

GUIDE FOR THE DEVELOPMENT OF

National Quality Policies

National Quality Policies

DEVELOPMENT GUIDE

Vienna, Austria 2016



Acknowledgements

This guide has been prepared by the United Nations Industrial Development Organization (UNIDO) under the overall supervision and guidance of Mr. Bernardo Calzadilla-Sarmiento, PhD, Director, Department of Trade, Investment and Innovation (TII), in conjunction with Mr. Toshiyuki Miyake, PhD, Industrial Development Officer and project manager.

The document draws on UNIDO's long-lasting experience in the areas of Quality Infrastructure and National Quality Policy development in the ECOWAS and ECO region and in countries such as Bangladesh, Malawi, Mozambique, Pakistan and Zambia. More specifically it is based on work carried out under the regional project *Achieving good governance and sustainability through quality policy formulation in the ECO region and also* builds on work from previous publications including *Leveraging the Impact of Business Environment Reform: The Contribution of Quality Infrastructure* and *Quality Infrastructure* - *building trust for trade*, published by the Donor Committee for Enterprise Development (DCED) and UNIDO, respectively.

UNIDO greatly acknowledges the work of Mr. Martin Kellermann, Mr. Beer Budoo, Ms Eva Oduor, Mr. Justin Bayili and Dr. Geoffrey Roland Visser and the valuable support to this publication provided by Mr. Steffen Kaeser, Mr. Ouseph Padickakudi, Mr. Otto Loesener, Ms. Dominika Dor-Skrobot and Ms. Dorina Nati.

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Abbreviations and Acronyms

BIPM Bureau International des Poids et Mesures

ECO Economic Cooperation Organization

ECO Trade Agreement

IAF International Accreditation Forum

International Electro-technical Commission

ILAC International Laboratory Accreditation Cooperation

International Organization for Standardization

ITU International Telecommunications Union

LMD Legal Metrology Department

NAB National Accreditation Body

NMI National Metrology Institute

QI Quality Infrastructure

NSB National Standards Body

OIML International Organization of Legal Metrology

Regional Institute for Standards, Conformity assessment, Accreditation and

Metrology

SDO Standards Development Organization

SME Small and Medium Enterprises

SPS Sanitary and Phyto-Sanitary

TBT Technical Barriers to Trade

WTO World Trade Organization

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The ability of countries to exploit commercial opportunities, to compete on global markets and to participate in international value chains is often challenged by their difficulties in demonstrating compliance with quality requirements and trade rules. Setting up a Quality Infrastructure System is one of the most positive and practical steps that a developing nation can take on the path forward to developing a thriving economy as a basis for prosperity, health and well-being.

A Quality Infrastructure is a system contributing to governmental policy objectives in areas including industrial development, trade competitiveness in global markets, efficient use of natural and human resources, food safety, health, the environment and climate change. It offers a complete package addressing the needs of the nation's citizens, of customers and consumers, and of enterprises and other organizations that offer them products and services. The Quality Infrastructure System covers essential aspects such as policy, institutions, service providers, and the value-adding use of international standards and conformity assessment procedures.

The National Quality Policy (NQP) is the basic government instrument that sets out the objectives of the Quality Infrastructure system in relation to Metrology, Standardization, Accreditation and Conformity Assessment, to build the foundation for effective trade.

1.1 THE NEED FOR A NATIONAL QUALITY POLICY

The world trading system is developing relentlessly. A vast array of good practices has evolved in the past decades with regard to quality infrastructure systems that support trade whilst still ensuring the safety and health of the peoples, the fauna and flora and the environment. Some of these practices are encoded in the WTO TBT Agreement, some are provided for in the working and recognition arrangements of international organizations such as ISO and IEC, BIPM and OIML, ILAC and IAF, whilst others have just evolved as good practices to be followed.

Countries that wish to benefit from the world trading system, i.e. enhance their exports in order to drive their own socio-economic development agenda, have little choice but to pursue compliance with these international requirements and good practices. On the other hand, in many countries quality infrastructures have developed over many years, and have served the countries well in the past. The same applies to the regulatory framework.

The problem is that the quality infrastructure and especially the regulatory framework have developed in an organic way in the absence of a clear government policy framework and they have become entrenched restrictions that hinder trade rather than support trade.

Therefore, many countries have seen the need to fundamentally re-engineer their national quality infrastructure system in order to connect much more effectively with the international trading regimes. This is of particular importance for smaller economies that have to satisfy their much larger trading partners that have well-developed systems in place. The development and implementation of a National Quality Policy has become a necessity in this respect, because without solid government policy guidance, the required alignment of the country's quality infrastructure system with that of their main trading partners will be seriously hampered.

1.2 WHO IS THIS GUIDE FOR?

This Guide is designed as a reference document to help Government officials who wish to develop their Quality Policy in a way that stimulates national, regional and international trade. It is aimed mainly at civil servants at all levels that are involved in policy development, implementation or review, but it will also be beneficial for anyone who needs to understand the policy-making process in governments as regards quality infrastructure and technical regulation. Political leaders at all levels of government can also consider using the recommendations provided in this guide as a standard of good practice in

National Quality Policy development and it could therefore provide guidance and measures to evaluate the policy development work of the civil servants.

The Guide focuses on the processes of National Quality Policy development, and lists key issues that need to be addressed at the national level in order to fit into the broader context of regional integration and the alignment of the national quality infrastructure system with regional and international processes and coordination activities.

1.3 ELEMENTS OF POLICY DEVELOPMENT

In general, a National Policy can be seen as a set of interrelated decisions taken by a government concerning the selection of goals and the means of achieving them within a specified situation where those decisions, in principle, are within the power of the government to achieve¹. From a practical perspective, this translates into the way in which the government converts its political vision into programmes and actions to deliver desired outcomes or changes in the real world. Policy development

is therefore a fundamental function of government. Policy development starts with examining the underlying rationale for and future effectiveness of a policy. Thereafter it is about deciding what needs to be done and how to do it, and reviewing it on an ongoing basis of how well the desired outcomes are being delivered. Exactly, the same would apply to the development of the National Quality Policy.

1.4 FEATURES OF GOOD POLICY MAKING

In general, good policy making is characterized by the following generic features, namely:

FORWARD LOOKING	Defining policy outcomes and taking a long view.	
OUTWARD LOOKING	Taking account of the national, regional and international situation, learning from the experience of other countries; recognizing socio-economic, cultural and political variations.	
INNOVATIVE, FLEXIBLE	Questioning established ways of dealing with things, encouraging new and creative ideas, identifying and managing risks.	
JOINED UP	Looking beyond institutional boundaries, setting cross-cutting objectives, defining and communicating joint working arrangements across departments and ministries, ensuring that implementation is part of the policy process.	
INCLUSIVE	Consulting those responsible for implementation and those affected by the policy, carrying out an impact assessment.	
EVIDENCE BASED	Basing policy decisions upon the best available evidence from a wide range of sources, ensuring that evidence is available in an accessible and meaningful format.	

¹ William Jenkins, *Policy Analysis: A Political and Organizational Perspective*, 1978. London. Martin Robertson

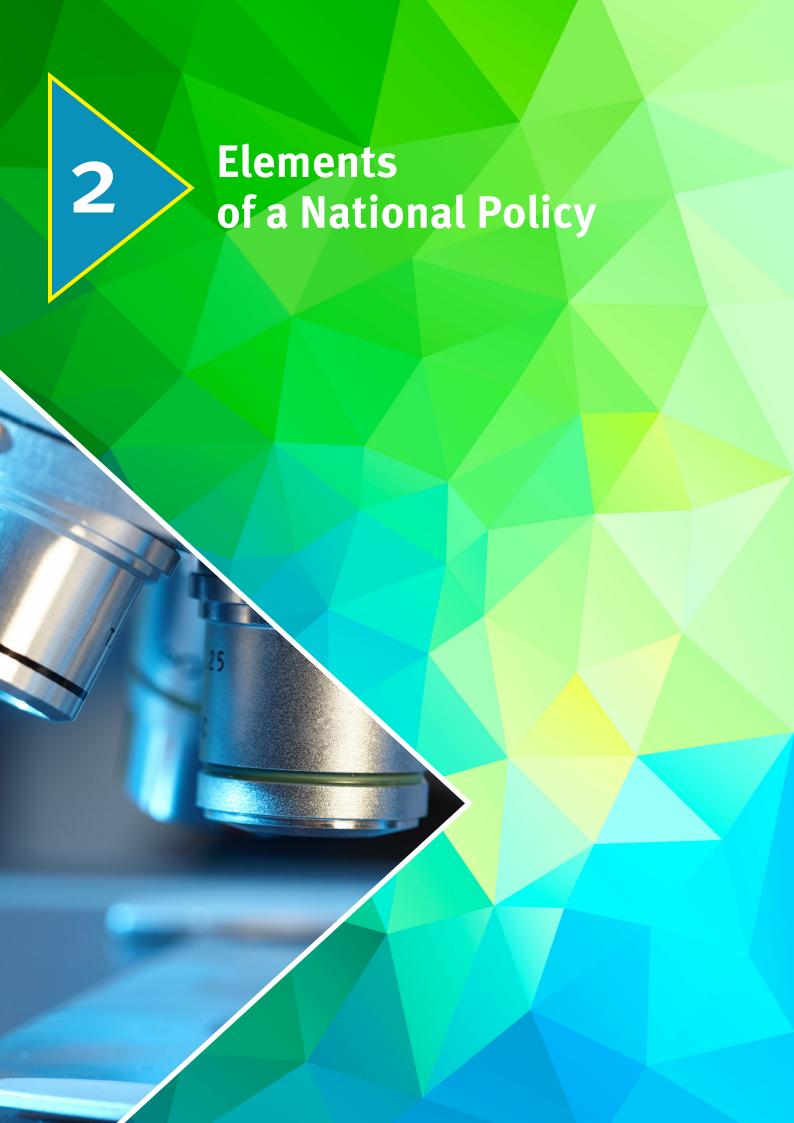
EVALUATED	Systematic evaluation of the effectiveness of policy is built into the policy development process.
REVIEW	Existing/established policy is constantly reviewed to ensure it is really dealing with the problem/challenges it was designed to solve.
LESSONS LEARNT	Learning from experience of what works and what does not and building on the lessons back into the policy developing process.

Table 1: Main generic features of good policy making

It follows that during the development of a National Quality Policy, these generic features of good policy making should be considered as well. Special attention should be given to the consultation process, as the implementation of a National Quality Policy will seriously impact many entities in both the

public and private sector. Continuous and wide consultations throughout the whole development process is therefore indicated, e.g. it would not be good enough just to circulate the final draft for public comment after it has been developed in isolation by a small group of government officials.





The National Quality Policy should contain the broad-based sections as discussed below. The various elements of the Policy and the Implementation Plan/Strategy and their inter-relationships are shown in Figure 1 below.



Figure 1: The various elements of the Policy and the Implementation Plan/Strategy and their inter-relationships

2.1 POLICY VISION/GOAL

The Vision or Goal that is to be achieved through the implementation of the policy by the end of the specified period of time has to be clearly articulated. The Policy Vision/Goal should be a tough one, but should be achievable. It is sometimes also described as the Impact the implementation of the policy will have. A short, concise

and hard-hitting Policy Vision/Goal goes a long way to concentrate the minds of everybody involved as to what ultimately is to be achieved through the implementation of the National Quality Policy – it should be the rallying point for all the objectives, outcomes and measures of the policy.

2.2 POLICY OBJECTIVES

The Policy Objectives describe what is to be achieved for the benefit of the country, for society or for the environment once the policy has been fully implemented. The objectives show the way towards the Policy Vision/Goal. This may include new infrastructure, new systems, new processes or procedures, new knowledge, increased skills, better employment opportunities or changed attitudes. It is good practice to limit the objectives to four or five main objectives in order not to dilute the focus of policy implementation.

2.3 POLICY OUTCOME

The Policy Outcomes describe in specific detail what will be achieved as a result of implementing the policy. The outcomes should be specific, measurable, attainable, result-orientated and time-bound targets for accomplishing the Policy Vision/Goal

2.4 POLICY MEASURES

The Policy Measures describe what needs to be done in order to realize the Policy Outcomes or Objectives. A Policy Measure therefore does not exist on its own, and should always be in line with relevant WTO Agreements. It addresses the problem, challenge or issue that is identified as hindering the attainment of the Policy Vision/Goal.

Hence, these will be the indicative outputs of the policy. The Policy Measure gives rise to the identification of the specific action steps detailed in the Implementation Plan or Strategy that have to be taken to implement the Policy Measure. This section would be the most detailed section in the policy.



Tthe Implementation Plan or Strategy follows a specific logic, and takes the policy implementation process a few steps further to its logical conclusion. It provides for specific Activities and concomitant Expected Outcomes for each of the Objectives and Measures. The Expected Outcomes collectively ensure that the Policy Vision is realized.

3.1 ACTIVITIES

Like the Policy, the Implementation Plan or Strategy follows a specific logic, and takes the policy implementation process a few steps further to its logical conclusion. It provides for specific Activities and concomitant Expected Outcomes for each of the Objectives and Measures. The Expected Outcomes collectively ensure that the Policy Vision is realized.

3.2 RESPONSIBILITIES, TIME LINES AND BUDGETS

The Activities are defined in terms of Responsibilities and Time Lines, and broad Budget requirements are indicated. These will facilitate implementation and management, and assist in the final evaluation. It is obvious that not all the

activities can be pursued in parallel. There are some that will have to wait for others to be implemented first. These have to be taken into account in the Implementation Plan/Strategy.





The National Quality Policy does not exist on its own. It should be developed within the applicable global and regional contexts and should interface seamlessly with relevant national policies. The National Quality Policy is cross-cutting in nature – it spans the responsibility envelopes of many parts of the government, i.e. Ministries and their Agencies.

4.1 GENERAL

The present global trading environment is characterized by trade growth that is generally higher than trade growth at the national level. Any country that wishes to develop socio-economically and deal with poverty, environmental challenges and gender issues needs to tap into this global trade growth. It follows that the country needs to understand the challenges its manufacturers, suppliers and exporters face in accessing the international markets. These markets are characterized by: (i) high expectations from sophisticated customers, (ii) technical regulations that are becoming more onerous as authorities battle to look after the interests of society and the environment in the face of vast amounts of products of dubious safety and quality flooding the markets, and (iii) product value chains spanning many countries as producers and manufacturers endeavour to bring down costs.

Empirical evidence suggests that standardization (i.e. standards, metrology and accreditation) and its conformity assessment companions (inspection, testing and certification) play important roles in technological progress, productivity and trade. Consequently, a country's industry faces a formidable array of challenges at the global level. Over and above issues such as the logistics, management and financial, the required product or service quality demanded by the purchasers and/or regulatory

authorities, needs to be achieved. The SME sector in particular is normally very hard pressed in all these challenges. Although the product or service quality is the responsibility of the manufacturer or service provider, they will need the unstinting support of an internationally recognized and effective quality infrastructure system.

Compliance with standards is a voluntary action on the part of the manufacturer or supplier. Non-compliance may limit potential market share or it may be a contractual misconduct, but it is not illegal per se. Non-compliance with technical regulations on the other hand is an offence and punishable by law. In all countries, governments have tried to ensure the safety and health of society and the health of the environment for decades. Unfortunately, these regulatory frameworks are frequently of an ad hoc nature, fragmented, with many overlaps amongst regulatory authorities and frequently non-compliant with the WTO TBT Agreement and regional trade agreements. This state of affairs comes about because many Ministries are involved, each conducting technical regulation according to own practices in the absence of definitive national guidelines - continuously drifting further apart. Such technical regulations are ineffective, inefficient and add to the transaction costs of the local producers or suppliers rendering them uncompetitive.

NATIONAL QUALITY POLICY CONTENT



The need for the country to increase exports to foster socio-economic development, the quality and safety requirements of the global markets, high level technical requirements set by major purchasers and the global product value chains, as well as the technical regulation regimes of major trading partners set the boundaries within which the National Quality Policy has to be developed and implemented. his context needs to be explained in adequate detail in the opening sections of the National Quality Policy.

4.2 NATIONAL POLICY ENVIRONMENT

The National Quality Policy does not exist on its own. There are usually quite a number of policies already in place that contain references to standards, quality and technical regulations. These policies typically deal with industrial development, enhancement of the export trade, environmental controls, food safety and/or security, science and technology development and similar issues. The references to standards, quality and technical regulation usually do not relate to a holistic view of a quality infrastructure system, nor provide national guidance on a common approach to technical regulation. But, these policies do provide very important interfaces for a National Quality Policy.

The National Quality Policy should therefore link the policy measures relating to standards, quality and technical regulation contained in all of these important policies. Actually, the development of a NQP will provide a formidable opportunity for a country to holistically review quality issues mentioned in the other policies and amend/change parts of those policies that may not be in compliance with international guidelines and rules. It should be remembered that the other policies may have been formulated at a time and/or by people not fully familiar with international guidelines and rules which may have changed in the meantime. In fact, the National Quality Policy is probably the one policy that can do this in a meaningful way. This notion is depicted graphically in Figure 2.



Figure 2: Relationship of Quality Policy to other policies

NATIONAL QUALITY POLICY CONTENT



The policy environment of the country should be sketched, briefly discussing the various policies and the measures contained therein related to standards, quality and technical regulation. It should be stressed that the National Quality Policy does not supersede any of these policies, but endeavours to consolidate and bind them together as regards the quality infrastructure and technical regulation regime, in order to provide the country with a particular, effective and efficient system that enjoys international recognition. This system serves both the authorities and the private sector, supporting all of these policies and more.

4.3 INTERNATIONAL AND REGIONAL OBLIGATIONS

4.3.1 International obligations

Standards and technical regulations together with their conformity assessment services are dealt with decisively in the WTO Agreement on Technical Barriers to Trade (WTO TBT Agreement). The basic tenets of standards development, e.g. transparency, inclusiveness and consensus, are clearly defined. Mutual recognition of conformity assessment outputs is advocated amongst WTO member states. The reasons for technical regulation are enumerated, as are

transparency obligations *vis-á-vis*. other WTO member states. It would therefore be very important to ensure that the National Quality Policy does not contain anything that conflicts with the WTO TBT Agreement. It would also be important to link the policy measures of the National Quality Policy to the obligations the country has as a WTO member state in respect of the WTO TBT Agreement.

4.3.2 Regional obligations

Free Trade Areas absolutely dominate the more than 150 Regional Trade Agreements notified to the WTO, i.e. agreements on the extensive reduction of trade restrictions between member states, usually covering the overall trade

in goods. And at the center of trade restrictions, standards and/or technical regulation issues are frequently to be found

APPLYING TO ECO:

The same applies to the Economic Cooperation Organization (ECO).

Some of the ECO Member States have signed the ECO Trade Agreement (ECOTA), which will establish mechanisms to promote and sustain mutual trade and economic cooperation within ECO, and other may follow. The objectives of the Agreement are to foster, support, and boost regional trade based on common principles, and to reinforce economic cooperation among ECO Member States through the elimination of non-tariff barriers, reduction of tariffs, and exchange of concessions. To help support the implementation of the ECOTA, harmonisation of the standards at regional level, amongst others, is of utmost importance.

The National Quality Policy must take cognisance of the ECOTA obligations of the country. In addition, some ECO Member States have trade agreements with various trading partners not common to all. Such trade agreements should also be clearly elucidated in the National Quality Policy to ensure that all commitments of the country are considered in its implementation.

NATIONAL QUALITY POLICY CONTENT



The government is strongly encouraged to indicate clearly that its obligations with respect to the WTO TBT Agreement will be fulfilled if it is a WTO member and that the National Quality Policy takes this into consideration. If the country is not yet a WTO member, then this would be a useful place to spell out its future plans for accession to the WTO.

The government should also set out its commitment to meet all its ECO obligations as regards the regional QI structures and harmonization efforts should these be established.



The shape of the Quality Infrastructure system has many implications, not least those of having to comply with international and/or regional obligations contained in various agreements, but also to link up with the international Quality Infrastructure organizations through which international recognition is obtained. It is therefore important that the government assumes overall responsibility for the effectiveness and efficiency of the Quality Infrastructure system.

The Quality Infrastructure (QI) system and its services have become extremely important in the socio-economic development of any state. The shape of the QI system has many implications, not least those of having to comply with international and/or regional obligations contained in various agreements, but also to link up with the international QI organizations through which international recognition is obtained. It is therefore important that the government assumes overall responsibility for the effectiveness and efficiency of the QI system. Many countries established standards bodies, metrology institutes in the distant past, and more recently maybe accreditation bodies. The way in which these have been organized (independent or integrated organizations, government departments or organizations of public law, etc.), the services they offer or are responsible for, and the way in which they relate to technical regulation implementation, may no longer meet international good practices.

This "non-conformity" develops organically for a number of reasons, e.g. a lack of clear policy guidelines, ministries consider the matter too technical and leave it to the institutions to do what they consider appropriate, etc. It does mean however, that the government should seriously consider taking responsibility afresh to establish a proper policy environment that meets international good practices and that is consistent with overall government policies. It usually entails the re-engineering of the QI system, and this is where the government will experience opposition from the institutions as they stand to "lose" some of their powers or income. In this respect the government therefore needs to state their commitment to change and re-engineering in unequivocal terms, i.e. make it clear to all that "business as usual" is no longer good enough and that changes must be implemented. Obviously, such changes have to take place within customs and practices of government restructuring all countries have those.

NATIONAL QUALITY POLICY CONTENT



It is recommended that the government should signify its unequivocal resolve to re-engineer the QI system in line with international and regional (e.g. ECO) agreement obligations and good practices. This re-engineering will take place in consultation with affected parties, but the needs of the country prevail over the wishes and short term objectives of the institutions involved. Only by re-engineering the QI system in this way will unacceptable conflicts of interest be resolved, its services be accepted in the international markets, backing for the local industry to penetrate markets established and the support for the implementation of technical regulations realized.



Over and above issues such as the logistics, management and financial, the required product or service quality demanded by the purchasers and/or regulatory authorities, needs to be achieved. The SME sector in particular is normally very hard pressed in all these challenges. Although the product or service quality is the responsibility of the manufacturer or service provider, they will need the unstinting support of an internationally recognized and effective quality infrastructure system.

6.1 FUNDAMENTALS

The QI system is generally understood to be the totality of the policy, legal, regulatory and administrative frameworks and the institutional arrangements (public and/or private) required to establish and implement standardisation, 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, demanded either by authorities

(e.g. in the case of technical regulation) or the marketplace (e.g. contractually or inferred).

The Quality Infrastructure system is a combination of initiatives, institutions, organizations, activities and people. It includes a national quality policy and institutions to implement it, a regulatory framework, quality service providers, enterprises, customers and consumers (who include citizens as "consumers" of government services) - as visualized in Figure 3 below.

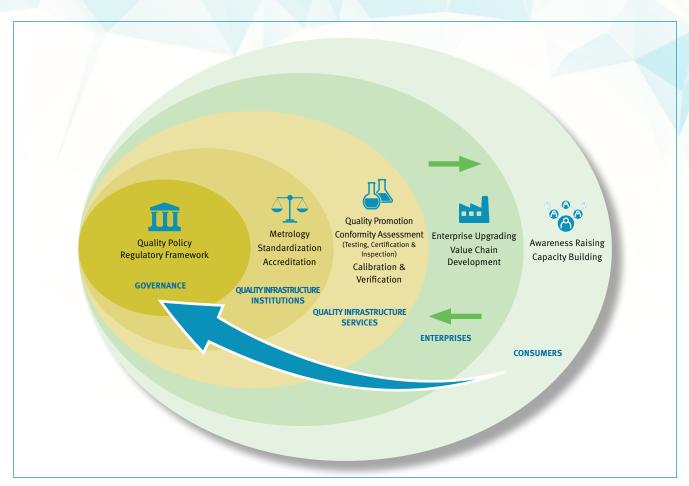


Figure 3: Quality Infrastructure System

A QI system can be a powerful tool for defining, developing and verifying quality requirements for products and services. It verifies and demonstrates that products and services actually meet these requirements. It ensures that the quality requirements and the products and services they generate meet the state-of-the-art requirements and best practice essential for participating in international trade. The QI system should be seen as a dynamic system, meaning its parts interact with each other to provide overall results which are greater than could be achieved by the parts working individually.

As such, the QI system is a catalyst for improving the quality of products and services on a national scale. It

therefore helps to stimulate demand for these products and services, which invigorates individual businesses and the economy as a whole. By helping national industry to meet the requirements of export markets, a QI increases the competitiveness of the nation's economy and its ability to participate in global trade and in value chains.

Because there is no ready-made QI model that will suit all countries, a tailor-made approach is necessary. The QI adjusts to meet the national and regional requirements that have been identified by a thorough assessment of needs.

The main elements of the QI system and their relevance are listed in Table 2.

DOMAIN	INSTITUTION(S)/ COUNTERPART(S)	DESCRIPTION OF SERVICE/RELEVANCE
		Governance
NATIONAL QUALITY POLICY	Government AgenciesRelevant Ministries	The NQP is the basic government instrument for establishing and overseeing the QI system. The government can use the development of the NQP as a opportunity to increase awareness of the importance of the QI system and how the different national actors can benefit from it. It can do this by inviting broad stakeholder participation to develop the NQP.
REGULATORY FRAMEWORK	Government agenciesRelevant Ministries (see Note 1 below)	Because of the mandatory nature of technical regulations, they have the potential to become technical barriers to trade (TBT) that prevent of hinder the flow of goods and services between nations. In particular, the inconsistent use of standards and regulations can create technical barriers. Therefore, the QI system needs to include a national regulatory framework that each regulator can work within in order to ensure consistency.
	Quali	ty Infrastructure Institutions
STANDARDS	 National Standards Body (NSB) Standards Development Organizations (SDO) Industry based standards organizations (see Note 2 below) 	A standard is the publication of a formal document (i.e. the standard) developed by consensus, containing the requirements that a product process or service should comply with. Standards are considered essentiall voluntary in themselves. Suppliers can therefore choose whether to us standards or not. It is only once they are called up in a contract, for example or referenced in technical regulation, that compliance with standard becomes a legally binding obligation.
METROLOGY	 National Metrology Institute (NMI) Legal Metrology Department (LMD) Calibration Laboratories (see Note 3 below) 	Metrology is the technology or science of measurement. Metrology can be subdivided into scientific metrology (the development and organization of the highest level of measurement standards), legal metrology (the assurance of correctness of measurements where these have an influence on the transparency of trade, law enforcement, health and safety) and industrial metrology (the satisfactory functioning of measurement instruments used in industry, production and testing).

NOTE 1: Please refer to chapter 6.3. Governance.

NOTE 2: Although most NSBs are government departments or organizations of public law, a few private NSBs exist. The SDOs can be public or private entities and work either in concert with the NSB or are completely independent.

NOTE 3: The NMIs are invariably public organizations and so are by definition the LMDs. Calibration laboratories may be public or private.

Accreditation is the activity providing independent attestation as to ACCREDITATION National Accreditation Body (NAB) the competency of an individual or an organization to offer specified Private sector accreditation body conformity assessment services (e.g. testing, inspection or certification). (see Note 4 below) **Quality Infrastructure Services** A strong quality infrastructure system protects businesses from unfair OUALITY Government agencies competition, reduces barriers to trade and helps companies to compete **PROMOTION** Industry Associations in the global trading system. It is therefore important to promote and Private Enterprises create demand for quality infrastructure services and thus create a sustainable quality culture. Inspection is the examination of a product design, product, process **INSPECTION** Import inspection agencies or installation and determination of its conformity with specific General inspection agencies requirements or, on the basis of professional judgement, with general (see Note 5 below) requirements. Inspection is often conducted on consignments such as import inspection, to ensure that the whole consignment is equivalent to the product sample tested. **TESTING** Test laboratories Testing is the determination of a product's characteristics against the requirements of the standard. Testing can vary from a non-destructive Clinical laboratories evaluation (e.g. X-ray, ultra sound, pressure testing, electrical, etc. where Environmental laboratories after the product is still fit for use) to a total destructive analysis (e.g. chemical, mechanical, physical, microbiological, etc. where after the (see Note 6 below) product is no longer fit for use), or any combination thereof. **CERTIFICATION** Product certification organizations Certification is the formal substantiation by a certification body after an evaluation, testing, inspection or assessment, that a product, service, System certification organizations organization or individual meets the requirements of a standard. (see Note 7 below) Measuring equipment does not maintain its accuracy over time after it has **CALIBRATION &** Metrology Institute been put in service, and has to be recalibrated at given intervals. Hence, VERIFICATION Calibration laboratories calibration services are important to ensure that measuring equipment used in trade, health care, environmental control, law enforcement, manufacturing, and many others remain accurate within specified parameters. The calibration and verification of measuring equipment falling within the scope of legal metrology regulations can be provided by the legal metrology department or calibration laboratories. **Enterprises ENTERPRISE** Private Enterprises Private sector enterprises are in many cases the ones demanding quality infrastructure services. In order to promote a sustainable quality culture **UPGRADING** Industrial Unions among private enterprises, it is crucial to create the link between the **VALUE CHAIN** services offered by national quality infrastructure institutions and private sector enterprises. **UPGRADING** The emphasis of a QI system should be on markets and consumers. **AWARENESS** Consumer Associations Interaction is particularly intense between enterprises and customers/ RISING consumers. Enterprises offer products and services and receive direct **CAPACITY** and indirect feedback from consumers in the form of sales and levels of BUILDING customer satisfaction.

NOTE 4: NABs are usually a government department or organization of public law. Private sector multinational accreditation bodies exist, and are mostly found in the certification to private standards domain.

NOTES 5, 6 and 7: These can be public or private agencies.

The QI institutions should collectively provide services to the manufacturers, producers or suppliers of products and services, the authorities as well as consumers. The QI institutions can be in the public or in the private domain. In many countries conformity assessment services (i.e. inspection, testing and certification) are progressively being provided by the private sector rather than by government laboratories, whereas governments retain the responsibility to ensure that the fundamentals, i.e. standards, metrology and accreditation are maintained. The technical competency of QI services is demonstrated through accreditation to international standards such as ISO/IEC 17020 (inspection bodies), ISO/IEC 17021 (system certification organizations), ISO/IEC 17025 (test and calibration laboratories) and ISO/IEC 17065 (product certification organizations).

Good international practices have evolved regarding the structuring (i.e. independence or combinations) of the QI institutions in a country, but there are many acceptable combinations still possible depending on local custom and practices, policies and resource constraints. Some constructs however, give rise to conflicts of interest and should be avoided, e.g. accreditation and conformity assessment services. In addition, certain combinations are increasingly seen as unnecessary barriers to trade, e.g. national standards bodies and technical regulation administration (see 3.2), and are no longer defensible at the international level.

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

6.2 OPTIMIZED QI STRUCTURE

An optimized QI structure takes into account all elements of the QI system, including markets and consumers (6.2.1), the institutional structure (6.2.2), related quality

infrastructure services (6.2.3) and governance and the role of the regulatory framework (6.3).

6.2.1 Markets and consumers

The increased choice of competing products brought by global markets and the downward pressure on prices resulting from competition mean that customers will tend to reject products that they do not perceive as being quality products, even though their price may be low. Global markets and competition will probably tend to give them a choice of better quality at the same price.

The emphasis of a QI system should therefore be on markets and consumers. All component parts of the QI system act dynamically on each other. This inter-action is particularly intense between enterprises and customers/consumers. Enterprises offer products and services and receive direct

and indirect feedback from consumers in the form of sales and levels of customer satisfaction.

Markets also provide feedback - although not necessarily as swiftly as coming from the point of sale - on quality infrastructure services, quality infrastructure institutions and governance. This feedback allows review, modification and improvement of the different components and of the whole quality infrastructure – which underlines the dynamism and system nature of the QI system.

Against this background, it is crucial to create a link between the services offered by quality infrastructure institutions and markets and consumers.

6.2.2 Quality Infrastructure Institutions: Accreditation, Metrology, Standardization

One of the considerations for the optimization of the QI structure would be the international organizational structure of the same. At the international level accreditation, metrology and standards are separated. Within each of them there are subdivisions that would not necessarily be advantageous for a country, e.g. ILAC and IAF (accreditation), BIPM and OIML (metrology), ISO, IEC and ITU (standards). It would therefore make a lot of

sense to have an independent national standards body, an independent metrology institute and an independent accreditation body at the national level. This however, is a rather expensive solution, and not always financially viable in smaller economies. Some combinations at the national level are acceptable (as shown in Figure 4 below), i.e. they do not give rise to conflicts of interest, namely:

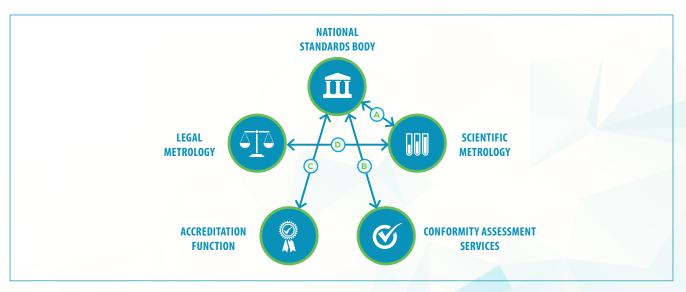


Figure 4: Possible combinations of QI instituions at national level

- A. National standards body combined with scientific metrology;
- B. National standards body combined with conformity assessment services;
- National standards body combined with the accreditation function; and
- D. Scientific metrology combined with legal metrology.

Combinations (B) and (D) are quite common in smaller economies, as there are many synergies to be had in such groupings. Combination (C) is not very common, but it is a very workable construct if a fairly well developed conformity assessment service infrastructure exists in both the public and private sectors – the *caveat* is that no conformity assessment service may be provided by such an organization as this would be a case of serious conflict of interest. Combination (A) is also fairly common, but usually combined with (B). Factors that influence

the choices include the available long-term government funding, availability of trained and skilled technical personnel, custom and practices in the public sector, and the preferences of major trading partners.

The QI structure will also be influenced by the regional QI organizations, i.e. current and future (ECO) structures. Establishing and maintaining QI organizations, especially for standards, metrology and accreditation demand long-term financial commitments from government, as these are seen as "good for country" services for which a specific beneficiary cannot be readily identified, i.e. it is difficult to send an invoice to a specific beneficiary. Governments of smaller economies are often hard-pressed to commit the necessary resources, hence are looking for regional support. Hence, a trend to establish regional organizations that can provide accreditation and selected scientific metrology services for example to more than one country is slowly emerging.

APPLYING TO ECO:

The ECO Statutes make provision for establishment of a specialised regional quality infrastructure. The permanent body may be preceded by establishment of an interim committee/organ to make better utilization of the time in the run up to the establishment of a permanent structure. One of its responsibilities of such a body would be to coordinate regional quality infrastructure and technical regulation activities and to promote development of the same in the region. As this is an evolving undertaking, it is recommended that the government remains aware of these developments, ensure it tracks the same and influences them where necessary, and in such a way play an effective role in its establishment. On the other hand, the government should also ensure that the development and activities of the country's QI system are aligned with these endeavours.

In addition, the evolving ECO regional quality policy recognises the importance of coordinating the quality infrastructure activities and the need to cooperate in reducing unnecessary barriers to trade. Until the formal structures are fully established, ECO Member States are encouraged to cooperate with one another in forums that have harmonisation as their focus. The National Quality Policy should include a commitment to participate in such regional and international coordinating structures with the aim of achieving better harmonisation while at the same time effectively representing the needs of its domestic stakeholders.

NATIONAL QUALITY POLICY CONTENT



The government is encouraged to clearly articulate the optimum QI structure for the country as regards accreditation, metrology and standards. It is virtually certain that it may have to re-engineer the current structure either partially or in totality, make adjustments and establish new organizations. If the QI system complies fully with international good practices the government may confirm the current setup depending on how close the current structure is to international good practices and pre-conditions contained in relevant (ECO) agreements. The main responsibilities of the future QI organizations have to be clearly spelt out. It is important to create confidence that the country will be well-served in terms of these three fundamental OI services.

6.2.3 Quality Infrastructure Services

CALIBRATION



Measuring equipment unfortunately does not maintain its accuracy over time after it has been put in service, and has to be recalibrated at given intervals. Hence, calibration services are important to ensure that measuring equipment used in trade, health care, environmental control, law enforcement, manufacturing, and many others remain accurate within specified parameters. Calibration services, whose working standards are traceably calibrated against national (or regional) measurement standards, can be provided by the national metrology institute, by the legal metrology department and by independent calibration laboratories in both the public and private sector. Larger industrial organizations or authorities may even establish their own in-house calibration facilities. The government should establish a policy environment where all of these can prosper and offer their services at market related pricing. Their technical competency should be denoted by accreditation to ISO/IEC 17025. It should be clear that the national metrology institute and the legal metrology department do not have a legal monopoly on calibrations services. In fact, the national metrology institute should have programmes in place to help independent calibration laboratories achieve the appropriate level of competency and get accredited.

Although scientific metrology, i.e. the establishment and maintenance of measurement standards, can be provided at the regional level or shared between national bodies within the region, calibration laboratories have to be close to where the action is. Therefore, a number of calibration laboratories need to be established at national level. A regional calibration laboratory will find it difficult to handle the volume of work and the logistics of travelling with measurement standards across boundaries and through customs are extremely challenging at the best of times.

NATIONAL QUALITY POLICY CONTENT



The government is encouraged to clearly state that calibration services may be provided by both public and private sector calibration laboratories. Accreditation to ISO/IEC 17025 should be strongly advocated without making it a legal requirement with the exception of calibration laboratories active in the implementation of legal metrology requirements. The national metrology institution should be charged with the responsibility to help build calibration capacity in the country.

LEGAL METROLOGY



Legal metrology (including its subset weights and measures) ensure that transactions that are based on measurements are equitable for both the "supplier" and the "purchaser", i.e. in trade, health services, environmental control and

law enforcement. The responsibility for legal metrology is vested in the state; it is a type of technical regulation. Legal metrology has a massive influence on trade, and has the potential to be trade restrictive if legal metrology requirements between trading partners are different, e.g. quantity requirements for pre-packaged consumer products. At the international level the International Organization for Legal Metrology (OIML) endeavours to harmonize legal metrology regulations and type approval testing and certification of measuring equipment as much as possible, thereby facilitating trade.

In a modern economy that wishes to trade at the regional and international level, the legal metrology system should therefore be fully compatible with OIML recommendations and the regional (i.e. ECO requirements). The type approval of measuring equipment should be based on OIML test reports wherever possible. The calibration and verification of measuring equipment falling within the scope of legal metrology regulations can be provided by the legal metrology department, but due to the immense logistical

challenges many economies are slowly designating private companies to do so once they are accredited to ISO/IEC 17025 and meet specified legal requirements, mostly to do with company registration and liability.

It is important that the legislation is easy to administer. In many countries legal metrology legislation (or weights and measures legislation) is a few decades old, and frequently out of date. In this case it would be very appropriate to modernise the legislation. Good practice indicates that the legal metrology legislation should be of the enabling type, and that the technical details of the measuring equipment and other norms are promulgated as regulation under the legal metrology legislation. In this way it is much easier to update the technical details as and when necessary without having to take it through the Parliamentary process.

NATIONAL QUALITY POLICY CONTENT



The government is encouraged to clearly state that it will modernize the weights and measures, upgrade it to legal metrology, and base it fully on OIML recommendations. The government should also commit resources to the upgrading of the technical capacity of the legal metrology laboratories and inspectorate. Accreditation for the laboratories to ISO/IEC 17025 and the inspectorate to ISO/IEC 17020 should be implemented. The liberalization of calibration and verification services under specified conditions should be planned and implemented in the future.

It is of vital importance that the legal metrology obligations of ECO are fully realized in the re-engineering of legal metrology system.

CONFORMITY ASSESSMENT SERVICES



In the distant past, government laboratories had a monopoly on the testing and certification business, especially for the implementation of technical regulations. In more modern economies this has changed dramatically for a number of reasons, namely:

- » The investments to establish and maintain the conformity assessment services required are substantial, and governments are no longer in a position to provide for such investments over a broad spectrum of inspection agencies, laboratories and certification bodies;
- » Public service providers are mostly required to implement civil service human resources policies and conditions of service, which are not adequate to keep highly skilled technical personnel; and
- » Private sector service providers are able to adapt to changing market requirements much more readily, whereas public entities are subject to controls heavy bureaucracy and red tape that are difficult to change.

In modern economies the governments are therefore comprehensively liberalizing the testing and certification business. The private sector has responded by establishing a vibrant conformity assessment service sector. The main challenge that such countries face is how to engender trust in the technical competency of the inspection bodies, test laboratories and certification bodies. This is where accreditation plays a very important role. Without accreditation, conformity assessment service providers, whether in the public or private sector, find it increasingly difficult to have their results, reports and certificates accepted by regulatory authorities and the market place alike, both at home and in the export markets.

APPLYING TO ECO:

Within ECO the same applies. Stated ECOTA principles foresee harmonious economic relations between the parties and fair conditions of competition and trade amongst them. This means amongst others, that for any product or service to cross boundaries amongst ECO member states without further inspection, testing and certification (especially for the implementation of technical regulations), it will have to be inspected, tested and certified by service providers accepted by all, i.e. accredited. Hence, it would also be appropriate that the same systems are implemented in the home markets, thereby minimizing unnecessary barriers to ECO intra-regional trade, at the same time easing the conformity assessment burden of local manufacturers and suppliers, rendering them more competitive.

The general acceptance and implementation of the Halaal certification scheme based on the standard developed by the Standards and Metrology Institute for Islamic Countries (SMIIC) is a good example of such harmonization.

NATIONAL QUALITY POLICY CONTENT



Firstly, the government is encouraged to state clearly that inspection, testing and certification services may be provided by both public and private sector calibration laboratories at market related pricing. Public institutions such as the national standards body or government laboratories for example should not be given any preferential treatment, nor should the perception be created that they have a monopoly on certain testing. The organization requiring third-party inspection, testing and certification should be given a choice of competent service providers.

Secondly, in order to engender general acceptance of conformity assessment services, accreditation to ISO/IEC 17020 (Inspection bodies), ISO/IEC 17021 (quality management system certification bodies), ISO/IEC 17025 (testing and calibration laboratories) and ISO/IEC 17065 (product certification bodies) should be strongly advocated without making it a legal requirement with the exception of service providers active in the implementation of technical regulations and SPS measures.

Thirdly, the ECO trade requirements and pre-conditions for regional acceptance of conformity assessment services need to be factored into the policy measures.

6.3 GOVERNANCE

6.3.1 Technical Regulation Framework

Just as manufacturers, exporters and suppliers utilise standards, metrology, accreditation, calibration and demonstrate conformity assessment services to compliance of their products and services with contractual obligations and market preferences, so they also have to provide reputable evidence to the regulatory authorities that their products and services meet technical regulation requirements. In the past regulatory authorities would conduct the inspections, test the products, certify them and release them for marketing - a pre-marketing approach. Due to the massive increase in trade this is no longer feasible from a logistics perspective, over and above the fact that it is a very costly and frequently a very ineffective way of controlling the integrity of products and services falling within the scope of technical regulations, i.e. final inspection is not effective on its own, all the production activities that go beforehand should be under control as well.

Modern regulatory frameworks focus much more on post-marketing matters such as risk assessment, market surveillance and the imposition of sanctions for non-compliance, assigning the responsibility for compliance testing of products or services fully to the manufacturer or supplier. The challenge for many countries is that their regulatroy framework is still steeped in the "pre-market approval" tradition, and changing to a post-market regime is an extremely radical step. The building blocks of a

Technical Regulation Framework depicted graphically in Figure 5 are a useful basis to consider such a change. These building blocks should be properly articulated for the legal system and situation in the country (with full consideration of ECO obligations), and should be ensconced in legislation to ensure that all the Ministries and their agencies follow these general principles for greater legal certainty and transparency in developing and implementing technical regulations. If all of these are properly defined and implemented, then transactional costs will be minimized rendering suppliers more competitive, and compliance with

the WTO TBT Agreement (and related ECO obligations) as well as the goal of technical regulation will be realized.

The National Quality Policy should set the responsibilities for the development and implementation of such a Technical Regulation Framework, and should set a time limit in which it has to be achieved. Complete details regarding the development of a Technical Regulation Framework should be provided in the Implementation Plan or Strategy. As a matter of principle, the envisaged Technical Regulation Framework must align seamlessly with the regional approach to technical regulation.

APPLYING TO ECO:

A common approach to technical regulation is fundamental to the success of the ECOTA. The regional trade agreement ECOTA does not provide for a definitive approach to technical regulation in ECO even though a common approach is implied. The Regional Quality Policy provides for the development and adoption of a common approach to technical regulation across all ECO Member States, and mentions a predisposition for a regulatory system that follows the recommendations of the United Nations Economic Commission for Europe (UNECE). Hence it will be very important for governments to retain an active interest in the development of the ECO regional technical regulation approach dealing with the relevant modalities - see Figure 5². A certain amount of flexibility will have to be retained in the development of the national Technical Regulation Framework to ensure its future compatibility with the evolving ECO approach.

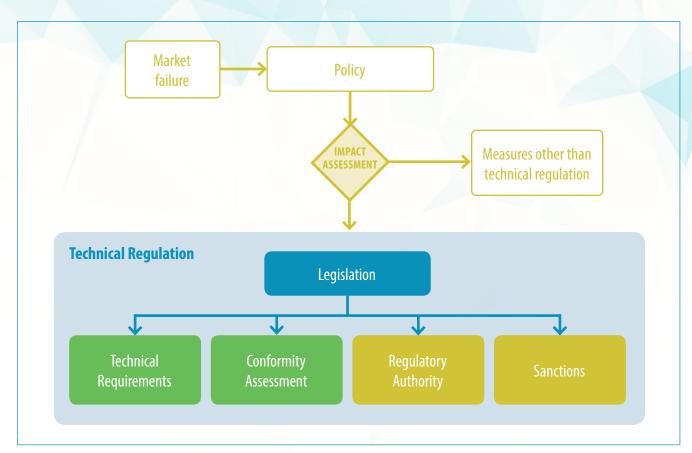


Figure 5: Building blocks of a Technical Regulation Framework

² The European Union for example, implemented the New Directives and Global Approach in the 1990s containing all relevant modalities to force the harmonization of technical regulation across all Member States.

The building blocks of a Technical Regulation Framework in more detail:



The **Impact Assessment** must determine whether the proposed technical regulation will adequately deal with the market failure, whether all of society will benefit if implemented, can the technical requirements 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 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 should be followed throughout.



The **Regulatory Authority** should be responsible for any pre-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.

It is therefore very clear that the services of the QI are important in the development and implementation of technical regulations. International standards should be the basis for technical regulation, and the conformity assessment should be provided by technically competent laboratories and certification bodies (i.e. accredited) and whose measuring equipment is appropriately calibrated

to ensure correctness of measurements. The linkages between the building blocks of a technical regulation also indicate the reasons why international good practice no longer tolerates a national standards body being a regulatory authority: It is seen as a conflict of interest and a means of extracting rent.

NATIONAL QUALITY POLICY CONTENT



The government is strongly encouraged to clearly state its intentions to embark on a fundamental regulatory reform programme. The key elements of this regulatory reform programme should be the review of the current technical regulation regime of the country across all relevant Ministries and their agencies, the development of a modern Technical Regulation Framework containing details regarding all the technical regulation building blocks, the full utilization of the QI for standards, accreditation, metrology and conformity assessment services (and the full implementation of the regional ECO obligations). The re-engineered technical regulation regime should focus on risk assessment, market surveillance, not be unnecessarily trade restrictive, and local and imported products should be dealt with in similar fashion – yet the protection of the health and safety of the population, the health of the fauna and flora and the environment should not be compromised, neither should protection of the consumer against gross exploitation as regards quality.

6.3.2 Regulatory Authorities

A question that inevitably surfaces in the discussion and decisions regarding technical regulation implementation is the number of regulatory agencies that are required or desired, i.e. is there an optimum number or not. Regulatory agencies are by definition public entities, created by legislative instruments. They are routinely given authority of entry, search and inspection without having to obtain warrants in monitoring products, processes and services for compliance with relevant technical regulation requirements. Regulatory authorities need legal protection

from spurious claims by suppliers that would hinder their effectiveness. No government would easily provide this level of authority to private sector entities.

In most countries Ministries have established regulatory authorities, frequently more than one, within their own sector of responsibilities. Each regulatory authority requires a management structure, administrative infrastructure, accommodation and logistical support to fulfil its responsibilities. This comes at a cost to the state.

Hence a growing number of countries are questioning the need for such a large number of regulatory authorities, and are seriously considering what the optimum number for the country would be for the administration of all technical regulations and even SPS measures.

A single, supra-national regulatory agency would in all probability be very cumbersome. Four or five regulatory agencies seem to be a very workable solution for smaller economies. Issues that would need to be clarified include:

- the responsibilities of these four or five have to be very clearly allocated to ensure that no overlaps or gaps develop in the seamless implementation of technical regulations,
- ii. a product should preferably be handled by only one regulatory authority to minimise transactional cost to the supplier and ultimately the consumer,

- iii. the development and approval of technical regulations should remain within relevant Ministries and should not be allocated to the regulatory authorities, and
- iv. the accountability of the regulatory agencies has to be clearly indicated, i.e. under which Ministries will they operate

If the notion of a small number of regulatory authorities is politically difficult to realize because individual Ministries are reluctant to consider such a construct, then each Ministry will remain responsible to establish regulatory agencies under its own auspices and control. In this case coordination of their responsibilities and activities increases immensely in complexity, and a higher level coordinating structure has to be established (see 6.3.3).

NATIONAL QUALITY POLICY CONTENT



The government has to state the number of regulatory authorities it wishes to see established once the policy has been implemented, i.e. a single supra-national authority, four or five optimised sectoral authorities or every Ministry establishes its own. If a smaller number is proposed, then the mechanism (i.e. an Intern-Ministerial Working Group or similar) to determine their scope of activity, accountability and the merging of the current authorities need to be articulated. The basic responsibilities of regulatory authorities should be stated. The process to separate technical regulation administration from the national standards body as indicated by international good practices should be included.

6.3.3 Technical Regulation Coordinating Office

Technical regulation has become very complex and is one of the major barriers to trade in spite of the WTO TBT

Agreement obligations that member states have to comply with.

APPLYING TO ECO:

This is specifically so in regional context such as ECO where member states wish to establish a regional free trade area.

The issues that give rise to this state of affairs are largely to be found at national level amongst the member states. Technical regulation regimes are of an *ad hoc* nature with every Ministry and its agencies developing and implementing them in accordance with own practices that have diverged immensely over time. There are overlaps in responsibilities ensconced in the legislative instruments, with the same product being regulated by many regulatory agencies, all leading to a heavy increase in transactional costs to the suppliers.

This has led to regulatory reform programmes especially in the OECD countries, and part of these programmes has been the establishment of a higher level technical regulation oversight entity. These high level oversight entities ensure that technical regulations are developed strictly in accordance with WTO TBT Agreement obligations, that the responsibilities of regulatory authorities are clarified and coordinated, that the country's regulatory regime is optimized in terms of effectiveness and efficiency, and that older technical regulations are reviewed to determine whether they are still valid or need to be revised.

If the decision is made that such a high level technical regulation oversight entity needs to be established, then its accountability needs to be clarified. An analysis of those established by OECD countries indicates that there are mainly two possibilities. In some countries this oversight

entity is placed within the Ministry of Trade and Industry (or similar). This has the advantage that this Ministry is usually responsible for the implementation of the WO TBT Agreement (and its ECO counterpart), and therefore has the knowledge commensurate with the activities of the oversight entity. The risk is that other Ministries will find it difficult if a Ministry at the same level has a say in how they operate, and may not be so keen to implement its recommendations. The second possibility is to place

the oversight entity at a higher political level, e.g. Prime Minister's Office. This has the advantage that it is seen as a higher level Ministry, therefore other Ministries will be more inclined to follow its instructions. The risk is that such a Ministry will have little knowledge about the requirements of the WTO TBT Agreement (and its ECO counterpart). Hence it will be more challenging for it to provide leadership to the oversight entity.

NATIONAL QUALITY POLICY CONTENT



The policy should provide for the establishment of the high level oversight entity, e.g. a Technical Regulation Coordination Office or similar. Its basic coordination responsibilities as regards technical regulation should be listed, clearly indicating that it does not develop technical regulations, neither is it involved in the management of QI institutions or regulatory authorities. Its accountability, i.e. under which Ministry it operates, also needs to be indicated.

6.4 INTERNATIONAL AND REGIONAL LIAISON

6.4.1 International

A strong and vibrant international QI community has developed over the past decades due amongst other factors to the growing importance of standards, quality and technical regulation in global trade and product value chains. Renowned QI organizations such as ISO, IEC, ITU, BIPM, OIML, ILAC, IAF and many others have a massive

influence on international standards, metrology and accreditation as the fundamentals of the whole QI service delivery system. This means that national institutions need to connect effectively with these international institutions for a number of reasons:



In the first place, QI institutions need to represent their country's interests, not only in the annual general assemblies, but more so in the technical committees of strategic importance for its industry where international standards and norms are debated and decided upon.



Secondly, QI institutions should act as a conduit of advance information regarding international trends in standards, metrology and accreditation for the benefit of the manufacturing industry and service sector. This helps the industrial and service sector to plan ahead and not be surprised by new international standards, norms and recommendations when they eventually are approved and published.



Thirdly, international institutions such as the BIPM, OIML, ILAC and IAF manage the international recognition agreements or arrangements whereby the national capabilities are recognized at the international level, facilitating the acceptance of national conformity assessment reports and certificates in the international markets and by regulatory authorities abroad.

The government as the ultimate custodian of the country's QI and the supervisory entity of its public institutions should commit to supporting the relevant international

liaison of the QI institutions, but it should do so within a strategy that would benefit the country's industrial sector and the regulatory environment.

NATIONAL QUALITY POLICY CONTENT



The government is strongly encouraged to articulate its commitment to support the QI institutions in maintaining membership of the relevant international organizations at levels that are meaningful, i.e. corresponding member, associate member, full member, etc. Additional issues that should be addressed include the following:

- The QI organizations must develop a strategy for attendance of technical committees that are important for the country's industrial development, not only general assemblies; and
- International recognition for QI organizations should be sought through appropriate multilateral recognition arrangements or agreements.

APPLYING TO ECO:

6.4.2 Economic Cooperation Organization (ECO)

The promotion of intra-regional trade among the ECO Member States is very much dependent on the implementation of functional, effective and coordinated quality infrastructures in each of the Member States.

The Statute/Charter of the specialized regional quality infrastructure (permanent or interim) mentioned above, will include, inter alia, the following:

- » Harmonizing of national standards;
- » Harmonizing conformity assessment, accreditation and metrology practices;
- » Facilitate and phase-out/remove technical barriers to trade;
- » Enhance quality and safety of products, environment and consumer protection through the application of harmonized standards, conformity assessment, accreditation and metrology practices; and
- » Share/Disseminate information on standards, conformity assessment, accreditation and metrology that will promote scientific and technological progress in the ECO region.

The National Quality Policy should take cognisance of the above and the QI institutions should participate fully in related activities at the appropriate levels.

NATIONAL QUALITY POLICY CONTENT



The government is encouraged to state its support to the establishment of a specialized regional quality coordinating body. The government is also encouraged to include the responsibilities of the QI organizations to work together with their counterparts in other ECO Member States in order to fulfil its ECO obligations regarding the harmonisation of standards and technical regulations.



Over and above the establishment of a modern, effective and efficient QI System and Technical Regulation Framework, a number of important activities are required to augment or support these two.

7.1 PRIVATE SECTOR INVOLVEMENT

It is ultimately the private sector that will pay for the QI system and the implementation of technical regulations, either directly or through taxes. It is therefore of utmost importance that the private sector is directly involved in the development of the National Quality Policy, in the implementation thereof, and ultimately in the governance structures of the QI institutions. The government may have to take the lead in establishing the policy framework for the QI system and to play their chosen role, even provide the resources to establish and maintain some of the institutions, but the private sector has to agree to accept some important responsibilities, such as:

- » even though the QI institutions may be government departments or organizations of public law, the private sector should play a meaningful part in their governance structures, i.e. Councils or Boards.Good practice indicates that the private sector should constitute at least fifty percent of the governance structures to filter out any sector motivations or inappropriate political influences. The private sector should be prepared to assume this role, and the government should provide the policy environment for it to take place;
- » the private sector should play the major role in the various national technical committees of the QI institutions in order to bring their real-life and business experience to bear on the discussions and decisions made in the same. Ultimately it is the private sector that has to implement the standards and technical regulations. It is especially technical regulations, based on standards, that can lead to unbearable situations if their requirements are difficult to understand or impossible to implement. The

- policy should ensure that QI institutions establish the technical committees with appropriate private sector participation;
- » the private sector should play an important role in the deliberations regarding standards, metrology and accreditation at the regional (i.e. ECO) and international level. The national standards body, national metrology institution and the national accreditation body has the responsibility to represent the country at the regional and international level, but the private sector should accompany the public sector representatives to ensure that the needs of the country are placed on the agenda of the discussions, and to ensure that future trends are timely reported back to the industry;
- » The private sector has the responsibility to upgrade their products, processes and services to meet the quality, safety and health requirements of the market place and of the regulatory authorities, not only at home, but also in the export markets. The investment to meet this challenge is usually quite substantial, and whilst the government may support SMEs to some extent in this endeavour, the private sector will still bear the bulk of the investment costs;
- » The private sector will be heavily involved in the training and skills development of people that are needed in the development of quality related practices, laboratories, production value chains, etc. The government may establish the training institutions, but the private sector will have to allow its staff to attend the appropriate training, fund the training, and pay the staff accordingly after successfully completing the same.

NATIONAL QUALITY POLICY CONTENT



The role and responsibilities of the private sector needs to be clearly articulated in the National Quality Policy. Issues that need to be addressed include the following:

- Representation in the governance structures of the public QI institutions;
- Representation in the technical committees of the QI institutions;
- Support in representing the country in various regional (i.e. ECO) and international QI organizations and technical committees;
- Upgrading the products and services to meet stated standards, quality and technical regulation requirements;
- Developing the skills of staff; and
- Participation in advocacy and other quality system related publicity events.

7.2 NON-GOVERNMENTAL ORGANIZATIONS

Non-governmental organizations, including the chambers of industry, trade and commerce, play a significant role in many countries – they function as a voice of society and their influence is a growing phenomenon world-wide. It is therefore appropriate that the National Quality Policy solicits their active support in a variety of roles in order

to harness their influence in reaching the objectives of the National Quality Policy, in particular the promotion of quality and excellence throughout society. The role of the non-governmental organizations in the implementation of the National Quality Policy is particularly significant as regards the following:



In many areas non-governmental organizations provide training and skills development, augmenting the work of public institutions. Hence, training and skills development of the technical staff necessary for an effective QI system could be a very important role for non-governmental organizations.



Non-governmental organizations frequently manage well-organized information infrastructures. Dissemination of quality, safety and health information, as well as advocating improvement of quality generally and the environment in particular, would therefore be a natural extension of such information systems – this being very much in support of an improved society as a whole.



Non-governmental bodies as the "spokesperson" of society have an important role to play in the development of standards and concomitant conformity assessment services. The same applies to the development of technical regulations which are basically designed to protect society and the environment. Their presence in technical committees and similar forums is therefore of paramount importance, and should be actively supported by the government and facilitated by the relevant QI institutions.

NATIONAL QUALITY POLICY CONTENT



The involvement of non-governmental organizations needs to be solicited in the National Quality Policy. Specific issues that non-governmental organizations should get involved in could be addressed include the following:

- Promotion and participation in education and training of quality related activities;
- Participation in the dissemination of quality-related information;
- Implement activities that promote the improvement of quality and the environment; and
- Actively participate in the technical committees for standards, metrology and accreditation.

7.3 MEDIA

The media is a powerful force in all societies. Hence the media should be encouraged to become actively involved in the dissemination of information related to standards, technical regulation and the overall improvement of the quality of products and services. It would even be more

useful for the government to develop a communication strategy in which the media can play a prominent part. The use of the electronic media (e.g. Internet websites, Facebook, Twitter, etc.) should get special attention, as this is the way in which most societies now communicate.

NATIONAL QUALITY POLICY CONTENT



The full participation of the media should be encouraged and hence highlighted in the National Quality Policy. The government should consider the development and implementation of a concentrated communication strategy that includes the electronic media, and mutually supportive cooperation between the QI institutions and the media.

7.4 INTERNATIONAL DEVELOPMENT PARTNERS

International development partners are active in almost all developing economies in establishing trade supportive infrastructures and systems. The whole field relating to standardization and technical regulation field is no exception. There are a number of common challenges that should be dealt with to optimise such development support. These include the propensity of development partners to have to follow specific policy or business goals of the funding government, and the hesitancy of recipient Ministries to involve others for the greater good of the country. Both of these often lead to duplication of effort by different development partners, e.g. the establishment

of more than one laboratory for micro-biology in various Ministries where one would be more than sufficient for the country, or the establishment of more than one accreditation organization in the country. The recipient country would benefit most from such technical assistance if it could be coordinated amongst the various development agencies and amongst national Ministries that are the direct recipients of such support. The National Quality Policy therefore needs to clearly articulate the responsibilities of recipient Ministries for starters, thereafter requesting development partners to cooperate in the coordination efforts.

NATIONAL QUALITY POLICY CONTENT



All the partner or recipient organizations as well as the development partners should be encouraged through the National Quality Policy to coordinate their efforts for the good of the country as a whole. Specific issues that could be highlighted are the following:

- Support for the implementation of the National Quality Policy;
- Coordinate support of other development partners for the execution of priority programmes;
- Support the transfer of quality-related technology to the country;
- Support the knowledge and information which allows for the development of an adequate quality and technology infrastructure;
- Support the country's participation in the regional (ECO) and international structures; and
- Provide training and skills development for the country's technology professionals within the QI system and technical regulation regime.

7.5 DIVERSITY MAINSTREAMING

Women are half the world population hence constitutes half the consumer and labour market. Therefore, inclusion of women in the society and economic activities is an essential key to sustainable development, although gender roles may differ depending on various elements such as tradition, culture, religion, history and politics. The importance of gender equality is well established in international development field and listed as one of the poverty reduction goals for Millennium Development Goals

(MDG) and its successor Sustainable Development Goals (SDG).

As with gender issues, there are also other diversity challenges that may need to be considered in developing the National Quality Policy. These could include minority groups, SMEs, rural communities, and the like. The goal of the National Quality Policy is that all of society needs to benefit equally from its implementation.

APPLYING TO ECO:

Each ECO Member State will have specific issues of its own that need to be identified.



Most governments have been making efforts and taking actions for gender equality, empowerment of women and other diversity issues through its policy and development strategy and plan. In order to ensure that National Quality

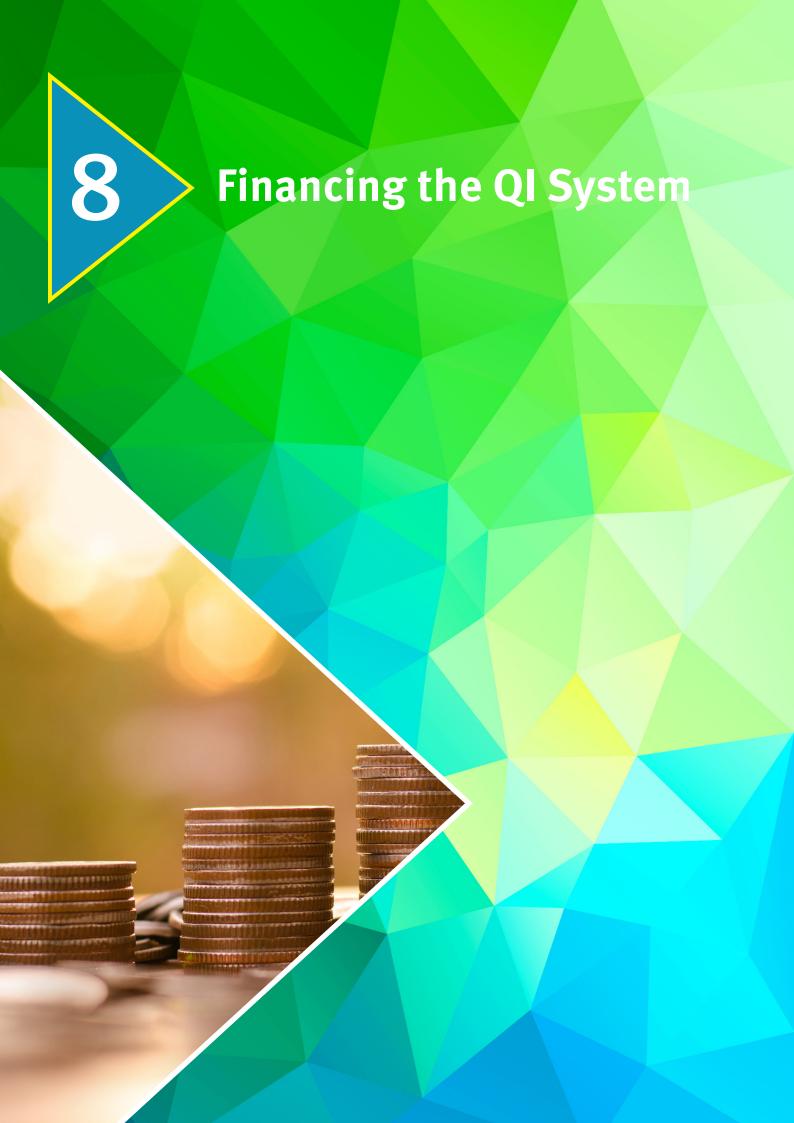
Policy contributes to the sustainable social and economic development goals of the country, the diversity equality needs to be integrated in the National Quality Policy.

NATIONAL QUALITY POLICY CONTENT



All the quality-related institutions and service users should be encouraged through the National Quality Policy to be aware and make effort to improve the gender/diversity equality. Issues that can be addressed include the following:

- Coordination mechanism with the gender/diversity-related ministry/institution/department of the government;
- Appointment of gender-promoting personnel in the quality/diversity-related institutions;
- Establishment of inter-institutional gender/diversity network;
- Support the employment of women and diverse groups in the quality-related institutions;
- Support the education/training of women/diverse groups in the field of quality;
- Support quality of the products with high potential for gender/diverse equality and women/diversity group empowerment; and
- Monitoring mechanism by recording and numeration of gender balance at different level: employment (by position), training enrolment and completion, quality service users, quality-certificate holders (e.g. ISO), etc.



The government has to clearly articulate its commitment for the long-term funding of the standards, metrology and accreditation activities where this cannot or would not be funded by others.

8.1 GOVERNMENT RESPONSIBILITIES REGARDING THE QI SYSTEM

An analysis of the finances of QI institutions world-wide, indicate that governments retain the responsibility to fund the three fundamentals namely standards, metrology and accreditation in almost all countries. It is only in a few of the biggest economies where the private sector is highly developed, financially powerful and fully motivated to do so. It is obvious that governments would fund QI institutions that are government departments or organizations of public law (i.e. statutory organizations). But even in the case where they are private organizations, governments frequently provide a large percentage of the funds for standards development, standards information, scientific metrology and accreditation (especially at start-up) under cover of specific agreements between the state and these institutions.

The reason is that these three fundamentals of the QI services can be described as "good-for-country" activities, i.e. the whole country benefits, for which an account cannot be presented to a specific beneficiary for payment

thereof. Some smaller economies have tried in the past to have industry pay for standards development on a sectoral basis, but on the whole these have not been sustainable. The same applies to the establishment and maintenance of national measurement standards. Accreditation can become much more self-sufficient once 200 to 300 entities have been accredited, but even in this case, governments frequently retain the responsibility to fund the international liaison activities *vis-á-vis*. ILAC and IAF and the costs of international recognition.

The government therefore has to clearly articulate its commitment for the long-term funding of the standards, metrology and accreditation activities where this cannot or would not be funded by others. In the case of QI institutions that earn income from services rendered, e.g. a national standards body providing conformity assessment services, government may specifically identify its commitment for standards development, standards information and international liaison activities.

NATIONAL QUALITY POLICY CONTENT



The government should commit to provide long-term resources for the development of standards, standards information, metrology and accreditation and the related institutions. It should also commit resources for the establishment of conformity assessment services, but with the view of commercializing them as soon as possible. Additional commitments would include resources for the international and regional liaison work of the

8.2 FINANCING CONFORMITY ASSESSMENT SERVICES AND CALIBRATION

Conformity assessment bodies and calibration laboratories, whether in the public or private sector, should operate on the "user pays" principle so as not to distort the market. This is of particular importance for those in the public sector.

It is especially the political level wishing to support the SME sector that frequently demands that QI institutions provide conformity assessment or calibration services at prices below cost. This is the wrong approach, as it compromises the long term financial sustainability of the QI organizations. The SME sector does warrant support, but any such support should be provided in other ways, e.g. by refunding SMEs a percentage of the costs they paid for conformity assessment or calibration services on presentation of a positive report or certificate.

Another problem that has to be addressed is the propensity of government departments to demand conformity assessment services from public QI institutions without wanting to pay for them. This is also the wrong

approach, as it will unnecessarily stretch the financial support the institution receives from its line Ministry for fundamental services. Government departments and their Agencies need to get into the habit of budgeting for the conformity assessment services they require, and pay the public QI institutions accordingly. They would have to pay private service providers in any case, and the world-wide tendency is for governments to liberalize conformity assessment services, and allow private sector organizations to provide the bulk thereof (see also 6.2.4).

It has to be borne in mind though that some conformity assessment services are very profitable and relatively simple to run so that the private sector will have no difficulty in investing in and providing these services, e.g management system certification. On the other hand, product certification schemes are more complex operations and unlikely to attract the private sector. This means that the public sector may have no other alternative but to provide these services at high costs if they are needed.

NATIONAL QUALITY POLICY CONTENT



The policy should state clearly that conformity assessment services have to be paid for by everybody including the state. SME support should be provided for, but not as a reduction of service fees of the QI institutions, but as a possible percentage repayment based on presentation of positive conformity results.

8.3 FINANCING TECHNICAL REGULATION

Financing technical regulation is complex. Many would argue that technical regulations are unilaterally imposed by the state; hence the state should pay for the administration thereof. But, the burden on the state if it had to fund technical regulation in totality would be horrendous. Hence, many variations in which suppliers carry part of the

financial burden have developed over time. This is seen as an equitable system as the costs are allocated directly to those that need to be monitored by the state instead of having to be funded by all taxpayers. Two issues need to be specifically considered:



The main responsibility of the regulatory agency is to conduct market surveillance and impose sanctions where products or services do not meet the requirements of the relevant technical regulation. In many countries, the state would fund this activity. The risk is that if the state does not have the necessary finances, this important function does not get implemented properly, and some suppliers will be quick to exploit the lack of market surveillance and market low quality products and services to the detriment of society, fauna and flora and the environment. Hence, in some countries, regulatory authorities get paid a levy for the privilege of being monitored by the regulatory authority. If these levies are agreed to by all parties, promulgated by the state, and paid directly to the regulatory authority, then this is a useful alternative to direct state funding. The risk of underfunding will be largely mitigated.



In a well-designed technical regulation regime, the supplier would be responsible for providing compliance evidence to the regulatory authorities. This means that the supplier has to have the product or service tested or assessed by an institution acceptable to the regulatory authorities. If the conformity assessment services have been liberalized and the supplier has a choice of technically competent services providers, i.e. accredited and designated, then there should not be a problem. If the regulatory authority demands that the compliance testing has to be conducted by itself, or a single designated laboratory, then there is a problem. Such a situation usually leads to unnecessary and expensive re-inspection and re-testing, and the regulatory body will be perceived to be able to extract rent from suppliers.

The government should therefore decide on the funding model considering local practices but based on international good practices for technical regulation implementation, and state this very clearly in the National Quality Policy.

The development of technical regulations, products and service market surveillance and legal metrology activities should be dealt with decisively.

APPLYING TO ECO:

The decision will also be influenced by the agreements reached at ECO level as regards the acceptance of compliance evidence from one member state to another. Once ECO moves towards a free trade area, this will become one of the main trade related issues to be agreed upon.



NATIONAL QUALITY POLICY CONTENT



The government should state how the work of the regulatory agencies is to be funded, i.e. by the state or through a levy paid by suppliers. In the case of levies, the policy should provide broad guidelines as to how these will be agreed upon between suppliers and the state. Conformity testing should be dealt with separately, and the suppliers should be made responsible for such payments.



It is quite logical that the QI System and the Technical Regulation Framework can be given legitimacy primarily through appropriate legislation. The National Quality Policy should therefore spell out quite clearly the government's commitment to review all current legislation, and revise what needs to be revised, and develop and promulgate what needs to be developed anew. This would not only be the case if the QI institutions are public entities, but also to provide overall guidance as to the way in which standards, metrology and accreditation together with calibration and conformity assessment will be provided for in general, and for technical regulation development and implementation in particular.

Typical examples of legislation that should be considered in this context include the following:



A **Standards Act** providing for the development and publication of national standards, their legal standing and how they can be referenced within other pieces of national legislation. This Act could also establish the national standards body if it is in the public sector, provide for its governance, responsibilities, activities and finances.



A **Metrology Act** providing for the International System of Units, so-called SI-system, and the establishment and maintenance of the national measurement standards. This Act should also provide for the establishment of the national measurement institution, its governance, responsibilities, activities and finances.



A **Legal Metrology Act** providing for the control over measuring equipment in trade, health services, environmental control and law enforcement amongst others, included pre-packaging requirements for consumer commodities. This Act should also provide for the establishment of the legal metrology department, its governance, responsibilities, activities and finances.



An **Accreditation Act** that provides for the use of accreditation as the primary means to denote technical competency of conformity assessment service providers, not only for products but also in the case of services required by society at large, e.g. medical or pathology laboratories. This Act should also provide for the establishment of the national accreditation organization (or in its absence designate the regional or another national body as the *de facto* national body), its governance, responsibilities, activities and finances.



A **Technical Regulation Framework Act** that provides for the development and promulgation of an agreed way of developing and implementing technical regulations in the country across all responsible Ministries and their Agencies in compliance with the WTO TBT Agreement (and its ECO counterpart). This Act should contain guidance on conducting an impact assessment beforehand to determine the validity of developing a technical regulation, the use of standards for the technical requirements, preferred conformity assessment methodologies, responsibilities of the regulatory agencies and the imposition of sanctions. This Act could also contain the establishment of the higher level oversight body to coordinate all technical regulation activities of the various Ministries and QI organizations to ensure the country's compliance with the Technical Regulation Framework Act, the WT TBT Agreement (and its ECO counterpart).

NATIONAL QUALITY POLICY CONTENT



The government should commit to the review of all current legislative instruments that deal with the QI system, and revise them where required. These should be listed where known. Additional legislation necessary to support the implementation of the policy also needs to be listed, together with the government's commitment to develop and promulgate it quickly.



10.1 GENERAL

It is important to identify and allocate responsibilities for the implementation of the National Quality Policy, and to articulate a review process whereby the Cabinet as its "owner" can be appraised regarding implementation progress or otherwise in order to direct additional measures should the need arise. The process starts with the development and approval of the Implementation Plan or Strategy (see section 3), followed by the execution of its actions by a variety of responsible entities, all of which are designed to achieve the National Quality Policy outcomes, objectives and ultimately its vision.

10.2 LEAD MINISTRY

A specific Ministry should be given the lead role in all of this. Candidates that come to mind are the Ministry of Trade and Industry (or similar) as the one responsible for the country's compliance with the WTO TBT Agreement (and its ECO counterpart) and for the main QI institutions in the public sector, or the Ministry of Planning (or similar) as the one responsible for government organizational structures and overall coordination of government activities. In

some countries the Ministry of Science and Technology (or similar) is responsible for the QI institutions in the public sector, rather than the Ministry of Trade and Industry. The responsibility as lead Ministry for the implementation of the National Quality Policy should therefore be carefully considered by the relevant Ministries and approved by Cabinet. This responsibility should be clearly stated in the National Quality Policy.

10.3 INTER-MINISTERIAL COORDINATING COMMITTEE

In order to obtain buy-in from all relevant government departments, the lead Ministry should be supported by a committee/structure in which all relevant Ministries and even QI institutions and agencies are represented, because the National Quality Policy, especially if it also deals with the technical regulation regime, will be cross-cutting, i.e. impacting many Ministries. This coordinating committee/structure should be approved by Cabinet to ensure the full and unreserved cooperation of all Ministries. It should consider the Implementation Plan/Strategy before it is presented to Cabinet for approval, and thereafter monitor its fulfilment on a regular basis, e.g. every three to six months, and report back to Cabinet. The coordinating committee/structure should be authorized to:

» Commission studies, request information from concerned institutions and conduct research to obtain information and data;

- » Review and adopt findings of investigations on the current status of the Quality Infrastructure system;
- » Develop and endorse recommendations with regard to establishing policies, functions and roles of the institutions concerned and in relation to developing or revising the enabling legislation for the Quality Infrastructure;
- » Adopt plans for the modernization of the Quality Infrastructure and assign implementation to specific agencies or persons;
- » Progress the decisions and recommendations made to the highest level of the government for modernizing the legislation, rules and procedures for the concerned departments as provided for in procedures and practices established by the government; and
- » Monitor and oversee implementation plans on a regular basis until successful implementation.

NATIONAL QUALITY POLICY CONTENT



The National Quality Policy should deal with the following:

- Designation of the lead Ministry for its implementation and their main responsibilities;
- Establishment of an Intern-Ministerial Coordination Committee and its responsibilities;
- Clear articulation of the responsibility of each Ministry and its organs and agencies to implement the National Quality Policy as it relates to them, and the execution of activities as detailed in the Implementation Plan/Strategy as their responsibility; and
- Guidance regarding the evaluation of implementation progress or otherwise and the report back to Cabinet.

Definitions

There are quite a few expressions utilised within the QI and technical regulation domain that have very specific meanings. These need to be defined to ensure that there are as few as possible misunderstandings in the understanding of the contents of the National Quality Policy. These definitions are spread amongst quite a few

international standards and normative documents, such as ISO/IEC Guide 2, ISO 9000, ISO 17000, WTO TBT Agreement and the International Vocabulary of Basic and General Terms of Metrology. A selection that could be considered for inclusion in the National Quality policy are listed below.

Accreditation

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

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 determination of its conformity with specific requirements or, on the basis of professional judgement, 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 System

means the totality of the institutional framework (public or private) required to establish and implement standardization, metrology (scientific, industrial and legal), accreditation and quality infrastructure services, such as conformity assessment services (inspection, testing and product-and system certification), calibration and verification, necessary to provide acceptable evidence that products and services meet defined requirements, be it demanded by authorities (regulatory framework or quality policy), the market place (contractually or inferred) and/or consumers.

Quality management

means the coordinated activities to direct and control an organization with regard to quality.

Standard

means 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

means 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 labelling requirements as they apply to a product, process or production method.

Testina

means the determination of one or more characteristics of an object of conformity assessment in accordance with a specified way.

Verification

means the procedure of examining a measunring instrument to ascertain and confirm that it complies with legal metrology requirements.

APPLYING TO ECO:

Additional relevant definitions agreed to at the ECO level should also be considered. There may also be others that are necessary to facilitate a better understanding of the National Quality Policy for readers in the specific country. Obviously these need to be incorporated as well.

Annex A

Typical content list of a National Quality Policy

No.	NQP Section	NQP Subsection	Guidance reference
	Foreword		
1	Introduction	International and regional context	Section 4.1
		Trade as a driver for development and poverty reduction	Section 4.1
		Definition of the QI and TRF	Section 6.1
		Policy environment	Section 4.2
2	Review of current situation	National Quality Infrastructure	Sections 6.1 and 6.2
		Technical Regulation Framework	Section 6.3
		Compliance with WTO TBT Agreement and related regional obligations	Section 4.3
		Gap analysis	
3	Vision		Section 2.1
4	Objectives of the NQP		Section 2.2
5	The future QI		Sections 6.1 and 6.2
6	The Technical Regulation Framework		Section 6.3
7	Education and Training		Section 7.1
8	Role of other stakeholders	National TBT Enquiry Point	
		Export promotion	
		 International Development Partners 	
9	Role of other stakeholders	Private sector	Section 7.1
		Non-governmental Organizations	Sections 7.2 and 7.3
		 International Development Partners 	Section 7.4
10	International and regional liaison		Section 6.4
11	Financing the QI and TRF	Government	Section 8.1
		Confirmity assessment	Section 8.2
		Technical regulation	Section 8.3
12	Legal framework		Section 9
13	Implementation	Lead Ministry	Section 10.2
		Inter-Ministerial Coordination Committee	Section 10.3
		Implementation Plan/Strategy (5 years)	Section 3

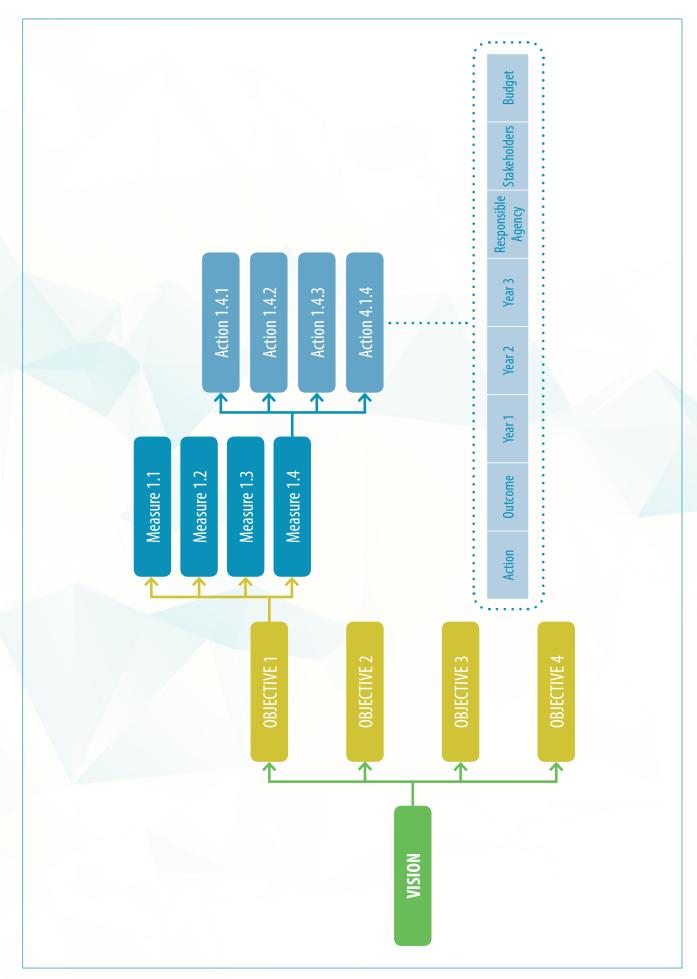


Figure 6: Typical Quality Policy and Implementation Plan elements

