10

How to Reform: Interventions and Approaches

INTRODUCTION

Once the needs for quality infrastructure (QI) services have been clearly identified (as covered in module 2) and the elements of the QI have been mapped using the diagnostic tools (module 9), then the challenge is how to go about developing appropriate projects to close the gap between demand and supply regarding QI services. For the successful development of the QI, a policy environment that recognizes its importance, and through which its effective development can be guided, is of paramount importance. Hence, this module starts with the policy environment that must precede more specific interventions and approaches for each of the main QI service groups.[1] The reengineering of the technical regulation regime is as important in this respect as developing capacity in the QI. Completing this module are discussions about financing such developments, enabling innovation, and resolving conflicts of interest.

10.1 QUALITY POLICY AND STRATEGY

Many countries established national standards bodies (NSBs) in the wake of industrial development after World War II. These were mostly established by governments and then left to their own devices in accordance with the motto, "Standardization is technical, you are technical, get on with it."

These NSBs were given the responsibility to develop and publish national standards, with testing and certification services frequently added. Many times, they were also mandated to implement compulsory standards (a form of technical regulation)—in a way, a "one-stop shop" approach. Thereafter, other ministries and their agencies developed and implemented technical regulations as they saw fit as they sought to protect the citizenry and environment from harmful market failures or for political purposes such as protecting local industry from imports—the latter obviously being unacceptable in terms of the requirements of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement).[2]

Evaluations of the QI and technical regulation regime in many low- and middle-income countries in the past decade have confirmed this picture. With countries wishing to gain the maximum advantage from the developing global trade, this ad hoc and fragmented QI and technical regulation situation has to be streamlined, starting with the government creating a clear policy environment in this regard.

In general, a national policy can be seen as a set of interrelated government decisions concerning the selection of goals and the means of achieving them within a specified situation where those decisions, in principle, are within the power of the government to achieve. The private sector is an important partner in the implementation of the national quality policy (NQP), but without a policy environment conducive to the development of an effective and efficient QI, the private sector will be hard pressed to play its proper role.

From a practical perspective, the policy environment translates into the way in which the government converts its political vision into programs and actions to deliver desired outcomes or changes in the real world. Hence, developing an NQP starts with examining the underlying rationale for and future effectiveness of the QI and technical regulation regime. Thereafter, it is about deciding what needs to be done and how to do it as well as reviewing, on an ongoing basis, how well the desired outcomes are being delivered.

10.1.1 The policy environment

The NQP does not exist on its own. There are usually quite a number of policies already in place that contain references to standards, quality, and technical regulations. These policies typically deal with industrial development, enhancement of the export trade, environmental controls, food safety or security, science and technology development, and similar issues.

These references to standards, quality, and technical regulation do not relate to a holistic view of a national QI, nor do they provide guidance on a common approach to technical regulation; they focus on the specifics of that policy. The NQP should *link and coordinate* the policy measures relating to standards, quality, and technical regulation contained in all of these important policies.

10.1.2 Typical NQP content

The typical content of an NQP is listed in table 10.1. The following subsections then discuss some of the individual elements in more detail.

10.1.3 Review of current situation

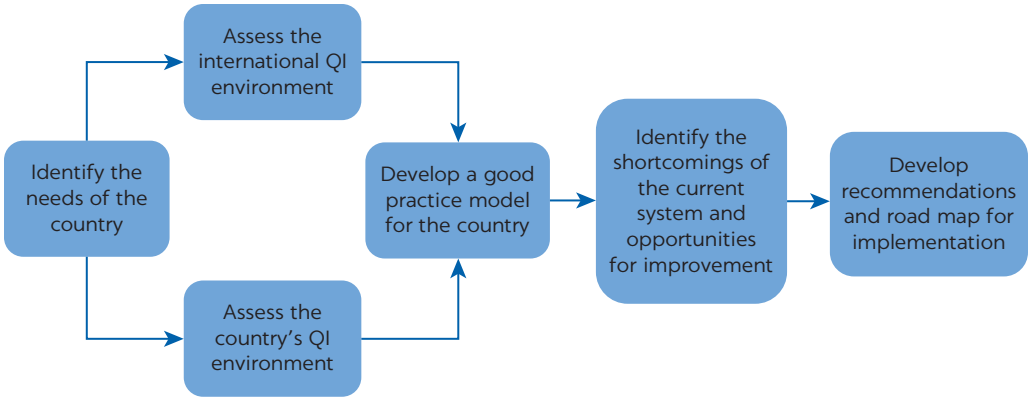
The current situation should be carefully mapped and considered in the light of international good practices and the demonstrable needs of the country. Often, an analysis of the strengths and weaknesses (internal) and threats and opportunities (external) of the current QI are also included. From this information, a gap analysis can be performed, which then leads to the policy objectives and policy measures (figure 10.1).

TABLE 10.1 Typical content of a national quality policy

NQP SECTION	SUBSECTIONS AND COMMENTS
Foreword	The relevant minister (for example, Trade and Industry) expresses political support for the implementation of the policy.
1. Introduction	• International and regional context • Trade as a driver for development and poverty reduction • Definition of the national quality infrastructure and technical regulation framework • Policy environment
2. Review of the current situation	• National quality infrastructure (QI) • Technical regulation framework (TRF) • Compliance with WTO TBT Agreement and related regional obligations • Gap analysis
3. Vision	• Where the country wishes to be in time (5 or 10 years)
4. Objectives of the NQP	• QI that meets country needs and is accepted internationally • A technical regulation regime common across all authorities compliant with international and regional obligations
5. The future NQI	• Organization and responsibilities of the NSB, NMI, and NAB • Provision of calibration, inspection, testing and certification services • Role of government in relation to the private sector
6. The TRF	• The necessity of regulatory impact assessments (RIAs) • Use of standards as the basis for technical regulation • Conformity assessment for regulatory purposes • Regulatory authorities, their responsibilities, and activities • Coordination of the technical regulation system
7. Education and training, awareness, and communication	• The role of tertiary education institutions • Registration of quality-system professionals
8. Information network	• National TBT Inquiry Point[a] • Cooperation with the trade promotion organization
9. Role of other stakeholders	• Private sector • Nongovernmental organizations • International development partners • Academia
10. International and regional liaison	• Liaison with international and regional organizations • Commitment for active participation in international and regional technical committees
11. Financing the NQI and TRF	• Government responsibility for standards, metrology, and accreditation • Conformity assessment: "user pays" principle • Technical regulation
12. Legal framework	• Review of current legislative instruments • Development of new legislative instruments
13. Implementation	• Lead ministry • The private sector as one of the key drivers of the NQP • Interministerial and private sector coordination committee • Implementation plan or strategy (five years)

Source: Adapted from Kellermann 2011.
Note: NAB = national accreditation body; NMI = national metrology institute; NQP = national quality policy; NSB = national standards body; QI = quality infrastructure; WTO TBT Agreement = World Trade Organization Agreement on Technical Barriers to Trade.
a. The TBT Inquiry Point is an official or office in a member government designated to deal with inquiries from other WTO members and the public on technical barriers to trade.

FIGURE 10.1
Process for designing the future QI



Source: Kellermann 2011. ©National Metrology Institute of Germany (PTB). Reproduced with permission from PTB; further permission required for reuse.
Note: QI = quality infrastructure.

10.1.4 Notes on recommended NQP content

Vision. Vision is considered as the future state of affairs that should be realized in a given time. Many low- and middle-income countries have established a fairly comprehensive vision regarding the development of the country, called "Vision 2030" or something similar, and supported by a variety of development policies. The NQP vision likewise should support such a national vision for the country.

Policy objectives. The policy objectives describe what is to be achieved for the benefit of the country, for society, or for the environment once the policy has been fully implemented. The objectives show the way toward the policy vision or goal. They may include new infrastructure, new systems, new processes or procedures, new knowledge, increased skills, better employment opportunities, or changed attitudes. It is good practice to limit the objectives to four or five main ones to avoid diluting the focus of policy implementation.

The future QI. The future QI must be clearly articulated—especially the fundamentals of standards, metrology, and accreditation—because these are basically government responsibilities in most low- and middle-income countries. If the country has had a QI for many years, it is fairly certain that it may have to be reengineered either partially or in totality. This may entail adjustments to current structure or even the establishment of new organizations. If the fundamentals comply fully with international good practices, then they should be reaffirmed. It is important to create confidence that the country will be well served in terms of these three fundamental QI services.

As for the provision of calibration and conformity assessment services, space should be provided for the development of market-related services, whether provided by public or private sector organizations. The main responsibilities of all the future QI organizations have to be clearly spelled out. In a more modern economy, the government will progressively withdraw from this sector, allowing the private sector to play an increasingly important role.

Technical regulation framework. The NQP should clearly articulate the government's desire to reengineer an ad hoc and fragmented regulatory regime.

It may already list some high-level measures that a technical regulation framework will comply with, including use of standards as the basis for technical regulations, provision of conformity assessment services by accredited and designated organizations, responsibilities of the regulatory authorities, performance of regulatory impact assessments (RIAs), and so on. The main policy measure would be the development of a definitive technical regulation framework that will eventually become law.

An important issue that needs policy guidance is the coordination of the technical regulation activities of the various regulatory authorities as well as their interface with the QI services. Many countries are considering the establishment of a coordination office or similar facility to ensure such coordination.

Education and training. QI services rely heavily on properly trained and experienced people. The policy should spell out how their competencies will be developed and what the roles of tertiary education institutions are in this regard. Some quality-system technologists, such as quality-system auditors and nondestructive testing technicians, have to be registered either internationally or within a national system. The policy measures regarding these should be elucidated.

Roles of other stakeholders. The roles and responsibilities of stakeholders other than the government should be clearly spelled out. These stakeholders would include the private sector and nongovernmental organizations (NGOs). The international development partners should also be featured strongly in the policy if the country is the recipient of such technical development cooperation. The main issue here is that such projects should support the implementation of the NQP instead of being geared to the "wants" of specific recipients.

International and regional liaison. International organizations exist for all three of the fundamental QI services—standards, metrology, and accreditation. In the case of the latter two, international recognition is gained through these international organizations. Most of the process to gain international recognition is operated through the relevant regional organizations. The policy should clearly spell out how the country envisages active participation in such organizations for the benefit of the country, not only in general assemblies, but especially in technical committee structures.

Financing the QI. This is an important element of the NQP, where the government commits to the funding of the fundamentals (standards, metrology, and accreditation) as "good for country" services. It should also be made clear that conformity assessment services should be market-related and paid for by the clients, including the government.

Legal framework. The QI fundamentals—that is, the organizations providing standards, metrology, and accreditation services—are mostly established by legislation, except where they are not-for-profit private companies. Such legislation is necessary to give legal certainty to the status of national standards, measurement standards, and the use of accreditation in conformity assessment for regulatory systems. The legislation may exist but may need review and revision, or it may have to be developed. All of these possibilities need to be clearly articulated in the policy.

Implementation. Responsibilities for the implementation of the NQP must be detailed, because nobody will undertake those responsibilities otherwise. This is

specifically necessary because the NQP is cross-cutting in relation to ministry sectors, and one ministry will have to be given the lead responsibility.

10.1.5 NQP development

Many countries have specific processes in place to develop government policy and to have them approved by the cabinet or parliament as relevant, and these must be followed when developing the NQP; otherwise, its approval may be compromised. However, it has been shown in many countries that a fully participative process before even starting to write the text is the most profitable approach. It is especially the private sector that needs to be intimately involved in its development, because it will have to implement many of the policy measures and finance even more of them.

The following steps for NQP development have been usefully employed in various technical assistance programs:

- *Assessment of the current QI system and technical regulation regime* of the country and their compliance or otherwise with international good practices
- *Seminars for the public and private sectors* to convey information regarding international good practices and the possible weaknesses of the national system
- *Separate workshops for the public and private sectors,* in which the needs of both the public sector (ministries and their regulatory authorities involved in technical regulation development and implementation, including those involved in sanitary and phytosanitary [SPS] measures) and the private sector (organized industry and business associations, major companies, NGOs, and so on) can be determined in a nonconfrontational way
- *Workshops combining both the public and private sectors* that may be contemplated
- *Development of a first working draft of the NQP* based on the information gleaned in the workshops and the assessment against international good practices
- *Circulation of the working draft* to the main interested parties (such as ministries, organized business, and industry associations) for comment
- *Collation and analysis of the comments* as well as one-on-one discussions with organizations raising substantive comments, to gain a better understanding of their positions
- *Updating of the working draft* to include relevant comments
- *Workshops with various stakeholders to validate the content* of the NQP working draft
- *Finalization of the draft NQP* before submitting it to the political level for approval—that is, the lead ministry, cabinet, and parliament (if required)

Once the working draft of the NQP is taking shape, it is useful to start the development of an implementation plan in cooperation with the various ministries, agencies, and QI institutions that will have to implement its measures. These discussions may also influence the content of the NQP in a positive way. This parallel development will eventually save a fair amount of time because in many countries a high-level implementation plan with a budget has to accompany the draft NQP in its journey through ministries and cabinet for approval.

10.2 REFORMING THE QI LEGAL AND INSTITUTIONAL FRAMEWORK

A review and revision of the QI legal framework is mostly a political process. The reengineering of QI institutions, on the other hand, is more complicated at the human level. Issues such as workplace, level of appointment, loss of influence, and many more play an increasing role as the level of reengineering rises. In some countries, this may entail discussions and negotiations with trade unions. Careful planning, with attention to the minutest details, as well as open and honest discussion with staff representatives is extremely important to prevent silent sabotage tactics or stalling of the process in courts of law.

10.2.1 Reforming the legal framework

In many countries, the fundamental QI organizations—standards, metrology, and accreditation—are government-type organizations established by legislation. In many cases, this legislation is quite a few years old owing to the reluctance of the institutions to start a review and revision process, because these processes take many years to be concluded. The result is that such legislation is out-of-date, does not contain measures important in a modern economy, and in some cases is no longer workable. This means that it requires urgent attention and renewal.

The review and revision of current legislation, as well as the development of new legislation, should follow the development and approval of the NQP because this would indicate the contents of the revised or new legislation. Each country has its own processes to develop draft legislation that should be followed. Whatever the final steps are to get the draft legislation approved by the ministry, then by the cabinet, and ultimately by parliament, a consultative process with stakeholders to determine content is an important start.

Where such QI organizations are private sector organizations, albeit registered as nonprofit organizations, legislation may still have a role to play. For example, whenever a private organization is given a role in regulatory affairs, this has to be governed by appropriate legislation. The government may confer regulatory mandates if the legal system of the country allows for it, or a contractual arrangement may exist between the government and such a private sector organization. Another example is that the national standards require legal standing, even though they may be developed by a private sector organization. These types of legislation and their outcomes must also be reevaluated from time to time to ensure that they remain up-to-date and that they serve the country in an appropriate manner.

10.2.2 Reengineering the institutional framework

Things get a bit more complicated if the institutional framework has to be reengineered. A typical example would be if the NSB loses its mandate to develop and implement technical regulations or mandatory or compulsory standards. In this case, the responsibilities and activities of the NSB must be transferred to a regulatory authority—either an existing one or a new authority that must be established. This will require a new set of legislation to start the process. The actual transfer will need to be carefully planned to ensure that the transitional period does not lead to an "anything goes" situation in the marketplace.

Experience would suggest that, in this example, the regulatory activities to be transferred should be reorganized in the NSB in a separate division or department, together with all the relevant personnel, long before the actual transfer takes place. In this interim period, the personnel will be able to stabilize, and new processes can be developed and implemented where necessary. When the transfer date comes about, personnel, equipment, and processes can be transferred as a complete package without much interruption to the new organization. Other examples could follow a similar trajectory.

10.2.3 Establishing a new organization

Establishing a new organization—whether a test laboratory, an accreditation body, or a regulatory authority—will have its own challenges, such as the following:

- A council or board has to be established, and it has to develop its own working procedures.
- A director or similar head has to be found and appointed, and then the required technical and administrative personnel have to be recruited and appointed.
- In most cases, intense training programs will have to be implemented to ensure that the new personnel are in a position to provide the required services.
- Quality management systems have to be developed and implemented in accordance with international standards from the relevant ISO/IEC 17000 ("Conformity Assessment") series or even ISO 9001 ("Quality Management Systems—Requirements") in the absence of the former. Ultimately, international recognition will have to be sought through accreditation or peer reviews.
- Appropriate premises have to be found and equipment purchased, installed, and commissioned. This is a task for the experts, especially in the case of laboratories, and less so in the case of organizations with mostly administrative functions.

In almost all of these cases, it does help if the country can gain the support of a similar organization in another country that is known to follow international good practices or is at a more advanced level of development. This support can be in the form of a consultancy, or "twinning arrangement," whereby the experienced organization seconds some of its personnel to help the new organization establish viable and effective systems or provides attachments for the new organization's people—that is, enabling them to work in the experienced organization for some time—to learn at the hand of existing, proven processes.

10.2.4 Reengineering the technical regulation regime

Establishing a new technical regulation regime is probably the most challenging institutional reform in the QI environment. Many countries operate a decentralized technical regulation regime, whereby each ministry is responsible for the development and establishment of technical regulations in its own sphere of responsibilities. These ministries and technical regulations may have developed their own ways over the years, and the differences may be quite large, over and

above the question of whether they make sense or are in compliance with WTO TBT Agreement requirements.

The implementation of a new technical regulation regime has to start with the promulgation of appropriate legislation in this regard. This must give legal standing to the technical regulation framework (see module 7: Technical Regulation, section 7.9.3, and section 10.7 below), the concepts of which should have been developed in a consultative manner among all the relevant ministries and their agencies as well as organized business and industry to give it the best chance of success. Thereafter, a detailed implementation plan, approved by the cabinet or a similar body, needs to be in place to ensure total support from all the affected authorities. The appropriate budget will also be required to be available. All of these steps demand clear and resolute leadership at the highest political and public administration levels.

To change the entrenched processes will take intense training on the new technical regulation processes (which includes the difficult "unlearning" of the old ways), establishment of new internal and publicly available procedures, and in some cases even new organizational structures. The support of an experienced development partner well versed in modern technical regulation regimes is a bonus. It is useful if a time limit is set for the changeover, after which the old technical regulations cease to exist. Otherwise, the process can drag on indefinitely as some authorities procrastinate, to the detriment of the country.

Such a reengineering of the whole technical regulation regime will require the appointment of a lead ministry, supported by a coordination committee representative of all the affected ministries and their agencies, to take overall responsibility for implementing the changes. The lead ministry and coordination committee should be accountable to the cabinet and report at least every six months on progress or otherwise, so that high-level decisions can be made to unblock institutional lethargy or address reluctance for change. As an alternative, a technical regulation coordination office with sweeping powers over ministries and their agencies in relation to technical regulation development, implementation, and maintenance can be established by legislation to spearhead such a process.

10.3 CREATING AN AWARENESS, INFORMATION, AND TRAINING CAMPAIGN

The QI could be seen as having a multiplicity of stakeholder groups, among which awareness needs to be created, information provided, and training programs offered. Creating understanding and a general awareness among producers and manufacturers about the benefits associated with supplying products that comply with standards and technical regulations is not an easy task. Moreover, the authorities will use the services of the QI only in developing and implementing regulations if the QI is fully trusted. For their part, consumers are continuously looking for a body that will ensure the quality of products and services in the marketplace, but it should not cost so much that businesses are unable to effectively use the services.

The QI certainly strives to satisfy these demands by delivering appropriate services, but more is needed. It also has to sensitize its stakeholders to the necessity and uniqueness of its services in a world that suffers from information overload. A proper communication strategy is required to reach the

relevant target audience with the appropriate message and to cleverly use the channels of communication. Such a strategy can emanate from the government or from the individual QI organizations, depending on the QI structure and government practices. Experience has shown that training in some of the QI service disciplines is a useful strategy to enhance awareness among specific stakeholders.

10.3.1 Developing a communication strategy

A communication strategy, once developed, should be reviewed at least annually to ensure it remains up-to-date. Some of the issues that need to be clearly thought through include the following:

- *Objective.* The communication strategy should have a key objective. There are many permutations possible regarding the communication channels, content, and stakeholders. The process of planning for this multichannel, multicontent, multistakeholder environment can become extremely complicated. A key objective to serve as the rallying point is therefore important.
- *Budget*. Communication requires a budget. Having a fixed budget is not a bad idea, as it focuses minds on achieving the maximum impact with the budget available.
- *Audience.* Targeting the appropriate audience is important, whether in the public sector, private sector, or society at large. The results from stakeholder mapping could be a useful source of information.[3]
- *Message.* The message needs to be articulated in a way that will grab the attention of the target audience. In a time-starved world, people will pay attention only to an idea or truth they cannot resist. This idea will help in deciding on the appropriate channel of communication.
- *Channels.* The channels of communication must be carefully chosen. Some of the possibilities include *media* (local, national, international, print, broadcast, web, social); *lobbying* (local and national government, funding bodies, special interest groups); *marketing* (brand, website, advertising, brochures, fliers, video); and *events* (conferences, launch events, public speeches, tours of building sites).
- *Synergy.* It is important that the chosen channels work together. Each channel will have a specific role in achieving the overall objective, but each one should be leveraged or supported by the other—that is, the whole should be greater than the sum of the parts.
- *Evaluation.* It is important to get feedback on the communication strategy's efficacy or otherwise. A multichannel approach is much more difficult to evaluate than a single channel for which the communication industry has developed metrics.

10.3.2 Creating awareness

In the QI environment, there are world days for standards, metrology, and accreditation. The international organizations provide communication materials for these events that are based on a specific theme each year. A successful awareness-raising event can be a national conference based on the theme, inviting foreign dignitaries from the IAF, ILAC, the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC),

the International Bureau of Weights and Measures (BIPM), or the International Organization of Legal Metrology (OIML), together with speakers from major national stakeholders. A keynote address by the relevant minister ensures that the local news media will be there in force.

If newspapers are still a major part of the communication world in the country, a weekly QI supplement that explains the need for effective and efficient use of QI services can reach the general population. Advertising on television is expensive, and if it is contemplated, the message must be carefully designed to ensure that it has impact and guides viewers to wish to seek more information. The publication of a new standard that may affect society widely may be launched at an event to which a wide variety of stakeholders are invited. The same applies to new metrology, accreditation, and conformity assessment services. New and appropriate legal metrology issues affect the consumer directly and are often the basis of good stories to use in creating awareness.

10.3.3 Disseminating information

Printed material should be developed that can be distributed in one-on-one discussions, meetings, conferences, visits, and so on. Practical guidelines for the implementation of standards and quality assurance systems in the small and medium enterprise (SME) sector help in the understanding of adopted international standards that require a specific level of knowledge not always in place in this sector.

The electronic media have become the most effective way to communicate. The importance of an effective and up-to-date website for the QI institution cannot be overemphasized. All the relevant information regarding the QI organization and its services should be available. A useful strategy is to link the websites for the bodies representing the three QI fundamentals—standards, metrology, and accreditation—in such a way that the viewer can migrate from one to another without having to do a search. The same applies to linking these with the website for the country's trade promotion organization.

10.3.4 Providing training

Technically skilled personnel are required in inspection bodies and laboratories, conducting quality management audits and accreditation assessments. In addition, manufacturers and suppliers need to be trained to implement quality management systems effectively and regulatory authorities to conduct risk-based market surveillance.

It is frequently QI organizations that have to provide such training. The appropriate training and technical support material has to be developed. The trainers have to be carefully selected; not everyone who is a skilled and knowledgeable technical person is a good trainer. It is useful to establish more technical training as a joint venture between the QI organization and a tertiary education institution such as a technical college. One provides the training expertise, the other the technical expertise. Registration schemes based on training and on-site evaluations for quality system auditors and assessors have to be established in line with international practices.

Anecdotal evidence would suggest that an effective training program for private industry frequently results in further conformity assessment business for the QI service provider. The multinational QI service providers are a good

example of this approach. The one issue that needs to be carefully considered is that such training must not become consultancy, which is a conflict of interest with the provision of conformity assessment services and which would result in the denial of accreditation.

10.4 DEVELOPING STANDARDIZATION FOR COMPETITIVENESS

This topic has two elements: One is the development of standards and their implementation to enhance the competitiveness of the local industry. The other—and the more likely scenario for low- and middle-income countries—is the enhancement of local industry's capacity to comply with the standards, including the technical regulations, of the more developed markets to render them more competitive in the home market as well as for exports.

Standards can support local industry competitiveness, in both respects, as follows:

- International standards describe the product requirements for international markets. National standardization can support their implementation by translating the international standards into the local language, reducing the standards' coverage and complexity to the product processing level of the country, incorporating local specificities (such as those requested by technical regulations), and developing guidelines and other products that support the implementation of the standards. The same applies to management system standards such as ISO 9001 ("Quality Management Systems—Requirements"); ISO 22000 ("Food Safety Management Systems—Requirements for Any Organization in the Food Chain"); hazard analysis and critical control points (HACCP); and others.
- National standards could describe the quality requirements for community products in local markets or for native products in local and international markets.
- National standards or guidelines could describe processes and methods to be followed to support the compliance of products with international standards.
- National standards or guidelines could describe processes and methods to increase productivity.
- National standards could support innovation (see section 10.10).
- International and national standards should be used as a basis for technical regulation, hence reducing inconsistencies and duplication between the voluntary system and the state-regulated system.

10.4.1 New standards and competitiveness

When establishing a standardization system, a low- or middle-income country's first priority is usually to publish the standards that are going to be used as the basis for technical regulations. That is also the driver for the development of regional standards, because technical regulations are the most frequent nontariff trade barriers to deal with. These national and regional standards are, more often than not, adoptions of international standards in compliance with the WTO TBT Agreement requirements, albeit with small variations to deal with local peculiarities.

Once this need has been satisfied to a large degree, the question then surfaces: What next? Can a low- or middle-income country develop an indigenous national standard for local products that is then recognized at the international level to give the local industry a competitive advantage, even for a short time? The standardization system realities would suggest that this scenario would be unlikely. The "making" of public standards recognized at the international level is controlled by the standards-making countries, and less so by low- and middle-income countries.

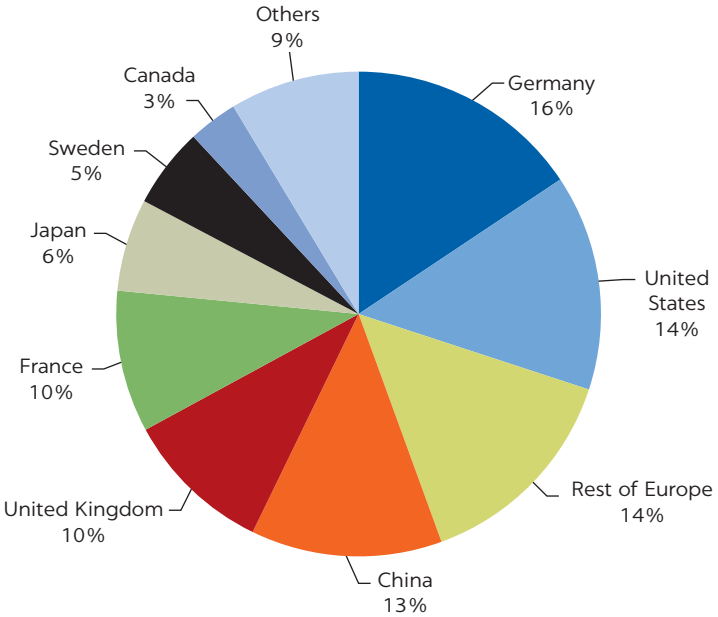
There are obvious exceptions, where indigenous standards that have been developed for purely local products have gained relevance in regional markets—for example, cassava, quinoa, Caribbean hot sauce, and other products in some African and South American countries. However, although more than 75 percent of ISO members are from low- and middle- income countries, the countries that hold the secretariats of the 246 active ISO technical committees (subcommittees are excluded from this data set) are dominated by the major industrialized countries.[4] Particularly, China, France, Germany, Japan, the United Kingdom, and the United States collectively control nearly 70 percent of the ISO technical committees (figure 10.2).

The second question under this "What next?" scenario is whether the NSB should adopt and publish the international or regional standards that will support innovative industries and foster higher productivity (see also section 10.9). These could be the standards published for quality management systems or emerging technologies, or they could be standards dealing with social issues such as environmental management, workplace safety—the list can go on and depends on the country realities and demands.

The answer depends to some extent on the language issue. International standards, such as those from the ISO and IEC, are usually available only in

FIGURE 10.2

Countries' control of ISO technical committees, by share of secretariats held, 2017



Source: World Bank, from ISO 2017 data.
Note: ISO = International Organization for Standardization.

English and French. The same applies to the private standards used in trade. ISO and IEC standards used to be available in Russian as well, but since the demise of the Soviet Union, they no longer are. Local entrepreneurs such as SMEs are not always well versed in these languages. Therefore, it is useful, if such standards are adopted as the national standard, to make them available in the local language. If English or French is well understood, the ISO and IEC standards may even be adopted as national standards in their original language but offered at a lower price to make them more accessible for the SME sector.

10.4.2 Compliance with standards to enhance industry competitiveness

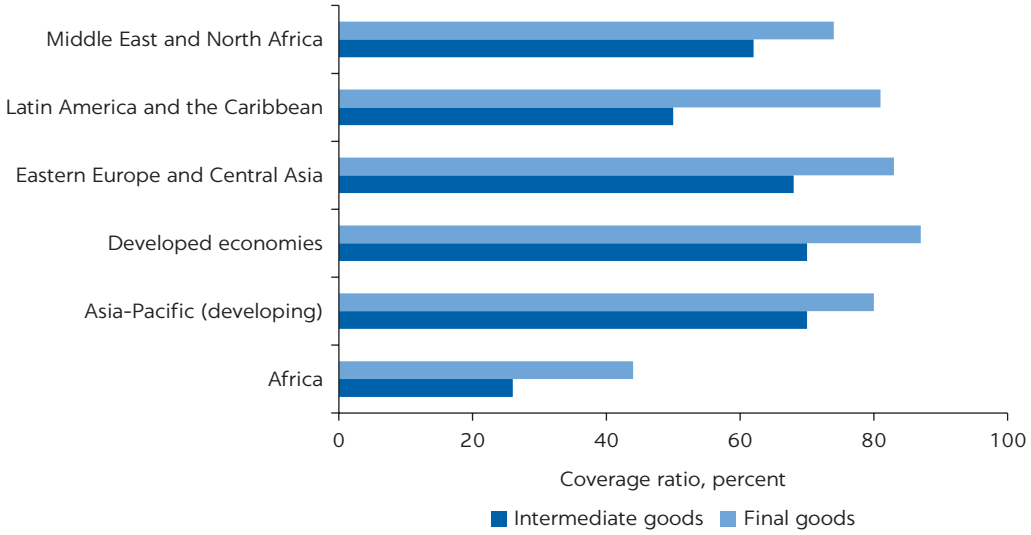
Standards and their mandatory counterpart, technical regulations, are pervasive, affecting economic operators throughout the production chain within the company as well as in national and global value chains. Any company wishing to place products or services on the market or trying to export will encounter them. Figure 10.3 shows just how pervasive technical regulations are in trade in intermediate and final goods in various parts of the world.

Capacities for compliance

If a manufacturer wishes to export, the important question is what the quality requirements are. It matters little to the manufacturer whether the requirements are contained in a technical regulation set by government; based on a national, regional, or international standard; or contained in a private standard with the concomitant certification providing access to the target market. The challenge is to meet the requirements.

FIGURE 10.3

Share of goods trade subject to technical regulation, by region, 2014



Source: ITC 2016.

Note: The "coverage ratio" is the share of trade subject to at least one technical regulation. The 2014 dataset used covered 53 economies, as reported by Franssen and Solleder (2016). The sample of "developed economies" included 25 European Union economies (treated as one economy, owing to identical trade regulations); Hong Kong SAR, China; Israel; and Japan. The sample of "Asia-Pacific (developing)" economies included Afghanistan, China, India, Nepal, Pakistan, the Philippines, and Sri Lanka.

Smaller and less productive firms find it harder to cover fixed costs to comply with standards and regulations. The same requirement represents a bigger obstacle to a low- and middle-income country's small firms, which are likely to have lower capacity to comply. The International Trade Centre (ITC) has found that when the frequency of regulatory or procedural trade obstacles increases by 10 percent, the value of exports decreases by 1.6 percent for large firms and by 3.2 percent for small firms (ITC 2016).

Impact of private standards

Private standards mainly aim at environmental conservation, ensuring food safety, protecting social and human rights, or promoting good agricultural and manufacturing practices (see also module 3: Standards, section 3.3).

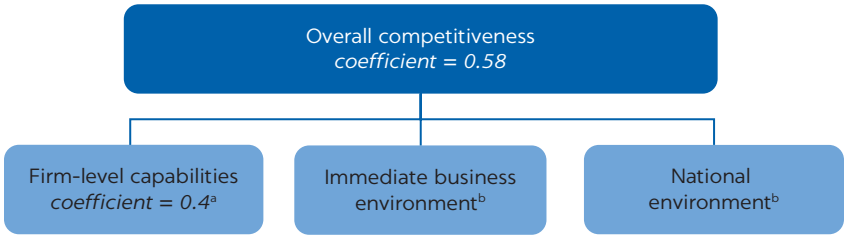
New research, based on 180 private sector standards worldwide, indicates that strong positive connections exist between the number of voluntary standards operating in a country and its gross domestic product (GDP), institutional quality, and logistics performance (ITC 2016). A country's SME competitiveness is also a strong predictor of standards' availability.

Among the factors influencing competitiveness (such as firm-level capabilities, immediate business environment, and national environment), firm-level capability is the variable most strongly associated with the number of standards operating in a country (ITC 2016). A 1.0 unit increase in the ITC firm-level capabilities score (on a range of 0–100) is associated with a 0.4 unit increase in the number of available standards (figure 10.4). The other two factors are not influenced meaningfully by the number of standards operating in the country.

Considering this high level of interdependence, the question is what comes first: the private standards operating in the country or the higher level of competitiveness of the SME sector? Certification bodies operate as commercial entities and choose the locations for their business operations based on where they can make a profit. This will happen only if the economy has a sufficient number of potential clients; that is, the competitiveness has to be established first. In general, one or two progressive companies in a low- or middle-income country may obtain certification from abroad, after which a market may develop, enticing the certification organization to set up shop in that country.

FIGURE 10.4

Influence of standards availability on factors in country competitiveness



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Note: Coefficients are based on a linear model explaining standards availability, controlling for GDP and income level (the only coefficients significant at the 10-percent level).
a. A 1.0 unit increase in the firm-level capabilities score (on a range of 0–100) is associated with a 0.4 unit increase in the number of available standards in a country.
b. Neither the immediate business environment nor the national environment is influenced significantly by the number of available standards in a country.

Advantages of global value chains

The ITC research indicates that compliance costs are lower for the more competitive economic operators, especially when they can become involved in global value chains (ITC 2016). When standards are set by companies, producers and other stakeholders (such as buyers in the supply chain) are more likely to share implementation and certification costs. This evidence suggests that when lead firms set standards, they are more likely to help defray some of the compliance costs that otherwise would be borne entirely by suppliers.

Accessing global value chains, however, is easier said than done (see module 2: The Importance of QI Reform and Demand Assessment, section 2.2.5). Lead firms have an incentive to look for the most suitable suppliers before entering into commercial relationships with them. Therefore, SMEs must be competitive to integrate successfully into such chains.

In view of this situation, during the initial QI reform period, SMEs will likely need some support through training, awareness raising, or financial levers such as tax breaks if they are to comply with the more stringent standards. Otherwise, there is a risk of pushing entire SME clusters out of the market. For more information on how to help SMEs meet higher standards, see section 10.9 of this module ("Enabling a Higher Quality of Domestic Products to Meet Standards").

Standards for enhancing the competitiveness of economic operators

To make standards work for trade and to reap the maximum benefits from trade opportunities, policy makers may focus on five areas:

- *Make information on standards and technical regulations accessible to firms.* Information on standards and technical regulations operating in target markets is not always easy to obtain. It is especially the SME sector, with limited capacity in this regard, that is most helpless. An effective standards information center and WTO TBT Inquiry Point are a good start.
- *Encourage and enable firms to adopt standards and comply with technical regulations.* Support in the form of technical consultancy and financial assistance (bonus system or subsidized fees) are avenues to explore.
- *Invest in quality assurance services.* The QI services must be available and affordable. They need to be internationally recognized.
- *Improve governance at home to facilitate border crossing.* This is a major challenge because the technical regulation regimes of many countries are fragmented, and costly overlaps are common. A common technical regulation framework, compliant with international good regulatory practices and acceptable to main trading partners, is an absolute necessity to enhance the competitiveness of local economic operators, especially in the SME sector (see section 10.2.4 above).
- *Leverage international mechanisms that facilitate trade.* These are bilateral and multilateral recognition agreements to get trading partners to accept national QI service outputs (see module 7: Technical Regulation, section 7.5.2, regarding technical regulations; and module 5: Accreditation, section 5.5.1, regarding accreditation systems).

Trade promotion organizations (TPOs) are likely to play a key role in such an action plan, notably because they are active in the technical infrastructure relevant for standards and regulations in many countries (ISO and ITC 2010).

10.5 STRENGTHENING METROLOGY AND ACCREDITATION

Metrology is highly technical, whereas accreditation is a more administrative type of operation. Both require highly skilled personnel and the implementation of formal quality management systems.

10.5.1 Metrology

It is an expensive and technologically demanding exercise to establish a national metrology system. At the top of the system, as a rule, is a national metrology institute (NMI) that is legally empowered to establish and maintain the national measurement standards, and thus (a) ensures their traceability to international measurement units, and (b) guarantees the dissemination of the measurement units to private and state institutions. Even if the NMI decentralizes its tasks, it remains accountable for the metrology system of the country; and in this case, the monitoring of the designated institutes now responsible for the various national measurement standards will place special demands on the umbrella organization.

The process of establishing a viable and internationally recognized metrology system consists of a number of essential elements, including the following:

- *Informed knowledge of the country's economy-related metrology needs* as well as regulatory-related demands in terms of measuring equipment subject fields and accuracy classes
- *Demonstrated relationship of the national measurement standards to the international measurement units* through accreditation mechanisms and ultimately through the determination of the country's calibration and metrology capabilities (CMCs)
- *Ensuring of the traceability chain* from the national measurement standards to state metrology systems (for example, legal metrology) and the private sector through appropriate calibration systems
- *Integration into international and regional metrology organizational structures,* their expert committees, and interlaboratory comparison schemes as a mechanism for knowledge transfer and establishing the country's position as trustworthy regarding metrology

The development trajectory of a national metrology system can be usefully characterized as a basic stage, which develops into an advanced stage, ultimately culminating in a mature stage, as follows:

- *In the basic stage,* capacity is available in terms of a small range of equipment for measurements such as mass, length, volume, temperature, and pressure used in everyday activities in basic manufacturing, in processing plants, and in legal metrology.
- *In the advanced stage,* the range of equipment is extended as defined through economywide surveys and sectoral benchmarking at the international level, resulting in more sophistication, higher accuracy classes, and a broader scope of measurements.
- *In the mature stage,* high-level laboratory capacity is available to support the innovative sector of the country while maintaining the basic- and advanced-stage gains.

The metrology system of many low- and middle-income economies would probably hover somewhere between the basic and advanced stages.

Establishing even the basic metrology system is a long-term endeavor. Major challenges include the availability of appropriate laboratory space complete with the necessary environmental controls, the appointment and training of skilled metrologists, the sourcing and commissioning of measurement equipment, the establishment of a quality management system, and interlaboratory comparisons of the measuring equipment or alternatively the calibration thereof at an advanced NMI. A cooperation or twinning agreement between the fledgling NMI and an advanced NMI in another country is a profitable approach. Advanced and mature NMIs are generally ready to share their knowledge; for example, metrologists can be trained or attached to gain practical experience, and measuring equipment can be calibrated.

In the advanced stage, cooperation agreements between NMIs are equally valid. The focus, however, shifts to collaborative research projects and the development of more effective or more accurate measurement equipment and processes. As a mature NMI, the organization becomes the twinning partner of newly established NMIs. Most development projects will focus on establishing NMIs and supporting their quest to establish the first basic national measurement standards and initiate the calibration system. A few long-term projects may even take the NMI into the advanced stage.

A major challenge for development projects is the propensity of leading experts to replicate the high levels of accuracy they are accustomed to in their own institutes, not realizing that it is not needed by the low- or middle-income country and that the capacity to maintain such high levels of accuracy is frequently beyond the capabilities of the recipient country. This leads only to frustration and eventually the collapse of the established technical infrastructure.

By the same token, it is of vital importance that the technical capacity to maintain the newly acquired national measurement standards is established at the same time as getting the NMI off the ground. Failure to do so will eventually lead to the sad situation that the national measurement standards are no longer operational or properly calibrated—in other words, no longer useful.

10.5.2 Accreditation

A newly established accreditation body, whether at the national or regional level, faces a number of challenges:

- *Managing the start-up financing* (subsidies) in the first few years before its business has expanded to the point where the income from accreditation services covers costs
- *Finding lead assessors, system assessors, and technical assessors* with the relevant technical backgrounds who have been properly trained in accreditation processes and who have been evaluated in this respect and registered
- *Developing and fully implementing the quality management documentation* of the accreditation body, compliant with ISO/IEC 17011 ("Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies")
- *Designing and populating the website with all the relevant information* so that organizations seeking accreditation can prepare themselves properly and stakeholders seeking information on accredited organizations and their scopes can be informed fully

- *Gaining customers before it is internationally recognized* as a signatory of the ILAC and IAF multilateral recognition arrangements (potential customers are looking for an internationally recognized accreditation certificate)
- *Managing the process of becoming a signatory* to the ILAC and IAF multilateral recognition arrangements through peer reviews

This is a steep learning curve, and although it is possible for an accreditation body to deal with these challenges on its own, this will take quite a few years. Support from development partners that are well versed in accreditation matters is recommended because this can speed up the process appreciably and helps avoid costly and time-consuming mistakes. The development partner will be able to train assessors and monitor their performance, provide consultancy on developing and implementing the quality management system, assess the performance level and state of implementation of the elements required for international recognition, and conduct risk assessments to highlight deficiencies that may require political intervention.

Entering into a "twinning arrangement" with a more experienced accreditation body that has already been internationally recognized is a possibility that should be explored (see also module 5: Accreditation, section 5.6.3). The twinning partner not only provides information on proven systems, but also supports operations in a meaningful way. Assessments will be conducted by a team from both organizations, and a joint accreditation certificate may be issued. This gives the accredited organization a recognized certificate and helps the newly established accreditation body gain practical experience and a track record before it is peer-reviewed for international recognition.

Regarding financing, the setup and start-up phases would have to be financed by the government or a similar authority. In most cases, these financing arrangements would have to cover at least the years until international recognition is attained. To determine the fee structure, benchmarking against an accreditation body in a country of similar economic power provides good information. With this information, together with an understanding of the number of potential clients and the capacities of the accreditation body, the expected income can be deduced and a break-even point ascertained.

Of crucial significance is the understanding that initial assessments will generate a much higher income than the income from annual monitoring once organizations have been accredited. This results in much lower turnover after a few years, once the bulk of potential clients have been accredited. Developing new accreditation services (that is, for sectors not included in the start-up phase) can alleviate this to some extent.[5]

Becoming a signatory of the ILAC and IAF multilateral recognition arrangements is the final step for achieving international recognition. Anecdotal evidence suggests that this process can take five to seven years. The application process is well defined and includes a peer evaluation by teams established by ILAC and the IAF or a recognized regional cooperation body. The peer evaluation will include the witnessing of an actual assessment without the "twinning partner." The development partner will be able to conduct a pre-peer assessment evaluation, thereby highlighting last-minute issues that need correction.

10.6 SPECIAL CONSIDERATIONS FOR QI DEVELOPMENT PROJECTS

Whereas standards bodies and metrology institutes may require a certain basic infrastructure and operational systems before any specifics can be accommodated, this is generally not the case for conformity assessment service providers such as inspection bodies, test laboratories, and certification bodies. The scope of their services needs to be clearly defined before any capacity building or even their establishment is planned. The scope will be determined by the demonstrable needs of the country to support the private sector or the regulatory authorities (see module 2: The Importance of QI Reform and Demand Assessment). Some of the issues that need to be considered for developing capacity in this area are discussed below.

10.6.1 Whether to establish national or regional QI institutions

The establishment of full-fledged national QI institutions requires considerable investment and ties up resources on a long-term basis. For smaller low- and middle-income countries with limited financial means and a relatively modest demand for QI services, this may be neither feasible nor useful. Instead, the common use of a regional QI service provider may be the better approach. For an initial estimation of the extent to which QI capacities could be established at a regional level, it is useful to consider a clustering of QI services in terms of "cost" and "demand" criteria (Miesner 2009).

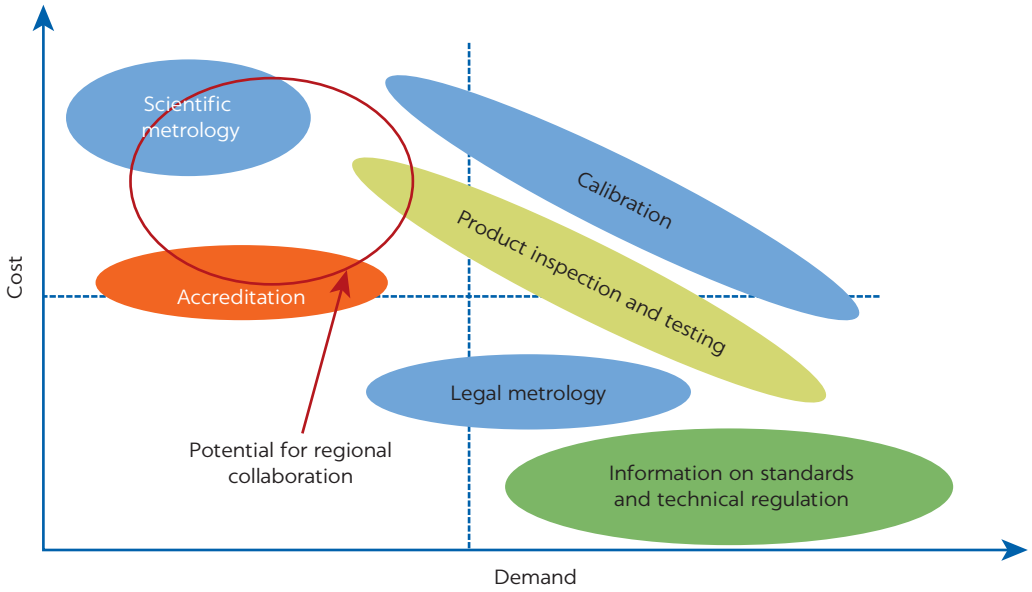
Figure 10.5 provides a conceptual picture of a region's QI services landscape, with the cost of the services on the vertical axis and the demand for such services on the horizontal axis. Smaller countries in the region may decide that the higher cost of establishing services such as scientific metrology is beyond their resource capabilities, in which case a regional structure would make sense. On the other hand, even a costly service such as calibration, because of the frequent uptake of such services, may warrant the cost of establishing such a service at the national level.

Hence, figure 10.5 indicates that even the smallest country should establish legal metrology and information services. For the implementation of legal metrology measures, a local presence is required. Legal metrology is a sovereign task of the state. This is also an area where the positive impact of even rudimentary (that is, cost-effective) measures will rapidly be felt by consumers. As for information systems, we are living in the information age. A well-designed standards information system will connect the country with international systems, thereby providing local industry and authorities with vital information on international standards and technical regulation information.

The areas of product testing and calibration contain a wide range of possible services that prevent a clear allocation, but inspection and testing for technical regulations (a high-demand area) may have to be provided for at the national level. High-end calibration and accreditation, on the other hand, are low-demand or low-frequency, high-cost services that are prime candidates for a regional approach. Before coming to a conclusion for a specific region, real data should be factored into the evaluation.

System certification is an area that shows a wide spread of cost versus demand or frequency. Establishing certification services such as Global G.A.P. (Good Agricultural Practice) or Forest Stewardship Council (FSC) are expensive, and the demand may not be that high at the national level; hence, a regional approach

FIGURE 10.5
Clustering of QI services by cost and demand



Source: Adapted from Miesner 2009. ©National Metrology Institute of Germany (PTB). Reproduced with permission from PTB; further permission required for reuse.
Note: QI = quality infrastructure.

may be indicated. On the other hand, ISO 9000 ("Quality Management System" series) type certification would be of great benefit to the SME sector. Establishing a local certification service would better serve this important sector, owing to lower costs, language issues, and better knowledge regarding local conditions.

Cost and demand are not the only aspects to be considered in deciding whether to establish regional or national QI institutions. Other aspects that could play a role include the proximity of service delivery to where it is needed, strategic interests, financial sustainability, availability of technical expertise, transportation logistics and rapid customs clearance for test sample movements, and national sensitivities. The last should not be dismissed out of hand; it may be that they are important to the recipient countries. A proper business case should be developed that carefully considers all of these before any national or regional organization is established.

10.6.2 Whether to support one organization or multiple ones

During the planning stage of development projects, it needs to be decided whether the capacity building will target only one organization or whether a whole group should become beneficiaries. This can be analogized to a balanced or unbalanced strategy. In the case of a central laboratory required for the testing of food products for the European Union (EU) market, for example, only one such laboratory is required in a low- or middle-income country, and the development project can be focused on that specific laboratory. If broad-based support for the domestic economy is required, it may be advisable to support the whole network of QI.

For example, if calibration laboratories should be the beneficiaries, it may be far more profitable for the country if a few calibration laboratories are supported, thereby avoiding a monopolistic marketplace. On the other hand, if a case could be made for developing the capacity in one laboratory

(for example, microbiological testing), external requirements may indicate that more than one laboratory is needed, such as one for testing fish for export and another for testing red meat for export because the European Commission has designated them so.

10.6.3 Whether to support multinational providers

A tough decision is whether to support capacity building in a multinational conformity assessment service provider, such as Global G.A.P., Fairtrade, or FSC. On the one hand, their presence in a low- or middle-income country may be a significant element in fostering exports; on the other hand, they have their own finances to do so.

A related issue that needs to be carefully considered in this case is whether supporting such a multinational provider will lead to a situation in a low- or middle-income country that binds trade to a system governed by a private standard, which may be detrimental to SMEs that would have difficulty in accessing services because of price pressures. The services of these multinationals do not always come cheap; they are in business to generate profits for their shareholders, after all.

10.6.4 Additional basic considerations

Avoid overcapacity. The major challenge for development partners is the "silo" mentality of ministries in a low- or middle-income country, a number of which wish to have their own capacity, when it would make much more sense if only one laboratory were established (that is, properly equipped, with technical staff trained and helped to gain accreditation) because of the limited amount of testing that is required. A lot of modern test equipment is designed to be operational most of the time to retain its accuracy, rather than switching it on once a week or twice a month for the little testing that comes its way. The inevitable result of setting up two laboratories, when one would be more than enough, is that both will run far below capacity, the financial sustainability of both will be compromised, and scarce human resources will be spread thinly—over and above the fact that the electronic equipment will become less accurate more rapidly.

Laboratory space and environmental controls. Test laboratories and inspection bodies need specific equipment with known measurement characteristics that functions optimally in a specific laboratory space. The equipment has to comply with specific environmental requirements (for example, temperature, humidity, freedom from dust, and lack of vibration). And the appropriate safety and health requirements (for example, for X-ray machines, handling of explosive gases, handling heavy test samples and materials, and so on) need to be considered. To specify such requirements, experts in the specific field should be consulted.

No laboratory space, no equipment. Without the necessary laboratory space with related environmental controls being available up front, it is bad practice to deliver equipment. The equipment cannot be commissioned, and many cases exists in low- and middle-income countries where such equipment has not been unboxed for years. When it is eventually commissioned, it is no longer up-to-date, or components have perished and cannot be replaced because parts are hard to come by, with the end result that the expensive equipment is basically useless—and scarce funding has been totally wasted.

Electricity supply. Electricity supply is a challenge frequently overlooked by development partners. In high-income countries, electricity supply voltage is fairly stable, at 230 volts ± 5 percent or 110 volts ± 5 percent. In low- and middle-income countries, this is seldom the case where variations of more than 10 percent are common and spikes of more than 100 percent are experienced, over and above the fact that electricity can become very intermittent—that is, the overload on the system leads to blackouts, sometimes for hours on end. Sensitive electronic testing and measuring equipment is not always able to operate accurately in these conditions, and projects must ensure that uninterruptable power supply (UPS) equipment is installed where required.

A related issue concerns the plugs that electronic equipment is frequently delivered with. For safety reasons, the plugs are an integral part of the equipment and cannot just be unscrewed and replaced with others if the standards for plugs and sockets in the low- or middle-income country differ from those of the supplier country. Removing the integral plug mostly results in the warranty becoming void, or worse, the wiring is stripped bare and pushed into sockets without a plug, thereby creating an unsafe condition.

Maintenance. A major issue to consider, and one often overlooked when providing sophisticated electronic equipment to low- and middle-income countries, is the availability of maintenance services. This challenge becomes even more pronounced when different donors provide equipment with similar functions but from different manufacturers. A better option would be if both donors were to provide the same manufacturer's equipment, thereby enhancing the possibility of a proper maintenance service being established in the country. In metrology, it may be good practice to also develop this capacity in the NMI as part of the project.

10.6.5 Proficiency testing

For complex testing regimes, proficiency testing (that is, interlaboratory comparisons) is frequently the only way in which the technical capability of a specific laboratory can be demonstrated. These comparisons can be part of the project design, and regional interlaboratory comparisons help alleviate the challenge of too few laboratories existing in the country to conduct them in a meaningful way.

Developing the ways and means to transport test samples across borders without having them tampered with by customs officials also is a major challenge. Sometimes the only way to do so is for technicians to take them across personally, together with very official government letters explaining the purpose of such samples. This holds true for samples for both calibration and testing laboratories.

10.7 STREAMLINING AND HARMONIZING TECHNICAL REGULATIONS WITH INTERNATIONAL STANDARDS AND TARGET MARKETS

Whereas compliance with standards is a voluntary decision, compliance with technical regulations is mandated by law, should the manufacturer or supplier wish to enter a specific market.

The harmonization of standards across economies is generally at an advanced stage because of the adoption of international standards by national

standards bodies all over the world. In low- and middle-income countries, it is not uncommon to find that more than 80 percent of the national standards are adoptions of ISO, IEC, or Codex Alimentarius Commission (CAC) standards, albeit sometimes with small changes to deal with local realities (for example, voltage variations of 10 percent rather than 5 percent in high-income countries).

Technical regulations are a totally different picture. Surveys in many low- and middle-income countries have shown that the country's technical regulation regime is fragmented and of an ad hoc nature, sometimes not even fully compliant with WTO TBT Agreement requirements if the country is a WTO member. The various ministries and their agencies develop and implement technical regulations in a manner they see fit, frequently without even considering their compliance with WTO TBT Agreement requirements. The technical requirements contained in these technical regulations are often not based on international standards either; they are local developments with major differences from the international standards.

The net result of such situations, which have developed organically over many years, is that trade is hampered by the multiplicity of regulatory approaches, overlaps between regulatory authorities regarding specific products, different technical requirements imposed by the different authorities, less-than-transparent compliance systems, regulatory fees payable to more than one regulatory authority for the same product, and many other impediments. The increase in transaction costs to the industry can be quite substantial, running higher than 20 percent in some cases, thereby compromising the competitiveness of the local industry relative to its international competitors.

To alleviate this problematic situation, some low- and middle-income countries have embarked on reviews of their technical regulation regimes, sometimes compelled into doing so as a result of bilateral trade negotiations with major trading blocs or countries. These major trading partners obviously wish to reengineer the technical regulation regime of the low- or middle-income country in a way that would be beneficial for their own exporters and importers. Such a country then has an unenviable decision to make: whether it will align its technical regulation regime with that of the one trading partner while maybe compromising trade relations with some of its other trading partners.

Unfortunately, these decisions are often fudged at the political level by not considering all the facts and risks—for example, wishing to sign such trade agreements as quickly as possible without fully understanding the long-term ramifications of their decisions or while being pressured by promises of massive technical development support. A typical example would be the alignment of the technical regulation regime for products falling within the narrow scope of the trade agreement while keeping the rest of the country's technical regulation systems intact. The result of such a decision would be the further fragmentation of the technical regulation regime to the detriment of the overall trade environment, thereby compromising the competitiveness of the country's own industry even more.

Another challenge arises when the sophisticated technical regulation regimes foisted in such a manner upon a low- or middle-income country presuppose a sophisticated QI and/or legal system that is totally beyond the country's capacity. As a result, the country readily accepts imports from the trading partner, but its export industry still finds it extremely difficult to penetrate the other trading partner's markets.

An appropriate approach would be to review the whole technical regulation regime, and if it needs to be modernized, to do so across the board (see module 7: Technical Regulation). It would be much more profitable all around to develop and implement a modern and transparent technical regulation regime, based on international good regulatory practices, that is consistently followed by all of its regulatory authorities and would satisfy most of its trading partners. If the low- or middle-income country is a member of a regional trade agreement, its obligations in relation to the regional obligations have to be factored into the decisions as well.

This is, of course, a much more involved reengineering exercise that would take years to complete. Hence many governments are reluctant to embark on such a massive undertaking fraught with potential political upheavals and backlashes from regulatory authorities that see no reason for change, often fearing for the safety of their jobs.

10.8 THE ROLE OF STANDARDS COMPLIANCE IN GLOBAL VALUE CHAINS AND FOREIGN DIRECT INVESTMENT

Global value chains (GVCs) and foreign direct investment (FDI) are important elements for industrial development. Local companies wishing to participate in GVCs or benefit from FDI will need to use QI services. GVCs and FDI can be instrumental in developing the relevant QI services where these do not yet exist, but there are differences between what GVCs and FDI can accomplish—differences that have to be taken into account when establishing QI development projects.

10.8.1 Global value chains

A value chain is considered to be made up of the full range of activities that are required to bring a product—from its conception, design, sourcing of raw materials and intermediate inputs, and manufacturing to marketing and distribution—to the final consumer (see module 2: The Importance of QI Reform and Demand Assessment, section 2.1.2). Some value chains operate across country boundaries (that is, at the global level) and are therefore known as global value chains.

GVCs make a significant contribution to international development (UNCTAD 2013). GVC-related value-added trade contributes an estimated 30 percent to the GDP of low- and middle-income countries—significantly more than the 18 percent in high-income countries. Furthermore, the level of participation in GVCs is associated with stronger growth of GDP per capita. GVCs can be an important mechanism for low- and middle-income countries to enhance productive capacity by increasing the rate of technology adoption as well as workforce skill development, thus building the foundations for industrial development.

There are, however, challenges for low- and middle-income countries associated with a GVC approach:

- GVCs' contribution to growth may be limited if the work done in-country is relatively low-value-adding (contributing only a small part of the total value added for the product or service).

- There is no automatic process that guarantees diffusion of technology, skill building, and upgrading. Low- and middle-income countries thus face the risk of operating in permanently low-value-added activities.
- GVCs have potential negative impacts on the environment and social conditions, including poor workplace conditions and suboptimal occupational safety and health systems.
- The value chain's "owners" can relocate their production (often to lower-cost countries) with relative ease, which create additional risks such as job insecurity.

Countries therefore need to carefully assess the costs and benefits of proactive policies to promote GVCs or GVC-led development strategies. Promoting GVC participation implies targeting specific GVC segments, and GVC participation can form only one part of a country's overall development strategy (see module 2: The Importance of QI Reform and Demand Assessment, section 2.1.2).

Once the decision has been made to embrace a specific GVC, then the infrastructure to participate needs to be put in place. Over and above the management, financial, and transportation-related challenges, compliance with the relevant standards and technical regulations becomes extremely important because the in-country part of the production needs to fit absolutely seamlessly into the global chain of production. Some of the QI-related elements that may be required include the following:

- *An in-depth study to identify the standards required for in-country production.* Such a study is vital to identify international standards and the national standards of other countries, all of which will be augmented by company-specific standards and specifications. Various technical regulations may also play an important part in the value chain and need to be identified.
- *Technical capacity to meet the identified standards and technical regulations.* Local industry may need to develop this capacity through training of the workforce and establishing testing facilities that need to be accredited. The provision of metrology capabilities in relation to national measurement standards and accredited calibration laboratories will feature prominently.
- *Certification of in-country manufacturers.* Manufacturers may need to be certified to ISO 9001 ("Quality Management Systems—Requirements"), for example, or to environmental management standards such as ISO 14001 ("Environmental Management Systems—Requirements with Guidance for Use"). In the food processing industry, certification to HACCP or a similar facility is required in most cases. A national certification body, suitably accredited by an internationally recognized accreditation body, has to be established if it does not yet exist, or such services have to be "purchased" from abroad.

An effective public-private partnership between the government of the low- or middle-income country and the GVC "owner" is a useful vehicle to implement the required QI services and to address the challenges described here. The GVC "owner" usually has the technical know-how to develop the particular QI services required in the country, even if it can access them abroad. Whether it *will* develop them in the country may differ from one GVC "owner" to another.

It would be useful if the government could provide political support and resources for the QI services' establishment and capacity development and get

the cooperation of the GVC "owner" in this respect to establish them as part of the local QI. Even development projects could consider this as a strategy. In this way, the transfer of technology, skill building, and upgrading becomes more sustainable. If the GVC "owner" then decides to move the in-country part of the GVC to another country, the low- or middle-income country may be able to lure other GVCs because of the availability of a recognized QI infrastructure specifically geared for such production.

10.8.2 Foreign direct investment

Foreign direct investment is an investment in the form of a controlling ownership in a business in one country by an entity based in another country. FDI is distinguished from portfolio foreign investment (the purchase of one country's securities by nationals of another country) by the element of control. Strategically, FDI comes in three types:

- *Horizontal:* The company carries out the same activities abroad as at home (for example, an automotive company assembling cars in both Japan and South Africa).
- *Vertical:* Different stages of activities are added abroad. "Forward vertical FDI" is where the FDI takes the firm nearer to the market (for example, a Japanese vehicle manufacturer acquiring a car distributorship in the United States). "Backward vertical FDI" is where international integration moves back toward raw materials (for example, a Chinese vehicle manufacturer acquiring a tire manufacturer or rubber plantation in Malaysia).
- *Conglomerate:* An unrelated business is added abroad. This is the most unusual form of FDI because it involves attempting to overcome two barriers simultaneously—entering a foreign country and a new industry. This leads to the analytical solution that internationalization and diversification are often alternative strategies, not complements.

10.8.3 GVC and FDI outcomes

There are many similarities between GVC and FDI outcomes at the operational level. The main difference is that, in the case of FDI, the foreign company has a controlling interest in the local company, whereas in a GVC this is not the case. A local company acquired through FDI can become a part of the GVC of the parent company; in fact, this is usually the driver behind such investments.

Once a foreign company has invested in a local company, it will not consider moving the in-country production part to another country as easily as would be the case if it just subcontracts. Hence, the sustainability of such foreign-owned companies may be higher than if they are local companies that have been subcontracted into a GVC. FDI may therefore facilitate more sustainability in the long term.

The challenges regarding QI services in companies established through FDI are, to a large extent, the same as those noted earlier for the GVC situations.

10.9 IMPROVING THE QUALITY OF DOMESTIC PRODUCTS TO MEET STANDARDS

A real desire of many low- and middle-income countries' governments is to enable manufacturers and suppliers to produce higher-quality domestic

products meeting international or just national standards. This is difficult to achieve without the wholehearted desire of the local industry to do so. Local industry, especially the SME sector, is able to sell its products to the local market on price rather than quality. Investing in the design, manufacturing controls, final inspection, and third-party testing and certification is not always at the forefront of its thinking. There are a number of approaches that have been used successfully in some countries, as detailed in the following paragraphs.

If the state purchases a vast number of products and services in all countries, a scheme whereby the government rewards SMEs for implementing and maintaining quality measures is a useful one to consider. A typical example would be that the state gives suppliers that provide products that demonstrably meet national standards (for example, carrying the product certification mark of the NSB) preferential treatment in the tender process. This means that their product can be a bit more expensive than the cheapest by a small percentage (for example, 2 percent), and they would still get the contract. The state gets products that are quality-guaranteed, and the SME gets reimbursed for its certification costs.

A second possibility is for the state to directly support the SME sector financially for implementing a quality management system such as ISO 9001 and then to defray some of the certification costs. A useful scheme to consider is one whereby the state pays back 50 percent of the certification costs once the company has been certified. If the company maintains its certification for another two years, then the state pays back another 25 percent. Providing such finances *before* certification does not work, nor does paying back the full costs when certified. There has to be an incentive for the company to maintain its certification.

A third possibility is a joint approach by a major private sector company such as a mining group and the NSB. The mining group pledges 10–15 percent of its purchases from SMEs. These have to comply with private purchasing specifications that are issued by the NSB or even by the mining company. The NSB then has a contract to inspect the production controls of the SME against requirements agreed to between the mining company and the NSB, in the process helping the SME to implement controls where they are lacking. The final products are batch-inspected and tested to ensure compliance.

In many countries, public procurement constitutes a major share of the market. Therefore, going beyond the SME sector, the role of government in public procurement can be leveraged to stimulate the quality of products at all levels and eventually inculcate a quality culture. Possibilities include (a) requiring compliance with standards in all state tenders; and (b) tax incentives for new technologies (such as solar heating or energy efficiency in housing) only if compliance with standards is proven.

In this way, the state can try and "pull" a sector toward compliance. For a scheme to succeed, it must have a financial or social benefit for the company to become interested and to maintain quality criteria once they have been implemented.

10.10 ENABLING INNOVATION

An innovation is defined generally by the *Oslo Manual* of the Organisation for Economic Cooperation and Development (OECD) and Eurostat as "a new or

improved product or process (or combination thereof) that differs significantly from the unit's previous products or processes and that has been made available to potential users (product) or brought into use by the unit (process)" (OECD and Eurostat 2018). More radical thinking considers innovations as mutations that revolutionize the economic structure from within by destroying old ones and creating new ones.

In our technological age, with ever faster technology developments, innovation is widely recognized as one of the essential drivers of successful businesses and a key contributor to the productivity and socioeconomic development of nations. Hence, in many countries, there is a strong focus on public funding of research and development (R&D) and on intellectual property rights as instruments of innovation policy and business strategy. The question is, what is the role of the QI in all of this?

It is now generally accepted that the QI can support innovation in a number of ways (ISO 2015):

- Existing standards can codify and spread the state of the art in various technologies, disseminating knowledge both within and outside the relevant industry community.
- Standards can facilitate the introduction of innovative products by providing interoperability between new and existing products, services, and processes, hence providing a technological platform on which other innovation can take place.
- Innovations can more easily gain market acceptance if they comply with existing standards for safety, quality, and performance.
- Standards can have an important catalytic role in demand-side measures to encourage innovation such as outcome-based regulations or public procurement of innovation.
- Standards can help to bridge the gap between research and marketable products or services. A standard can codify the results of publicly funded research, thus making them available as a basis for further innovation.

10.10.1 The QI and innovation systems

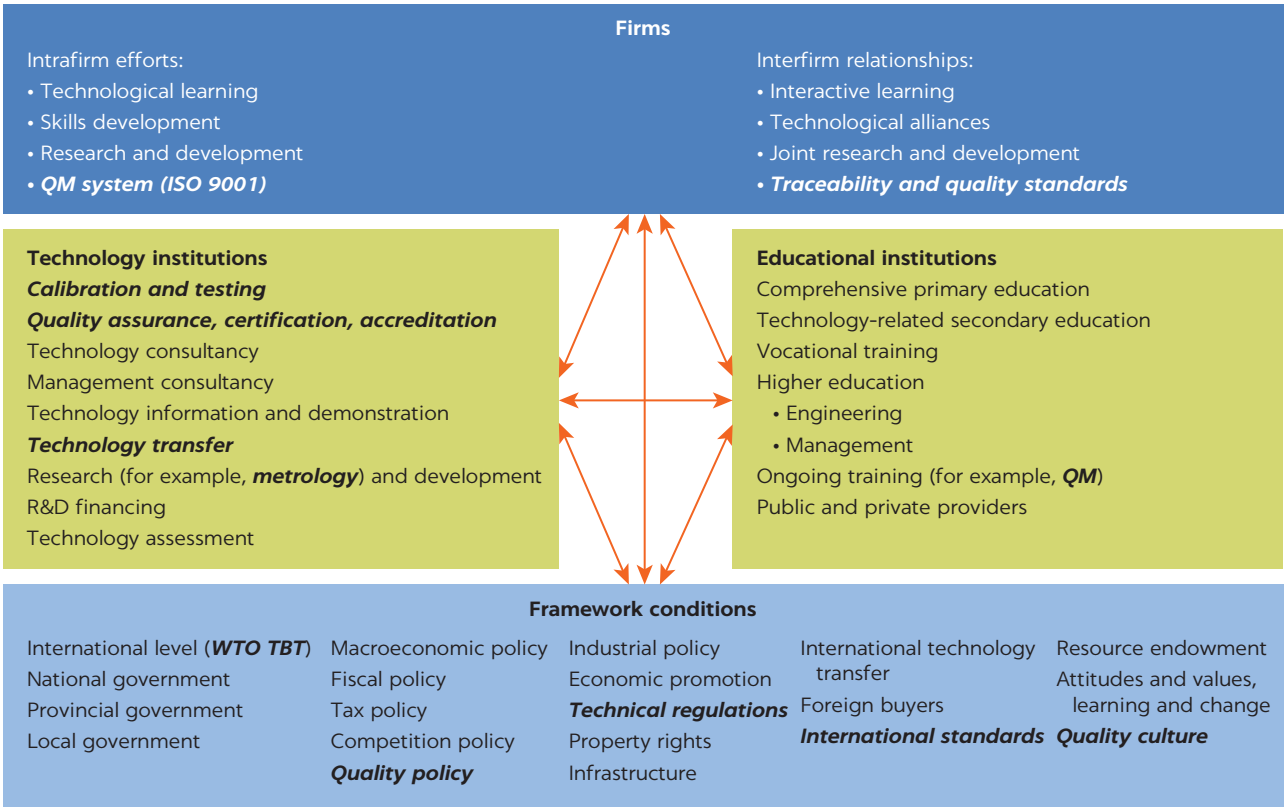
It has been argued that innovation can be fostered in a systematic way where firm-level innovation is central to the whole endeavor. However, certain framework conditions are also necessary, as well as support from technology institutions and the education sector. Together, these factors constitute the four-pillar model of innovation (Harmes-Liedtke 2010).

If innovation can be fostered in this way, it may be useful to consider the elements of such an innovation system when developing QI development programs. These are then also elements that need to be addressed in the demand assessment of the country. The four-pillar model is depicted graphically in figure 10.6.

Pillar 1: the firm. This is where a large part of innovation takes place, and firms should be the target of any efforts to stimulate innovation. The measure of effectiveness of an innovation system is the extent to which firms use innovation to create a competitive advantage. Within the firm, the implementation of a quality management system, such as ISO 9001, is the backbone of a continuous improvement and learning process. Interaction with other firms, in particular suppliers and customers, is also a key driver of technological learning and innovation.

FIGURE 10.6

The four-pillar innovation model and the QI's relevance within it



Source: Harmes-Liedtke 2010. ©National Metrology Institute of Germany (PTB). Reproduced with permission from PTB; further permission required for reuse.
Note: QI-related elements are bold and italicized. ISO = International Organization for Standardization; ISO 9001 = "Quality Management Systems—Requirements"; QM = quality management; R&D = research and development; "WTO TBT" = World Trade Organization Agreement on Technical Barriers to Trade.

Benchmarking, or the application of standards in value chains, is an example related to quality issues in the interfirm relationship.

Pillar 2: framework conditions. Macroeconomic, regulatory, political, and other framework conditions define the set of incentives firms can appropriate. For example, technical regulations for consumer protection or to meet the quality requirements of global buyers may push the firms to adapt and innovate. The legal framework and the development level of the QI show the level of the quality culture in a given country and may induce firms to either innovate or be an impediment to innovation.

Pillar 3: technology institutions. In a low- or middle-income country, the diversity of such institutions may be quite limited. There could be some public research institutions (such as agriculture extension), but their agendas and outcomes are rarely related to the needs and absorption abilities of local firms. More relevant for such countries are service providers of the QI like calibration and testing laboratories or certification bodies. Nevertheless, because the demand for such services is still small, it requires a lot of support from the government and the development partners to make these services accessible, especially to the local SMEs, in low- and middle-income countries.

Pillar 4: educational and training institutions. Other entities, such as vocational training institutes and sometimes business associations, have their own training providers. Quality management and other quality-related topics often are part of the training curricula. There is certainly some overlap with the third pillar; some research institutions will do some training, and some training institutions (especially universities) may be involved in R&D. However, it is crucial to understand that even in the case of universities, their core mission is training. Another type of overlap may occur as specialized training providers offer quality-related consultancy and support in the implementation of quality management systems.

Highlighting the quality issues within the model shows the relevance of the QI in all four pillars. On the other hand, the existence of QI elements within the whole system does not mean that these elements are already connected with each other and with the rather distant elements of the innovation system. The task of the innovation system promotion is therefore to "build" bridges within and between each pillar to overcome fragmentations.

It is important to point out that the relevance of different elements of an innovation system depends on the country's stage of development. In a country where "catch-up innovation" is the predominant pattern, a highly specialized, leading-edge R&D institution will battle to find clients for its services. Fundamental technology services, such as those provided by the QI, may be more appropriate. The demand assessment preceding any QI development project should take these realities in account.

10.10.2 The QI and "incremental" innovation

Innovation can be considered simply as being a new idea, device, or method. This can be accomplished by newer and higher-quality products or by more efficient processes—a notion that would resonate more with the realities of a low- or middle-income country than would the idea that innovation presupposes a radically new technology, as further described below.

Programs of organizational innovation should be linked to organizational goals and objectives, to the business plan, and to competitive market positioning. Typical goals of innovation in manufacturing and services organizations could include the following:

- Improved quality
- Extended product range
- Reduced labor costs
- Improved production processes
- Reduced material costs
- Reduced environmental footprint of the organization
- Replacement of products
- Reduced energy consumption
- Compliance with regulatory requirements

These goals vary among the improvements to products, processes, and services and dispel a popular myth that innovation deals mainly with new product development. Most of the goals could apply to any organization. Whether innovation goals are successfully achieved depends greatly on the environment

prevailing in the firm. Conversely, common causes for failures in programs of innovation include poor goal definition, poor alignment of actions to goals, poor participation by staff, poor monitoring of results, and poor communication and access to information.

Looking at these goals of innovation and mapping them against the QI services, it quickly becomes apparent that almost all of the goals would benefit from the proper use of standards, metrology, accreditation, and conformity assessment.

10.10.3 The QI and "radical" innovation

For years after World War II, many thought that standardization and radical innovation were opposites and that standardization inhibited innovation. This has been proven to be a totally false concept. Even radical innovation needs standardization more than ever before. One example: The cell phone was an innovation—a radical, disruptive technology—when it was first brought to market. Soon a number of major electronics and telephone companies provided cell phones to the market, but each had its own connectivity system; global communication was difficult and frequently not possible. It was only with the advent of the Global System for Mobile communications (GSM) standard, enforced by the European Commission to ensure seamless communication in Europe, that global communication became a reality. In the meantime, the GSM standard has become the de facto international standard that has made the cell phone the success that it is (ISO 2015).

Three fields—health care, digital photography, and the commercialization of new technologies—exemplify the effective use of standards in innovative technologies (ISO 2015).

Modern health care. Advances in wireless health care are providing improved sources of understanding of diseases and their treatment and are revolutionizing the provision of health services in both high-income and low- and middle-income countries. But the medical technology sector is highly fragmented, highly competitive, and highly regulated.

The challenge is to ensure connectivity among all the wireless devices to gain full interoperability for the benefit of the whole system. Standards are the only way to do so, and they can even support differentiation of products as long as they connect. Standards must be applied when systems are "exposed"—that is, not part of a bigger system—not necessarily when they are not.

Digital photography. Digital photography was a disruptive innovation that replaced film-based photography in a very short time. In its initial phases, every company offering digital cameras had its own file formats for the digital images, with the result that general connectivity between camera, printer, and other software was challenging. It was only when the ISO and IEC established the Joint Photographic Experts Group (JPEG) in 1986 to develop an International standard for digital photography files that this issue was addressed.

The first JPEG standard was issued in 1992 and quickly became the preferred method for the whole industry. Today, all digital cameras, irrespective of manufacturer (which may still employ unique company file formats), can also provide JPEG files, as do all cell phones with built-in cameras. All printers and other peripherals recognize such files, as does all word processing and Internet software. Digital images have become a lingua franca of the information technology (IT) age, and billions of images are uploaded daily to various social media sites.

Commercialization of newly developed technologies. Standards create a common framework for innovation: they define common vocabularies; establish the essential parameters of a product or service; and provide for safety considerations, testing processes, and how to move to prototyping and full commercial production. As the "set of rules," standards make a difference in that (a) it becomes less likely to duplicate what has already been produced, allowing the organization to concentrate on innovative activities that will really add value; (b) innovative products will more easily integrate with the rest of the system; and (c) investors may have more confidence that the innovation will be successful.

10.10.4 The specific role of QI institutions in innovation

The above sections describe why QI services are important in innovation. It is important however, that the QI institution consider the way in which it engages with the private sector to foster innovation. This could include joint research projects, testing, or consultancy toward the improvement of products or processes, for example.

Building capacity in QI institutions is in itself an innovative process, but the understanding of the QI institution's role in an innovation system (as described earlier, in 10.10.2) should likewise be fostered. It is easy for the QI institution to be focused on providing QI services for the more effective implementation of technical regulations, because this is a major issue in many low- and middle-income countries. The role it can play in innovation by cooperating with the private sector in a proactive way—thereby establishing services that go beyond the conformity assessment related to technical regulation implementation—should not be neglected. Development projects can play a useful role in establishing such synergies in relation to innovation, because it may be unlikely to come naturally to the QI institution.

The importance of innovation and its reliance on standards has been given further substance in the establishment of a new ISO technical committee: ISO/TC 279, Innovation Management. ISO/TC 279's scope is defined as "standardization of terminology, tools and methods, and interactions between relevant parties to enable innovation."[6] At the time of this writing, the technical committee was in the process of developing seven international standards:

- "Fundamentals and Vocabulary"
- "Innovation Management System—Guidance"
- "Assessment—Guidance"
- "Tools and Methods for Innovation Partnership—Guidance"
- "Strategic Intelligence Management"
- "Intellectual Property Management"
- "Idea Management"

Adopting these international standards may be a useful approach in countries where innovation systems are seriously considered as a mechanism for development.

10.11 SOLVING CONFLICTS OF INTEREST

Two related areas of conflict need to be considered. It is inevitable in the reengineering of the QI, and especially the technical regulation regime, that conflicts surface between some of the operators as one has to relinquish "powers" that

have been part of its business model for years. Such powers may guarantee an income more through legislated fees than from an operator's own performance—that is, income independent of its technical performance or effectiveness. The second conflict of interest that needs to be addressed is that some QI services cannot or should not be provided by the same organization.

10.11.1 Conflicts regarding QI services

At the international level and in high-income economies, the three fundamentals of the QI—standards, metrology, and accreditation—are institutionally separated. In fact, at the international level, standards are developed and published by many international organizations. The three pinnacle organizations regarding the WTO TBT Agreement are the IEC, the ISO, and the International Telecommunication Union (ITU). The three bodies referenced in the WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) are the CAC, the World Organisation for Animal Health (OIE), and the International Plant Protection Convention (IPPC). In metrology, we have the BIPM and OIML, and in accreditation ILAC and the IAF.

In smaller low- and middle-income economies, a complete separation is not always feasible owing to resource constraints, and the question becomes which services can be combined without creating a conflict of interest. The major issue is where the provision of conformity assessment services fits in. The basic rule is that conformity assessment services and accreditation must be kept strictly separated. In many low- and middle-income countries, NSBs also provide conformity assessment services and even calibration services.

In some examples of combined services, conflicts may be avoided:

- Although not common, there is no conflict of interest if standardization and accreditation are combined, provided that the organization does not offer conformity assessment services and the impartiality of the national accreditation body (NAB) can be demonstrated. Typical examples are the Standards Council of Canada (SCC), Standards Malaysia (SM), and the Cyprus Organisation for Standardisation (CYS).
- There is no conflict of interest if the NSB is also the designated NMI. This is the case in many low- and middle-income countries.
- There is no conflict of interest if the NSB develops and publishes standards and provides conformity assessment services on the basis thereof. In this case, the NSB may not also be the NAB; that would be a clear conflict of interest. This is the case in the bulk of NSBs in low- and middle-income countries. In the EU, this construct is frowned upon, albeit for reasons related to the EU technical regulation regime modalities rather than for being a basic conflict of interest.
- Metrology and accreditation make for an uneasy combination because calibration services should be accredited, and most NMIs in low- and middle-income countries provide calibration services over and above their responsibilities for maintaining the national measurement standards.

There are business issues that also could determine whether the NSB should be providing conformity assessment services. But these have to do with service quality, adaptability to deal with changing market circumstances, competition in the marketplace, and the like. These decisions would be dependent on the level of maturity of the conformity assessment market, not on inherent conflicts of interest.

10.11.2 Conflicts regarding technical regulations

In many countries, NSBs were mandated to implement mandatory or compulsory standards (that is, technical regulations). At the time, this was quite acceptable. The NSB developed the standard; the minister declared it mandatory; and the NSB inspected, tested, and certified products before they could be marketed. This approach had quite a few advantages; for example, scarce resources could be optimally used, and the NSB, as the center of technical excellence, could be used to best effect to safeguard the health and safety of the population and protect the consumers. When international trade was at a low level, all of this was fine.

But this approach has become far less acceptable as international trade flows have increased. It is seen as an unnecessary trade restriction or technical barrier to trade (TBT) by trade partners because of the premarket certification conducted by one organization—that is, tests and certification of products conducted in the country of origin often had to be repeated. Furthermore, this work of the NSB is funded by the payment of levies by the suppliers—levies specified by legislation. The income from this source has become the bulk of the income for the NSB, a situation that was supported by the government, because it relieved the financial pressure on state funding.

The outcome, however, was that the NSB collected the levies but was not always as diligent in conducting the inspection, testing, and certification. Second, the system lent itself to corrupt practices, with suppliers paying the fees to get rid of the inspectors without having to deal with the actual inspection, testing, and certification. In other words, the NSB was given a license to extract rent.

This system is now considered a conflict of interest by quite a few of the major trading nations. Hence, during negotiations on trade agreements, pressures are mounting on low- and middle-income countries practicing such a system to implement a more modern and trade-friendly technical regulation regime. This is a major undertaking with massive organizational and especially financial ramifications. The regulatory activities of the NSB have to be separated and placed in a regulatory authority, if one exists, or a new one has to be established. The conformity assessment measures have to be liberalized such that suppliers get a choice of technically competent service providers. In the process, the NSB loses its guaranteed funding and has to radically change its business model to that of a service provider competing with the other designated service providers.

The NSBs are understandably reluctant to go this route, and it takes resolute political will on the part of the government to implement such changes. The government also has serious decisions to make regarding the funding of the regulatory authority, which in all probability will no longer be collecting levies from suppliers.

Anecdotal evidence from countries where such radical changes have been implemented indicate that, if handled correctly, the NSB can flourish as a conformity assessment service provider provided the regulatory authority does not conduct the conformity assessments and the NSB delivers good service. The reengineering modalities were discussed earlier in sections 10.2.2 and 10.2.4.

10.11.3 Conflicts between mandatory standards and food safety systems

NSBs predate food safety authorities by many years in quite a few low- and middle-income countries. It was therefore quite natural for these countries to

implement food safety through the mechanism of mandatory or compulsory standards (as discussed earlier, in section 10.11.2). As these countries developed, the necessity for a food safety authority became more pressing, and many established food safety authorities.

Unfortunately, the interface between the previous mandatory standards system and the food safety system was not always clearly articulated or a transition period was not agreed to. The situation became even more complex because the NSB and the food safety authority reported to different line ministries—for example, the Ministry for Trade and Industry and the Ministry of Health. Furthermore, the legislation of the two systems was not aligned to ensure a clear description of the interfaces, resulting in two pieces of overlapping legislation mandating two different regulatory authorities to control the same products. This situation was exacerbated by establishing similar premarketing controls for the food safety system—for example, certification of the product before it could be marketed. The result was that suppliers had to comply with two sets of regulations, frequently with differing technical requirements; had to pay two sets of levies for two sets of product certification; and saw their transactional costs increase dramatically—increases of 20 percent being not uncommon.

Some governments have requested that the two regulatory authorities sort out the overlaps, but that usually fails. The reasons are manifold: the NSB stands to lose too much income from mandatory standards for food products; the food safety authority does not wish to use the laboratories of the standards body because it is establishing its own; the legislation of both has to be revised, and everybody is reluctant to do so, because it takes too much time and energy; and so on.

The only way to resolve this impasse is for the government to take the lead by first developing the policy that provides clear guidance on the overall system it wishes to implement, and then developing and promulgating the necessary legislation, after which a massive reengineering program has to be embarked on by all the relevant ministries and their agencies.

Development projects can make a major difference in this regard, but such projects must appreciate that a holistic approach is required. Too often they are aligned with the wishes of the recipient ministry, without considering other ministries that are also involved. Such projects unintentionally worsen the situation, hardening the attitudes of both the NSB and the food safety authority to the detriment of the low- or middle-income country's safety and health systems as well as diminishing the competitiveness of the local suppliers.

Modern thinking and CAC standards on food safety systems (for example, CAC/GL 82-2013, "Principles and Guidelines for National Food Control Systems") consider the whole value chain to be controlled—the "field to fork" approach. Product certification methodologies based on the systems as defined in ISO/IEC17067("ConformityAssessment—FundamentalsofProductCertification and Guidelines for Product Certification Schemes") are not seen as adequate any longer because they deal mostly with the final product and its method of production in the factory. What happens on the field and during transportation of the product after it has left the processing plant, for example, is not considered. The elements of a modern food safety system and its interface with laboratories, inspection bodies, and the NSB are described in module 2: The Importance of QI Reform and Demand Assessment, section 2.2.3.

The best approach to deal with this conflict is to get the three ministries involved in a modern food safety system—the ministries responsible for

agriculture, health, and trade and industry—to cooperate and develop a new approach for the country. This approach should take cognizance of the WTO TBT and SPS Agreements, good standardization practice (module 3: Standards, section 3.4), and the CAC "Guidelines for National Food Control Systems" (CAC/GL 82-2013), and it should be based on a "field to fork" approach. It should clearly define the responsibilities of the various agencies involved, liberalize conformity assessment, and base market surveillance on good international practices, including risk assessments. This approach should be finalized as a government policy that is approved for implementation at least by the cabinet to ensure the unstinting support of all the relevant ministries.

An implementation plan has to be developed that will have far-reaching consequences—a plan starting with the development or revision and promulgation of the necessary legislation, organizational restructuring, training of a skilled labor force, and many more actions. This is a massive undertaking, demanding clear leadership and the unstinting political support of the whole of government because difficult and painful decisions will have to be made regarding the deconstruction of entrenched systems, relocation of personnel, establishment of new structures, accentuating the role of accreditation, and developing the appropriate funding models for the system as a whole.

The impact of such a reengineering exercise would be extremely positive for the country's socioeconomic development, providing it with a viable food safety system while at the same time enhancing the competitiveness of the producers and food processing industry.

NOTES

1. The "organizations" of the QI ecosystem provide such things as national standards, calibration, test reports, certification reports, and accreditation certificates. The term "QI services" is used as a collective term to denote these outputs of QI organizations.
2. The WTO TBT Agreement aims to ensure that technical regulations, standards, and conformity assessment procedures are nondiscriminatory and do not create unnecessary obstacles to trade. At the same time, it recognizes WTO members' right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety and protection of the environment. The TBT Agreement strongly encourages members to base their measures on international standards as a means to facilitate trade. Through its transparency provisions, it also aims to create a predictable trading environment (see module 7: Technical Regulation, section 7.1).
3. Stakeholder mapping is a technique whereby the organization lists and considers all its stakeholders in various categories, such as clients, influencers, authorities, consumer organizations, the media, and so on.
4. See "Who Develops Standards," ISO website: https://www.iso.org/who-develops-standards.html.
5. The recognition of an accreditation body is related to the specific accreditation services it provides. These could include the accreditation of inspection bodies, testing and calibration laboratories, product and management system certification bodies, bodies providing certification of persons, and many more. Details can be obtained from the ILAC and IAF websites: respectively, https://ilac.org/ and https://www.iaf.nu/.
6. For more information, see "ISO/TC 279 Innovation Management" on the ISO website: https://www.iso.org/committee/4587737.html.

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