

Challenges of QI Reform

INTRODUCTION

Building new capacity in the quality infrastructure (QI) or reforming customs and practices that have been around for decades is a challenging business in the best of times. The project evaluations of development partners that are available in the public domain are a useful source of positive and negative outcomes and the reasons thereof. Many of these are the sources of the discussions in this module (Kellermann and Keller 2014).

11.1 PROJECT PREPARATION AND MANAGEMENT

11.1.1 Start with long-term planning to build the QI

***Key message:** Embed technical assistance for building the QI into longer-term planning, going beyond a single-phase project. This allows governments to mobilize their contributions to ensure that they are sequenced with international input. It is furthermore important to seek commitment and support for long-term strategies among key stakeholders, including the industry and nongovernmental organizations (NGOs).*

Strengthening national QIs is a long-term undertaking that requires donor commitment beyond a single project. The international recognition process for accreditation bodies, for example, takes—if everything is implemented as planned—about five to seven years, as does the establishment of metrology capacity of reasonable accuracy. The time to establish a national standards body (NSB) and operate it effectively will not be much different.

Yet, the short-term perspectives of development partners that are driven by donors' budget cycles of two to four years often negatively affect project results. Typical challenges associated with such short time frames include the following:

- Overambitious targets may be set because of the need to “deliver” tangible results quickly.

- Short-term planning causes “stop and go” donor support, with gaps between different projects, during which parts of initial achievements are lost.
- Patchiness of technical assistance without a clear overall plan leads to poor donor coordination, duplications among projects, and resource redundancy.

The need for a longer-term engagement is especially evident where national QIs are at the initial stage of development and the support required clearly exceeds the scope and length of one single intervention. Experience shows that achieving the technical and financial sustainability of newly established institutions in particular requires sustained support over a longer period. Clear planning of donor support beyond the limited duration of one project gives partner countries the visibility needed to mobilize their own resources or to call on complementary donor assistance. In addition, longer-term plans of donors that are widely shared with the government and the development community also contribute to enhancing aid harmonization.

Good practice is to embed projects into a longer-term plan for stepwise assistance over several project phases, including the following elements:

- Align planning with the beneficiary government’s own strategies.
- Outline the longer-term objectives and explain how the project intends to achieve them over time.
- Set clear and realistic intermediate objectives for each project phase.
- Make funding of subsequent phases conditional on achieving intermediate objectives.
- Use the input from periodic evaluations to adjust the overall strategy and to tailor subsequent project phases to evolving changes in context and needs.

Moreover, it is not only donor support that may follow short cycles. Recipient priorities and strategies also shift with election cycles or changes in global policies. Donors should therefore seek commitment and support widely for long-term strategies among key stakeholders, including the government, industry, and NGOs.

11.1.2 Analyze demand and supply for quality services to set the right priorities

***Key message:** In project preparation, gain a clear understanding of demand and supply for QI services in the country or region to be covered by the project to set the right priorities.*

Many if not most projects include components that aim at “upgrading” institutions that provide quality-related services (for example, inspection, testing, and certification) to serve the needs of the private sector. This upgrading is often expected to enable local companies to conform to quality standards and technical regulations—an important element of their competitiveness both at home and in export markets. To prevent redundancies and duplications, donor support needs to be geared toward strengthening those quality-related services that are in demand but not available or accessible for users.

The rivalry between ministries or their agencies, rent seeking, and national pride that gets in the way of common sense or good business practice are frequently the underlying challenges in this regard, leading to some of the typical undesirable side effects of QI development projects:

- The purchase of expensive testing or calibration equipment that is already available in the country may lead to the underuse of both (see module 10: How to Reform: Interventions and Approaches, sections 10.5.1 and 10.6.3). This happens quite easily if the partner institutions in the country are not the same for the different development partners—for example, if two microbiology laboratories are established under two different ministries, whereas one central laboratory could be more than adequate.
- An undesirable outcome of funding redundant capacities might be market distortion and crowding out of other, often private, service providers by establishing a public sector laboratory that becomes the de facto testing facility for technical regulations or sanitary and phytosanitary measures (SPS).
- Limited domestic demand might not justify significant investments in expensive equipment for some highly specialized services. On the supply side, not all services necessarily need to be available domestically. This is especially the case where such services exist at competitive prices in neighboring countries and are accessible or where regional capacity has been established (see module 10: How to Reform: Interventions and Approaches, section 10.6.1).

Therefore, pivotal for project preparation is an in-depth assessment of demand for and supply of QI services in the country or region—not, as is often done, a simple assessment of the capacities of potential beneficiary institutions. The modalities for conducting an in-depth needs assessment are discussed in detail in module 2. Because of its complexity, the demand assessment will require dedicated resources (funding and experts) and should be conducted as a preparatory stage. If this is not possible, such an assessment should at least be conducted, albeit at a lower level, during a project inception phase.

As an additional caveat, beneficiary institutions that operate as profit centers are often interested in developing services that are potentially most profitable. Although such a focus may contribute to their financial sustainability, it may at the same time leave gaps in other areas that are critical for export capacity, for example, but are not profitable enough for private players to provide. Stimulating but not distorting markets and taking into account the “public good” dimension of certain services should be one of the guiding principles of any needs assessment.

11.1.3 Use regional projects appropriately

Key message: *Use regional approaches to project design that are appropriate to the project environment. In strengthening the quality systems in regional projects, pay attention that enhancing the QIs at the national level does not disproportionately benefit the more advanced economies.*

Current wisdom tends to favor “regional approaches” as a means to support the establishment of QI services in a cost-effective manner for a group of smaller economies in which a purely national approach would be cost prohibitive.

To capitalize on economies of scale and scope, a development partner may choose to deliver assistance to several countries of a region within the same project. This could be particularly beneficial in the case of regional common markets. *Economies of scale* may include sharing of scarce resources (for example, a specific expert getting involved in several countries) or sharing

project overhead cost (for example, one preparation mission, one shared project office for several countries). An *economy of scope* could involve the potential for exchanging experiences and transferring know-how among recipient countries; in other words, less-developed recipient countries should be able to profit from a more advanced country's knowledge.

Whereas the economies of scale and scope are worthy project targets, the difficulties in coordinating such large projects should not be underestimated. Challenges that need to be considered include the following:

- Regional projects are more complicated to design and plan than a national project because they have to cater to the multiplicity of needs of more than one country.
- If the countries' interests are not aligned, that can lead to "competition" for resource allocation.
- Logistics can be more challenging. For example, travel becomes more complicated, language differences among recipient countries may require continuous translation or interpretation services, and transferring samples (such as for interlaboratory comparisons) without having them tampered with by customs officials can be quite daunting.
- Design of regional projects that are of high relevance to all countries covered is particularly difficult in cases of "asymmetry" of economies or their development stages and where there are no common key industries. The need to make "one fit for all" might lead to schematic designs that are unsatisfactory for everyone.

The presence of a more advanced "lead country" (for example, Vietnam in the Mekong Region or South Africa in Southern Africa) through which know-how is transferred can facilitate regional cooperation, both formal and informal. On the other hand, political sensitivities (such as the risk that the lead country is perceived as too dominant) need to be taken into consideration. Not only may a leading country be perceived as dominant; it may even be tempted to take advantage of the situation. An enhanced QI established at regional level for the benefit of all may have a disproportionately beneficial effect on the dominant, more advanced economy and widen the gap among participating countries rather than narrowing it.

Approaches that have proved to be successful in regional projects include the following:

- Economies of scale and learning have been achieved by coordinating input, such as by combining expert missions to a number of countries.
- By coordinating related elements of different national projects in the region, some benefits of economies of scale and scope can be realized while avoiding the pitfalls of a "schematic approach."
- Strengthening the existing formal and informal regional cooperation structures between QI institutions in the region and using the expertise available in more advanced countries in projects in less advanced countries has paid dividends in both transnational and regional projects because such links tend to remain in place after project closure.

Where a regional QI institution is the recipient of development support within such a regional project, care should be taken not to overlook the need for a national presence of QI institutions. (See module 10: How to Reform: Interventions and Approaches, section 10.2.2 for a detailed discussion of institutional reengineering.)

11.1.4 Work through the right counterpart

Key message: *Counterpart institutions for QI projects should be directly responsible for the fields covered.*

The selection of the right counterpart institution for the project is a crucial success factor. The counterpart institution may be in the public or private sector. Experience has shown that cooperation with an organization directly responsible for the fields addressed by the project is the most effective. Elements that need to be considered during project design and planning include the following:

- The choice of the counterpart institution should not be influenced by factors such as historical bias or political expediency (for example, “Our partner has always been the Ministry of Trade and Industry”).
- If the QI development project covers a variety of technical fields that fall within the competences of several organizations, it may be necessary to work with several counterparts (a multistakeholder approach). It is important that the ownership of the project is “anchored” within the right one.
- Care should be taken not to get embroiled in institutional rivalries where an institution not formally mandated for a certain function tries to “capture” most of the project benefits to the exclusion of other key players, or where there is a sense among institutions of “whose turn is it next” to channel project resources.

Creating win-win situations when establishing new institutions, especially when transferring responsibilities from one organization to the next, is important to consider. It is especially the transfer of responsibilities (for example, separating regulatory functions related to mandatory standards from the NSB, establishing independent entities for scientific and legal metrology, separating various accreditation functions from ministries to establish a national accreditation body serving all, and so on) that needs high-level political support and careful planning. This is because the institution “losing” the responsibility may fight relentlessly to maintain the status quo, as the change could have a major influence on its annual income or constitute a loss of power, real or perceived.

11.1.5 Execution modalities, project governance, and management

Key message: *Define, agree upon, and implement enabling governance and management structures for projects. Sound project planning, monitoring, and evaluation are key success factors for development assistance projects in the field of QI because they often address issues of high technical complexity through working with multiple partners. Active and diverse project steering committees add significant value. Beyond the project level, a formalized mechanism of donor coordination at the country and regional levels is essential.*

Experience and postproject evaluations show that the success or failure of development projects in the field of QI is directly related to the project governance and operational management. This includes the application of proper planning, monitoring and evaluation, and logical frameworks. Although this may be true for any project, the complexity of building QI renders this more general principle even more important. Clear terms of reference and the separation of

the strategic and day-to-day management are important elements of good project governance. The same applies to decision-making powers that match accountabilities and responsibilities.

Execution modalities

In line with their commitments under the Paris Declaration on Aid Effectiveness (OECD 2005), many development partners are gradually shifting toward some degree of national execution for their projects. National execution means that donor funds are channeled through the national systems of beneficiary countries and that recipient governments have the final “executive” responsibility for project implementation.

To ensure efficiency and reduce transaction costs, the following challenges need to be managed:

- The key challenge is to strike a balance between commitments to national execution of aid delivery and aid effectiveness (that is, “managing for results”), considering the specific absorption capacities of each country and its institutions. Delivery modalities should be tailored to the institutional capabilities of the counterparts while at the same time ensuring that a healthy degree of ownership is transferred.
- Where development agencies have the choice to decide on modalities of delivery, forms of “joint execution” or “mixed execution,” combined with mutual accountability, seem to work best. Subcontracting the elements of projects to local counterparts seems to be a reasonable way to gradually move toward more partner-led implementation, as are forms of joint decision making.
- National procurement systems are often cumbersome and not yet ready to cope with the sourcing of sophisticated technical equipment. Similarly, gaining access to the right, highly qualified expertise is not an easy task for low- and middle-income countries. Hence, sourcing sophisticated equipment and highly qualified expertise may still best be done by the international counterpart.

Project governance

QI capacity development usually involves many different stakeholders. To gain their active support, representatives of the main interested parties should be involved in project governance. Approaches that could be considered include the following:

- A project steering committee representing the broad stakeholder groups may add significant value. But, within the steering committee, the functions of “stakeholder involvement” and decision making at the strategic level should not be mixed—that is, changes to project agreements can be made only by its signatories. The tension between involving many stakeholders in project steering while not blurring decision-making power might be lessened by dividing the steering committee into voting members and observers.
- The decision-making process (consensus or executive) should be transparent and clear to all committee members.
- In addition to the status regarding the implementation of activities, the steering committee should be kept informed of all important financial data. Sharing financial data with counterparts is also a good way of capacity building, because it allows counterpart institutions to gain experience in planning their own projects in the future.

- Including representatives from related donor-funded projects as observers is a good way to improve informal donor coordination.

Operational management

At the operational level, a choice has to be made between day-to-day management on the “field level” or managing the project at the development agency headquarters. Both have positives and negatives that need to be considered for a specific project. Normally, these decisions depend on the financial volume of the project and the practices of the development agency. Therefore, the liberty to choose is limited.

Where decision-making power is delegated to the field office or counterparts, implementation risks need to be minimized by strengthening the financial and operational monitoring systems that should operate continuously during the project implementation phases. The task of monitoring complex projects may be commissioned externally, at least for strategically important projects with high implementation risks. Whatever the modalities chosen for project governance and management structures, these should be agreed to by all project partners before implementation.

Use of experts

A decision will have to be made regarding the use of experts, who could be either (a) embedded in the local project office for most of the project duration, or (b) available only for short, intermittent stays. Both approaches have strengths and weaknesses (table 11.1).

The decision of whether to embed experts in the local office or use short-term experts could also depend on the state of the QI and the gaps that need to be addressed. The establishment of a QI institution and moving it from rudimentary to basic level (as discussed in module 2: The Importance of QI Reform and Demand Assessment, section 2.2.2) may necessitate an embedded expert, whereas for enhancing an advanced or mature QI institution, short-term experts would suffice.

TABLE 11.1 Strengths and weaknesses of embedded versus intermittent experts

EXPERT TYPE	STRENGTHS	WEAKNESSES
Embedded	<ul style="list-style-type: none"> • Always available in a consultative capacity when the recipient needs support. • May become better known and hence would be able to guide, manage, or drive development on a day-to-day basis. • Can keep their “finger on the pulse” regarding political and other developments and sensitize the project management group accordingly—useful in countries that are undergoing political upheaval or major shifts in policy when new governments come into power. 	<ul style="list-style-type: none"> • May be “misused” to conduct activities that the recipient organization’s staff should be conducting, especially if milestones have to be met. • If an embedded expert is not accepted by the recipient institution for whatever reason, then the project will suffer due to silent sabotage or outright refusal of cooperation. • Overhead costs of the project have to consider the not-insignificant costs of establishing the expert in the field.
Intermittent	<ul style="list-style-type: none"> • Having to use recipient institution staff may have the advantage that what has been implemented will be sustainable after the end of the project. • Not “misused” for daily work but can concentrate on giving advice. In a project implementation based on milestones, experts will not be used until the “homework” has been done. This increases the pressure to act and leaves the responsibility with the recipient institution. 	<ul style="list-style-type: none"> • Available for short periods of time and may or may not be available when the recipient is urgently seeking answers to a specific challenge. • Intermittent experts have to rely on the work ethic of the recipient institution staff to get things done.

11.2 CHALLENGES OF QI INSTITUTIONS IN LOW- AND MIDDLE-INCOME COUNTRIES

Many low- and middle-income countries established NSBs decades ago, either as government departments or as statutory bodies. Owing to limited resources, they were established as organizations providing all services—they developed standards, looked after scientific metrology, and provided conformity assessment and calibration services. Sometimes they were even tasked with the evaluation of other laboratories in the country. Frequently, they were also given a mandate to implement mandatory standards. As low- and middle-income countries endeavor to gain the maximum advantage from the massive increase in global trade, this QI model is coming under increasing pressure because of some inherent conflicts of interest.

In addition, many of these institutions' business models cannot cope with the technological advances in QI service delivery, or they have become less effective and efficient through complacency. The financial challenge is that if the institution is involved in the implementation of mandatory standards, it is paid a levy by suppliers and this income is to some extent independent of whether it provides decent service, leading to allegations that it has been given the wherewithal to extract rent. Such behavior increases the transaction costs unnecessarily for suppliers.

11.2.1 Institutional arrangements

Key message: *Ensure that institutional arrangements do not lead to conflicts of interest.*

At the international level, independent organizations look after the interests of each of the fundamental QI functions: standards, metrology, and accreditation. Such independence is mirrored in most high-income economies. In low- and middle-income economies, it is frequently too resource-intensive in terms of finances, buildings, and skilled staff to establish independent organizations for each of these functions. Hence, some of the functions are combined. This is not an issue as long as specific conflicts of interest are considered (accreditation and conformity assessment in the same organization, for example, being a clear conflict of interest) and if governance, management, and business model risks and concerns are appropriately addressed.

11.2.2 Standards development and publication

Key message: *Standards development and publication should be benchmarked against modern good standardization practices: streamlining the technical committee structures and activities at the national level through effective project management, actively participating in regional and international technical committees where it matters for the country, and making standards available to market as rapidly as possible.*

The process of developing consensus-based standards at the international level by the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and others is largely regulated by the World Trade Organization (WTO) Agreement on Technical Barriers to Trade

(TBT Agreement) and ISO/IEC Directives (ISO 2017). The body of international standards is comprehensive and easily accessible. A similar situation exists at national level in the more developed economies. It is, however, difficult to obtain a complete picture in many low- and middle-income countries, where the processes may vary widely.

Typical challenges regarding the development of standards that are experienced in some NSBs of low- and middle-income countries include the following:

- The annual or six-monthly standards work program is established by the NSB without meaningful input from stakeholders; it is based on what the NSB believes the needs to be. In addition, it is extremely rigid, and any emerging need is “parked” until the next financial year or two, after which the private sector finds another avenue to fulfill its needs.
- In some cases, technical committees are limited in size by NSB rules, and representation is mainly from the public sector rather than the private sector that would be the main affected party. This is exacerbated if members are paid sitting fees that strain the budget of the NSB, over and above the fact that it attracts members who have little input into the process; they attend only to gain the sitting fee.
- Adopting international or regional standards is very much a preferred methodology, but language problems surface quite frequently. The ISO, IEC, and other international standards are readily available in English or French, but these may not be well understood in a low- or middle-income country. Therefore, standards have to be translated, an aspect that requires resources over and above the difficulty of translating technical English or French into a language that may not have the technical vocabulary in the first place.
- Active participation in the technical committees at the international level is limited if not totally absent, even though NSBs have registered as participating or observer members in many of them. This comes about mainly because of financial constraints and sometimes a perception in the low- or middle-income country that it lacks the expertise to participate at the international level. On the other hand, such NSBs often have an exemplary record (typically more than 95 percent) of voting on draft international standards. However, they do not provide any comments during the public commentary period nor when voting, raising the suspicion that it is a mechanistic-type voting of ticking the right boxes without considering what they are voting for.

Typical challenges for low- and middle-income countries regarding the publication of standards include the following:

- The changeover from a purely hard-copy system to an information technology (IT)-based system is not complete or has not been planned well. Older national standards—and these could still be the bulk of standards published—are available only in hard copy, and there is no plan in place to get them digitized as soon as possible.
- National standards cannot be obtained through Internet-based systems; for example, the IT infrastructure is not capable of providing such services, or payment through credit card or electronic funds transfer (EFT) is not possible or limited to in-country transactions.

- Standards, once approved, are printed in hard copy with a print run of a few hundred or thousand. Standards that are not in great demand sell slowly, and after a few years when the standard is updated or revised, most of these copies have to be trashed, wasting precious resources.
- Print-on-demand systems that would alleviate the situation described above are waiting for capital expenditure approval, which is not forthcoming because it is not seen as a priority. Once the print-on-demand system is installed, the older standards cannot be provided in this way because they have not been digitized yet.
- Documentation control of the final, approved text of national standards is weak or totally absent. Files reside on the computers of the technical committee secretariats, and there is no central depository with controlled access to ensure that the text is not tampered with after approval.
- The five-year cycle of review of published standards is not fully implemented. Even when implemented in part, there is no indication in the standard itself whether it has been reviewed and reissued without change or revised.

In addition, as technology develops at an ever-increasing pace, the approaches to standardization are also evolving quite rapidly at the international level, shifting the goal posts in ways that challenge the NSBs in low- and middle-income economies. Predicting the trajectory of these changes is a challenge even for international standards bodies and standards bodies in high-income countries. Hence, NSBs in low- and middle-income countries and their development partners will need to keep a close watch on developments and adjust projects accordingly.

11.2.3 Metrology in one institution

Key message: Metrology is technology-intensive. The facilities, skilled staff, and technical support must be available and maintained at a high level for the metrology institution to succeed.

Metrology services in low- and middle-income countries usually start with the state controlling weights and measures in trade through a legal metrology department or agency, which is then often given the responsibility to establish and maintain national measurement standards. When national standards are procured, they may even come with calibration certificates traceable to international standards.

The challenges to maintain these national standards, and to enhance them as industry develops, are numerous:

- There is a big difference between operating a legal metrology service and maintaining national measurement standards. The former is a regulatory function, whereas the latter is a more scientific endeavor. The psychological makeup of the metrologists involved in these two functions would be different. In countries where the legal metrology department is responsible for national measurement standards, anecdotal evidence indicates that they are of a much lower priority and maintenance often suffers, because the bulk of the staff would be legal metrologists focused more on the implementation of the measurement controls in trade than on spending time with the “less interesting” laboratory equipment.
- Maintaining the calibration status of national measurement standards is a major challenge. Issues that need to be resolved on a continuous basis include

obtaining adequate foreign exchange to pay for the calibration thereof abroad as well as the logistics to get measuring equipment to the foreign national metrology institute (NMI) and back without physical interference that would negate the calibration status. Such measuring equipment also requires high-level mechanical and electronic maintenance, both of which are difficult to source in many low- and middle-income countries.

- Maintaining the laboratory conditions, especially environmental controls, required for the continued functioning and accuracy of the national measurement standards is challenging. These frequently include the less-than-reliable power supply, which in some countries could be interrupted weekly for hours on end. This means that an uninterruptible power supply (UPS) has to be provided, which could strain project budgets.

Over and above these challenges, every now and then, low- and middle-income economies need to upgrade their national measurement standards to allow for new technological developments within the country. These could require a much higher level of technical sophistication than what the current infrastructure can provide. Developing such higher technical capabilities is a major challenge for a low- or middle-income country, one that it seldom can manage on its own within a reasonable time frame. A challenge of similar nature but with quite different consequences is the propensity of some experts to recommend very sophisticated measuring equipment that the country does not need, and worse, cannot operate and maintain.

11.2.4 Accreditation

Key message: *An internationally recognized accreditation service is no longer a “nice to have” but a necessary precondition for gaining acceptance for conformity assessment results of local companies in the international markets. Establishing such an accreditation service is a long journey of quite a few years—requiring finances, dedication, and the assurance that it will be independent from undue political interference or financial pressures that would affect its trustworthiness.*

Few low- and middle-income countries have national accreditation bodies (NABs) that have been fully operational and internationally recognized for a number of years. If one exists, it will be of very recent date. Many such countries do, however, have some mechanism akin to accreditation in some ministries or even in the NSB that is responsible for the evaluation of laboratories, for example.

Establishing a fully functional NAB is a daunting task. Some of the challenges that a low- or middle-income country may face include the following:

- In smaller countries, the amount of accreditation work in the private sector and technical regulation may not warrant the establishment of an NAB. From a financial sustainability perspective, it has been shown that 200–250 accredited organizations are the break-even point for NABs.
- In many low- and middle-income countries, the number given above is unattainable unless the medical and pathology laboratories, for example, are forced to acquire accreditation as a precondition for providing such services. In this case, the full cooperation of the Ministry of Health must be sought, and the discussions of whether it will allow an organization outside its control (the NAB) to conduct the assessment of these laboratories can become quite intense.

- If an NAB is not an option, a regional accreditation body (RAB) might be (as further discussed in module 5: Accreditation, section 5.5). In this case, the modalities and mandate of the RAB's involvement in matters related to regulatory work will have to be carefully defined.

From the establishment of an NAB until it can gain international recognition takes between five and seven years, or even longer. Before the International Laboratory Accreditation Cooperation (ILAC), the International Accreditation Forum (IAF), or recognized regional cooperation bodies will send peer review teams to assess the accreditation body, the newly established accreditation body needs to (a) train its assessors and lead assessors; (b) develop and implement its management system and documentation compliant with ISO/IEC 17011 (“Conformity Assessment—Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies”); and (c) gain experience in conducting assessments and actually accredit a few organizations. Frequently, being able to demonstrate their independence to gain international recognition is another challenge for accreditation bodies that are part of organizational structures vulnerable to political and financial interference.

Until the NAB gains international recognition, companies will be reluctant to make use of its services because the accreditation certificate will be of limited value internationally. To overcome this “chicken and egg” situation, newly established accreditation bodies can enter into “twinning agreements” with an accreditation body that is already internationally recognized. This arrangement will help the newly established accreditation body gain the necessary experience for the peer review as clients may be issued a joint accreditation certificate (see module 10: How to Reform: Interventions and Approaches, section 10.5.2, for a more detailed discussion). But finding the appropriate twinning partner can be a major challenge; not many accreditation bodies are keen on such arrangements because they affect their operational efficacy.

11.2.5 Conformity assessment

Key message: *Conformity assessment is a reality in commercial transactions. Hence, conformity assessment services should be technically competent and market-related regarding cost and service delivery. The appropriate balance between public and private sector service providers is of paramount importance to deliver affordable conformity assessment services to both larger enterprises and the SME sector without distorting the market.*

Conformity assessment is not a trade barrier as such but an everyday reality in commercial transactions. Yet conformity assessment arrangements can have important implications for competitiveness and market access. A number of international and regional systems have developed with the objective of establishing networks of conformity assessment bodies (mostly within the private sector) whose competence can be relied upon by all members and users. In low- and middle-income countries, however, the provision of conformity assessment services is often inadequate, costly, government-driven, and centralized.

Over and above all the challenges related to providing a technically competent service, public sector providers of conformity assessment services are frequently hamstrung by the civil service bureaucracy they have to operate within. The obvious solution would be to liberalize the conformity assessment environment—that is, implement policies whereby these services are

progressively shifted toward the private sector. This, however, means that public service providers no longer enjoy their real or perceived monopolistic situation, and their business model may not be able to deal with the new market realities. In addition, governments may be reluctant to let organizations over which they have no direct control provide such services in the regulatory domains.

Such a change in the policy environment will require well-structured arguments based on the business case showing the cost savings from liberalizing conformity assessment services, to convince the government to initiate and push through the changes, and to withstand the inevitable backlash from public sector organizations that see only their income threatened. Access to the highest political levels is a prerequisite for such discussions to be fruitful. The possibilities of generating synergies between public sector institutions and private sector service providers should not be underestimated.

On the other hand, public sector organizations may be receptive to moving services to the private sector if they can be convinced of the advantages of doing so—of moving away from stifling bureaucratic systems.

The third stakeholder group to be convinced would be the regulatory authorities responsible for technical regulation, food safety, and SPS measures. They need to understand that market-related conformity assessment services are actually more effective and efficient in the long term and that technical competency needs to be ensured through accreditation.

11.2.6 Cross-cutting challenges

Key message: *Establishing a vibrant QI requires the understanding and commitment of high-level public sector officials, a holistic approach to QI-related legislation, representative governance structures, and the retention of skilled personnel in the QI institutions.*

Low- and middle-income countries are often challenged to implement good practices in QI development. It is one thing for development partners to establish QI institutions, appropriately train people, and provide expensive equipment, but it is quite another for the recipient country to do these same things.

Challenges of a cross-cutting nature that should be taken into consideration in any development work include the following:

- The reengineering of the QI generally entails a drastic review of legislative instruments. In low- and middle-income countries, this is a time-consuming and tiresome endeavor. But without the review of out-of-date or insufficient legislation, or the development of new legislation and promulgation thereof, the QI cannot be transformed into an effective and efficient support service for the benefit of the whole country. Generally, any legislation older than about 5 years *should* be reviewed, and anything older than 10 years *must* be reviewed.
- Metrology, standards, and accreditation are activities for the common good that are seldom self-financing in a low- or middle-income country context. Hence government commitment to adequate and long-term funding through the national budget is an absolute necessity.
- The QI organization's service delivery is heavily dependent on trained and skilled personnel. Hence, development partners spend large sums on training. These skilled people often are then frustrated by civil service remuneration packages that do not take cognizance of their competencies. They leave the

public QI institutions, which are then without the necessary skills and may even lose accreditation or recognition. Means should be found to compensate such personnel adequately, even within a civil service context.

- Governance, in the form of councils or boards, is important because there are fiduciary and strategic responsibilities regarding the QI institutions. Custom and practice in low- and middle-income economies is to load these bodies with representatives from the public sector (that is, ministries), and the private sector is underrepresented. This alienates the QI institution from the very sector it needs to serve. The challenge is to get eminent industrialists to serve on councils or boards: they bring business acumen, act as marketing agents in the private sector, and have a far better idea of the strategies the QI institution needs to pursue to render a proper service.
- The knowledge regarding the role and importance of the QI in the well-being of the low- or middle-income country is often inadequate in the public sector, even though the notion of a regime to protect the consumer from market failures is in place. The challenge is to establish a knowledge base regarding what constitutes good QI practices across all the various ministries and their agencies—and not only the ones responsible for the implementation of the WTO TBT and SPS Agreements.

11.3 STRATEGIC APPROACHES TO SUPPORT QI DEVELOPMENT

The concept “strategy” has many meanings. For this discussion, a “strategic approach” is seen as the framework that guides the choices that determine the nature and direction of the development partner’s support for QI development in a given low- or middle-income country.

Such a “strategic approach” must enable development partners to make a difference that matters to a critical mass of appropriate stakeholders. This means, however, that the “strategic approach” would be different depending on the country being considered and depending on the resources the development partner is able to muster for the specific project. Obviously, the demand assessment of the country (see module 2: The Importance of QI Reform and Demand Assessment) defines the technological requirements regarding the QI, and it should have a major influence on the project design, but there are a few other strategic issues that need to be considered as well (Racine 2011).

11.3.1 Institutions and sound governance for a modern, effective QI

Key message: *Good governance is absolutely essential for the effective and efficient operation of QI institutions—governance in which political interference is minimized and board or council members have the necessary business acumen and are fully representative of the public and private sectors.*

An effective QI is dependent on the principles of good standardization practice (as detailed in module 3: Standards, section 3.4), including transparency, consensus, impartiality, and technical credibility. These principles depend on institutional rather than technological factors. If they are ignored, no amount of investment in technology or staff training can create a modern, effective QI. Fulfillment of these principles depends largely on the overall structure of the QI and the governance of individual institutions.

Most high-income countries have made good progress in establishing high-quality governance and legislation for their QI organizations in recent years. Regional trade arrangements like that of the European Union were often the drivers initiating such developments. In low- and middle-income countries, the picture is different. Some of these countries have adopted or are in the process of adopting a more modern approach to QI governance, whereas others are still stuck in governance systems of the Soviet era or systems that were established decades ago, when an “all-in-one” type thinking was prevalent.

Step 1: Restructure the QI to remove political interference and conflicts of interest

Low- and middle-income countries with a largely monolithic QI or a QI integrated with political institutions will need to restructure their QI. Removing political interference and conflicts of interest requires providing more autonomy to QI institutions, a goal best achieved by establishing independent institutions. Several possibilities need to be factored into such decisions:

- Good practice is for the accreditation body to be independent from other QI institutions, although in some countries it is combined with the NSB, provided that conformity assessment services are not available from such a construct.
- Scientific metrology, accreditation, and standards bodies should not be involved in the implementation of technical regulations, mandatory standards, or other regulatory activities. Their involvement in the development of the same should be limited to services contracted for by the regulatory authority on a needs basis.
- QI organizations should be free from political interference and have the autonomy to respond to market demands and to represent their country in the relevant regional and international organizations.
- The provision of conformity assessment services by the NSB, or calibration services by the NMI or legal metrology department or agency, should be carefully considered. If these bodies can operate in respect of market forces, and there is generally good governance of public entities, they may be fine. If not, it may be better for them to be separated.

Step 2: Follow good governance principles

As a second step, principles of good governance should be applied. The composition and terms of reference of the boards or councils of the fundamental QI institutions responsible for standards, metrology, and accreditation should reflect the need for stakeholder involvement. Too often, especially if they are public sector organizations, their boards or councils are mostly made up of lower-level bureaucrats as representatives of ministries, together with a few private sector representatives from business and industry associations. In addition, such boards or councils are acting more like an executive management than as a governance structure directing and controlling the institution regarding the interests of its many stakeholders, objectives and strategy, and overall finances.

Issues that would need to be addressed include the following:

- The membership of the board or council should reflect the main stakeholders of the institution. These would normally be the public and private sectors. The private sector will to a large extent determine the demand and therefore

the financial sustainability of the institution, either through monies appropriated through taxes (government funding) or through payments for services. Hence, they should constitute the majority of the board or council, even if they are appointed by the relevant minister in the case of a public entity. The boards of private sector QI organizations would obviously be appointed by the shareholders. The number of board or council members should not be too small nor too big: 10–16 has proven to be a useful number. The members should be appointed for their expertise and knowledge regarding standards, marketing, and finances.

- The board or council should have the authority to determine the strategy of the institution. Checks and balances can easily be included to ensure that this strategy is aligned with relevant government policies such as export, industrial development, food safety and security, and the like. The board or council should also have a meaningful say in the appointment of the head of the institution if it does not appoint the person outright. The head of the institution should not be susceptible to changes in government administration. Given the learning curve involved in managing a QI institution effectively, frequent changes to the head of the institution reduce technical capacity and institutional memory.
- The board or the council should be given the fiduciary responsibility for the QI institution. If it is a public sector institution, these would have to comply with the framework of approved government policy. If it is private sector institution, these would be subject to the requirements set by the shareholders' meeting. The fiduciary responsibility should include the approval of the annual business plans and annual budgets. The management of the institution should be able to operate within this approved budget without having to obtain approval for normal expenditures from the board or council, or even from the ministry in the case of public sector organizations. Finally, the board or council should have the responsibility to appoint financial auditors and demand compliance to generally accepted accounting practices by the management.

11.3.2 Involving public and private sector stakeholders for a demand-driven QI

Key message: Stakeholders, especially those that will be affected by QI services, must be involved in QI-related decision making.

Upgrading the QI requires addressing the technological gaps and worker skills identified through proper demand assessments (see module 2: The Importance of QI Reform and Demand Assessment). But that alone will not create an effective QI capable of achieving lasting international recognition. Nor is there a technocratic solution for developing a QI over time that can respond to economic and social needs. Getting a broad range of stakeholders involved in the decision making about the QI and providing them with a measure of political autonomy is a first step in achieving a demand-driven QI that will have a better chance of remaining relevant to its client base.

International practice often requires a QI institution to establish a forum where stakeholders and interested parties can provide input and recommendations for the government or the board or council to consider regarding the institution's services and operations. Forum members may include representatives or individuals from industry, importers, academia, authorities, purchasers, and consumer organizations. Such a forum should not have any governance

authority over the QI institution but should provide the governance structures with appropriate advice on policy and practice.

11.3.3 Coordinating the QI organizations

Key message: *The QI is complex, and its institutions require a holistic approach and coordination to ensure that there are no gaps and overlaps in responsibilities. This requires a clear policy environment within which they can operate as well as an overarching coordination office overseeing the relationships between the QI and the technical regulation environment.*

Coordinating the QI is another element that needs to be addressed, especially in low- and middle-income countries where market demand is still underdeveloped and consumer pressure is too weak to articulate the needs of the economy. Coordination is important during the early stages of QI development to ensure that a holistic goal is pursued. It is also important once the QI has developed; otherwise, gaps and overlaps develop between the actual and perceived responsibilities of institutions, especially in the regulatory domain, resulting in unnecessary transaction costs for suppliers.

Laws determine which areas are regulated by whom through technical regulations, food standards, or SPS measures. In turn, regulatory authorities prepare technical regulations, food standards, and SPS measures using standards developed and published by the standards body. For implementation, these require inspection, testing, and certification as well as accurate measurements. Trained inspectors, auditors, and assessors are required in all of them. The calibration and testing laboratories need to be accredited to demonstrate their technical competency, as do the certification and inspection bodies. In addition, all of these require international acceptance if they are to remain relevant in export markets. Such a system can become very complicated very quickly, and this web of relationships makes it difficult to operate effectively and efficiently without proper coordination.

Develop a national quality policy

The QI structure, governance, and coordination should be given substance in the development and implementation of a national quality policy (see module 10: How to Reform: Interventions and Approaches, section 10.1, for a detailed discussion of quality policy development). The quality policy should be developed with the meaningful involvement of all the stakeholders from the public and private sector as well as academia and NGOs.

An effective quality policy will clearly define the overall QI organizational structures, their governance, coordination, required reforms, and timelines for implementation. This is a useful place to start a high-level discussion and reach a consensus on the way forward on QI strategy and modalities between the government, public sector, private sector, and consumers.

Establish a technical regulation coordination office

A technical regulation coordination office can make a big difference in coordinating the QI's interface with the technical regulation regime. Many of the Organisation for Economic Co-operation and Development (OECD) countries have established a high-level office with regulatory powers to coordinate the various activities and systems related to technical regulation development and implementation, including the role the QI plays in this respect. This office can

make sure that no gaps and overlaps exist among the regulatory authorities in terms of their mandates and the products they are responsible for. It ensures the country's compliance with international or regional obligations such as the WTO TBT Agreement when given the mandate to vet any newly developed technical regulation for compliance with such obligations. Where a country has embarked on a major technical regulation regime reengineering exercise, this office can act as the coordinator.

In the case of low- and middle-income countries, such a coordinating office can have an even bigger impact in streamlining and modernizing the technical regulation regime. Many such countries battle with a legacy of ad hoc and uncoordinated technical regulation systems across their many ministries and agencies—regimes that may not comply with WTO TBT Agreement requirements, may not even be effective, and may result in high transaction costs for suppliers and industry. Many low- and middle-income countries also battle with the legacy of overregulation through mandatory standards, which need to be reduced.

Such a coordinating office, backed by the highest political level of the low- or middle-income country, has the time and inclination to oversee a project of such major proportions—whereas ministries and their agencies may be inclined to retain the status quo, for whatever reasons—because it would have more staying power than a development project with its limited time horizon.

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