7

Testing

7.1 INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

TABLE 7.3 Pillars and building blocks of a testing laboratory

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

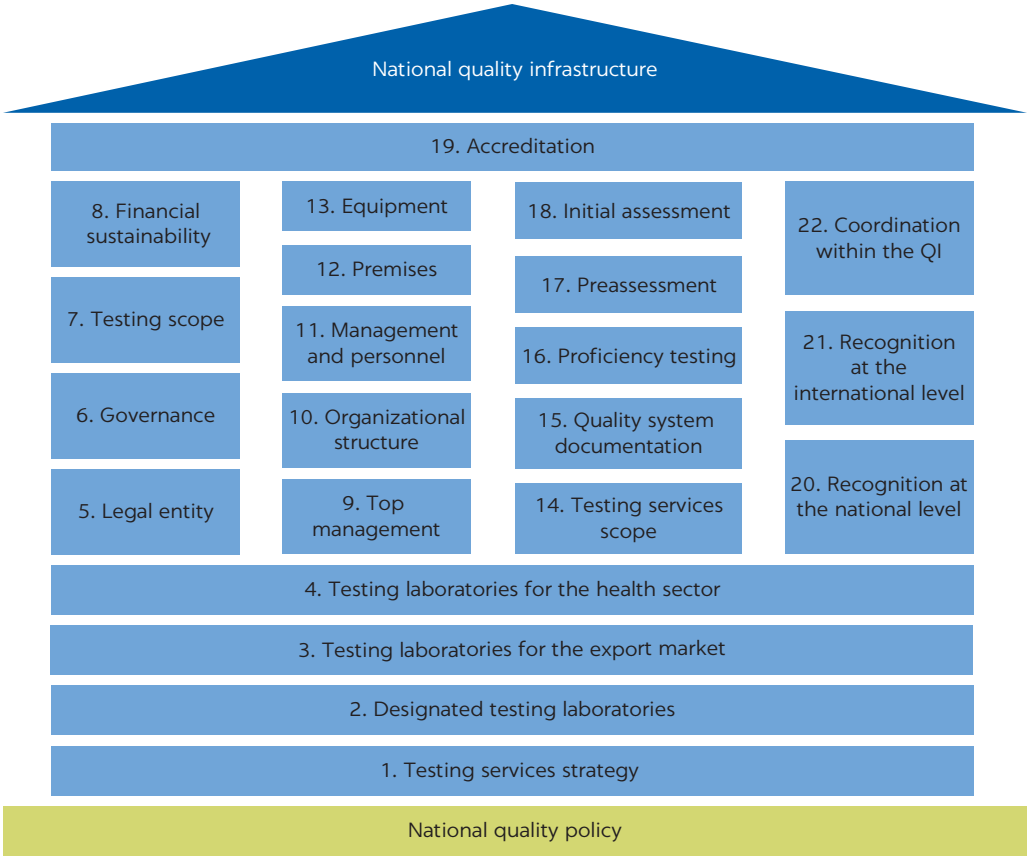
Note: QI = quality infrastructure.

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

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

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

FIGURE 7.1
House of testing for a national quality infrastructure



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

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

7.2.1 Benchmark and significance

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

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

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

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

7.2.3 Testing services strategy (building block no. 1)

What is meant

Major

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

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

How can it be demonstrated?

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

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

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

Existing information/reporting/monitoring

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

7.2.4 Designated testing laboratories (building block no. 2)

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring

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

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

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring

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

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

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring

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

7.3 PILLAR 1: LEGAL AND INSTITUTIONAL FRAMEWORK, INDIVIDUAL LABORATORIES

7.3.1 Benchmark and significance

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

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

7.3.2 Legal entity (building block no. 5)

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring

- Relevant legislative instruments of ministries
- Relevant articles of incorporation

7.3.3 Governance (building block no. 6)

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring

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

7.3.4 Testing scope (building block no. 7)

What is meant

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

How can it be demonstrated?

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

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

Existing information/reporting/monitoring

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

7.3.5 Financial sustainability (building block no. 8)

What is meant

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

How can it be demonstrated?

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

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

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

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

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

Existing information/reporting/monitoring

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

7.4 PILLAR 2: ADMINISTRATION AND INFRASTRUCTURE

7.4.1 Benchmark and significance

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

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

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

7.4.2 Top management (building block no. 9)

What is meant

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

How can it be demonstrated?

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

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

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

Existing information/reporting/monitoring

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

7.4.3 Organizational structure (building block no. 10)

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring

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

7.4.4 Management and personnel (building block no. 11)

What is meant

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

How can it be demonstrated?

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

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

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

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

Existing information/reporting/monitoring

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

7.4.5 Premises (building block no. 12)

What is meant

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

How can it be demonstrated?

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

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

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

Existing information/reporting/monitoring

- Review of laboratory accommodation in the light of defined requirements

7.4.6 Equipment (building block no. 13)

What is meant

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

How can it be demonstrated?

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

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

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

Existing information/reporting/monitoring

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

7.5 PILLAR 3: SERVICE DELIVERY AND TECHNICAL COMPETENCY

7.5.1 Benchmark and significance

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

7.5.2 Testing services scope (building block no. 14)

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring

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

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

What is meant

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

How can it be demonstrated?

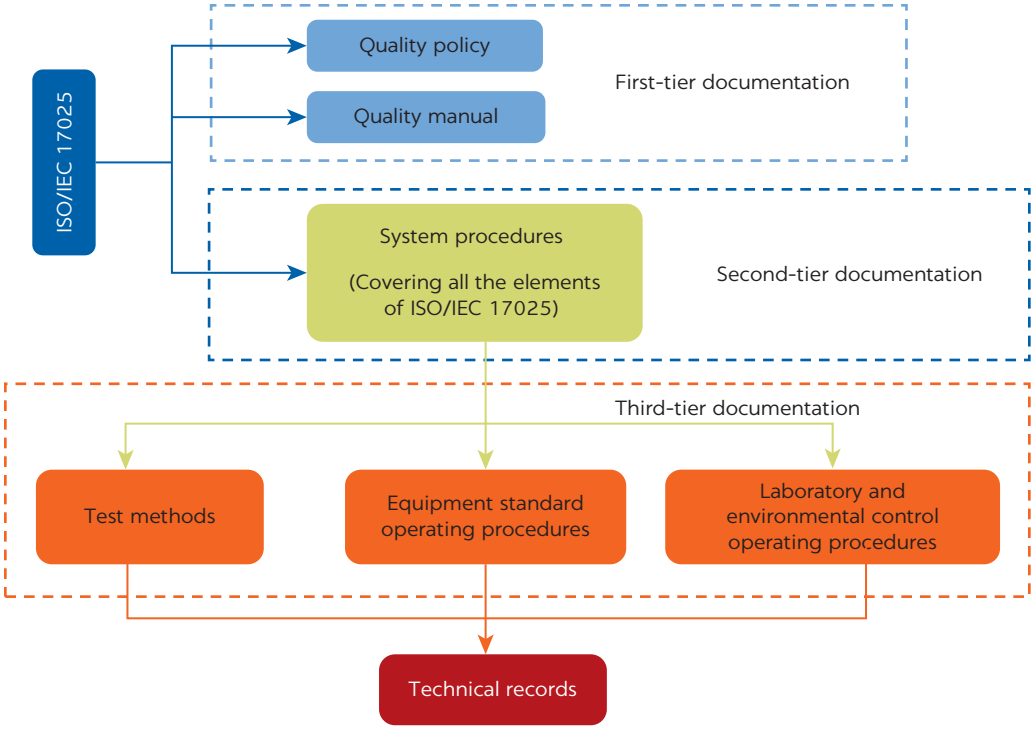
The quality management system documentation is generally organized on three tiers, generically known as policy documents, procedures, and work instructions. These are supported by records of the test reports or certificates, calibration records, internal audit records, management review records, and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

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

Existing information/reporting/monitoring

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

FIGURE 7.2
Typical testing laboratory documentation system



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

7.5.4 Proficiency testing (building block no. 16)

What is meant

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

How can it be demonstrated?

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

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

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

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

Existing information/reporting/monitoring

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

7.5.5 Preassessment (building block no. 17)

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring

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

7.5.6 Initial assessment (building block no. 18)

What is meant

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

How can it be demonstrated?

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

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

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

Existing information/reporting/monitoring

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

7.5.7 Accreditation (building block no. 19)

What is meant

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

How can it be demonstrated?

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

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

Existing information/reporting/monitoring

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

7.6 PILLAR 4: EXTERNAL RELATIONS AND RECOGNITION

7.6.1 Benchmark and significance

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

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

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

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

What is meant

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

How can it be demonstrated?

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

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

Existing information/reporting/monitoring

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

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

What is meant

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

How can it be demonstrated?

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

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

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

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

Existing information/reporting/monitoring

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

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

What is meant

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

How can it be demonstrated?

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

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

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

Existing information/reporting/monitoring

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

NOTE

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

STANDARDS REFERENCED IN SECTION 7

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

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