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Innovation, Technology and Entrepreneurship Global Practice

The National Quality Infrastructure

A Tool for Competitiveness, Trade, and Social Well-being

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EXECUTIVE SUMMARY

Standards play an important role in global trade. They define how products, processes, and people interact with each other and their environments. They enhance competitiveness by offering proof that products and services adhere to requirements of governments or the marketplace. When used effectively, standards facilitate international trade, contribute to technology upgrading and absorption, and protect consumers and the environment.

The national quality infrastructure (NQI) is the institutional framework that establishes and implements standardization, including conformity assessment services, metrology, and accreditation. While there are several approaches to the institutional set up an NQI, the best-practice approach is a decentralized system with the component organizations acting as legally autonomous units.

Governments play a crucial role in designing, developing, and implementing an effective NQI. In countries with weak capacities, governments can lead coordination efforts by setting up technical committees, establishing testing facilities, and adopting standards into technical regulations for the purposes of consumer or environmental safety. They can help reduce transaction costs by gathering and disseminating information on standards and raising awareness about the benefits of adopting them. Government support has also proven critical in training technical personnel within NQI organizations.

There are several constraints to the successful development and implementation of a national quality infrastructure, including overly restrictive mandatory standards, conflicts of interest and political interference, lack of harmonization with international standards, limited financing, and lack of qualified personnel.

Developing an NQI begins with an assessment of the current system and identification of areas where reforms are required. The legal framework should establish transparent, independent institutions within a national structure that can work with international organizations such as the WTO. Stakeholder involvement is essential for a viable reform process and subsequent adoption by industry. The World Bank and other donor agencies are assisting a number of countries in the development of NQIs in order to encourage industrial development, reduce barriers to trade and entrepreneurship, and facilitate global technical cooperation.

1. THE NATIONAL QUALITY INFRASTRUCTURE

Standards are everywhere, yet they are largely invisible. They define how products, processes, and people interact with each other and their environments—assessing their features and performance, conveying information, and providing means of communication. Under the right conditions, standards benefit trade, productivity, and technological progress. Standards also support government efforts to protect consumers and the environment and improve safety and health.

1.1. Trade

Changing global trade flows have enhanced the role of quality standards in economic development over the past decade.

Box 1: Getting the Standards Jargon Right

Common misunderstandings among policymakers, economists, and technical experts arise from different interpretations of terminology. This can obstruct policy dialogue and impede reform. The international organizations that de facto "govern" the global NQI—ISO, IEC, ILAC, IAF, BIPM and the WTO[a]—use strict definitions to avoid misunderstanding:

- "Standards" refer to voluntary standards developed by industry or by national standards bodies with the participation of industry. They can be classified according to specific functions. This classification is useful in understanding the economic effects of standards, although most standards cannot be neatly classified into a single category.
  - Compatibility standards define relationships between independent entities for the purpose of interoperability. They guarantee that an intermediary component can be directly used in a larger system comprised of specific inputs and outputs.
  - Interchangeability standards, also called variety-reducing standards, define the common characteristics of two or more entities. In this way, they generate economies of scale and economies of learning in production.
  - Information and reference standards establish a common technical language in which to compare attributes and convey descriptive technical information (specifications).
  - Minimum quality standards provide signals that a given product conforms to certain defined characteristics, thereby reducing the transaction cost of user evaluation. These are often used to signal that a product meets health or safety requirements.
- "Technical regulations" are mandatory and are typically developed by policy-making branches of the government. Governments can utilize technical regulations to control the quality of products and to protect citizens from harmful market practices and failures. The WTO Technical Barriers to Trade (TBT) Agreement lists five legitimate uses of technical regulations: national security requirements, prevention of deceptive practices, protection of human health or safety, protection of animal or plant life or health, and protection of the environment.
- "Mandatory standards" do not exist in WTO terminology. In this brief they will be used to designate standards that are mandatory but are developed by national standards bodies, contrary to the WTO Code of Good Practice for the Preparation, Adoption, and Application of Standards.

[a] ISO – International Organization for Standardization; IEC – International Electrotechnical Commission; ILAC – the International Laboratory Accreditation Cooperation; IAF – International Accreditation Forum; BIPM – Bureau International des Poids et Mesures; WTO – World Trade Organization.

Quality upgrading by producers not only improves products and services to meet increasingly demanding customer expectations, but also enhances opportunities for expansion into new export markets. Increasingly, participation in world trade requires that suppliers comply with compatibility and interchangeability standards determined by lead buyers in global value chains in a variety of sectors. A growing number of these standards are not company-specific but are shared voluntary international standards that span supply chains, countries and economic sectors.[1]

The nature of participation in the global economy has evolved. Production is fragmented into smaller tasks along production chains. Research and development, design, production, marketing, and sales involve inter-firm contractual relationships often referred to as the "global value chain." In parts of the chain, compatibility standards are used to reduce transaction cost and create interchangeable and modular parts, while minimum quality standards ensure that the lead buyer has control over the quality of goods produced along the supply chain.[2]

Producers that face growing pressure to meet quality requirements require coordination and certification. Accordingly, a comprehensive system of interrelated actors that facilitate the setup, diffusion, and certification of standards becomes crucial. The term "national quality infrastructure" (NQI) denotes the complete public and private institutional framework required to establish and implement standardization, conformity assessment services (inspection, testing, certification), metrology, and accreditation. These services are needed to describe products and services and prove that they meet defined requirements, as required by governments (technical regulation) or the marketplace (contractually or inferred).

By diffusing market and technological information across borders, standards allow countries to compete in new international markets. They enhance transparency and allow foreign producers to incorporate national preferences and technical specifications and adapt their products and services accordingly. By establishing product and process characteristics or performance, information standards reduce transaction costs between business partners in distant countries and reduce information asymmetries. The global standard ISO 18185[3] enables the 12 countries that pioneered it to avoid unnecessary delays during customs inspections, reducing times and costs for cross-border trading.

Standards that are not well documented, difficult to find, or imprecisely defined can hinder trade. Moreover, using country-specific standards makes it more difficult to realize global economies of scale. The proliferation of standards may impose additional costs on firms. Among firms surveyed in the Latin America region, those facing technical regulations have additional compliance costs for each export market, which can increase their investment costs by up to 10 percent.[4] Governments can play an important role in facilitating trade by harmonizing national standards with international standards. In addition, governments can facilitate diffusion of international standards and standards of major trade partners to leading export industries.

1.2. Quality and Technology Upgrading

An effective NQI provides firms with opportunities to improve the quality of their products as well as contribute to technological change by enabling them to access codified technologies when interchangeability standards between trading partners are shared.

Interchangeability and reference standards are used to codify the technical characteristics and market preferences for products and processes, facilitating knowledge absorption and technological change. Standards have proven effective in promoting the adoption of desirable process and product characteristics (reliability, durability, etc.) and providing

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1 The most famous example is the ISO 9001 quality management systems standard.

2 Humphrey, J. and H. Schmitz 2000. "Governance and Upgrading: Linking Industrial Cluster and Global Value Chain Research." IDS Working Paper 120, Institute of Development Studies, University of Sussex, Brighton, UK; Kaplinsky, R. 2000. "Spreading the Gains from Globalisation: What Can Be Learned from Value Chain Analysis?" Working Paper 110, Institute of Development Studies, University of Sussex, Brighton, UK.

3 This standard dictates a protocol for electronic recognition of the seal number affixed on freight and for checking seal conditions electronically. This approach is expected to dramatically expedite customs clearance for cargo in ports and enhance competitiveness for small and medium-size enterprises

4 World Bank, 2007, *Quality Systems and Standards for a Competitive Edge*, Washington, DC.

roadmaps to improve quality. For example, the ISO 9001 standard provides an organization with a model to follow for the design, implementation, and assessment of quality management systems. Processes that are subject to ISO 9001 standards are more likely to enhance product uniformity and conformance to specifications.

Standards are also credited with fostering the diffusion of technological best practices. When knowledge is exchanged in private transactions, it does not generate spillovers to third parties. However, because information embodied in standards is nonproprietary, it creates a pool of technical information that can be transferred across companies and countries, freely accessed by entrepreneurs, scientists, and engineers, and used to generate new ideas and technologies.

Inadequate incentives and lack of coordination can result in an under-investment in standards development. Another risk of a different nature is the strategic use of standards for private gain. Companies can use compatibility standards defining product specifications for specified inputs and outputs in the global value chain as strategic instruments, undersupplying such standards to expand their market power. This can occur when the content of standards covers technological areas in which few firms have property rights or the exclusive resources needed to use a technology. Governments can play a vital role in coordinating and disseminating standards and in ensuring that they are not misused to hinder competition.

1.3. Safety, Health, and the Environment

Protecting human safety, health, and the environment are important ends of standards. Leaving product choice entirely up to consumers when information about quality is asymmetric can have harmful effects. Notorious examples in recent times include the safety issues raised by imported Chinese toys, pet food, and pharmaceuticals.[5] The NQI can help the government protect consumers and safeguard human health, safety, and the environment.

Minimum quality and safety standards allow consumers to assess the quality or safety of a product before purchasing it and enable regulators to exclude unsafe products from the market. Failure to comply with international minimum quality reference standards can have significant consequences. In 2007, the European Union placed an import embargo on shrimp from Costa Rica due to its failure to document all value-chain links in accordance with the requirements for fishery product certification. Likewise, environmental management standards help organizations comply with environmental laws and regulations and minimize adverse effects of their operations on the environment.

2. THE STRUCTURE OF THE NQI

The national quality infrastructure consists of a variety of organizations which play a role in establishing standards, evaluating whether products, process or services fulfill specified technical requirements, and certifying that requirements are met. There are several approaches to the institutional setup of the national quality infrastructure. Some best-practice approaches to NQI feature a decentralized system with the various bodies acting as legally autonomous units. The main components of the NQI are described in Figure 1.

Standards are formal documents which set forth the requirements that a product, process, or service should meet. Standards are voluntary, and producers can choose whether to use them. But once they are included in contracts or referenced in technical regulations, complying with them becomes a legal obligation. Standards provide the basis for evaluating conformity assessment and defining the requirements for such assessments.

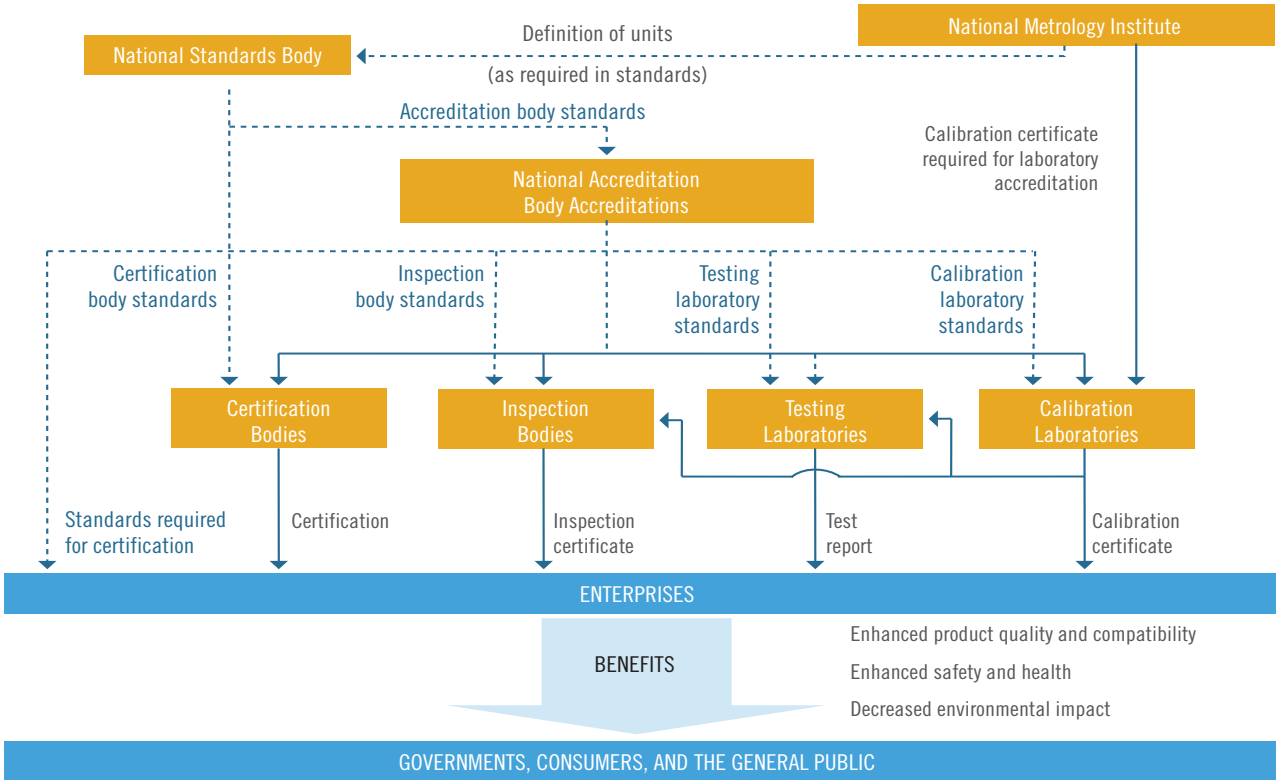
National standards bodies bring together public and private stakeholders to develop official voluntary national standards. Standards bodies usually adopt standards through consensus and publish them to make them available to industry, public institutions, and consumers.

2.1. Conformity Assessment

Conformity assessment consists of testing, inspection, and certification. Testing is the determination of a product's characteristics against the requirements of the standard.

[5] See *http://assets.opencrs.com/rpts/RS22713_20070828.pdf.*

FIGURE 1: THE NATIONAL QUALITY INFRASTRUCTURE



Source: World Bank, 2007, Quality Systems and Standards for a Competitive Edge, Washington D.C. Standards

Inspection encompasses the examination of a product design, product, process, or installation and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements. Certification is the formal substantiation by a certification body after an evaluation, testing, inspection, or assessment, that a product, service, organization or individual meets the requirements of a standard.

In many countries, conformity assessment services are increasingly being provided by the private sector rather than governments, while governments retain responsibility for maintaining the fundamentals—standards, metrology, and accreditation. Typically, the more industrialized and the larger the economy, the more the private sector is involved. Foreign direct investment has been a driving force for certification to international standards in many developing countries following the liberalization of the market and international harmonization of standards. This situation has given rise to a number of multinational conformity assessment bodies, most operating as private for-profit companies. However, small, fragile, or low-income economies do not have the critical mass of demand to attract investment in a broad range of conformity assessment services, which means that local firms either seek them abroad—which can be difficult for practical and economic reasons—or the government plays a role in the supply of services.

2.2. Metrology

Metrology is the science of measurement. It can be subdivided into:

- *Scientific metrology*, the development and organization of the highest level of measurement standards;

- *Legal metrology*, the assurance of correctness of measurements where these have an influence on the transparency of trade, law enforcement, health, and safety; and
- *Industrial metrology*, the satisfactory functioning of measurement instruments used in industry, production, and testing.

A national metrology institute establishes the national measurement system used to maintain, develop, and diffuse measurement standards for basic units and to diffuse metrological expertise to the economy. These institutes operate in the primary calibration market: they disseminate measurement standards by providing calibration services to independent calibration laboratories and other organizations responsible for regulations and standards. Countries often have a single national metrology institute—but when there are several, each is responsible for distinct measurement areas.

2.3. Accreditation

Accreditation is the procedure by which an authoritative body (the accreditation body) gives formal recognition that an organization is competent to conduct specified conformity assessment services (i.e. testing, inspection or certification). The accreditation body evaluates the personnel and supporting management system of the candidates for accreditation and can request practical tests for laboratories when relevant.

Most countries have a single national accreditation body responsible for all areas of accreditation.[6] Countries have a single accreditation body for all areas of accreditation in order to benefit from the economies of scale and economies of learning in accreditation, as well as provide a single point for international agreement. A single accreditation body also avoids confusion in the market, which could arise if multiple agencies claim to be at the top of the NQI chain. When a country does not have an accreditation body, certification bodies can seek accreditation abroad. However, this solution is suboptimal in practice, as it creates a grey market for certification. Following the initial accreditation, there is no national body to monitor the practices of the certification bodies and ensure compliance with acceptable procedures.

3. THE ROLE OF THE GOVERNMENT IN THE NQI

Governments have taken leading roles in establishing NQI organizations, specifically by providing the necessary technical support infrastructure for the development of industry. In fact, there are no examples of countries where a functioning quality infrastructure has developed without government support. In most countries, only once an industry has attained critical mass can NQI organizations—especially those providing conformity assessment services—migrate from government organizations providing subsidized services to commercial organizations providing services at market prices. Even then, governments often still support NQI organizations.

3.1. Addressing Coordination Failures

In most developing countries, where industry is nascent and capacity is weak, governments can perform a coordinating role, forming technical committees to facilitate voluntary standardization, preparing mandatory technical regulations, establishing common measurement infrastructure, and establishing the necessary testing facilities.

Governments can also play a role in correcting market failures in the diffusion of formal standards. Some standards are network goods, and the value of adopting the standard increases with the number of adopters. If the cost of adopting the standard is high, the market may never reach the critical mass of users necessary for the individual benefits of standards to exceed their costs. Many standards also involve significant adoption barriers caused by a lack of technical skills, time, or resources, which make them poorly understood and difficult to adopt. Governments can compensate for such market failures by creating programs and policies that promote the widespread diffusion of standards.

In most countries, most firms do not have their own proper facilities for testing, metrology, and calibration, and the availability of external facilities is limited. The existing market demand often does not provide sufficient incentive for

[6] The EU for example, requires that its member states have a single accreditation body.

independent firms to set up testing and calibration services and cover their costs. However, sometimes the industrial development of a specific sector depends on the availability of such services. In such cases, the government needs to facilitate their creation.

Similarly, in the early stages of developing an accreditation system, government support is critical to support the national accreditation body. When an accreditation body has limited capacity and access to very few assessors capable of offering specialized technical services, the pace of accreditation and range of sectors in which the accreditation body can work are limited. Without an established customer base, the accreditation body will find it difficult to be self-sustaining through accreditation fees. It will need government support to train technical personnel. Once a critical mass of customers exists, the government should gradually phase out its financial contributions. Countries with limited resources and a small customer base can pool their resources and establish a regional accreditation body that is recognized in each economy. A promising example of this is the Central American Accreditation Forum (FOCA). FOCA's purpose is to establish mechanisms of analysis, promotion, cooperation, and coordination among the accreditation bodies of the Central American region in order to strengthen and consolidate the accreditation structures of these countries. Within FOCA, Costa Rica, El Salvador, Honduras, Guatemala, Nicaragua, and Panama have joined together to share resources and quality service providers.

3.2. Reducing Transaction and Search Costs

Information is a public good, and this suggests a role for government. Knowing the characteristics of standards required by users or established in norms by governments in diverse potential markets is key for market access. However, acquiring such information is costly, and it is usually not efficient for each producer to invest in that endeavor. Governments can provide the necessary platform for accumulating, disseminating, and discussing information. Likewise, governments can also raise awareness about the impacts of adopting standards.

4. CONSTRAINTS TO SUCCESS

4.1. Top-down Standards that are Technically Obstructive and Mandatory

While most products and services in OECD countries need only comply with voluntary standards, this concept remains foreign to many countries, where thousands of products must comply with technical regulations with no clear impact on social welfare. Often these technical regulations are imposed from the top down, with little involvement of industry and other stakeholders. Such a process tends to produce regulations that can be overly prescriptive. Often, there is scant capacity in the policy-making and regulatory bodies to develop technical regulations that comply with international trade requirements while safeguarding safety, health, and the environment.

This approach stifles innovation and makes it difficult for firms to develop or import new products that do not meet existing and often outdated standards. By decreasing variety, excessive technical regulations also reduce diversity in the pool of products that can be used as the basis of future innovation.

A primary mechanism for creating a quality infrastructure that fuels economic growth and provides useful services is streamlining technical regulations. For the past decade, the trend throughout the world has unambiguously shifted toward voluntary standards. This has been largely driven by WTO and EU membership requirements, the latter being much more stringent. The WTO TBT Agreement requires that technical regulations avoid unnecessary obstacles to trade, which implies shifting the balance between technical regulations and voluntary standards. Giving national standards bodies the responsibility to develop mandatory standards creates another obstacle to private sector development. In this case, private producers can effectively draft technical regulations to protect their market power.

4.1.1. Mandatory Product Certification versus Market Surveillance

Enforcement of mandatory standards largely relies on mandatory certification, a cumbersome and expensive procedure for many products for which self-declaration and market surveillance would be adequate. Compulsory certification can affect a significant number of businesses

in developing countries, with substantial cost implications. According to IFC surveys of entrepreneurs, 25 percent of SMEs were required to certify their goods in Uzbekistan. In Ukraine, mandatory certification affected some 84 percent of the revenues of survey respondents.[7] Mandatory certification is of limited value for public health, consumer protection, safety, or the environment and should be discontinued.

Many countries have transitioned from mandatory certification to market surveillance, a more efficient and less burdensome means of ensuring that products and processes adhere to technical regulations. Market surveillance and the use of self-certification have several advantages over certification. Under a market surveillance system, producers are responsible for using internal processes to ensure that their products are in compliance with the necessary regulations, and in some cases, may be required to apply a mark of conformity to the product. A gradual transition from mandatory certification to market surveillance would significantly reduce the financial and technical burden imposed on producers.

4.2. Standards and NQI Processes that Obstruct Trade

Where there are differences between countries' standards, lack of harmonization can create a net welfare loss in both an importing and exporting country. Differences in standards and technical regulations between countries, even when justified due to national preferences or health or safety concerns, can create technical barriers to trade.

Even when national standards or technical regulations have been harmonized, incompatible conformity assessment procedures can deter trade, since complying with a standard or technical regulation is only useful if compliance can be demonstrated to the buyer or government at reasonable cost. Duplication of testing and certification can be very costly. A recent survey of firms in developing countries showed that 44 percent of firms had to conduct significant duplication of testing procedures to meet foreign requirements after domestic requirements had been met, and 30 percent had to conduct complete duplication of testing procedures. Sixty-eight percent of firms cited testing and certification costs as an important reason for not exporting.[8]

4.3. Conflicts of Interest

Developing an effective NQI system requires a separation of functions, often accompanied by changes in the legal status, autonomy, and governance structure of NQI bodies. However, removing political interference and conflicts of interest can be very difficult, as existing institutional heads have a stake in maintaining the status quo. Moreover, existing NQIs are often tied to political economy considerations, discouraging reform.[9]

In some countries, the NQI system is centrally controlled by the state. In these countries, the same institution is responsible for the conducting standard development, certification, and accreditation activities, posing a significant conflict of interest. In Ukraine, for example, the State Committee for Technical Regulations and Consumer Protection (Derzhstandart) is responsible for the development and approval of standards, product certification, inspection of producers, market surveillance, and consumer protection. Not only is it problematic that the entire process is completely controlled by one organization, but the overlapping of commercial and regulatory functions and the discretionary powers of Derzhstandart to control the certification market create considerable conflicts of interest. In Bolivia, a single entity, IBMETRO, is responsible for providing industrial calibration services to the market and accreditation services for market players who compete with its own calibration services.

4.4. Limited Financing

Funding constraints, combined with failure to appreciate the importance of the NQI, can limit the resources available for reform. NQI upgrading requires a significant time and financial investment (Table 1). The amount needed for the

[7] Racine, 2011, Harnessing Quality for Global Competitiveness in Eastern Europe and Central Asia, World Bank, Washington DC.

[8] World Bank, 2007, Quality Systems and Standards for a Competitive Edge, Washington DC.

[9] For example, the legacy of the Gosstandart system is strong in a number of Commonwealth of Independent State (CIS) countries for a variety of reasons. Most importantly, trading in CIS countries is still dominated by intraregional trade, particularly with the Russian Federation, which continues to use a derivative of the Gosstandart system. For a country that trades mostly with the CIS, reforming away from a Gosstandard system toward international best practice models would mean losing markets without a guarantee of finding new ones.

TABLE 1: ESTIMATED COSTS AND TIME INVOLVED IN DEVELOPING A NATIONAL QUALITY INFRASTRUCTURE

COMPONENT	INVESTMENT COST (MILLION US$)	DEVELOPMENT TIME FOR HARMONIZATION (YEARS)
National metrology institute	5–200	15
Legal metrology	0.5–5	5
Secondary calibration and testing laboratories	2–500	2–15
National accreditation body	0.5–2	5
National standards body	0.5–2	5

Source: Author calculations.

development of a standardization system alone, including expertise transfer, development of technical committees, and purchase of information technology, may reach US$2 million over five years. Most of the operating costs of the standards body must also be covered by the government. Although membership fees and sales of standards generate income, they are unlikely to generate sufficient income to cover operating costs in most small economies and in economies where demand for voluntary standards remains low.

At the firm level, limited time and financing impede implementation of a quality management system. Implementation time depends on many factors, including the level of complexity of the company, level of quality, the skill level of personnel, and the degree of management commitment. New personnel may need to be hired and parts of the company may need to be restructured. The financial cost of implementing quality management systems can be a barrier to certification, especially for SMEs.

4.5. Limited Human Capacity

An effective NQI system and the quality of the services offered are directly dependent upon the quality of its human capital. Many developing countries lack technically qualified personnel and cannot retain skilled staff due to their inability to provide competitive salaries.

In more technical areas, such as metrology, specialized human capital is needed to increase capacity in the country and guarantee precise measurements and a supply of reliable services. Accurate measurement depends on well-equipped laboratories as well as on the presence of competent and well-paid staff. Scientific personnel must have specialized training and research experience. Likewise, technical staff must be able to construct testing modules and to maintain measurement instruments.

Similarly, the objectivity of the accreditation and conformity assessment processes largely depends on the quality of the technical staff. Assessment teams must have sufficient collective scientific and technical skills to understand the testing and calibration activities of laboratories and the management systems of certification bodies. In the area of laboratory accreditation, technical expertise requires assessors with knowledge of the latest technologies and scientific practices. Human capital must be developed by training personnel who will manage the system's quality services.

5. INTERVENTIONS AND INSTRUMENTS

Most governments need to make investments to reform or upgrade their national quality infrastructure. But they must ensure that they are cost effective, do not replicate services that are available in neighboring countries, and are matched by measures to stimulate demand for quality.

Once institutions have been reformed or upgraded in the context of harmonization with international norms for NQI—including the adoption of relevant management processes—capacity building and technology upgrading can be targeted to individual aspects of NQI to achieve "quick wins," provide demonstration effects, and avoid repeating mistakes. The end goal should be to have an internationally harmonized NQI that responds to the needs of society without duplicating the role of the private sector.

5.1. NQI Strategy

NQI systems are at different levels of development across countries and regions. An initial step in implementing NQI upgrading will be to conduct an assessment and develop a strategy for upgrading, harmonization, and reform, as appropriate. In many countries, there may be constraints to the level of NQI infrastructure development feasible in initial stages. Thus, choices will need to be made about which minimum infrastructure and services are necessary given cost and capacity constraints. Governments have typically taken a leading role in this process.

The development of an NQI strategy should involve stakeholders. Armenia used this process to develop its national strategy for the reform of the NQI in 2010. A number of working sessions and continuous consultations between the government, NQI bodies, and industry and consumer groups were held. One favored method is to develop a national quality council that identifies needs and articulates a response strategy. The council can provide a forum for gathering and disseminating information and discussing and solving problems. The tasks of the council should be defined by the stakeholders, but should include coordinating and implementing the national strategy for NQI. Strategies for individual NQI institutions can then be derived from the national strategy. Figure 2 provides one approach to coordinating the NQI. It is structured to receive and integrate inputs from a range of stakeholders, through the establishment of a national quality council.

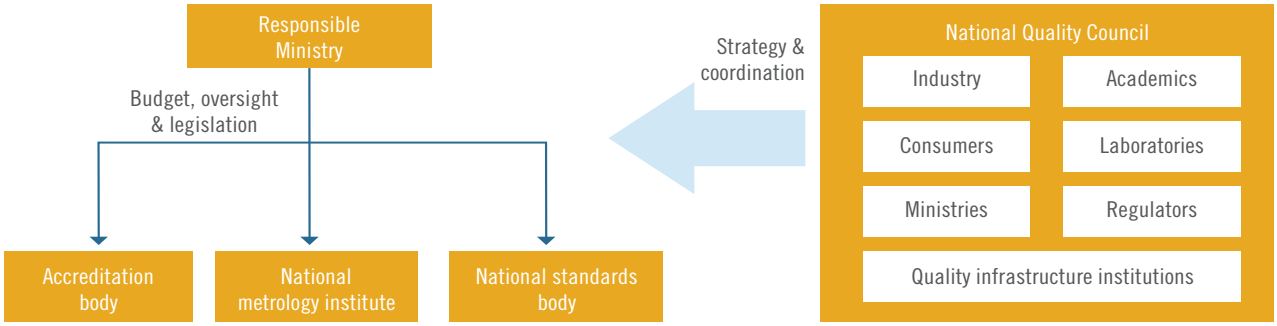
5.2. Structure of the NQI

The first step toward establishing an internationally recognized national quality infrastructure is ensuring good governance and creating institutions free from conflicts of interest. To achieve this, countries will need to either build or restructure their national quality infrastructure upon the principles of transparency, openness, consensus, impartiality, and technical credibility. No amount of staff training or technological investment can create a modern NQI if these principles are ignored.

Once a clear strategy has been developed, a legal framework must be developed to ensure proper functioning of the NQI. National legislation must be drafted or updated to reflect the agreed upon structure, governance, and functions of the NQI. It must also reflect WTO TBT principles, the guidelines of the main international NQI bodies, and the direction of a national NQI strategy. For example, in Mexico the Federal Metrology and Standardization Law, originally passed in 1992, was reformed in 1997 to accommodate guidelines of trade partners under the North American Free Trade Agreement.

Well-governed institutions—free from conflicts of interest—are a necessary condition for an effective and internationally recognized quality infrastructure. To achieve this, some countries will need to reform and restructure their NQI and create independent, transparent institutions that hear the voices of all stakeholders in the system. At the very least:

FIGURE 2: ONE APPROACH TO COORDINATING THE NATIONAL QUALITY INFRASTRUCTURE



- Accreditation bodies must be independent from all other NQI institutions.
- Metrology, accreditation, conformity assessment, and standardization bodies should not be involved in the development of technical regulations, mandatory standards, or other regulatory activities.
- Metrology, accreditation, and standardization bodies should be free from political interference and able to respond to market needs and represent their countries in relevant international organizations.

Some countries will need to consider the closure of state-owned bodies that offer services that are either not aligned with the needs of the economy or not necessary after a transition to voluntary standards. In other cases, when there is market demand, the state can consider privatization or movement to an NQI based on public and private ownership and cooperation. In all cases, liberalizing the market for conformity assessment to voluntary standards and enabling any entity—domestic or foreign—to compete, will have positive effects on cost and service availability in the economy. A functioning national accreditation system, based on either local or foreign accreditation, will be necessary for the market to function effectively.

Following this, investments in infrastructure and skills can begin. Potential sources for investment include the national budget and projects implemented through funds provided by various donor agencies. Recent projects have included those in Turkey, Former Yugoslav Republic of Macedonia, Moldova, the Kyrgyz Republic, and Albania. Such projects provide equipment, know-how transfer, specialized premises, and public awareness campaigns.

5.3. Standards and Technical Regulations

Harmonizing national standards with regional and international trade partners is a key step in supporting global NQI integration, though it can be highly technical and does not happen overnight. National standards bodies should use three closely linked strategies to harmonize their standards: adopting international standards, influencing international standardization activities, and coordinating with trade partners to adopt regional standards appropriate to the region's needs.

There can be a tradeoff between standardization and competition, as excessively rigid standards can reduce competition, product variety, and technological progress. The national standards body plays an important role in determining which standards the country should adhere to based on the existing economic environment and goals. While the adoption of certain environmental and labor standards may be a useful strategy of product differentiation for certain firms, it may not be efficient for the whole sector and may block existing comparative advantages.

A limited set of technical regulations can be developed to protect consumers, health, safety, and the environment. According to good practices, technical regulations are developed by government and often by designated regulatory agencies under ministries.[10] Developing technical regulations with no involvement of the national standardization body is global best practice and will help avoid conflicts of interest. Careful reviews of technical regulations should ensure that they do not impose technical barriers to trade and unnecessary constraints to businesses. A regulatory management system can be developed to support the institutions involved in the technical regulation regime.

5.4. Conformity Assessment

There are two ways in which governments can enforce technical regulations: i) requiring a premarket approval of products through mandatory certification; and/or ii) through market surveillance, allowing companies to certify that certain standards have been met and then verifying this through spot checks and consumer complains. The tendency in developed countries has been to move toward market surveillance.

Within market surveillance, a government monitoring agency has the duty to ensure that only complying products are placed on the market by testing products and applying appropriate sanctions to the supplier. Utilizing these methods, governments relinquish some of their involvement in the certification process by transferring the responsibility for conformity with technical regulations to the producer. While this practice can be beneficial in minimizing government

[10] These government bodies are not considered part of the NQI.

activities required for conformity assessment, it is not suitable for every product. Products deemed as particularly dangerous still require mandatory certification.

Enforcing technical regulations is most effective when the focus of the market is on process conformity rather than product conformity. A focus on product certification often involves imposing a long list of detailed technical product characteristics to avoid deviation. Process certification is less restrictive while still able to ensure that the desired requirements are met for health and safety standards.

Ensuring that conformity assessment systems are harmonized with international standards and guidelines is also important for global integration. Accreditation is the last level of quality control in conformity assessment, since it can provide credibility to certification, testing, inspection, and calibration bodies so that their services are recognized and respected domestically and abroad. To be recognized, a conformity assessment body can seek accreditation from its country's own national accreditation body. It can also seek accreditation abroad, although this involves several practical and economic barriers.

5.5. Metrology

A first step toward the modernization of the metrological framework is a needs and gap assessment of the types of measurement standards currently in place, what is required, and what level of accuracy is needed. A new approach for the selection of equipment and reference standards needs to be applied in market economies. Metrological needs should be determined by conducting a thorough and realistic demand survey.

It is important to distinguish between the three areas of metrology—scientific, industrial, and legal. In mature industrial economies, a public or private national metrology institute is responsible for scientific metrology, and commercial calibration laboratories are responsible for industrial metrology. Public legal metrology organizations oversee the regulatory field (official controls, trade, consumer protection, safety, and the environment). Countries can support the modernization of their enterprise sector by significantly reducing the number of regulated metrology instruments. Too broad a scope of legal metrology results in costs and technical constraints on enterprises introducing new technologies.

Countries typically have a single national scientific metrology institution responsible for disseminating measurements in the economy in all areas of metrology. This is because scientific metrology is very expensive, so having more than one national reference standard for the same measurement would not be viable; it requires technical skills that are particularly scarce in developing countries; it requires adopting international process standards that are difficult and lengthy to implement; and it requires participating in international inter-comparisons[11] to ensure that the NMI's measurements are recognized across borders and that those measurements in industry that are traceable to the NMI's measurements, through calibration, are also recognized by trade partners.

Calibration laboratories help firms ensure that their equipment allows them to manufacture products in accordance with buyer requirements. To play a credible role in the conformity assessment system, testing and calibration laboratories and inspection bodies must display many of the same characteristics as certification bodies, notably, impartiality, objectivity, and confidentiality. Objectivity relies heavily on the procedures guiding the evaluation process, the equipment used, and the skills and qualifications of staff. Equipment and measurement reference systems must be calibrated to other internationally accepted metrological references to ensure traceability.

5.6. Accreditation

Impartial, objective, and technically credible accreditation systems have complete institutional separation of accreditation from regulatory, conformity assessment, and metrology functions. All scopes of accreditation should fall under the responsibility of a single body. Conformity assessment bodies involved in regulatory and voluntary markets should be subject to the same accreditation systems. Internal laboratories and

[11] This includes the International Committee of Weights and Measures (CIPM) MRA.

commercial laboratories should also be subject to the same voluntary accreditation system.

To be recognized internationally, accreditation decisions on the performance of interested entities should be based on widely recognized international standards that establish operational requirements.[12] These standards are not only useful because they are used globally, but because they have been improved through international consensus over several decades to include impartiality, objectivity, and confidentiality practices in addition to sound management practices. For full recognition, national accreditation bodies must comply with international requirements, join regional or international accreditation organizations, and through them, participate in mutual recognition arrangements (MRAs) based on peer evaluation and acceptance of their accreditation systems. Membership in an MRA is required to guarantee the credibility of domestic certificates and test reports in importing countries.

Most solid accreditation systems are built through international and regional cooperation. This often takes the form of compliance with guidelines and membership in international or regional accreditation organizations. In instances where there is no regional accreditation body, small economies can join forces to develop and share accreditation capabilities, thereby reducing costs, although this is rarely done. Countries in Eastern Europe have found it easier to develop their accreditation bodies than those in Africa, because of the presence of experienced national accreditation bodies who share their knowledge in regional accreditation associations.

The accreditation body can be either public or private, although private bodies typically benefit from a public mandate and public funding when the market is not developed. To ensure that the accreditation body is customer-driven, it is useful to involve both public and private stakeholders in its governance. This helps ensure impartiality and build public confidence in the organization. Technical consultative committees of external specialists can help ensure that accreditations are granted on the basis of sound and objective technical decisions.

6. NQI DEVELOPMENT ACTIVITIES BY DONOR ORGANIZATIONS

6.1. World Bank Activities

6.1.1. Indonesia Industrial Technology Development Project

The Industrial Technology Development Project (approved December 1995) in the amount of $47.0 million had the objective of enhancing the competitiveness of Indonesian industry, especially SMEs. The NQI component of the project amounted to $3.07 million and included technical assistance to the National Metrology Center in the form of a twinning agreement with Australia's primary metrology center (CSIRO). The aim of the agreement was to build management and institutional capacity and provide laboratory equipment to upgrade the technical proficiency of calibration laboratories under the national laboratory system. Technical assistance for the Center for International Standards was provided to hold quality awareness seminars for SMEs, develop outreach centers in the regions, and train staff. More than 3000 SMEs participated in the Center for Industrial Standards quality awareness seminars, and about 700 firms were trained in documentation procedures for adopting ISO 9001.

The objective of improving Indonesia's system of industrial NQI was substantially achieved. Project performance indicators show that the number of accredited calibration labs at the Institute of National Metrology doubled and the percent of calibration labs showing acceptable inter-comparison tests increased from 50 to 80 percent. The Center for Industrial Standards also got four of five labs internationally recognized and into conformance with ISO requirements.

6.1.2. Kyrgyz Republic: Reducing Technical Barriers for Entrepreneurship and Trade (RTBET) Project

The Reducing Technical Barriers for Entrepreneurship and Trade project (approved July 2006), a technical assistance loan in the amount of $5 million, aims to streamline the

[12] Such standards include ISO/IEC guides 17021, 17024 and EN 45011 for certification bodies, ISO standard 17025 for calibration and testing laboratories, ISO 15189 for clinical testing laboratories, ISO 15195 for clinical reference/calibration laboratories and ISO/IEC standard 17020 for inspection bodies.

national technical regulation and standards framework for business, develop systems to enhance product quality and safety, and increase enterprise competitiveness in pilot sectors. The key project outcomes will be a decrease in the cost of regulatory compliance for business and, in the longer term, a diversification in its exports.

The project consists of the following components: 1) Strengthen the capacity of the public sector to develop the new technical regulatory framework based on the Law of Fundamentals of Technical Regulation; 2) Strengthen the capacity of the National Institute of Standards and Metrology (NISM) to perform its functions; And 3) Develop a modern domestic quality and certification infrastructure capable of providing critical services to the industry.

A number of noteworthy achievements have been made thus far. The list of products subject to mandatory certification continues to be streamlined. A total of 17 technical regulations are now in force in various sectors ranging from food and agricultural products to construction and transportation services and have replaced some over-restrictive mandatory standards. The Kyrgyz Republic is steadily emerging as a center of high-precision metrology in Central Asia based on the two state-of-the-art reference laboratories in temperature and mass acquired under the project by the Kyrgyz Center for Standards and Metrology. The latter is now capable of providing higher precision measurement and calibration services to various users, from public providers (health services) to private-sector companies (producers and manufacturers). The epidemiology laboratory of the Ministry of Health is now also able to provide testing services in a wide range of fields, ranging from food to environmental quality, based on the radiology and physics equipment procured under the Project. The Kyrgyz Accreditation Center, established under the project, continues to make steady progress toward international recognition and formally initiated its bid for candidacy to the International Laboratory Accreditation Cooperation (ILAC).

6.1.3. Ghana Micro, Small and Medium Enterprise Project (active, approved January 2006)

The project component, of approximately $6.1 million, aims to enhance competitiveness and employment within Ghanaian MSMEs and provide an enabling environment to boost investments by reducing selected business constraints, including technical barriers to trade, among other suggested reforms.

The main objectives to be achieved by addressing the problems of technical regulation in Ghana are the following:

- Establishment of the new system in accordance with international requirements through the introduction of a regulatory and institutional framework;
- Strengthening the capacity of Ghanaian certification bodies and laboratories, specifically their personnel and technological level, for the purpose of integrating them into the global conformity assessment network;
- Raising awareness of Ghanaian producers of the benefits and utility of conformity assessment, introducing incentives for them to install quality management and hazard analysis and critical control point (HACCP) systems with the aim of expanding the market for conformity assessment services.

As a result of the project activities, Ghana should have an upgraded and decentralized system of technical regulation with clear-cut procedures and responsibilities. This system will comply with international requirements and will be ready for integration into the global conformity assessment network (International Laboratory Accreditation Conference, International Accreditation Forum, equivalence agreements, reputable voluntary certification systems). Ultimately, Ghana will have the appropriate infrastructure in place, including a national accreditation body, accredited and equipped laboratories and certification bodies, qualified personnel, and relevant documentation.

6.2. NQI Activities Outside the Bank

6.2.1. Physikalisch-Technische Bundesanstalt (PTB)

Under Germany's Federal Ministry for Economic Cooperation and Development (BMZ), PTB participates in a number of technical cooperation projects in developing and transition countries. Several of them are conducted in cooperation with the European Union, the World Bank, and other organizations. PTB is currently involved in nearly 50 development policy projects through which it assists more than 80 partner countries.

PTB international technical cooperation supports all aspects of the quality infrastructure, from conceptual design to practical implementation. PTB projects aim to establish and expand

internationally recognized quality infrastructures in developing countries and emerging economies, enabling them to improve their global competitiveness. PTB provides technical consulting and system consulting, training, and occasionally equipment.

6.2.2. United Nations Industrial Development Organization (UNIDO)

UNIDO has a comprehensive program to help developing countries and economies in transition to overcome the shortcomings of their standards and conformity infrastructure. The services offered include:

Standards:
- Establishment or strengthening of standardization bodies
- Harmonization of standards at the national and regional level
- Assistance to participation in regional and international standards-setting activities
- Assistance in developing product conformity mark schemes

Metrology:
- Establishment or strengthening of laboratory capacities for legal and industrial metrology, in accordance with industrial and export requirements
- Assistance in laboratory networking and inter-laboratory comparisons
- Support to laboratory accreditation

Product testing:
- Establishment or strengthening of laboratory capacities, primarily for chemical and microbiological analysis, coupled with upgrading of specialist laboratories for industries with high export potential (such as food products)
- Assistance in the harmonization of testing procedures, laboratory networking and inter-laboratory comparisons
- Support to laboratory accreditation

Certification:
- Developing national certification capability
- Pilot projects for capacity-building related to specific systems standards (ISO 9000, ISO 22000, ISO 14000 etc.)

Traceability:
- Developing national capacity to comply with EU 'farm to fork' traceability laws
- Undertaking pilot projects to promote compliance with traceability laws

Accreditation:
- Establishment or strengthening of accreditation bodies
- Helping national accreditation bodies to obtain international recognition from IAF and ILAC through peer evaluations

Together with the World Association of Industrial and Technological Research Organizations (WAITRO), UNIDO has created an Internet-based portal for laboratory development called LABNET. LABNET contains a guide for the accreditation process, technical requirements for laboratory development, references to relevant organizations and on-line documents, information about training programs, job opportunities, and a discussion forum.

7. ADDITIONAL RESOURCES

7.1. International and Regional Organizations

Standardization Bodies
- Euro-Asian Interstate Council for Standardization, Metrology and Certification (EASC)
- European Committee for Standardization (CEN)
- International Organization for Standardization (ISO)

Accreditation Bodies
- Asia Pacific Laboratory Accreditation Coordination (APLAC)
- European co-operation for Accreditation (EA)
- International Accreditation Forum (IAF)
- International Laboratory Accreditation Cooperation (ILAC)
- Pacific Accreditation Coordination (PAC)

Metrology Bodies
- Asian-Pacific Metrology Program (APMP)
- Eurasian Cooperation of National Metrological Institutes (COOMET)

- General Conference on Weights and Measures (CGPM)
- International Bureau of Weights and Measures (BIPM)
- International Committee on Weights and Measures (CIPM)
- International Organization of Legal Metrology (OIML)

7.2. World Bank Staff and Consultants

Enrique Aldaz-Carroll
Lorenzo Costantino
Mona Haddad
Bernard Hoekman
Steven Jaffee
Jean-Louis Racine
Ben Shepherd
Christina Tippmann
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7.3. External NQI Experts who Have Worked with the World Bank

John Gilmour
Karl-Christian Goethner
Alex Inklaar
Robert Kaarls
Martin Kellermann
Clemens Sanetra
Huseyin Ugur

7.4. Data

Annual surveys

- ISO (International Organization for Standardization).ISO Survey of Certifications
- ___ ISO Members

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