5

Accreditation

5.1 INTRODUCTION

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

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

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

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

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

TABLE 5.1 Pillars and building blocks of accreditation

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

Note: QI = quality infrastructure.

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

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

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

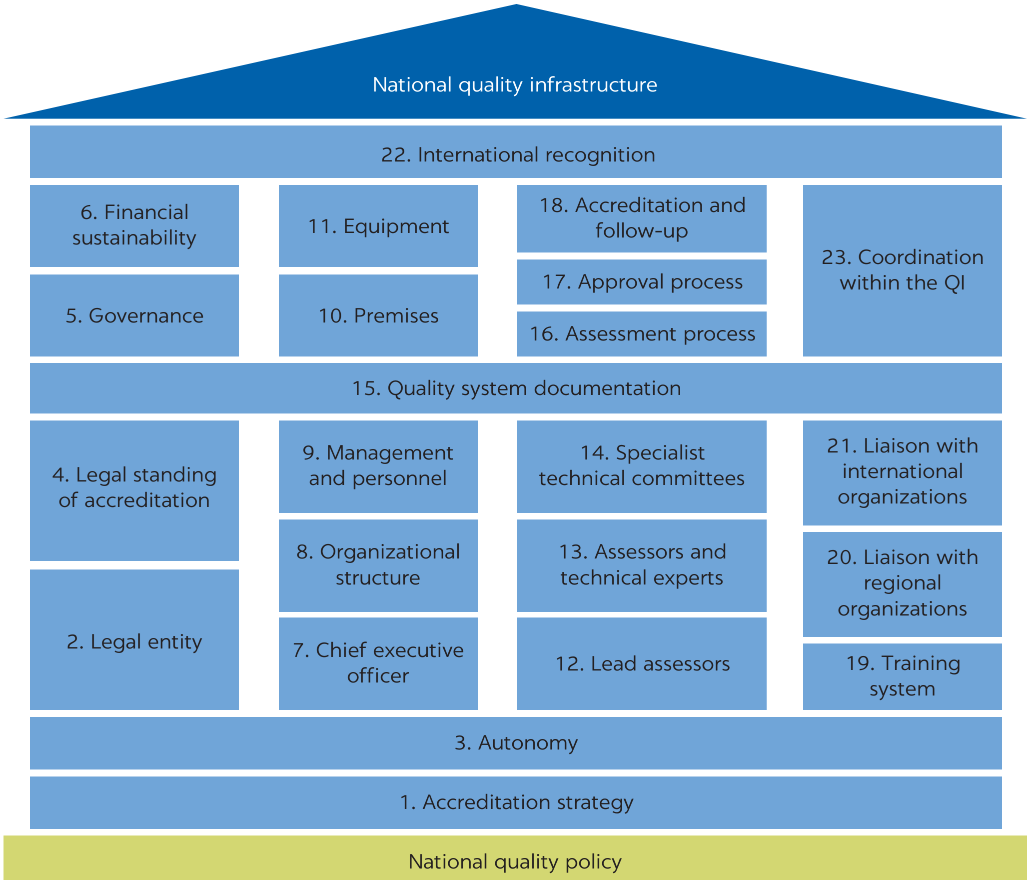
5.2 LEGAL AND INSTITUTIONAL FRAMEWORK

5.2.1 Benchmark and significance

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

FIGURE 5.1

House of accreditation for a national quality infrastructure



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

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

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

International recognition is obtained, in theory, through recognition by either ILAC or the IAF; signing of their multilateral recognition agreements; or arrangements after a successful peer evaluation process based on ISO/IEC 17011 ("Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies"). In practice, recognition is also dependent on the custom and practice of specific countries, especially because regulatory authorities are sometimes reluctant to accept ILAC or IAF recognition at face value. Because of the increase of accreditation bodies worldwide, many peer reviews are now arranged through recognized regional cooperation bodies or groups (not to be confused with regional accreditation bodies providing an accreditation service) rather than by ILAC and the IAF themselves.[1] Liaison with such regional groupings is therefore an important fundamental necessity where these exist; liaison with the international organizations can follow thereafter.

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

5.2.2 Accreditation strategy (building block no. 1)

What is meant

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

How can it be demonstrated?

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

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

Existing information/reporting/monitoring

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

5.2.3 Legal entity (building block no. 2)

What is meant

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

How can it be demonstrated?

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

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

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

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

Existing information/reporting/monitoring

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

5.2.4 Autonomy (building block no. 3)

What is meant

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

How can it be demonstrated?

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

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

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

Existing information/reporting/monitoring

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

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

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring

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

5.2.6 Governance (building block no. 5)

What is meant

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

How can it be demonstrated?

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

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

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

Existing information/reporting/monitoring

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

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

5.2.7 Financial sustainability (building block no. 6)

What is meant

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

How can it be demonstrated?

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

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

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

Existing information/reporting/monitoring

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

5.3 ADMINISTRATION AND INFRASTRUCTURE

5.3.1 Benchmark and significance

The organizational structure of the NAB or RAB must be conducive to providing the full complement of accreditation services that its stakeholders require. Good governance principles require the NAB or RAB to have a proper management executive, and the subject fields of accreditation suggest that the NAB or RAB should have divisions dedicated to accreditation services in these fields.

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

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

5.3.2 Chief executive officer (building block no. 7)

What is meant

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

How can it be demonstrated?

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

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

Existing information/reporting/monitoring

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

5.3.3 Organizational structure (building block no. 8)

What is meant

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

How can it be demonstrated?

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

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

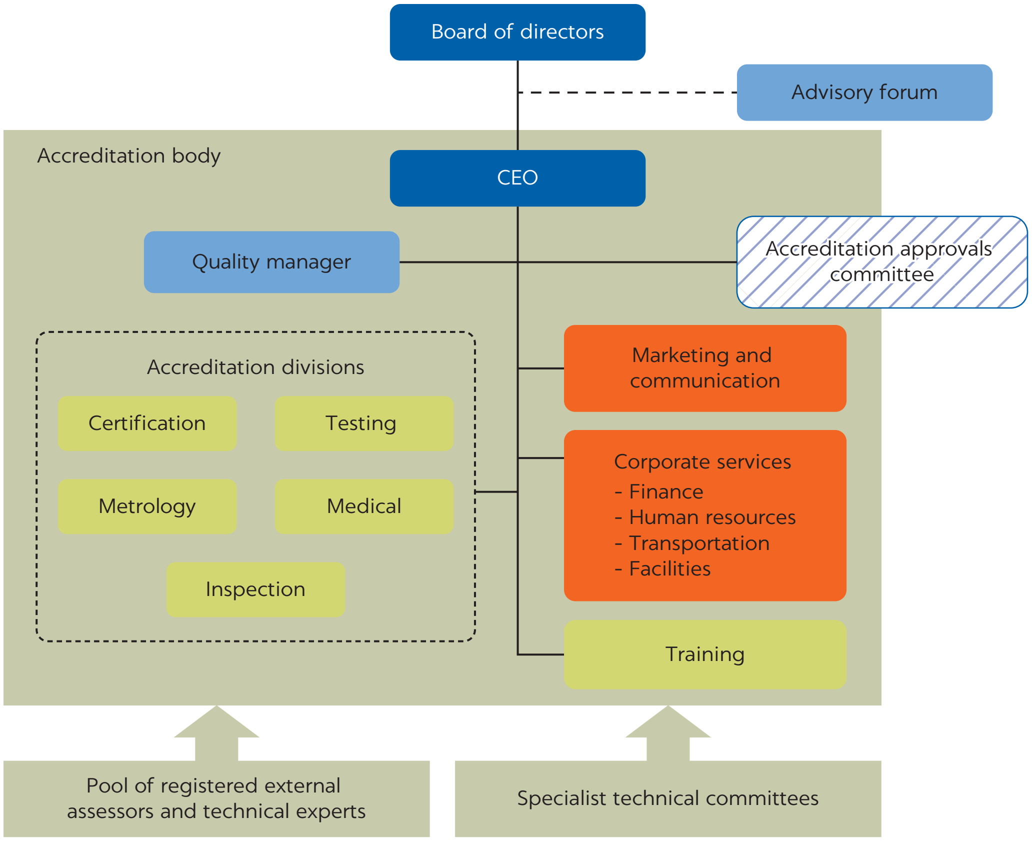
- *External assessors and technical experts.* The NAB or RAB seldom employs all the assessors and technical experts required as full-time staff and has to depend on a vast pool of external assessors and technical experts. These have to be managed, and the appropriate element within the NAB or RAB organizational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

Existing information/reporting/monitoring

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

FIGURE 5.2

Typical organizational structure of a national or regional accreditation body



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

5.3.4 Management and personnel (building block no. 9)

What is meant

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

How can it be demonstrated?

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

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

Existing information/reporting/monitoring

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

5.3.5 Premises (building block no. 10)

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring

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

5.3.6 Equipment (building block no. 11)

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring

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

5.4 PILLAR 3: SERVICE DELIVERY AND TECHNICAL COMPETENCY

5.4.1 Benchmark and significance

International recognition is a nonnegotiable fundamental for the NAB or RAB for its trade-related areas of activity; it is also good practice for the other areas, such as medical laboratories and so on. Without such international recognition, the NAB's or RAB's services will largely be inconsequential. International recognition is achieved by becoming a signatory of the ILAC and IAF multilateral recognition arrangements or agreements, respectively. Achieving signatory status is based on the positive outcome of peer reviews of the NAB or RAB by either ILAC or the IAF directly or through a regional coordination body or group recognized by them.

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

5.4.2 Lead assessors (building block no. 12)

What is meant

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

How can it be demonstrated?

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

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

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

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

Existing information/reporting/monitoring

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

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

What is meant

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

How can it be demonstrated?

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

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

Existing information/reporting/monitoring

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

5.4.4 Specialist technical committees (building block no. 14)

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring

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

5.4.5 Quality system documentation (building block no. 15)

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring

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

5.4.6 Assessment process (building block no. 16)

What is meant

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

How can it be demonstrated?

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

The assessment team is thereafter selected with an appropriate lead assessor and technical assessors. The team conducts a full on-site assessment to determine compliance with the relevant standard. Nonconformities are identified, and the organization is given a specified time frame in which to resolve them, after which they are reassessed. The team compiles a full report with a recommendation of accreditation. The report is submitted to an accreditation approvals committee for consideration.

Existing information/reporting/monitoring

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

5.4.7 Approval process (building block no. 17)

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring

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

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

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring
- Quality system documentation
- Database of accredited organizations
- Surveillance reports
- Reassessment reports
- Reissuance of accreditation certificate records

5.5 PILLAR 4: EXTERNAL RELATIONS AND RECOGNITION

5.5.1 Benchmark and significance

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

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

5.5.2 Training system (building block no. 19)

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring
- Training programs for lead and technical assessors
- Database of lead and technical assessors and their personnel records

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

What is meant

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

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

How can it be demonstrated?

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

- *Regional cooperation bodies or groups.* Because of the increase of accreditation bodies worldwide, many peer reviews for international recognition are now arranged through recognized regional cooperation bodies or groups rather than by ILAC and the IAF themselves. Liaison by accreditation bodies with such cooperation bodies or groups is therefore an important fundamental necessity. The situation regarding recognition of such regional cooperation bodies or groups by ILAC and IAF is fluid, and the latest information regarding the status of such bodies needs to be obtained from the ILAC and IAF websites.
- *Regional accreditation committees or forums.* Various regional accreditation constructs (committees, forums, and so on) have also been established as the outcome of trade agreements leading to regional common markets. In many cases, NAB or RABs are members by default, having to represent their countries in these regional constructs. Some regional accreditation constructs have full-time staff and premises; others are liaison-type committees with only a secretariat. Some are forums where a regional approach to accreditation is discussed and agreed to; others only coordinate accreditation development activities across the region. There is no one model that is superior to others (Kellermann and Keller 2014).
- *Regional accreditation service entities.* RABs providing accreditation services to smaller countries in the region covered by the relevant trade agreements are being established and are slowly gaining recognition through ILAC and the IAF. These are usually registered as not-for-profit private sector entities in one of the countries of the region. They are not membership organizations, but their governance may include representatives of the region. In the initial stages, they may be funded by the member states of the region. A country without an NAB can enter into a formal agreement with such an RAB to act as the de facto or in some cases even the de jure NAB. In some regions, member states establish accreditation focal points to act as a liaison between the RAB and entities wishing to be accredited, as well as to play a role in the training and registering of local assessors to be used by the RAB.

Existing information/reporting/monitoring

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

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

What is meant

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

How can it be demonstrated?

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

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

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

- *Automotive sector:* United Nations Economic Commission for Europe (UNECE) 1958 and 1998 Agreements, managed by the World Forum for Harmonization of Vehicle Regulations (also known as UNECE Working Party 29)
- *Electrotechnical sector:* The IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE) Certification Body (CB); Equipment for Use in Explosive Atmospheres (IECBx); and Quality Assessment System for Electronic Components (IECQ) schemes, managed by the IEC
- *Legal metrology equipment:* Mutual Acceptance Arrangements managed by the International Organization for Legal Metrology (OIML)

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

Existing information/reporting/monitoring

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

5.5.5 International recognition (building block no. 22)

What is meant

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

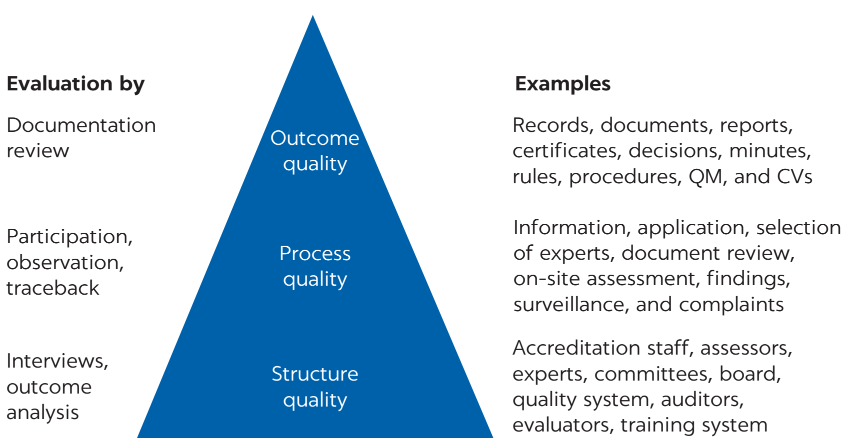
How can it be demonstrated?

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

Becoming a signatory is a long journey; it takes quite a few years. The NAB or RAB has to demonstrate compliance with the requirements of ISO/IEC 17011, and it must demonstrate that it can conduct assessments successfully. This is not so easy, because most organizations that wish to be accredited prefer to be accredited by an internationally recognized accreditation body. A newly

FIGURE 5.3

Evaluation pyramid for compliance with ISO/IEC 17011



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

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

Existing information/reporting/monitoring

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

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

What is meant

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

How can it be demonstrated?

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

Existing information/reporting/monitoring

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

NOTE

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

STANDARDS REFERENCED IN SECTION 5

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

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

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