

# Inspection

---

## 6.1 INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**TABLE 6.2** Building blocks of a country's inspection sector

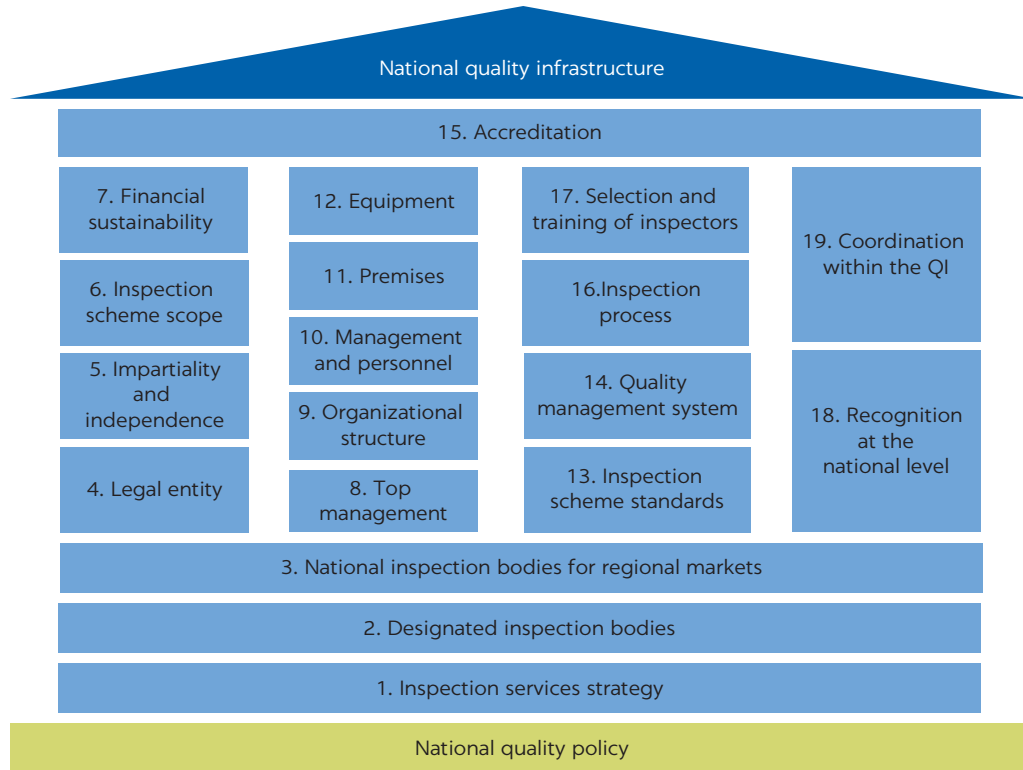
PILLAR	BUILDING BLOCK	
	NO.	DESCRIPTION
1: Legal and institutional framework, inspection services sector	1	Inspection services strategy
	2	Designated inspection bodies
	3	National inspection bodies for regional markets

**TABLE 6.3** Pillars and building blocks of an inspection body

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

Note: QI = quality infrastructure.

**FIGURE 6.1**  
**House of inspection for a national quality infrastructure**



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

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

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

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

### 6.2.1 Benchmark and significance

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

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

## 6.2.2 Inspection services strategy (building block no. 1)

### **What is meant**

Major	<p>Following on from the quality policy (see module 10 of the QI Toolkit), an inspection services strategy gives meaning to the implementation of the quality policy regarding the establishment of technically competent inspection bodies in both the public and private sectors. The inspection services strategy is about</p> <ul style="list-style-type: none"> <li>• Making the right choices regarding the overall approach to the use of inspection bodies in the country;</li> <li>• Providing technically competent inspection services within the public sector;</li> <li>• Getting the mix right between public and private sector inspection bodies;</li> <li>• Using accreditation (to ISO/IEC 17020) to demonstrate the technical capability of inspection bodies in both the public and private sectors;</li> <li>• Designating the private sector inspection bodies providing services in the regulatory domain;</li> <li>• Using inspection services in government purchases; and</li> <li>• Building capacity in inspection bodies, especially the training of inspectors, to provide required inspection services in the most innovative, effective, and efficient way.</li> </ul>
-------	--

### **How can it be demonstrated?**

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

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

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

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

***Existing information/reporting/monitoring***

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

**6.2.3 Designated inspection bodies (building block no. 2)**

***What is meant***

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

***How can it be demonstrated?***

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

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

***Existing information/reporting/monitoring***

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

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

***What is meant***

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

**How can it be demonstrated?**

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

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

**Existing information/reporting/monitoring**

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

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

**6.3.1 Benchmark and significance**

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

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

**6.3.2 Legal entity (building block no. 4)**

**What is meant**

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

**How can it be demonstrated?**

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

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

***Existing information/reporting/monitoring***

- Relevant legislative instruments of ministries
- Relevant articles of incorporation

**6.3.3 Impartiality and independence (building block no. 5)**

***What is meant***

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

***How can it be demonstrated?***

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

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

***Existing information/reporting/monitoring***

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

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

***What is meant***

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

***How can it be demonstrated?***

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



**Existing information/reporting/monitoring**

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

**6.3.5 Financial sustainability (building block no. 7)****What is meant**

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

**How can it be demonstrated?**

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

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

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

**Existing information/reporting/monitoring**

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

**6.4 PILLAR 2: ADMINISTRATION AND INFRASTRUCTURE****6.4.1 Benchmark and significance**

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

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

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

### 6.4.2 Top management (building block no. 8)

#### *What is meant*

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

#### *How can it be demonstrated?*

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

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

#### *Existing information/reporting/monitoring*

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

### 6.4.3 Organizational structure (building block no. 9)

#### *What is meant*

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

**How can it be demonstrated?**

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

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

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

**Existing information/reporting/monitoring**

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

**6.4.4 Management and personnel (building block no. 10)****What is meant**

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

**How can it be demonstrated?**

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

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

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

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

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

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

**Existing information/reporting/monitoring**

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

**6.4.5 Premises (building block no. 11)**

**What is meant**

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

**How can it be demonstrated?**

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

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

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

**Existing information/reporting/monitoring**

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

**6.4.6 Equipment (building block no. 12)**

**What is meant**

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

**How can it be demonstrated?**

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

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

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

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

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

#### **Existing information/reporting/monitoring**

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

## **6.5 PILLAR 3: SERVICE DELIVERY AND TECHNICAL COMPETENCY**

### **6.5.1 Benchmark and significance**

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

### **6.5.2 Inspection scheme standards (building block no. 13)**

#### **What is meant**

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

#### **How can it be demonstrated?**

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

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

**Existing information/reporting/monitoring**

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

### 6.5.3 Quality management system (building block no. 14)

**What is meant**

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

**How can it be demonstrated?**

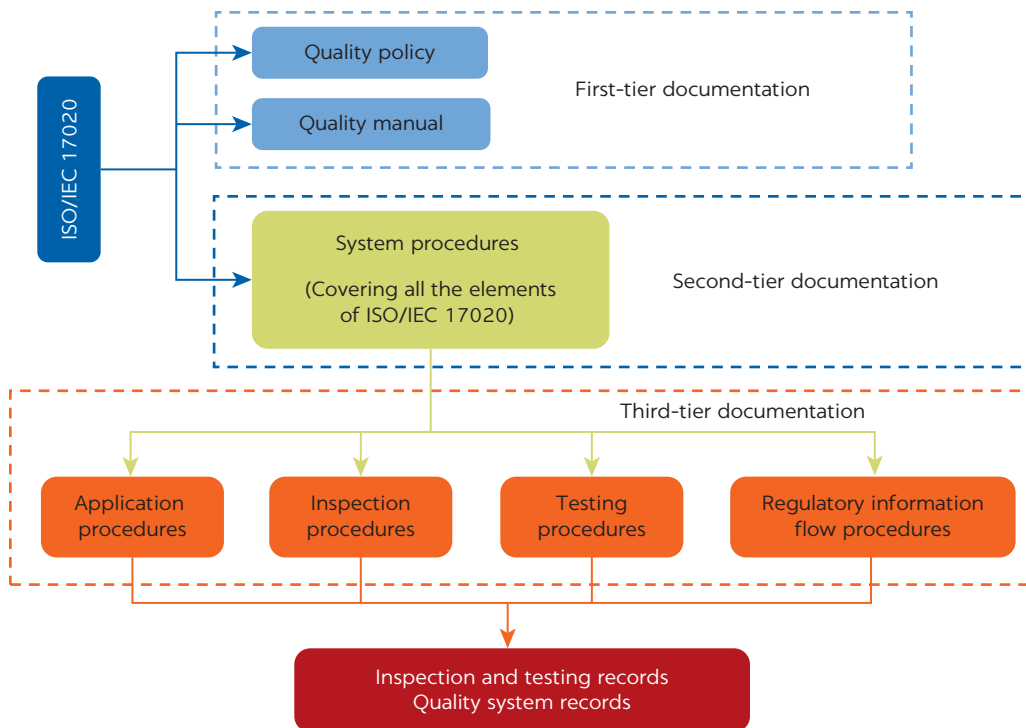
The inspection body has to implement and maintain a formal quality management system. It may be similar to the requirements of ISO 9001 (“Quality Management Systems—Requirements”), or it may be as detailed in the accreditation standard (for example, ISO/IEC 17020). The elements of such a formal quality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

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

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

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

**FIGURE 6.2**  
**Typical inspection body documentation system**



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

**Existing information/reporting/monitoring**

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

**6.5.4 Accreditation (building block no. 15)**

**What is meant**

Major	<i>Preassessment.</i> An inspection body may request a preassessment before an initial assessment is conducted to determine whether a formal quality management system is in place.
Fundamental	<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 inspection body is competent to conduct the inspection 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 inspection body receives an accreditation certificate carefully detailing its inspection scheme scopes, and its data are added to the publicly available information of the accreditation body.
Fundamental	<i>Designation.</i> Once accredited, commercial inspection bodies operating in the regulatory domain can request designation as such from the regulatory authority.

***How can it be demonstrated?***

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

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

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

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

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

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

***Existing information/reporting/monitoring***

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



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

### 6.5.5 Inspection process (building block no. 16)

#### ***What is meant***

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

#### ***How can it be demonstrated?***

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

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

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

#### ***Existing information/reporting/monitoring***

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

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

#### ***What is meant***

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

#### ***How can it be demonstrated?***

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

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

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

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

***Existing information/reporting/monitoring***

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

## **6.6 PILLAR 4: EXTERNAL RELATIONS AND RECOGNITION**

### **6.6.1 Benchmark and significance**

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

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

***What is meant***

Major

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

***How can it be demonstrated?***

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

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

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

**Existing information/reporting/monitoring**

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

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

**What is meant**

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

**How can it be demonstrated?**

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

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

**Existing information/reporting/monitoring**

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

**NOTE**

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

**STANDARDS REFERENCED IN SECTION 6**

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.

- . 2012. “ISO/IEC 17020: Conformity Assessment—Requirements for the Operation of Various Types of Bodies Performing Inspection.” 2nd ed. Ref. no. ISO/IEC 17020:2012(E), ISO, Geneva.
- . 2012. “ISO/IEC 17065: Conformity Assessment—Requirements for Bodies Certifying Products, Processes and Services.” Ref. no. ISO/IEC 17065:2012(E), ISO, Geneva.

## REFERENCE

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