5

Accreditation

INTRODUCTION

Of the three core elements of the quality infrastructure (QI), accreditation is a much more recent phenomenon than standards and metrology, having developed mostly after World War II. But accreditation has become as important as standards and metrology, especially in countries that are dependent on global trade, because of its facilitating role in international recognition systems for the services of the QI.

5.1 DEFINITION AND SCOPE

Accreditation in the QI context is the formal attestation or statement by an independent third party (the accreditation body) that a conformity assessment body or calibration laboratory is competent to carry out a specific conformity assessment task or calibration services. This statement is based on the positive outcome of a review determining whether the conformity assessment body or calibration laboratory fulfills the relevant criteria for its accreditation (ISO and IEC 2004).

From the point of view of conformity assessment, accreditation is applicable in the case of laboratories, inspection bodies, certification bodies, validation and verification bodies, and bodies that certify personnel. Accreditation has been practiced in laboratories since the 1940s. Users of laboratory services are therefore often familiar with accreditation and have a good understanding of its value. Accreditation of certification bodies is a more recent activity. This has come about in response to the extraordinary demand for certification and hence the need to demonstrate the technical competency of the certification bodies. Similarly, accreditation of inspection bodies is a recent and growing activity.

Generally speaking, the international standards of the International Organization for Standardization and International Electrotechnical Commission (ISO/IEC) 17000 series ("Conformity Assessment") have come to dominate the accreditation environment, but national standards or norms not harmonized with the ISO/IEC 17000 series are still used in some countries.

For international recognition, however, the application of the ISO/IEC 17000 series is very much an imperative.

Other international systems related to the QI that require accreditation include the following:

- *Good Manufacturing Practices (GMP)*, as defined by the World Health Organization (WHO), which are used by pharmaceutical regulators and the pharmaceutical industry worldwide
- *Principles of Good Laboratory Practice (GLP)*, as defined by the Organisation for Economic Co-operation and Development (OECD), which are applicable to nonclinical studies conducted for the assessment of the safety or efficacy of chemicals (including pharmaceuticals) to humans, animals, and the environment and have been introduced in many countries

Private sector certification systems based on private standards (see module 3: Standards, section 3.3) frequently use their own accreditation criteria to recognize conformity assessment bodies wishing to participate in the particular certification scheme. The same applies to the automotive industry: the vehicle manufacturers operate their own accreditation mechanisms to manage their suppliers.

Accreditation as a concept is also used in many disciplines other than conformity assessment—for example, the accreditation of universities, financial institutions, medical facilities, vocational training institutions, and so on. Although the concept of accreditation is similar to that practiced in the QI, these disciplines are not considered in this module; the standards and norms they use are different from the ISO/IEC 17000 series, for example. The scopes of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement) and Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) can also be considered for refining the scope of accreditation within the context of the QI.

5.2 INTERNATIONAL STANDARDS

The international standards published by the ISO and IEC dealing with accreditation are listed in table 5.1. As these are continuously updated, details on the latest issues should be obtained from the ISO. Accreditation of each type of conformity assessment body (CAB) is further discussed below.

5.2.1 Accreditation of QI services

Calibration laboratories. Accreditation has traditionally covered calibration laboratories (as discussed in module 4: Metrology) as well as, more recently, other supporting services for laboratories such as proficiency testing providers, reference material providers, and metrology research laboratories.

Testing laboratories. Accreditation initially focused on laboratories undertaking conventional testing of products and materials in biology, chemistry, engineering, and physics. The scope of accreditation is very specific and is expressed in terms of a combination of disciplines, products, tests, and standards. For example, a laboratory may be accredited for chemical testing of steel for carbon and various alloying elements by the methods described in a particular standard,

TABLE 5.1 Standards for the accreditation of common conformity assessment bodies (CABs) and calibration laboratories

TYPE OF CONFORMITY ASSESSMENT BODY (CAB)	INTERNATIONAL STANDARD FOR ACCREDITATION OF THE CAB	REQUIREMENTS AND STANDARDS FOR CAB CLIENTS
Calibration laboratories	ISO/IEC 17025:2017	Various measurement- and instrument-specific requirements
Testing laboratories (general)	ISO/IEC 17025:2017	Various measurement- and product-specific requirements
Proficiency testing providers	ISO/IEC 17043:2010	Providers of proficiency testing schemes
Producers of certified reference materials (CRMs)	ISO 17034:2016	The production and assignment of property values of CRMs
Medical laboratories	ISO 15189:2012	Various diagnostic tests
Inspection bodies	ISO/IEC 17020:2012	Various product and regulatory requirements
Certification bodies		
a) Quality management system	ISO/IEC 17021-1:2015	ISO 9001:2015
b) Environmental management system	ISO/IEC 17021-1:2015	ISO 14001:2015
c) Food safety management system	ISO/IEC 17021-1:2015	ISO 22000:2005 HACCP[a]
d) Product certification	ISO/IEC 17065:2012	Various product-specific requirements
e) Service and process certification	ISO/IEC 17065:2012	Various service- and process-specific requirements
f) Certification of persons	ISO/IEC 17024:2012	Various skill-specific requirements
g) Validation and verification	ISO/IEC 17029 (under development)	Various validation and verification requirements

Note: IEC = International Electrotechnical Commission; ISO = International Organization for Standardization; Listed ISO and ISO/IEC standards are further described among the references at the end of module 5.

a. Hazard analysis and critical control points (HACCP) is a systematic preventive approach to food safety from biological, chemical, and physical hazards in production processes that can cause the finished product to be unsafe. An international guideline is published by the Codex Alimentarius Commission (CAC/RCP 1-1969) that has been adopted as a national standard by many countries.

but the same laboratory may not be accredited for other methods. In recent years, the same principles have been applied to laboratory medicine (where the principal objective is diagnosis and monitoring rather than conformity assessment), diagnostic imaging (medical radiology and others), forensic science, and software testing.

Certification bodies. Accreditation for certification bodies in the early 1980s was originally concerned with product certification bodies whose scopes could be readily defined in terms of products and standards and in relation to performance or safety. Accreditation for certification bodies for management system standards was developed in the 1990s with the advent of ISO 9001 ("Quality Management Systems—Requirements"), and it became extraordinary successful. The definition of the scopes became much broader than the very precise definitions for laboratory work and product certification because they relate to general industry activities. Certification schemes for other system standards—such as ISO 14001 ("Environmental Management Systems"), ISO 22000 ("Food Safety Management Systems"), and hazard analysis and critical control points (HACCP)—followed.

Inspection bodies. Inspection bodies are the most recent type of conformity assessment service being subjected to accreditation. The significance of this accreditation is on the increase as government inspectorates in many countries are reduced and their activities are taken over by the private sector. In these situations, accreditation provides assurances of continuing competence and

is used by governments as an element in the recognition or designation of inspection bodies.

Certification of persons. Although not a conformity assessment service, certification of persons is considered part of the ISO/IEC 17000 series ("Conformity Assessment"), and international recognition is arranged through the International Accreditation Forum (IAF) recognition arrangements. This certification relates to the recognition of individuals possessing particular knowledge, experience, or skills and demonstrating the ability to apply those skills. These criteria are distinct from having acquired academic qualifications, although such qualifications may be a prerequisite for the certification process.

The process of personnel certification must be independent of the training programs leading to certification. The breadth and scope of certification programs today are tremendous; programs exist for safety professionals, nondestructive testing experts, supply and purchasing management professionals, the construction industry, quality system auditors, and many others.

Validation and verification bodies. Validation and verification is a confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. Validation and verification as conformity assessment are understood to be a confirmation of the reliability of information contained in claims. Other terms in use for the object of assessment by validation and verification are statement, declaration, assertion, prediction, or report.

Both activities are distinguished according to the perspective of each assessment regarding the timeline of the assessed claim. *Validation* is applied to claims regarding an intended use or projected effect (confirmation of plausibility). *Verification* is applied to claims regarding events that have already occurred or results that have already been obtained (confirmation of truthfulness).

5.2.2 Accreditation as the measure of competence and impartiality

The final objective of accreditation is to provide an independent view on whether the entity accredited is technically competent and impartial. Hence, over and above the management system documentation and controls that must be implemented, the technical competence of the individuals working in this entity is of paramount importance.

Likewise, the accommodation and environmental control requirements can be quite substantial, especially in the field of metrology. The controls are usually more stringent as the measurement, calibration, and testing accuracies increase. All of these will be assessed during the accreditation process.

5.3 UTILIZATION AND OUTCOMES OF ACCREDITATION

Accreditation has grown from its humble beginnings as just a measure of a laboratory's competence within a specific economy to a system with wide acceptance and use worldwide. The increase in trade of the past two or three decades demanded more certainty across borders regarding the integrity of conformity assessment results. Accreditation emerged as the vehicle to provide this

certainty, countering expensive and time-consuming reassessments every time a product enters a new market.

5.3.1 Users of accreditation

Governments. Accreditation is used by governments as a robust and credible framework to establish and enhance government-to-government trade agreements. These could be bilateral or multilateral negotiated agreements, or accreditation could be required as the precondition for the acceptance of conformity assessment outputs across member states of a common market. The long-term aim is the fully accepted use and recognition, by both the public and private sectors, of accredited conformity assessment services among the members of the agreements. In this way, the free-trade goal "inspected, tested, and certified once, accepted everywhere" is slowly being realized.

Regulatory authorities. Accreditation represents an internationally recognized "stamp of approval" of conformity assessment services used to demonstrate compliance of products with technical regulations and sanitary and phytosanitary measures. Credible accreditation schemes that are developed with due recognition of international standards are at the core of such acceptance. Such accreditation schemes can therefore help regulatory authorities meet their own legislative responsibilities in a globally accepted manner.

Businesses. Accreditation provides businesses that are producing goods and services with greater confidence in obtaining competent services from inspection bodies, laboratories, and certification bodies. Businesses can therefore select such suppliers from further afield, knowing they will receive services that conform to recognized standards of competency. Having products assessed and certified as conforming to a particular standard allows manufacturers and service providers to distinguish themselves from less reputable suppliers, thereby creating a competitive advantage. Accreditation also ensures that standards, specifications, and conformity assessment methods are the same, allowing one accredited certificate to be recognized worldwide. This lowers the cost of conformity assessment and reduces the risk of goods or services being rejected by international trading partners.

Consumers. Goods and services that have been tested and certified create consumer confidence if the conformity assessment is impartial and technically competent. Accreditation supports the notion that such testing and certification, from whichever country of origin, can provide trustworthy answers regarding quality and safety.

5.3.2 Outcomes of accreditation

Economy. Accreditation contributes to the overall development of the economy in that it helps open export markets to national industries, it underpins industrial development by strengthening competition, and it creates transparency in the markets by the clear description of competency scopes of accredited organizations. Accreditation also supports the implementation of anticorruption measures in that it requires of accredited organizations the traceability of results, annual audits, on-site assessments, peer evaluations, and management of records all along the process value chain.

Health and safety. Accreditation provides authorities and society with the assurance that services related to health and safety—such as medical laboratories, inspection bodies for occupational health and safety, inspection bodies for pressurized equipment, inspection bodies for lifts and escalators, and so on—are competent, thereby enhancing the safety and health of society as a whole. For medical laboratories, the ISO has published a specific international standard (ISO 15189, "Medical Laboratories—Requirements for Quality and Competence"), whereas other health- and safety-related services are handled by a combination of inspection and laboratory standards as relevant.

Environment. Environmental concerns are continuously growing, and many services are required by authorities, communities, and individuals regarding the efficacy of environmental protection measures. These could be inspection, laboratory, and certification services or a combination thereof. Accreditation assures authorities and communities that such services are competent, thereby underwriting the truthfulness of environmental protection measures.

5.4 IMPACT OF ACCREDITATION

5.4.1 U.K. Department for Business, Innovation, and Skills: The economics of accreditation

Attempting to estimate, in monetary or equivalent terms, the impact of accreditation presents considerable challenges because accreditation is an additional layer of assurance in a complex QI that could operate without it. A study conducted in the United Kingdom reached a number of indicative conclusions (Frenz and Lambert 2013). The research drew upon a wide spectrum of evidence, including published literature and case studies, interviews with experts in businesses and associations, empirical and statistical data, and a survey of United Kingdom Accreditation Service (UKAS) customers.

The report shows that accreditation provides assurance of technical and managerial competence and reliability across diverse parts of the economy, in both the market and public service sectors. The direct total cost to users was relatively low, but the leverage was high—that is, by supporting the QI, which in turn enabled higher-quality, more innovative, and safer economic activity.

There are multiple routes to economic benefit, and each shows a significant return on investment, although not all could be directly quantified. Commercial benefits to businesses, and to economic performance, arise through the promotion of innovation and productivity. It has been possible to arrive at an indicative quantification of these benefits, using information from the UKAS surveys:

- *In the market for the services covered by UKAS*, the immediate value to users—measured in willingness to pay and in-service quality—could be indicatively estimated at around £295 million per year.
- *Downstream effects on growth and productivity*—through support for both innovation-enhancing knowledge flows and technical and managerial efficiency—have been shown to be significant in estimated models of economic performance. These could be indicatively quantified as a further value of approximately £320 million per year.

Therefore, the measurable benefits of accreditation were estimated to be £600 million per year. Additionally, the following channels of impact could

be identified, although it was beyond the resources of the study to undertake the research and evidence gathering that would enable quantification. It would, however, be a plausible assumption that the totality of these benefits could be substantial, even though an educated guess at the order of magnitude was not possible:

- *Public health and safety* are advanced by accredited services in areas as diverse as diagnostic imaging, pathology laboratories, forensic testing, and the management of the risks from asbestos in buildings.
- *International trade* is enabled through the assurance of quality and reliability, while international mutual recognition of accredited testing and certification reduces potential barriers to trade.
- *Efficiency in industry* is promoted by accreditation support for the integrity of the national calibration and traceability hierarchy—the national measurement system (as discussed in module 4: Metrology)—which, among other things, leads to the avoidance of costs such as from waste and reworking arising from nonconforming measurement.

5.4.2 Technopolis Group and German Institute for Standardization: Development prospects for conformity assessment and accreditation in Germany

A research study on conformity assessment and accreditation in Germany was funded in 2012–13 by what was then the Federal Ministry for Economic Affairs and Technology (BMWi). The aim of the project was twofold: (a) to determine the economic importance of conformity assessment and accreditation, and (b) to identify the guidelines for future political involvement of the BMWi in this area (Technopolis Group and DIN 2013). The former determination was based on an analysis and forecast of the market for conformity assessment. Then, based on the conclusions regarding demand for the conformity assessment, demand for accreditation in selected areas was formulated. Two additional issues were also addressed:

- Which economic and technology areas should be part of the regulatory domain (for example, technical regulations, sanitary and phytosanitary measures, pharmaceutical regulations, and so on)?
- In which fields of the regulatory domain would a proof of competence through accreditation make sense?

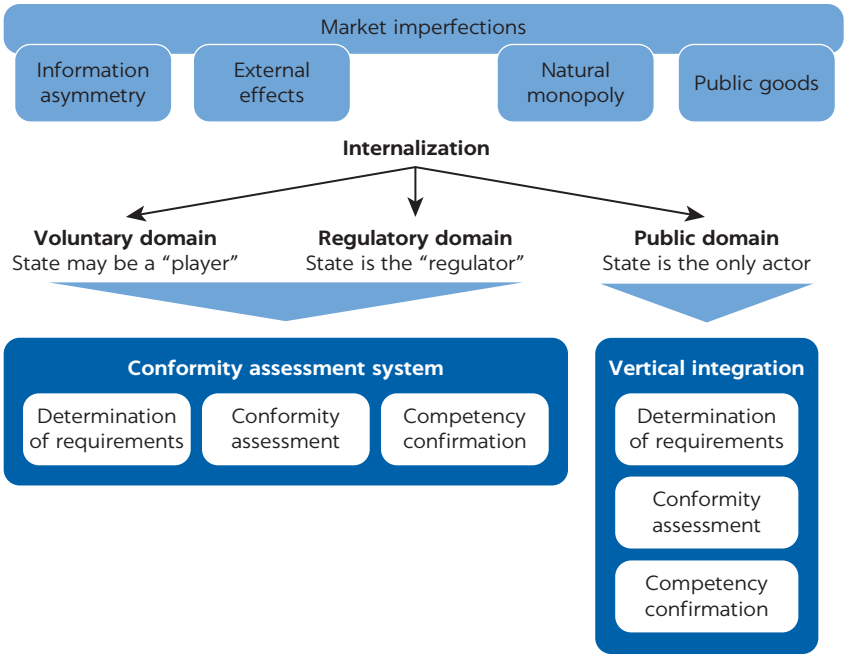
The Technopolis Group developed an economic model to determine or at least estimate the economic importance of conformity assessment and accreditation (figure 5.1). The elements of the conformity assessment system included the following:

- *Determination of the requirements* (for example, standards)
- *Conformity assessment*—that is, a demonstration that a product, process, system, person, or conformity assessment body meets specified requirements
- *Confirmation of the competence* of the conformity assessment service providers, which can be performed by public authorities or an independent accreditation body

In 2010, nearly 5,400 conformity assessment service providers were active in Germany, with a turnover of €8.8 billion. The study estimated that approximately €6 billion of this turnover was generated in Germany. About 3,300 of the service providers held one or more accreditation certificates of the German

FIGURE 5.1

The role of conformity assessment to address market failures



Source: Technopolis Group and DIN 2013. ©Federal Ministry for Economic Affairs and Technology (BMWi). Reproduced with permission from BMWi; further permission required for reuse.

Accreditation Body (DAkkS). But the economic importance of conformity assessment and accreditation is significantly higher because of their indirect effects:

- There is a "leverage effect" of the two instruments, because sales volume depends on them in the product and services markets. These are large multiples, estimated as a factor of 35–60 in conformity assessment, which translates to about 100 for accreditation.
- Public policy considerations show that many markets would not function at all or far less than optimally if conformity assessment and accreditation could not be used to address market imperfections.

As for the second objective of the study—to set guidelines for the future political activities of the BMWi in this area—two possibilities presented themselves in the regulatory domain: (a) shifting some of the voluntary domain sectors into the regulated domain, and (b) moving some of the public domain sectors (that is, the state conducting conformity assessment) into the regulated domain (that is, the state relinquishing conformity assessment but retaining regulatory authority responsibilities).

The latter could be construed as a type of deregulation. The German government should therefore evaluate its relevant public domain activities to decide whether the private sector's conformity assessment service providers could not take over the state's activities without compromising the health and safety of society in the process—that is, if and when the state's role changes to that of the regulator. On the other hand, moving voluntary domain activities into the regulatory domain should be contemplated only in specific cases where market imperfections or failures have resulted in demonstrable medium- and long-term health and safety risks that will not be addressed by the voluntary domain actors.

5.5 INTERNATIONAL AND REGIONAL RECOGNITION

Accreditation is considered one of the main facilitators for the recognition of conformity assessment results in foreign markets—expressed as "inspected, tested, and certified once, accepted everywhere." Hence international recognition, including regional recognition, is an important parameter for any national or regional accreditation body to pursue.

5.5.1 International recognition: The IAF and ILAC

The two major international organizations managing conformity-assessment recognition arrangements are the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF).[1] ILAC provides for multilateral recognition arrangements regarding accreditation of testing and calibration laboratories, medical laboratories, and inspection bodies. The IAF provides for them regarding accreditation of management system certification bodies, product certification bodies, and personnel certification bodies. ILAC and the IAF work closely together to ensure that no overlaps exist between their portfolios.

Accreditation bodies can become "associate members" (ILAC) or "accreditation bodies" (IAF) as a precursor to becoming signatories to the recognition agreements or arrangements. Signatory status is achieved only once a peer evaluation resulting in a positive outcome is conducted, based on the requirements of ISO/IEC 17011 ("Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies") and the related interpretation documents of ILAC and the IAF. The peer evaluations of accreditation bodies by recognized regional cooperation bodies or groups are accepted in full by both ILAC and the IAF (as further discussed in section 5.5.2 below, "Regional Recognition").

Signatories commit to (a) maintain compliance with ISO/IEC 17011 and the relevant IAF and ILAC interpretation documents, and (b) recognize the competence and impartiality of accredited conformity assessment bodies by all other signatories to the recognition arrangements. This facilitates the acceptance of the output of accredited organizations (for example, test reports, calibration certificates, and product- and management-system certificates), not only in the territories of all the signatories, but also worldwide. Such acceptance by other actors is not guaranteed; it still depends on the customs and practices of the markets and regulatory authorities.

Therefore, international recognition through the ILAC and IAF systems can be productively used by market actors and regulatory authorities to accept the certificates and results of conformity assessment bodies and laboratories that are accredited by accreditation bodies (even those in other countries) that are signatories to the relevant recognition arrangements. This, however, requires the market actors or regulatory authorities to engage positively with this international system; it is not a given that this must happen. The situation is strengthened if the governments involved formalize such recognition in a bilateral or multilateral recognition agreement. In regional common markets, such recognition is often provided for in the regional markets' legal instruments.

5.5.2 Regional recognition: Regional accreditation cooperation bodies and groups

At the regional level, a number of organizational types related to accreditation have developed over the past few decades that should not be confused. These consist of the bodies and groups involved in the recognition of accreditation bodies as well as the committees and forums established in common markets to harmonize accreditation issues (similar to the regional metrology organizations, as covered in module 4: Metrology, section 4.9). For regular regional accreditation bodies providing accreditation services, see section 5.6.

Owing to the increase of accreditation bodies worldwide, many peer evaluations for international recognition are now arranged through recognized regional cooperation bodies and groups rather than directly by ILAC and the IAF themselves.[2] Liaison between national accreditation bodies and these bodies and groups is therefore an important necessity. The situation regarding recognition of these bodies and groups by ILAC and IAF is very fluid, and the latest information regarding the status of such bodies needs to be obtained from the ILAC and IAF websites.[3]

At the time of this writing, six such bodies or groups were recognized, as it is these groups that perform most of the peer evaluation activities, no longer ILAC and the IAF (map 5.1):

- European Cooperation for Accreditation (EA), recognized by both ILAC and the IAF
- Asia Pacific Laboratory Accreditation Cooperation (APLAC), recognized by ILAC

MAP 5.1

Regional accreditation cooperation bodies and groups recognized by the IAF and ILAC, 2018

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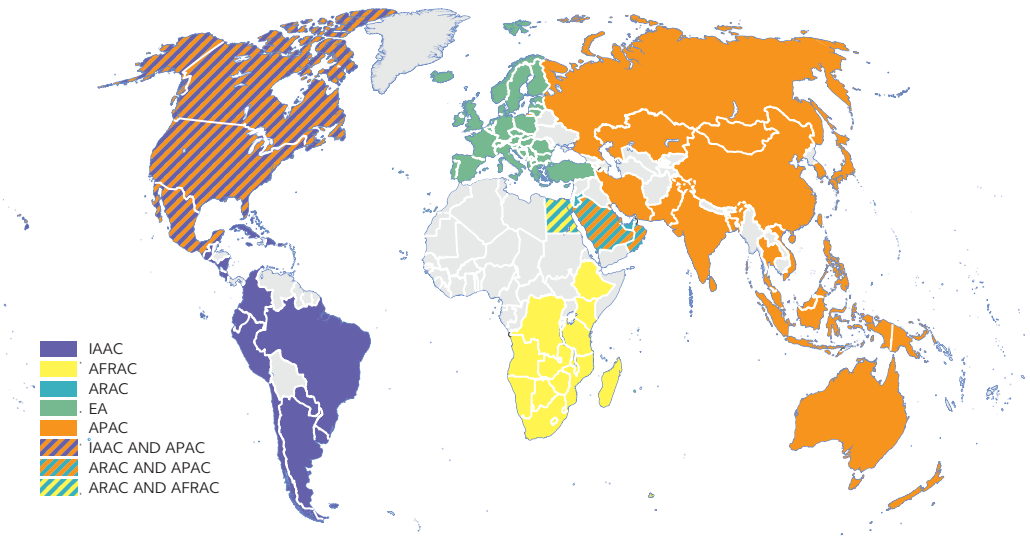

Source: World Bank, from ILAC and IAF membership data.
Note: The breakdown indicates countries whose accreditation bodies are signatories to multilateral recognition arrangements or agreements. Countries of nonsignatory members, e.g., associate members, are not included. Breakdown is as of January 2019. AFRAC = African Accreditation Cooperation; APLAC = Asia Pacific Laboratory Accreditation Cooperation; ARAC = Arab Accreditation Cooperation; EA = European Cooperation for Accreditation; IAAC = InterAmerican Accreditation Cooperation; IAF = International Accreditation Forum; ILAC = International Laboratory Accreditation Cooperation; PAC = Pacific Accreditation Cooperation.

- Pacific Accreditation Cooperation (PAC), recognized by the IAF
- InterAmerican Accreditation Cooperation (IAAC), recognized by both ILAC and the IAF
- African Accreditation Cooperation (AFRAC), recognized by both ILAC and the IAF
- Arab Accreditation Cooperation (ARAC), recognized by both ILAC and the IAF

In addition to the ILAC- and IAF-recognized regional cooperation bodies and groups, regional accreditation cooperations, committees, and forums have been established as the outcome of trade agreements leading to regional common markets. These common markets do not always coincide with the accreditation bodies and groups recognized by the IAF and ILAC. In many cases, NABs and RABs are members by default, having to represent their countries in these regional constructs. Some of these 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. Many of them coordinate their activities with the recognized IAF and ILAC regional cooperation bodies and groups.

5.5.3 Other recognition mechanisms

A number of sector-specific accreditation and recognition schemes are managed by organizations other than ILAC and the IAF, including these typical examples:

- *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 (IECEx); and Quality Assessment System for Electronic Components (IECQ) schemes, managed by the IEC
- *Legal metrology equipment:* Mutual Acceptance Arrangements (MAAs), managed by the International Organization for Legal Metrology (OIML)
- *Pharmaceutical sector:* Good Manufacturing Practices (GMP), managed by WHO
- *Environmental health and safety research facilities:* Principles of Good Laboratory Practice (GLP), managed by the OECD
- *Private sector standards:* Certification schemes based on private standards such as GLOBAL G.A.P., Fairtrade, the Forest Stewardship Council (FSC), the Marine Stewardship Council (MSC), and others (see module 3: Standards, section 3.3 on "Private Standards")
- *Food sector:* Establishment of Halal certification schemes in some Muslim countries, the certification bodies of which are accredited

All of these entities have their own scheme-specific requirements, and details can be found on their respective websites. National accreditation bodies can get involved in some of these (for example, GMP and GLP), but others are managed by the relevant private sector multinational certification organizations.

5.6 REGIONAL AND NATIONAL ACCREDITATION BODIES

Accreditation services are provided either by national accreditation bodies or regional accreditation bodies.

5.6.1 Regional accreditation bodies

Regional accreditation bodies (RABs)—organizations that provide accreditation services to smaller countries in a region established by a trade agreement—have been established in some regions and are slowly gaining recognition through ILAC and the IAF, such as Southern African Development Community Accreditation Services (SADCAS). 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. They may even be provided with funds from the member states of the region in the initial stages until they become self-sufficient.

A country without a national accreditation body can enter into a formal agreement with an RAB to act as the de facto, or in some cases even the de jure, national accreditation body. The RABs face some serious challenges in managing the logistics to service the extensive areas and multiplicity of the membership of such a regional common market—challenges that are exacerbated if language differences exist among member states. Sometimes, political issues and general distrust between members states get in the way. A further complication to be managed concerns the relations between the RAB and national accreditation bodies that may have been established in some of the member states.

5.6.2 National Accreditation Focal Points

In regions with an RAB, member states may establish national accreditation focal points (NAFPs) to act as liaisons between the RAB and entities wishing to be accredited. Furthermore, these NAFPs may play a role in the training and registering of local assessors to be used by the RAB to bring down accreditation costs for conformity assessment bodies in the smaller economies. In addition, they are often tasked with promoting the role of accreditation through awareness seminars, training of potential accredited organizations, and so on.

The focal point may be established in a relevant ministry (good option) or in the national standards body (not such a good option due to possible conflicts of interest). The role of NAFPs as liaison mechanisms is diminishing, however, because of modern communication links that result in entities wishing to be accredited communicating directly with the RABs.

5.6.3 National accreditation bodies

National accreditation bodies (NABs) provide accreditation services mostly within their countries, although some operate outside their national borders as well. There is no international agreement in place that would limit the number of accreditation bodies operating in a country, but it makes sense to do so (even though some governments may prefer to have more than one, each operating in a specific sector) for two reasons: First, every accreditation body has to obtain international recognition on its own. This is a costly process for the country unless the accreditation market is so big that it does not really matter.

Second, the question as to which one represents the country in international or regional forums could lead to some disquiet among the NABs and the government.

The EU required all member states to ensure that a single NAB be established for the implementation of technical regulations as of 2010. Germany, for example, had to merge nearly 20 accreditation bodies into a single NAB as a result.

To eliminate market uncertainty and competitive behavior among NABs that could compromise the accreditation process, many NABs sign agreements to keep out of the others' markets. In the Southern African Development Community (SADC), for example, the SADC Accreditation Service (SADCAS, the regional accreditation body) and SANAS (the South African National Accreditation Service) signed an agreement whereby SANAS would transfer all its accreditations that were outside South Africa but within SADC to SADCAS once SADCAS had achieved the appropriate international recognitions through the IAF and ILAC.

The same applies in the EU, where the NAB of one member state is not supposed to operate in the territory of another member state if both are internationally recognized. European accreditation bodies do, however, operate in countries outside the EU, but often transfer the accredited organizations to an NAB once it has achieved international recognition for the relevant scopes. In the United States, however, a limited measure of competition is tolerated.

Accreditation has become an important tool for the government in determining the technical capabilities of conformity assessment service providers. In general, governments are withdrawing more and more from direct inspection, testing, and certification activities in the regulatory field, transferring them to private sector operators. On the other hand, NABs could be public or private sector bodies. The legal issue that has to be managed is whether private sector bodies can operate with the required legal immunity in the technical regulation or sanitary and phytosanitary domain. This will depend on the legal system of the country; such immunity can be conferred on private sector bodies in some countries but not in others.

NABs and RABs can become signatories (that is, gain international recognition) for specific types of accreditation functions. The NAB or RAB does not gain a blanket international recognition through the IAF or ILAC. These are generally aligned with the international standards shown in table 5.1.

Becoming a signatory to the IAF or ILAC is a long journey; it takes quite a few years, even though the peer evaluation through regional bodies recognized by ILAC and the IAF is largely standardized. 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. The peer evaluation is conducted on three levels:

- *Documentation review*. Records, documents, reports, certificates, decisions, minutes, rules, procedures, quality manuals, curricula vitae (CVs) of auditors, and the like of the NAB or RAB are evaluated by the peer evaluation team for compliance with ISO/IEC 17011, ILAC, or IAF requirements.
- *Participation, observation, and tracing back*. The peer evaluation team observes the NAB or RAB assessment team during an actual assessment to evaluate their performance and to determine whether they follow the NAB or RAB procedures.

- *Interviews and outcome analysis*. The peer evaluation team interviews accreditation staff, assessors, experts, committees, board, auditors, and evaluators and checks the quality and training systems to determine whether the overall operation of the NAB or RAB has, as an outcome, accreditations that are trustworthy.

The time that it takes to get recognized is a challenge, because the companies seeking accreditation are looking for internationally recognized accreditation certificates. One way out of this dilemma is for the NAB or RAB seeking recognition to sign a "twinning agreement" with another NAB that is already recognized. The assessments are conducted by teams representing both, and the accreditation certificate may be issued jointly. They are considered adequate evidence of successful accreditations by the IAF and ILAC. Once the NAB or RAB is internationally recognized, it becomes the sole accreditation organization for the entities accredited, and the twinning partner relinquishes its certificates.

A related issue is whether the NAB should be an independent organization or whether it can be combined with others in the QI. The main challenge is to ensure that the accreditation body operates totally autonomously from any financial pressures and other services that could compromise its impartiality. Therefore, most countries opt for a totally independent NAB. In a few countries, a combination of the NAB with the national standards body is operational (for example, the Standards Council of Canada, Standards Malaysia, and the like). The important parameter that precludes a conflict of interest is that no conformity assessment and calibration services may be provided by the entity.

The accreditation body could lose its recognition status. This is possible should the accreditation body consistently no longer meet the requirements of ISO/IEC 17011 and the related ILAC and IAF documents. All accreditation bodies are evaluated from once a year to once every four years where such evidence could be generated. Another reason for losing its signatory status would transpire if the accreditation body fails to pay its ILAC and IAF membership fees. Both ILAC and the IAF try to get the delinquent accreditation body on board again rather than summarily and publicly rescind its signatory status. Eventually, however, when the accreditation body does not respond in a positive way, it will disappear from the official list of ILAC and IAF signatories.

NOTES

1. The term "multilateral recognition arrangement" is used throughout this section as a generic term for various forms of recognition agreements or arrangements without denoting a specific form thereof. ILAC uses the term "mutual recognition arrangement" (MRA) for its scheme, whereas the IAF uses the term "multilateral recognition arrangement" (MLA). The word "agreement" is sometimes reserved for intergovernmental agreements, but this practice is not universal.
2. Because these organizations cannot be named regional accreditation bodies (RABs), in that this would bring about confusion with RABs providing actual accreditation services, ILAC and the IAF have given the organizations different names. ILAC lists them as Regional Cooperation Bodies or Recognized Regional Cooperation Bodies, whereas the IAF calls them Recognised Regional Accreditation Groups.
3. For up-to-date information, see the ILAC "Recognised Regional Cooperation Bodies" web page (https://ilac.org/ilac-mra-and-signatories/recognised-regional-cooperation-bodies/) and the IAF "Regional Accreditation Groups" web page (https://www.iaf.nu/articles/Regional_Accreditation_Groups/130).

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