The National Quality Infrastructure

Standards 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, they facilitate international trade and contribute to technology upgrading and absorption. This brief discusses the importance, the central elements, and constraints to success of national quality infrastructure.

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Introduction

Standards may simply be defined as a set of rules for ensuring quality; they define how most 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. Standards also spur and disseminate innovation, solve coordination failures, and facilitate the development of profitable networks.

Quality and standards are inherently linked. Quality is the degree to which the innate characteristics of a product, process, or person fulfill stated and unstated customer requirements and expectations; comply with stated norms, regulations, and laws; or both. Standards are often used to codify technological requirements expected by customers or governments, making them an essential element in the effort to upgrade quality in a country.

The National Quality Infrastructure (NQI) is the institutional framework that establishes and implements the practice of standardization, including conformity assessment services, metrology, and accreditation. This brief outlines the central components of the NQI, discusses measures to develop an effective quality system, and addresses challenges to implementation.

The importance of standards and systems

When used effectively, standards play an important role in global trade, contributing to technology upgrading and absorption, and protecting consumers and the environment. This section discusses the impact of standards on these areas.

Trade

Changing global trade flows have enhanced the role of quality standards in economic development over the past decade. 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 in a variety of sectors requires that suppliers comply with standards determined by lead buyers in global value chains. A growing number of these standards are not specific to companies but are shared internationally that span supply chains, countries, and economic sectors.[1] 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.

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 up to 10 percent (World Bank 2007). Governments can play an important role in facilitating trade by harmonizing national standards with international ones. In addition, governments can facilitate diffusion of international standards and the standards of major trade partners to leading export industries.

Quality and technology upgrading

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

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, and so on) and providing roadmaps to improve quality. For example, the International Standards Organization ISO 9001 standard provides an organization with a model to follow for the design, implementation, and assessment of quality management systems.

Standards are also credited with fostering the diffusion of technological best practices. When knowledge is exchanged in private transactions, it does not spill over 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 underinvestment in standards development. Another risk of a different nature is companies using 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.

Safety, health, and the environment

Protecting human safety and health and the environment are important ends of standards. 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. Notorious examples in recent times include the safety issues raised by imported Chinese toys, pet food, and pharmaceuticals (Morrison 2007). The NQI can help the government protect consumers and safeguard human health, safety, and the environment.

Central elements of the NQI

The NQI comprises a variety of organizations each of which plays a role in establishing standards; evaluating whether products, process, or services fulfill specified technical requirements; and certifying that these requirements are met. The best practices approach to NQI as set forth by the World Bank is based on a decentralized system with the various bodies acting as legally autonomous units. Each of the central components of the NQI is described in Figure 1.
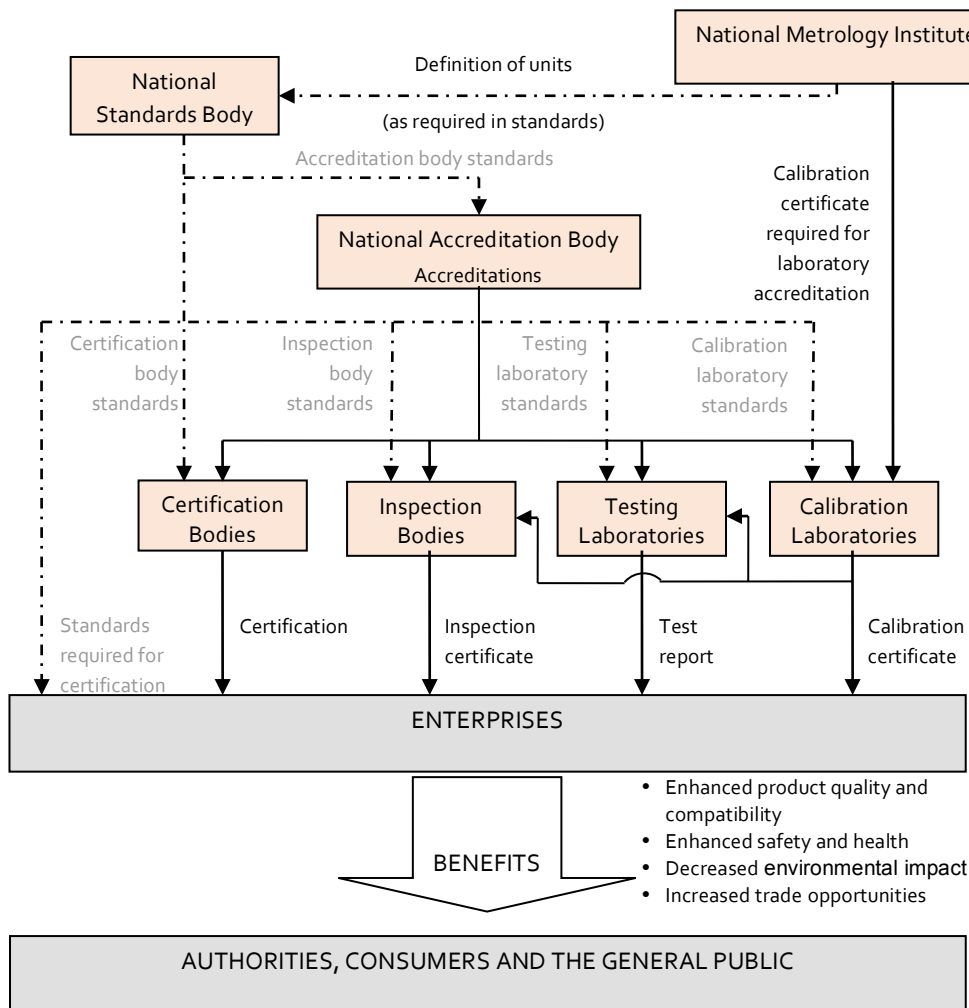
Conformity Assessment

Conformity assessment comprises testing, inspection, and certification of products or services. Testing is the determination of a product's characteristics against the requirements of the standard. Inspection encompasses the examination of a product design, end product, or process, and the determination of its conformity with 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 larger and more industrialized the economy, the more the private sector is involved. FDI 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.

Figure 1: The National Quality Infrastructure

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National Metrology Institute

National
Standards Body          Definition of units

                        (as required in standards)        Calibration
                        Accreditation body standards      certificate
                                                          required for
        National Accreditation Body                       laboratory
        Accreditations                                    accreditation

Certification   Inspection   Testing     Calibration
body            body         laboratory  laboratory
standards       standards    standards   standards

Certification   Inspection   Testing      Calibration
Bodies          Bodies       Laboratories Laboratories

Standards    Certification   Inspection   Test     Calibration
required for                 certificate  report   certificate
certification

ENTERPRISES

            BENEFITS        • Enhanced product quality and
                              compatibility
                            • Enhanced safety and health
                            • Decreased environmental impact
                            • Increased trade opportunities

AUTHORITIES, CONSUMERS AND THE GENERAL PUBLIC
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Source: World Bank 2007.

Metrology

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

- **Scientific metrology** is the development and organization of the highest level of measurement standards.

- **Legal metrology** is the assurance of correctness of measurements where these have an influence on the transparency of trade, law enforcement, health, and safety.

- **Industrial metrology** is 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.

Accreditation

Accreditation is the procedure by which an authoritative body (the accreditation body) formally recognizes that an organization is competent to conduct specified conformity assessment services (that is, 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 in order to benefit from the economies of scale and economies of learning in accreditation, as well as to 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, though this is often a suboptimal solution.

Constraints to NQI success

Constraints to the successful development and implementation of an NQI include overly restrictive, mandatory, top-down standards; political conflicts of interest and interference; lack of harmonization with international standards; limited financing; and lack of qualified personnel.

Technically obstructive mandatory standards

A primary mechanism for creating a quality infrastructure that fuels economic growth and provides useful services is the streamlining of mandatory standards known as technical regulations.[2] While most products and services in OECD countries need only comply with voluntary standards, this concept remains foreign to many developing countries, where thousands of products must comply with mandatory technical regulations with no clear impact on social welfare. Often 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 and do not comply with international trade requirements.

Such overly restrictive and mandatory technical regulations stifle trade. Countries should minimize such restrictive measures to only what is necessary for safety and health. Restrictive measures also stifle innovation and make 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 for future innovation.

Mandatory product certification vs. 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. Mandatory certification can affect a significant number of businesses in

developing countries, with substantial cost implications. Moreover, it has limited value for public health, consumer protection, safety, or the environment.

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 mandatory 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; in some cases, they 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.

Conflicts of interest

In some countries, the NQI system is centrally controlled by the state and 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 (Derzhstadart) is responsible for the development and approval of standards, product certification, inspection of producers, market surveillance, and consumer protection. Because the entire process is completely controlled by one organization, the overlap of commercial and regulatory functions and the discretionary powers of the organization to control the certification market creates considerable conflicts of interest. Similarly in Bolivia a single entity is responsible for providing industrial calibration services to the market and accreditation services for market players who compete with its own calibration services.

Developing an effective NQI system requires 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, because existing institutional heads have a stake in maintaining the status quo. Moreover, existing NQIs are often tied to political economy considerations, discouraging reform.[3]

Limited Financing

Particularly in developing countries, funding constraints, combined with a failure by the government 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 funding needed for the 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, it is unlikely to be sufficient to cover operating costs in most small economies and in economies where demand for voluntary standards remains low.

Table 1: Estimated Costs and Time Involved in Developing an NQI

Component	Investment cost (US$ millions)	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

At the firm level, limitations in time and financing impede implementation of an NQI system. Implementation time depends on many factors, including the level of complexity of the company, level of quality in production, the skill level of personnel, and the degree of management commitment to upholding standards. It may be necessary to hire new personnel and restructure parts of the company. The financial cost of implementing quality management systems can be a barrier to certification, especially for small and medium enterprises.

Limited human capacity

An effective NQI system and the quality of the services offered are directly dependent upon the quality of a firm's human capital. Companies in many developing countries lack technically qualified personnel and cannot provide competitive salaries to attract and retain skilled staff.

In more technical areas like metrology, specialized personnel are needed to guarantee the reliability of an NQI system. To ensure accurate measurement, well-equipped laboratories, as well as scientific personnel with specialized training and research experience, are needed. Similarly, the objectivity of the accreditation and conformity assessment processes largely depends on the quality of the technical staff.

Constructing an effective NQI

Most governments need to invest in reforming and upgrading their NQI. But it must be ensured that they are cost-effective, do not replicate services available in neighboring countries with whom collaborations can be established, 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. A number of components are required to establish an NQI that meets domestic and international market requirements.

NQI Strategy

NQI systems are at different levels of development across countries and regions. An initial step in upgrading NQI is to conduct an assessment and develop a strategy for upgrading, harmonization, and reform, as appropriate. In many countries, the level of NQI infrastructure development feasible in initial stages may be constrained by cost and capacity, necessitating choices about which minimum infrastructure and services are necessary. Governments have typically taken a lead role in this process.

The development of an NQI strategy should involve stakeholders. One successful method is to develop a national quality council that identifies needs and articulates a response strategy. The council provides a forum for gathering and disseminating information and discussing and solving problems. Its tasks 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.

Structure of the NQI

The first step toward establishing an NQI that will be internationally recognized is to ensure good governance and create institutions free from conflicts of interest. To achieve this, countries will need to either build or restructure their NQI on 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 the World Trade Organization's Technical Barriers to Trade principles, the guidelines of the main international NQI bodies, and the direction of a national NQI strategy.

To achieve well-governed institutions free from conflicts of interest, countries may need to reform and restructure their NQI and create independent, transparent institutions that are responsive to all stakeholders in the system. Minimum standards include the following:

- 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 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.

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.

A tradeoff between standardization and competition may be needed, 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 for 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 many good practices across the world, technical regulations are developed by government, often by designated regulatory agencies under ministries, with no involvement of the national standardization body. Reviews of technical regulations should ensure that they do not impose technical barriers to trade and unnecessary constraints to businesses.

Conformity Assessment

Two ways in which governments can enforce technical regulations are (1) requiring a premarket approval of products through mandatory certification and (2) conducting market surveillance, allowing companies to certify that certain standards have been met and then verifying this through spot checks and consumer complains. Developed countries have tended 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. Under 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 activities required for conformity assessment, it is not suitable for every product. Products deemed as particularly dangerous still require mandatory certification.

Enforcement of 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. Process certification is less restrictive than product conformity but still can 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.

Metrology

A first step in modernizing a metrological framework is to conduct a needs and gap assessment of the measurement standards currently in place, what they cover, whether they meet requirements and at what level of accuracy. 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 scientific, industrial, and legal metrology. 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. A single institution is economically necessary because (1) scientific metrology is very expensive, so having more than one national reference standard for the same measurement would not be viable; (2) it requires technical skills that are particularly scarce in developing countries; (3) it requires adopting international process standards that are difficult and lengthy to implement; and (4) it requires participating in international inter-comparisons[4] to ensure that the national metrology institution'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.

Accreditation

To ensure an impartial, objective, and technically credible accreditation system, it must be completely separate 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 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.[5] These standards are not only useful because they are used globally, but also 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 and join regional or international accreditation organizations through which they can 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, most often in the form of compliance with guidelines and membership in international or regional accreditation organizations. 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.

Conclusion

The National Quality Infrastructure is an important tool that can be utilized to improve competitiveness and facilitate global trade. Countries can become more competitive by abolishing overly-restrictive mandatory standards and harmonizing standards with regional and international trade partners. This should be complemented by the development of quality institutions which embody the principles of transparency, openness and good governance. Governments have a central role to play in the development and upgrading of National Quality Infrastructure institutions, to facilitate international harmonization and recognition.

References

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Endnotes

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

[2] For the past decade, the trend throughout the world has unambiguously shifted toward voluntary standards, largely driven by WTO and EU membership requirements.

[3] For example, the legacy of the Gosstandart system is strong in a number of Commonwealth of Independent States (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.

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

[5] Such standards include International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) standards: 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.