

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 <ul style="list-style-type: none"> • 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.	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

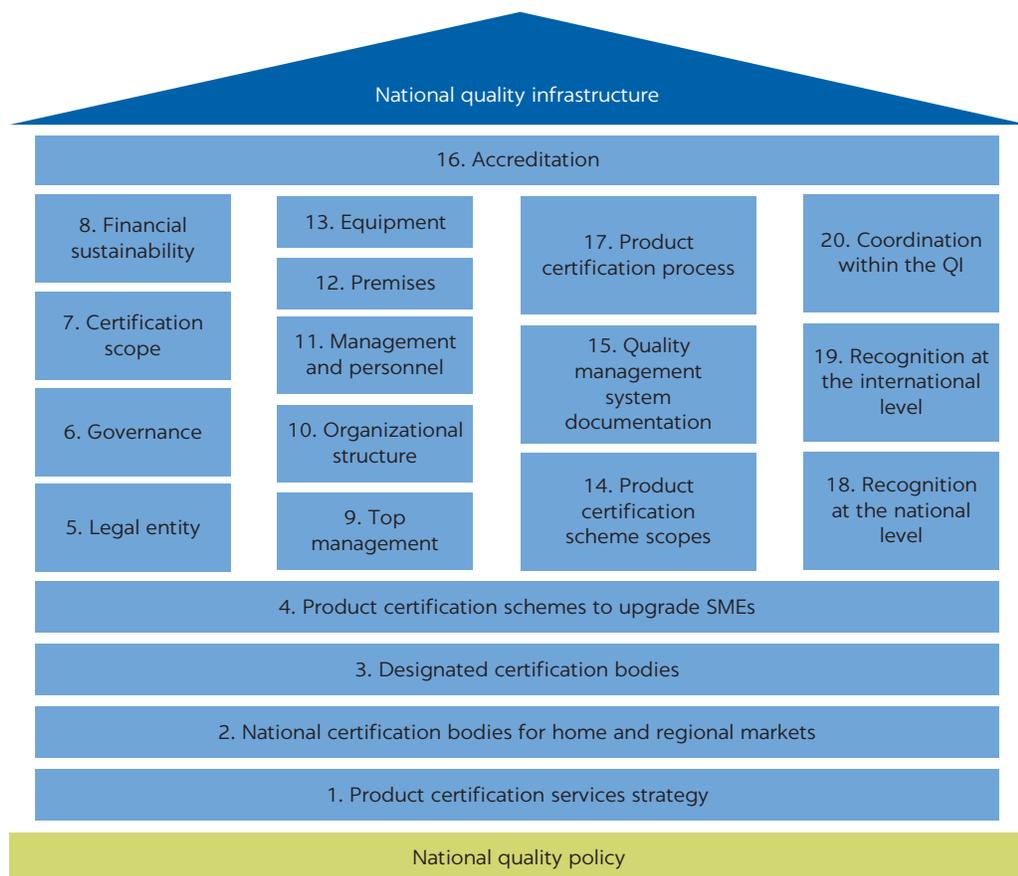
TABLE 8.4 Pillars and building blocks of a product certification body

PILLAR	BUILDING BLOCK	
	NO.	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	<p>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</p> <ul style="list-style-type: none"> • 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.
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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.
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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.
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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.
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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.
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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.
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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.
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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 subsopes 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.
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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.
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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.
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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.
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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.
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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.
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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.
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How can it be demonstrated?

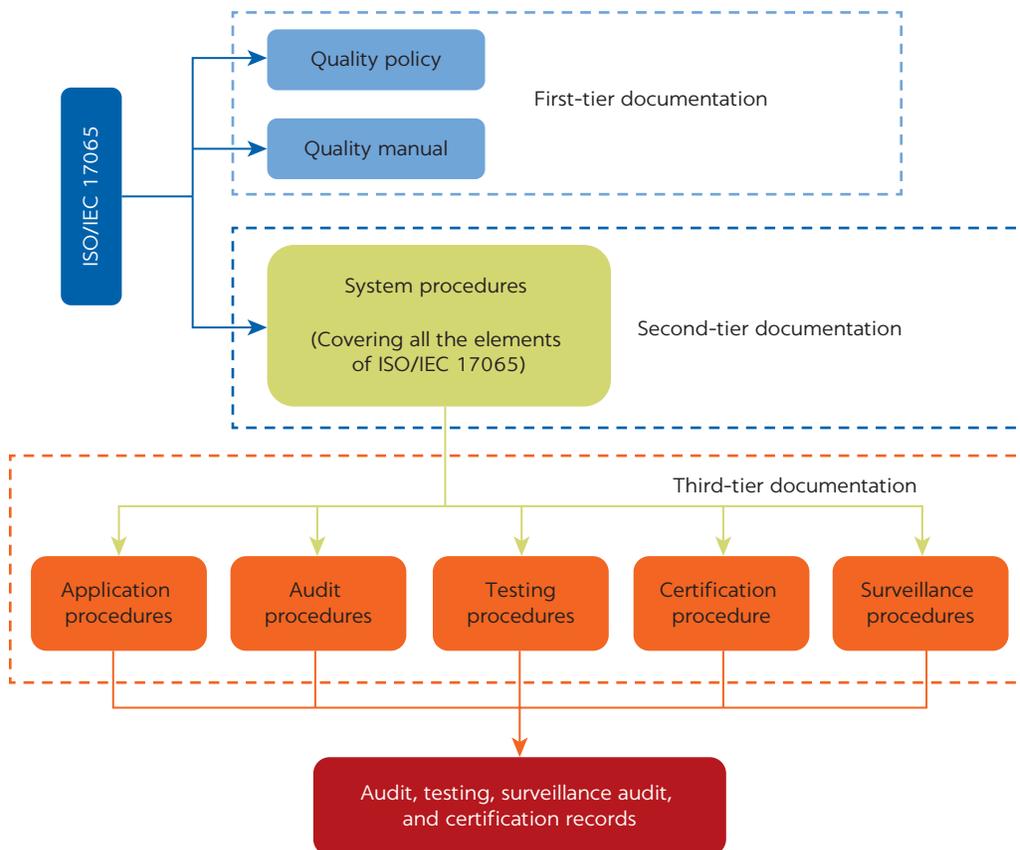
The quality management system documentation is generally organized on three tiers, generically known as policy documents, procedures, and work instructions. These are supported by records of the audits, certification records, internal audit records, management review records, and records of nonconformities 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	<i>Preassessment.</i> 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	<i>Initial assessment.</i> 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	<i>Accreditation.</i> 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.
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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.

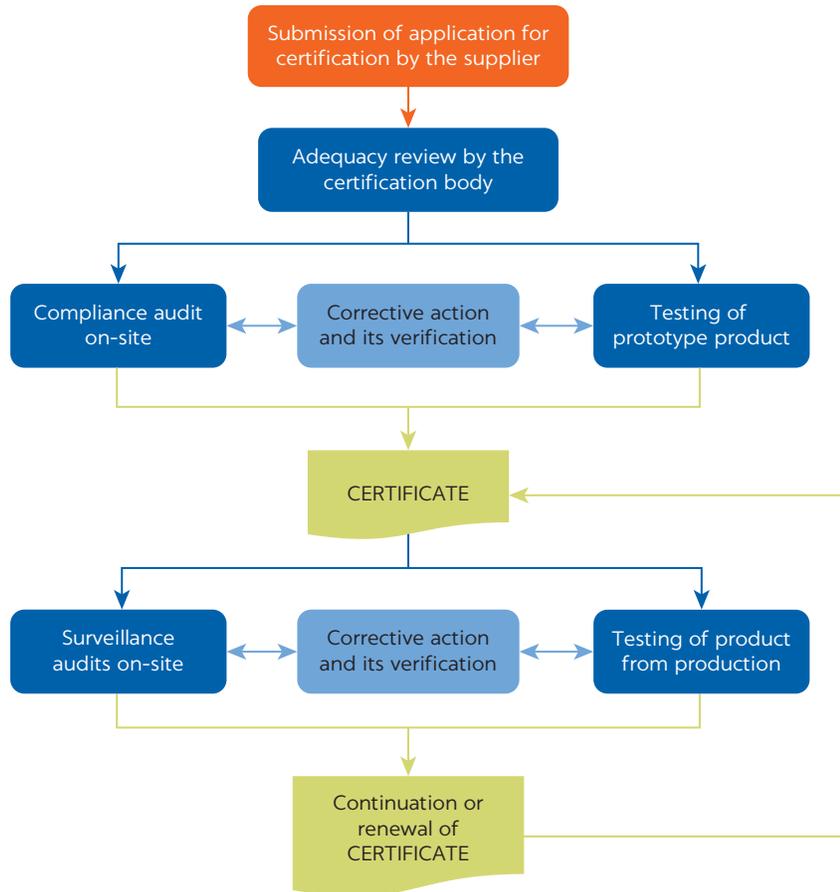
Adequacy audit. The certification body evaluates the quality management system documentation of the applicant to determine whether to proceed to the on-site audit and to determine sampling of the product and concomitant product testing requirements.

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



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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.
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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.
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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.
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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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- ITC (International Trade Centre). 2011. *Export Quality Management: A Guide for Small and Medium-Sized Enterprises*. Geneva: ITC.
- Minzberg, H., B. Ahlstrand, and J. Lampel. 1998. *Strategy Safari: The Complete Guide through the Wilds of Strategic Management*. Edinburgh: Pearson Education, Prentice Hall.

