrated?

The quality management system documentation is generally organized on three tiers, generically known as policy documents, procedures, and work instructions. These are supported by records of the audits, certification records, internal audit records, management review records, and records of nonconformities and others required by the relevant accreditation standard. A typical quality management documentation system for a certification body is shown in figure 8.2.

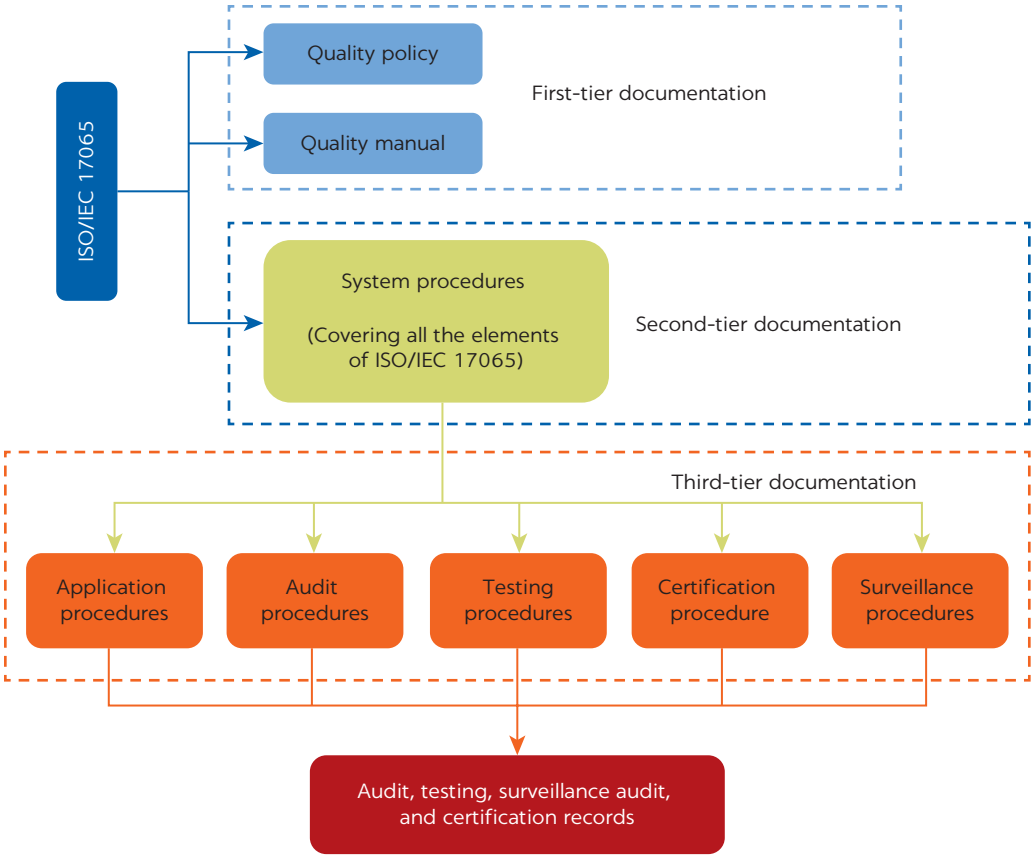
The accreditation process usually includes an assessment of the quality management documentation, before a preassessment or initial assessment is conducted, to ensure that all the elements of the relevant accreditation standard are addressed. The certification body normally has six months to rectify any nonconformities identified in the quality management documentation before on-site assessments are considered.

Existing information/reporting/monitoring

- Quality management documentation
- Internal audit results
- Management review records
- Accreditation records

FIGURE 8.2

Typical product certification body documentation system



Note: ISO/IEC 17065 = "Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services."

8.5.4 Accreditation (building block no. 16)

What is meant

Major	*Preassessment*. A certification body may request a preassessment before an initial assessment is conducted to determine whether or not a formal quality management system is in place.
Fundamental	*Initial assessment*. The initial assessment for accreditation is an on-site visit by a team from the accreditation body to determine whether the quality management system documentation is fully operational and whether the certification body is competent to conduct the audits and certification defined in its scope.
Fundamental	*Accreditation*. Once all nonconformities have been cleared, the accreditation body submits the assessment report to its approvals committee for a final decision. Should accreditation be granted, the certification body receives an accreditation certificate carefully detailing its product certification scheme scopes, and its data are added to the publicly available information of the accreditation body.

How can it be demonstrated?

Preassessment. Once the quality system documentation has been assessed, the certification body may request a preassessment by the accreditation body. The preassessment is usually a one-day visit by the lead assessor of the accreditation body to determine whether a formal quality management system is in place, without determining whether the certification body is competent to conduct certification. In some cases, the accreditation body may require a preassessment as a precondition for the initial assessment. Nonconformities detected during the preassessment have to be corrected before an initial assessment can take place.

Initial assessment. The initial assessment is conducted by an accreditation body team consisting of a team leader and technical assessors and experts. The certification body has to ensure that there are sufficient records to confirm that the system is implemented before the initial assessment, for example, certification audits must have been successfully completed. Most accreditation bodies also require a complete internal audit and management review cycle to have been completed.

The certification body staff will have to demonstrate to the technical assessors that they are competent to conduct certification audits and complete the audit reports. The system for the testing of products will likewise be carefully audited for compliance. Any nonconformities identified during the initial assessment usually have to be demonstrably corrected within six months; otherwise the complete initial assessment may need to be repeated.

Accreditation. The assessment report detailing all the findings of the assessment team, evidence of the correction of any nonconformities, and a recommendation for accreditation is submitted to the approvals committee of the accreditation body. If accreditation is granted, then the certification body receives an accreditation certificate that will detail the scope of its product certification schemes. The accreditation certificate usually has a validity of three to five years, during which follow-up assessments are conducted on an audit basis. An initial assessment is repeated to reissue the accreditation certificate.

Should the follow-up audits reveal nonconformities, the certification body will be given a specified amount of time to rectify them. Failure to do so will result in the suspension of the accreditation, followed by the withdrawal of the accreditation certificate if no progress is achieved. During suspension, the testing laboratory may not claim accreditation status.

Existing information/reporting/monitoring

- Accreditation application
- Assessment result of the quality management system documentation
- Preassessment record
- Initial assessment reports and records
- List of identified nonconformities
- Records of closeout of nonconformities
- Accreditation certificate
- Public records of accreditation body

8.5.5 Certification process (building block no. 17)

What is meant

Fundamental	The approach and processes a certification body follows to certify a product must comply with the requirements of ISO/IEC 17065 or a similar standard used for its accreditation.

How can it be demonstrated?

The approach and processes that certification bodies follow to certify a product have been harmonized to a great extent, and generally follow the structure as defined in ISO/IEC 17065. Small variations may occur when other standards are used to accredit the certification body, but the fundamentals will remain the same. The process is depicted graphically in figure 8.3.

Application. Application forms must be completed, and specified information on the company, its operations, and products must be provided for the certification body to determine the scope of certification, the prototype product testing requirements, and the appointment of a team leader for the audit.

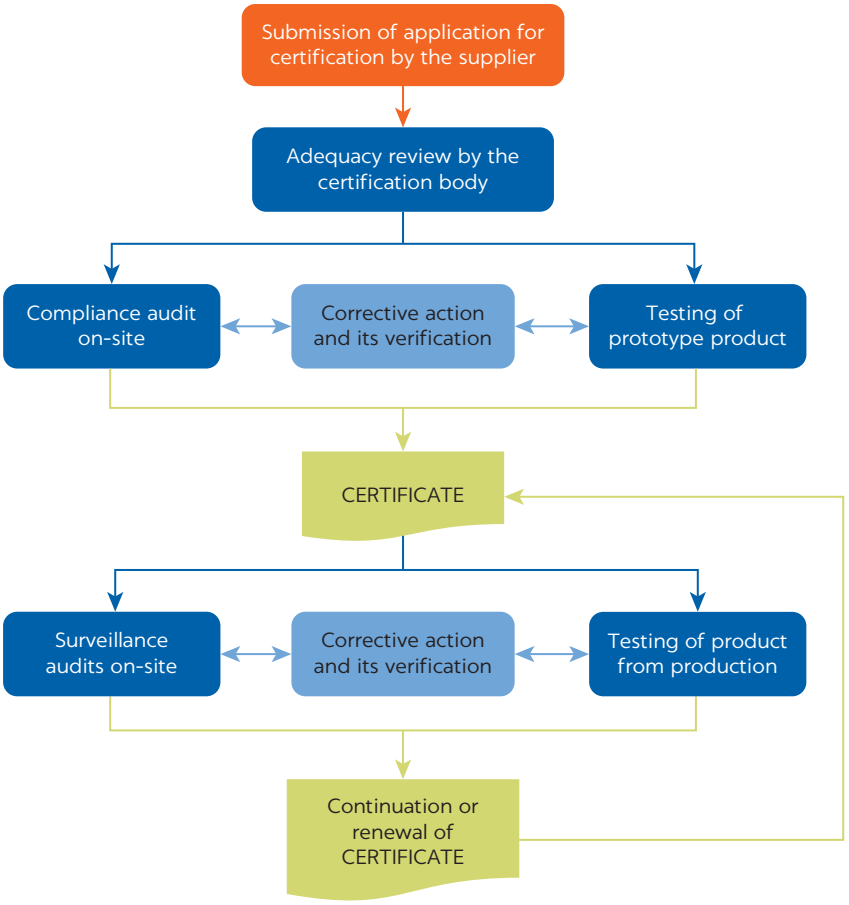
Adequacy audit. The certification body evaluates the quality management system documentation of the applicant to determine whether to proceed to the on-site audit and to determine sampling of the product and concomitant product testing requirements.

Initial on-site audit. The team leader assembles a team of auditors and experts concomitant with the scope of certification and the complexity and the size of the operation. The team evaluates the implementation and effectiveness of the quality management and control system on-site and the quality controls implemented by the manufacturer to ensure the continuous quality of the product. The team then prepares a final report after nonconformities have been cleared.

Testing of prototype product. Samples of the product for which certification is sought are tested against all the requirements of the relevant standard. The testing can be conducted by the certification body, or it can be subcontracted by them to a competent (that is, accredited) laboratory. In special cases—for example, with expensive or unique testing equipment not available elsewhere in the country—the certification body may witness testing at the manufacturer's premises, provided it is confident regarding the technical competency of the manufacturer's testing.

Certification. Authorized persons, or a committee totally independent of the audit team, review the audit and test reports and decide whether to grant certification. Certification documentation is issued to the applicant if the decision is positive, and the manufacturer is licensed to affix the product certification mark to the product and packaging.

FIGURE 8.3
Schematic of the product certification process



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

Surveillance audits. After certification, the certification body conducts surveillance audits at defined intervals (depending on the product and other circumstances) and conducts audit testing on products sampled from production. This can be as frequently as once a month in the beginning until the certification body has gained confidence in the manufacturer's quality control. The surveillance audits are usually not as comprehensive as the initial on-site audit unless nonconformities are discovered, in which case the audit may be intensified.

Continuation or reissue of certificate. Depending on the modalities of the product certification scheme as determined by the certification body, the certificate may be an open-ended certificate that stays valid as long as requirements continue to be fulfilled. Other schemes require a reissue of the certificate after a specified time, usually after one, two, or three years.

Details of certified companies, together with their scope of certification, are made known publicly on the certification body's website. Failure to correct 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 also withdrawn. Thereafter, the manufacturer may no longer use the product certification mark.

Existing information/reporting/monitoring

- Certification body quality management and process documentation
- Application records
- Audit reports and records
- Test reports and records
- Certification person(s) records
- Certification body website

8.6 PILLAR 4: EXTERNAL RELATIONS AND RECOGNITION

8.6.1 Benchmark and significance

Whereas accreditation may be the condition for the recognition of the competency of a product certification body in the nonregulated market, in the regulated market further steps are frequently necessary. These have to do with the legal accountability of the certification body once it starts providing certification services to support the implementation of technical regulations or sanitary and phytosanitary measures.

The technical term for this official recognition by the authorities is "designation" (ISO/IEC 17000, "Conformity Assessment—Vocabulary and General Principles"). Countries may use others—for example, the "notified bodies" of the European Union (EU). Many multinational product certification schemes have their own mechanisms to recognize certification bodies providing certification services in support of these schemes. Without such recognition, product certification bodies will find it difficult to penetrate these potentially lucrative markets.

8.6.2 Recognition at the national level (building block no. 18)

What is meant

Minor	Recognition at the national level is facilitated by accreditation to the relevant international standard (for example, ISO/IEC 17065). Recognition may be by the market, or it can go a step further in being designated by a governmental authority for specific product certification schemes related to the implementation of regulations.

How can it be demonstrated?

Recognition at the national level in the marketplace has developed to the point where accreditation to the relevant international standard (such as ISO/IEC 17065 or a similar standard) has overtaken all other types of recognition arrangements in importance. Being a government agency, such as the NSB, is no longer good enough. Such accreditation should be provided by an accreditation body that is a signatory to the International Accreditation Forum (IAF) Mutual Recognition Agreement.

Recognition by regulatory authorities through designation is now largely based on accreditation plus some additional legal requirements not covered by accreditation (for example, legal liability in the country, up-to-date tax returns, and so on). Competency assessments by regulatory authorities against their own requirements, for example, are slowly being abandoned in lieu of an independent accreditation.

Existing information/reporting/monitoring

- Official lists of accredited certification bodies
- Official lists of regulatory authorities regarding designated certification bodies

8.6.3 Recognition at the international level (building block no. 19)

What is meant

Major	Recognition at the international level is extremely difficult because no international recognition system has been established for various product certification bodies or their marks. Regional common markets may facilitate regional recognition.

How can it be demonstrated?

Recognition at the international level has two elements. Accreditation to ISO/IEC 17065 by a recognized accreditation body may facilitate the recognition of certification body results by at least the other members of the IAF Mutual Recognition Agreement. But the acceptance of the product certification mark in the marketplace is much more challenging. No international system exists for the mutual acceptance of product certification marks, nor is it likely that one will be established in the near future, even though accreditation provides independent evidence of the product certification body's competence.

Hence, product certification marks have to "earn" their acceptance in foreign markets primarily through marketing strategies. For the multinational private sector certification bodies, this may be easier to realize than for national product certification bodies. Individual recognition arrangements between two certification bodies to accept the outcome of the audits and testing results of the other, and on that basis to license suppliers to use both product certification marks, is a way of gaining recognition in foreign markets.

The situation in a regional common market (or under a free-trade agreement) may be slightly different, in that national product certification marks are mutually recognized in the member states through a political decision coupled with a demonstration of capability (that is, accreditation) or peer reviews of the certification bodies. But even in this case, a communication strategy to publicize the political decision and make it credible in the marketplace is indicated.

Existing information/reporting/monitoring

- System certification strategy and its implementation plans
- IAF membership data
- Regional recognition systems relevant to the country
- MRAs between the national certification body and counterparts based in other countries

8.6.4 Coordination within the QI (building block no. 20)

What is meant

Minor	Coordination among the certification bodies of the country is based largely on activities managed through voluntary associations.

How can it be demonstrated?

A national certification body association in which membership is voluntary can be helpful in coordinating some elements of product certification activities—for example, lobbying governmental authorities, facilitating discussions on a better understanding of international certification standards, and so on.

In addition, a technical regulation coordination office (or a similar facility) may enforce coordination of activities between product certification bodies and the regulatory authorities, as well as with the NSB, national accreditation body (NAB), and national metrology institute (NMI) with respect to the implementation of technical regulations.

Existing information/reporting/monitoring

- Regulatory authority policies, pronouncements, and documentation
- Certification body association documentation and minutes of meetings
- Technical regulation coordination office mandate and pronouncements

NOTES

1. According to the definitions in ISO/IEC 17067 ("Conformity Assessment—Fundamentals of Product Certification and Guidelines for Product Certification Schemes"), a "certification service" is defined by the rules, procedures, and management for carrying out certification; a "certification scheme" is a certification service for specified products to which the same specified requirements, specific rules, and procedures apply.
2. In quite a few low- to middle-income economies, the national product certification mark is a prerequisite for demonstrating compliance with mandatory standards. Whereas a mandatory standards system may still be compliant with the technical regulation requirements of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement), the use of the national product certification mark as the demonstration of compliance of the product is considered an unnecessary trade barrier and as a license for the NSB to extract rent. Economies that still practice such a system should seriously consider changing to a more trade-friendly system.

STANDARDS REFERENCED IN SECTION 8

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). 2004. "ISO/IEC 17000: Conformity Assessment—Vocabulary and General Principles." Ref. no. ISO/IEC 17000:2004(E), ISO, Geneva.

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Minzberg, H., B. Ahlstrand, and J. Lampel. 1998. *Strategy Safari: The Complete Guide through the Wilds of Strategic Management*. Edinburgh: Pearson Education, Prentice Hall.

9

System Certification

9.1 INTRODUCTION

System certification (more accurately, quality management system certification) developed after World War II as a confidence indicator for the ability of companies to supply quality products, building on the concepts of final inspection, quality control, and ultimately quality assurance. Management certification came to the fore with the publication of ISO 9001 ("Quality Management Systems—Requirements") in 1987.

But ISO 9001 is not the only standard used for system certification. Many have been published since then—some of them by international standards bodies, others developed as private standards. Table 9.1 provides an overview of some of the better-known system standards, even though it is far from complete. Some of them are pure system standards, but others include requirements for the products as well, even though they are not specifically considered product certification schemes.

Evaluating a country's needs regarding system certification services is complex, and many facets need to be taken into consideration. The issue is also complicated by commercial considerations of the private standards certification bodies that frequently operate a closed shop; that is, they do not allow local certification bodies to participate in their schemes, forcing suppliers to use foreign certification bodies. On the other hand, certification schemes based on international standards or their national adoptions can be offered by national certification bodies, provided they are appropriately accredited.

It is useful to differentiate between basic, advanced, and mature certification schemes, depending on the maturity levels of the quality infrastructure (QI) in a country (table 9.2). These have to be considered in relation to the needs of manufacturers, regulatory authorities, and the marketplace; in other words, the evaluation becomes a multifaceted exercise. The trend worldwide is that governments may initiate the establishment of public sector certification bodies, but these are soon eclipsed by private sector certification bodies as the market for system certification develops.

TABLE 9.1 Overview of leading 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
	Supply chain security	ISO 28000:2007
	Petroleum and natural gas	ISO 29001:2010
	Energy	ISO 50001
Private standard	Aerospace	AS 9100[a]
	Automotive	IATF 16949:2016
	Food safety and horticulture	British Retail Council (BRC)
		GLOBAL G.A.P.
		FSSC 22000
	Social accountability	SA 8000
		Fair Trade
	Telecommunication	TL 9000[b]
	Occupational health and safety	OHSAS 18000
	Ecolabeling	EU Ecolabel
		Forest Stewardship Council (FSC)
		Marine Stewardship Council (MSC)
		Green Dot

Note: AS = aerospace; EU = European Union; IATF = International Automotive Task Force; FSSC = Food Safety System Certification; GLOBAL G.A.P. = Global Good Agricultural Practice; IEC = International Electrotechnical Commission; ISO = International Organization for Standardization; IT = information technology; HACCP = hazard analysis and critical control points; OHSAS = Occupational Health and Safety Assessment Series; SA = Social Accountability; TL = telecommunication. The standards are continuously being revised, and information regarding the latest issue must be obtained from the publishing organization. For a more detailed description of the various system certification schemes, see module 6, section 6.5, of the QI Toolkit.

a. AS 9000 is published by the International Aerospace Quality Group (IAQG), a nonprofit cooperative organization incorporated under Belgian law, comprising three sectors: the Americas (AAQG), Asia/Pacific (APAQG), and Europe (EAQG).

b. TL 9000 was developed and is published by the QuEST Forum, a Business Performance Community (BPC) within the Telecommunications Industry Association (TIA).

This section of the Comprehensive Diagnostic Tool consists of two subsections: the first dealing with the system certification sector as a whole, and the second with the evaluation of an individual system certification body. The former (on the system certification sector) deals primarily with the evaluation of the country's needs, taking into consideration both the public and the private sectors. The basic building blocks for evaluating the country's needs regarding system certification are listed in table 9.3.

The pillars and building blocks for evaluating a specific certification body are listed in table 9.4.

To depict the pillars and building blocks in a graphical way that would indicate the state of system certification in a country at a glance, they can be put together as shown in figure 9.1. For a complete description of the construction, interpretation, and use of this graphic or of the matching radar diagram, see section 1: Comprehensive QI Assessment.

TABLE 9.2 Maturity levels of a country's system certification schemes, by characteristic

CHARACTERISTIC	RUDIMENTARY (VERY LITTLE IS IN PLACE)	BASIC (LOW- TO MIDDLE-INCOME COUNTRY APPROACH)	ADVANCED (ECONOMYWIDE APPROACH, SECTORAL APPROACH)	MATURE (TOTALLY FREE-MARKET APPROACH)
Certification body infrastructure	No local certification bodies established; some foreign ones may be operating	A few certification bodies to support • Main exported products; and • Critical technical regulation implementation	System certification scheme services defined through economywide surveys and defined sectoral needs	System certification schemes determined by free-market principles
Recognition	None	Through accreditation	Through accreditation and designation	Through accreditation and designation
Establishment	None	Mostly public sector certification bodies	Good mix of public and private sector certification bodies Public sector certification bodies looking after SME sector	Predominance of private sector certification bodies; public sector certification bodies mostly looking after SME sector
Services	Ad hoc services by outside certification bodies	Selected system certification services	Small range of system certification services	Wide range of system certification services
Human resources	None	Training on the job	Training on the job Training courses in auditing Foreign auditor registration schemes	Training on the job Training courses in auditing methodologies Auditors as a professional profile Local and foreign auditor registration schemes
Demand orientation	Ad hoc by specific organizations	Demand surveys, mostly through projects	Demand surveys Stakeholder participation and consultative mechanism	Free-market instruments and constructs to ensure demand orientation

Note: SMEs = small and medium enterprises.

TABLE 9.3 Building blocks for evaluating a country's system certification sector

PILLAR	BUILDING BLOCK NO.	BUILDING BLOCK DESCRIPTION
1: Legal and institutional framework, system certification sector	1	System certification services strategy
	2	Designated system certification bodies
	3	Certification bodies for the export markets
	4	System certification schemes to upgrade SMEs
	5	Training and registration of auditors and lead auditors

Note: SMEs = small and medium enterprises.

TABLE 9.4 Pillars and building blocks of a system certification body

PILLAR	BUILDING BLOCK NO.	BUILDING BLOCK DESCRIPTION
1: Legal and institutional framework, individual system certification bodies	6	Legal entity
	7	Governance
	8	Certification scope
	9	Financial sustainability
2: Administration and infrastructure	10	Top management
	11	Organizational structure
	12	Management and personnel
	13	Premises
	14	Equipment

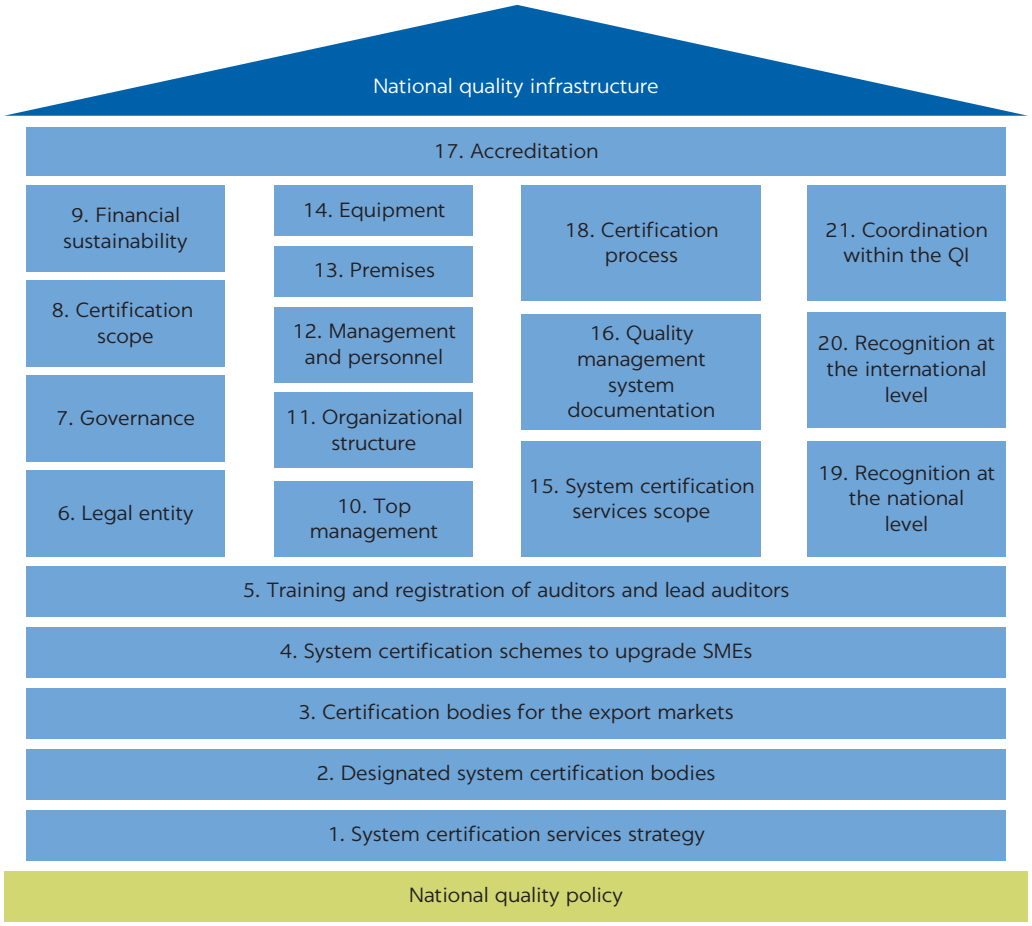
continued

TABLE 9.4 *continued*

PILLAR	BUILDING BLOCK NO.	BUILDING BLOCK DESCRIPTION
3: Service delivery and technical competency	15	System certification services scope
	16	Quality management system documentation
	17	Accreditation
	18	Certification process
4: External relations and recognition	19	Recognition at the national level
	20	Recognition at the international level
	21	Coordination within the QI

Note: QI = quality infrastructure.

FIGURE 9.1
House of system certification for a national quality infrastructure



Note: QI = quality infrastructure; SMEs = small and medium enterprises. The four "pillars" of the QI—represented by the blue columns containing the "building block" numbers—are as follows (left to right): "legal and institutional framework," "administration and infrastructure," "service delivery and technical competency," and "external relations and recognition."

9.2 PILLAR 1: LEGAL AND INSTITUTIONAL FRAMEWORK, SYSTEM CERTIFICATION SECTOR

9.2.1 Benchmark and significance

System certification has become an entry-level requirement in many markets, as indicated, for example, by the growth of the generic ISO 9001 certificates worldwide. It is especially the small and medium enterprises (SMEs) sector that is

frequently challenged to obtain such certification before it can access foreign markets or get into the supply chain of the multinational and retail organizations or major purchasers at the local level. The choice of which system certification to pursue is complex, and it is determined to a large extent by market forces in both the local and export markets (see table 9.1).

System certification has also found its way into the regulatory domain. Compliance with ISO 9001; hazard analysis and critical control points (HACCP); ISO 22000 ("Food Safety Management Systems—Requirements for Any Organization in the Food Chain"); and others is frequently demanded by the regulatory authorities to support the need to ensure the integrity of products influencing the health and safety of people, the environment, and the fauna and flora of the country.

System certification bodies providing such services, whether public or private sector aligned, should be accredited to ISO/IEC 17021 ("Conformity Assessment—Requirements for Bodies Providing Audit and Certification of Management Systems") or a similar standard by a recognized accreditation body to ensure their technical competency and to facilitate their recognition for regulatory purposes and in the marketplace. The government's role in the initial stages of establishing system certification bodies is important. But such services should not remain the sole domain of public sector certification bodies; they should be liberalized from the beginning to allow private sector certifications bodies to be established and prosper.

9.2.2 System certification services strategy (building block no. 1)

What is meant

Major

Following on from the quality policy (see module 10 of the QI Toolkit), a system certification services strategy gives meaning to the implementation of the quality policy with regard to the establishment of technically competent system certification bodies in both the public and private sectors. The system certification services strategy is about

- Making the right choices regarding the overall approach to the use of certification bodies in the country;
- Getting the mix right between public and private sector certification bodies;
- Using accreditation to designate certification bodies providing services in the regulatory domain; and
- Building capacity in certification bodies to provide required system certification services in the most innovative, effective, and efficient way.

How can it be demonstrated?

The system certification strategy can be seen as an intended plan to set a pattern, create a unique position, follow a specific perspective, and implement a specific tactic—all to enable the government and the private sector collectively to make a difference to a critical mass of the right customers and to connect their purposes with those of their customers and external stakeholders (Minzberg, Ahlstrand, and Lampel 1998).

The strategy should take cognizance of the country's demonstrated needs regarding system certifications services in important sectors (for example, the regulatory domain, main export sectors, the industrial sector, and so on). The strategy should give appropriate space for the private sector to establish certification bodies, including system certification services required in

regulatory work. It may even provide for the total migration of system certification services to the private sector. The mechanism of designating certification bodies for technical regulation implementation should be detailed. Priority development sectors should be identified, and government support for the development of certification bodies by the private sector should be provided for.

The system certification strategy should be a formal document approved at least by the relevant ministries and, in some countries, by the cabinet because it will be cross-cutting regarding ministries in its implementation. The system certification strategy should be publicly available—that is, on the relevant ministry website or in hard copy. The activities, business plans, and budgets of the various ministries regarding public certification bodies should be aligned with the strategy. The private sector will make its own business plans, depending on the space it is given in the strategy.

Existing information/reporting/monitoring

- Relevant government policies, strategies, and implementation plans
- Review of the extent of public sector certification body capacity and capabilities
- Relevant ministry (for example, Trade and Industry, Science and Technology, and so on) websites

9.2.3 Designated system certification bodies (building block no. 2)

What is meant

Major	System certification bodies mandated to provide certification services in the regulatory domain should be designated by the relevant authorities based on their technical competence (that is, accreditation) and their legal liability in the country.

How can it be demonstrated?

Regarding the system certification services sector as a whole, an important element that needs to be defined in a legislative instrument is the use of accreditation as one of the preconditions of designating certification bodies providing certification services for regulatory purposes. Such certification services may be required in technical regulation implementation, health and safety systems, environmental controls, transportation, building and construction, and legal metrology. In addition to their technical competence, designated certification bodies should be able to be held legally liable in the country regarding the integrity of their services.

Existing information/reporting/monitoring

- Accreditation Act, decree, regulation, or similar law, if relevant
- Relevant legislative instruments of ministries
- Official lists of designated certification bodies for the regulatory domain

9.2.4 Certification bodies for the export markets (building block no. 3)

What is meant

Major	Certification bodies to provide system certification services for major exported products are recognized by the export market and its authorities.

How can it be demonstrated?

The export market regulatory authorities frequently demand system certification of suppliers of exported products as support for the quality of such products before they can be legally exported and marketed. A variety of systems exist through which local system certification schemes are recognized by the authorities in the export markets. Typical examples include certification to ISO 9001 as a generic scheme or, for food safety, HACCP or ISO 22000.

As for the marketplace, certification to ISO 9001 (quality management); ISO 14001 ("Environmental Management Systems—Requirements with Guidance for Use"); and Fair Trade or "Social Accountability (SA) 8000: International Standard" are frequently helpful in accessing markets. In the food sector, compliance with GLOBAL G.A.P. (Global Good Agricultural Practice) has become a necessity to access the European market, as is the British Retail Council (BRC) for the British market. Ecolabeling schemes are becoming important as well. The better-known ones include the European Union (EU) Ecolabel (generic); Forest Stewardship Council (FSC) for wood and wood-based products; Marine Stewardship Council (MSC) for marine products; and Green Dot (generic).

The most relevant of these for the export sector of the country should be clearly identified. Thereafter, appropriate system certification schemes should be established at the local or regional level, and an appropriate accreditation scheme should be developed by a recognized accreditation body. Where this is not feasible, foreign certification operators that are accredited for the relevant scopes should be invited to establish themselves in the country.

Existing information/reporting/monitoring

- Government export policies and strategies
- Recognition agreements between the government and export market authorities
- Market intelligence regarding relevant system certification in the export markets

9.2.5 System certification schemes to upgrade SMEs (building block no. 4)

What is meant

Minor	SMEs are supported through government programs to implement ISO 9001-, 14001-, or 22000-compliant management systems and obtain certification, all to upgrade the quality of their products and services.

How can it be demonstrated?

In most low- and middle-income countries, SMEs are the most prevalent type of firm in the industrial sector. However, they are seriously challenged to provide high-quality products and services that are fully compliant with national standards or to compete with larger manufacturers or multinational companies. Governments therefore often implement support programs to facilitate the SMEs' compliance with the more important management standards, such as ISO 9001, ISO 14001, HACCP, or ISO 22000.

Well-designed support programs consist of training of selected SMEs in quality management systems, consultancy support for the implementation of the required formal approaches, and some financial payback after a positive outcome of the certification process (for example, 50 percent of the audit and certification fees). Thereafter, the financial support is partially continued if the SME

retains its certification in the years following. Failure by the SME to maintain its certification obviously leads to a cessation of financial support.

Existing information/reporting/monitoring

- Formal documentation of government support programs for the certification of SMEs
- Records of certification bodies
- Records of financial support to SMEs once certification has been granted
- Official lists of certified SMEs by certification bodies

9.2.6 Training and registration of auditors and lead auditors (building block no. 5)

What is meant

Major	Auditors and lead auditors for system certification audits must be appropriately trained, gain relevant experience, and be registered as such.

How can it be demonstrated?

Auditors used in the certification body's auditing teams have to be trained, gain experience, and then be registered in a national or multinational registration scheme as proof of their competence. In the initial stages, a multinational auditor scheme may be relevant, but as the pool of auditors grows, a national auditor registration scheme may be indicated.

An auditor may be registered after being trained in the auditing of a specific certification standard (such as ISO 9001, ISO 14001, and so on) and having conducted a number of prescribed audits under the watchful eye of a registered lead auditor. The auditor registration remains valid for a specified number of years (for example, three years), during which a number of audits must have been performed to retain the registration. When the certification standard is revised, the auditor has to be retrained and reregistered within a specified time. The same applies to the registration of lead auditors.

The information regarding the registration of auditors and lead auditors with their specific scopes must be publicly available. Such a system certifications auditor registration scheme may be established by the government or through an association of certification bodies.

Existing information/reporting/monitoring

- Public information of relevant multinational auditor registration schemes
- Public information of the national auditor registration scheme

9.3 PILLAR 1: LEGAL AND INSTITUTIONAL FRAMEWORK, INDIVIDUAL SYSTEM CERTIFICATION BODIES

9.3.1 Benchmark and significance

To be recognized, system certification bodies have to demonstrate their competency; that is, they will need to be accredited. Hence, it is important that the certification body clearly define the scope of its services because its accreditation will be defined accordingly (for example, certification to ISO 9001, ISO 14001, HACCP, and so on).

Their financial sustainability is an important parameter, and especially public certification bodies should be given the freedom to determine the pricing of their services in accordance with the market. In other words, the government should not force them to offer certification services below market prices. SMEs that require financial support to have their systems certified may be given such support, but it should not be through below-market pricing of public certification bodies' certification services.

9.3.2 Legal entity (building block no. 6)

What is meant

Major	A certification body shall be a legal entity, or a defined part of a legal entity, such that it can be held legally responsible for the outcome of its certification services. Certification bodies may be a public or a private sector entity.

How can it be demonstrated?

The individual certification body shall be established by legislation or articles of incorporation, depending on whether it is a public or private sector entity. The legislation or articles of incorporation must define the governance, financial provisions, and responsibilities and functions of the certification body. Being able to demonstrate its legal organizational form is a prerequisite for accreditation.

Existing information/reporting/monitoring

- Relevant legislative instruments of ministries
- Relevant articles of incorporation

9.3.3 Governance (building block no. 7)

What is meant

Fundamental	The certification body should have a governance structure in charge of strategy approval and overall fiduciary responsibilities, whether it is appointed by a relevant minister, by the parent ministry, or by shareholders.
Major	Good governance models suggest that the members of the governance structure should be individuals with specific knowledge regarding system certification and market realities.

How can it be demonstrated?

A certification body may be (a) an independent public or private sector entity, or (b) a part of a greater entity. Each of these will have a different governance structure, depending on the extent of its independence. Whatever the case, the governance structure should have the authority to determine the strategy for the certification body, approve the business plans and budget, and exercise overall fiduciary responsibility over the certification body.

Existing information/reporting/monitoring

- Legislative instrument establishing the certification body, if relevant
- Articles of incorporation, if relevant
- Government decisions or decrees, if relevant
- Official organizational structure
- Annual reports of the certification body

9.3.4 Certification scope (building block no. 8)

What is meant

Fundamental	The certification body has to clearly define the scope of the certification services it offers. These are also the basis of its accreditation.

How can it be demonstrated?

Many system certifications are possible (for examples, see table 9.1). The certification body has to define which of these it offers or plans to offer system certification services for. These should be aligned with the demonstrable needs of its chosen target market, as established by demand surveys. The scope will determine the requirements for its auditing processes, auditor registration, and other elements required in terms of its accreditation as determined by the accreditation body.

Existing information/reporting/monitoring

- Official description of the scope of system certification services offered
- Accreditation scopes
- Certification body business strategy and plans
- Certification body annual budgets

9.3.5 Financial sustainability (building block no. 9)

What is meant

Fundamental	The finances for establishing the certification body can be provided from government sources or through financial support from industry. Once operational and accredited, the certification body should become financially self-sufficient.

How can it be demonstrated?

Establishing a certification body will require a fair amount of financing in the initial stages, especially before it is accredited. Before being accredited, it may battle to gain customers because these generally wish to be certified by a recognized certification body. There are situations where a nonaccredited certification body may be able to gain customers because it is well known in the marketplace, but these situations fade once suppliers become more sophisticated. However, once established and accredited, a certification body should become self-sufficient; that is, government or industry subsidies should not be necessary for its medium- to long-term existence. Income should cover all operational costs fully, with surpluses to finance future developments. Private sector certification bodies ultimately have to deliver dividends to their investors.

SMEs frequently find it difficult to pay for certification services. Hence, many governments wish to support the SME sector by subsidizing certification fees. Such support should not be provided by below-cost certification services rendered by public certification bodies because this will negatively affect their financial sustainability, distort the market, and constrain the establishment of private sector certification bodies. Such financial support, if necessary, should be provided directly to the enterprises through programs designed to help SMEs continue their certification over longer periods.

The certification body's overall financial situation of the past three to five years would be a good indication of its financial sustainability. The situation should show a positive trend over the years under review. A positive trend in the

income generated from certification services would be a further indicator, as would business plans for future developments.

Existing information/reporting/monitoring

- Annual government budget allocations
- Business plans of the certification body
- Annual reports of the certification body
- Monthly and annual financial statements of the certification body

9.4 PILLAR 2: ADMINISTRATION AND INFRASTRUCTURE

9.4.1 Benchmark and significance

The certification body's organizational structure must be conducive to providing the full complement of system certification services included in its scope and required by its stakeholders. Good governance principles require the certification body to have a top management, and the subject fields of its certification services (such as quality management, environmental management, food safety, and so on) suggest that the certification body should have divisions dedicated to certification services in these fields.

Over and above these general guidelines, the certification body must comply with the requirements of ISO/IEC 17021 relating to organizational structures or with any other relevant standards it wishes to be accredited for. These usually include a separation of personnel involved in audits from the certification decision, registered auditors, and lead auditors. The certification body will have to demonstrate that its personnel are free from any undue commercial, financial, and other pressures that might influence their technical judgment.

9.4.2 Top management (building block no. 10)

What is meant

Major	The top management of the certification body is responsible for the technical management of the certification body and is accountable for the quality and integrity of its services. Effective communication channels must exist between the top management and personnel, as well as between top management and higher-level management or governance structures.

How can it be demonstrated?

There is no standardized list of the major functions and responsibilities carried out by the top management, but some typical functions include the following:

- Supports operations and administration of the certification body governance structures by advising and informing its members and interfacing between governance structures and personnel
- Oversees the development, marketing, promotion, delivery, and quality of certification services
- Recommends the annual budget for approval and prudently manages the certification body resources within those budget guidelines
- Effectively manages the human resources of the certification body according to authorized personnel policies and procedures

- Assures that the certification body and its mission and services are consistently presented using strong, positive images to relevant stakeholders
- Oversees the identification of resource requirements and possible income sources, including ascertaining the strategies for approaching funders

Existing information/reporting/monitoring

- Governance structure decisions and minutes
- Official top management job descriptions
- Agreed-upon top management key performance indicators

9.4.3 Organizational structure (building block no. 11)

What is meant

Major	System certification services cover a range of subject fields, including quality management, environmental management, food safety, and so on. It therefore follows that the organizational structure of a certification body should have divisions that optimally support its scope of services and groupings within it.

How can it be demonstrated?

Good management practice suggests that the organizational structure of the certification body should take cognizance of groupings within its scope of services. Such a structure would also facilitate the accreditation process. Important elements include an impartiality committee and a certification committee. Also important is an organizational construct to manage the pool of external auditors.

It is necessary that a quality manager have the defined responsibility and authority for ensuring that the management system related to the quality of certification services is implemented and followed at all times. The quality manager must have direct access to top management, where decisions are made on certification body policy or resources. A typical organizational structure for a system certification body, with its basic elements, is shown in figure 9.2.

Existing information/reporting/monitoring

- Approved organizational structure
- Governance structure decisions
- Financial system documentation

9.4.4 Management and personnel (building block no. 12)

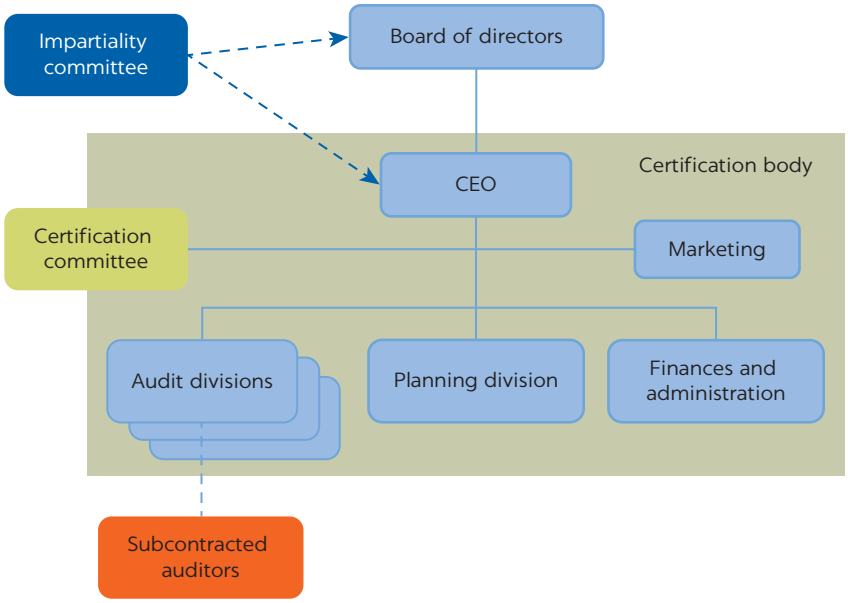
What is meant

Major	Certification is primarily a people-based activity operating within specified scopes. The management and personnel must therefore have the appropriate skill sets assured by appropriate training, qualifications, and experience. These would include management and technical knowledge as required by the various activities within the certification body scopes. Registered auditors and lead auditors are essential.

How can it be demonstrated?

In the first place, the system certification body should operate with an organizational structure approved by its governance structures. For each of the positions, the skill set (qualifications, training, and experience) should be clearly and

FIGURE 9.2
Organizational structure of a system certification body



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formally stated. The administrative staff should not be more than 20 percent of total staff; the major proportion should be technical staff.

Second, there should be few staff vacancies levels on either the management and technical levels; more than 95 percent of those positions should remain filled. Anything less indicates that the certification body cannot operate effectively or efficiently. Staffing challenges often include a lack of skilled people in the country, but even more so, inadequate remuneration resulting in the departure of trained staff for more lucrative offers elsewhere.

Third, technical staff should have the necessary skills set of education, training, and experience to be able to manage and conduct audits within specified scopes. Auditors and lead auditors must be registered and their registrations kept up-to-date. This applies to those permanently employed, as well as those subcontracted as required.

Existing information/reporting/monitoring

- Approved organizational structure
- Approved criteria for technical staff
- Actual staffing levels
- Staff turnover figures
- Registration records of auditors and lead auditors

9.4.5 Premises (building block no. 13)

What is meant

Major	Appropriate office accommodation for personnel is required. The offices should have meeting rooms where clients can be received, rather than in the offices of personnel, to ensure that information about other companies remains confidential. Storage space for records is essential.

How can it be demonstrated?

Office space conducive to a positive working environment is necessary for the staff of the certification body. Meeting rooms where clients can be received rather than in the offices of personnel, especially auditors and lead auditors, are important to keep information of other clients confidential. Space for storing and ease of retrieval of the records of audits and certifications is essential. The effect of the location of the offices of the certification body on business should not be underestimated; the offices should be relatively easily accessible by clients.

Existing information/reporting/monitoring

- Review of certification body accommodation in the light of defined requirements

9.4.6 Equipment (building block no. 14)

What is meant

Major	Equipment requirements for the certification are largely fulfilled by an effective, efficient, and secure information technology (IT) system.

How can it be demonstrated?

An efficient and effective IT system that can handle the quality management system documentation and the audit and certification records is important. Its access control should be such that the integrity of all records can be ensured at all times.

Existing information/reporting/monitoring

- Consideration of the effectiveness and efficiency of the IT system
- Consideration of the access control of the IT system

9.5 PILLAR 3: SERVICE DELIVERY AND TECHNICAL COMPETENCY

9.5.1 Benchmark and significance

Accreditation by an independent and recognized accreditor body is the primary recognition mechanism for certification bodies (see building block no. 17). This may be accreditation to ISO/IEC 17021 or similar sector-based systems, thereby demonstrating the certification body's technical competency. All of them require the implementation of a formal quality management system, the appointment of appropriately skilled personnel, and internal audit procedures and management review to ensure continuous compliance.

9.5.2 System certification services scope (building block no. 15)

What is meant

Fundamental	The certification body must have a clear description of the certification services it provides, including their applicability regarding national or international standards.

How can it be demonstrated?

The certification body should clearly define the scope of its system certification services. This should preferably be in terms of published standards, whether public or private, or whether national, regional, or international. The applicability of the certification services in various sectors is an important addition to the general information. This information should be publicly available.

Existing information/reporting/monitoring

- Quality management system documentation
- Certification body website
- Certification body marketing material and brochures
- Accreditation records

9.5.3 Quality management system documentation (building block no. 16)

What is meant

Fundamental	The quality management system documentation must comply with the requirements of the relevant accreditation standard.

How can it be demonstrated?

The quality management system documentation is generally organized on three tiers, generically known as policy documents, procedures, and work instructions. These are supported by records of the audits, certification records, internal audit records, management review records, records of nonconformities, and others required by the relevant accreditation standard. A typical quality management documentation system for a certification body is shown in figure 9.3.

The accreditation process usually includes an assessment of the quality management documentation before a preassessment or initial assessment is conducted, to ensure that all the elements of the relevant accreditation standard are addressed. The certification body normally has six months to rectify any nonconformities identified in the quality management documentation before on-site assessments are considered.

Existing information/reporting/monitoring

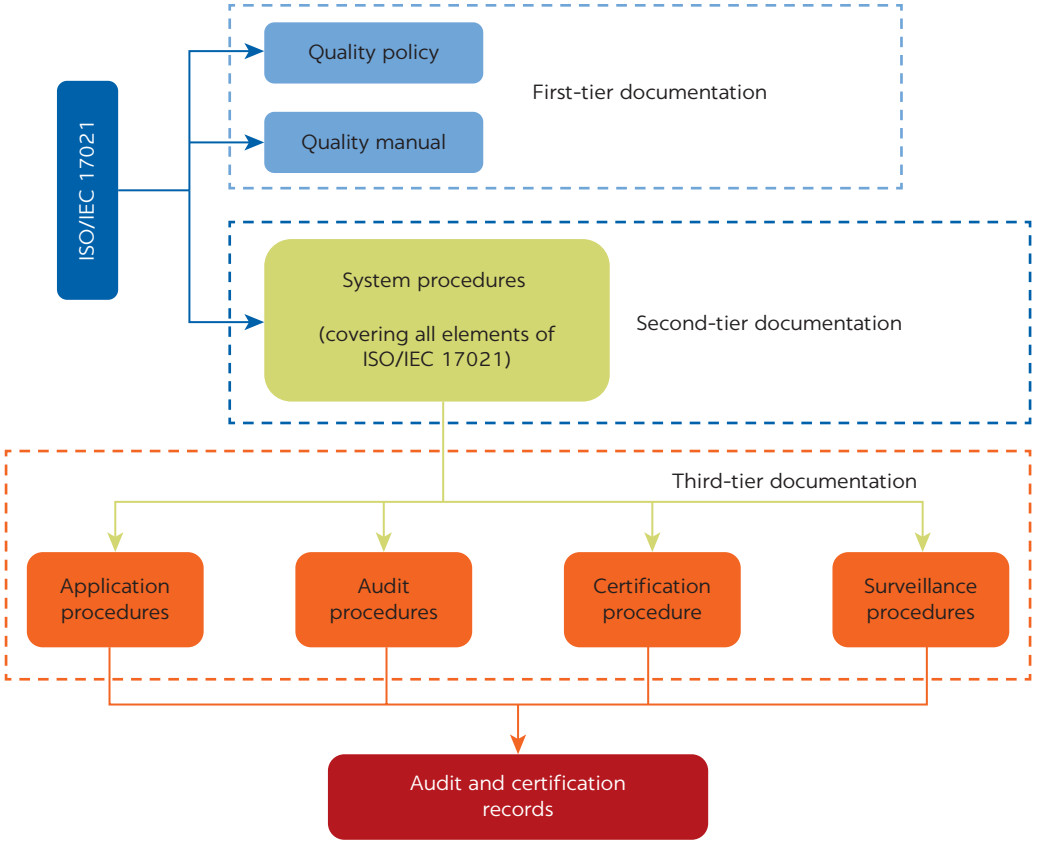
- Quality management documentation
- Internal audit results
- Management review records
- Accreditation records

9.5.4 Accreditation (building block no. 17)

What is meant

Major	*Preassessment.* A certification body may request a preassessment before an initial assessment is conducted to determine whether a formal quality management system is in place.
Fundamental	*Initial assessment.* The initial assessment for accreditation is an on-site visit by a team from the accreditation body to determine whether the quality management system documentation is fully operational and whether the certification body is competent to conduct the audits and certification defined in its scope.

FIGURE 9.3
Typical quality management system documentation for a certification body



Note: ISO/IEC 17021 = "Conformity Assessment—Requirements for Bodies Providing Audit and Certification of Management Systems."

Fundamental	*Accreditation.* Once all nonconformities have been cleared, the accreditation body submits the assessment report to its approvals committee for a final decision. Should accreditation be granted, the certification body receives an accreditation certificate carefully detailing its system certification scopes, and its data are added to the publicly available information of the accreditation body.

How can it be demonstrated?

Preassessment. Once the quality system documentation has been assessed, the certification body may request a preassessment by the accreditation body. The preassessment is usually a one-day visit by the lead assessor of the accreditation body to determine whether a formal quality management system is in place, without determining whether the certification body is competent to conduct certification. In some cases, the accreditation body may require a preassessment as a precondition for the initial assessment. Nonconformities detected during the preassessment have to be corrected before an initial assessment can take place.

Initial assessment. The initial assessment is conducted by an accreditation body team consisting of a team leader and technical assessors and experts. The certification body has to ensure that there are sufficient records to confirm that the system is implemented before the initial assessment; for example, certification audits must have been successfully completed. Most accreditation bodies

also require a complete internal audit and management review cycle to have been completed.

The certification body staff will have to demonstrate to the technical assessors that they are competent to conduct certification audits and complete the audit reports. Any nonconformities identified during the initial assessment usually have to be demonstrably corrected within six months; otherwise the complete initial assessment may need to be repeated.

Accreditation. The assessment report detailing all the findings of the assessment team, evidence of the correction of any nonconformities, and a recommendation for accreditation is submitted to the approvals committee of the accreditation body. If accreditation is granted, then the certification body receives an accreditation certificate detailing its scope. The accreditation certificate usually has a validity of three to five years, during which follow-up assessments are conducted on an audit basis. An initial assessment is repeated to reissue the accreditation certificate.

Should the follow-up audits reveal nonconformities, the certification body will be given a specified amount of time to rectify them. Failure to do so will result in the suspension of the accreditation, followed by the withdrawal of the accreditation certificate if no progress is achieved. During suspension, the certification body may not claim accreditation status.

Existing information/reporting/monitoring

- Accreditation application
- Assessment result of the quality management system documentation
- Preassessment record
- Initial assessment reports and records
- List of identified nonconformities
- Records of closeout of nonconformities
- Accreditation certificate
- Public records of accreditation body

9.5.5 Certification process (building block no. 18)

What is meant

Fundamental	The approach and processes a certification body follows to certify a company must comply with the requirements of ISO/IEC 17021 or a similar standard used for its accreditation.

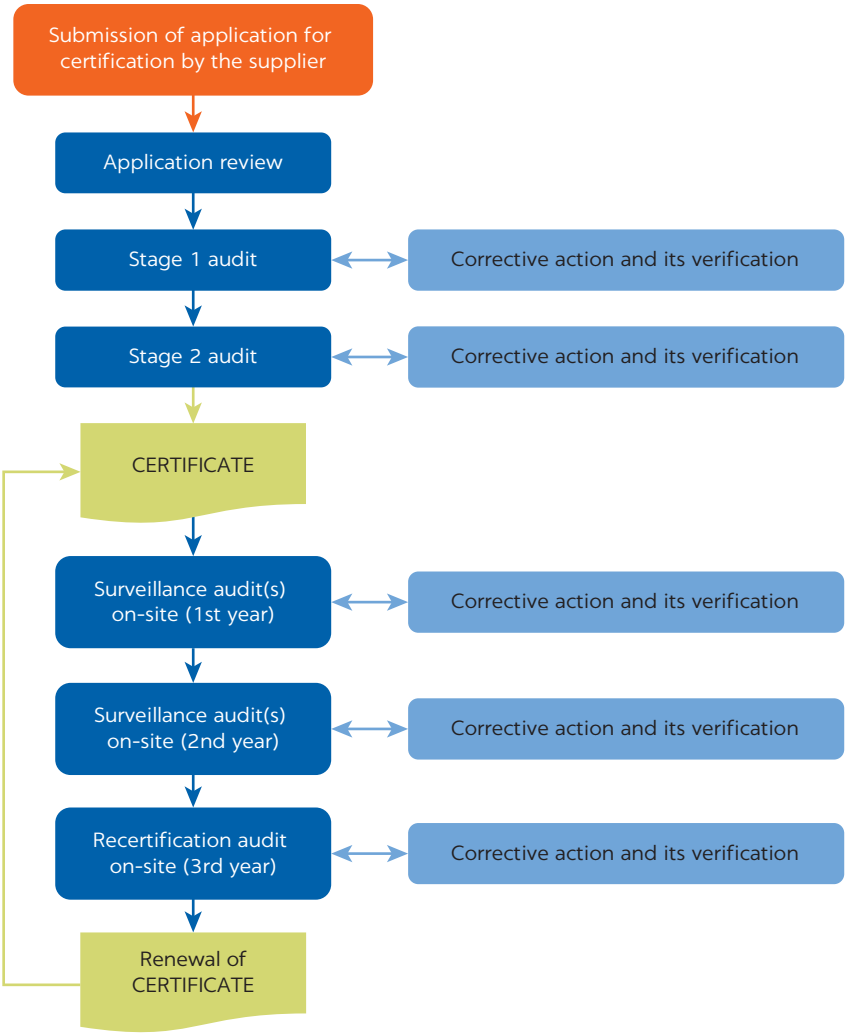
How can it be demonstrated?

The approaches and processes that certification bodies follow to certify companies have been harmonized to a great extent, and they generally follow the structure as defined in ISO/IEC 17021. Small variations may occur when other standards are used to accredit the certification body, but the fundamentals will remain the same. The process is depicted graphically in figure 9.4.

A typical system certification process proceeds as follows:

- *Application:* Application forms must be completed, and specified information on the company and its operations must be provided for the certification body to determine the scope of certification and appoint a team leader for the audit.

FIGURE 9.4
Schematic of the system certification process



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- *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 the 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.
- *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 known publicly on the certification body's website. Failure to correct the 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.

Existing information/reporting/monitoring
- Certification body's quality management and process documentation
- Application records
- Audit reports and records
- Certification committee records
- Certification body website

9.6 PILLAR 4: EXTERNAL RELATIONS AND RECOGNITION

9.6.1 Benchmark and significance

Whereas accreditation may be a precondition for the recognition of the competency of a system certification body in the nonregulated market, further steps are frequently necessary in the regulated market. These have to do with the legal accountability of the certification body once it starts providing certification services to support the implementation of technical regulations or sanitary and phytosanitary measures.

The technical term for this official recognition by the authorities is "designation" (ISO/IEC 17000, "Conformity Assessment—Vocabulary and General Principles"). Countries may use others—for example, the "notified bodies" of the EU. Many multinational system certification schemes have their own mechanisms to recognize certification bodies providing certification services in support of these schemes. Without such recognition, system certification bodies will find it difficult to penetrate these potentially lucrative markets.

9.6.2 Recognition at the national level (building block no. 19)

What is meant

Major	Recognition at the national level is achieved through accreditation to the relevant international standard. Recognition may be by the market, or it can go a step further in being designated by a governmental authority for specific system certification services related to the implementation of regulations.

How can it be demonstrated?

Recognition at the national level in the marketplace has developed to the point where accreditation to the relevant international standard (such as ISO/IEC 17021 or a similar standard) has overtaken all other types of recognition arrangements in importance. Such accreditation should be provided by an

accreditation body that is a signatory to the International Accreditation Forum (IAF) Mutual Recognition Agreement.

Recognition by regulatory authorities through designation is now largely based on accreditation, plus some additional legal requirements not covered by accreditation (for example, legal liability in the country, up-to-date tax returns, and others). Competency assessments by regulatory authorities against their own requirements, for example, are slowly being abandoned in lieu of an independent accreditation.

Existing information/reporting/monitoring

- Official lists of accredited certification bodies
- Official lists of regulatory authorities in respect of designated certification bodies

9.6.3 Recognition at the international level (building block no. 20)

What is meant

Major	Recognition at the international level can be achieved by various means. Accreditation by an IAF-recognized accreditation body is a good start. Sectoral arrangements are in place as well, especially for certifications schemes based on private standards, such as Fair Trade, the FSC, the MSC, and others.

How can it be demonstrated?

Accreditation to ISO/IEC 17021, for example, by a recognized accreditation body facilitates the recognition of certification body results among at least the other members of the IAF Mutual Recognition Agreement. Such accreditation may also facilitate recognition in countries not yet part of the Agreement.

Other certification schemes based on private standards may have differing approaches. Hence, a careful analysis of the main exports of the country will reveal the need for recognition of the relevant certification bodies, and the concomitant international scheme for achieving the same. In some cases, it may not be possible to establish a certification body at the national level for private standard certification schemes, because they frequently operate as a closed shop with only their own certification body allowed to conduct audits (see module 6, section 6.5, of the QI Toolkit).

Existing information/reporting/monitoring

- System certification strategy and its implementation plans
- IAF membership data
- Other international recognition systems relevant to the country

9.6.4 Coordination within the QI (building block no. 21)

What is meant

Minor	Coordination among the certification bodies of the country is based largely on activities managed through voluntary associations.

How can it be demonstrated?

A national certification body association in which membership is voluntary can be helpful in coordinating some elements of certification activities—for example, lobbying governmental authorities, facilitating discussions on a better

understanding of international certification standards, establishing auditor registration schemes, and so on. This will obviously depend on whether a number of certification bodies are operating in the country.

In addition, a technical regulation coordination office (or a similar facility) may enforce coordination of activities between certification bodies and the regulatory authorities, as well as with the national accreditation body (NAB), national standards body (NSB), and national metrology institute (NMI) with respect to the implementation of technical regulations.

Existing information/reporting/monitoring

- Regulatory authority policies, pronouncements, and documentation
- Certification body association documentation and minutes of meetings
- Technical regulation coordination office mandate and pronouncements

STANDARDS REFERENCED IN SECTION 9

ISO (International Organization for Standardization). 2015. "ISO 9001: Quality Management Systems—Requirements." 5th ed. Ref. no. ISO 9001:2015(E), ISO, Geneva.

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10

Technical Regulation

10.1 INTRODUCTION

A technical regulation is "a document which lays down product characteristics or their related processes and production methods, including applicable administrative provisions, with which compliance is mandatory" (WTO 1995, annex 1). The administrative provisions are normally considered to include conformity assessment, responsibilities of the regulatory authority, and sanctions. Technical regulations are therefore legally binding prescription and must be applied by all parties.

Authorities, when developing and implementing technical regulations, must comply with the provisions of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement) if the country is a WTO member. National and foreign suppliers must comply with the technical regulations developed and implemented by the regulatory authorities concerning the products they market in the country, and authorities have a surveillance responsibility to ensure that suppliers do so.

The elements of technical regulation as defined in the WTO TBT Agreement include technical requirements and administrative provisions. The former should be based on international standards, and the latter are normally considered to include the conformity assessment provisions, regulatory authorities, and sanctions. (See module 7 of the QI Toolkit, for a comprehensive discussion.) Good regulatory practice requires a coordinated approach to all of these at the national level, which would be given legal standing in a technical regulation framework. The pillars and building blocks of a technical regulation regime, as shown in table 10.1 and detailed in this Comprehensive Diagnostic Tool, are based on such good regulatory practice.

To depict the pillars and building blocks in a graphical way that would indicate the state of technical regulation in a country at a glance, they can be put together as shown in figure 10.1. For a complete description of the construction, interpretation, and use of this graphic or of the matching radar diagram, see section 1: Comprehensive QI Assessment.

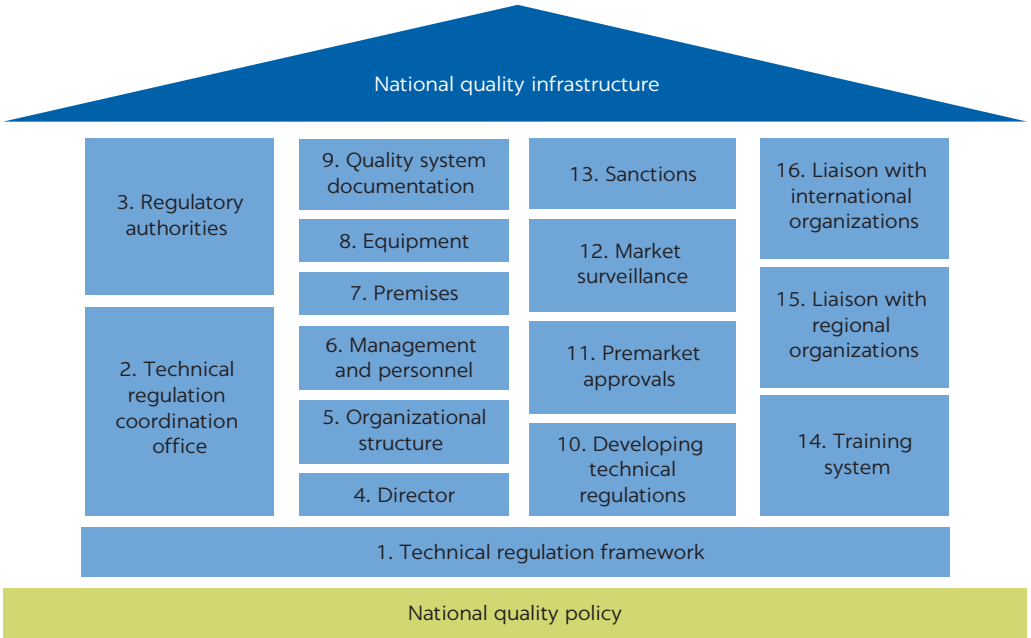
(*Note:* Legal metrology is part of technical regulation, but it is dealt with separately; see section 11: Legal Metrology.)

TABLE 10.1 Pillars and building blocks of a country's technical regulation regime

PILLAR	BUILDING BLOCK NO.	BUILDING BLOCK DESCRIPTION
1: Legal and institutional framework	1	Technical regulation framework
	2	Technical regulation coordination office
	3	Regulatory authorities
2: Administration and infrastructure	4	Director
	5	Organizational structure
	6	Management and personnel
	7	Premises
	8	Equipment
	9	Quality system documentation
3: Service delivery and recognition	10	Developing technical regulations
	11	Premarket approvals
	12	Market surveillance
	13	Sanctions
	14	Training systems
4: External relations and recognition	15	Liaison with regional organizations
	16	Liaison with international organizations

Note: The term "technical regulation regime" denotes the broader collection of sometimes quite different approaches to technical regulation in a country, whereas a technical regulation framework is a common approach followed by all the regulatory authorities. The European Union (EU) New Approach and Global Approach Directives are typical technical regulation frameworks.

FIGURE 10.1
House of technical regulation for a national quality infrastructure



Note: The four "pillars" of the QI—represented by the blue columns containing the "building block" numbers—are as follows (left to right): "legal and institutional framework," "administration and infrastructure," "service delivery and technical competency," and "external relations and recognition."

10.2 PILLAR 1: LEGAL AND INSTITUTIONAL FRAMEWORK

10.2.1 Benchmark and significance

Technical regulation is the responsibility of government and its competent authorities. Government should enact the necessary legislation to establish a technical regulation framework that will guide the development and implementation of technical regulations across all ministries and regulatory authorities. Its development is frequently also dealt with in a national quality policy (see module 10 of the QI Toolkit). Without such a technical regulation framework,

- Each ministry and regulatory authority will continue to develop and implement technical regulations in their own way, which may or may not comply with the WTO TBT Agreement; and
- Coordination between regulatory authorities and between those authorities and the quality infrastructure (QI) service providers will suffer, and costly and unnecessary overlaps or gaps will develop over time, potentially rendering local suppliers uncompetitive and compromising the safety and health of the country's people, fauna and flora, and the environment.

Regarding the coordination of technical regulation, a technical regulation coordination office (or a similar facility) should be established at the highest appropriate political level to (a) coordinate the responsibilities of the various regulatory authorities—and to coordinate them as well with the QI service providers—to minimize overlaps; (b) ensure compliance with the WTO TBT Agreement and requirements; and (c) ensure the development and implementation of an effective and efficient technical regulation regime within the country.

The number of regulatory authorities is dependent on the customs and practice of the country, the size of the market, and resource constraints. In many countries, every ministry establishes the number of regulatory authorities it deems necessary; in some countries, the number has been reduced to four or five sectorally focused regulatory authorities, and in small economies, only one supraregulatory authority responsible for all technical regulations has been established. The first option is expensive but politically acceptable; the last option is financially efficient but politically challenging.

10.2.2 Technical regulation framework (building block no. 1)

What is meant

Fundamental	A technical regulation framework is enshrined in legislation that provides guidance for all the modalities of the development and implementation of technical regulations across all ministries and regulatory authorities at the national, regional, and local levels.

How can it be demonstrated?

The technical regulation framework should detail all the modalities for the development and implementation of technical regulations by all ministries and regulatory authorities at the national, regional, and local levels. Details that should be covered include the following:

- Regulatory impact assessments (RIAs)
- The use of international, regional, or national standards as the basis of technical regulation

- The use of technically competent and designated conformity assessment service providers
- The responsibilities of regulatory authorities regarding premarket approvals, in-market surveillance, and the imposition of sanctions
- Administrative and legal sanctions

The technical regulation framework should be a legislative instrument, such as an act of parliament, that takes precedence over any other legislation that may authorize ministries or regulatory authorities to develop and implement technical regulations. The technical regulation framework must comply with the requirements of the WTO TBT Agreement if the country is a WTO member, as well as with regional TBT agreements, protocols, or legislation, if relevant. Its promulgation must be notified to the WTO TBT Secretariat if the country is a WTO member.

Existing information/reporting/monitoring

- Relevant legislative instruments, such as acts of parliament
- Relevant ministry papers
- WTO TBT notifications of the country

10.2.3 Technical regulation coordination office (building block no. 2)

What is meant

Major	Technical regulation is complex, even at the national level. A technical regulation coordination office should be established at the highest political level to coordinate technical regulation activities of the regulatory authorities among each other and with the QI service providers.

How can it be demonstrated?

In many countries, a number of ministries and regulatory authorities develop and implement technical regulations. To minimize overlaps and gaps in their responsibilities and actual regulatory work, a technical regulation coordination office (however named) should be established at the highest political level necessary to enforce such coordination (see module 7 of the QI Toolkit). This office should also coordinate the interfaces between the regulatory authorities and the other QI service organizations to ensure the optimum usage of standards, metrology, accreditation, and conformity assessment services in the development and implementation of technical regulations.

Existing information/reporting/monitoring

- Technical regulation framework act or similar law
- Technical regulation coordination office records

10.2.4 Regulatory authorities (building block no. 3)

What is meant

Fundamental	The regulatory authorities must be recognized entities, and their sphere of responsibility must be clearly defined to minimize regulatory overlaps and gaps.

How can it be demonstrated?

Whatever the number of regulatory authorities, they should be clearly identified in the technical regulation framework, and their spheres of responsibility should be properly and uniquely defined to minimize regulatory overlaps and gaps regarding the products they are responsible for. In other words, the technical regulations they are responsible for must be assigned to them. This information has to be publicly available to safeguard against confusion in the marketplace.

The number of regulatory authorities may be reconsidered during a regulatory reform process (see module 7 of the QI Toolkit). The optimum number of regulatory authorities is as much a resource issue as it is a political decision. If changes are contemplated (reducing or expanding the number), then care should be taken that, during the changeover process, the implementation of the relevant technical regulations does not suffer.

Existing information/reporting/monitoring

- Technical regulation legislation
- Official ministerial decisions
- National WTO TBT Inquiry Point information[1]

10.3 PILLAR 2: ADMINISTRATION AND INFRASTRUCTURE

10.3.1 Benchmark and significance

The implementation of technical regulations has two sides: First, suppliers must demonstrate that the products they wish to place on the market comply with the technical requirements of the technical regulation. Second, the regulatory authority has the responsibility to monitor the products in the marketplace to ensure that suppliers market only compliant products.

The demonstration of compliance may be a self-declaration of conformity by the supplier, or it may be by inspection, testing, and certification of third-party conformity assessment service providers. These third-party providers should be technically competent and acceptable to the regulatory authority (that is, "designated").

(*Note:* The third-party assessment service providers are not considered in this section, but they are discussed in the sections on accreditation, inspection, testing, and certification [sections 5, 6, 7, and 8, respectively]. The same applies to the regulatory authority as the conformity assessment body. This section is dedicated to the regulatory authority's oversight responsibilities to ensure that suppliers and products comply with technical regulation requirements.)

In some economies, the regulatory authority conducts such conformity assessments as required by the technical regulation, but in general that is no longer seen as good regulatory practice for these reasons:

- The regulatory authority can quickly become obsessed with testing and retesting to bolster its budget income, and hence may neglect its market surveillance responsibility.
- The regulatory authority may create the perception that it, not the supplier, is responsible for the integrity of the product.

- Final product testing, especially on an audit sample basis, is not an ideal way of ensuring that all of the production complies with requirements; the whole production value chain has to be considered.

Using the national product certification mark for the final product testing is no longer seen as good practice, either, because it is considered to be trade-restrictive and arguably contrary to WTO TBT Agreement principles.

The regulatory authority is responsible for monitoring the compliance of products with technical regulations. These responsibilities include the premarket approval of high-risk products, market surveillance of all products falling within the scope of technical regulations, and the imposition of sanctions when nonconformities are discovered. The regulatory authority will also test products as an audit sample at irregular intervals to verify the conformity assessment evidence provided by the supplier. Because of the regulatory nature of its responsibilities, the regulatory authority will of necessity have to be a government-type organization in most jurisdictions, unless such regulatory powers can be conferred on a private sector organization in terms of national legislation.

10.3.2 Director (building block no. 4)

What is meant

Major	The regulatory authority must be managed by a director (whatever the actual title) who is accountable for the compliance of products in the marketplace that fall within the scope of the technical regulations the regulatory authority is responsible for.

How can it be demonstrated?

There is no standardized list of the major functions and responsibilities carried out by the director of a regulatory authority, but some typical functions include the following:

- Supports operations and administration of the relevant ministry by advising and informing its members, interfacing between the ministry and staff
- Oversees the design, marketing, promotion, delivery, and quality of services with regard to technical regulation implementation
- Recommends the annual budget for ministry approval and prudently manages the regulatory authority's resources within those budget guidelines according to current laws and regulations
- Effectively manages the human resources of the regulatory authority according to authorized personnel policies and procedures that conform with current laws and regulations, especially the training and appointment of inspectors
- Assures that the regulatory authority and its mission, programs, and services are consistently presented using strong, positive images to relevant stakeholders, including the relevant minister and ministry
- As the responsible executive, considers the premarket approval of high-risk products, where relevant, and initiates sanctions when nonconforming products are uncovered in the marketplace
- Liaises with third-party conformity assessment service providers, where relevant
- Oversees fundraising planning and implementation, including identifying resource requirements, researching funding sources, and establishing strategies to approach funders

Existing information/reporting/monitoring

- Relevant technical regulation legislation
- Official ministerial decisions
- Official director job description
- Agreed-upon director key performance indicators

10.3.3 Organizational structure (building block no. 5)

What is meant

Fundamental	The organizational structure of the regulatory authority must facilitate the effective and efficient execution of all technical regulations it is responsible for, and it should have divisions that optimally support these groupings and their subject fields.

How can it be demonstrated?

The regulatory authority is usually a government department or a statutory body, rarely a private sector organization. As a government department, it can rely on support services, such as government finances and human resources, whereas if it is an independent public sector organization, it has to provide for these itself.

Technical regulation authorities deal primarily with trade-related issues, and preventive components include premarket approval of high-risk products. The repressive component consists primarily of market surveillance. Premarket approval is mostly a head office activity, whereas the market surveillance is largely a field service activity. Over and above the head office technical staff, an appropriate number of regional inspection offices are required for effective and efficient market surveillance close to markets.

Other areas to consider in the organizational structure, especially if the regulatory authority is an independent organization, include support functions, such as human resources, finance, transportation, and others.

Existing information/reporting/monitoring

- Approved organizational structure
- Ministry decisions
- Ministerial decisions
- Financial system documentation

10.3.4 Management and personnel (building block no. 6)

What is meant

Major	Market surveillance and premarket product approval is primarily a people-based activity operating within a specific technical environment, assuming that testing and certification are conducted by third-party organizations. The management and personnel must therefore have the appropriate skill sets assured by appropriate training, qualifications, and experience. These would include management and technical knowledge as required by the various activities within the technical regulation fields, including the appointment of inspectors with appropriate knowledge of their legal authority with regard to entry and search.

How can it be demonstrated?

In the first place, the regulatory authority should operate with an organizational structure approved by the ministry or its council. For each of the positions,

the skill set (qualifications, training, and experience) should be clearly and formally stated. Special attention should be given to the training and appointment of inspectors, concerning not only their technical capabilities but also their knowledge about their legal authority with regard to entry and search. The ratio between technical and administrative staff is a good indicator of efficacy, with a good guideline being that administrative staff make up no more than 20 percent of the total.

Second, there should be few staff vacancies on either the management or technical levels; more than 95 percent of those positions should remain filled. Anything less indicates that the regulatory authority cannot operate effectively or efficiently. Staffing challenges often include a lack of skilled people in the country, but even more so, inadequate remuneration resulting in the departure of trained staff for more lucrative offers elsewhere.

Existing information/reporting/monitoring

- Approved organizational structure
- Training records of staff
- Appointment and withdrawal records of inspector certificates
- Actual staffing levels
- Staff turnover figures

10.3.5 Premises (building block no. 7)

What is meant

Fundamental	Technical regulation implementation is partly a technical endeavor, but mostly of an administrative nature. Appropriate accommodation for head office staff and technical activities has to be provided, as well as appropriate accommodation in regional offices for inspectors and their equipment. Confidentiality of the information also has to be safeguarded.

How can it be demonstrated?

If the regulatory authority is involved in testing and certification, then the concomitant premises for a laboratory or certification body have to be provided (see sections 6, 7, and 8 on "Inspection," "Testing," and "Product Certification," respectively).

Appropriate office space for staff needs to be provided, as well as a few meeting rooms for individual customer discussions to safeguard information lying around on desks and in work spaces. In regional or border control offices, appropriate office space, as well as space for operating or storing inspection equipment are required.

Existing information/reporting/monitoring

- Consideration of the regulatory authority premises in relation to design, environmental controls, access, and maintenance
- Review of laboratories and environmental controls
- Review of office space and meeting rooms
- Technical requirements as advised by experts in specific technical regulation fields

10.3.6 Equipment (building block no. 8)

What is meant

Fundamental	A wide range of equipment is necessary as denoted by the technical regulation to be inspected and, if relevant, tested and certified. Inspection offices should be issued with appropriate inspection equipment. Working standards should be maintained against which inspection equipment can be calibrated continuously. Working standards must be traceably calibrated to national measurement standards at predetermined intervals.

How can it be demonstrated?

Equipment used in the test laboratories of the regulatory authority should comply with good laboratory practices. (See sections 7 and 8 on "Testing" and "Product Certification," respectively, for further details and diagnostics.) The equipment necessary to inspect products covers a vast range of instruments. Expert advice is required to evaluate the range of instruments and their respective accuracy classes properly.

The accuracy of the regulatory authority's equipment should be above reproach to ensure that any challenge, legal or otherwise, can be dealt with. Hence, it is good practice to keep working standards against which inspection equipment can be calibrated. The working standards must be calibrated traceably to the national measurement standards at defined intervals. The inspection equipment used by inspectors in the field should be calibrated frequently against the working standards.

Existing information/reporting/monitoring

- Consideration of the technical regulation fields of activity
- Demonstrable equipment needs of the regulatory authority
- Review of working standards
- Review of inspection equipment
- Review of maintenance measures for all measuring equipment

10.3.7 Quality system documentation (building block no. 9)

What is meant

Major	It is good practice for the regulatory authority to operate in accordance with a formal quality management system. This includes compliance with ISO/IEC 17025 regarding laboratory services, ISO/IEC 17065 for product certification, and ISO/IEC 17020 for inspection activities.

How can it be demonstrated?

The laboratories of the regulatory authority should comply with the requirements of ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories"); it would even be appropriate to have been accredited. The same applies for relevant product certification activities that should comply with ISO/IEC 17065 ("Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services"). See sections 7 and 8 on "Testing" and "Product Certification," respectively, for details.

As for its inspection activities, it is good practice to comply with ISO/IEC 17020 ("Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection"). Accreditation of inspection activities

will independently demonstrate the competency of the regulatory authority, thereby enhancing its standing among stakeholders, and will support the authority in legal disputes.

For all of these, quality system documentation is required. It should be developed in three levels: policies, general procedures, and work instructions or standard operating procedures. Appropriate records are an important element of the quality management system. It is especially the premarket approval records and inspection records that are important as legal documents indicating an effective implementation of the technical regulation legislation. The more modern approach would base these on a proper information and communication technology (ICT) system.

Existing information/reporting/monitoring

- Consideration of the regulatory authority's formal quality management system and its compliance with relevant standards, such as ISO/IEC 17020, ISO/IEC 17025, and ISO/IEC 17065

10.4 PILLAR 3: SERVICE DELIVERY AND TECHNICAL COMPETENCY

10.4.1 Benchmark and significance

The development and implementation of a technical regulation must comply with the requirements of the WTO TBT Agreement if the country is a WTO member. Furthermore, if a technical regulation framework has been promulgated (see section 10.2.2), the process has to follow the framework's guidelines as well. Good regulatory practices include

- A requirement that the technical regulation be based on international standards, where these exist and are appropriate;
- Notification of draft technical regulations to the WTO TBT Secretariat 60 days before they are promulgated;
- Conformity assessment procedures that facilitate mutual recognition among WTO members; and
- Granting of transition periods for implementation

The preventive component of trade-related technical regulation consists of premarket approval of high-risk products. This could be product type approval, consignment inspection, compliance of the supplier with a defined quality management system, or any combination of these, as relevant. The organizations responsible for these must be clearly identified. They could be technically competent third-party conformity assessment service providers that conduct the testing and certification, or they could include the regulatory authority conducting consignment inspections before products are released for the market. The combinations will be determined by the technical regulation requirements.

Market surveillance is the repressive part of technical regulation implementation. Registered inspectors with appropriate entry and search authority inspect market activities as they relate to technical regulation legislation or regulations. Upon uncovering noncompliant products, the inspectors, in coordination with

the director, institute sanctions and legal proceedings against the relevant suppliers.

In a modern economy, the regulatory authority needs to demonstrate its integrity and technical competency in order to engender trust among all stakeholders. It is therefore good practice if the regulatory authority is accredited to ISO/IEC 17020 for its inspection activities; to ISO/IEC 17025 for its testing work; and to ISO/IEC 17065 if it is involved in product certification, for its laboratory as well as on-site work.

10.4.2 Developing technical regulations (building block no. 10)

What is meant

Fundamental	The development of a technical regulation is initiated by the state or its competent authorities once a market failure is identified. Before embarking on the development of a technical regulation, the responsible ministry should initiate a regulatory impact assessment.
Fundamental	The WTO TBT Agreement requires the technical regulation to be based on an international standard, if available and suitable.
Fundamental	Draft technical regulations must be notified to the WTO TBT Secretariat 60 days before its promulgation.

How can it be demonstrated?

Regulatory impact assessment. Once the state indicates that it wishes to deal with a market failure by developing and implementing a technical regulation, it should initiate a regulatory impact assessment (RIA) to determine the severity of the problem, identify various options for dealing with the problem, determine the socioeconomic advantages and disadvantages of the various options, and consider whether the infrastructure to implement the technical regulation is available in the country or whether it will have to be developed. The RIA should provide the authorities with the necessary information to make an educated decision.

Referencing standards. The WTO TBT Agreement requires that the technical regulation be based on an international standard, should a relevant one exist. Such a standard could also be an international standard adopted as a national standard. Replicating the text of the standard in the actual technical regulation is no longer seen as good practice because updating it presents challenges as technology develops. A better practice is to reference standards either directly or indirectly. Some economies prefer direct referencing; others, like the European Union (EU), use indirect referencing, depending on the juridical system and political preferences. For a detailed description of the referencing possibilities, see module 7, section 7.4, of the QI Toolkit.

Notification to the WTO. All draft technical regulations falling within the scope of the WTO TBT Agreement, whichever ministry or authority develops them, must be notified to the WTO TBT Secretariat if the country is a WTO Member 60 days before the regulation is to be promulgated. This is to give other WTO members the chance to comment. All comments received have to be considered without favoring any particular country. Once the technical regulation is promulgated, a transition period for its implementation should be agreed upon by stakeholders. The WTO suggests six months.

National consultation process. Good regulatory practice suggests that technical regulations should be developed in an open and transparent manner. If a regulation is based on a national or international standard, then a large part of the technical regulation is already subject to a public consultation process. The RIA can also be seen as part of the national consultation process. Progressive jurisdictions publish draft technical regulations for public comment, and if the socioeconomic impact is immense, public hearings are also held. All of this presupposes that there is time for public comment; some technical regulations have to be implemented immediately to deal with a crisis, in which case such consultations are of secondary importance.

Existing information/reporting/monitoring

- Relevant technical regulation legislation
- Records of RIAs conducted
- Records of all the ministries regarding the development of technical regulations
- Notification records of the WTO TBT Secretariat
- Published implementation transition periods

10.4.3 Premarket approvals (building block no. 11)

What is meant

Fundamental	For selected high-risk products, the regulatory authority implements a consignment inspection regime to ensure that products meet technical regulation requirements before they are released to the market.

How can it be demonstrated?

Certain high-risk products may have such a deleterious effect on people, fauna and flora, and the environment that the technical regulation requires each consignment to be inspected and released before marketing. These products would typically include certain types of processed food, such as canned fish. The regulatory authority would inspect and sample each consignment of such products to determine whether the products meet stated requirements.

The regulatory authority may conduct the inspection, testing, and certification, or it could designate third-party inspection bodies to do so. The latter would typically operate in the country of origin of the imported products to ensure that only compliant products are shipped. The regulatory authority will typically inspect consignments on home soil—namely, at all the ports of entry, at the premises of manufacturers or producers, and in local warehouses. The testing and certification could be conducted by accredited and designated test laboratories if the regulatory authority does not do so.

Establishing the testing and certification capacity for all products that are subject to technical regulations requires immense resources. Hence, low- and middle-income countries will frequently have to rely on testing and certification evidence from the exporting countries for products that are imported. The regulatory authority has the responsibility in this case to evaluate such inspection and test certificates offered by the importers or suppliers to ascertain whether they (a) relate to the products under consideration, (b) provide evidence of compliance with the local technical regulation, and (c) are likely to be fraudulent.

The inspection and sampling plans of such products have to be formalized, taking into consideration the risks associated with products that do not comply with stated requirements. These procedures should be publicly available. Inspection and testing of perishable goods are a specific challenge regarding the time to market release, as are freight and warehousing charges of consignments awaiting release. Bond stores are often used for warehousing products away from ports of entry or factories to alleviate congestion in such cases.

The regulatory authority must keep complete records of all consignment inspections in a way that precludes tampering and such that they can easily be retrieved as required. The record-keeping system must be able to withstand the scrutiny of a court of law.

Existing information/reporting/monitoring

- Relevant technical regulation legislation
- Formal consignment inspection procedures of the regulatory authority
- Consignment inspection records of the regulatory authority

10.4.4 Market surveillance (building block no. 12)

What is meant

Fundamental	The regulatory authority must provide for the market surveillance of all products falling within the scope of the technical regulations for which it is responsible and use risk assessments to prioritize their activities.

How can it be demonstrated?

Market surveillance is an audit activity whereby a regulatory authority monitors the compliance of products in the marketplace with technical regulations. It is a combination of inspection and testing of a select number of products; it is not the certification thereof. The supplier is responsible for the routine compliance testing and certification of the product; market surveillance determines whether the supplier has complied with its responsibilities.

Without market surveillance and the imposition of sanctions, technical regulation fails as some suppliers eventually cut corners with noncompliant products. On the other hand, market surveillance cannot cover all the products falling within the scope of technical regulations; it is logistically not feasible. Therefore, regulatory authorities have to rely on inspecting selected products or suppliers; that is, it becomes an audit function. (For further details, see module 7, section 7.7, of the QI Toolkit.)

In planning market surveillance, the regulatory authority should follow the principles of proportionality; that is, the action taken should be in accordance with the level of risk or nonconformity, and the influence upon the economic entity should not be more than necessary for performing the task of market surveillance. Market surveillance can be either planned or off-schedule, depending on the ongoing nature of the activity or for dealing with an immediate threat or at the request of a court of law.

Existing information/reporting/monitoring

- Working plans of the regulatory authority
- Risk assessment methodology used by the regulatory authority
- Market surveillance records

10.4.5 Sanctions (building block no. 13)

What is meant

Fundamental	The regulatory authority must implement administrative sanctions to remove nonconforming products from the marketplace and institute legal proceedings against suppliers if they fail to heed administrative sanctions.

How can it be demonstrated?

When nonconforming products are uncovered in the marketplace, the sanctions take two forms: administrative sanctions and legal proceedings. Administrative sanctions are imposed by the regulatory authority on the supplier of nonconforming products with the aim of removing such products from the marketplace. The administrative sanctions, as provided for in technical regulation legislation, should include a cessation of all marketing in all cases. Thereafter, depending on the severity of the nonconformance, products may have to be recalled and reworked, destroyed, or reexported (in the case of imported products), depending on circumstances and the nature of the nonconformance.

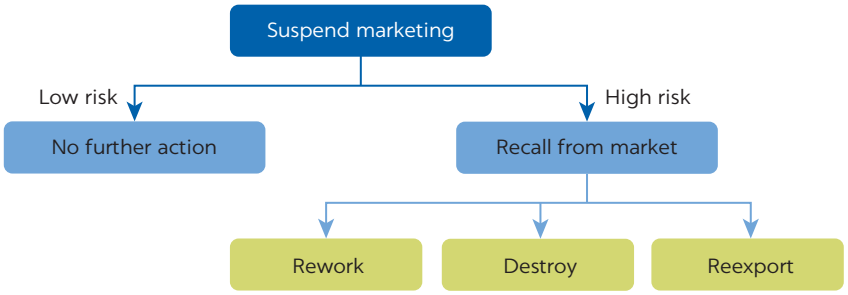
These sanctions take the form of a formal order issued to the supplier of the products. Once the supplier has complied with the order, all further sanctions cease. Administrative sanctions are depicted graphically in figure 10.2.

Should the supplier fail to heed the order, then the regulatory authority initiates legal proceedings through the courts to get the supplier to deal with the issue. The court may order the confiscation of offending products by the state or impose fines or even jail sentences, depending on the severity of the issue and the judicial custom and practice of the country. The regulatory authority should not be given the mandate to impose fines, because this only opens the door for corrupt practices.

Existing information/reporting/monitoring

- Market surveillance planning documents
- Market surveillance records
- Records of sanctions instituted
- Records of relevant court proceedings

FIGURE 10.2
Typical administrative sanctions against noncompliant products



10.4.6 Training system (building block no. 14)

What is meant

Major	Trained and skilled inspectors are a vital component of an effective and efficient market surveillance system.
Major	Over and above their technical background, inspectors should also be trained in the authority and responsibilities they have in a legal sense. They should be appointed and issued with an inspector's identification, and this should be withdrawn if the inspector leaves the service.

How can it be demonstrated?

(*Note:* Technical staff working in laboratories are discussed in sections 7 and 8 on "Testing" and "Product Certification," respectively.)

High demands are placed on appropriately educated, trained, and experienced inspectors and technical staff. Inspectors should have the necessary technical background for the specific products they will be involved in, as well as a proper grounding in risk analysis and inspection techniques.

Inspectors are generally empowered by legislation to enter and search premises and vehicles without a search warrant, where products that fall within the scope of technical regulations are suspected to be marketed. To ensure that they operate professionally and in compliance with the law, inspectors must be trained in the legal aspects of their work. Thereafter, they are officially appointed as inspectors and issued a card identifying them as such. This identification card should be shown to the responsible persons when entering premises or vehicles for inspection. The identification card must be withdrawn once the inspector is no longer involved in inspections.

The regulatory authority must therefore provide for the training of its own staff—a requirement that increases with the development of the technical regulation regime into a much more preventive one as it is reengineered as a regulatory management system. Initial training programs can be initiated by technical development programs, but eventually they have to be internalized and provided by the regulatory authorities, possibly in collaboration with tertiary technical education institutions.

Existing information/reporting/monitoring

- Training programs
- Training records
- Appointment records of inspectors
- Records of inspectors' identity cards issued and withdrawn

10.5 PILLAR 4: EXTERNAL RELATIONS AND RECOGNITION

10.5.1 Benchmark and significance

An international recognition mechanism for a technical regulation regime does not exist. However, if the country is a member of the WTO, all its obligations in relation to the WTO TBT Agreement must be fulfilled. These include the notification of the modalities of the technical regulation regime, development of technical regulations, and the establishment of a national WTO TBT Inquiry Point, among others. A specific ministry, usually the ministry responsible for trade and industry, should be designated by the government to take responsibility for this compliance.

10.5.2 Liaison with regional organizations (building block no. 15)

What is meant

Major	If the country is a member of a regional construct, then it may be that technical regulation is being harmonized across the region through protocols, regional legislation, or similar arrangements. This means the country must participate in the relevant technical forums at the regional level.

How can it be demonstrated?

One of the necessities of a regional common market is the harmonization of technical regulations across all member states to facilitate the free movement of goods throughout the region. Various mechanisms to develop and foster such harmonization are used, such as the following:

- Promulgation of regional technical regulations that all member states must implement
- Regional harmonization of standards, metrology, accreditation, and conformity assessment modalities to support technical regulations
- Regional recognition of technical regulation premarket approvals
- Regional recognition agreements on product certification and so on

Member states of such regional common markets should participate actively in relevant regional technical regulation forums where such issues are discussed and agreed upon for implementation across the region.

Existing information/reporting/monitoring

- Membership of regional common markets
- Regional TBT protocols, agreements, or similar arrangements
- Regional common market technical regulation forums
- Reports of attendance at regional technical regulation discussions

10.5.3 Liaison with international organizations (building block no. 16)

What is meant

Fundamental	If the country is a member of the WTO, then it must comply fully with the requirements of the WTO TBT Agreement regarding notifications and information about standards, conformity assessment, and technical regulations.
Fundamental	The WTO member must designate the notification authority responsible for the notifications and convey this information with contact details to the WTO TBT Secretariat.

How can it be demonstrated?

The WTO TBT Agreement places a number of obligations on WTO member states regarding notifications and information (table 10.2).

Existing information/reporting/monitoring

- Notification authority records
- WTO TBT Agreement records of notifications

TABLE 10.2 WTO TBT Agreement notification responsibilities

ITEM	REFERENCE	TYPE OF MEASURE	PERIODICITY
I	*Statements on implementation and administration of the WTO TBT Agreement*		
a	Article 15.2	Administrative arrangements, laws or regulations, measures in existence or taken to ensure the implementation and administration of the TBT Agreement	Upon entry into force of the WTO Agreement When revised or updated
II	*Notifications of proposed and adopted technical regulations or conformity assessment procedures by central and local governments*		
a	Article 2.9	Technical regulations	Ad hoc
b	Article 2.10	Technical regulations (urgent)	Ad hoc
c	Article 3.2	Technical regulations (local government)	Ad hoc
d	Article 5.6	Conformity assessment procedures	Ad hoc
e	Article 5.7	Conformity assessment procedures (urgent)	Ad hoc
f	Article 7.2	Conformity assessment procedures (local government)	Ad hoc
III	*Notification of bilateral or multilateral agreements (Article 10.7)*		
a	Article 10.7	Bilateral or multilateral agreements on technical regulations, standards, and conformity assessment procedures	Ad hoc
IV	*Notification under paragraphs C and J of the Code of Good Practice on the Preparation, Adoption, and Application of Standards (Annex 3 to the Agreement)*		
a	Annex 3, paragraph C	Acceptance of or withdrawal from the *Code of Good Practice for the Preparation, Adoption and Application of Standards*	Once originally When status changes
b	Annex 3, paragraph J	Work programs on standardization activities	Biannually

Source: WTO 1995.
Note: TBT Agreement = Agreement on Technical Barriers to Trade; WTO = World Trade Organization.

NOTE

1. The WTO TBT 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 technical barriers to trade.

STANDARDS REFERENCED IN SECTION 10

ISO and IEC (International Organization for Standardization and International Electrotechnical Commission). 2012. "ISO/IEC 17020: Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection." 2nd ed. Ref. no. ISO/IEC 17020:2012(E), ISO, Geneva.

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REFERENCE

WTO (World Trade Organization). 1995. "Agreement on Technical Barriers to Trade." Treaty document, WTO, Geneva.

11

Legal Metrology

11.1 INTRODUCTION

Legal metrology is the technical regulation side of metrology. Whereas scientific and industrial metrology provides society with accurate and trustworthy measurements over a broad spectrum, legal metrology is specifically concerned with the accuracy of measurements where these have an influence on the transparency of economic transactions, health and safety, and law enforcement. Legal metrology may have originated from the need for fair trade, but it has developed a much wider scope in recent decades.

The main objective of a modern legal metrology regime is to protect citizens from the negative consequences of false measurements—for example, in law enforcement, commercial transactions, labor environments, and health and safety systems. All over the world, governments lay down requirements in legislation for measuring instruments, measurement and testing methods, and prepackaging insofar as they are necessary to realize these objectives. Preventive as well as repressive measures are applied.

Preventive measures include the type approval of measuring equipment before it may be marketed. It includes the calibration and verification of such instruments before they are put into operation, as well as the recalibration and reverification of such instruments after a specified time.[1] *Repressive measures* include market surveillance to reveal any illegal usage of measuring instruments or noncompliance with prepackaging requirements.

People using measuring instruments in the field of legal metrology will not be metrological experts, and hence the government must take responsibility for the credibility of such measurements. Therefore, measuring instruments falling within the scope of legal metrology measures should guarantee correct measurement results under working conditions, throughout the whole period of use, and within permissible errors. Such measuring instruments are type-approved to ensure their fitness for purpose.

It should be quite obvious that legal metrology measures can become major barriers to trade. For example, differences in prepackaging requirements will hinder cross-border trade in prepackaged goods. Countries are therefore urged to harmonize their legal metrology measures with international norms and in common markets. These are frequently enforced as

top-down regional legislation, such as the Measurements Instrument Directive of the European Union (EU).

The International Organization of Legal Metrology (OIML) was established in 1955 specifically to promote the global harmonization of legal metrology measures, and the OIML has published many guidelines and model regulations that countries could use as the basis for national legal metrology legislation.

Legal metrology measures are very much influenced by the society they are designed to protect. It does not make sense, for example, to demand metered taxis when taxi fares are generally negotiated between taxi drivers and passengers. Nor does it make sense to establish sophisticated laboratories to conduct the type testing of measuring instruments when all of them are being imported with a type testing certificate from a recognized organization. It is therefore important to differentiate between the legal metrology needs of a least developed country from that of a fully industrialized, high-income country that may also be a member of an advanced common market.[2] This differentiation at four levels is shown in table 11.1; additional sublevels are also possible, if required.

Evaluation of the country's legal metrology regime is therefore heavily dependent on its level of development and the needs of society as a whole. It is therefore incomplete without knowledge of the actual needs of society and authorities and the capacity for implementation of industry and suppliers.

The building blocks of the legal metrology regime relating to the four pillars are listed in table 11.2.

To depict the pillars and building blocks in a graphical way that would indicate the state of legal metrology in a country at a glance, they can be put together as shown in figure 11.1. For a complete description of the construction, interpretation, and use of this graphic or of the matching radar diagram, see section 1: Comprehensive QI Assessment.

TABLE 11.1 Maturity levels of a country's legal metrology, by characteristic

CHARACTERISTIC	RUDIMENTARY (VERY LITTLE IN PLACE)	BASIC (LOW- TO MIDDLE-INCOME COUNTRY APPROACH)	ADVANCED (ECONOMYWIDE APPROACH, SECTORAL APPROACH)	MATURE (INNOVATIVE, CUTTING-EDGE TECHNOLOGY)
Legal metrology measures	Weights and measures for goods trade over the counter, such as mass of consumer goods	Weights and measures for goods traded over the counter, such as mass and volume of consumer goods and fuel	As under "basic," but extended to prepackaged goods, water and electricity meters, and selected law enforcement scopes	Measures covering the whole spectrum of trade, law enforcement, and health and safety
Legal metrology authority	Government department responsible for all legal metrology measures	Government department responsible for all legal metrology measures	Government authority responsible for all legal metrology measures Designated private sector metrology entities conducting selected calibration and verification activities	Government authority accountable for all legal metrology measures Designated private sector metrology entities conducting a wide range of legal metrology activities
Legal metrology laboratory infrastructure	Working measurement standards for the calibration and verification of mass within the scope of legal metrology measures	Working measurement standards for the calibration and verification of mass and volume within the scope of legal metrology measures	Working measurement standards for the calibration and verification of all measuring equipment within the scope of legal metrology measures Laboratory for verifying the type testing of a few significant measuring instruments	As under "advanced," but extended to high-level laboratories for type testing of at least all measuring equipment manufactured in the country

continued

TABLE 11.1 *continued*

CHARACTERISTIC	RUDIMENTARY (VERY LITTLE IN PLACE)	BASIC (LOW- TO MIDDLE-INCOME COUNTRY APPROACH)	ADVANCED (ECONOMYWIDE APPROACH, SECTORAL APPROACH)	MATURE (INNOVATIVE, CUTTING-EDGE TECHNOLOGY)
Membership	None	Active RLMO member (where relevant)	Active RLMO member (where relevant) OIML membership	Active RLMO member (where relevant) OIML membership Active in OIML committees Signatory of OIML Certification System
Services	Calibration and verification service	Type approval of measuring equipment Calibration and verification services Market surveillance	Type approval of measuring equipment Market surveillance Calibration and verification services; some calibration services liberalized	Type approval of measuring equipment Prepackaging certification scheme Market surveillance; calibration and verification services largely liberalized
Human resources	Training on the job	Training on the job Training through donor projects	Training on the job Training courses in legal metrology	Training on the job Training courses in legal metrology Legal metrologist as a professional profile
Demand orientation	None	Demand surveys, mostly through donor projects	Demand surveys Stakeholder participation and consultative mechanism	Strong instruments and constructs to ensure demand orientation

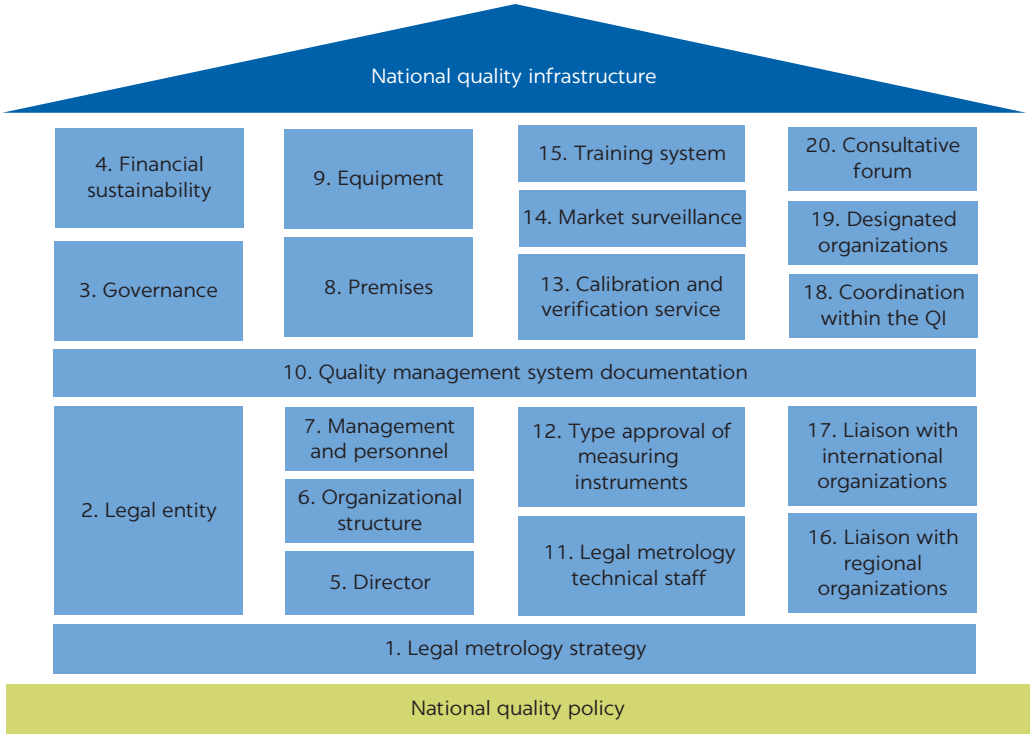
Note: OIML = International Organization of Legal Metrology; RLMO = Regional Legal Metrology Organization.

TABLE 11.2 Pillars and building blocks of the legal metrology regime

PILLAR	BUILDING BLOCK	
	NO.	DESCRIPTION
1: Legal and institutional framework	1	Legal metrology strategy
	2	Legal entity
	3	Governance
	4	Financial sustainability
2: Administration and infrastructure	5	Director
	6	Organizational structure
	7	Management and personnel
	8	Premises
	9	Equipment
	10	Quality management system documentation
3: Service delivery and technical competency	11	Legal metrology technical staff
	12	Type approval of measuring instruments
	13	Calibration and verification services
	14	Market surveillance
	15	Training system
4: External relations and recognition	16	Liaison with regional organizations
	17	Liaison with international organizations
	18	Coordination within the QI
	19	Designated organizations
	20	Consultative forum

Note: QI = quality infrastructure.

FIGURE 11.1
House of legal metrology for a national quality infrastructure



Note: QI = quality infrastructure. The four "pillars" of the QI—represented by the blue columns containing the "building block" numbers—are as follows (left to right): "legal and institutional framework," "administration and infrastructure," "service delivery and technical competency," and "external relations and recognition."

11.2 PILLAR 1: LEGAL AND INSTITUTIONAL FRAMEWORK

11.2.1 Benchmark and significance

Legal metrology is, in the first instance, the responsibility of government because it is the technical regulation expression of metrology. Government must enact the necessary legal metrology legislation, and it has to establish the legal metrology authority with the mandate to enforce such legislation.[3] Without this legal mandate—which should include the appointment of legal metrology inspectors and their powers of entry and search—the legal metrology authority will find it difficult to enforce legal metrology legislation.

Regarding its governance, the legal metrology authority should have a head, frequently called the legal metrology director, who has the executive responsibility for the legal metrology system. The director should have a direct link to the top levels of the relevant ministry, and even to the relevant minister, because of the trade- and society-related—and sometimes very political—impacts of legal metrology legislation enforcement. The director could be supported by a legal metrology council or representative committee that can advise him or her on legal metrology needs.

An international recognition mechanism for legal metrology authorities does not exist. However, membership of the OIML is highly desirable. Active participation in its technical committees and in the OIML Certification System (OIML-CS) will bring about benefits for the country regarding

harmonization of legal metrology measures as the maturity levels of industry and suppliers, and the sophistication of consumers, increase over time.

Because of the necessity of market surveillance, legal metrology is not a good candidate for a regional implementation organization. Yet, legal metrology measures are one of the major trade-related issues to be harmonized at the regional level or within common markets, and coordination organizations are frequently established for this purpose. In such cases, the national legal metrology authority must participate actively in such regional legal metrology organizations (RLMOs).

11.2.2 Legal metrology strategy (building block no. 1)

What is meant

Major	Following on from the quality policy (see module 10 of the QI Toolkit), a legal metrology strategy gives meaning to the implementation of the quality policy regarding the establishment and maintenance of a legal metrology regime in the country. The legal metrology strategy is about • Making the right choices regarding the legal metrology focus in the short, medium, and long terms; • Establishing and supporting the legal metrology authority; and • Building capacity in the public and private sectors to establish and maintain an effective and efficient legal metrology regime.

How can it be demonstrated?

The legal metrology strategy (also known as the legal metrology policy) should detail the development and implementation of the legal metrology regime over the short, medium, and long terms, including the following:

- The promulgation of new or revised legislation
- Road map for the implementation of legal metrology measures over time with regard to specific measuring equipment, whether related to trade, law enforcement, or health and safety
- Alignment of regulations with OIML recommendations
- Introduction of prepackaging requirements or the revision of older regulations
- Harmonization of legal metrology regulations with regional requirements
- Establishment of legal metrology inspection offices across the country
- Legal metrology–related laboratory capacity development
- Capacity development with regard to inspection equipment for market surveillance
- Training system for legal metrology experts
- Awareness and education of consumers regarding weights and measures
- Road map for the liberalization of calibration and verification activities—that is, designation of private sector organizations to take over these functions from the state

The legal metrology strategy should be a formal document approved at least by the relevant ministry, and in some countries, even by the minister or cabinet, depending on national custom and practice. The legal metrology strategy should be publicly available—that is, on the ministry website or in hard copy. The activities, business plans, and budgets of the legal metrology authority should be aligned with the legal metrology strategy to ensure its implementation.

Existing information/reporting/monitoring

- Relevant ministry (for example, Trade and Industry) website
- Relevant ministry papers
- Legal metrology authority website
- Annual reports of the legal metrology authority

11.2.3 Legal entity (building block no. 2)

What is meant

Fundamental	The legal metrology authority shall be a legal entity, or a defined part of a legal entity, with the mandate to establish and maintain the legal metrology regime in order to safeguard the interests of society regarding measurements. The legal metrology authority is invariably a governmental department or a public institution (such as a statutory body). It may be an independent institution, but it can also be combined with scientific or industrial metrology.

How can it be demonstrated?

The legal metrology authority should be established by a legislative instrument—that is, a Legal Metrology Act or a similar law. The legislative instrument should be of an enabling nature but must define at a minimum the governance, financial provisions, and responsibilities and functions of the legal metrology authority, and it must provide for the appointment and powers of entry and search of legal metrology inspectors. It should also provide for the promulgation of second-tier legal metrology regulations containing the details of measuring equipment or prepackaging. The responsibilities should include representing the country in regional and international legal metrology forums. A useful guidance document is "Elements for a Metrology Law, OIML D 1" (OIML 2004).

Specific details, such as type approval, calibration and verification, methods of use, and so on concerning specific measuring equipment, should be contained in regulations that are promulgated in terms of the Legal Metrology Act without having to revise the Act itself. These can then be promulgated in accordance with an agreed-upon road map by the authorities, or they can be revised and updated as technology develops. They should be based on the relevant OIML recommendations or harmonized regional regulations. The same applies to the prepackaging requirements.

In smaller economies, the legal metrology authority is frequently also responsible for the establishment and maintenance of the national measurement standards (see subsection 4.2.5 in section 4: Metrology). This may be a workable solution, and the model metrology legislation published by the OIML even provides for such a combination (OIML 2004). It may be necessary for dealing with scarce metrology resources, but it poses a serious challenge. Scientific metrology and legal metrology share the same technology, but their approaches to service delivery are totally different. Scientific metrology is a scientific, voluntary function, whereas legal metrology is a regulatory function. The operational focus of the personnel will of necessity also be very different. Anecdotal evidence suggests that one or the other, usually legal metrology, becomes the main focus of activities and the other one is neglected. Operational measures to combat this neglect must be in place, or the scientific metrology part should be separated and placed in another organization if it is too small to be established as an independent entity; the national standards body (NSB) may be a good choice.

Existing information/reporting/monitoring

- Legal Metrology Act, decree, regulations, or similar law
- Legal metrology authority's website and annual reports

11.2.4 Governance (building block no. 3)

What is meant

Fundamental	The legal metrology authority is by nature a governmental-type organization—either a government department or a statutory body. As a government department, it will be part of the civil service structures. Depending on the country's custom and practice, it may have a council in the case of a statutory body. Whatever the governance construct, it should have the mandate to approve the strategy, business plans, and budget of the legal metrology authority, and it should hold the director to account.
Major	If a council has been established, then good governance models suggest that the members of the council should be individuals with specific knowledge regarding legal metrology and market realities.

How can it be demonstrated?

If the legal metrology authority is a government department, then its director will be accountable to the senior management levels of the relevant ministry, which will be responsible for strategy and fiduciary oversight. Because of the impact that legal metrology measures have on society and the potential political fallout if things go wrong, it is good practice if the director has a direct communication link to the relevant minister.

If a council constitutes the governance of the legal metrology authority, then the balance between private sector members and public servants is important. The more-progressive legal metrology authorities have private sector representatives on their councils as well as public servants. The council members should be appointed in their individual capacities because of their knowledge, experience, or qualifications relating to the functions of legal metrology, and not only as representatives of business or industry associations or specific public institutions.

Good governance principles suggest that the director of the legal metrology authority should be a full member of the council but should not be allowed to hold a leadership position on the council, such as chair, vice-chair, or secretary. If the national metrology institute (NMI) is an institution separate from the legal metrology authority, then it is good practice for senior management representatives of both the NMI and the NSB to serve on the council. The council should have the mandate or authority to (a) approve the business strategies; (b) appoint the director and consider his or her performance; (c) approve the budget and monitor performance of the organization against the budget; and (d) approve the organizational structure.

Existing information/reporting/monitoring

- Legal Metrology Act, decree, regulation, or similar law
- Ministerial decrees, if relevant
- Legal metrology authority's council policy papers
- Legal metrology authority website and annual reports
- Government regulations regarding public entities

11.2.5 Financial sustainability (building block no. 4)

What is meant

Fundamental	Being a regulatory body, the legal metrology authority has to have its finances provided by government sources. Services, such as type approval, calibration, and verification, may have to be paid for by clients but are usually controlled by legislation; hence they are not market-related. Whatever the source of funding, measures should be in place that also ensure the financial sustainability of the legal metrology authority for the medium to long term.

How can it be demonstrated?

As a regulatory authority, the legal metrology authority should have its market surveillance–related activities funded by the government. Clients needing type approval of instruments or calibration and verification services may have to pay for these, but because they relate to regulations (that is, clients have no choice in the matter), they are frequently determined by legislation and hence are seldom market-related. This puts pressure on the finances of the legal metrology authority, and government assurances that appropriate funding will also be forthcoming in the medium to long term are essential.

Care should be taken that the financing model for the legal metrology authority does not rely heavily on service fees due to a strain on government finances. These then quickly become the focus of survival for the authority, with a concomitant neglect of the market surveillance function, which should remain a major responsibility. Once the calibration and verification services are starting to be liberalized and private sector organizations are designated to provide these, the market surveillance function will eventually be the main remaining activity (other than type approvals) for the authority.

The legal metrology authority's overall financial situation of the past three to five years would be a good indication of its financial sustainability. The situation should show a positive trend over the years under review. A formal government commitment to support the legal metrology authority to carry out its responsibilities regarding the implementation of legal metrology legislation, as well as specific financial support for its international and regional liaison activities, are positive indicators of the legal metrology authority's financial sustainability.

Existing information/reporting/monitoring

- National quality policy
- Annual government budget allocations
- Annual reports of the legal metrology authority
- Monthly and annual financial statements of the legal metrology authority

11.3 PILLAR 2: ADMINISTRATION AND INFRASTRUCTURE

11.3.1 Benchmark and significance

Legal metrology activities have a preventive as well as a repressive focus. It follows that the organizational structure and facilities of the legal metrology authority should support both as effectively and efficiently as possible. This means that, over and above a head office with laboratories, the legal metrology authority also has to have inspection offices to cover all the regions of the country; it should be as close to the market as possible to optimize surveillance activities.

Good governance principles require the legal metrology authority to have a proper management executive, and the subject fields of legal metrology indicate that the "advanced" or "mature" authority should have divisions dedicated to type approval activities, calibration and verification services in the field, and inspectors dedicated to market surveillance—all of which need to be ably supported by the necessary corporate services, such as finance, human resources, training, and facility services. The director, as the executive head, has specific legal responsibilities dealing with approval of instrument types, as well as the initiation of sanctions should illegal usage of measuring instruments or improper prepackaging be uncovered.

Facilities are a vital factor in the success or otherwise of legal metrology. Without laboratory space and environmental controls appropriate for the specific legal metrology fields and accuracy levels the legal metrology authority is engaged in, proper testing and calibration of measuring instruments will be difficult. An additional challenge is the availability of mobile calibration and verification equipment of appropriate accuracy in all regional offices to be used in the field.

11.3.2 Director (building block no. 5)

What is meant

Major	The director (whatever the actual title) is responsible for the execution of the legal metrology authority's responsibilities as provided for in legislation and for the implementation of its medium- to long-term development plans. The director acts as a direct liaison between the ministry or council and management of the authority, and communicates to the ministry or council on behalf of management. The director is the public face of the authority.
Minor	Depending on the legislation, custom, and practice relevant to the legal metrology authority, the director may be appointed by the relevant minister or the council. Recent tendencies suggest that the director should be appointed for a limited period only, typically five years. He or she can be reappointed if relevant key performance indicators are more than fulfilled.

How can it be demonstrated?

There is no standardized list of the major functions and responsibilities carried out by the director of a legal metrology authority, but some typical functions include the following:

- Supports operations and administration of the ministry or council by advising and informing its members, interfacing between the ministry or council and staff
- Oversees the design, marketing, promotion, delivery, and quality of services with regard to legal metrology
- Recommends the annual budget for ministry or council approval and prudently manages the legal metrology authority's resources within those budget guidelines according to current laws and regulations
- Effectively manages the human resources of the legal metrology authority according to authorized personnel policies and procedures that conform with current laws and regulations, especially the training and appointment of legal metrology inspectors
- Assures that the legal metrology authority and its mission, programs, and services are consistently presented using strong, positive images to relevant stakeholders, including the relevant minister and ministry

- As the responsible executive, considers the type approval of measuring instruments and initiates sanctions when illegal use of instruments or inappropriate prepackaging is uncovered
- Oversees fundraising planning and implementation, including identifying resource requirements, researching funding sources, and establishing strategies to approach funders

Existing information/reporting/monitoring

- Relevant legislation (Legal Metrology Act or similar law)
- Official ministerial decisions
- Council decisions and minutes, if relevant
- Official director job description
- Agreed-upon director key performance indicators

11.3.3 Organizational structure (building block no. 6)

What is meant

Fundamental	Legal metrology has preventive and repressive components. It therefore follows that the organizational structure of the legal metrology authority must facilitate the effective and efficient execution of both and should have divisions that optimally support these groupings and their subject fields.

How can it be demonstrated?

For legal metrology authorities dealing primarily with trade-related issues, preventive components include type approval of instruments, calibration and verification of the same, and a certification scheme for prepackaging. They may also develop recommendations regarding legal metrology regulations that would be promulgated by the minister, for example, as mandated in legal metrology legislation.

The *repressive component* consists primarily of market surveillance. The *preventive component* consists of head office activities well as field services, whereas market surveillance is largely a field service activity. Over and above appropriate head office technical staff, an appropriate number of regional inspection offices are required for effective and efficient market surveillance close to markets.

For advanced legal metrology authorities operating in fields other than trade, such as law enforcement, health and safety, and so on, organizational structures to deal with these have to be in place. These would differ from those dealing with trade and have to be arranged in accordance with the needs of those sectors. Expert advice is indicated to evaluate these properly.

Other areas to consider in the organizational structure include

- Support functions, such as human resources and finance;
- Training and development responsibility for the common good in relation to the country's legal metrology infrastructure, such as calibration and verification; and
- A technical division for the maintenance and calibration of legal metrology reference and inspection measurement standards

Existing information/reporting/monitoring

- Approved organizational structure
- Ministry or council decisions
- Ministerial decisions
- Financial system documentation

11.3.4 Management and personnel (building block no. 7)

What is meant

Major	Legal metrology is primarily a people-based activity operating within a specific technical environment. The management and personnel must therefore have the appropriate skill sets assured by appropriate training, qualifications, and experience. These would include management and technical knowledge as required by the various activities within the legal metrology fields, such as the appointment of legal metrology inspectors with appropriate knowledge regarding their legal authority with regard to entry and search.

How can it be demonstrated?

In the first place, the legal metrology authority should operate with an organizational structure approved by either the ministry or council. For each of the positions, the skill set (qualifications, training, and experience) should be clearly and formally stated. Special attention should be given to the training and appointment of legal metrology inspectors concerning not only their technical capabilities but also their knowledge of their legal authority with regard to entry and search. The ratio between technical and administrative staff is a good indicator of efficacy, with a good guideline being that administrative staff make up no more than 20 percent of the total.

Second, there should be few staff vacancies on either the management or technical levels; more than 95 percent of those positions should remain filled. Anything less indicates that the legal metrology authority cannot operate effectively or efficiently. Staffing challenges include a lack of skilled people in the country, but even more so, inadequate remuneration resulting in the departure of trained staff for more lucrative offers elsewhere.

Existing information/reporting/monitoring

- Approved organizational structure
- Training records of staff
- Appointment and withdrawal records of legal metrology inspector certificates
- Actual staffing levels
- Staff turnover figures

11.3.5 Premises (building block no. 8)

What is meant

Fundamental	Legal metrology is a partly technical, partly administrative endeavor. Specific requirements regarding laboratory space have to be observed. Appropriate accommodation for head office staff has to be provided, as well as appropriate accommodation in regional offices for inspectors and their equipment.

How can it be demonstrated?

Each of the legal metrology fields has specific requirements regarding the laboratory space within which it can operate at the required accuracy. These requirements include environmental controls (temperature, light levels, and so on). Some calibration equipment is large and heavy (for example, weights for calibrating weighbridges), and ease of access for such equipment must be considered. The same applies to fixed outside installations (for example, calibration installations for road tankers).

Appropriate office space for staff needs to be provided, as well as meeting rooms for individual customer discussions and meetings of legal metrology technical committees. Regional offices need appropriate office space, as well as storage space for inspection equipment.

Existing information/reporting/monitoring

- Consideration of the legal metrology authority premises in relation to design, environmental controls, access, and maintenance
- Review of laboratories and environmental controls
- Review of office space and meeting rooms
- Technical requirements, as advised by experts in specific legal metrology fields

11.3.6 Equipment (building block no. 9)

What is meant

Fundamental	A wide range of metrology equipment is necessary, as denoted by the measuring instruments falling within the scope of the legal metrology regulations. Regional and inspection offices should be issued with appropriate working standards and inspection equipment. Reference standards should be maintained against which working standards and inspection equipment can be calibrated continuously. Reference standards must be calibrated against national measurement standards at predetermined intervals.

How can it be demonstrated?

The equipment necessary to implement legal metrology requirements cover a vast range of measuring instruments. It ranges from high-technology scales for smaller quantities to very heavy weights for the calibration of weighbridges, outside tanks and rigs for calibrating road tankers, volumetric equipment mounted on trailers for the calibration of fuel dispensers—the list is endless. Expert advice is required to evaluate the range of instruments and their respective accuracy classes properly.

The accuracy of the legal metrology authority's equipment should be above reproach. It is good practice to maintain instruments at three levels, where possible:

- At the highest level would be the legal metrology reference standards, which are calibrated against the national measurement standards at predetermined intervals (see subsection 4.3 in section 4: Metrology).
- The following level would be working standards that are calibrated at fairly short but still predetermined intervals against the reference standard.
- The third level would be the inspection equipment that inspectors use in the field, which is calibrated frequently against the working standards.

When no calibration laboratories are available, the legal metrology reference standards are also often used to calibrate the measuring instruments of clients.

Existing information/reporting/monitoring

- Consideration of the legal metrology fields of activity
- Demonstrable metrology equipment needs of the legal metrology authority
- Review of reference measurement standards

- Review of working standards
- Review of inspection equipment
- Review of maintenance measures for all measuring equipment

11.3.7 Quality management system documentation (building block no. 10)

What is meant

Major	It is good practice for the legal metrology authority to operate in accordance with a formal quality management system. This includes compliance with ISO/IEC 17025 regarding laboratory and on-site calibration services, as well as with ISO/IEC 17020 for its inspection activities.

How can it be demonstrated?

The laboratories of the legal metrology authority should comply with the requirements of ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories"); it would even be appropriate to have been accredited. The same applies to on-site calibration and verification services.

As for its inspection activities, it is good practice to comply with ISO/IEC 17020 ("Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection"). Accreditation of inspection activities will likewise independently demonstrate the competency of the legal metrology authority, thereby enhancing its standing among stakeholders and supporting the authority in legal disputes.

For both of these, quality management system documentation is required. It should be developed in three levels: policies, general procedures, and work instructions or standard operating procedures. Appropriate records are an important element of the quality management system. It is especially the type approval records, calibration and verification records, and inspection records that are important as legal documents indicating an effective implementation of the legal metrology legislation.

Existing information/reporting/monitoring

- Consideration of the legal metrology authority's formal quality management system and its compliance with relevant standards, such as ISO/IEC 17020 and ISO/IEC 17025

11.4 PILLAR 3: SERVICE DELIVERY AND TECHNICAL COMPETENCY

11.4.1 Benchmark and significance

The preventive component of trade-related legal metrology consists of type approval of measuring instruments, calibration and verification of the same, and the management of a certification scheme for prepackaging. Type approval would largely be of an administrative nature with a technical content unless type approval testing is undertaken by the legal metrology authority itself. Calibration and verification services have a laboratory component, but they are largely concerned with providing such services in the field.

A prepackaging certification scheme is similar to a quality management certification scheme (see section 9: System Certification) with a focus on the compliance of prepackaging measurements with legal requirements.

Market surveillance is the repressive part of legal metrology. Registered legal metrology inspectors with some serious entry and search authority inspect market activities as they relate to legal metrology legislation and regulations. On uncovering illegal use of measuring instruments or inappropriate prepackaging, inspectors, in coordination with the director, institute sanctions and legal proceedings against the relevant suppliers. These constitute administrative-type sanctions handed down by the director, followed by court proceedings if the administrative sanctions are not appropriately responded to by the suppliers.

In a modern economy, the legal metrology authority needs to demonstrate its integrity and technical competency in order to engender trust among all stakeholders. It is therefore good practice if the legal metrology authority is accredited to ISO/IEC 17020 for its inspection activities and to ISO/IEC 17025 for its testing and calibration work, both in the laboratory as well as on-site.

11.4.2 Legal metrology technical staff (building block no. 11)

What is meant

Fundamental	Legal metrology is a technical endeavor. The people involved in legal metrology testing, calibration, and verification have to be trained and experienced in order to do justice to the technological level that is required.
Fundamental	The legal metrology inspectors should have not only good knowledge of the technology they operate in but also a full understanding of their responsibilities and authority regarding entry and search under legal metrology legislation. They should be appointed and issued with an inspector's identification, and this should be withdrawn if the inspector leaves the service.

How can it be demonstrated?

Technical staff of the legal metrology authority may come from various disciplines, such as physics, engineering, chemistry, and many more. Over and above the basic education at a university or technical college, further training, as well as experience in legal metrology practices, is an important element in developing metrologists. Legal metrology training courses at the tertiary level are indicated.

Legal metrology inspectors are generally empowered by legislation to enter and search premises and vehicles without a search warrant where they suspect activities subject to legal metrology legislation take place that they may wish to inspect. To ensure that they operate professionally and in compliance with the law, legal metrology inspectors must be trained in the legal aspects of their work. Thereafter, they are officially appointed as inspectors and issued a card identifying them as such. This identification card should be shown to the responsible persons when entering premises or vehicles for inspection. The identification card must be withdrawn once the inspector no longer is involved in inspections to ensure that it is not used in any disreputable practices.

Existing information/reporting/monitoring

- Approved organizational structure
- Formal job descriptions

- Personnel records regarding education, training, and experience
- Annual training plans and concomitant records
- Legal metrology inspector training records
- Records of legal metrology inspector cards issued and withdrawn

11.4.3 Type approval of measuring instruments (building block no. 12)

What is meant

Fundamental	A measuring instrument used in activities covered by legal metrology legislation has to be tested against defined standards and be type approved before it can be marketed.

How can it be demonstrated?

The preventive measures start with the type approval of measuring instruments. The type of instrument is tested against a defined technical regulation, either national standards or, better still, an OIML International Recommendation or its national adoption. Thereafter, the instrument is granted type approval by the legal metrology authority if it meets all the legal requirements. With serially manufactured measuring instruments, it shall be assured by calibration and verification that each instrument fulfills requirements before it is placed in use.

The testing of the instrument type can be conducted by the legal metrology authority if it has the capability to conduct all the tests; otherwise, it can subcontract the testing to an accredited laboratory. For low- and middle-income countries, such testing would normally be conducted in the country of origin of the measuring instruments. Establishing the infrastructure to conduct these types of tests is expensive, and the number of tests to be conducted would be minimal.

A measuring instrument can also be accompanied by an OIML test certificate denoting its compliance with an OIML International Recommendation. Such a test report can be used by the legal metrology authority (after assuring its authenticity and applicability for the requirements set in the national technical regulation) to issue the type approval. This would be the most elegant solution for smaller legal metrology authorities.

The legal metrology authority must keep proper records regarding all the measuring instruments it has type approved and must be able to provide this information on request or make it publicly available on information technology (IT) platforms.

Existing information/reporting/monitoring

- Formal type approval procedures of the legal metrology authority
- Type approval records of the legal metrology authority

11.4.4 Calibration and verification services (building block no. 13)

What is meant

Fundamental	The legal metrology authority must provide calibration and verification services for measuring instruments within the scope of legal metrology regulations insofar as they are not provided by designated private sector organizations.

How can it be demonstrated?

All measuring instruments within the scope of legal metrology regulations have to be calibrated and verified within stated intervals. In smaller economies, the legal metrology authority will undertake these activities. The legal metrology authority should have the appropriate calibration equipment, transportation facilities, and manpower to do so because most of such services will have to be rendered in the field.

As industry and trade develops, the country's legal metrology authority will no longer be in a position to service all such instruments. Designated organizations can then be empowered to provide such services (see building block no. 19). The owner of such measuring instruments is legally responsible to see to it that the instruments are calibrated and verified as provided for in the regulations.

Existing information/reporting/monitoring

- Working plans of the legal metrology authority
- Records of calibrations and verifications
- Records of designated organizations

11.4.5 Market surveillance (building block no. 14)

What is meant

Fundamental	The legal metrology authority must operate a market surveillance system to ensure that measuring instruments in the marketplace are type approved and appropriately calibrated and verified. In addition, prepackaging must be inspected to ensure that it complies with legal metrology requirements. Illegal instruments, uncalibrated instruments, or unverified and illegal prepackaging must be identified and sanctions initiated against suppliers.

How can it be demonstrated?

Appropriate market surveillance is a major responsibility of the legal metrology authority. The market surveillance should be fully planned, with some time allocated for unplanned visits following complaints. The market surveillance must be conducted by legal metrology inspectors from the head office and regional offices where these have been established, because they have the necessary authority to enter and search premises or vehicles where legal metrology-related activities are suspected.

When illegal measuring instruments are uncovered, or type approved instruments that have not been calibrated and verified as required, the operations related to these measuring instruments must cease and further sanctions must be initiated against their suppliers or the persons responsible for their use. The same applies to the inspection of prepackaged goods in the marketplace.

Whereas the above measures are appropriate for trade-related measuring instruments, others, such as those used in law enforcement or health and safety, must be inspected in accordance with their defined market surveillance programs. Expert opinion is necessary to evaluate the appropriateness or otherwise of such market surveillance activities.

Existing information/reporting/monitoring

- Market surveillance planning documents
- Market surveillance records
- Records of sanctions instituted

11.4.6 Training system (building block no. 15)

What is meant

Major	Trained and skilled legal metrologists are a vital component of an effective and efficient national legal metrology system. Training courses provided by the legal metrology authority or tertiary education institutions to train such legal metrologists are important.

How can it be demonstrated?

High demands are placed on appropriately educated, trained, and experienced legal metrologists and technical staff. The legal metrology authority must therefore provide for the training of its own staff, a requirement that increases with the development of a whole legal metrology system. Initial training programs can be initiated by technical development programs but eventually have to be provided by the legal metrology authority in collaboration with tertiary technical education institutions.

Existing information/reporting/monitoring

- Training programs
- Training records

11.5 PILLAR 4: EXTERNAL RELATIONS AND RECOGNITION

11.5.1 Benchmark and significance

Legal metrology has a major impact on trade. It is therefore important for the country to align its legal metrology measures with internationally accepted standards. In this respect, active participation in the technical work of the OIML and relevant RLMOs is of paramount importance. At the national level, legal metrology, as one of the technical regulation outcomes, must be fully integrated into the country's technical regulation regime.

11.5.2 Liaison with regional organizations (building block no. 16)

What is meant

Major	If the country is a member of a regional construct, then the legal metrology authority may be required to participate actively in regional legal metrology activities if these are part of the regional agreements. This means also participating in technical committees at the regional level.

How can it be demonstrated?

It is useful for a legal metrology authority to participate in relevant regional organizations. These provide a forum where legal metrology issues can be discussed and regional approaches can be harmonized. At the time of writing (January 2019), six regional metrology organizations were considered as liaison organizations by the OIML:

- Asia-Pacific Legal Metrology Forum (APLMF)
- Euro-Asian Cooperation of National Metrological Institutions (COOMET)
- European Cooperation in Legal Metrology (WELMEC)
- Intra-Africa Metrology System (AFRIMETS)
- Inter-American Metrology System (SIM)
- Gulf Association for Metrology (GULFMET)

In addition to these liaison organizations, regional metrology bodies have been established as the outcome of trade agreements leading to regional common markets. Some of these would be the same as the OIML liaison organizations, others not. In many cases, legal metrology authorities are members by default, having to represent their countries in these regional bodies. Some regional metrology bodies have full-time staff and premises; others are liaison-type committees with only a secretariat. Most are forums where a regional approach to legal metrology is discussed and agreed to for implementation in the regional common market.

In some cases, regional systems for the recognition of type approval certificates may have to be adopted by member states. The same applies to prepackaging requirements. It is therefore important that the legal metrology authority participate actively in such regional constructs.

Existing information/reporting/monitoring

- Membership of the legal metrology authority in the OIML liaison organizations
- Reports of participation by the legal metrology authority in the regional organization's activities
- Regional trade agreement membership status of the country
- Relevant regional treaties, protocols, agreements, or legislation on legal metrology
- Annual reports of the legal metrology authority
- Internal reports of regional metrology body meetings

11.5.3 Liaison with international organizations (building block no. 17)

What is meant

Major	The relevant international organization from a legal metrology perspective would be the OIML. Hence, once the legal metrology authority moves from a basic to an advanced level (table 11.1), it should pursue membership in the OIML.
Major	Once the legal metrology authority moves from the advanced to a mature level (table 11.1), it should participate actively in the relevant technical committees of the OIML, and it should consider becoming a signatory of the OIML Certification System.

How can it be demonstrated?

The International Organization of Legal Metrology (OIML) is an intergovernmental treaty organization established in 1955 with the remit to promote global harmonization of legal metrology measures. Membership is on two levels: full membership or corresponding member. Corresponding members have observer status in OIML activities. The OIML collaborates closely with the International Bureau of Weights and Measures (BIPM) on international harmonization on metrology matters.

The OIML publishes metrological guidelines for the elaboration of national and regional requirements concerning the manufacture and use of measuring instruments for legal metrology. The OIML also publishes model regulations that provide members with an internationally agreed-upon basis for the establishment of national or regional legislation on various categories of measuring instruments. The publications are developed by technical committees and

subcommittees composed of representatives of member countries. Cooperative agreements exist between the OIML and the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC), with the objective of avoiding conflicting requirements in international standardization.

The OIML Certification System gives suppliers of measuring instruments the possibility of obtaining an OIML certificate or test report to indicate that a given instrument type complies with the requirements of the OIML International Recommendation. These are issued by OIML member states that have established Issuing Authorities responsible for processing applications from manufacturers wishing to have their instruments certified. These certificates may be accepted for type approval purposes by national legal metrology authorities.

Membership and participation by the legal metrology authority in the activities of the OIML and its committees is therefore extremely helpful in facilitating the harmonization of the national legal metrology measures with international good practices.

Existing information/reporting/monitoring

- Legal metrology strategy and its implementation plans
- OIML membership data
- OIML technical committee data
- Annual reports of the legal metrology authority
- Business plans and minutes of the legal metrology authority's technical committees
- Formal communication records of the legal metrology authority with the OIML

11.5.4 Coordination within the QI (building block no. 18)

What is meant

Fundamental	Coordination between the legal metrology authority and the fundamental quality infrastructure (QI) organizations (the NSB, NMI, and national accreditation body [NAB]) is important to ensure that the legal metrology measures integrate seamlessly with national standardization measures—in other words, that national standards, national measurement standards, and accreditation are optimally used in the implementation of legal metrology legislation.

How can it be demonstrated?

Legal metrology legislation implementation is dependent on national standards (for example, adoption of OIML International Recommendations); metrology (for example, traceable calibration of legal metrology reference standards to national measurement standards); and accreditation (for example, of designated calibration and verification laboratories). Hence, coordination between the legal metrology authority and the NSB, NMI, and NAB will be important to ensure effective and efficient legal metrology legislation implementation.

If the NSB, NMI, and NAB are governmental organizations, then their line ministries are in a good position to ensure such coordination, especially to ensure that all are implementing the quality policy measures. Otherwise, the director of the legal metrology authority should initiate formal communications in this

regard on a regular basis. A technical regulation coordination office (whatever its name) coordinates the activities of the regulatory authorities (the legal metrology authority) with the rest of the QI regarding the development and implementation of technical regulations, ensuring that costly overlaps and gaps in service delivery are kept to a minimum.

Legal metrology should also maintain a good working relationship with ministries responsible for health, labor, the environment, and other areas where accurate measurements are the basis for regulatory interventions, especially if the legal metrology legislation goes beyond the traditional weights and measures used in trade and incorporates measuring instruments used in such regulation. The same applies to relationships with consumer organizations that would be able to support the legal metrology legislation implementation through advocacy.

Existing information/reporting/monitoring

- Line ministry policies, pronouncements, and documentation
- Legal metrology authority annual reports
- Minutes of liaison meetings between the legal metrology authority and the NSB, NMI, and NAB
- Technical regulation coordination office mandate and pronouncements

11.5.5 Designated organizations (building block no. 19)

What is meant

Major	As the legal metrology regime matures, calibration and verification services will be more than the legal metrology authority can handle, and it will have to designate technically competent organizations to render such services on its behalf.

How can it be demonstrated?

As the legal metrology regime matures and more and more suppliers have to be serviced to ensure that their measuring instruments fall within the scope of legal metrology legislation, the legal metrology authority can no longer cope with this increase in services required. Private sector organizations involved in the supply of measuring instruments and calibration laboratories will have to be authorized—that is, designated—by the legal metrology authority to provide such services on its behalf.

Accreditation to ISO/IEC 17020 or ISO/IEC 17025, as appropriate, would be the starting point for such designation, with the legal liability at the national level of the to-be-designated organization an additional requirement. Appropriate legislation (for example, specific articles in the Legal Metrology Act and its regulations) is also required to provide guidance on the designation process and to protect both the legal metrology authority and designated organizations against spurious claims in this regard.

Existing information/reporting/monitoring

- Legal metrology legislation and regulations
- Formal procedures for designating institutes
- Official documentation of designated organizations
- Work program of the legal metrology authority
- Annual reports of the legal metrology authority

11.5.6 Consultative forum (building block no. 20)

What is meant

Minor	Stakeholders play an important role in determining choices regarding the legal metrology regime. Stakeholders would include the suppliers of measuring instruments, retail organizations, and consumer organizations. A consultative forum representing stakeholders can provide useful advice to the legal metrology authority.

How can it be demonstrated?

It is good practice for the legal metrology authority to understand the needs of the stakeholders for developing and maintaining the legal metrology regime. Hence, a consultative forum representative of stakeholders is a useful construct to provide such feedback. The consultative forum should meet at least once annually, or more frequently, if indicated by circumstances.

Existing information/reporting/monitoring

- Legal metrology strategy and its implementation
- Communication strategy or plan and its implementation
- Minutes of consultative forum meetings
- Key performance indicators of senior management
- Stakeholder mapping results

NOTES

1. *Calibration* establishes the relationship between the value indicated by the measuring instrument and the actual value of a metrology standard. *Verification* determines whether this indicated value falls within limits of accuracy as specified by regulation.
2. Least developed countries (LDCs) are low-income countries confronting severe structural impediments to sustainable development. They are highly vulnerable to economic and environmental shocks and have low levels of human assets. There are currently 47 countries on the list of LDCs, which is reviewed every three years by the United Nations (UN) Committee for Development (CDP), a subsidiary body of the UN Economic and Social Council.
3. The legal metrology authority may be a government department or a public sector agency or authority established by relevant legislation. Whatever its organizational form, it should have the mandate to implement and enforce legal metrology legislation and its regulations.

STANDARDS REFERENCED IN SECTION 11

ISO and IEC (International Organization for Standardization and International Electrotechnical Commission). 2012. "ISO/IEC 17020: Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection." 2nd ed. Ref. no. ISO/IEC 17020:2012(E), ISO, Geneva.

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OIML (Organization of Legal Metrology). 2004. "Elements for a Law on Metrology." International document OIML D 1, Edition 2004 (E), OIML, Paris. http://workgroups.oiml.org/tcsc/tc-03/tc-03-d1/D001-e04.pdf.


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