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

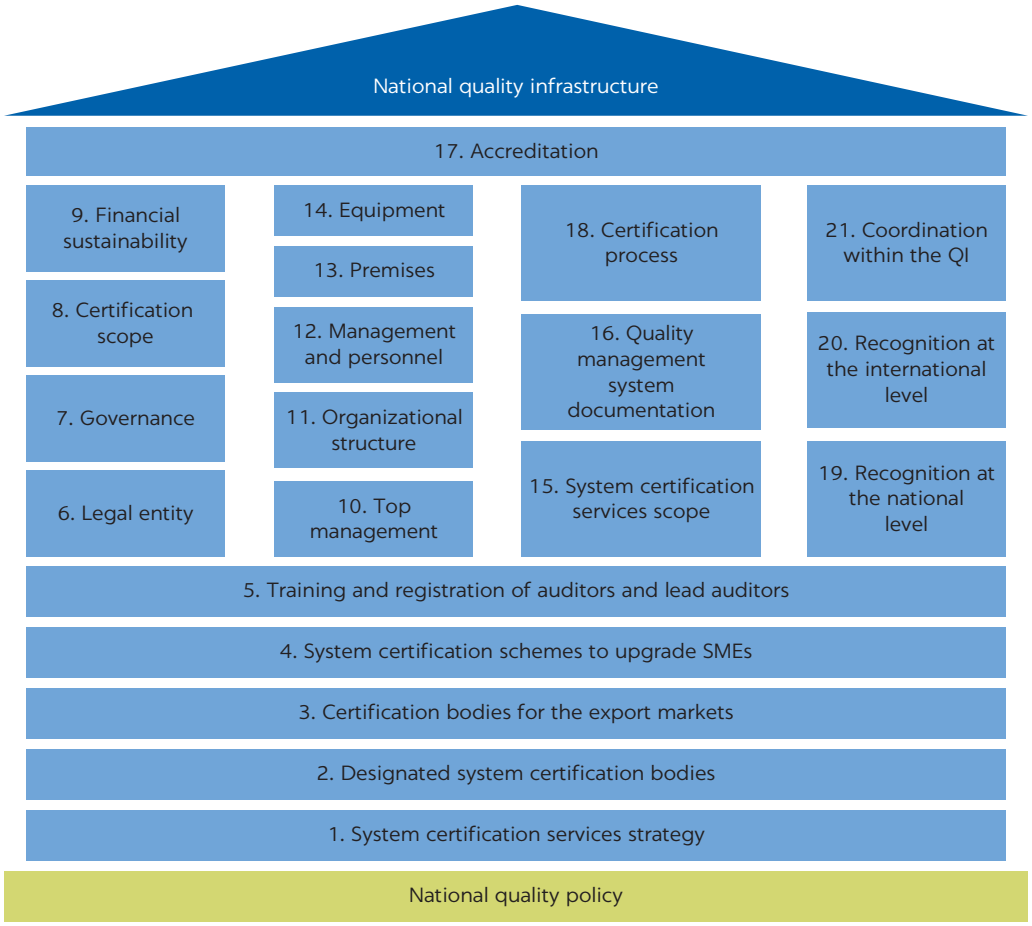
continued

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)

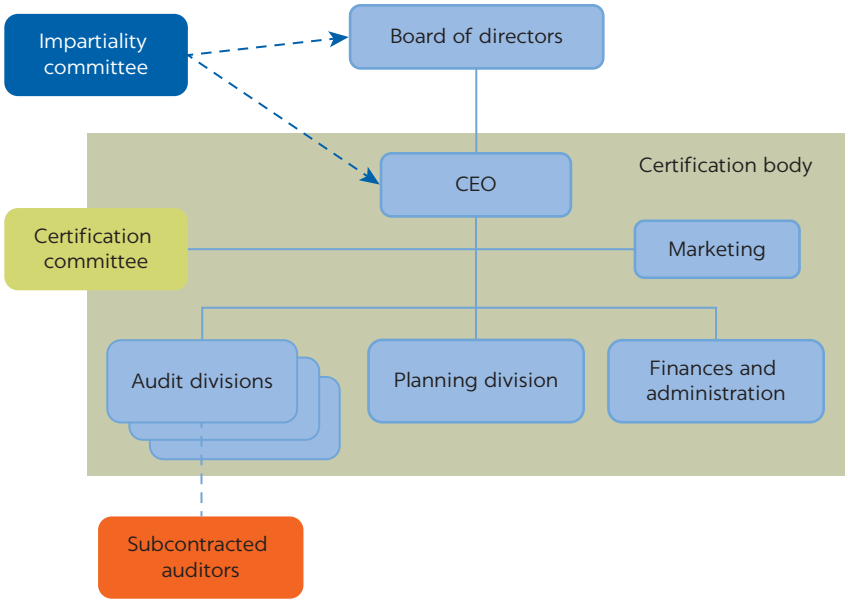
What is meant

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

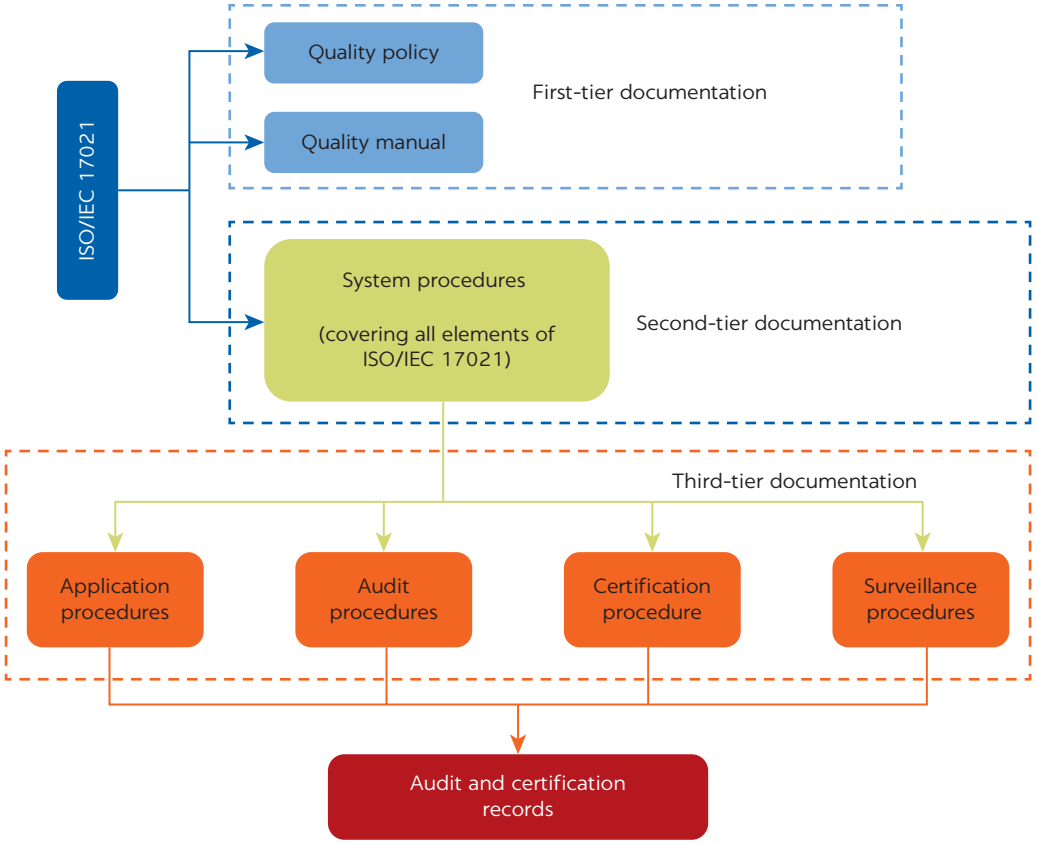
- Quality management documentation
- Internal audit results
- Management review records
- Accreditation records

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.

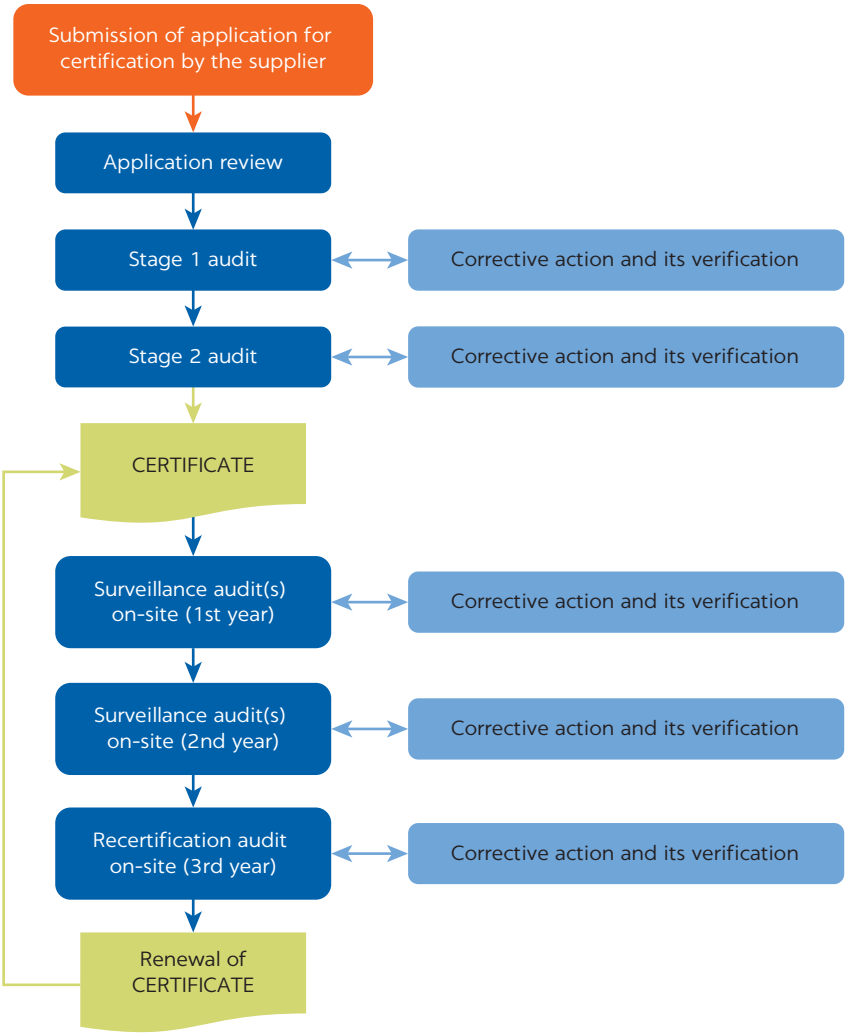
How can it be demonstrated?

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



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

- *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

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