Thoughts on a National Quality Policy
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Contents

List of abbreviations and acronyms

BIPM	Bureau International des Poids et Mesures
CAC	Codex Alimentarius Commission
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
LMD	Legal Metrology Department
NGO	Non governmental Organization
NMI	National Metrology Institute
NQI	National Quality Infrastructure
NSB	National Standards Body
OIE	Office international des épizooties
OIML	Organisation Internationale de Métrologie Légale
SDO	Standards Development Organization
SME	Small and Medium Enterprise
SPS	Sanitary and Phytosanitary (Measures)
TBT	Technical Barriers to Trade
UN	United Nations
WTO	World Trade Organization

Foreword

> A powerful force drives the world towards a converging commonality, and that force is technology. The result is a new commercial reality – the emergence of global markets for standardized consumer products on a previously unimagined scale of magnitude.
>
> *Theodore Levitt*

As the globalization of the markets continues its relentless pace and as it is shaped by technological developments, more and more governments are carefully reconsidering the overall arrangement of their national quality infrastructure. This is coming about because enterprises in the developing economies in particular face daunting challenges in accessing markets in the more developed economies. Over and above the financial, management, logistics and skills challenges, they also need to have access to a supportive but internationally recognized quality infrastructure that can provide the independent attestation of product or service quality, without which access to developed markets is well-nigh impossible.

At the same time, it is becoming apparent that the technical regulation regimes of developing economies are oftentimes in disarray, fragmented, non-compliant with WTO-TBT and SPS Agreement requirements, with massive overlaps occurring amongst various regulatory agencies. These agencies, sometimes up to six of them, stand on each other's feet in trying to control the integrity of products entering the market, thereby creating bureaucratic chaos for suppliers. These technical regulation regimes, therefore, constitute a major impediment to trade. But the technical regulation regime and the national quality infrastructure are interwoven in complex ways that cannot be separated. Hence, if a country reviews the one, it cannot but review the other as well.

Lastly, as governments are pursuing good governance in order to integrate better with the international community, and establish policy frameworks conducive to social, ecological and market-economic development, they also realize that the establishment of an effective and efficient quality infrastructure contributes in no small way to good governance. An effective and efficient quality infrastructure together with an efficient technical regulation framework can promote the rule of law at the technology level; can help in the fight against corruption; can simplify bureaucratic processes; and enhance macro-economic stability.

With the foregoing in mind, it is therefore logical that governments need to develop the appropriate policy framework in order to re-engineer the quality infrastructure and the technical regulation regimes, and to determine the proper division of the responsibilities, i.e. a division of work. Such a policy framework is known by many names, but for this publication the name National Quality Policy is utilized. This publication provides guidelines as to the elements such a policy should contain, and provides some recommendations on the optimum arrangement of the quality infrastructure and the technical regulation regime. In the final analysis, however, the National Quality Policy should be written in the style of the country and should meet demonstrable needs.

In order to obtain the biggest buy-in for the National Quality Policy, the government will have to engage in extensive debate with a whole variety of stakeholders. Proper re-engineering of both the quality infrastructure and the technical regulation regime in most countries inevitably requires much and often painful change. Involving the stakeholders early on in discussions about the environment and, hence, the policies makes them realize they should not be happy with the *status quo*, makes them aware that there are many views of the world, and many possible futures – which prepares them to deal with the "changing tomorrow". It is only continuous conversation that gets people involved, and when they feel involved they contribute.

Note: In the examples shown in this publication, names of countries or regions and other elements that have to be altered in accordance with country specifics have not been used, but were placed in square brackets, denoting that the actual names have to be filled in, e.g. *[Country]* or *[Region]* or national standards body *[NSB]*, etc.

1 Organizational multiplicity

Before discussing the possible content of a National Quality Policy in the sections following, it is useful to consider the multiple possibilities regarding the institutions that make up the National Quality Infrastructure. In this context, the National Quality Infrastructure is considered as the totality of the institutional framework (public or private) required to establish and implement standardization, metrology (scientific, industrial and legal), accreditation and conformity assessment services (inspection, testing and product- and system certification) necessary to provide acceptable evidence that products and services meet defined requirements, be they demanded by authorities (i.e. in technical regulation or sanitary and phyto-sanitary measures) or the market place (i.e. contractually or inferred).

1.1 Legal status

The very first policy issue to be decided by a country is the legal status of its NQI institutions. The possibilities range from purely government departments to organizations that operate in accordance with normal industry profit motives. Even though ISO members do not of necessity represent the totality of the NQI in most countries, a study of the current ISO membership provides some useful pointers in this regard. In its most recent publication *ISO Members 2009*[1], information is provided regarding the profiles of ISO membership organizations.
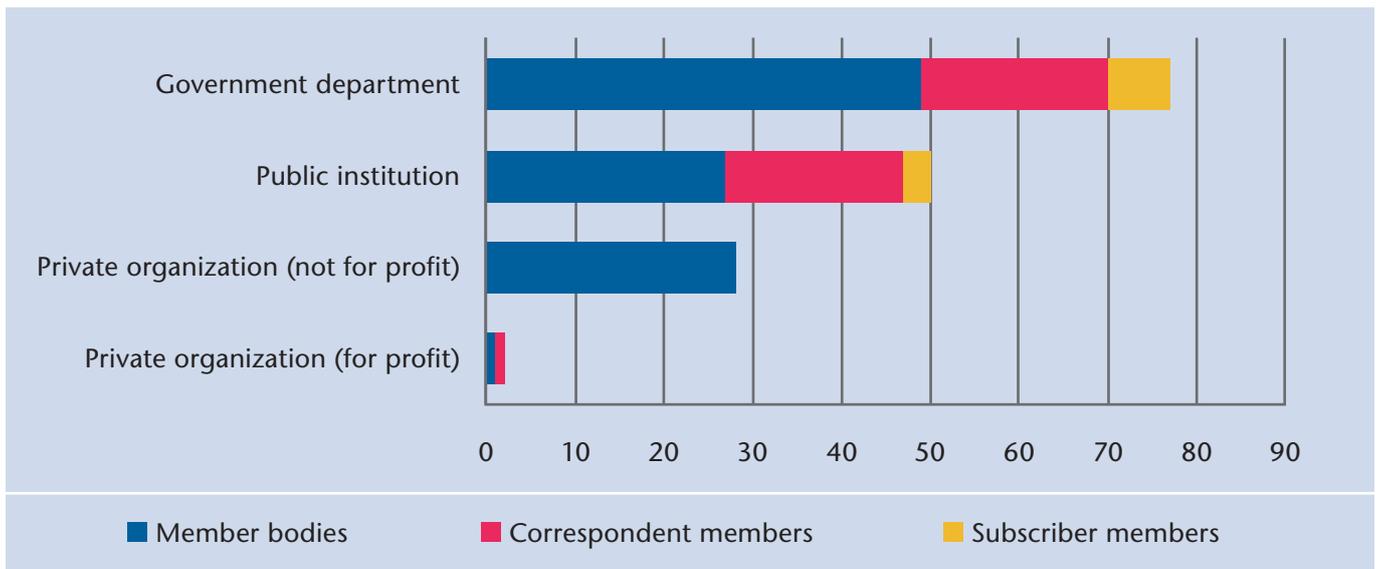

Figure 1: Legal status of ISO members

With regard to the legal status of the ISO members, the large majority of these are government departments or public institutions as can be seen in Figure 1. Comparing the figures of 2003, 2006 and 2009, it is noteworthy that the number of private organizations (for profit) has declined from 8.8% (2003) to 1.2% (2009), i.e. only two are left. This may indicate that these NSBs, even though they demand payment for services, have taken on greater public good responsibilities or that they are unable to maintain the profit model and have changed the basis upon which they operate. Private (not-for-profit) organizations, however, have increased from 7.5% (11) to 20.4% (33) over this period. This may be as a result of the realization by industry that an effective NQI is important and that a public-private partnership with government may be the best way forward. Concomitantly, the percentage of government departments and public institutions has slowly decreased from 50% (74) to 47.5% (77) and 33.5% (49) to 30.9% (50) over this period, even though the absolute numbers have increased slightly as the membership of ISO increased from 147 to 162 during this time.

1.2   Funding

A very similar mix emerges when comparing the sources of revenue for the ISO membership. Nearly a quarter of the ISO members are funded 100% by their governments, about a third are still dependent on government for more than 50% of their funding, with the rest scattered fairly equally between just below 50% and less than 20% as can be seen in Figure 2. Government funding, therefore, remains an extremely important part of the business model of any ISO member, clearly indicating the public nature of its business.
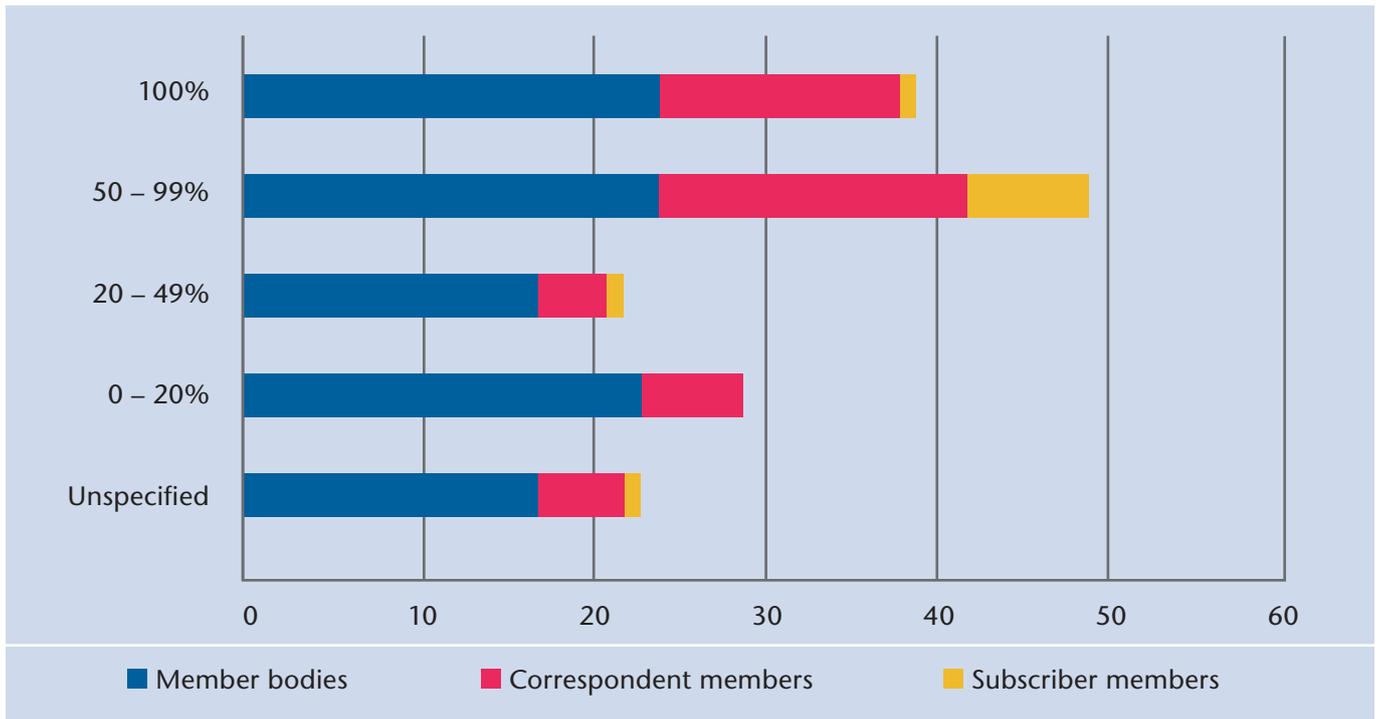
Figure 2: Sources of revenue of ISO members
(Percentage of revenue from government grants)

A comparison of the changes is difficult to make because of the large number of ISO members declining to provide figures in 2009, whereas in 2003, all provided this information. The number of ISO members obtaining 100% of their funding from government grants has remained fairly constant though, as has the number of those that obtain between 50% and 99% of their funding in this way.

1.3   Services rendered

Developing countries with a totally decentralized NQI are fairly rare, as the costs involved in maintaining different institutions for the various elements of the NQI are high, and the availability of scarce human resources beyond most. Industry is also generally not in a position to establish the necessary infrastructure and unless government does so, it does not happen. It is, therefore, quite common in such countries to find the national standards body as a government-type institution, having been made responsible for the majority of the NQI services. An analysis of the ISO membership provides the evidence that this is indeed the case – see Figure 3.

The situation in fully industrialized countries is quite different, with conformity assessment services provided by a myriad of private and multinational service providers operating at market-related pricing, and the standards bodies, metrology institutes and accreditation bodies established independently of each other. What is also quite evident in industrialized countries, is the clear separation between the standards domain and the regulatory frameworks. This is generally not the case in developing economies, and proper checks and balances need to be introduced through appropriate policy.
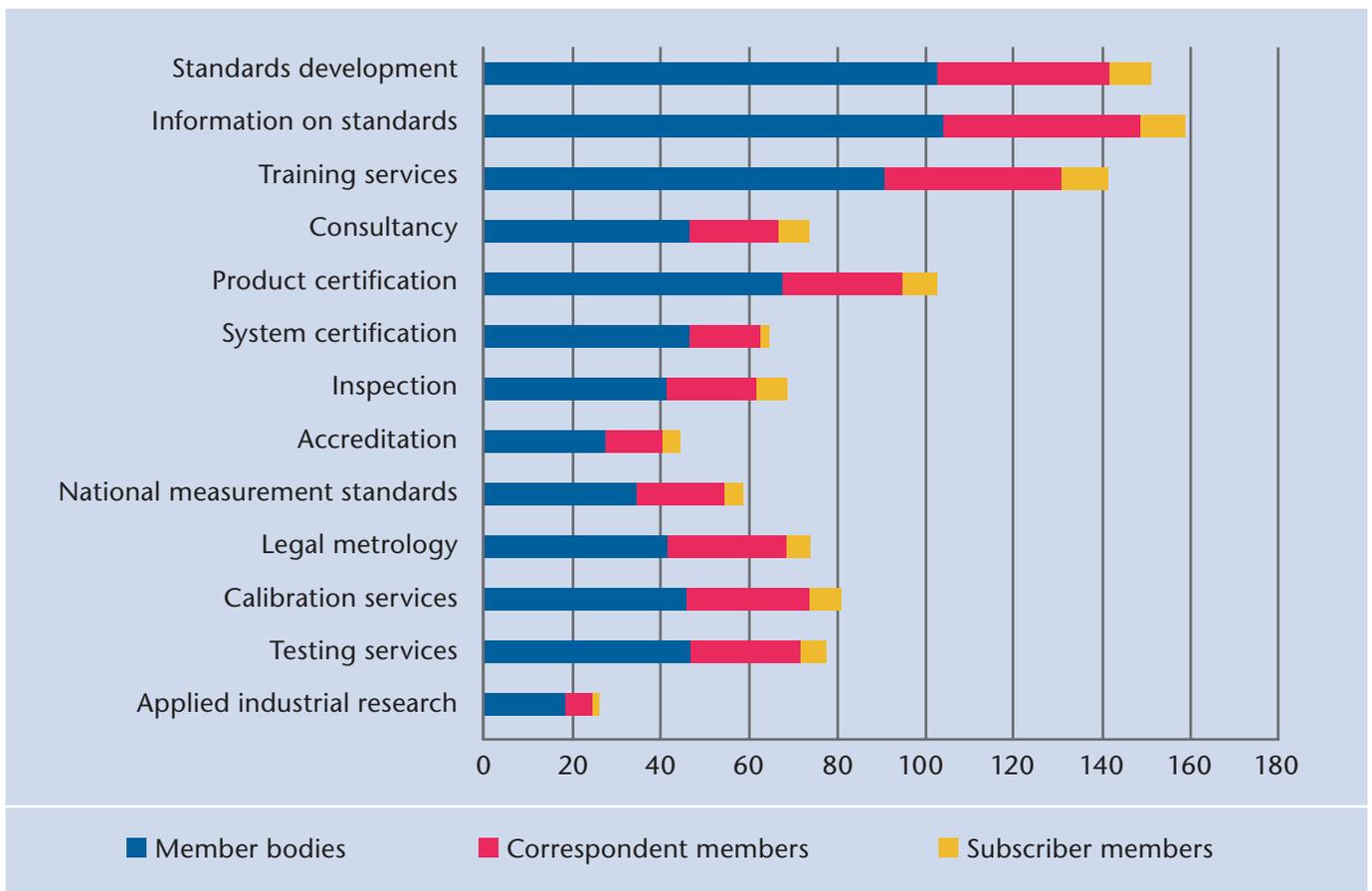
Figure 3: Services rendered by ISO members

Therefore, this is the next big policy issue that a government has to decide, namely in how far can it afford to establish independent institutions, and what is the commercial freedom it will allow such governmental type organizations in providing services at market-related prices or not? What is the role of private industry, and will it be possible, or indeed desirable, to establish the conformity assessment side of the NQI as a public-private partnership or even a private-not-for-profit organization?

What is also very important from a policy perspective is the real danger that especially inspection capacity and laboratory capacity established by any number of ministries in order to service their regulatory framework, leading to massive duplication and overlaps. This has two major implications. Firstly, it increases pressure on the small pool of skilled experts available in the country, and it results in the non-optimal utilization of expensive laboratory equipment, rendering the whole system non-viable from a financial perspective. Secondly, in order to gain finances, such laboratories unnecessarily re-test many imported products falling within the scope of technical regulations, thereby, creating totally unnecessary barriers to trade.

1.4   Review of current situation and designing the future

Considering the discussions in the preceding sections, it is strongly recommended that a careful analysis is conducted of the current situation in the country, a review is provided on the international and regional situation in which the country finds itself, and a final state that should be strived for is determined. The resulting gap analysis will provide an idea of the work and re-engineering that will be required to get the country from the current, unsatisfactory state, to where it wishes to position itself regarding its NQI and its technical regulation framework. All of this information needs to be utilized when developing the National Quality Policy as discussed in detail in the following sections. This process can be depicted graphically as shown in Figure 4. Obtaining the services of international experts in this area could be a useful addition to the quality of the final decisions, as they may be able to provide a more international or regional perspective than local experts.

Conducting such an analysis goes beyond the scope of this publication, but there are quite a few publications available from PTB, the World Bank, ISO and ITC, for example, that provide useful guidance in this regard. In addition, the National Quality Policy should be embedded within other policy frameworks, especially those that deal with local and international trade, development of the local producers and industry and even poverty reduction policies. Without such an overall policy framework, the National Quality Policy does not mean much, and, in the end, may prove to be wasted.
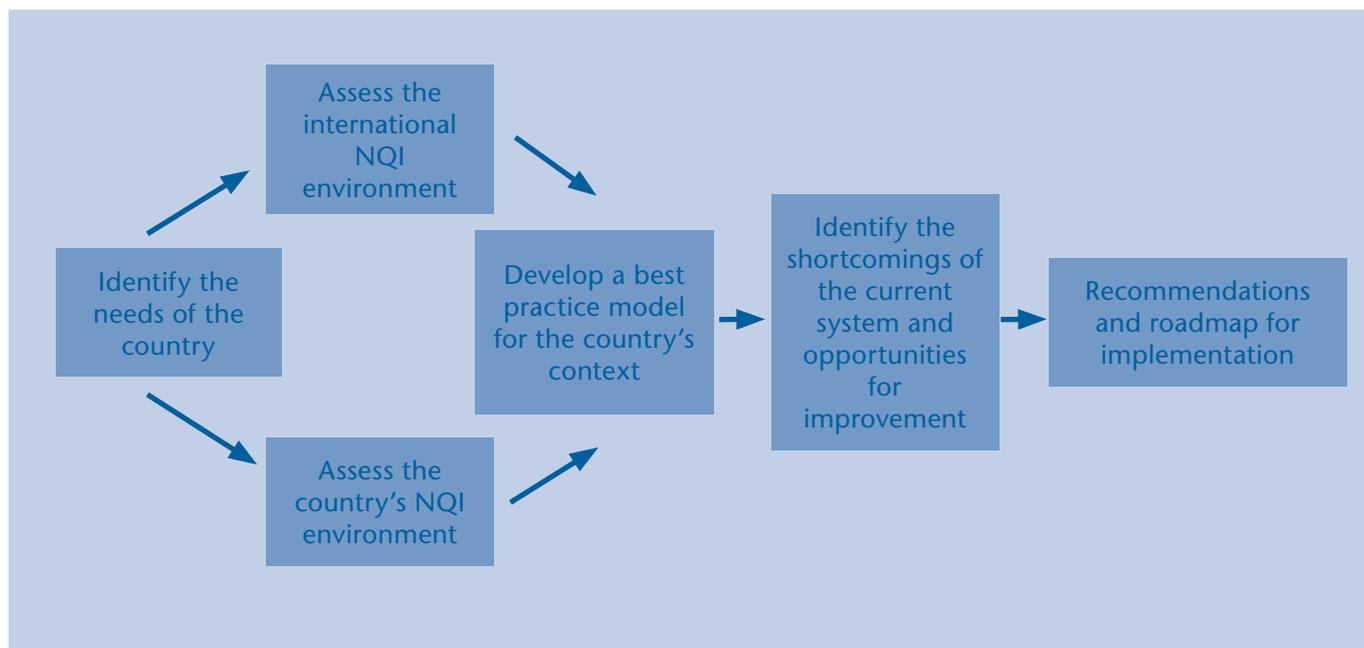
Figure 4: Designing the future NQI and technical regulation framework

1.5   Overall structure of the National Quality Policy

This paper discusses the elements that would make up a well-defined National Quality Policy, and it follows a specific logic. In many countries, however, government policy documents have to follow a preferred framework or defined structure and contents. In such cases, it is obvious that the country preferences should be followed. The elements listed in this guideline then have to be placed in their proper order or combined or even separated as country preferences dictate.

It should also be noted that the examples are exactly that – examples. They serve mainly as prompting material to develop the proper wording in a National Quality Policy within the context of national customs and practices and the national usage of language. They should not be followed slavishly

2   Introducing the National Quality Policy

The Introduction of the National Quality Policy has to describe in a fair amount of detail the current international trends, the local situation and why it has become necessary to re-engineer the National Quality Infrastructure (NQI) and the technical regulation regime. Some of the issues that it is useful to highlight typically include the effect of globalization, challenges faced by enterprises, the current situation regarding the NQI and the technical regulation regime, and the overall commitment of government, namely:

- *In the present environment of increased globalization, empirical evidence suggests that standardization and its conformity assessment companions have a very important role to play in technological progress, productivity and trade. Increasingly, global purchasers demand products and services that meet rigorous and advanced standards of quality, not only to ensure that such products and services integrate flawlessly with others in the supply chain, but also to satisfy customer expectations and to comply with a maze of technical regulations in importing countries.*

- *In order to compete successfully in developed markets, [Country's] industry, especially the SME sector, faces a formidable array of challenges. Over and above the logistics, management and financial issues, one of the major stumbling blocks is the attainment of demonstrable product and/or service quality demanded by regulatory authorities, as well as the major players in the markets. Hence, in order to fully exploit the possibilities of foreign markets, [Country's] industry needs to have access to an internationally recognized, but supportive national quality infrastructure that can provide the required independent evidence of product compliance.*

- *[Country] realizes that its national quality infrastructure and its technical regulation regime may not yet be developed to their full potential, and that they are not fully harmonized with those of its major trading partners. It follows that these need to be addressed in a holistic manner, as they cut across many ministries, agencies and stakeholders. Hence, as [Country] re-engineers and upgrades the national quality infrastructure, enhances its technical regulation regime and organizes the relationship between the two, it must decide how to cater for technological and quality needs, minimize environmental, health and safety externalities, and at the same time avoid unnecessary and costly barriers to trade.*

- *In recognizing the above realities, the government of [Country] commits itself to re-engineering, strengthening, upgrading and maintaining the national regulatory, standardization, metrology, accreditation and conformity assessment infrastructures to facilitate trade, enhance exports, accelerate economic development and reduce poverty while at the same time protecting the health and safety of its people and the environment as a logical outflow of the overall objective of [vision for the next decade], [trade or development policy], [poverty reduction policy], and the UN Millennium Development Goals.*

3   Vision for the National Quality Policy

3.1   Future state

"Vision" has many meanings. For the purposes of this publication, "Vision" is seen as the future state of affairs, technically attainable, yet always just out of reach. Hence, in this part of the National Quality Policy, the government describes the state of affairs a few years into the future, i.e. what the country should look like with regard to the NQI and the technical regulation regime if all the elements of the National Quality Policy have been successfully implemented and what the overall outcome should be. The actual time period to achieve the desired state of affairs should preferably also be identified.

Most states have an overall vision for the country, e.g. called Vision 2020 or similar. Most of these describe an overall state of the country that needs to be attained in a decade or so. Most of the visions major on key themes such as industrial development, trade, poverty reduction, health system development, education, the provision of water and sanitation, etc. This is frequently augmented by a Trade Promotion and/or on Economic Development and/or a Poverty Reduction Policy that provides more detail to realize the vision.

At the international level, the United Nations environment is subscribing to the Millennium Development Goals of which there are eight, with 49 proposed indicators. Although these Millennium Development Goals do not specifically deal with the NQI or even the technical regulation regime, these do have an influence on the attainment of the Millennium Development Goals. All of the above policy instruments are very important with regard to the envisaged National Quality Policy. They form the backdrop or framework into which the National Quality Policy has to be positioned as it would be less valuable to have it stand on its own.

First Example (vision embedded in a national policy setting)

- *The government of [Country's] economic development policy provides a medium-term framework for achieving the country's long-term development aspirations as embodied in [Country's Vision 2020] and the Millennium Development Goals.*

- *Amongst the objectives of the [Economic Development and Poverty Reduction Policy] that relate directly to the activities and outputs of the national quality infrastructure and the technical regulation regime are:*

  - *Accelerated growth and poverty reduction;*

  - *Promotion of science, technology and innovation;*

  - *Raising agricultural productivity and ensuring food security;*

  - *Managing the environment and ensuring the optimal utilization of natural resources;*

  - *Building economic infrastructure;*

  - *Improving water resource management and access to safe drinking water and sanitation and*

  - *Promotion of good governance.*

- *These can only be achieved by implementing quality standards and a transparent technical regulation regime, as well as by expanding primary processing and value adding, increasing the competitiveness of local manufacturing and a vigorous pursuit of exports to difficult markets – all of which relate directly to an effective and productive national quality infrastructure.*

- *Hence, in parallel with the implementation of the Economic Development and Poverty Reduction Policy, the government of [Country] is seeking to develop, establish and maintain an effective and efficient National Quality Infrastructure that would gain international acceptance. At the same time, the government of [Country] will develop and implement a common approach to technical regulation, i.e. a National Technical Regulation Framework (NTRF), and ensure that the division of work between the NQI and the authorities responsible for the administration of the technical regulation is properly coordinated*

Second Example (stand alone vision)

- *The [Country's] government plans, during the next two decades, to ensure the establishment of an environment that would help [Country's] society prosper in different economic, social and technological areas, taking into account the opportunities, potential and changes that are anticipated at the regional and international levels in the upcoming era.*

- *During the next five years, [Country] is seeking to develop an effective and efficient National Quality Infrastructure that would meet international standards. Here, the government of [Country] will focus on quality and technical competency to ensure that the proper environment exists for national goods and services to gain a competitive edge in international markets, leading thereby to expanded exports and hence the sustainable growth of [Country's] society.*

3.2   Current state

In this section, the current state of the NQI and the technical regulation regime needs to be described. Obviously this would be very different in each country. It is important, however, that not only the national standards body and its service deliveries are described, but that all the ministries and their Agencies that are involved in the development and publication of normative documents, whether called standards or not, be listed. The same applies to the provision of inspection, testing and certification services. In many countries the regulatory agencies operate such services, and these should be made known. It is also useful not only to deal with manufactured products, but also with food standards, as these are frequently subject to SPS measures as well as technical regulations[2] , and both require a functioning NQI to be properly implemented.

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[2] Technical regulations could cover any subject, from car safety to energy-saving devices, to the shape of food cartons. Technical regulations could include pharmaceutical restrictions, or the labelling of cigarettes. Most measures related to human disease control fall under the TBT Agreement, unless they concern diseases which are carried by plants or animals (such as rabies). In terms of food-labelling requirements, nutritional claims and concerns, quality and packaging regulations are generally not considered to be sanitary or phytosanitary measures and, hence, are normally subject to the TBT Agreement.

In this section the organizational structures of the various forms of the NQI institutions should be clearly articulated. Examples would be whether the institutions are government departments, statutory organizations or private not-for-profit organizations. In the latter case it is important to detail the agreements or memoranda of understanding between the government and the private organizations that are in place, if any. These private organizations do, after all, represent the country at the regional and international level in the relevant international and/or regional QI structures. These agreements may have to be revised or updated as a consequence of the development and implementation of the new Quality Policy. The influence that government policies have currently, or the lack thereof, on the governance and/or strategies of the NQI institutions may also be relevant. The current state of the relevant legislation of the government departments or the statutory bodies is also an important parameter to be detailed.

Very important issues that need to be described are the overlaps and the unclear legislation of various agencies that lead to unnecessary bureaucratic activities with regard to – especially – the development and implementation of technical regulation and SPS measures. Evidence from many developing countries suggests that the food safety domain is especially prone to such overlaps and duplication of control measures, e.g. between the national standards bodies acting as regulators and the food safety agencies. These overlaps and gaps have developed over many years, are difficult to deal with at the institutional level, are massive impediments to trade, and – even worse – they lead to products being unnecessarily expensive without any real advantage to the consumers regarding their protection against unsafe and shoddy goods. Countries should not shy away from addressing these issues. It is often better to get outside help to conduct such an assessment of the current state, than to try and get it done by one's own people. They will invariably overlook many inadequacies, as they have grown accustomed to them.

On the other hand, by definition, regulations which address the microbiological contamination of food, or set allowable levels of pesticide or veterinary drug residues, or identify permitted food additives, fall under the SPS Agreement. Some packaging and labelling requirements, if directly related to the safety of the food, are also subject to the SPS Agreement.

4   Objectives of the National Quality Policy

The government has to spell out very clearly what the objectives (e.g. the envisaged purposes) of the National Quality Policy are. This clarity of thought is important in that it would guide the debate regarding the details of the policy and its implementation. The objectives would also become the key performance indicators at the end of the specified implementation time that would tell whether the policy has been successfully implemented or not. In general, and in no particular order of importance, the key objectives of a National Quality Policy can be summarized as follows, namely:

1. To strengthen the national metrology system and, in particular, raise the profile of metrology as a significant component in the country's overall activities;
2. To establish the appropriate framework for the development and publication of national standards, to clearly define the role of the national standards organization at the pinnacle of all standardization work, and to involve of all stakeholders in the process;
3. To expand the use of accreditation into all of the national regulatory environment;
4. To provide a framework for the establishment of conformity assessment service providers in both the public and private domain, that are, in addition, technically competent;
5. To give clear mandates and elaborate a proper division of work regarding the administration of technical regulation and SPS measures and
6. To provide a national quality promotion strategy that builds on the national quality infrastructure and assists the country's enterprises in becoming globally competitive.

These key objectives may be augmented by secondary objectives, depending on the situation in the country. In most countries these objectives would only be attained through an appropriate legal framework, and the active involvement of the state, private industry, academia, non-governmental organizations and society. The details should be discussed in later sections of the National Quality Policy.

Typical National Quality Policy wording for the key objectives could include the following:

- *The primary objective of the Quality Policy is to ensure that goods and services emanating from or traded in [Country] are designed, manufactured and supplied in a manner that matches the needs, expectations and requirements of the purchasers and consumers as well as those of the regulatory authorities in the local as well as in the export markets.*

- *In support of the primary objective, the implementation of the Quality Policy should raise quality consciousness amongst both the suppliers and the consumers, and it is an undertaking to introduce and maintain a quality culture in public life and throughout society.*

- *The immediate outcome of the implementation of the Quality Policy will be the design and establishment of a world-class metrology, standardization, accreditation, inspection, testing and certification infrastructure, i.e. the NQI, and the support of the application of its techniques, practices and service provisions to demonstrably comply with international standards throughout.*

- *In parallel to the establishment of the NQI, the technical regulation regime of [Country] will be reviewed and adjusted, including its related legislation, to meet regional and international requirements such as the [Regional Trade Protocol], the WTO-TBT and SPS Agreements and international best practices. This includes the establishment of effective cooperation amongst the NQI institutions and the national regulatory authorities, and also with their regional and international counterparts.*

- *The service delivery of the NQI is totally dependent on a trained and skilled workforce, hence, developing the human resources necessary to support the various standardization, quality and technical regulation programs is a central theme throughout the Quality Policy.*

5 Drivers (or rationale) for the Quality Policy

In this section, the government has to spell out the drivers for embarking on the re-engineering of the NQI and the technical regulation regime. In a sense, they should follow logically from the environment that has been sketched in the Introduction (see section 1 above) as well as in the NQI- and Technical-Regulation-related issues contained in the Trade Policy *et al.* (see section 2 above).

In reality though, there are only few but extremely powerful drivers for a total re-engineering of the NQI and the Technical Regulation environment. Failure to satisfy the drivers would have such negative consequences for the country, that they are actually non-negotiable. Such re-engineering brings about massive change, which in turn results in a lot of painful adaptations. Hence, the drivers have to be clearly articulated to be fully understood in order to garner the support for the massive re-engineering exercise from all stakeholders. Some of the following may be drivers in many countries, and the list in the Quality Policy needs to be harmonized with a respective country's realities, namely:

- *The desire of the government to efficiently and effectively manage their regulatory responsibilities in order to achieve two of its primary mandates, namely the protection of society and the environment;*

- *The need of those that are being regulated to deal with a transparent and reliable state-regulatory system without having to battle with bureaucratic vagaries on a day-to-day basis;*

- *The need of government to give industry a supportive standards, metrology, accreditation and conformity assessment service that is accepted globally and*

- *The need of industry to have access to conformity assessment services that are affordable, and accepted globally so that their products can be marketed under the motto: "Tested once, certified once, and accepted everywhere".*

6   The National Quality Infrastructre

The readers and users of the Quality Policy will come from all walks of life, such as senior policy makers of ministries, parliamentarians, NGO staff, journalists and many more. Not all of them would be as familiar with the elements that make up NQI as would be the institutions of the infrastructure itself, such as national standards bodies, testing laboratories, metrology institutes, and the like. It is therefore appropriate that a clear, but concise overview be given of the institutions that make up the NQI.

6.1   NQI institutions

The NQI institutions will not be described in detail here, as this would render the publication far too bulky. Three publications that contain very useful overviews are *(i) Dr Clemens Sanetra, Rocío M. Marbán, The answer to the global challenge: A National Quality Infrastructure, Physikalisch-Technische Bundesanstalt, Braunschweig, 2007; (ii) Road Map for Quality: Guidelines for the Review of the Standardization, Quality Management, Accreditation and Metrology (SQAM) Infrastructure at National Level, International Trade Centre UNCTAD/WTO, BAS-04-19.E, Genève, 2004; and (iii) Fast Forward – National Standards Bodies in Developing Countries, International Organization for Standardization (ISO), ISBN 978-92-67-10477-5, 2008.*

However, elements that could be included in the Quality Policy can be taken from the following, including a very useful table that lists in a concise way all the institutions, their service delivery and the typical organizational form, that would make up the NQI:

- *The National Quality Infrastructure is taken as the totality of the institutional framework (public or private) required to establish and implement standardization, metrology (scientific, industrial and legal), accreditation and conformity assessment services (inspection, testing and product- and system certification) necessary to provide acceptable evidence that products and services meet defined requirements, be it demanded by authorities (technical regulation) or the market place (contractually or inferred).*

- *NQI institutions should be able to provide a service to the suppliers of products and services, the consumers as well as the regulatory authorities. The NQI institutions can be in the public as well as the private domain and in many countries conformity assessment services (i.e. inspection, testing and certification) are progressively being provided by private industry rather than by government laboratories, whereas governments retain the responsibility to ensure that the fundamentals, i.e. standards, metrology and accreditation, are maintained.*

- *The optimum arrangement of the NQI at the national level is as much a government policy issue as a market-related service provision concern. The notion that two separate systems are required, i.e. one for the regulatory authorities and one for the market place, is outdated and leads to unnecessary duplication and inefficiency. In a modern NQI the technical competency issues as well as the required legal checks and balances, can appropriately be dealt with. Hence, a single, coherent NQI will advantageously serve both the regulatory authorities and the market place.*

National Quality Infrastructure Institutions and Service Outputs

Domain	Description of service	Institution(s)
Standards	Publication of a formal document (standard), generally developed by consensus, containing the requirements that a product, process or service should comply with. Standards are considered essentially voluntary in themselves. Suppliers can therefore choose whether to use standards or not. It is only once they are called up in a contract, for example, or referenced in a technical regulation, that compliance with standards becomes a legally binding obligation.	• National Standards Body (NSB) • Sectoral Standards Development Organizations (SDO) • Industry-based standards organizations Note: Although most NSBs are public organizations, a few private NSBs exist. The SDOs are mostly private.
Metrology	The technology or science of measurement. Metrology can be subdivided into scientific metrology (the development and organization of the highest level of measurement stadards), 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).	• National Metrology Institute (NMI) • National Calibration Service • Calibration Laboratories (public or private) • Legal Metrology Department (LMD) Note: The NMIs are invariably public organizations and so are, by definition, the LMDs. Calibration laboratories may be public or private.
Accreditation	The activity providing independent attestation as to the competency of an individual or an organization to offer specified conformity assessment services (e.g. testing, inspection or certification).	• National Accreditation Organization/Body Note: This is usually a public organization

National Quality Infrastructure Institutions and Service Outputs

Domain	Description of service	Institution(s)
Inspection	The examination of a product design, a product, a process or an installation and the determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements. Inspection such as import inspection is often conducted on consignments, to ensure that the whole consignment is equivalent to the product sample tested.	• Import inspection agencies • General inspection agencies Note: These can be public or private agencies.
Testing	The determination of a product's characteristics against the requirements of the standard. Testing can vary from a non-destructive evaluation (e.g. X-ray, ultrasound, pressure testing, electrical, etc. whereafter the product is still fit for use) to a totally destructive analysis (e.g. chemical, mechanical, physical, microbiological, etc. whereafter the product is no longer fit for use), or any combination thereof.	• Testing laboratories • Pathology laboratories • Environmental laboratories Note: These can be public or private laboratories.
Certification	The formal substantiation by a certification body after evaluation, testing, inspection or assessment, stating that a product, service, organization or individual meets the requirements of a standard.	• Product certification organizations • System certification organizations Note: These can be public or private organizations.

6.2   Governance structures of NQI institutions

Depending on whether the NQI institutions are a government department, a statutory body or a not-for-profit private organization, their governance will be vested in the minister or permanent secretary of the department, in a council or board of directors. The National Quality Policy will obviously have an influence on their future strategies and mode of operation. These governance bodies are generally small, i.e. 10 to 15 people, either from the public domain or private industry or both. Sometimes they are representative of the main stakeholders of the NQI institutions, and in other cases, such as in a properly constituted board of directors, they bring with them special expertise in policy, finances, marketing and the like.

In many countries the need has been identified to establish a forum that can bring together the myriad of stakeholders of the NQI to discuss relevant strategic issues, and which can pass these as strong recommendations to the various NQI governance structures. If such a forum is envisaged, then this should also be articulated clearly in the National Quality Policy, ensuring that its mandates or terms of reference are clearly spelled out. The relationship between such a National Quality Forum and the governance structures of the NQI institutions must be clear, i.e. in no way should the National Quality Forum usurp the authority of the council or board of directors to act out their responsibilities regarding policy and strategy of the institutions or their fiduciary responsibilities.

7   The Technical Regulation Framework

If the NQI is a bit foreign to most of the users and readers of the Quality Policy, this is even more so the case for the Technical Regulation Framework. Hence, it is even more important that a clear and concise depiction of the Technical Regulation Framework be provided before the government commitment to re-engineer what is in the country, is spelt out. The diagram of the building blocks of technical regulation depicted below is a very useful device to explain this very complex issue. The various elements (obviously to be amended and arranged in accordance with country specifics) that need to be contained in the Quality Policy include the following:

7.1   General

- *Technical regulation (which includes mandatory standards) is concerned with the safety and health of the population, the health of plants and animals, the protection of the consumer against deceptive practices, and the protection of the environment. Technical regulations are developed and administrated by competent authorities such as the ministries responsible for agriculture, construction, electricity, environment, health, industry and trade, telecommunication, tourism, transport, petroleum and mineral resources, and others. Because technical regulations should be based on the relevant international, regional and national standards, coordination with the [National Standards Body] and other NQI institutions is of paramount importance.*

- *Even though technical regulations should take national peculiarities into account, they must comply jointly with the requirements of the WTO-TBT Agreement and the [Regional Trade Protocol]. Hence, technical regulations are developed only for legitimate reasons, will ensure that products imported from any trading partner are accorded treatment no less favorable than products of national origin, and that products from all trading partners will be dealt with in an equal manner. Care shall be taken that technical regulations do not constitute unnecessary barriers to trade.*

- *Products manufactured in [Regional Common Market] Partner States that fall within the scope of technical regulations, and for which demonstrable conformity assessment procedures have been followed in the other partner state, i.e. have been awarded national quality marks, that may differ from those in [Country] but have a similar outcome, namely safe products, will be granted free cross-border movement without further testing and certification in accordance with the [Regional Trade Protocol].*

7.2   Technical Regulation Framework

- *A Technical Regulation Framework comprises a number of building blocks that have to be appropriately defined and implemented at national level taking into consideration international best practices, local realities and customs. If these are not properly defined, then the goal of technical regulation will not be realized.*

- *The building blocks of a Technical Regulation Framework are depicted graphically in the figure below. These building blocks shall be properly articulated for the legal system and situation in [Country] and shall be ensconced in legislation to ensure that all the ministries and their agencies follow the general principles for greater legal certainty and transparency in developing and implementing technical regulation, [including mandatory standards], in [Country].*
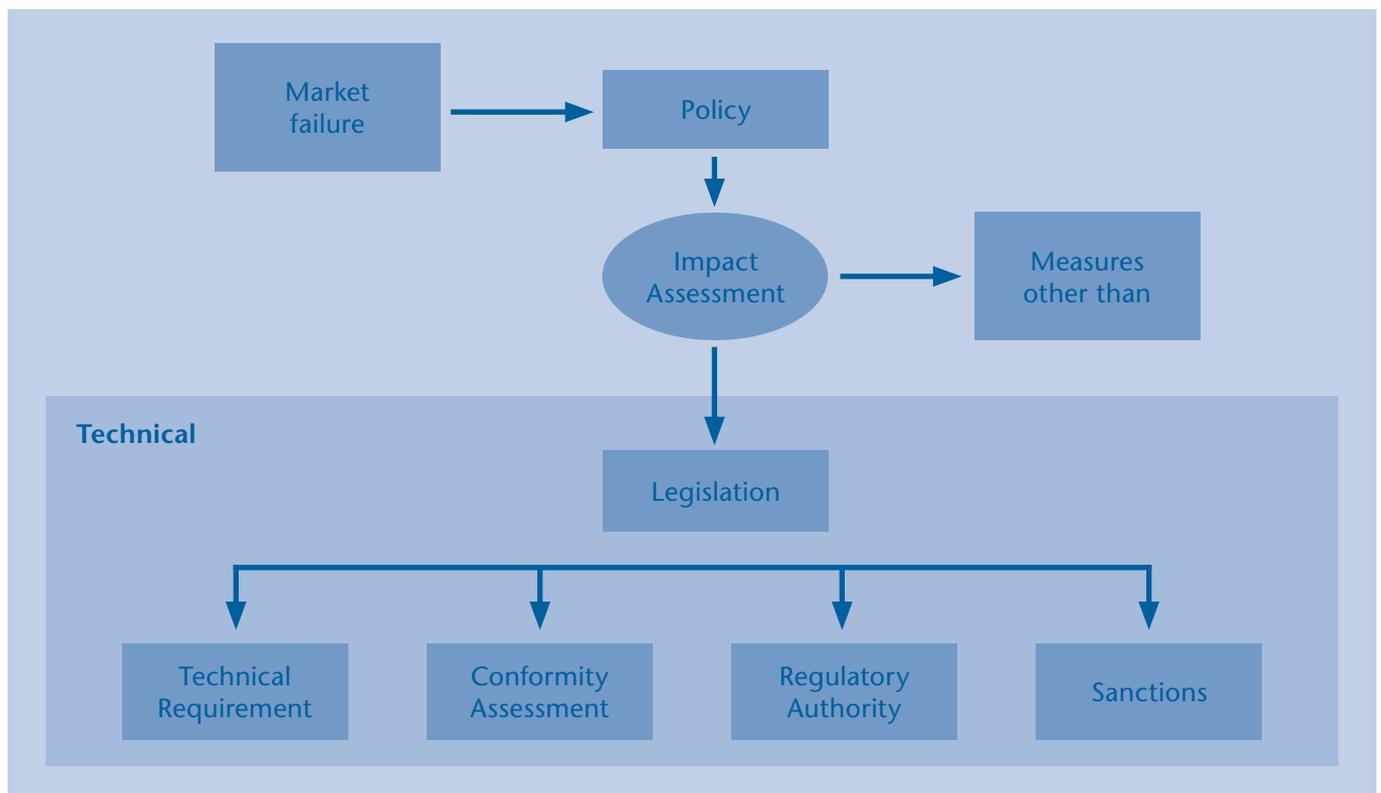

Figure 5 The building blocks of technical regulation

- *The **Impact Assessment** must determine whether the proposed technical regulation will adequately deal with the market failure, whether all of society will benefit if it is implemented, whether the technical requirements can be managed in the country and what the total costs and benefits will be. It should also consider the possibility of dealing with the market failure in ways other than technical regulation.*

- *The **Technical Requirements** should be based on international, regional or national standards, and should not become unnecessary barriers to trade.*

- *The **Conformity Assessment** services required to provide the independent evidence to the regulatory authorities that products and services meet technical regulation requirements can be provided by conformity assessment service providers in both the public and private domain, provided that they have been accredited as a measure of their competency and that they are so designated by the regulatory authority. The "user pays" principle will be followed throughout.*

- The **Regulatory Authority** *should be responsible for any market approvals if necessary, conduct market surveillance to ensure that suppliers meet the technical requirements, and implement sanctions in the event of product failures. The Regulatory Authority should, as a matter of principle, not be involved in the conformity assessment service provision.*

- *Sanctions, both administrative and judicial, are essential to ensure that all the suppliers meet requirements all the time.*

7.3   Technical Regulation Office

It has been shown in quite a number of economies that proper coordination amongst the various regulatory agencies that are responsible for the development and implementation of technical regulation and with the NQI can only be achieved if an oversight agency is established with the appropriate authority to enforce such coordination and to ensure that all the agencies and the NQI meet WTO-TBT and SPS Agreement requirements consistently. Typically such an office would be established in the highest political office of the country, as it needs to gain an insight into a number of ministries. The name of such an agency varies all over the world and a suitable one needs to be found for the country. Therefore, wording that needs to appear in the Quality Policy may look like the following:

- *In order to oversee the implementation of the Technical Regulation Framework, a [Technical Regulation Office] shall be established under the [highest political office, e.g. presidency or similar] with the following responsibilities:*
  a)   *Coordinate activities related to technical regulation development and implementation amongst the regulatory authorities and the NQI;*
  b)   *Ensure that the regulatory authorities follow the defined Technical Regulation Framework in developing and implementing technical regulation;*
  c)   *Ensure that all the regulatory authorities consistently meet the requirements of the WTO-TBT Agreement, the WTO-SPS Agreement and the [Regional Trade Agreement] and*
  d)   *Oversee the review of technical regulation already on the statute books by the regulatory authorities, in order to revise, confirm or withdraw such regulation and to make sure that it complies with the Technical Regulation Framework.*

8   Government commitment

8.1   General approach

There are a number of ways to deal with the government commitment. In this section, each of the elements of the NQI and the technical regulation regime can also be listed as a sub-heading and the government commitment with regard to that specific NQI institution can be listed. Another, and maybe a more elegant way, is to list the overall government commitment and then to describe the end state for each of the NQI institutions and the technical regulation regime separately, each in its own section. The latter approach will be followed in this publication.

Therefore, typical examples of the overall government commitment as contained in a National Quality Policy could be:

- *The government, through its various institutions, has an enabling, coordinating and educational role in the implementation of the Quality Policy. Its task is to outline the vision and the policy, and manage the general framework that will govern the place and activities of the concerned parties. It is, furthermore, responsible for establishing and maintaining the basic elements of the National Quality Infrastructure and for the creation of mechanisms to allow for the protection of the consumer on the one hand, and for full private sector participation on the other. In fulfillment of its role, the government will act in the best interest of the country and see to it that actions are jointly governed with transparency, coordination and cooperation amongst the various sectors.*

- *In order to create an environment that would be conducive to the establishment and proper functioning of an effective and efficient National Quality Infrastructure and Technical Regulation Framework, the government is committed to carrying out a profound restructuring of both the technical regulation regime and the quality infrastructure, and, where necessary, creating new structures, as well as a full review of concomitant legislation, in order to align them with international obligations and regional requirements.*

- *To minimize market failures, the government will review and consolidate legislation that defines the responsibilities of producers and suppliers to ensure that goods and services meet contractual and legal provisions so as to encourage fair and effective competition in order to provide consumers with the greatest range of products and services at appropriate prices; and ensure that both the public and private sectors have an equal chance with regard to providing conformity assessment services.*

- *To create a quality culture in [Country] in the public and private domains, the government will promote quality awareness campaigns, provide for the integrated approach to quality management in the public sector and promote and support the creation of mechanisms or institutions that contribute to awareness raising and knowledge dissemination regarding quality to all the segments of society.*

8.2   Metrology

Metrology is the science of measurement. Metrology concerns to the development of measurement standards and instruments providing for their use in the public and private domains. In order to distinguish between the development and application of metrology, metrology is divided into scientific, industrial and legal metrology. Typically, the government should accept responsibility for scientific and legal metrology, whereas industrial metrology is, to a large extent, the responsibility of industry. Hence, typical National Quality Policy pronouncements, depending on the extent of re-engineering required, can be the following:

- *To increase the awareness of metrology and to establish a common metrological framework as one of the fundamental building blocks of the quality infrastructure, the government will enhance and upgrade the national metrology system by establishing [Country's] metrology institute that will maintain national measurement standards capable of providing a reliable and accurate measurement service within [Country], whilst at the same time linking up internationally with the Calibration and Measurement Capability (CMC) recognition system administrated by the Bureau International des Poids et Mesures (BIPM).*

- *[Country's] metrology institute will ensure that a national calibration service is established, maintained and continuously improved to diffuse the national measurement standards into industry, regulatory authorities and society in order to ensure that all measurements emanating from [Country] are acceptable in trade and law enforcement. Calibration services can be provided by [Country's] metrology institute, the legal metrology department or private calibration laboratories provided that their calibration equipment is traceably calibrated to the national measurement standards kept by the [Country's] Metrology institute or another national metrology laboratory with known and recognized measurement capability. In addition, all calibration laboratories shall be appropriately accredited against the relevant international standards.*

- *As a companion to [Country's] metrology institute, and to ensure the equitable utilization of measurements not only in trade, but also in law enforcement, health services and environmental management, the government will upgrade the weights and measures department of the [National Standards Body] to a fully fledged legal metrology department. The legal metrology department shall have the responsibility to type-approve, calibrate and verify measurement equipment falling within the scope of its regulation, and to ensure the protection of consumers by controlling pre-packaging operations of products, all of which are to be based on international standards such as the Recommendations of the Organisation Internationale de Métrologie Légale (OIML).*

- *The legal metrology department will ensure that measuring equipment used in trade, law enforcement, health services and in the protection of the environment is appropriately type-approved, verified on placement into service and thereafter regularly calibrated and verified to ensure an equitable situation regarding the traders and consumers, and correctness of measurements in law enforcement, health services and environmental protection. The legal metrology department will establish national requirements for pre-packed goods based on international and regional standards and will ensure that suppliers comply with these.*

8.3   Standards

Standards are voluntary in themselves. It is only when they are referenced in a technical regulation or are elevated to become mandatory standards by law that compliance is enforced as a general regulatory principle. For most countries it is important to have a single, pinnacle organization designated as the National Standards Body (NSB). This NSB should be made responsible for the publication of all national standards, even though they may not develop them all, i.e. ministries and their agencies that develop standards should have them published by the NSB. In addition, the NSB has to ensure that the country is appropriately represented at the regional and international level regarding standards development. Whether the standards bodies are government departments, public entities or private-public partnerships will depend on the legal system, customs and practices of the country. The government is in all cases accountable to the World Trade Organization to ensure that all standards bodies within its territory keep to WTO-TBT Agreement requirements.

Typical National Quality Policy pronouncements in this regard are as follows:

- *With regard to national standards as the initial building block for most quality-related activities, the government will see to it that the standards development process is a voluntary activity that depends on achieving consensus amongst stakeholders, and which is implemented by or on behalf of [Country's Bureau of Standards] within a participatory and transparent environment. It will encourage the adoption of relevant international and regional standards based on demonstrated needs of [Country's] authorities, industry and the society, and ensure that all standards are periodically reviewed to ensure continuous conformity with technological developments, market trends and international requirements.*

- *The [National Bureau of Standards] will provide the framework required to develop and publish national standards and other normative documents at a national level, and to regularly review and update the same. Moreover, the [National Bureau of Standards] will participate in the process of developing regional and international standards where this is of relevance for [Country], and will coordinate these activities with the relevant local bodies.*

- *The development and publication of [Country's] national standards will take full cognizance of demonstrated national needs and will comply with international best practices and requirements as defined in the WTO-TBT Agreement and ISO/IEC Directives. International and regional standards will be adopted as far as is possible within the realities of [Country].*

- *To develop [Country's] national standards, the [National Bureau of Standards] will establish the relevant technical committees, which will develop the standards in conformity with approved guidelines and rules. Ministries, academic and scientific institutions will commit themselves to participating in these committees, along with individual entities or organized industry, traders and suppliers and civil society (NGOs, specialized associations and agriculture and tourism.*

8.4   Accreditation

Accreditation provides the means of determining the competency of conformity assessment service providers. Hence, establishing a national accreditation system is no longer negotiable. Any country that wishes to have the output of its NQI recognized in global markets has to ensure that its technical competency can be demonstrated. Being a government institution is no longer good enough. Hence, the question arises of whether a national accreditation body will be established, or whether foreign accreditation bodies will be accepted in lieu of a national body, or whether the country subscribes to a regional accreditation system should one be available.

A useful strategy for smaller countries is to initially establish an "accreditation desk or focal point" in an appropriate ministry that facilitates accreditation through a recognized foreign accreditation body[3], until such time that the accreditation business has grown to such an extent that a national accreditation body becomes a viable proposition. Hence, typical National Quality Policy pronouncements regarding accreditation could read as follows:

- As the third fundamental building block of the quality infrastructure, namely to facilitate independent attestation of the technical capabilities of the conformity assessment service providers to the satisfaction of the local and foreign markets and regulatory authorities, the Government will set up an "Accreditation Desk" in the [Ministry]. The Accreditation Desk will be responsible for facilitating accreditation of conformity assessment service providers such as inspection bodies, testing laboratories, calibration laboratories and certification bodies through foreign accreditation bodies in an internationally acceptable manner.

- Once the number of accredited organizations reaches a viable amount, the Government will be committed to transforming the Accreditation Desk into a fully fledged, independent [Accreditation Service of Country] that is recognized internationally through structures such as the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF). Only one such national accreditation body shall be established to be utilized by all regulatory authorities and the market place, namely the [Accreditation Service of Country] that will works in accordance with international standards, pursues international recognition and signs mutual recognition arrangements on behalf of [Country] with relevant international accreditation organizations. No other national body shall be established.

- The [Country's Accreditation Service] shall establish the relevant technical committees to handle all required sectors to be accredited, such as testing laboratories, calibration laboratories, bodies for the certification of products and management systems, inspection bodies and bodies carrying out training and the certification of quality-related personnel.

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[3] A PTB publication on the concept of "accreditation focal points" is currently under preparation and will be published in 2011.

8.5   Conformity assessment

Conformity assessment spans the whole gamut of services that are required to provide independent evidence that products or services meet standards or technical regulations. These could be inspection, testing, calibration, product certification and system certification or any combination thereof. Although the government may wish to provide such services, global developments indicate that sooner or later this should be handed over to private industry. Hence, the Quality Policy wording could be put together from the following

- *The overall objective of conformity assessment services is to demonstrate the quality of products and services independently of the manufacturer or the supplier. Hence, conformity assessment service providers shall pay attention to national needs, be transparent, be non-discriminatory and avoid unnecessary barriers to trade. Their activities shall be based on international standards and guidelines. They shall favor mutual recognition arrangements that would minimize retesting or recertification, thereby helping to reduce conformity assessment costs.*

- *Testing and inspection services, certification of product and management systems, and personnel for technical regulations or the market place may be provided by laboratories and inspection bodies in both the private and public domain that demonstrably fulfill the requirements of the relevant international standards and are accredited by an internationally recognized accreditation body.*

- *In order to provide conformity assessment services, especially to the SME sector, the government will establish, maintain and continuously improve the conformity assessment service providers and all quality-infrastructure-related institutions in the public domain. These would include inspection agencies, calibration and testing laboratories and certification bodies.*

- *Whilst enhancing the capacity of the public institutions, the government will create a policy environment that will not hinder, but rather facilitate the development of private conformity assessment service providers, and the government will utilize their services in public procurement and technical regulation provided that they can demonstrate their technical capability through accreditation.*

- *As a measure to ensure that the state is provided with quality products and services, the government will utilize [Country's] national standards to the fullest extent possible in state purchases, and will demand independent proof of compliance of delivered products and services with relevant standards through an appropriate mix of inspection, testing and certification. Establishing an incentive, i.e. preferential treatment, for enterprises that distinguish themselves in the process of quality improvement through product and/or system certification will be part of the overall approach.*

8.6   Education and training

The service provision of the NQI depends largely on trained and skilled people, even more so where highly sophisticated testing and metrology equipment is involved. In most countries these skills are not plentiful. Hence, the Quality Policy should exhort all the relevant institutions to do their utmost to increase the pool of skilled workers in the quality environment. Typical wording of the Quality Policy could therefore be:

- *Government and private academic institutions shall take the necessary steps to ensure that various stakeholders have the opportunity to obtain the knowledge and the skills they need to cope with the economy triggered by globalization challenges. Moreover, they should establish appropriate programs at different education levels including specialized adult training programs, with the aim to improve the quality culture, and to develop the specialized knowledge and expertise required for implementing the Quality Policy. They shall also take measures to develop and implement training and registration programs for auditors and consultants in quality and environmental management systems, health and safety in the workplace, and other relevant certification activities as defined in international requirements.*

8.7   Information network

A modern NQI and technical regulation environment cannot operate without very efficient electronic communication with the rest of the world's NQIs. This is also clearly articulated in the WTO-TBT and SPS Agreements that require member states to maintain efficient national enquiry points. Hence, the re-engineering of the national NQI would not be complete without establishing the necessary information networks. Typical wording that could be included in the Quality Policy is the following:

- *The creation of an adequate information network that involves all the various quality infrastructure institutions is decisive in guaranteeing the success of quality-related activities. This information network will be spearheaded by the [National Standards Body] as the appointed TBT Enquiry Point and the [Ministry of Agriculture] as the appointed SPS Enquiry Point, but which must be extended to include all the relevant stakeholders.*

9 Role of other stakeholders

It is not only the government that has a prominent role to play in the re-engineering of the NQI and the Technical Regulation Framework. The private sector has to be intimately involved right from the start in the design of the NQI as they would be one of the main beneficiaries of the services of the NQI. The same applies to the non-governmental organizations and society in general. In addition, in most developing economies, donor organizations are very active in providing technical, training and financial support to upgrade the NQI. The problem is that each donor organization has to ensure that principal policies are kept in mind during the projects. This can lead to overlaps between donor organization activities, often abetted by different counterparts in the country itself. This is not an optimal situation for the country and needs to be addressed holistically. The Quality Policy is a very good place to start. Hence, the following subsections provide wording that could be considered for inclusion in a Quality Policy, after being aligned with the country's realities.

9.1 The private sector

- The private sector has a very prominent role in the implementation of the Quality Policy, and its participation in the development of the national quality infrastructure is absolutely essential. In order to achieve the maximum benefit from the Quality Infrastructure, the private sector, in cooperation with others should:
  a) Improve the quality of its products and services, hasten the introduction of international practices in the field of quality and so contribute to the competitiveness of [Country's] products and services;
  b) Participate actively in representative structures and technical committees dealing with standardization, accreditation and metrology or related activities;
  c) Participate in and promote national quality events, including national quality awards and the like;
  d) Participate in and promote quality dissemination activities, such as congresses, seminars and the publication of information in journals, magazines and other suitable means of communication;
  e) Develop human resources, training the people needed for improving the quality of products and services;
  f) Invest in the development of quality infrastructure, benefiting from the improved market opportunities that result from the implementation of the Quality Policy and
  g) Participate in financing activities that support quality.

9.2 Non-governmental Organizations (NGOs)

- *The successful implementation of the Quality Policy will require the active involvement of all of society, in particular of associations for the promotion of quality and excellence, of chambers of industry, trade and commerce, and of the media in order to realize proclaimed objectives.*

- *Therefore, within the implementation process of the Quality Policy, NGOs are encouraged to take the following initiatives in coordination with relevant partners:*
  a) *Promote and participate in quality education and training activities;*
  b) *Participate in the dissemination of quality-related information;*
  c) *Implement activities that promote the improvement of quality and the environment;*
  d) *Promote the representation of relevant bodies in the technical committees in the field of standardization, metrology, accreditation and quality and*
  e) *Propose suggestions on quality policy improvement and better ways to implement the Quality Policy.*

- *The media is encouraged to become actively involved in the dissemination of information related to standardization and quality and the improvement of productivity, thereby contributing to the multiplication effect and the effect on the country.*

9.3   International development agencies

- *A number of international development and donor agencies are active in [Country]. All the partner or recipient organizations of the international development agencies in [Country] shall ensure that development and capacity building programs rare related to the NQI and technical regulation regime. They should:*
    a) *Support the implementation of the Quality Policy;*
    b) *Coordinate support of other partners for the execution of priority programs;*
    c) *Support the transfer of quality-related technology to the country;*
    d) *Support the transfer of knowledge and information which allows for the development of an adequate quality and technology infrastructure;*
    e) *Support [Country's] participation in relevant international organizations and*
    f) *Provide training for national specialists and technicians who would ease the implementation of the Quality Policy.*

10 Relationship with international organizations

A very strong and active international NQI community exists with renowned organizations such as ISO, IEC, ITU, CAC, OIML, BIPM, ILAC, IAF and many others that have a massive influence on international standardization and related activities. This means that the national institutions need to connect effectively with such international organizations. The same applies to regional organizations where the country is a member of a region that is moving quickly towards a common market or customs union type of arrangement. Typical wording for consideration in the Quality Policy is the following:

- *As is the case with technology, standards, metrology, accreditation and conformity assessment develop at a rapid pace at the international level. It is, therefore, especially important that the NQI institutions of [Country] are actively involved in the appropriate international forums, so that [Country's] regulatory authorities and industry remain firmly in touch with developments at the international level.*

- *Therefore, all the stakeholders have to cooperate to create conditions favorable for active participation in international organizations related to the various functions of the NQI institutions. These would include ISO, IEC, OIML, BIPM, CAC, ITU, IPPC, OIE, IAF, ILAC, etc. This would be achieved through strengthening the affiliation with these organizations and supporting the participation of representatives of [Country's] public and private sectors in the relevant general assemblies and technical committee meetings where it is of relevance to [Country].*

- *The government, together with the NQI institutions and all relevant stakeholders from organized business and organized industry, shall remain actively involved in the standardization and quality-related structures of the [Regional Structure] at all levels, such as the [example] (including its various Subcommittees) as provided for in the [Regional Trade Protocol], so as to ensure that [Country's] interests are properly catered for.*

- *Likewise, all the stakeholders shall cooperate to create conditions conducive to an effective understanding and participation in the implementation of the WTO-TBT and SPS Agreement requirements, as well as the [Regional Treaties], thereby collectively and individually fulfilling [Country's] obligations in regional and international matters related to the Quality Infrastructure.*

11 Financing the NQI and the Technical Regulation framework

An analysis of the NQI institutions worldwide indicates that governments retain the responsibility to fund the three main institutions to a large extent, even in relatively well-developed economies. Hence, governments have to commit themselves to funding the standards, metrology and accreditation institutions of the NQI. This is true even if the national standards body or accreditation body is a private not-for-profit organization, only the type of funding from the state will be different. In the case of a statutory body it is usually in the form of a government grant, also known as "core funding", for those activities that are considered to be in the interest of the whole country, i.e. no specific beneficiary can be identified. In the case of private bodies the funding is the result of a specific agreement or contractual arrangement between the state and the specific institution.

Conformity assessment bodies in the public domain should operate on the "user pays" principle so as not to distort the market, i.e. supply private service providers with an incentive to develop their services. Ultimately, governments should move out of the provision of conformity assessment services, and leave this part of the NQI to private industry. But this is a process and not something that will happen in the short term. Typical wording (which has to be adjusted for the type of organizational and legal structures of the NQI institutions envisaged) for the Quality Policy that deals with these complex issues could be the following:

- It is of vital importance to make the public and private financial resources available for the implementation of the Quality Policy. The government of [Country] will be responsible for financing the development, upgrading and restructuring the existing NQI institutions within the public sector. The financing of private sector institutions and organizations will remain the responsibility of the private sector, as is their involvement in technical committees and similar structures at the national, regional and international level.

- *In particular, the government will retain the full responsibility for the funding of:*
  a) *The development and publication of national standards by the [National Standards Body] as well as the maintenance of the standards information center;*
  b) *The establishment and maintenance of the national measurement standards by the [National Metrology Institute];*
  c) *The establishment and maintenance of a national calibration service until it has developed to the point where its users will be able to fund it;*
  d) *The legal metrology services in so far as they cannot be funded through the fees and levies paid by the users of measuring equipment falling within the scope of legal metrology legislation;*
  e) *The establishment and short-term operational expenses of the [National Accreditation Service], until such time as the number of accredited organizations reaches a level that the accreditation fees can do so;*
  f) *The establishment and maintenance of the membership of the [National Standards Body], [National Accreditation Service], [National Metrology Institute], the legal metrology department and other relevant institutions in international and regional organizations such as ISO, IEC, BIPM, OIML, CAC, IAF, ILAC, etc. relevant to the proper functioning of NQI activities;*
  g) *The establishment and maintenance of testing and calibration capacity in support of the Quality Policy, with the proviso that these services be commercialized as soon as possible in order not to compete with private industry on an unequal basis. Strategically important testing capacity that can never be successfully commercialized will continue to receive the appropriate funding until such time as it is no longer a strategic necessity and*
  h) *The establishment of proper market surveillance operations to ensure that technical regulations are complied with. The funding for the testing and certification of products falling within the scope of technical regulations remains the responsibility of the suppliers.*

- *In order not to distort the market, and to provide for a steady self-earned income of the NQI institutions in the public domain, private industry, and also government institutions that make use of the conformity assessment services of the NQI, have the responsibility to pay for such services. The pricing levels shall be set by the NQI institutions to cover costs, taking into consideration the capacity of especially the SME sector to pay for such services. Any governmental financial support for the SME sector shall not be demanded as a reduction of prices of the NQI institutions, but will be channeled to the SMEs in another way.*

12 Legal framework

It is quite obvious that much of the environment in which the NQI and the Technical Regulation Framework can be given legitimacy will have to be supported by legislation. Therefore, the Quality Policy should spell out the government's commitment to reviewing, developing and promulgating such legislation, especially if the NQI institutions are government departments or statutory bodies. In the case of private organizations, the appropriate wording regarding formal agreements or memoranda of understanding should be inserted instead. Typical examples are:

- *The business environment is affected amongst others by the legal and regulatory framework related to the quality infrastructure and technical regulations. Similarly, the quality infrastructure institutions, especially in the public domain, are bound by legislation that governs their objectives, regulatory authorities, governance, finances, processes and operations. To facilitate the implementation of the Quality Policy, the government of [Country] is committed to reviewing the existing legal framework as a priority measure, to benchmarking it against international best practices, and to ensuring that it complies with the international and regional obligations of [Country].*

- *Legislation that will be reviewed or developed shall include legislation for, but not limited to, the following:*
    a) *Establishment of the [National Bureau of Standards] and the requirements for the development and publication of [Country's] national standards;*
    b) *Fundamental metrology and the establishment of a [National Metrology Institute];*
    c) *Elevating the weights and measures activity to a legal metrology activity;*
    d) *Establishment of a [National Accreditation Service] and*
    e) *Definition of a National Technical Regulation Framework and the establishment of a Technical Regulation Office in the [presidency or similar].*

- *In establishing the Quality Infrastructure as envisaged in this policy, the current institutions have to be reviewed, new structures have to be established and responsibilities have to be allocated to ensure that the quality infrastructure environment is conducive to delivering the services required to support [Country's Vision 2020]. An integrated approach is required to ensure that there are no oversights, overlaps, duplication and conflicts of interest amongst the various institutions that constitute the Quality Infrastructure of [Country].*

- (Alternative) *The business environment is affected amongst others by the legal and regulatory framework related to technical regulation and SPS measures. Similarly, the quality infrastructure institutions, even though they are private not-for-profit organizations, are bound by statutes that govern their objectives, regulatory authorities, governance, finances, processes and operations. To facilitate the implementation of the Quality Policy, the government of [Country] is committed to reviewing current agreements (or memoranda of understanding) between itself and the NQI institutions, to benchmarking them against international best practices and international and regional obligations so as to ensure that the country is served effectively and efficiently by the NQI in relation to government policies and objectives.*

13 Definitions

Definitions of the various terms utilized in the Quality Policy can be found in ISO/IEC Guide 2, ISO/IEC 17000, the WTO-TBT Agreement and various other international standards. The most important are listed below as a guide to what needs to be included in the Quality Policy.

The following definitions apply to this Quality Policy unless the context determines otherwise:

- **Accreditation** *is the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks;*

- **Designation** *means the governmental authorization of a conformity assessment body to perform specified conformity assessment activities;*

- **Calibration** *is the set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material and the corresponding values realized by standards;*

- **Certification** *is the procedure by which a third party provides written attestation that a product, process or service meets specified requirements;*

- **Conformity assessment** *means the demonstration that specified requirements relating to a product, process, system, person or body are fulfilled;*

- **Inspection** *means the examination of a product design, product, process or installation and the determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements;*

- **Measurement standard** *means a material measure, measuring instrument, reference material or measuring system intended to define, realize, conserve or reproduce a unit, or one or more values of a quantity, to serve as a reference;*

- **Quality Infrastructure** *is the totality of the institutional framework (public or private) required to establish and implement standardization, metrology (scientific, industrial and legal), accreditation and conformity assessment services (inspection, testing and product- and system certification) necessary to provide acceptable evidence that products and services meet defined requirements, be it demanded by regulatory authorities (technical regulation) or the market place (contractually or inferred);*

- **Quality management** *means the coordinated activities to direct and control an organization with regard to quality;*

- **Standard** *is a document established by consensus and approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context;*

- **Technical regulation** *is a document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method.*
  Note: A mandatory or compulsory standard is also a technical regulation.

- **Testing** *means the determination of one or more characteristics of an object of conformity assessment according to a specified procedure.*