



UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

QUALITY POLICY

Technical Guide



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List of abbreviations

BIPM	Bureau International des Poids et Mesures
DCED	Donor Committee for Enterprise Development
ECO	Economic Cooperation Organization
ECOWAS	Economic Community of West African States
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
INetQI	International Network of Quality Infrastructure
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
ITU	International Telecommunication Union
LMD	Legal Metrology Department
MDGs	Millennium Development Goals
NAB	National Accreditation Body
NGO	Non-Governmental Organization
NMI	National Metrology Institute
NSB	National Standards Body
OIE	World Organisation for Animal Health
OIML	International Organization of Legal Metrology
QI	Quality Infrastructure
SADC	Southern African Development Community
SDGs	Sustainable Development Goals
SDO	Standards Development Organization
SME	Small and Medium-sized Enterprises
SPS	Sanitary and Phytosanitary
TII	Department of Trade, Investment and Innovation
TBT	Technical Barriers to Trade
WTO	World Trade Organization



Introduction

The ability of the producers and manufacturers of goods and services to take advantage of commercial opportunities, compete on global markets and participate in international value chains is often challenged by their difficulties in demonstrating compliance with international quality requirements and trade rules. Therefore, creating and sustainably implementing, a robust quality infrastructure system within countries and regions is often a crucial step on the path to developing a thriving economy which is fundamental to the prosperity and well-being of that country and/or region.

Quality infrastructure (QI) is a system comprising the organizations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes. Quality infrastructure is required for the effective operation of domestic

markets, and its international recognition is important to enable access to foreign markets. It is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing. It relies on metrology, standardization, accreditation, conformity assessment, and market surveillance.

In this respect, the Quality Policy (QP) is the policy adopted at national or regional level to develop and sustain an efficient and effective quality infrastructure. The QP specifies the overall policy vision/goal, the policy objectives, expected outcomes and required measures with respect to the development of the QI. In addition to the QP, an implementation strategy/plan should also be developed laying out the individual activities and specifying responsibilities, timelines and broad budgetary and other resource requirements with respect to the QP implementation.

1.1 THE NEED FOR A QUALITY POLICY

The world trading system is continuously developing. Over the past decades, vast arrays of good practices have evolved related to QI systems that support trade whilst still ensuring the safety and well-being of the people and the environment. Some of these practices are encoded in the World Trade Organization Agreements on Technical Barriers to Trade, Sanitary and Phytosanitary measures, and Trade Facilitation (WTO TBT, SPS and TF Agreements), some are provided for in the working and recognition arrangements of international organizations, such as e.g. the International Bureau of Weights and Measures (BIPM), the International Organization of Legal Metrology (OIML), the International Laboratory Accreditation Cooperation (ILAC), the International Accreditation Forum (IAF), the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), Codex Alimentarius, International Plant Protection Convention (IPPC) and World Organisation for Animal Health (OIE) whilst others have evolved elsewhere as good practices that should be followed.

Countries wishing 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

better understand and seek appropriate compliance with these international requirements and good practices. However, in many countries the quality infrastructure and the regulatory framework developed over years have served the countries well in the past, but may not be ideal to take advantage of these new dynamics. Here, the problem is that these developed in an organic way and, in the absence of an appropriate and overarching government policy framework. Over time such an uncoordinated approach has led to entrenched, and often unintentional, restrictions that possibly hinder rather than support trade.

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

1.2 WHO IS THIS GUIDE FOR?

This Guide is designed as a reference document to assist government officials and private sector counterparts wishing to develop a QP in a way that stimulates national, regional and international trade. It is primarily directed at those who are involved in QP development, implementation or review. However, it will also be beneficial for anyone who needs to understand the governmental policymaking process with respect to quality infrastructure and technical regulations. Furthermore, political leaders at all levels of government could consider using the recommendations provided in this Guide as a standard of good practice in QP development. It could, therefore, also provide insight, and guidance to those

who are tasked to evaluate the QI related policy development work of others.

The *Quality Policy Technical Guide* draws extensively on, and is intended to be used in conjunction with the *Quality Policy Guiding Principles* as well as the *Quality Policy Practical Tool* documents. While this Guide focuses on the context, elements and processes of QP development, the *Quality Policy Practical Tool* describes the steps that typically need to be undertaken to successfully formulate and agree upon a QP, and the *Quality Policy Guiding Principles* publication specifies the underlying elements for effective QP development.

QUALITY POLICY CONTENT

The policy environment of the country should be outlined, briefly discussing the various policies and the measures contained therein with respect to quality, standards and technical regulations. It should be emphasised that the quality policy does not supersede any of these policies, but endeavours to consolidate and bind them together, in order to provide the country with an effective, efficient and internationally-recognised quality infrastructure system. This system serves both the authorities and the private sector, supporting all of the existing policies and beyond.

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 a set of coordinated and mutually supportive programmes and actions to deliver desired outcomes or changes in the

real world. Policy development is therefore a fundamental function of government. It 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, which is followed by an ongoing review process to determine how well the desired outcomes are being delivered. This general policy development procedure also applies to the development of a QP.

1.4 GUIDING PRINCIPLES

Following a comprehensive review of national and regional quality infrastructure development approaches, five key principles have been identified as the core elements for effective QP development. Ideally, these should be addressed and integrated during the development and implementation of a QP. The key guiding principles allow countries and regions to adapt and tailor a QP to reflect their specific needs, while still ensuring a standardized approach in line with international best practices. The five key guiding principles are:

Coherence

This key principle emphasizes the need for the various QP and QI elements to seek and obtain appropriate synergies, agree on shared objectives, and encourage mutual support in achieving agreed outcomes. It also involves appropriate integration of, and alignment with, other national, regional and international policies that are intended to address quality related needs.

Ownership

Ownership emphasizes the need to address the way the QP and associated QI infrastructure are overseen, directed and implemented at the national and regional level.

Inclusiveness

This key principle emphasizes the need to address those subjects and/or areas which could influence the development of the QP, using appropriate consultative processes that include all necessary stakeholders, to promote the required and necessary ownership of intended outcomes and subsequent actions.

Optimization

Optimization emphasizes the pursuit of the most effective and efficient use of applicable, and available, national, regional, and international situation(s) and / or resource(s) when creating a QP.

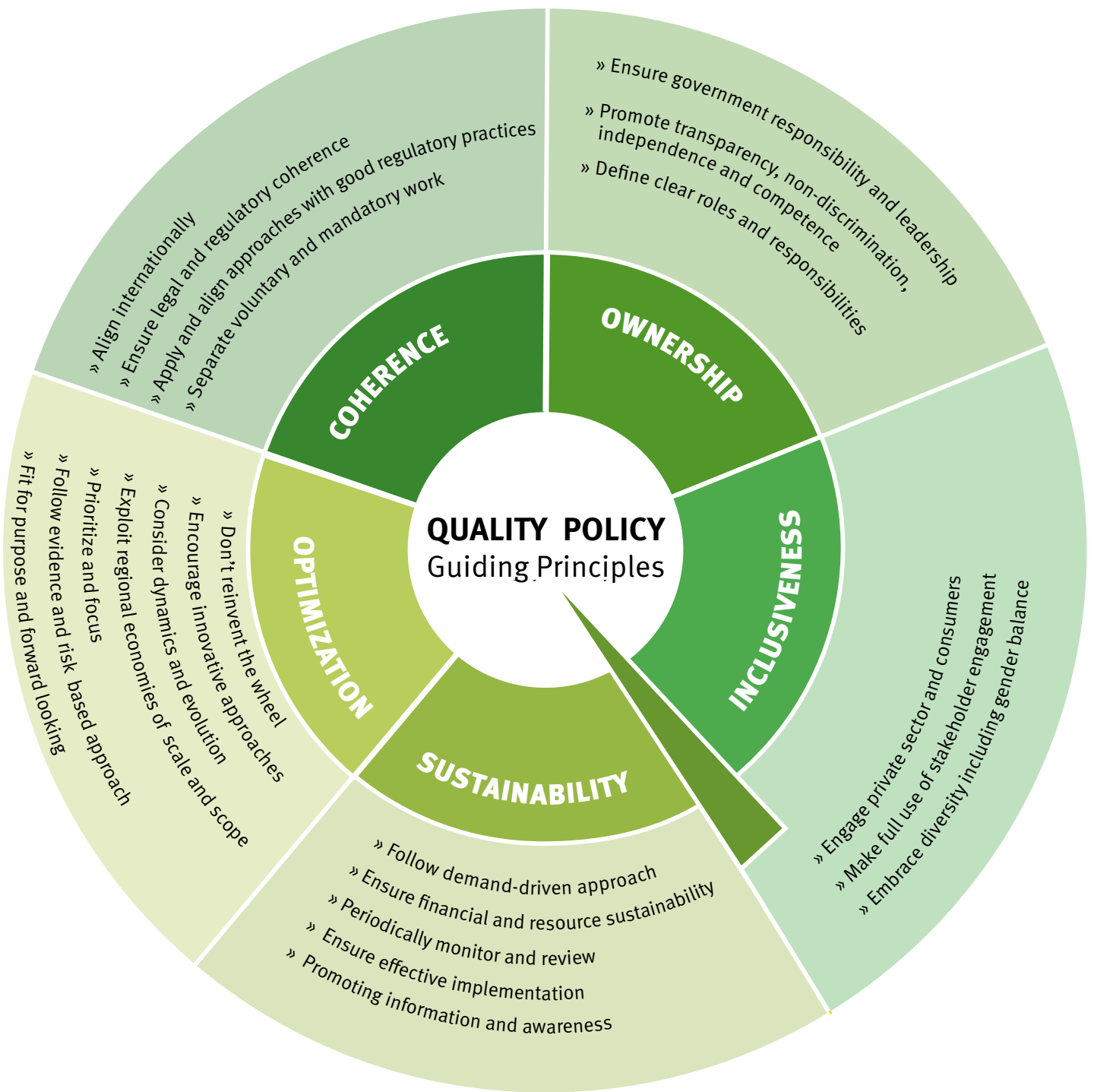
Sustainability

This key principle emphasizes the need to ensure the QP in support of the appropriate political, societal and economic objectives and the associated QI, with the necessary technical capability and capacity are maintained in the long term at the required level.

These key principles are further elaborated in UNIDO's publication *Quality Policy Guiding Principles*, along with a set of specific associated sub-principles. The subprinciples (see Figure 1) are provided to assist in addressing particular issues with the appropriate understanding, to mitigate against short term interests and promote a more holistic, inclusive and collaborative approach to identifying future needs and securing appropriate sustainability for the QI system.

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

FIGURE 1: FIVE GUIDING PRINCIPLES FOR QUALITY POLICY DEVELOPMENT





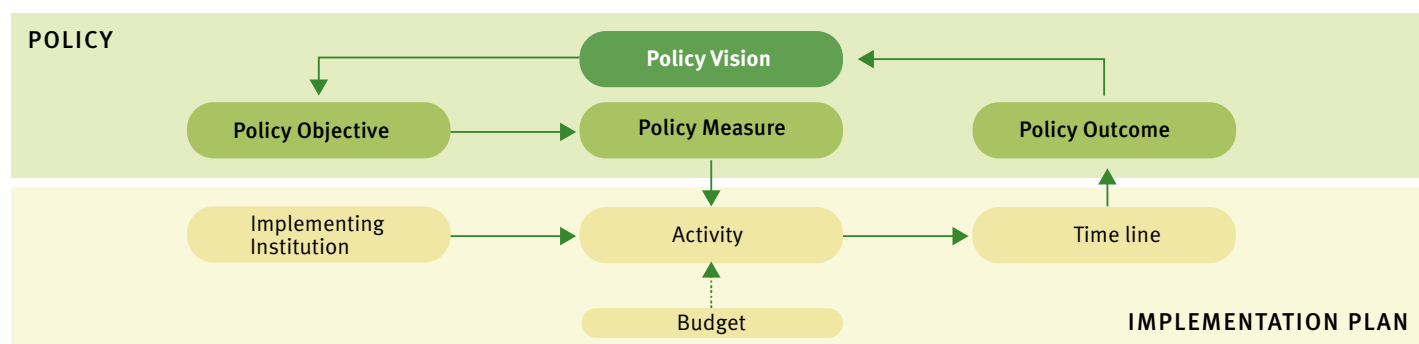
2

Elements of the Quality Policy

Core elements of the quality policy should include broad-based sections on the policy vision/goal, policy objectives, policy outcomes and policy

measures. The figure below illustrates the individual elements of the quality policy and the implementation plan/strategy as well as their interrelationships.

FIGURE 2: ELEMENTS OF THE QUALITY POLICY AND THE IMPLEMENTATION PLAN/STRATEGY AND THEIR INTER-RELATIONSHIPS



2.1 POLICY VISION/GOAL

The QP vision or goal describes what is to be achieved through the implementation of the QP by the end of a specified implementation period. It is sometimes also referred to as the overall impact of the policy implementation. The vision/goal needs to be clearly articulated and should be challenging, yet achievable.

A short, concise and compelling policy vision/goal helps concentrate the efforts of all stakeholders involved as to what the policy ultimately seeks to achieve. Hence, the vision/goal should be the rallying point for all the objectives, outcomes and measures of the QP.

2.2 POLICY OBJECTIVES

Policy objectives describe what is to be achieved for the benefit of the country, the society or the environment by the end of the QP implementation period. The objectives are the stepping stones leading up to the QP vision/goal. In particular, the objectives may include new infrastructure,

new systems, new processes or procedures, newly-acquired knowledge, enhanced 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 the QP implementation.

2.3 POLICY OUTCOMES

The section on policy outcomes describes in detail what is to be achieved as a result of the QP implementation. The outcomes should be specific, measurable, attainable,

results-oriented and time-bound targets for accomplishing the QP vision/goal.

2.4 POLICY MEASURES

The policy measures describe the concrete actions that are required to achieve the QP outcomes or objectives. Therefore, policy measures should not be seen in isolation and should always be in line with the WTO TBT, SPS and Trade Facilitation Agreements. In particular, policy measures address the problem, challenge or issue that is identified as the obstacle to attaining the overall policy vision/goal.

Hence, measures will be the indicative outputs of the QP. The policy measures serve as a basis to identifying specific action steps which need to be taken to implement the policy measures. These steps are detailed in the QP implementation plan/strategy. Typically, the section relating to policy measures will be the most detailed section of the QP document.



3

Elements of the Implementation Plan/Strategy

An implementation plan / strategy takes the QP implementation process a few steps closer to its logical conclusion. It provides for specific activities

and concomitant expected outcomes for each of the QP objectives and measures. The expected outcomes collectively ensure that the QP vision is realized.

In the QP implementation plan / strategy the individual activities are defined in terms of responsibilities and timelines. Indicative budget and associated resource requirements are also indicated. These facilitate implementation and management, and assist in the final

evaluation. However, not all activities can be pursued simultaneously. There are some activities that can only be started when others are completed. This prioritization needs to be reflected in the QP implementation plan/strategy.





▶ 4

Quality Policy in Context

The quality policy does not exist on its own. It should be developed within the applicable global and regional context and should interface seamlessly with relevant national policies. The quality policy is cross-

cutting in nature. It falls within the responsibility 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 address poverty, environmental challenges and gender issues needs to benefit from this global trade growth. Hence, the country needs to understand the challenges its manufacturers, suppliers and exporters face when accessing international markets. These markets are characterized by: (i) high expectations from informed customers, (ii) technical regulations that are becoming more onerous as authorities strive to look after the interests of the society and the environment, (iii) high levels of competition from suppliers wishing to exploit the same markets, means that customers have an increased choice of suppliers, many of whom can meet their demands and can demonstrate compliance with the regulations, and (iv) product value chains spanning many countries as producers and manufacturers endeavour to reduce costs while seeking to establish more stable and reliable sources of raw materials and other inputs.

Empirical evidence suggests that standards, metrology and accreditation and its conformity assessment companions (inspection, testing and certification) contribute significantly to technological progress, productivity and trade. Consequently, a country's industry faces several challenges at the global level. In particular, this includes logistics, management, financing and achieving the product²

or service quality demanded by the purchasers and/or regulatory authorities. These challenges particularly affect the small and medium-sized enterprises. However, although ensuring the product or service quality is the responsibility of the manufacturer, supplier or service provider, they require the 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 the potential market share or it may be a contractual misconduct, but it is not illegal per se. Non-compliance with technical regulations, however, is an offence and punishable by law. Governments have been trying to ensure the safety and well-being of the society and the environment for decades by introducing new rules and regulations. Unfortunately, such regulatory frameworks are often of an ad hoc nature, fragmented, with many overlaps amongst regulatory authorities and frequently not compliant with the WTO TBT Agreement and regional trade agreements. This is rooted in the fact that many different ministries are involved in the process. In the absence of clear national guidelines, each ministry conducts technical regulation according to its own practices, which continuously drives the individual efforts further apart. Such technical regulations are incoherent, ineffective, and inefficient and add to the transaction costs of the local producers or suppliers rendering them uncompetitive.

4.2 NATIONAL POLICY ENVIRONMENT

The QP does not exist on its own. Usually, there are already several policies 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, animal and plant health, and/or security, science and technology development and similar issues. However, usually references to standards, quality and technical regulations do not reflect a holistic view of the QI system, nor do they provide a uniform national guidance on technical regulations. Nevertheless, these policies do provide very important interfaces for a QP. The QP should link the policy measures relating to standards,

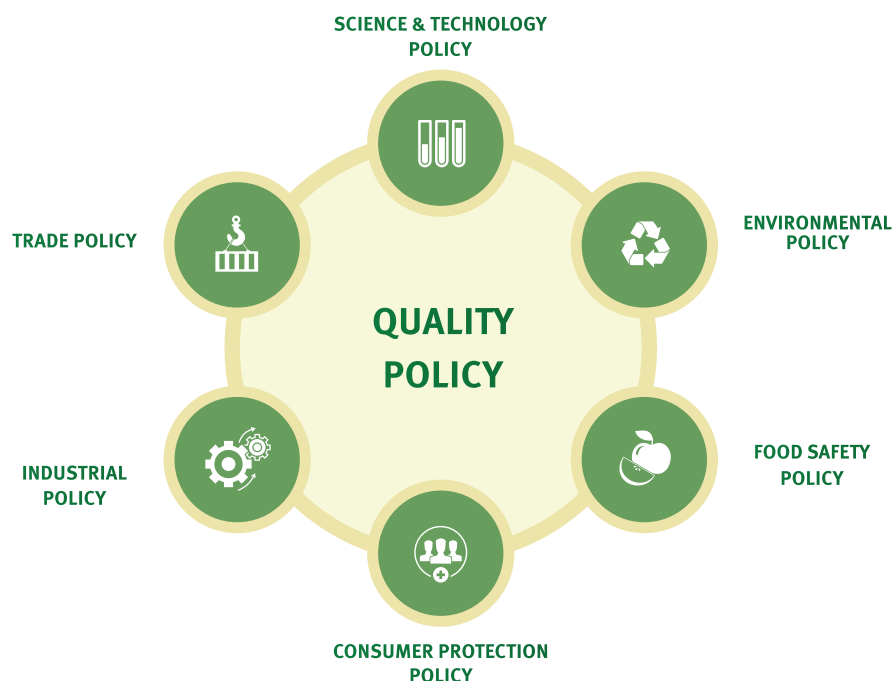
quality and technical regulations contained in all of the existing policies. In this respect, the development of a QP provides a formidable opportunity for a country to review quality aspects mentioned in other policies in a holistic manner, and amend/change those parts which are not in compliance with international rules and guidelines. It should be kept in mind that the other policies may have been formulated at a time and/or by people not fully familiar with international rules and guidelines and that these rules may have changed in the meantime. In fact, the QP is probably the only policy that can undertake this review in a meaningful way. This notion is depicted graphically in Figure 3.

QUALITY POLICY CONTENT

In the case of WTO member states, the governments are strongly encouraged to indicate clearly that their obligations with respect to the WTO TBT and SPS Agreements will be fulfilled and that the quality policy takes this into consideration. If the country is not yet a WTO member state, it is encouraged to spell out its future plans for accession to the WTO.

² For the purpose of this document term "product" will also cover "produce".

FIGURE 3: RELATIONSHIP OF THE QUALITY POLICY TO OTHER POLICIES



4.3 INTERNATIONAL AND REGIONAL OBLIGATIONS

Standards and technical regulations together with their conformity assessment services are dealt with decisively in the WTO TBT and SPS Agreements. 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. Furthermore, the reasons for technical regulations are enumerated, as are transparency obligations vis-à-vis other WTO Member States. Therefore, it is crucial to ensure that the QP does not contain anything that conflicts with the WTO TBT and / or SPS Agreements. It is further important to link the QP measures to the obligations the country has with respect to the WTO TBT and SPS Agreements.

In addition, there are over 150 Regional Trade Agreements (mostly free trade agreements) notified to the WTO. These are agreements on the extensive reduction of trade restrictions between WTO Member States, usually covering the overall trade in goods. Standards and/or technical regulation issues are often at the core of such trade restrictions. Regional trade agreements vary in scope. However, generally they aim to foster, support and boost regional trade based on common principles, and to reinforce economic cooperation among the member states, for example through the elimination of non-tariff barriers, reduction of tariffs, and exchange of concessions. Any such regional obligations should be clearly specified in the QP to ensure that all commitments of the country are considered when implementing the QP.





5

**Commitment of the
Government**

The size, depth and reach of the QI system has many implications, for example with respect to compliance with international and/or regional obligations and the necessity to link up with international quality

infrastructure organizations to obtain international recognition. It is therefore important that the government assumes overall responsibility for the effectiveness and efficiency of the QI system.

Many countries established standards bodies and metrology institutes in the past and, perhaps more recently, also accreditation bodies. However, the way in which these were 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 the implementation of technical regulations, 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 or when ministries consider certain matters too technical and leave them to the institutions to do what they consider appropriate, etc. Hence, the government should consider

taking responsibility afresh to establish a proper policy environment which meets international good practices and is consistent with overall government policies. Usually, this entails the re-engineering of the QI system. This is where the government might experience opposition from the institutions as they stand to “lose” some of their powers or income. Therefore, the government needs to express its commitment to change 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. Clearly, such changes have to take place within the established customs and practices of government restructuring.

QUALITY POLICY CONTENT

It is recommended that the government expresses its unequivocal resolve to re-engineer the QI system in line with international and regional agreements, obligations and good practices. This re-engineering should ideally take place in consultation with affected parties. However, the needs of the country prevail over the wishes and short-term objectives of the institutions involved. Re-engineering the QI system in this way can help resolve conflicts of interest, ensure that QI services are accepted internationally, provide backing for the local industry to enter foreign markets and create support for the implementation of technical regulations.





6

**The Quality
Infrastructure System**

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).

6.1 FOUNDATIONS

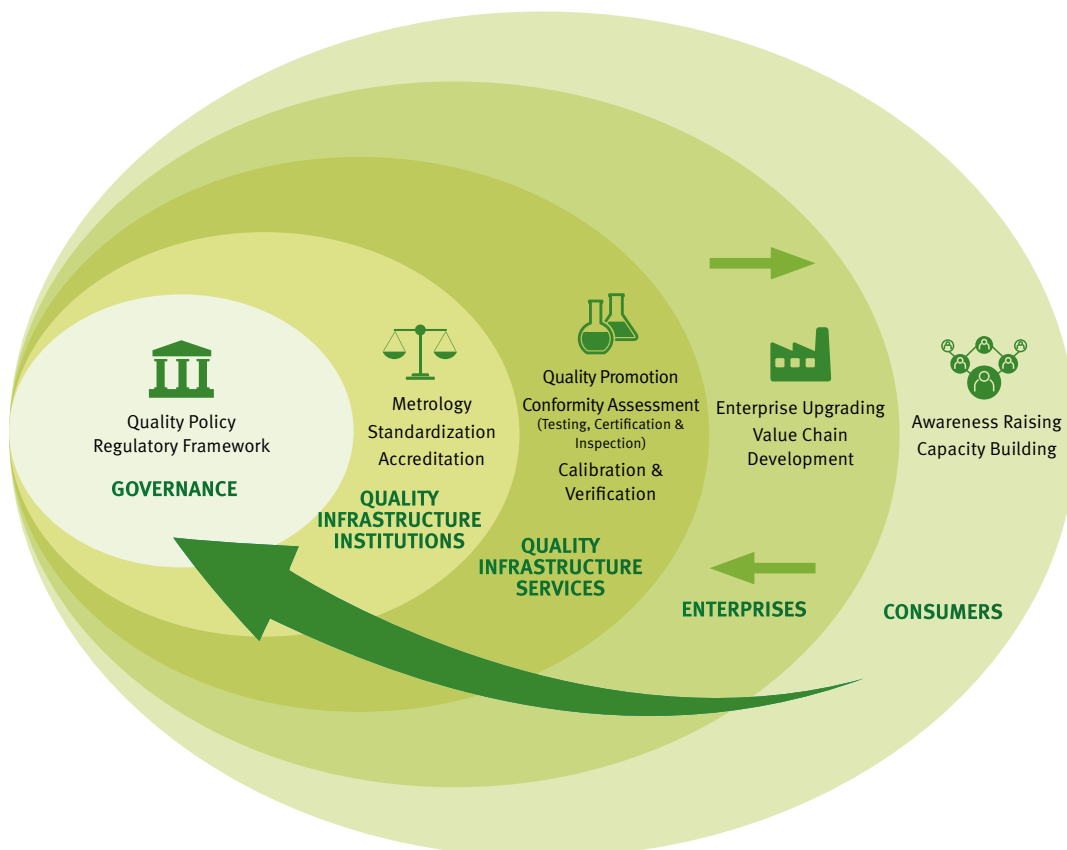
The QI system is a combination of initiatives, institutions, organizations, activities and people. It includes a QP and the institutions which implement it, a regulatory framework, quality service providers, enterprises, customers and consumers (who include citizens as “consumers” of government services), as visualized in Figure 4 below.

The QI system can be a powerful tool for defining, developing and verifying quality requirements for products and services. Furthermore, it ensures that the products and services appropriately meet the state-of-the-art requirements and best practices essential for successfully participating in international trade. Therefore, 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 those that could be achieved by the parts working individually and in isolation. As such, the QI system is a catalyst for improving

the quality of products and services on a national scale. It helps to stimulate demand for these products and services, which in turn invigorates individual businesses and the economy as a whole. By helping the national industry and commerce meet the requirements of export markets, the QI increases the competitiveness of the country’s economy and its ability to participate in global trade and value chains.

Since there is no ready-made QI model that would suit all countries, a tailored approach is necessary. The QI system should be adjusted to meet the national and regional requirements that were identified through a thorough needs assessment. An optimized QI structure takes into account all elements of the QI system, including governance (6.2), institutions (6.3), services (6.4) as well as markets and consumers (6.5).

FIGURE 4: QUALITY INFRASTRUCTURE SYSTEM



6.2 GOVERNANCE

A fundamental component of the QI system is that of governance. The leading role in setting up a QI system is played by the country's government which gives the initial impetus and is ultimately responsible for ensuring that the QI system fulfils policy objectives, meets the country's needs,

conforms to international standards and best practice, and complies with world trade rules. The government provides impetus by developing a QP and establishing the regulatory framework for the QI system.

6.2.1 TECHNICAL REGULATION FRAMEWORK

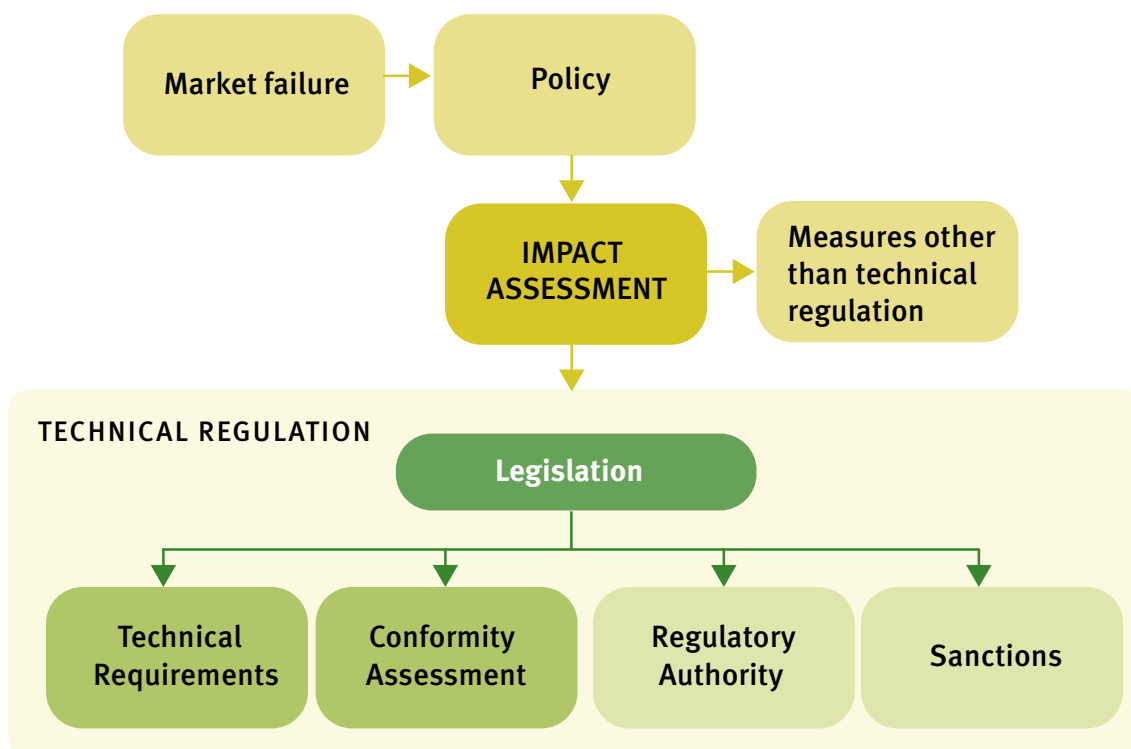
Just as manufacturers, exporters and suppliers utilise standards, metrology, accreditation, calibration and conformity assessment services to demonstrate compliance of their products and services with contractual obligations and market preferences, so they also have to provide reputable evidence to the 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 large increase in trade this is no longer feasible from a logistics perspective. Most of all, due to 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. This means that the final inspection is not effective on its own and 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 regulatory framework is still characterized by the “pre-market

approval” tradition, and changing to a post-market regime is a radical but often very necessary step. The building blocks of a Technical Regulation Framework depicted graphically in Figure 5 can be a useful basis for such a change. These building blocks should be properly articulated for the legal system and situation in the country with full consideration of international and regional obligations, and should be enshrined in the legislation to ensure that all 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 as well as the goal of technical regulation will be realized.

The QP should set out 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 / strategy. As a matter of principle, the envisaged technical regulation framework must align seamlessly with the regional approach to technical regulation.

FIGURE 5: BUILDING BLOCKS OF A TECHNICAL REGULATION FRAMEWORK



The building blocks of a technical regulation framework in more detail:

- » The Regulatory 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 using a technical regulation.
- » The Technical Requirements and SPS measures 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 and SPS related 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.

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. 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.

6.2.2 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. Furthermore, they are seriously considering what the optimum number for the country would be for the administration of all technical regulations and SPS measures.

A single, supra-national regulatory agency would likely be very cumbersome. Four or five regulatory agencies could be

a highly workable solution for smaller economies. Issues that need to be clarified in this respect 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.
- » A product should preferably be handled by only one regulatory authority to minimise transactional cost to the supplier and ultimately the consumer.
- » The development and approval of technical regulations and SPS measures should remain within relevant Ministries and should not be allocated to the regulatory authorities.
- » 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.

6.2.3 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. This challenge is particularly pronounced in regional contexts, 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 located within the Ministry of Trade and Industry or similar. This has the advantage that this ministry is usually responsible for the implementation of the WTO TBT and other bi-lateral or multilateral trade agreements, 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. Hence it will be more challenging for it to provide leadership to the oversight entity.

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.

6.3 QUALITY INFRASTRUCTURE INSTITUTIONS

The key institutional components in the quality infrastructure system are made up of the high-level institutions responsible for standardization, metrology and accreditation.

STANDARDIZATION

We all have certain expectations about the products and services we buy, consume and use. We expect them to be fit for their purpose, safe and easy to use, not harmful to human, animal or plant health or to the environment, reliable and efficient, interchangeable and compatible with other products and to provide their benefits at an economical cost. Standards are documented agreements that translate such desired characteristics into dimensions, tolerances, weights, processes, systems, best practice and other specifics so that products and services that conform to their requirements provide confidence to buyers and users.

For developing countries, international standards developed on the basis of worldwide consensus by experts in the field constitute an important source of technological know-how. By defining the characteristics that products and services are expected to meet on export markets, international standards give developing countries a basis for making the right decisions when investing their scarce resources.

Within a QI system, standardization is usually the responsibility of a National Standards Body (NSB) that may represent the country's interests within international organizations such as the International Organization for Standardization (ISO). The NSB may provide national delegations to participate in the development of international standards that are of key importance to their country's economy. Whether or not the NSB participates in the development of an international ISO standard, it is free to adopt and translate international standards as national standards provided it holds the right level of membership within ISO. By using international standards, it ensures that the country benefits from international, state-of-the-art knowledge and that locally produced products will meet the requirements demanded by export customers.

For consumers, conformance of products and services to international standards provides assurance about their quality, safety and reliability.

METROLOGY

Metrology is the science of measurement and it is a vital part of everyday life. For example, food is bought by weight, water and electricity are metered, and instruments analysing blood

samples must be precise. It is easy to understand that faulty measurements by medical devices, or in the maintenance of critical components such as for vehicle brakes or aircraft engines, can be highly dangerous. Accurate measurements and measuring equipment are needed for the protection of health, safety, the environment and consumers. They are also vital in contracts between individual business partners and in world trade in general.

Balances and other instruments in laboratories need to be calibrated so that they can provide reliable measurements. Firms cannot satisfactorily implement process controls to manufacture a product to standardized characteristics if control instruments such those measuring pressure and temperature are not properly calibrated.

Confidence in national measurement is assured by a national metrology institute (NMI) when it becomes signatory to the Mutual Recognition Arrangement of the International Committee for Weights and Measures (CIPM MRA). The CIPM MRA provides the institutional and technical framework for NMIs to recognize each other’s measurement standards and calibration certificates, thus supporting world trade.

ACCREDITATION

Accreditation is the process by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Within a quality infrastructure system, the body responsible for accreditation evaluates the competence of product, management system and personnel certification bodies, testing laboratories and inspection bodies. Its third party endorsement of the competence of the conformity assessment body – known as “accreditation” - indicates to customers and users of the services of these organizations that they can have enhanced confidence in their work while noting the contents of the specific schedule of accreditation related to that accredited facility.

Accreditation is often the responsibility of a national accreditation body (NAB) that may seek recognition of its accreditations within the frameworks of the International Accreditation Forum (IAF) and International Laboratory Accreditation Forum (ILAC).

IAF and ILAC promote and manage “mutual” or “multilateral” recognition “arrangements” (MRA) whereby the parties involved agree to recognize the results of each other’s testing, inspection, certification or accreditation. These MRAs can be an important step towards reducing the multiple

assessments that products, services, systems, processes and materials may need to undergo, especially when they are traded across borders. Since the IAF and ILAC MRAs facilitate the acceptance of goods and services everywhere on the basis of a single assessment in one country, they contribute to the efficiency of the international trading system to the benefit of suppliers and customers alike.

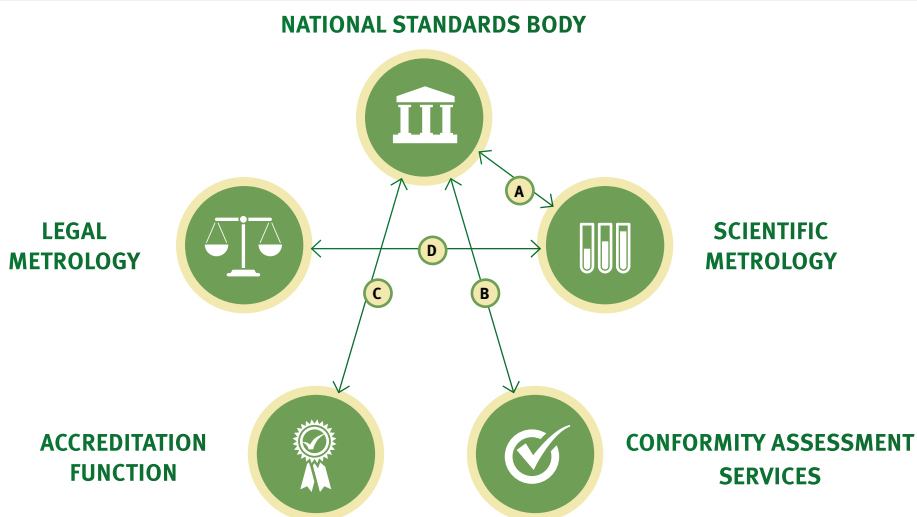
OPTIMIZING THE QI INSTITUTIONS

Good international practices have evolved regarding the structuring (i.e. independence or combinations) of the QI institutions in a particular country. However, there are many possible acceptable combinations depending on local customs, 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, and are no longer defensible at the international level.

When optimizing the quality infrastructure system, the international organizational structure of the QI should be taken into account. At the international level the fields of accreditation, metrology and standards are separated. Each of these is again subdivided, e.g. ILAC and IAF (accreditation), BIPM and OIML (metrology), ISO, IEC and ITU (standards). However, such a detailed subdivision would not necessarily be advantageous for a country. Instead, it is recommendable for a country to set up an independent national standards body, an independent metrology institute and an independent accreditation body. This solution, however, is rather expensive and not always financially viable in smaller economies. Certain combinations at the national level are acceptable, i.e. they do not give rise to conflicts of interest, namely:

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

FIGURE 6: POSSIBLE COMBINATIONS OF QI INSTITUTIONS AT NATIONAL LEVEL



Combinations (B) and (D) are quite common in smaller economies, as there are many possible synergies in such groupings. Combination (C) is not very common, but it is a highly 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, yet usually combined with (B). Factors that influence the choices include the available long-term government funding, availability of trained and skilled technical personnel, customs and practices in the public sector, and the preferences of major trading partners.

The QI structure is also influenced by the regional QI organizations. Establishing and maintaining QI organizations, especially for standards, metrology and accreditation demands long-term financial commitments from the government since these are seen as “good for country” services for which a specific beneficiary cannot be readily identified, i.e. the invoice cannot be issued to a specific beneficiary. Governments of smaller economies are often hard-pressed to commit the necessary resources and are therefore looking for regional support. Hence, a trend to establish regional organizations that can, for example, provide accreditation and selected scientific metrology services to more than one country is gradually emerging.

6.4 QUALITY INFRASTRUCTURE SERVICES

A further link in the quality infrastructure system chain is made up of the organizations that provide conformity assessment services and calibration services for quality infrastructure.

CONFORMITY ASSESSMENT

Conformity assessment denotes the processes and procedures that are used to demonstrate that a product or a service, management system, an organization or personnel meets specified requirements. These requirements are usually stated in international standards developed by organizations such as the International Organization for Standardization (ISO). The requirements for conformity assessment activities themselves are also given in international standards and this helps to ensure consistency worldwide, as well as cross-border acceptance of results.

The use of international standards is intended to harmonise conformity assessment activities throughout the world. This has far-reaching benefits for international trade in general. Agreements among nations or regions on the mutual acceptability of requirements, assessment methods, inspection or test results, etc., can all help to reduce or remove technical barriers to trade. These are requirements and rules – often defined in regulations - relating to importation and market access that vary from country to country. These may also restrict or even bar foreign products from entering a national market.

The World Trade Organization’s Agreement on Technical Barriers to Trade (WTO TBT Agreement) was established to ensure that technical regulations and standards, and the procedures for assessing conformity with them, do not create unnecessary obstacles to international trade. The WTO TBT Agreement promotes the recognition by countries of each other’s conformity assessment results as a way of reducing barriers to trade. It emphasizes that confidence in the reliability of conformity assessment results is a prerequisite to recognition of assessments. Therefore, a QIS in a developing country that is able to demonstrate the conformity of the nation’s products and services to international standards, and also to provide confidence in local conformity assessment activities, makes a significant contribution to the competitiveness of nation’s economy and industry.

Conformity assessment services are usually performed by organizations specialising in one or other activities, of which the main ones are described below. They may supply their services on a commercial basis, or they may be operated or mandated by the government.

TESTING

A product is tested against a specific set of criteria, such as performance or safety. Testing is the most common form of conformity assessment. Testing also provides the basis for other types of conformity assessment such as inspection and product certification.

INSPECTION

Inspection bodies play an essential role in cross-border trade. They act on behalf of governments and business partners (importers and exporters) by inspecting imported goods and materials. They are responsible for examining a huge range of products, materials, installations, plants, processes, work procedures and services, in the private as well as the public sector, and report on such parameters as quality, fitness for use and continuing safety in operation. The overall aim is to reduce risk to the buyer, owner, user or consumer of the item being inspected. Government and business often use their services to inspect imported goods and materials.

CERTIFICATION

Certification is when a certification body gives written assurance that a product, service, process, personnel, organization or management system conforms to specific requirements.

The most well-known examples are the certification of quality management systems and environmental management systems as conforming, respectively, to the ISO 9001 and ISO 14001 standards. More than a million business and public sector organizations worldwide have had their management systems certified to one or both of these standards. Newer management standards that also allow for certification address food safety (ISO 22000), energy management (ISO 50001) and information security (ISO/IEC 27001).

Product certification may consist of initial testing of a product combined with assessment of its supplier’s quality management system. This may be followed up by testing of samples from the factory and/or the open market. Other product certification schemes comprise initial testing and surveillance testing, while still others rely on the testing of a sample product - this is known as type testing. The type of certification scheme chosen will depend on factors such as the degree of potential risk to consumers and users of the product.

CALIBRATION SERVICES

Calibration services are important to ensure that measuring equipment used in trade, health care, environmental control, law enforcement, manufacturing and other fields remains 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 ideally 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. Furthermore, it should be clear that the national metrology institute and the

legal metrology department do not have a legal monopoly on calibration 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, it is recommended that calibration laboratories are located close to where the action is. Therefore, a number of calibration laboratories should be established at national level. A regional calibration laboratory would find it difficult to handle the volume of work on its own. Furthermore, the logistics of travelling with measurement standards across boundaries and through customs are extremely challenging at the best of times.

6.5 MARKETS AND CONSUMERS

There is increasing choice of competing products that are made available through participation in global markets and the downward pressure on prices resulting from competition. Therefore, customers tend to reject products that they do not perceive as being of the requisite quality, even though their price may be low. This is because global markets and competition offer them a wider choice and better quality at the same price.

Hence, the emphasis of the quality infrastructure system should be on markets and consumers. All component parts of the QI system interact dynamically with each other. This interaction is particularly pronounced 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 - on quality infrastructure services, quality infrastructure institutions and governance. This feedback allows for review, modification and improvement of the different components and of the entire quality infrastructure. This underlines the dynamism and systemic 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.

6.6 INTERNATIONAL AND REGIONAL LIAISON

A strong and vibrant international QI community has developed over the past decades, owing to the growing importance of standards, quality and technical regulations in global trade and product value and supply chains. International organizations such as ISO, IEC, ITU, BIPM, OIML, ILAC, IAF and many others have an important and necessary influence on international standards, metrology and accreditation as the fundamentals of the entire QI service delivery system. There are also several regional QI cooperation mechanisms. It is crucial that national institutions interconnect effectively with these international and regional institutions, namely:

In the first place, national 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 and commerce where international standards and norms are debated and decided upon. Secondly, national QI institutions should act as a conduit of latest advanced 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 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 is encouraged to commit to supporting the relevant international and regional liaison of the QI institutions. However, it should do so within a strategy that would benefit the country's industrial sector and the regulatory environment.

QUALITY POLICY CONTENT

The government is strongly encouraged to articulate its commitment to support the QI institutions in maintaining membership of the relevant international and regional 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.*

6.7 UNIDO's QI EXPERTISE

UNIDO has an extensive and proven track record in working with government, industry and other major stakeholders in developing countries to build QI systems. First of all, UNIDO can offer trainings to increase the understanding of what a QI system is and how a country can best profit from it. UNIDO's approach is holistic, from building awareness to helping to set up the QI system and get it running efficiently and effectively. Furthermore, UNIDO emphasizes hand-in-hand and hands-on cooperation with stakeholders on collective actions based on shared objectives. The examples below illustrate UNIDO's expertise in the QI field:

AFRICA

Malawi: Building a robust quality infrastructure system for local products and export

Mozambique: Setting up a demand-driven quality infrastructure system in line with private sector needs

Nigeria: Quality infrastructure development and support to local institutions

CEMAC: Strengthening national quality infrastructure systems and promote quality to foster regional cooperation

ECOWAS: Regional QP development and improved quality infrastructure services

ARAB REGION

Arab Region: Setting up regional accreditation to overcome technical barriers to trade

CENTRAL ASIA

Tajikistan: Quality infrastructure needs assessment and harmonization of technical regulations

Caucasus and Central Asia: Regional capacity building in quality infrastructure development and trade

ASIA

Bangladesh: QP development and support to metrology, standardization and accreditation

Pakistan: Support for National QP, accreditation, testing and calibration laboratories

Myanmar: Strengthening inspection and import control services to protect consumers

AMERICA

Haiti: Enhance export capacity and improve competitiveness in international markets

Nicaragua: Strengthening the quality infrastructure system to serve SMEs

Colombia: Increased compliance capacity in the cosmetics sector

The Americas: Support to standards development, metrology and accreditation





7

Supporting Sectors

In addition to the establishment of a modern, effective and efficient quality infrastructure system and technical regulation framework, a number of important activities are required to augment or support these two. In particular, it is important to secure the involvement of the private sector, non-governmental organisations, the media and international development partners,

while at all times ensuring diversity mainstreaming. The Quality Policy should clearly identify stakeholder groups, detailing their composition, who will be called upon to participate in the operation of the QI system, e.g. participate in standards development technical committees, or on the governance councils or boards of QI institutions.

7.1 PRIVATE SECTOR INVOLVEMENT

It is ultimately the private sector that pays 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 QP, in the implementation thereof, and 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 governance of such structures should be assured by a council or board comprising the private sector, the public sector and other stakeholders. No group should constitute more than 49% of the total membership. 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 and international levels. The national standards body, the national metrology institution and the national accreditation body each has the responsibility to represent the country at the regional and international levels, 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 endeavor, 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 who 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.

QUALITY POLICY CONTENT

The role and responsibilities of the private sector needs to be clearly articulated in the 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 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*
- » *Participation in advocacy and other quality system related publicity events*

7.2 NON-GOVERNMENTAL ORGANIZATIONS

Non-governmental organizations (NGOs), 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 QP solicits their active support

in a variety of roles in order to harness their influence in reaching the objectives of the QP, in particular the promotion of quality and excellence throughout society. The role of the non-governmental organizations in the implementation of the QP 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.

QUALITY POLICY CONTENT

The involvement of non-governmental organizations needs to be solicited in the quality policy. Specific issues that non-governmental organizations should get involved in 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*
- » *Actively participate in the technical committees*

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 is even better if the

government develops a communication strategy in which the media can play a prominent part. Particular attention should be paid to the use of electronic and social media (e.g. Internet websites, Facebook, Twitter, etc.), as this have become the primary means of communication in most societies.

QUALITY POLICY CONTENT

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

7.4 INTERNATIONAL DEVELOPMENT PARTNERS

In most developing economies, international development partners are actively involved in establishing the infrastructure and system that supports trade. The fields relating to standardization and technical regulations are

no exception. However, there are a number of common challenges that need to be addressed in order to optimise such development support. These include the hesitancy of development partners to follow specific policy or business

goals of the funding government and, at the same time, the hesitancy of recipient Ministries to involve other actors for the greater good of the country. Both issues often lead to duplication of efforts by different development partners, e.g. the establishment of more than one laboratory for micro-biology by various Ministries where one would have been more than sufficient, or the establishment of more than one accreditation body in the country. The recipient

country benefits most from such technical assistance that is coordinated amongst the various development agencies and amongst Ministries who are the direct recipients of the development support. Therefore, the QP needs to clearly articulate the responsibilities of recipient ministries and thereafter request development partners to cooperate in the coordination efforts.

QUALITY POLICY CONTENT

All the partners or recipient organizations as well as development partners should be encouraged through the 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 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 and international structures*
- » *Provide training and skills development for the country's technology professionals within the QI system and technical regulation regime*

7.5 DIVERSITY MAINSTREAMING

Women make up half of the world population and, hence, constitute half of the consumer and labour market. Therefore, inclusion of women in the society and economic activities is essential to sustainable development, although gender roles may differ depending on tradition, culture, religion, history and politics. The importance of gender equality is well-established in the international development field and listed as one of the poverty reduction goals as part of the Millennium Development Goals (MDGs) and its successor Sustainable Development Goals (SDGs).

As with gender issues, there are also other diversity

challenges that may need to be considered in developing the QP. These could include minority groups, SMEs, rural communities, and similar. The goal of the QP is to ensure that the entire society benefits equally from its implementation.

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

QUALITY POLICY CONTENT

All the quality-related institutions and service users should be encouraged through the 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-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*
- » *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.*



8

Financing the QI System

The government has to clearly articulate its commitment to the long-term funding of the standards, metrology and accreditation activities

where this cannot or would not be funded by others. This is crucial to ensure the sustainability of the quality infrastructure system.

8.1 GOVERNMENT RESPONSIBILITIES REGARDING THE QI SYSTEM

When analysing the financing of QI institutions world-wide, it becomes evident that in almost all countries governments retain the responsibility of funding the three fundamental pillars, namely standards, metrology and accreditation. Only in some of the biggest economies where the private sector is highly developed, financially powerful and fully motivated, QI institutions are financed by the private sector to a greater extent. It is obvious that governments fund QI institutions which are government departments or organizations of public law (i.e. statutory organizations). However, even in the case of private QI institutions, governments frequently provide a large percentage of funds for standards development, standards information, scientific metrology and accreditation activities (especially at start-up level). This is done in the form of specific financial agreements between the state and these institutions. The reason is that these three fundamental pillars of QI can be described as activities which are beneficial to the entire country and therefore the bill cannot be issued to a specific beneficiary.

In the past, certain smaller economies have tried to make industry pay for standards development on a sectoral basis, but on the whole this has 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. However, even in this case, governments frequently retain the responsibility to fund the international liaison activities vis-à-vis ILAC and IAF and the costs of international recognition.

Therefore, the government has to clearly articulate its commitment to 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 which earn income from services rendered, e.g. a national standards body providing conformity assessment services, the government may specifically identify its commitment for standards development, standards information and international liaison activities.

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 QI institutions.

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 in order not to distort the market. This is of particular importance for those in the public sector.

Frequently, the political level wishing to support the SME sector demands that QI institutions provide conformity assessment or calibration services at prices below cost. However, this approach is counter-productive, 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 cost they paid for conformity assessment or calibration services on presentation of a positive report or certificate.

Another problem that sometimes occurs is that government departments demand conformity assessment services from public QI institutions without wanting to pay for them. This approach is also counter-productive, as it unnecessarily

stretches the financial support the institution receives from its line Ministry for fundamental services. Government departments and their agencies should get used to budgeting for the conformity assessment services they require, and pay the public QI institutions accordingly. Were the services provided by a private institution, the government would also be required to pay. Furthermore, the world-wide tendency is for governments to liberalize conformity assessment services and allow private sector organizations to provide the bulk thereof.

However, it has to be borne in mind that some conformity assessment services are very profitable and relatively simple to run. The private sector will have no difficulty in investing in and providing such 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 when these are needed.

There is also an important unintended consequence of operating on the “user pays” principle which is the encouragement of competition based on lowest price in a

race to the delivery of cheap CA services that do not meet international requirements and are not sustainable in the long run – this needs to be recognised and avoided.

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 REGULATIONS

Financing technical regulation is complex. Many would argue that technical regulations are unilaterally imposed by the state; therefore, the state should pay for the administration thereof. However, the burden on the state, if it had to fund technical regulation in totality, would be excessive. 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 regulations. In many countries, the state would fund this activity. The risk is that if the state does not have the necessary financial means, this important function does not get implemented properly. In that case, some suppliers might be quick to exploit the lack of market surveillance and offer low-quality products and services to the detriment of the society and the environment. Hence, in some countries, suppliers of goods or services covered by technical regulations are charged a levy for 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 is responsible for providing compliance evidence to the regulatory authorities. This means that the supplier needs 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, there should not be a problem. However, if the regulatory authority demands that the compliance testing has to be conducted by itself, or a single designated laboratory, then a problem arises. Such a situation usually leads to unnecessary and expensive re-inspection and re-testing, and the regulatory body can be perceived as being 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. This should be clearly stated in the QP. It is recommended that the development of technical regulations, products and service market surveillance and legal metrology activities be dealt with decisively.

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.





9

Legal Framework

The quality infrastructure system and the regulatory framework primarily obtain their legitimacy through appropriate legislation. Therefore, it is essential that the QP clearly spells out the commitment of

the government to review the existing legislation and amend it accordingly as well as to develop and promulgate new legislation if required.

The legislation should not only apply to QI institutions which are public entities. Overall guidance should also be provided with respect to the provision of standards, metrology and accreditation services together with calibration and

conformity assessment, as well as for technical regulation development and implementation in particular.

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



A **Standards Act** providing for the development and publication of national standards, their legal standing and how these 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, the 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, including 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. This Act should contain guidance on conducting an impact assessment beforehand to determine the validity of developing technical regulations, 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 WTO TBT Agreement.

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

Implementation Measures

10.1 GENERAL

It is important to identify and allocate responsibilities for the implementation of the QP. Furthermore, a review process needs to be articulated, whereby the Cabinet as the “owner” of the QP can be appraised regarding the implementation progress or can 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 the individual actions by a variety of responsible entities, all of which are designed to achieve the outcomes, objectives and, ultimately, the vision of the QP.

10.2 LEAD MINISTRY

A specific ministry should be designated as the lead ministry to oversee the implementation process. This could be the Ministry of Trade and Industry (or similar) as the entity responsible for the main QI institutions in the public sector and for ensuring the country’s compliance with the WTO TBT Agreement. It could also be the Ministry of Planning (or similar) as the entity responsible for government

organizational structures and overall coordination of government activities. However, in certain countries, the Ministry of Science and Technology (or similar) is responsible for the QI institutions in the public sector. Therefore, the responsibility as lead ministry for the implementation of the QP should be carefully considered by the relevant ministries and approved by Cabinet. This responsibility should be clearly stated in the QP.

10.3 INTER-MINISTERIAL COORDINATING COMMITTEE

In order to obtain the buy-in from all relevant government departments, the lead ministry should be supported by a committee/structure, in which all relevant ministries, QI institutions and agencies are represented. This is important because the QP, 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
- » Monitor and oversee implementation plans on a regular basis until successful implementation

QUALITY POLICY CONTENT

The quality policy should address the following:

- » *Designation of the lead ministry for QP implementation and specification of its main responsibilities*
- » *Establishment of an Inter-Ministerial Coordination Committee and specification of its main responsibilities*
- » *Clear articulation of the responsibility of individual ministries and their organs and agencies to implement the quality policy and to execute the activities detailed in the implementation plan/strategy*
- » *Guidance regarding the evaluation of the implementation progress*

Glossary

There are many expressions utilized within the QI and technical regulation domain that have very specific meanings. These terms are defined to prevent possible misunderstandings of the contents of the QP. The terms and definitions that follow are used throughout this document are based on current best practice and understanding. Although these definitions should also be considered for inclusion in any resultant national or regional QP care should be exercised to also quote and reference the appropriate authorities and their documents.

Accreditation

third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks

[SOURCE: ISO/IEC 17000:2004, 5.6]

Calibration

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

Note - The formal definition of calibration is given in the International Vocabulary of Metrology (VIM).

Certification

third-party attestation related to products, processes, systems or persons

[SOURCE: ISO/IEC 17000:2004, 5.5]

Conformity assessment

evidence that specified requirements relating to a product, process, system, person or body are fulfilled.

[SOURCE: ISO/IEC 17000:2004, 2.1, modified]

Inspection

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

[SOURCE: ISO/IEC 17000:2004, 4.3]

Measurement Standard

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 Infrastructure³

system comprising the organizations (public and private) together with the policies, relevant legal and regulatory

framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes

The quality infrastructure is required for the effective operation of domestic markets, and its international recognition is important to enable access to foreign markets. It is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing.

It relies on

- » metrology,
- » standardization,
- » accreditation,
- » conformity assessment, and
- » market surveillance.

Quality Management

coordinated activities to direct and control an organization with regard to quality

[SOURCE: ISO/IEC 9000:2015, 3.3.4]

Quality policy

policy adopted at national or regional level to develop and sustain an efficient and effective quality infrastructure

Standard

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

Note - According to ISO/IEC Guide 2: 2004, a standard may be Mandatory. Under the WTO TBT Agreement a standard is a voluntary document, while a document of mandatory compliance is a technical regulation (https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm#annexl).

Technical regulation

document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory, and which can also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method

Note: This definition is used by the WTO TBT Agreement, which specifically deals with technical regulations, standards and CA procedures (See Annex A) and is consistent with the approach taken by ISO/IEC Guide 2, according to which a regulation is a document adopted by an authority providing binding legislative rules, and a technical regulation is a regulation that provides technical requirements, either directly or by referring to or incorporating the content of a standard, technical specification or code of practice.

The WTO Agreement on Sanitary and Phytosanitary Measures

³ Definition approved by DCMAS, June 2017

calls regulations which fall under its mandate simply “measures” (See Annex A). The Guiding Principles apply to SPS measures as well.

The WTO TBT Agreement, and hence its usage of the term technical regulation, focuses on products or processes and production methods, whereas for the Guiding Principles the terms regulation and technical regulation extend also to services.

Testing

determination of one or more characteristics of an object of conformity assessment, according to a procedure

[SOURCE: ISO/IEC 17000:2004, **4.2**]

Verification

procedure of examining a measuring instrument to ascertain and confirm that it complies with legal metrology requirements



Annex

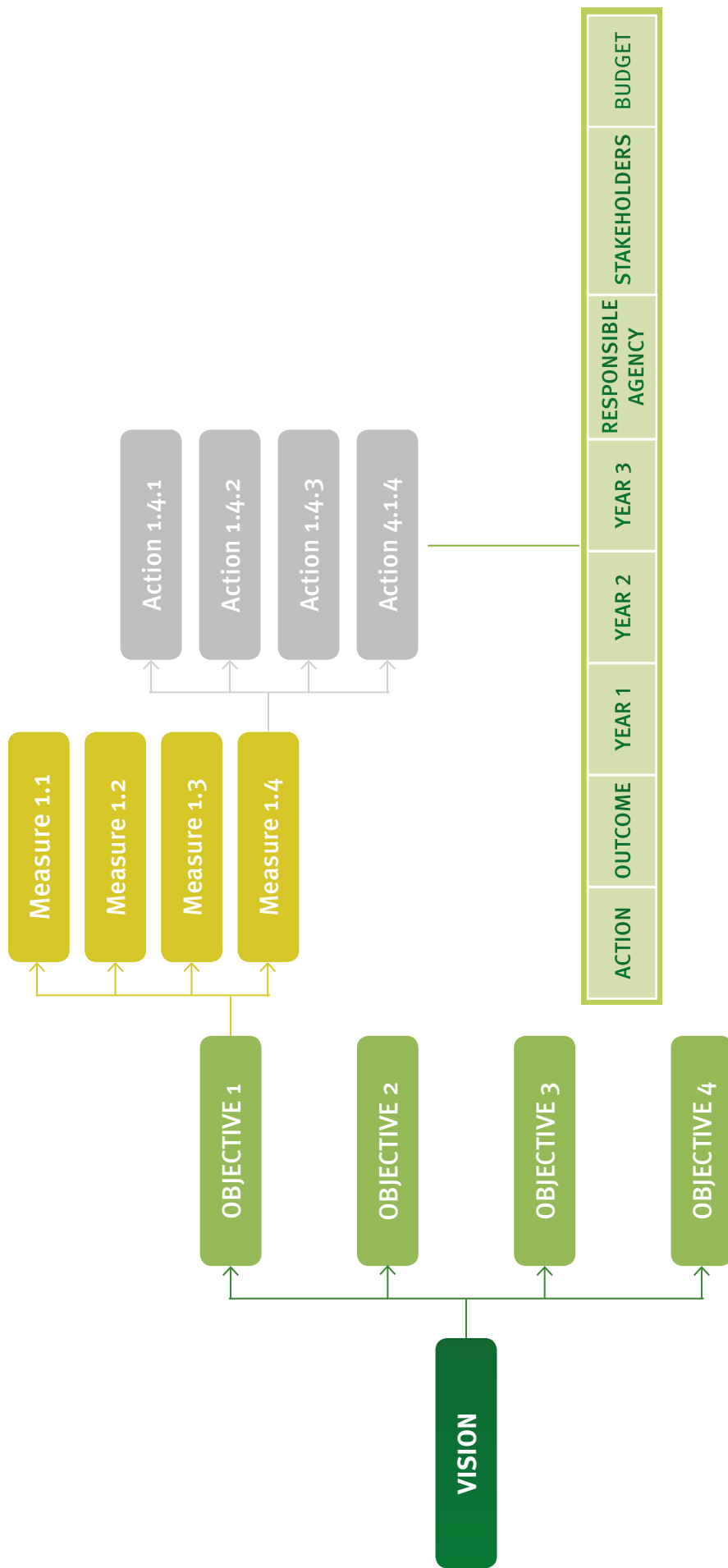


ANNEX

Typical Content List of a Quality Policy

No.	NQP Section	NQP Subsection	Guidance reference
	Foreword		
1	Introduction	International and regional context	Section 4
		Trade as a driver for development and poverty reduction	Section 4
		Definition of the QI and TRF	Section 6
		Policy environment	Section 4.2
2	Review of current situation	National Quality Infrastructure	Sections 6
		Technical Regulation Framework	Section 6.2.1
		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
6	The Technical Regulation Framework		Section 6.2.1
7	Education and Training		Section 7.1
8	Role of other stakeholders	<ul style="list-style-type: none"> ▪ 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 6.6
11	Financing the QI and TRF	▪ Government	Section 8.1
		▪ Conformity 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 7: TYPICAL QUALITY POLICY AND IMPLEMENTATION PLAN ELEMENTS





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