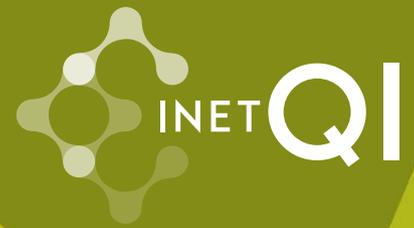




UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION



INTERNATIONAL NETWORK ON
QUALITY INFRASTRUCTURE

QUALITY POLICY

A Practical Tool



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INDUSTRIAL DEVELOPMENT ORGANIZATION

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Vienna, Austria 2018

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List of abbreviations

AB	Accreditation Body
BIPM	Bureau International des Poids et Mésures (International Bureau of Weights and Measures)
CA	Conformity Assessment
DCMAS	Developing Country Network for Metrology, Accreditation and Standardization
DCED	Donor Committee for Enterprise Development
ECO	Economic Cooperation Organization
ECOWAS	Economic Community of West African States
GRP	Good Regulatory Practice
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
MDGs	Millennium Development Goals
MSME	Micro, Small and Medium Enterprises
NAB	National Accreditation Body
NGO	Non-Governmental Organization
NMI	National Metrological Institute
NQC	National Quality Council
NSB	National Standards Body
OECD	Organization for Economic Co-operation and Development
OIE	International Organization for Animal Health
OIML	International Organization for Legal Metrology
RIA	Regulatory Impact Assessment
QI	Quality Infrastructure
QP	Quality Policy
SADC	Southern African Development Community
SC	Steering Committee
SDGs	Sustainable Development Goals
SDO	Standards Development Organization
SME	Small and medium-sized enterprises
SPS	Sanitary and Phytosanitary Measures
TBT	Technical Barriers to Trade
TFA	Trade Facilitation Agreement
TII	Department of Trade, Investment and Innovation
UN	United Nations
UNIDO	United Nations Industrial Development Organization
WTO	World Trade Organization

Executive Summary

Over the years, a wealth of knowledge has been accumulated by UNIDO and others involved in the implementation and/or improvement of a Quality Infrastructure (QI) in developing economies. The importance of establishing a Quality Policy (QP) to establish the primary objectives, roles and responsibilities of such a QI is well documented, but until now much of the guidance available has focused on “what” the QP should contain, rather than “how” to go about this very important process.

This practical tool is consistent with, and intended to be used in conjunction with, the UNIDO publications “Quality Policy Technical Guide”¹, which details the various elements of a QP, and “Quality Policy Guiding Principles”² which sets out five core principles for QP development, namely Ownership, Inclusiveness, Coherence, Optimization and Sustainability.

The tool adopts a process-based (step-by-step) approach, building on experiences obtained in different countries (each with their own specific context), and, in addition to answering the question of “what” to do, guides the reader through the practicalities of the “why”, “who” and “how” of each step. It also examines some of the challenges that are likely to be encountered, and ways to overcome or mitigate them.

¹ “Quality Policy Technical Guide”, UNIDO, Vienna, 2018

² “Quality Policy Guiding Principles”, UNIDO, Vienna, 2018

The QP development process is divided into five key stages, as follows;

- » **Stage 1:** Do the groundwork - Instil a sense of need for the QP, and promote ownership and coordination from within government
- » **Stage 2:** Conduct strategic planning - Define priorities and allocate resources
- » **Stage 3:** Prepare the draft QP - Provide for transparent consensus-building and assure coherence
- » **Stage 4:** Lobbying, advocacy and approval - Incorporate as part of national policy landscape
- » **Stage 5:** Implement, monitor and review the QP - Ensure effective and sustainable implementation

Some practical examples of QP development are presented in a series of Case Studies (Annex 6 to this Practical Tool).

Glossary

Champion (See Figure 1)

A person who sees value in, takes the initiative for, and leads the development of the QP. The champion acts as an information-sharing channel to top-level government circles and as a consensus builder.

Consensus

General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests, and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments.

NOTE: Consensus need not imply unanimity.

Drafting Group (See Figure 1)

Group responsible for the operational aspects of preparing the QP, working under the guidance of the Steering Committee.

Quality Infrastructure³

The 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

³Definition approved by International Network of Quality Infrastructure, June 2017

- » standardization
- » accreditation
- » conformity assessment
- » market surveillance

Quality Policy

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

Implementation Plan

A plan detailing the implementation process after the QP has been formally adopted, by specifying activities, responsibilities and a tentative time frame, as well as financial and resource implications.

Stakeholder

Person or organization that can affect, be affected by, or perceive itself to be affected by the QP.

Steering Committee (SC) (See Figure 1)

Group of (typically 10-15) stakeholders with the objective of defining the strategic direction of the QP development process, ensuring the availability of adequate resources, monitoring progress, and ensuring its successful conclusion.

NOTE: An existing structure or body with appropriate recognition/acceptance could also form the basis for such oversight.

Technical Sub-Committee (See Figure 1)

Group of subject matter experts convened to support the development of specific functional elements (standardization, conformity assessment, metrology, etc.) and/or sector components of the QP (for example, food safety; agriculture; tourism). These technical sub-committees (which could also be in the form of task forces, working groups, networks etc.) typically report to the SC and provide inputs into the Drafting Group.

FIGURE 1: TYPICAL ORGANIZATION STRUCTURE FOR QP DEVELOPMENT PROCESS



Introduction

The Quality Policy (QP) is the basic government instrument for establishing, formalizing, and overseeing the development and performance of a Quality Infrastructure (QI). Developing and agreeing upon the QP is one of the vital first steps in defining a QI that is relevant and appropriate for the specific context of a particular country. The QP typically defines the objectives and structure of the QI and a road map and schedule for setting it up.

Quality Infrastructure (QI) is a system that combines initiatives, institutions, organizations (public and private), activities and people. It includes 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. It is required for the effective operation of domestic markets, and its international recognition is important to establish its credibility in local and foreign markets. QI 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.

The QP provides details of the preferred QI structures and their relevant responsibilities, to facilitate a proper and coherent division of work within a particular country's context. The policy should also detail the relationship of the QI with the framework for technical regulations. No developing country can afford to duplicate effort and resources to establish parallel systems of standards, testing and certification; one for the market place and another for regulatory purposes.

In recent years, it has also become clear that a well-implemented QI contributes to governmental policy objectives in areas other than trade of goods and services; QI has thus proven useful, for example, for cross-cutting issues such as the efficient use of natural and human resources, food safety, health, the environment, climate change, and other topics that are included in the UN's 17 Sustainable Development Goals (SDGs) for 2030.

It is important to understand that the QI of any country comprises a number of institutions and service providers that must work together as a system. The absence or inadequacy of any one of the constituents will compromise the effectiveness and ultimately the efficiency of the system as a whole, thereby negatively affecting business, trade and sustainability-related objectives.

In most countries, the QI institutions are public or semi-public bodies; therefore governments must secure resources for their long-term viability and play a continuous and active role in their setup and supervision. This is why the Implementation Plan for the QP must include an indication of resources (including technical assistance, equipment, personnel and funding) that will be needed for it to achieve its intended outcomes.

Government can use the development of the QP as an opportunity to increase awareness among stakeholders of the importance of the QI, their own roles and responsibilities, and how the different national actors can benefit from it. It can do this by inviting broad stakeholder participation during the consensus-building process for the QP. Examples of stakeholders include representatives of the government's own ministries and agencies, regulatory bodies, trade and industry associations, chambers of commerce, consumer associations, and providers and users of calibration, testing, certification and inspection services. Their input will help ensure that the QP and QI meet the needs of the nation, while their participation will encourage implementation of the policy and "buy-in" to the Quality Infrastructure.

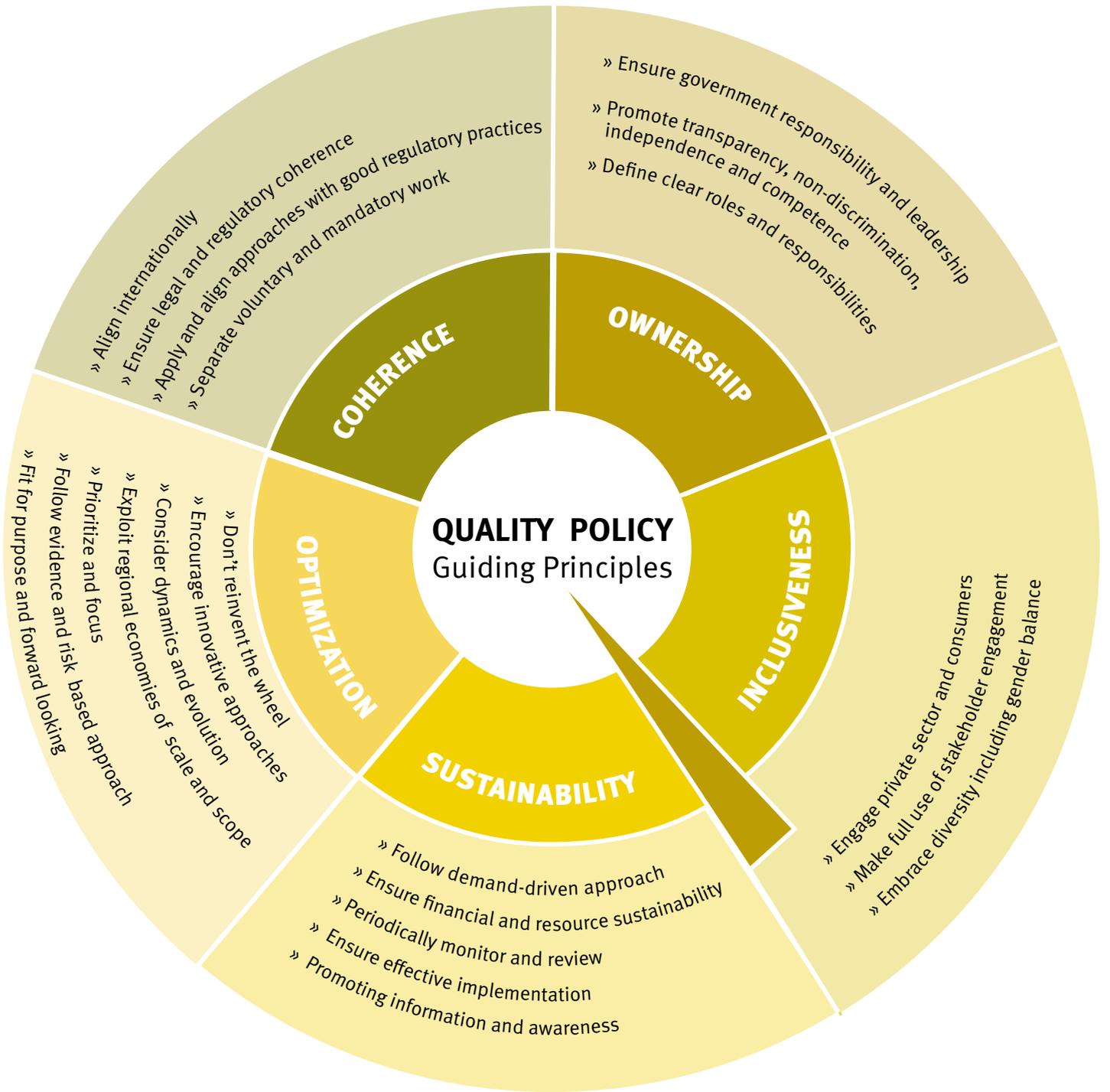
Whilst it is widely recognized that no "one-size-fits-all" template can be used, the STEPS that need to be undertaken in order to develop a sustainable and implementable QP are typically very similar. This document provides such a step-by-step approach for countries to develop (or improve) their QPs in a way that is participative and lasting. It draws extensively on, and is intended to be used in conjunction with, the UNIDO publications "Quality Policy Technical Guide", which details the various elements of a QP, and "Quality Policy Guiding Principles" which sets out five core principles, namely Ownership, Inclusiveness, Coherence, Optimization and Sustainability. The intent of the current Practical Tool is NOT to specify WHAT the QP should contain, or its specific format, but to describe in a simple, logical and practical way the STEPS that typically need to be undertaken in order to successfully formulate, agree upon, publish, disseminate, implement and/or revise a QP. This means that the QP will have been developed in a participative manner, agreed among the national stakeholders and considered and approved by the highest relevant authority in the country (i.e. government, cabinet, Prime Minister, President, etc.). The resulting QP should recommend the preferred options relating to the legal framework for the establishment of the QI institutions and their relationships and be a living document that is subject to periodic review and updating as the country's needs and expectations evolve over time.

Although the publication and formal adoption of the QP is of course important, the process by which it is developed can also be extremely beneficial to the country by bringing the various stakeholders together (each of them with a different perspective), and by building consensus among them.

Figure 2 presents a summary of the five underlying principles and 22 sub-principles for effective QP development⁴.

⁴"Quality Policy Guiding Principles", UNIDO, Vienna, 2018

FIGURE 2: UNDERLYING PRINCIPLES FOR EFFECTIVE QP DEVELOPMENT



Step-By-Step Approach to Quality Policy Formulation

The following provides a summary of the key stages that typically need to be followed in order to develop (or revise) and implement a QP once a decision has been made to initiate the process to do so.

Regardless of the motivations for developing a QP, the steps involved in the process are similar, and the five stages described in this Practical Tool can be adapted according to the specific needs and context of each country. In many cases, the steps do not necessarily follow a linear sequence; there will of course be some overlap and in some cases, a need to revisit some of the assumptions made in early steps later in the process.

It is important to emphasize that the development process for the QP should take into account the implications for its subsequent implementation. It is therefore appropriate to undertake the parallel development of an Implementation Plan that takes into consideration the financial viability of the QP, priorities (based on cost/benefit) and other resource implications.

There is no fixed or prescribed time-frame for each step, but it is unlikely that a truly participative and consensus-based QP can be developed in less than 12 months, depending on the specific context of each

country and its motivation for developing or revising its QP. On the other hand, the process should not extend beyond two years if it is to maintain momentum and the motivation of stakeholders.

Similarly, there is no golden rule for the ideal duration/validity of the QP. It may be convenient to align it with some other high-level development plans (where they exist), or simply adopt a 4- or 5-year improvement cycle. While the preparation of the QP may generate some enthusiasm in the early stages, it is also important to sustain interest and involvement during its implementation. Too long a duration might be detrimental to this purpose. In all cases though, regular (yearly) updates on achievements will help to keep the policy as a “living document”.

It has to be recognized that in many countries government policy development follows a specific path, often prescribed by government procedures, and the steps outlined in this Practical Tool might need to be aligned accordingly. The Case Studies in Annex 6 at the end of this Practical Tool provide examples of how a number of countries developed and implemented their QPs, the various stages that were applied in practice, and the lessons learned.

TABLE 1: 5-STAGE APPROACH TO THE QP DEVELOPMENT PROCESS

DETAILED STEPS	OBJECTIVE / OUTPUT	KEY PRINCIPLE(S)
1 DO THE GROUNDWORK	Instil a clear sense of need, ownership and coordination from top levels of government	
1.1 Establish the need (to prepare or revise the QP)	A clear rationale for establishing or revising the QP	» Optimization » Sustainability » Coherence
1.2 Foster leadership and buy-in	Interest and leadership from the highest level of government; potential resistance from key players has been overcome	» Ownership
1.3 Identify key stakeholders, including representatives from civil society and from business sectors	Stakeholders identified who can affect or will be affected by the QP	» Inclusiveness
1.4 Ensure appropriate oversight, and define roles and responsibilities	Responsibilities established for coordination; strategic and operational oversight in place to meet timelines Announcement defining what, when and how the QP and its implementation plan will be prepared	» Ownership » Coherence

DETAILED STEPS

OBJECTIVE / OUTPUT

KEY PRINCIPLE(S)

2 CONDUCT STRATEGIC PLANNING

Define priorities and allocate resources

2.1 Understand the context and define strategic objectives for the QP

Criteria defined to ensure the QP will reflect the real needs of the country

- » Optimization
- » Sustainability
- » Inclusiveness
- » Coherence

2.2 Carry out a Gap Analysis of the existing QI

Key issues to be addressed by the QP have been identified

- » Ownership

2.3 Conduct preliminary consultations with stakeholders

Awareness among stakeholders of the need for the QI; findings and issues of Gap Analysis discussed, and inputs gathered to allow for preliminary drafting of QP

- » Inclusiveness

2.4 Develop and analyse options

Lessons learned from others; benchmarking carried out; most cost-effective basis for the QI defined

- » Coherence
- » Sustainability

Resources identified and available

3 PREPARE DRAFT QP AND BUILD CONSENSUS

Provide for transparent consensus-building; assure coherence

3.1 Establish one or more Technical subcommittee(s) to prepare parts of the QP as needed

Basis for the QP to address needs of all sectors

- » Optimization
- » Inclusiveness
- » Coherence

3.2 Prepare a first draft of the QP

First draft produced and circulated to provide a starting point for stakeholder discussion

- » Inclusiveness
- » Coherence

3.3 Initial consultations on the draft QP

Inputs from relevant stakeholders provided
Detailed discussions concluded on implementation modalities

- » Inclusiveness

3.4 Incorporate feedback and include legal text

Second Draft of QP and its Implementation Plan produced and circulated

- » Optimization
- » Inclusiveness
- » Coherence

3.5 Circulate for public consultation and/or hold ‘validation’ workshops in the main activity centres of the country

Wider buy-in for QP; public comment received

- » Inclusiveness

3.6 Incorporate comments and prepare the “final” QP version together with the Implementation Plan

Further improved draft of the QP produced and circulated

- » Optimization
- » Inclusiveness
- » Coherence

4 ADVOCACY, LOBBYING AND APPROVAL		Incorporate as part of policy landscape
4.1 Advocacy and endorsement by institutional stakeholders	All implementation issues resolved and appropriate resources committed	» Inclusiveness
4.2 Obtain formal approval from top-level of government	QP formally adopted as part of overall policy Roles clearly defined and implementation plan approved	» Ownership » Coherence
5 IMPLEMENT, MONITOR AND REVIEW THE QP		Ensure effective and sustainable implementation
5.1 Publish QP	QP available to all citizens together with the implementation plan	» Inclusiveness
5.2 Communicate, promote and implement QP	Awareness among all stakeholders; liaisons established with partners and donors to facilitate implementation	» Inclusiveness
5.3 Monitor, review and improve the QP	QP is able to adapt to changing circumstances and national priorities	» Sustainability





STAGE 1

Do the groundwork

Preparing the groundwork for the subsequent consensus-building process is probably the most important stage of the entire process, and one which rarely attracts sufficient emphasis. If there is good leadership from within government; if all the relevant stakeholders are identified and involved; the

objectives for the preparation / revision of the QP are clear, and there is a well-coordinated plan to achieve them, then the remainder of the process should be relatively straightforward. The individual steps in this stage of the process are as follows:

STEP 1.1 ESTABLISH THE NEED (TO PREPARE OR REVISE THE QUALITY POLICY)

Intended outcome

A clear understanding of WHY the QP needs to be developed or revised.

Why?

To ensure that the relevant authorities (and specifically high-level government officials in the relevant Ministries) understand and agree on the need to begin the work and are supportive of it.

Who?

The catalyst to provoke the initiation of work on developing or revising the QP is likely to come from one or several of the following possible sources:

- » Ministry of Trade and Industry (or equivalent), as a result of an identified need to participate in (or increase) regional and/or international trade
- » Industry stakeholders who are not satisfied with the existing QI (or the lack thereof) to support their activities
- » Development Partners, who want to have confidence in the country's strategic ability to support trade capacity building initiatives
- » Regulators, who wish to ensure the effective deployment, implementation and monitoring of technical regulations
- » Consumers, who demand that products and services available on the market are safe

What and How?

The most powerful argument in favour of developing or revising the QP will come from a review of successful examples in other countries and/or regions, where this has resulted in tangible benefits and supported trade and other sustainable development initiatives. Some such examples are given in the Case Studies provided in Annex 6. It should be noted that many DEVELOPED countries have a QI that has evolved gradually and matured over a long period of time, without ever having a formally defined QP. A disciplined, systematic and consensus-based approach to developing and implementing a QP can, however, provide significant benefits for developing countries. Such countries, who are probably starting on their quality journey, can use not only the QP itself, but also the process for its development, to bring together the various public and private sector institutions involved in the QI, and agreeing clear responsibilities, authorities and interactions between them.

In some cases, a Gap Analysis might already have been conducted as part of earlier development projects, with a recommendation to prepare a QP to address issues related to deficiencies identified in the QI. For the purposes of this Practical Tool, however, we assume that such a Gap Analysis has not yet been conducted, and this will be addressed in Step 2.2 as part of the QP development process.

Challenges and mitigation measures.

For some countries, the decision to develop a QP is a spontaneous one, aimed primarily at ensuring the QI is formally defined and adopted, with the overall objective of enhancing participation in international trade and contributing to other sustainable development goals. In these circumstances, there might not be any immediate urgency for the QP to be published, and a comprehensive, fully participative consensus-building process can be foreseen. This can have the additional benefits of engaging all relevant stakeholders in a national dialogue aimed at breaking down eventual "silos" that may have been built up over the years, with the inevitable associated inefficiencies. It is, however, important to establish a clear timeframe for development of the QP, to avoid complacency and maintain the momentum of the process.

On the other hand, there may be external factors that provoke the decision to develop a QP and result in some time-pressures; for example, the need to achieve international recognitions for the quality infrastructure as a pre-condition to entering international trading partnerships. It is also becoming more and more common for Development Partners to require a formal QP as a pre-condition for investments in the various components of the QI in developing economies. Whilst this approach is to be applauded, it can lead to the country having a focus exclusively on achieving the end result (the formally-adopted QP), without making full use of the corresponding benefits associated with the policy development process, including proactive communications with and feedback from all the relevant stakeholders.

In these situations, the use of Development Partners and consultants can be extremely useful in order to facilitate and expedite the process by providing independent and impartial inputs. It is important to stress, however, that each country should develop a sense of "ownership" of its QP, rather than simply hiring a consultant to prepare it on their behalf, and should encourage the maximum participation of the relevant government organs at all stages of the QP development.

STEP 1.2 FOSTER LEADERSHIP AND BUY-IN

Intended outcome

Key players from government and other relevant stakeholders are sensitized and convinced about the need for and potential benefits of a formally-adopted QP. A leader / champion (or group of champions) for the process is identified.

Why?

To promote leadership and commitment from the highest appropriate level of government and to overcome potential resistance from other key players. Obtaining a sense of ownership at the governmental level for the formulation or revision of the QP is vital for the ultimate success of the project. Without one or more “champions” within government who understand the need for and are committed to the development of the QP, the initiative is likely to fail, or take an inordinate amount of time and effort.

Who?

Typically, the process will be initiated by one or more of the following “actors”:

- » Representative of the Ministry of Trade and Industry (or equivalent), often with support from business associations, as a result of the need to improve the country’s ability to export goods and services in an increasingly demanding international market, and in line with WTO TBT/SPS criteria.
- » The National Standards Body (usually one of the first QI components to be established in any ad-hoc system that may be established prior to the development of a formal QP), recognizing the need for better organization and discipline in order to clarify potentially conflicting roles and responsibilities for topics such as standardization, technical regulation, conformity assessment, metrology and accreditation.
- » Development Partners, who are increasingly requiring countries seeking technical assistance to have a formally adopted QP in order to provide confidence in their ability to make effective use of financing for initiatives that involve components of the QI.

Exactly WHO takes on the role of “champion” will vary depending on the overall stimuli that led to the decision to initiate the process of developing or enhancing the QP. Ideally, the “champion(s)” should be at the Ministerial level, or at least high-level government officials supported by colleagues in other parts of government.

What and How?

For the appropriate high-level government officials to provide leadership they may first need to be convinced about the need for and potential benefits of a formally-adopted QP, as well as the risks associated with not having such a national policy. It is to be hoped that this practical tool and the Case Studies herein, as well as other UNIDO publications, can be useful in providing justification for the initiative.

It should be emphasized that the benefits of developing a QP are twofold:

- » The consensus-building process for the QP, if conducted in line with the recommendations of this Practical Tool (with clear government leadership, and contributions from key stakeholders), can provide a unique opportunity to address national priorities (both public and private sector) and to ensure that the QI is aligned with those priorities.
- » The governance and strategic direction provided by a formally adopted QP should ensure the prioritization of resources for the QI that are appropriate within the national context, and its sustainability even under changing political and economic landscapes. Whilst the overall objectives for the QI will be to support the legitimate objectives of government via regulatory measures to protect the health and safety of its citizens and the environment, the QP is also a vital instrument for trade facilitation and economic growth, as well as contributing to the nation’s Sustainable Development initiatives.

On the other hand, if there is no clearly defined QP, the governance and interactions between the various institutions that comprise the QI can be confused, with overlap and sometimes conflicting priorities and objectives. This typically results in overall inefficiency of the system, increased bureaucracy, and un-necessary burdens both for the public and private sector entities and for citizens who rely on the QI institutions for their business and other needs.

Although there may already be local specialists who are knowledgeable in the technical aspects of a QI, the involvement of internationally recognized consultants can be useful at this early stage in order to support and reinforce the messages that are transmitted to high-level government officials. This may necessitate individual audiences or meetings with such officials from the various ministries involved (for example, Trade and Industry, Health, Agriculture, Fisheries and others), as well as focus group discussions and larger workshops, in which the simultaneous participation of the different ministries could be a challenge. It must be emphasized that the focus of these initial meetings and workshops is at the national government level, and they should not be confused with those to be conducted with other stakeholders later in the QP consensus-building process.

Prior to the meeting(s), it is beneficial to prepare a short (maximum 2-page) briefing note (“Concept Paper”) on what is being planned, the issues that need to be addressed, the benefits of formalizing the QP for the country, the risks associated with not having a formal QP, an overview of the steps involved, preliminary time-frames and some early recommendations. Some of the issues that it is useful to highlight typically include the effect of globalization, challenges faced by enterprises, the current situation regarding the QI and the technical regulation regime, and the need for a clear commitment of government. An example core text that might be used as a basis for such a Concept Paper is shown in Annex 1.

With adequate preparation, it is to be expected that these initial meetings and/or workshops could be held over a two-week period, though this will of course depend on the availability of the appropriate ministers and officials. Unlike the later workshops, these meetings are likely to be concentrated in the capital city.

Challenges and mitigation measures

Reactions to the QP development initiative are likely to vary between the different ministries - indifference or some opposition can be expected by those who feel threatened by the real or perceived changes in responsibilities, accountabilities and authorities that the QP and the associated QI might bring. This opposition may be overt (in which case it can be discussed openly) or covert (which is more difficult to identify and address). It is important during these initial steps, therefore, to establish a critical mass of support from within government to overcome such resistance to the change process. It is at this point that independent international consultants can have a facilitating role, using concrete examples of successes and failures from elsewhere. The style of government and the national culture is an important factor to be taken into account when seeking to obtain wider support.

STEP 1.3 IDENTIFY KEY STAKEHOLDERS

Intended outcome

Identification of those who will be affected by, or perceive themselves to be affected by the QP, so that their needs and expectations (and concerns) can be taken into consideration during the development process. Note that preliminary identification of the stakeholders can be conducted in parallel with Steps 1.1 and 1.2.

Why?

To ensure a comprehensive consensus-building process for the QP, that will, in turn, facilitate its effective implementation.

Who?

Initial identification of the key stakeholders is likely to be made by the project “champions” based on a preliminary analysis, prior to the establishment of the Steering Committee, and subsequently reviewed and modified as necessary as the QP development process evolves.

What and How?

In terms of the identification of the relevant stakeholders, the specific categories and their relevance to the QI and QP will depend primarily on the individual nation’s economy. For example, in some countries agriculture might be of key importance; in others it might be fisheries, or tourism. Some countries might have easy access to international accreditation on a regional basis; others not. Some may have technical regulations that are restricted to a small

number of regulatory bodies, whilst in others these could be spread over a large number of independent agencies.

The following generic categories of stakeholder should be considered and adapted for the specific context of each country:

Policy makers and regulators

- » Relevant Ministries
- » Government Agencies

Any pre-existing standards organizations

- » National Standards Body (if already constituted)
- » Other Standards Development Organizations
- » Industry-based standards organizations

Any pre-existing metrology organizations

- » National Metrology Institute (NMI)
- » Legal Metrology Department
- » Calibration Laboratories

Any pre-existing accreditation organizations (national or regional)

Other organizations

- » Quality associations
- » Inspection agencies (for example import inspection agencies)
- » Testing laboratories (for example medical, food testing, or environmental laboratories)
- » Product, system, or personnel certification bodies operating in the country
- » Industry, Trade and/or Service sector

- associations
- » Users (for example contractors, utility companies, private or public sector purchasing/procurement organizations, exporters, etc.)
- » Consumer organizations
- » Private sector organizations

Challenges and mitigation measures

The main challenge is to ensure that the relevant

stakeholders are identified in a timely manner and are able to provide their inputs into the QP development process. It is not realistic to expect that ALL stakeholders will be identified right at the beginning, prior to the establishment of the Steering Committee (See Step 1.4). This topic should, however, be a routine agenda item for the Steering Committee, not only in terms of its own membership, but also to ensure that the relevant stakeholders are invited to participate in the various consensus-building activities (including workshops and commenting on the draft QP).

STEP 1.4 ENSURE APPROPRIATE OVERSIGHT, AND DEFINE ROLES AND RESPONSIBILITIES

Intended outcome

Steering Committee membership and Terms of Reference defined (see Annex 2); drafting group appointed and a tentative schedule and work division circulated.

Why?

To provide oversight and support for the process, in terms of strategic planning and control, and the assignment of roles and responsibilities for the more operational aspects of the QP development. The Steering Committee can be important in order to ensure that there is sufficient diversity in the leadership and oversight to provide continuity to the process in the event of changes to the political landscape. The Steering Committee can eventually form the basis of a National Quality Council (NQC) or equivalent for the subsequent implementation and maintenance of the QP (See Stage 5).

Who?

Overall coordination should be a high-level official in the relevant Ministry (ideally the “Champion” defined in Step 1.2), and this person should Chair the Steering Committee. This is likely to be someone from the ministry responsible for the implementation of the WTO TBT Agreement in the country, or if the country is not yet a member of the WTO, then the Ministry responsible for trade and industry, or equivalent.

It is important to include high-level officials from other stakeholder ministries, especially those that develop and implement technical regulations.

If international consultants are to be used, it is important to assign clearly the national focal point(s) who will coordinate their interactions with the Steering Committee and other stakeholders.

The typical initial composition of the Steering Committee might include the following:

State bodies involved in regulatory and support/ planning activities, such as:

- » Ministry of Trade and Industry (or equivalent)
- » Ministry of Agriculture and/or Fisheries
- » Ministry of Health
- » Ministry of Defence
- » Ministry of the Environment/Energy/Water
- » Ministry of Finance

Representatives of Industry and/or Service sector organizations such as:

- » National Chamber of Commerce
- » National Industry Confederation
- » National Planning Commission (or equivalent)
- » Hotel and Tourism Associations

Consumer organizations

Representatives of any pre-existing QI institutions, such as:

- » National Standards Body
- » National Metrological Institute
- » Accreditation Body (or Accreditation Focal Point)
- » Governmental and/or Private sector laboratories (National Laboratory Association)
- » Management systems and product certification body associations

What and How?

One of the main activities of the Steering Committee should be to establish and monitor a high-level project plan for the development of the QP and its subsequent implementation, using the key stages and steps outlined in Table 1 (modified as appropriate), to define the “Who, What, When, Where and How” for the various stages. As mentioned previously, there is no fixed prescriptive approach or pre-defined time lines, and each country will need to develop its own plan based on the context in which the QP is being developed or updated. It is, however, vital that such a plan IS established, so that progress can be monitored and any corrections to the plan made

as the work progresses, using a “Plan-Do-Check-Act” (PDCA) approach.

Factors that can affect the project plan include:

- » The motivations for developing and formalizing the QP (including any specific time pressures)
- » The current status of the Quality Infrastructure components (including ad-hoc activities that may have been implemented prior to the establishment of a formal QP)
- » Resources (and in particular the human and financial resources) available to contribute to the project
- » National priorities
- » The demographics of the country (in terms of size, overall industrial policy, infrastructure and level of economic development)
- » Any political considerations (including political stability, upcoming elections and/or other factors that could influence the consensus-building process)

In addition to the high-level strategic planning and coordination, it is also important to define an operational drafting team who will actually “do the work” involved in the development of the QP, under the guidance of the Steering Committee. This drafting team will typically be responsible for the following activities (among others):

- » Coordinating and documenting the national context and potential priorities for the QP development (Stage 2).
- » Publicizing and organizing workshops for stakeholders at various stages during the awareness and consensus-building process and ensuring that feedback is adequately recorded and addressed.
- » Developing the first draft of the QP (Stage 3), taking into consideration the results of the previous stages, and the implications for the subsequent implementation of the QP.
- » Circulating the draft QP (via the SC) for comment among stakeholders.
- » Encouraging, stimulating and facilitating feedback in a structured and documented manner.
- » Incorporating feedback into the revised draft(s) as appropriate.
- » Liaising with legal advisors/Attorney General Office (or equivalent) to frame the QP within the appropriate legislative format and wording.
- » Ensuring that there is good communication when the QP is circulated for public consultation.
- » Coordinating/facilitating drafting of the final version of the QP, taking into consideration technical, administrative and legal aspects.
- » Publicizing the formal approval of the QP among stakeholders.

- » Preparing and following-up the implementation plan (to be initiated in parallel with the development of the QP).
- » Liaising with any International Consultants who might be involved in the development of the QP.

Challenges and mitigation measures

The main challenge is to ensure that the Steering Committee members are the appropriate ones and are prepared to participate actively in the process. Some typical challenges and their mitigation measures include the following:

Low participation and/or involvement in SC meetings

- » If the decision to initiate the development or revision of the QP and the associated concept paper (See Step 1.2) have been approved at an appropriate level of government, participants will be encouraged to attend the steering committee meetings and are likely to be more positive and receptive towards it.
- » Meetings need to be planned well in advance, and dates/times should not be changed, even if some key members are unable to attend. (Note that in some cases international consultants may need to report to meetings of the Steering Committee, and might not be available at short notice).
- » Each SC member should appoint a substitute who is able to represent them when needed.
- » Provide for remote participation (web-based or by teleconference).

Inadequate preparation for meetings

- » The ministry responsible for the coordination should ensure that there are sufficient resources available and that operational responsibilities are defined for planning and follow-up of meetings.
- » Inappropriate formulation of the SC
- » The SC should include a fixed set of core members in order to provide continuity, but its composition can be modified as the project evolves.
- » Consideration should be given to ensure the SC is inclusive in nature (for example, in terms of gender), and that no single stakeholder or institution dominates.
- » After an initial kick-off meeting, and once a full analysis has been made of the relevant stakeholders (see Step 1.3), other representations might need to be added to the Steering Committee.
- » The SC should not aim to include ALL stakeholders and should not be seen as a substitute for stakeholder workshops.



STAGE 2

Conduct strategic planning

“Failure to plan means planning to fail”

Benjamin Franklin

The QP articulates the government’s intentions regarding QI development in the country. The QP does not exist in a vacuum; it has to be promulgated within the context of industrial development, export promotion, trade promotion and other similar government policies, strategies, and priorities as well

as international commitments - see Figure 3. During the strategic planning stage, it is also important to begin thinking about the cost/benefit relationship of any changes to the QI that the policy will imply, and the resources that are likely to be required for its subsequent implementation.

FIGURE 3: CROSS-CUTTING NATURE OF THE QP



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Strategic planning is therefore a key stage in the development or revision of the QP, and the following

steps are important in order for the project to succeed:

STEP 2.1 UNDERSTAND THE CONTEXT AND DEFINE STRATEGIC OBJECTIVES

Intended outcome

An understanding of the current status of the overall national quality infrastructure, and a definition of the objectives and priorities for the QP and QI within the overall framework of the national development strategies.

affect the ways in which the QP is developed and implemented. Both national and international factors need to be considered when developing the QP, and a good understanding of these is important to help define priorities.

Why?

Every country presents a different situation, so it is important to establish the specific factors that

Who?

The initial context analysis should be conducted under the guidance of the Steering Committee, and subsequently presented, reviewed and modified as

necessary during the stakeholder workshops. Inputs from consultants can be useful at this stage, in order to provide an independent and impartial perspective.

What and How?

The context in which the country seeks to implement its QP includes the following factors⁵:

International context - This can include, for example:

- » key drivers and global trends that can have an impact on the country's aspirations and objectives
- » relationships with, perceptions and values of international business partners and the international community in general (including cultural, social, political, legal, regulatory, financial, technological, economic, and natural factors as well as the competitive environment) that are considered relevant
- » international agreements to which the country is a signatory

National context - This can include, for example:

- » governance, structure, roles and accountabilities
- » policies, objectives, and overall development strategies
- » capabilities in terms of resources and knowledge (e.g. capital, time, people, processes, systems and technologies)
- » information systems, information flows and decision-making processes (both formal and informal)
- » relationships with, and perceptions and values of national stakeholders
- » the country's culture
- » standards, guidelines and models adopted by the country
- » form and extent of contractual relationships and adherence to international norms and conventions

This means that there is no single uniquely-defined starting point for the development of the QP that applies for all countries - this will depend on the maturity of their existing Quality Infrastructure, national priorities and the needs and expectations of the relevant stakeholders.

It is convenient to think in terms of a "Hierarchy of Needs" and apply these to the various stages of the evolution of a Quality Infrastructure that is appropriate for the current level of development of the specific country. This suggests a "quality infrastructure

⁵Adapted from the definition given in ISO/IEC Guide 73:2009 (Risk management – Vocabulary)

journey" that prioritises initially the very basic needs of society, and that progresses through the various levels, with examples as follows⁶:

- » **Level 1:** focus on quality Infrastructure aspects that address issues such as water purity, food safety and health care. Examples may include the need for technical regulations (preferably based on international, regional or national standards), testing and medical laboratories and the associated metrological capabilities.
- » **Level 2:** Initiatives aimed at achieving the legitimate objectives of government; protection of the health and safety of citizens, supported by appropriate standards, technical regulations and conformity assessment services. Quality infrastructure to include basic legal metrology to provide confidence in local trade, and conformity assessment services to verify compliance with technical regulations (for both local production and imports).
- » **Level 3:** Initiatives aimed at promoting exports and facilitation of international trade. Participation in regional and international standards development; availability of internationally-recognized conformity assessment facilities, a national focal point for accreditation, and a NMI focused on legal and industrial metrology with traceability to international standards for the relevant measurements (prioritized according to the national needs).
- » **Level 4:** QI initiatives aimed at providing confidence in initiatives other than trade, that will contribute to Sustainable Development (energy efficiency; water efficiency; greenhouse gas emissions, IT compatibility and interoperability, etc). Development of metrological capabilities in these areas, and international recognition of conformity assessment activities (national accreditation focal point; recognition of regional accreditation initiatives).
- » **Level 5:** Innovative QI initiatives aimed at emerging technologies (nanotechnology; biomedical technologies etc), with the associated capabilities in scientific metrology.

Following a similar philosophy to define the national priorities and assign resources accordingly will facilitate the development of the QP and its subsequent implementation, rather than deciding priorities solely based on the availability of international donor funding.

Challenges and mitigation measures

Some governments in developing countries still

⁶ It is important to emphasize that the quality infrastructure should be defined in such a way that it can evolve to address these changing priorities over time as the country develops. The same core infrastructure should be capable of addressing both national and international policy objectives over the course of time, with the corresponding levels of recognition.

pursue national policy goals which frequently undermine trade, leading to a poor overall business environment. These goals may have been influenced by vested interests to limit competition or profit, by regulatory authorities, by interest groups lobbying for stronger national regulations than the prevailing international norms and/or “turf wars” between different stakeholder groups. This can be overcome by comprehensive engagement and awareness-building among stakeholder groups of the wider international implications of the QP.

Another challenge is to ensure that the QP is appropriate for the reality of the country, and that it can be used as a building block for future development. In terms of the prioritization of policy objectives, it is important to relate these to the overall maturity of the specific country, and avoid being too ambitious for the current stage of development. Whilst international funding initiatives are of course to be welcomed, these may not always align with the current level of maturity, thereby diverting national counterpart resources from where they may be better utilized.

STEP 2.2 CARRY OUT A GAP ANALYSIS OF THE EXISTING QUALITY INFRASTRUCTURE

Intended outcome

Clear assessment of the current capabilities of the QI, and the key areas to be addressed in the QP in order for it to achieve its objectives (see Step 2.1)

Why?

To define the starting point for the development of the QP. If the country does not have the appropriate QI (or does not make the best use of its current resources), it will not be able to achieve its overall development objectives.

Who?

It is important that the Gap Analysis be conducted by people who are impartial, who are seen to be impartial, and who are not inhibited from expressing concerns or criticisms of the current QI and its component institutions. Typically, the Gap Analysis will be led by an international consultant (or consultants), familiar with the national and international context in which the QI has to be effective, with unrestricted access to and collaboration from relevant interested parties.

What and How?

By definition, a Gap Analysis is a comparison between the desired state of the QI (to be defined in the QP) and the current (actual) situation. Prior to the initial drafting of the QP, therefore, the following activities should be carried out:

- » Analysis of the policy environment in which the QP has to be established.
- » Identification of the current QI in the country, especially its strengths, weaknesses and challenges compared to the objectives that have been defined in Step 2.1. This includes not only the institutions themselves, but the ways in which they collaborate and interact as a coherent whole.
- » The views of the clients of the QI institutions should be sought, especially the private sector,

given that the QI institutions may be unable to provide objective information themselves.

- » Analysis of the technical regulation regime, and custom and practices amongst the many responsible Ministries. The technical regulation regime should be benchmarked against criteria defined by the WTO TBT and/or SPS Agreements, the practices of major actual and potential trading partners, and the country’s sustainable development commitments.

Use of the SWOT methodology (“Strengths, Weaknesses, Opportunities and Threats”) and PESTLE analysis (Political, Economic, Social, Technological, Legal and Environmental) are tools that can be appropriate at this stage.

Other tools that can be useful in conducting specific gap analyses for QI are available from various international development partners.

Challenges and mitigation measures

By far the biggest challenge in conducting the gap analysis is for those involved to avoid the inevitable attempts to influence their findings in favour of “vested interests”. These vested interests might include “territorial” issues from existing institutions that could face streamlining, mergers or even extinction, or arise due to commercial interests of private sector organizations.

The best way to mitigate against these challenges is by the appropriate selection of a *team* (not an individual) to conduct the gap analysis. This should ensure that their competence and impartiality is recognized and accepted beyond doubt by all interested parties. Desirable behaviours for the assessment team include the following (according to the recommendations of ISO 19011 for an independent management system audit, which are considered to be relevant here):

- » ethical (fair, truthful, sincere, honest and discreet)
- » open-minded (willing to consider alternative ideas or points of view)
- » diplomatic

- » observant
- » perceptive
- » versatile (able to adapt to different situations)
- » tenacious (persistent and focused on achieving objectives)
- » acting with fortitude (able to act responsibly and ethically, even though these actions may not always be popular and may sometimes result in disagreement or confrontation)
- » culturally sensitive

It is, however, important to ensure that the team works well together, and that there is good complementarity between a variety of individual profiles.

STEP 2.3 CONDUCT PRELIMINARY CONSULTATIONS WITH STAKEHOLDERS

Intended outcome

The objectives to be achieved by the QP are endorsed and the Gap Analysis of the QI is confirmed/agreed by stakeholders, who are then involved, consulted and take an active role in the development of the QP.

Why?

This is another key stage in the development of a truly consensus-based QP, and if sufficient attention is given to the planning and execution of these consultations (typically “workshops”), in such a way that they really reach out to those who will be affected by the QP, then its subsequent implementation will be greatly facilitated. This facilitates awareness-building and the “buy-in” of the stakeholders, and a sense of ownership by seeking their inputs, rather than presenting them with a “fait-acompli” that is to be imposed. As stated in the UNIDO Publication “Guide for the Development of National Quality Policies”, **“Special attention should be given to the consultation process, as the implementation of a QP will seriously impact many entities in both the public and private sector. Continuous and wide consultations throughout the whole development process is therefore indicated, e.g. it would not be good enough just to circulate the final draft for public comment after it has been developed in isolation by a small group of government officials.”**

Who?

The Steering Committee should be responsible for overall coordination of these initial consultations/workshops, with operational support from the Drafting Group.

What and How?

The planning of initial awareness-building workshops is key to ensuring that the relevant stakeholders are given the opportunity (and have the resources) to participate BEFORE the first draft of the QP is prepared. Good communication ahead of time, and the provision of appropriate funding is particularly important for SMEs and consumers, who may not be organized into formal, well-funded associations, and are therefore more difficult to reach. Consideration could be given to having consultations with individual stakeholder groups and/or conducting workshops in geographic locations other than the capital city.

It is also important that any workshops be professionally facilitated, in order to ensure that all participants have an opportunity to voice their opinions. Workshops should be an opportunity for those who are directly involved in the coordination of the QP development to LISTEN, in order to ensure an approach that takes into consideration the views and concerns of all the relevant stakeholders, in a balanced way.

Together with the workshop invitations it is advisable to inform potential participants about the objectives of the workshop. This could be a “white paper” based on the original Concept Paper (see Stage 1) to explain what is being planned, the main issues that need to be addressed (taken from the gap analysis), the aims and benefits of formalizing the QP for the country, and an overview of the stages involved. This will help to put the workshop in its proper context, and, if signed by someone at a high level of government (for example a Minister), will encourage participation. It will also provide an appropriate focus for this stage of the consensus-building process and make these initial consultations with stakeholders more efficient.

Some of the issues that it is useful to highlight typically include the effect of globalization, challenges faced by enterprises, the current situation regarding the QI and the technical regulation regime, and the need for a clear commitment of government. It is also important to stimulate discussion about potential options (public, private or public/private partnerships) for the various components of the QI. See also Step 2.5.

A typical agenda for a one-day Workshop is given in Annex 3.

Challenges and mitigation measures

One of the biggest challenges is to stimulate and facilitate the participation of relevant stakeholders in the initial consultations and workshops. The difficulties in this respect can be seen in some of the Case Studies presented in this Practical Tool.

There are a number of ways in which this potential lack of participation can be mitigated, including:

- » Planning and announcing workshops well in advance, including, for example, circulating a “save-the-date” announcement before the definitive workshop programme becomes available. It is unrealistic to expect good participation if invitations are only issued less

than 20 days in advance.

- » Ensuring the participation of key opinion-formers and influential government officials / international consultants to provide keynote speeches that will attract stakeholders to take part.
- » Providing funding for some stakeholder groups to participate, as necessary (travel; accommodation).
- » Providing funding so that the consultations can be done in selected geographic locations other than the capital city.

As the QP preparation needs to reach out a large number of stakeholders, it is also useful to document

thoroughly the outcomes of consultative sessions and workshops. The ongoing work and results can thus be edited for clarity, and either posted on a website or circulated to stakeholders (especially those in remote regions). Similarly, transparency requires that virtually any view or position be accounted for in the QP development process. Stakeholders will certainly have divergent senses of priorities; these need to be reconciled and in some cases could be accommodated by adapting the time-line for the QP implementation. When the consensus-building process leads to a proposition being discarded, this entry should nevertheless be mentioned (in Annexes listing, for example, all comments and their treatment during the development process).

STEP 2.4 DEVELOP AND ANALYSE OPTIONS

Intended outcome

An understanding of the different ways in which the QI might be structured, how other countries have chosen to define their QPs, the lessons that can be learned, and the most appropriate solution for the country.

Why?

It has to be emphasized once again that there is no “one-size-fits-all” approach for the QI, and this should be appropriate to the context of the particular country in which it is being implemented. Instead of simply copying what others have done, it is likely that the best QP will be a hybrid solution that incorporates the good practices of several possible alternatives. In order to be able to make an informed decision, therefore, it is important to understand the different options that might be available.

Who?

This analysis should be conducted by a group of stakeholders specifically assigned to the task, supported as necessary by International Consultants, and under the overall guidance of the Steering Committee.

What and How?

Extensive guidance is provided in the UNIDO Quality Policy Technical Guide for the Development of QPs⁷, and will not be repeated here.

The first policy issue to be decided by a country relates to the options for the legal status of its QI institutions. These range from pure government departments to organizations that operate in accordance with normal business profit motives. The government also has to decide the extent to which it can afford to establish independent (governmental) institutions, and the commercial freedom it will allow such organizations to provide services at market-related prices. This is particularly the case for accreditation, where the

demand from conformity assessment services in the country might not justify setting up a national accreditation body, (AB) and it might be more cost-effective to rely on regional or international ABs to provide the necessary oversight of the local conformity assessment bodies, with a local “accreditation focal point” responsible for coordination.

There are several ways in which these various factors can be taken into consideration when analysing the options available, and the choice of the appropriate methodology will depend on the time and resources available. These include:

- » Study tours to countries with a similar national context (probably, but not necessarily within the same geographical region), to learn from their experiences (what went well, and what they would do differently if they could start over again).
- » Analysis of the various case studies presented in this practical tool.
- » Discussions with international agencies and consultants, who should be encouraged to present options, and not a single proposed solution.

Challenges and mitigation measures

As discussed previously in Step 2.3, the structure of the QI can include public, private or public/private partnerships. In some countries two or more functions may be conducted by sister organizations within the same overall structure, in which case real or potential conflicts of interest will need to be considered. This is particularly true in cases where standards bodies have previously taken on the role of “de-facto regulators”. Other examples of real or perceived conflicts may arise when sister organizations under the same parent organization are involved in standards development and the provision of conformity assessment services; accreditation and metrology; accreditation and regulatory activities, and other such combinations.

It is therefore important to define a structure that recognizes and manages these potentially

⁷Quality Policy Technical Guide, UNIDO, Vienna, 2018

conflicting roles and responsibilities for topics such as standardization, technical regulation, conformity assessment, metrology and accreditation among the various QI institutions. If these multiple activities are all centralized under a “single roof” (for example in small economies), then it is important to implement the appropriate “firewalls” between them. Whilst these firewalls may effectively manage real conflicts of interest, however, perceived conflicts of interest become almost inevitable and may also need to be taken into account.

On the other hand, if, for example, inspection and laboratory capacities are established by a number of different ministries in order to service their regulatory framework, this may lead to significant duplication of resources. Most institutions refer to their mandates in accordance with the Acts that established them, so a review of the content of these Acts in a holistic manner is important.

In order to initiate the consensus-building process (Stage 3) it may be appropriate to produce a second ‘White Paper’ resulting from the initial consultations and from strategic considerations that can be widely circulated for feedback. All options and their consequences should be included, and any unresolved issues clearly identified.







STAGE 3

**Prepare draft Quality Policy and
build consensus**

Consensus does not just “happen”. It needs to be guided and driven in stages, and the drafting team that is responsible for preparing the text of the QP must be prepared to go through various iterations until the

final version is agreed. The steps that are outlined in this stage will help to guide the consensus-building process.

STEP 3.1 ESTABLISH TECHNICAL SUBCOMMITTEES TO PREPARE PARTS OF THE QUALITY POLICY AS NEEDED

Intended outcome

Subject matter experts (in the form of technical subcommittees, task forces, working groups etc.) are designated and are able to contribute to specific topics that are relevant for the formulation of the QP.

Why?

The QP needs to address the (often numerous) viewpoints of society and the various stakeholder perspectives. It is important not only to focus exclusively on industrial / manufactured products, but also to address the needs of the food, healthcare, and service sectors (including tourism). These are unlikely to be covered by WTO/TBT rules, but they are frequently subject to SPS measures and technical regulations, and require a functioning QI to be properly implemented. It is also pertinent to consider the country’s commitments to environmental and social issues that might be involved in meeting sustainable development goals and targets.

It is unlikely that the Steering Committee or the drafting group will themselves have sufficient in-depth knowledge of each of these domains, and access to this expertise can be achieved by forming smaller technical groups of subject-matter experts (including consultants, where appropriate).

Who?

Experts in the specific topics that are relevant to the QP within the country’s context.

What and How?

There are inevitably a number of different perspectives of the various stakeholders for the content of the QP, and after the initial awareness-building workshops it may be appropriate to establish specific technical subcommittees (reporting to the Steering Committee), each with a clearly defined remit. These could include, for example, groups focused on:

- » Specific components of the QI and the relevant stakeholders (those who will be involved in or affected by the QP)
- » International trade (and specifically, WTO/TBT) implications of the QP
- » Food and agriculture, with a focus on SPS aspects
- » Implications for technical regulations, and the interactions between the various regulatory bodies
- » Sustainability issues (economic, social and environmental)

Challenges and mitigation measures

There may be some incompatibilities between the perspectives and recommendations of the different technical subcommittees. This can be mitigated by strong coordination and conflict resolution by the Steering Committee, which should meet regularly to review progress.

Whilst the objective should always be to achieve full consensus, it is important to adopt working / decision rules that have been defined and agreed at the beginning of the process.

STEP 3.2 PREPARE A FIRST DRAFT OF THE QUALITY POLICY

Intended outcome

A first working draft of the QP that can serve as a basis for further discussion and consensus building.

Why?

To form the foundation for initial stakeholder consultation and subsequent refinement of the draft QP.

Who?

This should be coordinated by the drafting team (see Stage 2), using inputs from the Technical Subcommittees, under the guidance of the Steering Committee, and with technical assistance (as necessary) from development partners and consultants.

What and How?

The initial drafting should take into consideration the following inputs:

- » The strategic direction for the QI that has been defined by the Steering Committee
- » Outputs from the initial awareness-building workshop(s) with stakeholders
- » Inputs from the Technical sub-committees (Step 3.1)
- » Preliminary implementation considerations for the QP (including realistic budgets and other resource implications).

The important topics to be addressed in the early drafts of the QP include:

- » Introduction with the justification for, and benefits of, the QP in the particular national context (See Stage 2).
- » Outline of the QI structure of the future. This should deal with all the public entities and provide space for private sector involvement.
- » Agreement on a common approach for the development of standards i.e., according to the requirements of Annex 3 of the WTO TBT Agreement.
- » Development of a common approach to technical regulation to be followed by all Ministries.
- » Definition of responsibilities of government, the private sector, NGOs and development partners.

Extensive examples of topics that are typically addressed in the QP and sample text are provided in the UNIDO publication “Quality Policy Technical Guide” and will not be repeated here. Some examples of experiences in the development and implementation of national and regional quality policies are presented in the Case Studies in Annex 6.

Even at this early stage of drafting, it is important to start thinking about the implementation strategy for the QP, once approved. This should include the prioritization of objectives, a tentative time-frame to achieve them, and the financial and resource implications. Whilst the QP should of course be forward-looking, it is vital that its effective implementation is realistic in the short-to-medium term and feasible in terms of the country’s (primarily economic) context.

Challenges and mitigation measures

It is important that the first draft is not perceived as being a definitive document developed by International Consultants or by a small group of government officials, for “rubber-stamping” by the stakeholders. This can be mitigated by providing possible alternative text and solutions, and by framing the draft in a way that allows for stakeholders to be able to comment on their preferred approach.

Another challenge is to avoid getting “bogged down” in legal text. The first draft of the QP should focus on technical/administrative aspects of the various topics to be included within the specific national context. It is of course advisable to have legal expertise available during the drafting process, but the legal language can be refined at a later stage.

The QP should be a “living document” that can (and should) be reviewed periodically as the country evolves (see Stage 5), and revised as necessary. This is not something that can realistically be done on a frequent basis, though, since it will involve a review by the relevant interested parties, consensus-building and submission for formal approval once again. With this in mind, it is important to make the QP as forward-looking as possible, to reflect possible future changes in its overall context.

STEP 3.3 INITIAL CONSULTATION

Intended outcome

All relevant stakeholders have been given the opportunity to participate and have provided their inputs into the formulation of the QP. These inputs are analysed and addressed in a structured, balanced way.

Why?

In order to build consensus and improve the first draft, and to facilitate the subsequent adoption and implementation of the QP.

Who?

Wherever possible, the same stakeholders that took part in the initial awareness-building workshop (Stage 2) should be invited to contribute their comments, as well as any additional stakeholders identified during the initial drafting. It may be appropriate at this stage

to include other stakeholders from outside the country, including (for example) regional QI organizations, Development Partners and others.

What and How?

There are a number of ways in which this might be done, ranging from “proforma” communications in governmental/ministerial media (with the objective of merely fulfilling the obligation to consult stakeholders), to more proactive methods aimed at stimulating greater input that can be taken into consideration when refining the draft. Clearly, the latter option is the most desirable (under normal circumstances), and the time and effort at this stage will be well spent, to ensure that any potential anomalies or problems are identified and resolved prior to the final public consultation for the QP. Such proactive circulation for comment can be achieved in the following ways:

- » By conducting Workshops to present the first draft to an audience of key stakeholders. A typical programme for this workshop is shown in Annex 4.
- » Formally circulating the draft to all participants of the initial awareness-building workshop, with a request to forward to other stakeholders as appropriate.
- » Making the draft available on an appropriate website, supported by press releases, and requesting the key stakeholders to place hyperlinks to the document on their own websites.
- » Highlighting any issues where specific comments and/or inputs are requested.
- » Allowing sufficient time for stakeholders to discuss the draft with their constituent members, in order to provide considered opinions. It is unlikely that this can be done effectively in less than 60 days (depending on the time of year).
- » Making available a “comments template” to oblige the stakeholders to be specific about the text in the QP to which their comment refers, and

requiring suggestions for alternative text, rather than simply criticizing existing text. An example of such a table is presented in Annex 5. Note that the use of such a template will also facilitate the collation of comments for subsequent analysis.

- » Sending a “friendly reminder” that comments are due about 2 weeks before the deadline.

Once the commenting period has expired, all comments received should be collated in order to provide inputs into Step 3.4.

Challenges and mitigation measures

There is always a risk that comments submitted by individuals purporting to represent a specific stakeholder group might not be representative. This can be mitigated by establishing clear communication channels and allowing sufficient time for consensus-building. It is particularly important to engage with SMEs and consumer organizations, and to facilitate discussion fora for them to be able to reach a consensus position among their constituents prior to submitting comments.

STEP 3.4 INCORPORATE FEEDBACK AND INCLUDE LEGAL TEXT

Intended outcome

Draft QP in a semi-final format that can be submitted for further evaluation and endorsement among stakeholders.

Why?

In order for stakeholders (including those in government) to be able to evaluate the full implications of the QP, and to be able to make additional comments prior to publication.

Who?

Drafting team, with inputs from the Steering Committee, legal/legislative experts and international consultants, as needed.

What and How?

As a result of Step 3.3, the coordination/drafting team should be able to collate and categorize the comments received and resolve many of them without the need for further consultation (particularly those of an editorial nature). Any systematic or contentious issues that are raised (potential “showstoppers”) should, however, be brought to the attention of the Steering Committee for consideration and, where appropriate, discussed “one-on-one” with the relevant stakeholders in order to understand better their concerns. If these concerns can be resolved (without generating additional potential conflicts with other stakeholders), the drafting team can incorporate the changes into a final draft QP to be

discussed at a public validation workshop, or series of workshops.

If the concerns cannot be resolved, or if conflicting viewpoints of diverse stakeholders cannot be reconciled, then it may be necessary to repeat Steps 3.1 – 3.4.

At this stage, the coordination/drafting team should seek assistance from lawyers/legislators and/or request support from the lead Ministry to incorporate the appropriate legal text and format in order to prepare the final draft QP for consideration by government.

Challenges and mitigation measures

Achieving full consensus among all stakeholders will always be a challenge. It is important to remember the definition of “Consensus” given in ISO Guide 2 (“Standardization and related activities -- General vocabulary”) which does not necessarily mean that there will ultimately be unanimity.

“Consensus” is defined as “general agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments”

This should be emphasized from the outset of the project, and reinforced as the QP development process progresses.

STEP 3.5 PUBLIC CONSULTATION AND/OR 'VALIDATION' WORKSHOP

Intended outcome

All citizens and stakeholder groups are given a final opportunity to provide inputs on the content and implications of the QP.

Why?

This is essentially the last stage in the consensus-building process, and should provide an opportunity for any final concerns to be voiced, based on the outputs of Step 3.4, before the QP is finalized.

Who?

It is to be expected that each country will have its own process for the assignment of responsibilities for public consultation on proposed government legislation. The Steering Committee is expected to liaise with the appropriate authorities.

What and How?

As with Step 3.3 (initial consultation on the Draft QP), the most proactive way of conducting a public consultation involves extensive communication using traditional and electronic means as well as social media.

Each country is likely to have its own well-developed criteria for public consultation on regulatory and/or policy issues, and these need to be followed if the QP is to have the appropriate level of approval and legitimacy.

According to Rodrigo and Amo⁸, (in the context of regulations, but equally appropriate here) *“Consultation systems should be designed according to each country’s context, legitimised by the inclusion of all groups of interest and by transparent procedures, while fighting to improve information quality and spreading the use of the new information technologies. Regulators should ask themselves: ‘Have all stakeholders had the opportunity to present their views?’. Regulations should be developed in an open and transparent fashion, with appropriate procedures for effective and timely input from stakeholders such as affected businesses and trade unions, other interest groups, or other levels of government”*

As with Step 3.3, it is convenient to request commenters to use a format similar to that shown in Annex 5, in order to facilitate the subsequent compilation and analysis.

Challenges and mitigation measures

As with all stages in the QP development process, the key challenge is to ensure that all the relevant interested parties (citizens and stakeholder groups) are given the opportunity to provide their comments. This can be mitigated by the use of extensive and comprehensive communication strategies, including traditional methods as well as social media, including an explanation of the objectives for the QP in terms of national development strategies.

⁸ Rodrigo, D, and Amo, P A, “Background Document on Public Consultation”, OECD Regulatory Policy Division, Public Governance and Territorial

STEP 3.6 PREPARE “FINAL” VERSION OF THE QUALITY POLICY AND IMPLEMENTATION PLAN

Intended outcome

A final version of the QP together with the Implementation Plan that can be officially endorsed by stakeholders and submitted for formal government approval and adoption.

Why?

This is the final step in the technical consensus-building process, after having incorporated any proposals from the public consultation.

Who?

The drafting group should prepare the final draft, but at this stage it is also advisable for the draft to

be endorsed by the Steering Committee before it is formally submitted for government approval (Stage 4).

What and How?

Once the comments from the public consultation have been collated and reviewed, their relevance and importance to the QP should be analysed, and the draft QP adapted accordingly.

The QP should now be at a stage where it has passed through several consensus-building stages, and has been refined to address all technical, administrative and legal issues. If the process thus far has been conducted in a transparent and proactive manner, the final draft of the QP should be relatively simple to produce.

The Implementation Plan should also be finalized together with the conclusion of work on the QP. This plan should include the prioritization of objectives, a tentative time-frame to achieve them, stakeholder responsibilities, and consideration of the financial and resource implications.

Challenges and mitigation measures

At this stage it is vital to take great care when incorporating comments from one specific stakeholder group, in order to avoid generating new concerns from other stakeholders. If insurmountable new issues are introduced at this late stage, then it could be necessary to repeat Stage 3 in its entirety, with the associated delays that would ensue.



STAGE 4

Advocacy, lobbying and approval

In order to provide legitimacy to the QP, it has to be incorporated as part of the overall policy landscape, and formally published and adopted.

STEP 4.1 ADVOCACY AND ENDORSEMENT

Intended outcome

All those who were involved in the consensus-building process are given the opportunity to see the “end result” and to give their endorsement of the QP.

Why?

To ensure full ownership of the QP by all stakeholders and facilitate its subsequent implementation.

Who?

Steering Committee (coordination)

What and How?

After the final draft of the QP has been prepared by the Drafting Group and endorsed by the Steering Committee, a final workshop (or workshops) should

be conducted to inform the relevant stakeholders of the outcome and to present the QP in its final version for validation. This workshop(s) can also be used as a basis for the promotion and advocacy for the QP, and to begin to focus attention on the implementation plan, once the QP has been formally adopted (See Stage 5).

Challenges and mitigation measures

If any concern or opposition is raised at this late stage and cannot be resolved, or if conflicting viewpoints of diverse stakeholders cannot be reconciled, then it may be necessary to repeat Stage 3. If the process thus far has been conducted in a transparent and proactive manner, though, this situation should not arise. In some cases, however, it might be necessary to continue with the publication of the QP in pursuit of the public good, despite ongoing resistance from specific stakeholders with vested interests that are irreconcilable and inconsistent with international best practices.

STEP 4.2 OBTAIN FORMAL APPROVAL

Intended outcome

The QP is formally approved for publication by the appropriate government authorities.

Why?

To provide legitimacy to the QP.

Who?

It is to be expected that each country will have its own process for the approval and publication of government legislation. The Steering Committee is expected to liaise with the appropriate authorities.

What and How?

After the validation workshop, the now final draft QP can be introduced into the political level for consideration and final approval by Cabinet / Parliament or equivalent as appropriate. Thereafter, the approved QP should be made widely available as a public document of government.

It is important to ensure that the QP foresees any changes that might be necessary to the overall legislative programme in order to align such legislation

with the policy objectives. Any conflicting requirements that affect other national policies (such as industrial, environmental, or trade policies) should already have been identified and addressed at an earlier stage (Stages 1 – 3).

Although the QP should be “apolitical” it does not exist in a vacuum, and it would be appropriate to judge the political climate (for example in the case of upcoming elections) to accelerate or delay its presentation to Government for approval, as needed.

Challenges and mitigation measures

This is where things can stall and the formal adoption process be delayed. If the development of the QP and its associated Implementation Plan has been genuinely collaborative and inclusive, however, the QP should already have the backing of the relevant government ministries who will support it for formal approval.



STAGE 5

**Implement, monitor and
review the Quality Policy**

The effective deployment of the QP throughout the various components of the QI can be a gradual adaptation of the existing infrastructure, or it may need

a complete overhaul and “re-engineering”. In either case, the following steps need to be taken:

STEP 5.1 PUBLISH QUALITY POLICY

Intended outcome

Formal adoption of the QP as part of overall government policy.

Why?

In order to provide legitimacy to the various components of the QI.

Who?

The way in which the QP is published can vary significantly from one country to another, with differing responsibilities. Once again, the Steering Committee has an important role to play in guiding the QP through the formal publication process.

What and How?

Depending on the specific legislative requirements in each country, the publication of the QP might, for example, be in the form of:

- » The confirmation or review of existing legislation and the drafting of new bills to go through the approval process
- » A formal law, published in the Official Government record
- » An administrative decree
- » A Policy Document issued and endorsed by the Government
- » Others according to the country context.

Challenges and mitigation measures

If there are any political changes that might affect the formal publication of the QP (for example upcoming elections, that might result in delays due to changes in government policy), it is important to foresee this possibility as early as possible in the QP development process. In this way, the schedule and forecast timing of publication can be adapted as appropriate, and avoid becoming a political issue.

STEP 5.2 COMMUNICATE, PROMOTE AND IMPLEMENT

Intended outcome

All national stakeholders and international partners are aware of the new QP and are able to adapt accordingly. QP translated into other languages (English; French etc) as necessary.

Why?

The QP will not be useful if it is not effectively implemented, and implementation may take a number of years. Hence, it is good practice that a high-level implementation plan is developed together with the policy itself (see Stages 2 and 3), including associated implementation and oversight responsibilities as well as “ball-park” budget forecasts and priorities. Some countries have national planning agencies which have issued guidelines to be followed when policy documents are prepared.

Who?

Once the QP has been published, the Steering Committee typically will transform to take on another

role; that of a “Quality Council” (or some similar designation), with the responsibility for overseeing the effective implementation of the policy. At this stage, it might be appropriate to review the membership of the Steering Committee, as it takes on this new role, to make sure it is still representative of the key stakeholders (relevant ministries and state authorities, non-governmental quality organizations, conformity assessment service providers, industrial, service sector and employees’ associations, as well as trade unions and consumer organizations, for example).

What and How?

It is almost inevitable that some pre-existing public QI institutions will need to undergo heavy re-engineering, implementing changes to their organisational structures, responsibilities, sources of income, etc. The corresponding legislation designating their roles and responsibilities will most likely have to be totally reviewed or developed from scratch. All of this needs to be coordinated at the highest level possible and will require public funding. The oversight responsibility must therefore be clearly identified, with accountability at least up to ministerial level.

A typical Implementation Plan should typically identify:

- » “Quick wins” – actions that can have an almost immediate impact, with minimal investment.
- » Short-term actions (implemented over the course of 1 – 3 years) that may be primarily administrative in nature and do not require significant investment.
- » Longer term actions (3 – 5+ years), that might require significant capital expenditure in, for example, buildings and equipment.

The Implementation Plan should not, however, include a detailed list of activities over the life of the QP because there are potentially so many uncertainties with regard to their implementation. Instead, it should assign priorities to the various short and long-term actions mentioned above, with emphasis on those that are most appropriate for the national/regional context. Yearly workplans by sector or functions should be prepared and used, and regular (yearly) updates on progress and achievements produced and circulated.

It is important that the publication of the QP be accompanied by appropriate communications to ensure that all stakeholders are made aware, not only of the Policy itself, but also of its implications. These communications can include:

- » Press releases
- » Seminars and workshops
- » Interviews with key government personnel (TV, social media)
- » Prominent placement on government and private sector websites
- » Publication of “Success stories” (from other countries – see, for example the Case Studies in Annex 6 of this Practical Tool)
- » Explanatory / guidance documents on (for example) “The new QP – what will it mean for “xxx” industry; “yyy” services; testing laboratories; medical laboratories; regulators; importers” etc.

Challenges and mitigation measures

- » “The devil is in the detail” is a common phrase that particularly applies at this stage. If, however, the QP has been developed in an open and transparent manner, much of the necessary groundwork (including forecast budgets) for its effective implementation is likely to have been initiated in parallel with the development itself.
- » Realistic forecasting of resource needs (including Human Resources, time and funding).

STEP 5.3 MONITOR, REVIEW AND IMPROVE

Intended outcome

The effective implementation of the QP is subject to ongoing coordination, and is able to adapt as necessary to keep pace with changes to the national and international context under which it was initially developed.

Why?

Factors affecting the implementation of the QP need to be coordinated and monitored, in order to ensure its effectiveness. The world is continually changing, and the QP and QI need to adapt accordingly and may have to be modified over time.

Who?

The Steering Committee (now transformed into the “Quality Council” or some other similar denomination)

What and How?

It is important to specify the authority and powers of the Council, and this must be done at the highest levels of government. Even if the council only has an advisory role, it should be assigned to a specific Ministry and

have a legal mandate to operate. If, for example, it has to promote the harmonization or consolidation of activities of institutions that come under other senior ministries, and induce them to behave or invest in a certain manner, it will need clear authority to be able to do that.

It is recommended that the implementation plan be considered as the “Planning” stage of an overall “Plan-Do-Check-Act” (PDCA) cycle, with periodic (annual) verification of progress against clearly defined milestones and performance indicators, with the identification and implementation of any necessary corrective actions.

As mentioned in Stage 3, it is vital that the QP be considered as a “living document” that can (and should) be reviewed as the country evolves beyond its short- and medium-term goals, and as its overall national context changes. In addition to monitoring progress against the implementation plan, therefore, the Steering Committee (now the “Quality Council”) should periodically review the QP for its ongoing suitability and adequacy. This could typically be scheduled for once every five years.

Challenges and mitigation measures

Ensuring the effective implementation of the QP

requires the continued engagement of the relevant stakeholders, ongoing communication, and ensuring that the appropriate resources continue to be available. It is therefore essential that the initial budgets be realistic (sources of information might include countries with a similar national context) and that their effective utilization is closely monitored.

There may also be potential conflicts introduced by the need to align national legislation with the new / revised QP. These conflicts can be avoided by the involvement of the relevant stakeholders from an early stage of the QP development process, to ensure that there are no “surprises”.

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ANNEX 1

Example of an Initial Concept Paper⁹

The following is one example for the development of a briefing note, that could be modified according to the specific needs of each country:

- » *In the present environment of increased globalization, a well-defined Quality Infrastructure that includes standardization, metrology and the associated conformity assessment components (including accreditation, testing, inspection and certification) has a very important role to play in technological progress, productivity and trade. Increasingly, global purchasers demand goods and services that meet rigorous and advanced acceptance criteria, not only to ensure that such products and services integrate flawlessly with others in the supply chain, but also to satisfy customer expectations and to comply with a maze of technical regulations in importing countries.*
- » *These same elements of the Quality Infrastructure also assist in the achievement of [Country's] legitimate objectives for national technical regulation, in order to protect the health and safety of its citizens, and the environment.*
- » *In order to compete successfully in developed markets, [Country's] industry, especially the SME sector, faces a formidable array of challenges. Over and above the logistics, management and financial issues, one of the major stumbling blocks is the attainment of demonstrable product and/or service quality demanded by regulatory authorities, as well as the major players in the markets. Hence, in order to fully exploit the possibilities of foreign markets, [Country's] industry needs to have access to an internationally recognized, but supportive national quality infrastructure that can provide the required independent evidence of product compliance.*
- » *[Country] realizes that its national quality infrastructure and its technical regulation regime may not yet be developed to their full potential, and that they are not fully harmonized with those of its major trading partners. It follows that these need to be addressed in a holistic manner, as they cut across many ministries, agencies and stakeholders. Hence, as [Country] plans/upgrades the national quality infrastructure, enhances its technical regulation regime and organizes the relationship between the two, it must decide how to cater for technological and quality needs, minimize environmental, health and safety externalities, and*

at the same time avoid unnecessary and costly barriers to trade.

- » *In recognizing the above realities, the government of [Country] commits itself to re-engineering, strengthening, upgrading and maintaining the national regulatory, standardization, metrology, accreditation and conformity assessment infrastructures to facilitate trade, enhance exports, accelerate economic development and reduce poverty while at the same time protecting the health and safety of its people and the environment as a logical outflow of the overall objective of [vision for the next decade], [trade or development policy], [poverty reduction policy], and the UN 2030 Sustainable Development Goals.*
- » *This overall definition of the framework and the roles and responsibilities for the National Quality Infrastructure is normally formalized in a Quality Policy, approved at the highest level of government. The effective implementation of the QP is expected to improve the competitiveness of both public and private sector organizations and contribute towards export enhancement, overall economic development, environmental protection and control of sub-standard products in the local market*

⁹ Kellermann, M., "Thoughts on a National Quality Policy", Physikalisch-Technische Bundesanstalt, 2011

ANNEX 2

Example of the Terms of Reference for a QP Steering Committee

PROJECT: DEVELOPMENT OF THE QUALITY POLICY IN (COUNTRY)

Background

As a result of the recommendations of the National Industrial and Economic Growth Policy published by the government on xx/yy/zzzz, the project to revise/develop a Quality Policy (QP) has been initiated. The objective of the QP is to define the roles and responsibilities of the various public and private institutions that will comprise the Quality Infrastructure, in order to support the overall strategy for economic growth and sustainable development in the most cost-effective way.

Purpose

The Steering Committee will be the governing body of the project to develop and implement the QP, and will provide strategic leadership and governance oversight to ensure its successful and timely completion.

Roles and responsibilities

The Steering Committee is expected to give key policy direction, liaise with governmental and development partners, guide the Drafting Committee and the various Technical Sub-committees in the execution of the project, and ensure effective oversight by receiving regular reports, reviewing the results of project evaluations that will take place periodically, and providing guidance to keep the project on track. It is expected to take the lead to promote policy dialogue and advocacy on issues identified by the Project, at Ministry level.

The specific responsibilities of the Steering Committee are to:

- » Approve the work plan and budget for the preparation of the QP, to ensure that resources are deployed to their most productive use;
- » Monitor the implementation of the QP development project ensuring that any strategic changes are undertaken in a timely manner so that the project achieves its goals;
- » *(If applicable)* Liaise with development partners to ensure that interventions from international experts will help to make the project more effective in delivering its intended outcome and impacts;
- » Review and endorse the recommendations for implementation of initiatives presented by the QP.

The Steering Committee will be supported in its role and functions by xxxx *(for example, the NSB)* that will serve as its Secretariat and prepare briefing papers and progress reports, providing all the necessary information and evidence it needs to make informed decisions.

This will include;

- » Circulation of relevant material to members in good time for preparation for each meeting.
- » Drafting of agendas for agreement with the Chairperson.
- » Keeping minutes and recording decisions made.
- » Reporting on progress with all aspects of the QP project implementation.

Membership

The Steering Committee will be made up of representatives from both public and private sector stakeholders including *(typical examples)*:

- » Ministry of Trade and Industry (Chairs the Steering Committee);
- » Ministry of Agriculture and Fisheries;
- » Ministry of Health;
- » Ministry of the Environment and/or Energy;
- » Ministry of Finance;
- » National Chamber of Commerce;
- » National Planning Commission (or equivalent);
- » National Industry Confederation;
- » Hotel and Tourism Association;
- » Consumer protection Bureau ;
- » National Standards Body;
- » National Association of Testing Laboratory;
- » National Association of Exporters;
- » National Metrology Institute;
- » National Accreditation Body (or Accreditation Focal Point).

Meetings

- » The Steering Committee is expected to meet quarterly and members will need to devote additional time reviewing project documentation;
- » Interim meetings may be convened as necessary by teleconference or electronic communications.

Governance:

- » The quorum for the Steering Committee will be X number of member institutions;

- » The Steering Committee will aim to achieve consensus on decisions made. In the event this proves impossible, decisions may be made by simple majority vote amongst participating members. In the event of a tie, the Chairperson will have an additional casting vote;
- » Individual members must be committed and must ensure continuity in participation to all meetings. Changes in individual participation should be notified to the Steering Committee in writing by the affected institution.

ANNEX 3

Example of Agenda for Initial Workshop on the Development of a Quality Policy

Time	Topic	Presenter(s)	Comments
09:00 – 09:30h	Opening Ceremony	High-level government officials; any international experts who might be involved	Important to start on time!
09:30 – 10:15h	Keynote address – “The importance of developing a formally adopted, consensus-based Quality Policy”	QP “Champion” (See Stage 1), or International Expert (also to act as Workshop facilitator)	This should address the specific national context (using outputs from Step 2.1)
10:15 – 10:30h	Networking Break		
10:30 – 12:30h	Components of a Quality Infrastructure, and current status of (Country) <ul style="list-style-type: none"> » Standardization/technical regulation » Metrology » Accreditation » Conformity Assessment 	Invited National or International Subject Matter Experts	
12:30 – 13:30h	Networking lunch		
13:30 – 15:00h	Breakout groups <ul style="list-style-type: none"> » Discuss current situation of each QI component, and topics for consideration/prioritization in the formulation of the QP. » Discuss Gap Analysis, preliminary action plans and potential options 	Introduction by workshop facilitator; All participants	Divided into groups (max 8 people per group).
15:00 – 15:30h	Networking Break		
15:30 – 17:00h	Feedback	Designated spokesperson for each group	Each group needs to document its feedback for subsequent input into the draft QP (Stage 3)
17:00 – 17:30h	Summary and closing	Workshop facilitator	

ANNEX 4

Example of Agenda for Consensus-building Workshop

Time	Topic	Presenter(s)	Comments
09:00 – 09:30h	Opening Ceremony	High-level government officials; any international experts who might be involved	Important to start on time!
09:30 – 10:15h	Keynote address – “Preparation of the Quality Policy” (or similar)	QP “Champion” (See Stage 1), or International Expert (also to act as Workshop facilitator)	This should outline the key points of the draft QP, and the process to be undertaken to build consensus
10:15 – 10:30h	Networking Break		
10:30 – 12:30h	Implications for <ul style="list-style-type: none"> » Standards development » Regulators » Metrology Institutes » Accreditation » Conformity Assessment <ul style="list-style-type: none"> » Laboratories » Certification Bodies » Inspection Agencies 	Invited National Experts	Wherever possible, these presentations should be made by respected local experts, who are supportive of the QP in their respective areas of activity.
12:30 – 13:30h	Networking lunch		
13:30 – 15:00h	Breakout groups <ul style="list-style-type: none"> » Discuss the draft QP and its implementation <ul style="list-style-type: none"> » opportunities » challenges » priorities » timelines 	Introduction by workshop facilitator; All participants	Divided into groups (max 8 people per group).
15:00 – 15:30h	Networking Break		
15:30 – 17:00h	Feedback	Designated spokesperson for each group	Each group needs to document its feedback for subsequent input into draft QP and the draft implementation plan (Stage 5)
17:00 – 17:30h	Summary and closing	Workshop facilitator	

ANNEX 5

Template for submission of comments

Submitter	Clause/ Subclause/ Annex/ Figure of Draft QP	Paragraph/ Line number	Type of comment (Editorial/ Technical)	Comment (justification for change)	Proposed change
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ANNEX 6

Case studies

NIGERIA: The development process of the Nigeria National Quality Policy (NNQP)

Context

Under the National Quality Infrastructure Project for Nigeria (NQIP), the underlying objective is to:

- » establish an appropriate framework for the development and publication of national standards, to clearly define the role of the national standards organization at the pinnacle of all standardization work, and to involve all relevant stakeholders in the process;
- » expand the use of accreditation into all of the national regulatory environment;
- » provide a framework for the establishment of conformity assessment service providers in both the public and private domain, that are, in addition, technically competent;
- » strengthen the national metrology system and, in particular, raise the profile of metrology as a significant component in Nigeria's overall market activities;
- » give clear mandates and elaborate a proper division of work regarding the administration of technical regulation, TBT (Technical Barriers to Trade) and SPS (Sanitary and Phytosanitary) measures and;
- » provide a national quality culture promotion strategy that builds on existing efforts.

Process of the Quality Policy formulation

Do the Groundwork

The Nigeria Quality Infrastructure Project supports the development of the missing standards and accredited testing and certification bodies within the framework of the National Quality Infrastructure (NQI) in order to improve the quality of products and services exchanged in the Nigerian, regional and international markets.

To this end, the Honourable Minister of Industry, Trade and Investment on 26 September, 2013, inaugurated a National Quality Policy (NQP) Drafting Committee. The policy drafting committee, after two months of review of existing policy options and preliminary consultations, identified the need for wider consultation.

Conduct Strategic Planning

Based on the recommendation of the National Quality Policy (NQP) Drafting Committee, a National Steering Committee (NSC) was constituted on 27 January, 2014 by the Honourable Minister of Industry Trade and Investment. The Committee was given the following terms of reference (ToR):

- » To review and harmonize existing Quality related policies in Nigeria
- » To prepare a draft NQP that is acceptable to all stakeholders
- » To support the approval and implementation of the NQP

As part of the governance process and the demonstration of ownership and commitment to the course, the Honorable Minister of Industry Trade and Investment was appointed as the Chairperson, while the standardization body, the Standards Organization of Nigeria (SON) became the Technical Secretariat. NSC had forty-eight (48) institutions as members drawn from Ministerial Departments and Agencies (MDAs) and members of Organized Private Sector (OPS).

Preparation of Draft QP/Consensus Building

To carry out the objectives of the NSC, 20 technical secretaries have been appointed from SON staff, including a Chairperson.

To work with the technical secretaries, five technical subcommittees were formed with Chairpersons selected to head each sub-committee, namely, Accreditation, Standardization, Technical Regulations, Conformity Assessment, Metrology, and one non-technical sub-committee on Information and Communication.

Implementation of the first objective of the committee which is to review and harmonize existing policies in Nigeria, was led by a UNIDO National Lead Expert on Policy in 2014. Each sub-committee chairperson worked with members of the steering committee and made submissions on their respective mandates to the technical secretariat. Sub-committee submissions by respective Chairpersons formed the basis for the preparation of the draft QP.

All submissions from the sub-committee Chairpersons

were received by the technical secretaries. A draft of the policy was developed by the technical secretariat, and ready for international peer review, which was carried out by a UNIDO International Expert in 2014.

Advocacy, lobbying and approval

After the review and validation of the international peer-reviewed zero draft version of the QP by the National Steering Committee, public consultations followed in November 2014, in various geopolitical regions of the country, namely, Calabar (Southern Region), Enugu (South East Region), Minna (North Central Region), Sokoto (North West Region) and Abuja where the final public validation was concluded.

All feedback from the public were cross reviewed with the zero draft for finalisation and thereafter presented to the Director General of the Standards Organization of Nigeria by the Chairperson of the Technical Secretariat. The DG SON, subsequently presented the final draft to the Honourable Minister of Industry Trade and Investment for an onward memorandum: "Prayer for Ratification" to the Federal Executive Council (FEC) and its subsequent presentation for legislation as a single executive bill.

Implement, monitor and review (continually improve)

In December, 2014, a published version of the Green Paper was presented to the public and copies were disseminated. During the waiting period for FEC ratification, there were some major changes in the political terrain, as a new government was voted into office in 2015, which required some changes in some parts of the document, specifically in section I, on "Vision, Objectives, and Drivers for the NQP", these parts were reviewed to allow the draft policy to be aligned with the new focus of the government.

Challenges

The issues encountered during the development stages, were as follows:

- » Stakeholder apathy in the development process of the policy, due to the fear that their regulatory power could be affected.
- » Stakeholders' non-conformance with technical advice on role and separation of institutional duties under a quality infrastructure framework.
- » Delayed buy-in of top leadership, due to poor understanding of the subject of a quality infrastructure national framework and its benefits or linkage to the country's priorities.
- » Change in government priority due to transition in government, which led to the delay of policy ratification by the Federal Executive Council.

The issues were addressed as follows:

- » Increased bilateral meetings with all key

stakeholder institutions and top government officials responsible for decision making.

- » Exposure of key stakeholders through study tours to countries with similar economic reality like Nigeria, where such quality infrastructures exist.
- » Publication of educative materials on the components of the project and its benefits, in fact-sheets, newsletters, featured appearances on radio and television programs.
- » Training of members of the media (print and electronic) on the subject of quality infrastructure and the method of coverage of the project implementation activities.
- » Implementation of a stakeholder engagement initiative, through the engagement of solely dedicated project focal person(s), situated and working for NQIP within stakeholder institutions for smooth implementation of activities.
- » Cost estimation of the implementation of the QP for an informed buy-in of the Federal Government.

Lessons learned

- » In the first year of the project, embark on massive nationwide campaigns on the subject of quality, to industry stakeholders, academic institutions, major market places, state governors and relevant federal government offices to secure buy-in.
- » Develop a brand communication strategy and provide funds to implement it as a full roll-out campaign to provide soft landing for the project implementation team; such that it demonstrates the linkage of the subject of quality infrastructure and its various benefits to both government, organised private sector, and the regular individual.
- » Make provisions for the extension of the project timeline for stakeholder engagement, consultations and advocacy in case the project cycle crosses into an election/transition year, to make up for lost time. Every new government needs a fresh round of advocacies and engagement to re-align their support for the project.

PAKISTAN: The development of Pakistan National Quality Policy (NQP)

Context

Under the EU funded Trade Related Technical Assistance (TRTA II) Programme implemented by UNIDO, the following was the context within which the development of Pakistan's NQP was pursued:

The technical regulation regime in Pakistan is of an ad-hoc nature, fragmented, non-compliant with international requirements and with overlaps among various regulatory agencies. This in turn undermines the integrity of products, creates bureaucratic chaos for suppliers and adds unnecessary transaction costs, rendering products non-competitive. In addition, the Government lacks the capacity collectively to review the existing technical regulation regime and the national quality infrastructure due to their complex interwoven nature. This however is obligatory in order to take full advantage of the increases in world trade by complying to the WTO Agreements on Technical Barriers to Trade (TBT) and Sanitary and Phyto-sanitary (SPS) measures.

The Government of Pakistan thus realizes that, in order to improve its industrial development and export performance, it must implement policies that facilitate compliance of manufactured products with global quality standards, meet expectations of consumers and facilitate integration of local industries into global value chains. UNIDO, under the TRTA II Programme, provided the Government of Pakistan with technical assistance in developing a NQP in order to integrate better with the international community, and establish policy frameworks conducive to social, ecological and market-economic development.

Process of the Quality Policy formulation

Needs Assessment

The National Quality Infrastructure (NQI) developments in Malaysia, Turkey and Vietnam were studied and the Pakistan situation was benchmarked against them. Moreover, the responsibilities of the national standards body, namely the Pakistan Standards and Quality Control Authority (PSQCA) were reviewed. Focus group workshops were held to gain inputs from wider stakeholder groups. One of the key initiatives to improve the quality infrastructure, as identified by a variety of stakeholders during discussions and workshops, was the development and implementation of a NQP.

Working Group Establishment

The Ministry of Science and Technology (MoST) established a Working Group including members from NQI organs and the Ministry of Commerce to draft the text of the National Quality Policy under the guidance of UNIDO.

Conduct Strategic Planning

UNIDO, in consultation with the Working Group, formulated a road map for the development of the NQP. Five policy objectives were identified during the consultation sessions and working group meetings. Four possible scenarios on a future re-engineering of the National Quality Infrastructure of Pakistan were developed and shared with MoST and representatives of the current NQI organizations to: (i) render the NQI acceptable to the international community, (ii) better serve the needs of the authorities and the private sector in Pakistan, and (iii) facilitate its financial sustainability in the long run.

Preparation of draft QP/consensus building

First Draft Of NQP: A workshop was held to garner the first detailed input for the development of draft text for the 1st working paper of the NQP. UNIDO developed a draft content list for the NQP based on international good practices and knowledge of Pakistan together with a short paragraph on the rationale for each article/sub-article. The draft content list was finalized in consultation with the members of the working group. Thereafter, the first working draft of the NQP was developed and circulated within MoST and members of the Working Group for review and comments.

Second Draft of NQP was developed and circulated to more than 80 stakeholders by MoST. The NQP Working Group established by MoST met under the Chairmanship of the Joint Technical Advisor, MoST and various comments from stakeholders were considered. A number of relevant comments were incorporated in the document, the list of regulatory authorities was completed, the vision was drafted and the document was completed. This completed 2nd Working Draft was presented to the 2nd National Quality Forum.

The 1st Working Draft Implementation Plan was developed based on the 2nd Working Draft of the NQP. The 1st Working Draft was discussed in the Working Group, and its modalities were presented in detail. The Policy Objectives and Measures taken from the NQP were further developed with activities, outcomes, timelines, budget and responsible implementation agency. The Working Group was requested to consider carefully all of these and provide recommendations as to whether the activities and outcomes were complete with regard to the Policy objectives and measures, the timeline reasonable, and to develop the initial budget figures. MoST and the Working Group members agreed to this draft implementation plan.

Advocacy, lobbying and approval

UNIDO, in collaboration with the Government of Pakistan, organized advocacy meetings on the NQP

with private and provincial stakeholders. Meetings with selected industrial companies indicated that it will be a major undertaking to convince provincial authorities, after devolution of power to provinces, that this would be in the interest of Pakistan as a whole. The provincial authorities were approached on the notion of a NQP. The re-organization of PSQCA, Pakistan National Accreditation Council (PNAC) and National Physical & Standards Laboratory (NPSL) as apex NQI organizations of Pakistan with specific service provision mandates was also welcomed. The notion that implementation of technical regulation should not be undertaken by the apex NQI organizations and that it could be undertaken at the provincial level, was enthusiastically supported.

The text of the draft NQP and Technical Regulations Framework, along with the implementation mechanism and associated budget, was finalized by the Working Group in consideration of some further comments from important stakeholders such as the Pakistan Business Council. This document was approved by MoST and presented to the Prime Minister's Cabinet for consideration, approval and implementation.

Implement, monitor and review (continually improve)

The NQP was approved by MoST and presented to the Prime Minister's Cabinet for consideration, approval and implementation. The NQP contains an implementation mechanism and associated budget.

Challenges

- » There is a trust deficit between the industry (private sector) and public NQI. Industry perceives NQI as the rent extractors and believes that NQI services should be provided free of charge.
- » NQI must connect with the international systems of standards, metrology and accreditation along with leveraged government investments in the QI.
- » Regulatory bodies have not been separated from NQI service providers, generating conflict of interest and weakening trade negotiations.
- » Common technical regulation approach across all ministries related to standards, conformity assessment, regulatory authorities, and sanctions has not been implemented and allocation of TRs to specific ministries has not been demarcated.

The issues were addressed as follows:

- » By raising the quality consciousness amongst both the suppliers and the consumers and fostering a quality culture in public life and throughout society. National Quality Forums were conducted to increase interaction between industry and public NQI so as to realize the importance and role of all the stakeholders in a cohesive NQP environment.
- » Staff of the NQI were trained on different aspects of NQP and TRs to instil adaptation of NQI best practices of benchmarked countries.

- » Restructuring of national standards body has been proposed to separate the roles related to regulatory and NQI service provider.
- » Strengthening the technical regulation regime through the implementation of a national Technical Regulation Framework to meet requirements such as the WTO TBT and SPS Agreements and international best practices, including the establishment of cooperation amongst the NQI institutions and the national regulatory authorities, and with their international counterparts.

Lessons learned

- » While proposing NQI and TR strategy by benchmarking good practices, local conditions should be given due consideration e.g. priority areas, availability of skilled manpower and resources;
- » As the NQI has a crosscutting role in various ministries and institutes, it requires attention from a high political level to create sustainable synergy;
- » The private sector should be seriously involved in shaping the NQI;
- » While initiating the NQI, composition and level of responsibility of the governance structures have to be clearly elaborated;
- » Seek appropriate international recognition for all service providers;
- » Conduct thorough surveys on the existing analytical labs (number and status) to determine the issue of capacity and competence to gain accreditation;
- » There should be clear demarcation between the role of regulatory bodies as enforcing bodies and NQI elements as service providers;
- » Adopt appropriate NQI reform strategies to sustain the NQI functions e.g. twinning, liaising, outsourcing and change averters versus change agents;
- » Consider the nature of decisions and the extent of their influence i.e. incremental or radical change;
- » Overall regulatory reform is absolutely necessary.

ECOWAS: The development process of ECOWAS Regional Quality Policy (ECOQUAL)

Context

The ECOWAS Common Industrial Policy (WACIP), adopted in 2010, identified the development of Standardization, Quality, Accreditation and Metrology (SQAM) amongst its ten priority Programmes to be implemented. The SQAM Programme was expected to facilitate the development of intra – trade within West Africa and the ECOWAS/UEMOA-UE Economic Partnership Agreement which is being prepared to develop trade between EU and the ECOWAS region.

Furthermore, the Regional Steering Committee (RSC) meeting of the transitional phase of the SQAM Programme held on the 8th and 9th of May 2012 in Abuja, Nigeria, strongly recommended the elaboration of the ECOWAS Quality Policy during the transitional phase which ended in December 2012, in order to take advantage of the implementation of the next phase (West Africa Quality System Programme, WAQSP) to operationalize the Policy and the West Africa Quality Infrastructure.

Process of the Quality Policy formulation

Do the groundwork

The adoption of ECOQUAL (ECOWAS Quality Policy), was deemed necessary to prepare a state of play vis-à-vis the existence of the national quality policies in the member countries. The ECOQUAL was necessary for the harmonization and alignment of the QIS in the region, in particular the next steps would be:

- » Ensure that existing quality policies or those to be prepared are in line with ECOQUAL
- » Support countries with draft quality policies for their technical or official adoption
- » Provide necessary assistance for the formulation and technical adoption of the National Quality Policies for countries without any NQP
- » Support all the countries for the development of action plans, with budget, in view of their National Quality Policies effective implementation

Those activities were than to be supported by the West Africa Quality Support Programme (UNIDO is an implementing agency). A team of experts at regional and national level was deployed to coordinate and facilitate the progress. The identification of key stakeholders was carried out depending on the each individual country context.

Conduct Strategic Planning

After initial discussions in Dakar, and based on the works of international expert, a national consultation

workshop on the strategic options of the ECOWAS QP was organised in each ECOWAS Member State in June 2012.

The objective of these two-day workshops was to:

- » inform and involve all stakeholders of ECOWAS Member States in the elaboration process of the ECOWAS Quality Policy;
- » collect national viewpoints on the selected options.

Based on the country reports of these workshops a draft ECOWAS QP document was prepared.

Preparation of draft QP/consensus building

The draft policies were prepared in 7 key Steps:

Step 1: Sensitization Workshop on the Regional Quality Policy, held in Accra, Ghana

Step 2: Organization of two national concertation workshops on the strategic options of the ECOWAS QP.

Step 3: Preparation of the draft ECOWAS QP taking into account national expectations.

Step 4: Dissemination of the draft document in the Member States and to the ECOWAS Commission legal department, to collect their observations and comments on the form and content of the document.

Step 5: Finalization of the draft document by incorporating the observations of the Member States; and then submission to the ECOWAS Commission.

Step 6: Meeting of National Experts on the ECOWAS QP from the 17th to 19th October 2012 in Niamey, Niger, followed by a meeting of Ministers in charge of Quality. The draft ECOWAS Quality Policy (ECOQUAL) was validated by the Ministers who recommended to the ECOWAS Commission that it be adopted by the statutory bodies.

Step 7: Adoption of the ECOWAS Quality Policy (ECOQUAL) and its implementation framework through SUPPLEMENTARY ACT A/SA.1/02/13 at the 42nd Ordinary Session of the ECOWAS Authority of Heads of State and Government, held from the 27th to 28th February 2013, in Yamoussoukro, Cote d'Ivoire.

Advocacy, lobbying and approval

All ministries in charge of quality and national focal points of the West Africa Quality Support Programme (WAQSP), mainly national standards bodies, were involved in the advocacy strategy for the official adoption of the QP. To support this strategy, the WAQSP

has taken advantage of the organization of ECOWAS meetings of ministries in charge of quality, to present the Programme achievements, and to organize side events focusing on the importance of adoption of national quality policies. All opportunities to meet the national ministers in charge of industry, to advocate for the adoption of policies and implementation plan were realized. Up to date, 7 countries out of 16 (including Mauritania), have officially adopted their policies. The ECOWAS Commission, with the support of the WAQSP, is continuing the advocacy. In this context, the ECOWAS Commission organized in January 2018, the first edition of the ECOWAS Quality Infrastructure Forum (ECOQUAF). During the forum, one of the main topics discussed was the development of quality policies. Representatives from several ministries in charge of quality were able to present the state of play of the NQPs in their countries.

- » The Mechanism to fund the Implementation Plan needs to be identified at national & regional level.
- » A key factor of success, is to ensure an anchoring of the policy at the highest public decision making level within the country.

Implement, monitor and review (continually improve)

It is expected that, with the support of the action plans and budget available, each country develops specific national plans and finds relevant financial resources for the implementation of the adopted NQPs. The WAQSP has secured a small budget for each country to continue advocacy at national level or to start implementing some key activities of the action plan of the NQP. This will contribute to give the necessary visibility to the merits to have a NQP, notably the direct positive impact of a QP on consumers.

To facilitate the dissemination, the WAQSP has started the drafting of a directory containing the set of officially adopted NQPs, as well as the ECOWAS QP. Furthermore, all policies will be available on the ECOWAS Quality and Industry database that is being created. It should be recalled that every five years the effectiveness of the implementation of ECOQUAL should be assessed. To this end a first review was done during the ECOQUAF 1st edition.

Challenges

Issues encountered and resolved in the formulation of QPs:

- » In some countries, the approval of the NQP was done without the drafting of an implementation plan (IP). Hence, the WAQSP has supported the designing of IPs for 15 countries.
- » A misunderstanding with other ministerial departments vis-à-vis- ministers of industry taking the leadership of the drafting of the Policy was also noted. The WAQSP has proposed the setup of a small coordination structure located at the Head of State, Vice President or Prime Minister's Office.

Lessons learned

- » The NQP drafting process should be inclusive.
- » The coherence with other policies at national & regional level, namely Food Safety, Quality in Health Department, etc. is a must.



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