

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION



INTERNATIONAL NETWORK ON QUALITY INFRASTRUCTURE

# QUALITY POLICY Guiding Principles



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# QUALITY POLICY Guiding Principles

Vienna, Austria 2018

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### List of abbreviations

BIPM	Bureau International des Poids et Mesures
CA	Conformity Assessment
CIPM	Comité International des Poids et Mesures
CIPM MRA	The CIPM Mutual Recognition Arrangement
GRP	Good Regulatory Practice
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
IDP	International Development Partners
ILAC	International Laboratory Accreditation Cooperation
INetQI	International Network of Quality Infrastructure
ISO	International Organization for Standardization
ITU	International Telecommunication Union
QP	Quality Policy
MSME	Micro, Small and Medium Enterprises
QI	Quality Infrastructure
OIML	International Organization of Legal Metrology
QP	Quality Policy
RIA	Regulatory Impact Assessment
SME	Small and medium-sized enterprises
SPS	Sanitary and Phytosanitary Measures
ТВТ	Technical Barriers to Trade
TFA	Trade Facilitation Agreement
UN	United Nations
UNIDO	United Nations Industrial Development Organization
WTO	World Trade Organization



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- » Bureau International des Poids et Mesures (BIPM)
- » The International Accreditation Forum (IAF)
- » The International Electrotechnical Commission (IEC)
- » The International Laboratory Accreditation Cooperation (ILAC)
- » The International Organization for Standardization (ISO)
- » The International Trade Centre (ITC)
- » The International Telecommunications Union (ITU)
- The International Organization of Legal Metrology (OIML)
- » The United Nations Economic Commission for Europe (UNECE)
- » The United Nations Industrial Development Organization (UNIDO)

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Successful and sustainable exports to the global marketplace are increasingly predicated by demonstrable compliance with international quality requirements for goods and services. An appropriate and internationally recognised Quality Infrastructure (QI) supports both domestic and global producers and consumers in the cost-effective fulfilment and proof of their mutual quality needs and aspirations. It also stimulates industrial development, trade competitiveness, innovation and the efficient use of resources, while ensuring food safety and protecting human health and the environment.

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.

One of the challenges that developing countries face is that, as the various components of the quality infrastructure develop, they may evolve independently and overlap in functions and responsibilities. One of the basic cornerstones for ensuring good governance of the QI is therefore the quality policy. Quality policies are a means to reform, consolidate, refine, and maintain an effective QI.

UNIDO has played a leading role in promoting good governance whilst assisting developing and transitional

Li Yong, UNIDO Director General

economies in developing modern QI systems, at both national and regional levels. Recognizing that appropriate interventions at the policy level are critical to strategically address QI related challenges, and ensure good governance, UNIDO has already supported 26 countries across three regions to develop their quality policies as a means to strengthen, consolidate and reform an effective and efficient QI.

To further complement these efforts, UNIDO and INetQI spearheaded the development of the Quality Policy Guiding Principles. The Guide offers policymakers guidance towards creating fundamental conditions to ensure good governance to help them find holistic and needs-driven solutions to facilitate access to international markets and integration into global value chains. This document has been drafted, reviewed and finalized through a broad consensus-building process.

An appropriate QP and the associated QI system can positively and substantially contribute to the UN Sustainable Development Goals (SDGs). UNIDO together with INetQI are committed to promote and accelerate inclusive and sustainable industrial development in developing economies with the aim of enhancing their trade capacities to achieve the SDGs.

In addition to this publication on 'Quality Policy – Guiding Principles', there are two other complementary publications that have been developed; 'Quality Policy – Practical Tool' and 'Quality Policy – Technical Guide'. This set of three guiding documents is aimed at supporting QI practitioners and policy makers to design and develop robust, holistic, and demanddriven QI systems.

Menh Malugoist Pikson

Merih Malmqvist Nilsson, INetQI Chair

# 1

# **Executive Summary**

Responsible governments want to realize more of the benefits of globalization for their nationals. Countries therefore increasingly seek to compete on quality, and not just price, to reach larger markets, gain greater access to international value chains to benefit their local industries, and create more affordable choices for their consumers. These objectives would be delivered more effectively by governments using a carefully considered, coherent and holistic strategy. Any subsequent interventions require political, administrative and technical considerations to be satisfactorily addressed.

The challenge therefore is to achieve such objectives

within a framework of good governance that promotes transparency when instituting requirements, eliminates discrimination against producers, and prohibits the introduction of higher than necessary safety or deceptive practice prevention measures for the consumer. Sophisticated technical requirements from current or potential trading partners are also a major concern in some countries where they can constitute a challenge to export-led economic growth.

To successfully access the global marketplace and/ or meet local technical regulatory requirements, including those intended to protect human, animal or plant life and health from imported pests and diseases, producers increasingly need reputable evidence that their products and services meet regulatory, technical and other requirements. There is therefore a corresponding drive to create a more robust, adaptive, cost-effective, user-friendly and sustainable quality infrastructure (QI) system that provides access to appropriate standardization, metrology, accreditation, conformity assessment, and market surveillance capability and capacity, along with attendant education and promotion programmes. An appropriate QI system can therefore assist governments and enterprises in managing their quality competitiveness and regulatory system. In numerous cases, QI has developed without coordination in response to often unforeseen needs. This in turn has led to the evolution of QI systems in a reactive, fragmented and thus dysfunctional manner. Many governments are therefore reconsidering the overall arrangement, and associated interaction, of their national QI-related organizations as they seek to create a more integrated, fit-for-purpose, efficient and user-friendly system. A quality policy (QP)-based approach has therefore gradually emerged with the aim of addressing this important set of needs. As a government instrument, a QP can specify the objectives of the national QI system in establishing and maintaining a suitable technical foundation for initiating and facilitating further development, including more effective trade, private sector growth and dissemination of information, and raising awareness about the principles and practices of quality management. The availability of a formally recognized QP to guide the QI can also contribute significantly to the successful achievement of many other government policy and wider societal objectives and in particular the Sustainable Development Goals (SDGs). These include industrial development, competitiveness in global markets (including participation in international value chains), efficient use and reuse of natural and human resources, food safety, health, the environment and climate change.

This document is intended to assist those responsible for initiating and developing a QP by providing a set of best practice principles to stimulate interactions that seek all-encompassing and need-focused solutions that address local needs and facilitate international integration.



# Context

Evidence from various development projects increasingly confirms that a suitable QI can play an instrumental role in economic and social development, through technology transfer and increased global trade. For producers, manufacturers and service providers to successfully access, and compete in the global marketplace they need to overcome many challenges. These include accessing funding, management expertise, appropriate logistical infrastructural support and skills. Enterprises situated in developing economies, especially micro, small and medium enterprises (MSMEs), also need costeffective access to an internationally-recognized QI. Such an infrastructure provides them with independent attestation of their produce, product or service that is increasingly required to successfully penetrate the markets of more developed trading partners and overcome technical barriers to trade (TBT). There are also many domestic benefits associated with investing in and maintaining a suitable QI. These include increased productivity, leading to job growth, increased consumer protection and greater innovation. Such QI institutions and needs-based services can be developed at national and/or regional level.

Many development agencies, and other organizations, have already assisted developing countries to implement some elements of the QI required to enable them to successfully access foreign markets. There is also an increasing realization that similar effort is required to support national regulatory bodies as they seek to sustainably address the sanitary and phytosanitary (SPS) requirements intended to protect human, animal or plant life and health from imported pests and diseases. This aspect is especially pertinent for those countries aiming to increase exports in agricultural produce and related products given the potential adverse effects of foreign pests and diseases on local crops and produce. Current activities could enable even greater foreign market penetration if they were better coordinated and harmonized at the national and regional level through a suitable QP.

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

#### 2.1 A QUALITY POLICY IN SUPPORT OF THE UN SUSTAINABLE DEVELOPMENT GOALS

Establishing an appropriate QP to guide the QI system can help to holistically address the quality and standards related issues that are an integral part of the triple bottom line (people, planet and prosperity) of an inclusive and sustainable industrial development strategy. A QP can directly address the need of a QI to also encourage innovation, promote investment and position a country or region to realize the many opportunities presented by increased intra-regional and international trade. This in turn should lead to increased prosperity, providing more opportunities for men and women across social groups, advance environmentally sustainable growth and ensure that benefits from technological progress deliver an overall higher quality of life. An appropriate QP and the associated QI system can positively and substantially contribute to 16 of the 17 United Nations Sustainable Development Goals<sup>1</sup>. Six UN Sustainable Development Goals are further elaborated in Annex A to illustrate how a QP/QI including metrology, standards, accreditation and conformity assessment are linked to, and underpin, these goals.

#### 2.2 A QUALITY POLICY IN SUPPORT OF TRADE-RELATED CHALLENGES

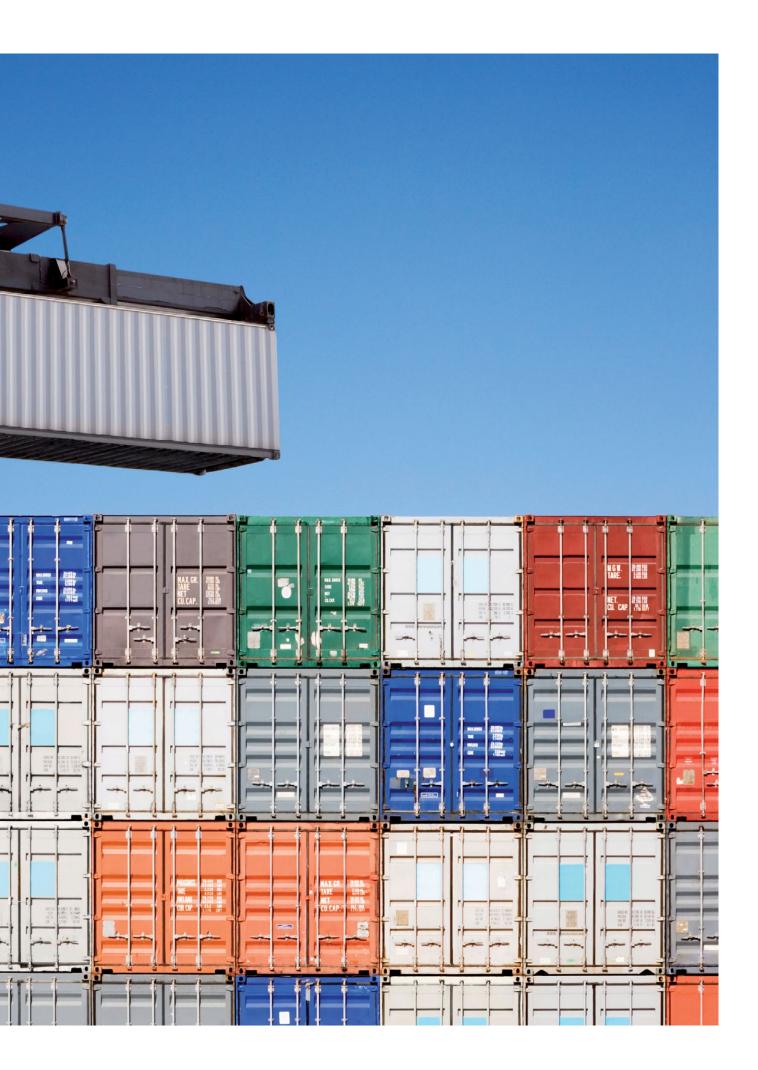
Governments increasingly see a need to better respond to, and appropriately address issues faced by their enterprises, including those related to international competitiveness while protecting against unintended TFA, TBT and SPS-related consequences associated with imports, such as unsafe food or substandard products. The private and public sectors also need reputable evidence that products and services meet regulatory, technical and other requirements. This often-unforeseen need has, in many cases, led to the evolution of a national QI that frequently lacks sufficient coordination, is disjointed, and thus unproductive. There are inherent conflicts of interest, inefficiencies, duplications of effort and costs that

<sup>&</sup>lt;sup>1</sup> 1: No poverty, 2: Zero hunger, 3: Good Health and Well Being, 4: Quality Education, 5: Gender Equality, 6: Clean Water and Sanitation, 7: Affordable and Clean Energy, 8: Decent Work and Economic Growth, 9: Industry, Innovation and Infrastructure, 10: Reduced inequalities, 11: Sustainable Cities and Communities, 12: Responsible Consumption and Production, 13: Climate Action, 14: Life below Water, 15: Life on Land, and 16: Peace, Justice and Strong Institutions.

are increasingly becoming apparent when adopting such a "laissez faire" approach. Many governments are therefore reconsidering the overall arrangement and interaction of their national QI-related organizations to create a more coherent, fit-for-purpose, efficient and user-friendly system. A QP-based approach has gradually evolved with the aim of fulfilling this important set of needs.

As a governing instrument, a QP can specify the objectives of the national QI system in establishing and maintaining a suitable technical foundation for initiating and facilitating more effective trade. The availability of a formally recognized QP to guide the QI can also contribute significantly to the successful achievement of other government policy objectives. These include industrial development, competitiveness in global markets and participation in international value chains, efficient use of natural and human resources, food safety, health, the environment, and climate change.







The quality policy role in strengthening and focusing national and regional quality infrastructure

#### 3.1 WHAT IS A QUALITY POLICY?

A QP is the policy adopted at a national or regional level to develop and sustain an efficient and effective QI. The importance of instilling and supporting a quality conscious culture, not only for trade promotion, but also to address national trade, and human, animal or plant health and safety needs, is an important and integral part of any quality initiative. A QP is therefore often related to a wider multi-sectoral development strategy and is an approach that is increasingly being adopted, usually at the national level, to further develop, consolidate, refine and appropriately sustain an effective and efficient national and/or regional QI system.

The QI system comprises 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 QI is required for the effective operation of domestic markets, and its international recognition is important to enable access to foreign markets. A QP also provides an overarching framework that links and underpins other national policies (e.g. development policy, trade policy, industrial and export policy, environmental policy, consumer protection policy, science, research and innovation policy, and investment policy). It also encourages an approach that seeks to understand and learn from, rather than simply emulate, practices from similar areas elsewhere as part of finding solutions tailored to address specific national and / or regional needs.

#### 3.2 THE IMPORTANCE OF A QUALITY POLICY AND WHAT IT AIMS TO ACHIEVE

A national or regional policy, including a QP, can be seen as a set of interrelated decisions and commitments adopted by a government/s under a united vision aimed at achieving a particular and stated quality competitiveness and public protection outcome. Policy development is a fundamental and very important function of government. It starts with the examination of an underlying need and establishes if there is a rationale for changing existing policy, or even establishing a new policy. If the proposal for policy change or new policy creation is subsequently agreed and sanctioned, a welldefined, inclusive and consultative process follows, leading to eventual promulgation, implementation and sustainable benefits. There is also a need to review policy effectiveness at addressing the original issue. including identifying any unintended consequences.

In spite of the apparent rigour of the process described

in the previous paragraph, national policies and QI components often evolve in a fragmented and piecemeal manner, frequently in ministry/organizational silos. This results in overlaps in function and responsibilities. Unintended gaps or unnecessary duplication between the technical capacity, and capability, required versus what is operationally available often frustrates, and can substantively impede, development and traderelated initiatives.

A QP should provide the shared forethought and clear strategic direction required for focusing and appropriately combining the efforts of the national and regional QI institutions in addressing identified development, trade, and other needs, while also ensuring appropriate separation of organizational, regulatory and voluntary roles and associated responsibilities.

## 3.3 HOW DOES A QUALITY POLICY SUPPORT AND ENHANCE THE NATIONAL AND REGIONAL QUALITY INFRASTRUCTURE?

The role of the QP is to provide a transparent and non-discriminatory framework to link and technically underpin other national policies, including the appropriate definition of QI roles and responsibilities. As policy ambiguities and inconsistencies are identified and addressed, institutional discrepancies and misalignments also become much more apparent, which allows for improved, and more sustainable resourcing. The resultant understanding of what is actually required regarding national and/or regional QI, versus what is already in place, operational and internationally recognized, allows organizational capacity and capability overlaps and gaps to be identified. Activities aimed at resolving these identified gaps through strengthening QI capability and/or capacity should also actively consider, and appropriately utilize, regional QI components. Such consideration will also assist in finding solutions that further strengthen regional and global integration, and encourage greater alignment with established QI best practices and principles.



# The key principles

#### 4.1 WHY IS THERE A NEED FOR A SET OF KEY PRINCIPLES?

Every country operates within a defined context and development agenda. It is therefore impossible to provide a universally-applicable template detailing what specifically should be addressed by any given QP. While some quality-related components have already been developed, and several documents already exist at sub-regional or national levels, these relate mainly to the development of QI.

A set of underlying, experience-based key principles allows each country to adapt and tailor these as appropriate for its own specific needs, and develop its QP and QI to best address its specific situation at a particular stage in its development trajectory. The best practice principles also provide a standardized approach that encourages the development of a QP which is achievable and relevant to the needs of the country, allows appropriate benchmarking, and promotes participation and buy-in by all relevant stakeholders.

Gathering the United Nations Industrial Development Organization's (UNIDO) cumulative expertise on national and regional quality policymaking in addition to the wide experiences of the organizations represented in the International Network of Quality Infrastructure, the key principles set out in paragraph **4.3** are provided to assist countries in developing an appropriate national and/or regional QP that helps create, or further strengthen, an associated QI system that is strategically aligned, fit-for-purpose and sustainable, as well as facilitating access to regional and global markets and protecting human, animal and plant health and safety and protection of the environment.

#### 4.2 WHAT DO THE ADDITIONAL SUB-PRINCIPLES AIM TO ACHIEVE?

To support and clarify implementation of the key principles of a QP, the sub-principles that are described in paragraphs **4.3.1** to **4.3.5** are intended to assist in addressing particular issues with the appropriate understanding and rigour. These subprinciples also assist in separating the creation and implementation of a QP from narrowly-focused political and/or organizational agendas. Such agendas can include the potential or actual misuse of quality issues and technical regulations to gain additional and unwarranted organizational revenues. The subprinciples therefore mitigate the potential for pursuit of short-term interests and promote a more holistic, inclusive and collaborative approach to identifying future needs and securing appropriate sustainability for the associated QI system.

As the development needs of the country evolve and change, and the maturity of its QI-related needs evolve, these same sub-principles can also assist in identifying any subsequent changes that might be necessary for the further evolution of the QP and/or QI.

#### 4.3 THE KEY PRINCIPLES EXPLAINED

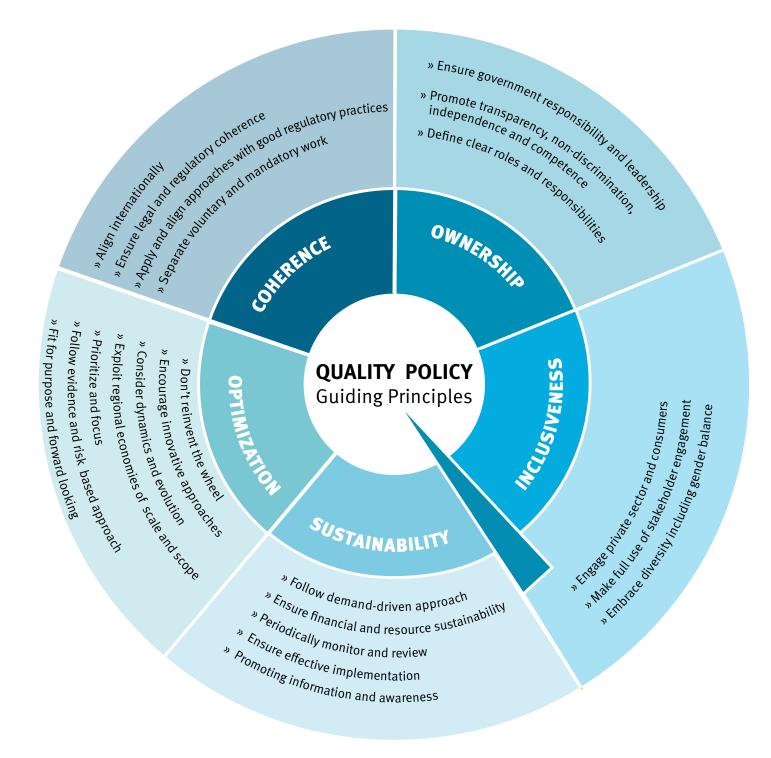
After a comprehensive and considered review of previous national and regional interventions related to QI development throughout the world, five key principles have been identified as the underlying elements for the effective development of a QP. These are Ownership, Inclusiveness, Coherence, Optimization and Sustainability. It should be noted that the principles have been arranged in a particular sequence. The key principles of Ownership, Inclusiveness, and Coherence, are more conceptual and aspirational. In combination they help create the necessary foundation for the creation of a robust QP. and are therefore described first. These are followed by the more technically-focused key principles of Optimization and Sustainability which are more relevant to the subsequent implementation of the QP and subsequent, ongoing operations.

In paragraphs 4.3.1 to 4.3.5, the five key principles

and their associated sub-principles are described and elaborated. Figure 1 provides a graphical representation of the key principles. As can be seen in Table 1, many of the sub-principles also support other key principles. The sub-principles that are directly associated with a key principle appear in the table marked as a **bold X**. Supportive sub-principles are indicated by an *italic X*.

It is important that each of these key principles is appropriately addressed during the creation or further refinement of a national and/or regional QP.

#### FIGURE 1: GRAPHICAL REPRESENTATION OF THE QUALITY POLICY PRINCIPLES



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#### TABLE 1: THE KEY PRINCIPLES AND THEIR ASSOCIATED SUB-PRINCIPLES

KEY PRIN-		SUB-PRINCIPLES																				
CIPLES	E G L	P T C	D R R	E P S	S E	E D	A I	E L C	A G R	S V M	F P F	E R A	P F	R E S	D E	E I A	D R W	D D A	F S	P M R	E E I	P I A
Own- er- ship		x	x	X	X	X	X		X								x	X			X	x
Inclu- sive- ness			x		x	X	x					x		x	X	x	x		X	x	x	x
Co- her- ence		x		x	x	x		x	x	x	x	x	X		X		x	x	x		x	x
Opti- miza- tion				x	x		x	x	x			x	x	x	x	x	x	x	x	x	x	x
Sus- tain- abil- ity		X		x	X	X	x			x		x	X	X	x	x	x	x	x	x	x	x

#### 4.3.1 OWNERSHIP

#### 4.3.1.1 Definition

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

#### **4.3.1.2** Why is Ownership important?

Although the benefits accrue to, and responsibilities are owned by, all the actualization of a value adding and continuously relevant QP requires that a specific ministry be mandated to take the leadership role and be accountable for such an initiative, recognizing the need to address political ownership, administrative, regulatory and technical issues. A logical choice, given its responsibilities related to the WTO TBT. SPS and Trade Facilitation Agreements and the regional counterparts, is the ministry responsible for trade & industry. The same ministry normally has overarching responsibility for many of the QI institutions in the public sector. Another potential candidate is the ministry responsible for government planning and the overall coordination of the government budget. In some countries, a ministry of science and technology is responsible for the QI institutions in the public sector, rather than a trade ministry. In other countries, the government may choose to house all QI elements and QP aspects in a single agency. All of this indicates that the responsibility as lead ministry for the implementation of the national QP needs careful consideration by the relevant ministries and approval at the highest political levels. Once agreed and formally decided, this responsibility should be clearly stated in the QP.

#### 4.3.1.3 Associated sub-principles

### Ensure government responsibility and leadership (EGL)

To move from an unstructured and uncoordinated QI approach to the creation and maintenance of a more cohesive, relevant and cost-effective QP/QI system, it is essential that government accepts overall national responsibility and acts as the driving force in the QP initiation, implementation, and maintenance processes. It is imperative, though, that the private sector and civil society encourage governments in this role, for they are the ultimate beneficiaries and are thus inherent co-owners of the process.

As the impact of the QP is cross-cutting, the work of many ministries is potentially impacted. To obtain and sustain support from all relevant government departments for the creation and maintenance of a QP, an assigned lead ministry needs to be supported by a suitable and agreed structure in which all relevant ministries, QI institutions/agencies, the private sector and civil society are represented at a decision-making level. To ensure high-level support and ongoing buyin, the national coordinating committee/structure should preferably be approved at the highest levels within government to ensure that at least all relevant ministries are involved, and continuously represented.

Issues could surface during the QP/QI implementation and maintenance processes that are more political, rather than technical, in nature. It is important therefore to clearly identify such issues and ensure that they are escalated to the appropriate political levels within the lead ministry for further consideration and appropriate attention at national, regional and/or international level. Functioning TBT, SPS and Trade Facilitation committees that are appropriately resourced at the national and regional level are a critical element in resolving some of these same issues.

### Promote transparency, non-discrimination, independence and competence (PTC)

Transparent and non-discriminatory oversight of both public and private QI institutions, which are appropriately independent and competent to provide the particular CA services, is necessary to achieve desired policy outcomes. It is required to minimize conflicts of interest and other unintended consequences, including erosion of trust in calibration, testing, inspection and certification results due to incompetence, inappropriate rent-seeking behaviour or lack of suitable and available technical capability/ capacity and corruption.

The difficulty of creating and implementing a QP should not be underestimated. There could well be opposition from some, or all, of the established QI institutions, not least because they fear they could lose some of their powers or, perhaps more importantly, one or more sources of income. Government therefore needs to unequivocally state its commitment from the beginning to impartially identifying issues that need to be addressed by the QP.

One aspect relates to subsidizing CA activities. It is important that the QP ensures that initial and/or ongoing subsidies of CA activities are transparent. This

#### 4.3.2 INCLUSIVENESS

#### 4.3.2.1 Definition

The key principle of Inclusiveness emphasizes the need to address those subjects and/or areas which could influence the development of the QP, using appropriate consultative processes that include all necessary stakeholders, to promote the required and necessary ownership of intended outcomes and subsequent actions. prevents future problems in the market place for CA service providers and users if, and when, these are subsequently reduced or removed.

#### Define clear roles and responsibilities (DRR)

A QP should ensure that the various national responsibilities and roles are defined and documented for the various public and private sector groups, civil society organizations and the citizens themselves. It is therefore important to identify existing organizational mandate overlaps or conflicts of interest to be addressed by the QP as part of creating a more cohesive and mutually supportive environment. In addition, the interaction with the corresponding regional and international organizations is examined and clarified.

#### 4.3.1.4 Benefits

The benefits of defined and motivated ownership for a QP/QI system are as follows:

- » It provides the authority and drive to move QI from the unstructured and uncoordinated approach that is still apparent in many countries to the more strategic, cohesive, relevant and cost-effective QP/QI system now required to address TFA, TBT and SPS issues.
- » A functioning and impartial oversight QP/QI mechanism not only ensures that agreed activities are performed in the most efficient and effective way within the various component institutions, but also increases the level of trust amongst users of the CA services being provided, both in local and export and import markets. It helps minimize organizational conflicts of interest and other unintended consequences associated with many of the current modes of QI operation where such oversight is lacking.
- » A functioning and impartial oversight QP/QI mechanism can also constructively address and resolve QI mandate overlaps or conflicts of interest that are a trademark of the "laissez-faire" approach to QI of the past. This oversight is essential to achieving the cohesive and mutually supportive QI environment that is now required to cost-effectively and efficiently deliver world class QI outputs.

#### 4.3.2.2 Why is Inclusiveness important?

Ultimately the private sector pays for a national QI system and the associated implementation of technical regulations. It is vital therefore that the private sector is directly involved in the development and implementation of a QP. Non-governmental organizations often play a significant role, functioning as a trusted voice of society. It is therefore appropriate that the initiatives supporting the creation and

implementation of a QP solicit their active support in a variety of roles to harness their influence in the promotion of quality throughout society. Although government normally takes the lead in establishing a set of policies and associated legislation for the QI system, and often provides resources, the private sector should also be encouraged to actively participate in governance structures, including technical committees of the QI institutions, and provide their perspectives in deliberations regarding standards, metrology, and accreditation at the regional and international level. The concept of inclusiveness should include the right for suppliers to access conformity assessment systems developed on the basis of the QI on a nondiscriminatory basis, in line with WTO Agreements. Where permitted, this should be extended to ensure the rights of service providers to participate in such systems.

In addition to the private sector, civil society should also be encouraged to participate in QP initiatives, including gender equality advocacy groups and women's organizations. Gender equality and empowerment of women should also be one of the connecting threads within the QP development process. Cooperation should therefore be sought with governmental and non-governmental entities responsible for issues, including gender advocacy and mainstreaming. Foreign stakeholders should not be excluded.

International development partners are active in almost all developing economies in establishing trade supportive infrastructures and systems, including standardization and technical regulation. Challenges in this regard include the tendency to follow the policy or business goals of a funding government, which is often coupled with a hesitancy on the part of intended recipient ministries to involve others who could provide a wider and more holistic perspective. This can lead to duplication of effort by different development partners. The QP therefore needs to articulate the responsibilities of recipient ministries while encouraging development partners to cooperate more closely regarding national QI infrastructure coordination.

#### 4.3.2.3 Associated sub-principles

#### Engage private sector and consumers (EPS)

The creation of a QP and an appropriate enabling environment requires a developmental approach that recognizes and balances the need for a public-goodcreated and sustainably-funded technical infrastructure against that which can, and should, be provided by the market, and driven by commercial/economic logic. Continuous and wide-ranging consultations throughout the QP creation and promulgation process are required to both communicate the need for a QP/QI system, and also educate users and consumers about the many benefits.

An assessment of who to include (stakeholder mapping), covering identification of stakeholder and priority stakeholder groups (i.e. regulators, government), private sector (including QI service

providers), producers (as consumers of services enterprises), final consumers and multinationals is vital at the initiation stage of any QP project.

Any project aimed at the creation and implementation of a QP also needs to recognize the existence of, and address the inherent issues associated with, existing and often powerful national QI-related, public-funded organizations with overlapping mandates and conflicts of interest that can actively inhibit private sector capacity building. It is therefore crucial to create and maintain an appropriate link between the services offered by QI institutions and the needs of the intended users and consumers.

#### Make full use of stakeholder engagement (SE)

Stakeholders can provide valuable inputs in determining appropriate key success criteria for guiding QP implementation, while providing opportunities to educate these various communities on the needs for, and benefits of, a QP/QI system. A representative group of stakeholders from the private and public sectors, consumers, producers and CA service providers, including international development partners (IDP), who can provide informed inputs on national, regional and foreign trading partner needs, should be defined. These can then be mapped for further action, including an assessment of the benefits to them of participation and their capacity for engagement.

It is important that a suitable, inclusive and ongoing consultative process is established, appropriately resourced and maintained. Such a process should seek to promote wider and deeper understanding through consensus building. The results of such consultations also provide important inputs to the subsequent monitor and review process. It is not sufficient to only circulate a final draft for public comment, especially if this has been developed in isolation by a select group of government officials, supported by staff from existing QI institutions with a narrow agenda.

#### **Embrace diversity including gender balance (ED)**

Diversity encompasses and embraces the varying characteristics of representatives of wider civil society, including women's organizations. To ensure a well-balanced and rounded QP that meets multiple development and trade-related needs, it is essential to involve civil society organizations, including gender institutions and women's organizations, in the QP initiation and implementation processes. Specific cultural groups might also be relevant within a particular country context, so it is important that this aspect is also assessed, and appropriately considered from the outset.

The make-up of QI institution staff should also be appropriately addressed in the QP to ensure that this also appropriately addresses diversity including, but not limited to, gender, religious and political beliefs, ethnicity, education, socioeconomic background, sexual orientation, and geographic location.

#### 4.3.2.4 Benefits

The benefits of an inclusive QP/QI system are as follows:

- Inputs from stakeholder groups, representing all the various constituents, provide different perspectives on local, regional and international needs. This helps ensure that the developmental approach required to establish and maintain an appropriate QP/QI system can correctly balance public-funded CA with what can and should be provided by the private sector for a particular period.
- » The same constituents can also provide important feedback on what is required to ensure that the CA services offered by national and regional QI institutions continue to meet the needs of the intended users and consumers.
- » Stakeholder inputs can be used to identify opportunities to educate various local communities, and potential users, on the benefits for them of a QP/QI system. Such communication activities should also be used to inform subsequent QP/QI monitoring and review processes.

#### 4.3.3 COHERENCE

#### 4.3.3.1 Definition

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

#### 4.3.3.2 Why is coherence important?

Governments have an inherent responsibility to promote the economic well-being of their citizens, ensure their safety and health, and protect the environment in which they live. Unfortunately, remedies that include regulation have frequently evolved in an ad hoc way. This leads to fragmentation, with many overlaps amongst regulatory authorities and gaps resulting in non-compliance with the World Trade Organization (WTO) TFA, TBT and SPS Agreements and regional trade agreements. Often many ministries are involved, each working according to its own understanding and adopting sometimes conflicting practices in pursuing its individual mandates due to an absence of more definitive national guidelines. The resultant systems and processes that are increasingly related to increasing trade are often ineffective, inefficient and add significantly to the transaction costs incurred by producers and suppliers, often rendering their products or produce uncompetitive.

National, inter and intra-regional efforts to establish and maintain a QI also need to include its integration with, and support of, trade and investment policies, enterprise competitiveness and national business environment reform, affordability, and sustainability and environmental impacts, including national and regional climate change adaptation and mitigation needs. It is vital therefore that, during the development of an QP, the issue of more coherent policy making is adequately addressed. Appropriate attention to appropriate organizational separation of mandatory, and voluntary activities, encouraging stakeholder and organizational buy-in, and subsequent adherence related activities is also required.

#### 4.3.3.3 Associated sub-principles

#### Align internationally (AI)

The QP needs to be aligned to, and appropriately address, national obligations in respect of the WTO TFA, TBT and SPS Agreements, mandatory requirements and best practice guidance in the various BIPM, OIML, IAF, ILAC, ISO, IEC, ITU, Codex Alimentarius, IPPC and OIE and other such internationally-recognized QI publications, other international developmental imperatives (e.g. the circular economy), and sustainability-related commitments (e.g. United Nations climate change adaption and mitigation commitments) as well as obligations of applicable trade agreements (bilateral or multilateral) with other economic partners. International acceptability of the results emanating from a QI system also requires demonstrable, continuous and trusted compliance with the various technical requirements also contained in the customer-specific requirements of foreign trading partners.

It is important therefore to ensure that the QP adequately assists the intended beneficiaries in achieving even greater national compliance with these WTO treaty commitments and those contained in any other regional trade agreements to which they are party, while simultaneously minimizing unintended negative consequences. In particular, the QP should emphasize the importance of basing national technical regulations, conformity assessment procedures, standards and SPS measures on relevant international standards, in line with WTO Agreements.

#### Ensure legal and regulatory coherence (ELC)

The contents of the QP should be appropriately balanced, coordinated and integrated with the aims and contents of existing national legislation and regulatory frameworks to promote greater policy cohesion and understanding of requirements. The establishment of a QP provides a unique opportunity for a country to review quality-related issues contained in other legislation and policies. It should also be used to identify areas that are no longer compliant with current international rules and best practices or serve the intended purpose. The implementation of the QP should also help identify and remove discriminatory, conflicting or unnecessarily restrictive requirements, reduce associated transaction costs, and promote greater user understanding and voluntary adherence.

The QP should therefore clearly elucidate government's commitment to reviewing relevant legislation, revising where necessary and developing and promulgating new policy elements as and where required. This is not limited to instances where QI institutions are public entities. There is a need for overarching guidance, and information dissemination and awareness raising concerning the appropriate provision of standardization, metrology, accreditation, conformity assessment and market surveillance capability. Attention should also be given to the development and implementation of future technical regulations, including demonstration of compliance aspects.

### Apply and align approaches with good regulatory practices (AGR)

Although sovereign governments have a right to intervene in the local market as and when necessary, the processes used in the regulatory technical evaluation of produce or a product by different ministries and government agencies are often uncoordinated and different even for the same item, difficult to understand and almost impossible to proactively and cost-effectively address, leading to increased transaction costs, uncompetitive suppliers and higher potential risk associated with imports.

In this connection, the QP can usefully be aligned with "good regulatory practices", including: transparency and public consultation, internal coordination of regulation, and assessment and analysis of alternatives, including through regulatory impact assessment (RIA). Regulators also need to consider the needs of economic operators and, depending on the available capability and capacity, try to assign greater responsibility for the demonstration of compliance to producers as associated production activities also need to be appropriately controlled. The QP should therefore encourage an approach to the creation of regulations that defines what is required, and why, rather than how to achieve compliance. Future regulations should embrace best international practice, scientific consensus and/or objective evaluation in a systematic way.

The QP should also address user education and understanding of, and promote voluntary compliance with, export and/or import requirements, and encourage the use of established voluntary tools and systems to enable CA results to be used for more than one purpose and/or test.

#### Separate voluntary and mandatory work (SVM)

Successful implementation of a QP needs an appropriate enabling environment that recognizes and balances the need for a public-good-created, and appropriately-funded QI against that which can, and should, be provided by the market to address various conformity assessment needs, and which should be underpinned by commercial/economic logic for sustainability. The public good aspects of such a QI, supporting both regulated and nonregulated areas, typically include:

- establishing and ensuring compulsory requirements, such as those contained in legislation or technical regulations;
- establishing the national standards body and related systems, and participating in the development of international standards by bodies such as ISO, IEC and ITU;
- » establishing the national metrology institute/ legal metrology authority and related systems, and participating in the international recognition arrangements for metrology, specifically the CIPM Mutual Recognition Arrangement (CIPM MRA) operated by the BIPM and the Certification System operated by the OIML; and
- » establishing the national accreditation body or appropriate systems, and participating in the international recognition of accreditation arrangements operated by ILAC and IAF.

There is therefore an increasing need to create more coherent, cost-effective and sustainable QI systems that involve the appropriate separation of regulatory and voluntary roles and responsibilities, while utilizing the results of conformity assessment activities to address multiple CA needs and only requiring additional results to address gaps in data and information.

#### 4.3.3.4 Benefits

The benefits of adopting a more coherent approach under a QP/QI system are as follows:

- » Policy and associated interventions are purposefully aimed at achieving the desired outcomes of many similar local, regional and international requirements, which removes unnecessary levels of subsequent evaluation and minimizes duplication of effort required to demonstrate compliance, leading to less effort and cost for this activity by local and regional producers and suppliers. This could also be the difference in making their produce or products competitive in other markets.
- » The alignment of the requirements of different national regulators under a common framework for policy creation, maintenance and surveillance makes the compliance-related activities much more predictable and easier to understand. This leads to less effort and cost on the part of producers and suppliers, which should also have a positive effect

on the cost of the items they produce or supply, as well as increased motivation for them to work proactively to demonstrate voluntary compliance.

» Allowing the utilization of the results of CA activities to address multiple CA needs, e.g. results to be used for more than one purpose and/or test so

4.3.4 OPTIMIZATION

#### 4.3.4.1 Definition

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

# **4.3.4.2** Why is Optimization important?

The QP/QI infrastructure should assist national enterprises in accessing foreign markets with products, produce and/or services of the requisite quality. It is crucial therefore that the QP is used to create and maintain an appropriate link between the services offered by QI institutions and the intended markets and consumers. Given the many and varied challenges in successfully and sustainably accessing foreign markets, and noting that the inherent technical complexities for each sector or product can be significantly different, the QP should promote the need and establish mechanisms to identify a set of agreed priority sectors, products and services. It is also important that these are periodically reviewed.

A set of agreed priority sectors, products and services assists in determining and optimizing the level of national and regional QI appropriate at a certain time for each of the selected areas, taking account of current levels of operation and acceptance in the market place and further QI capacity and capability development.

#### 4.3.4.3 Associated sub-principles

#### Fit-for-purpose and forward looking (FPF)

There is no ready-made and transferable QP/QI model that suits the needs of all countries. A tailormade, fit-for-purpose approach, on a case-by-case basis, is therefore necessary. This needs to take account of the developmental context of the specific country, including its current level of maturity and socioeconomic priorities and its intended development goals and trajectory.

A QP should appropriately address all QI aspects, including relevant technical regulations, by providing a framework for a coherent, tailored, fit-for-purpose and efficient system that can also address the current and future TBT, SPS and TFA-related needs of government, regulatory authorities and private enterprise in a way that addresses immediate priorities, whilst also that additional results are only required to address gaps in data and information, enables current CA service providers to provide a much more costeffective service and potentially encourages them to expand their scope of work into areas that have previously not been covered.

building a suitable foundation for what will be required as the country/region moves further along the chosen development trajectory.

#### Follow evidence and risk-based approach (ERA)

The QP/QI infrastructure should not only assist enterprises in accessing local and foreign markets with products/produce/services of the requisite quality, but also simultaneously minimize or avoid threats to public health, safety and the environment, including potential SPS-related risks associated with imports. Noting that technical complexities for sectors/products can be significantly different, it is important that the associated risks are identified and appropriately prioritized after consideration of the availability of funding and the intended trajectory for QI capacity and capability development. Such a risk determination should also consider and reflect national aspirations, country level needs, foreign market realities and current/proposed demand. The risk determination should also be based on relevant international standards, guidelines and recommendations, in line with the WTO TFA, SPS and TBT Agreements.

#### **Prioritize and focus (PF)**

To successfully and sustainably access markets, the QP should encourage a value chain approach based on a suitable needs and gap analysis. This should assist in aligning/matching CA supply and demand by identifying a set of priority sectors, products and services, to allow for focus on specific QI implementation and maintenance needs. These include the appropriate capacity, capability and focus of standardization, metrology and accreditation activities and the type of CA that is appropriate at a certain time for each of the selected areas.

#### Exploit regional economies of scale and scope (RES)

The development and implementation of a QP provides vital direction to assist a country in refocusing its QI activities and the necessary impetus for the appropriate use of the QI-related capability and capacity of regional partners to cost-effectively and efficiently address the requirements of the regional trading block and promote intra-regional trade. The same strategy can also be used to assist suppliers from different countries in the same region to collaborate in aggregating resources for trading as a regional grouping of suppliers with a foreign region. In both instances opportunities arise for better understanding of global quality needs and further strengthening of the national and regional QI systems as these are further developed to satisfy the associated requirements and standards.

#### Consider dynamics and evolution (DE)

A QP needs to recognize and balance the ever-changing national context, priorities and associated needs related to the provision of a public-good-created and publicly-funded QI against what can and should be provided by the market and driven by commercial/ economic logic. Many countries have long-established standards bodies and metrology institutes. Some have also created national accreditation bodies. The way in which these have been established/evolved, as independent or integrated organizations, government departments or agencies of government, and the services they are responsible for, might no longer meet the needs of the country or comply with international best practices. In both the development of a QP, and in future monitoring and review activities of the associated QI, adequate stakeholder participation (industry, trade, investment, labour, innovation, etc.) is vital. Feedback should be appropriately incorporated in subsequent remedial action(s) to ensure that the QP/ QI system remains relevant in addressing the needs of government and the intended users.

#### **Encourage innovative approaches (EIA)**

To address the ever-changing opportunities and challenges associated with ensuring that the QP and the associated QI remain relevant in a particular environment, the appropriate use of new and emerging research and technology (e.g. advances through and opportunities created by Industry 4.0, and initiatives identified through new thinking such as the circular economy) should be encouraged as part of evaluating solutions and remedies. This aspect is especially important given that historically available resources are likely to become increasingly limited. Given the increasingly rapid rate of change at the international level, it will become increasingly difficult, if not impossible, for developing countries to emulate the development practices that were previously successful. There will be an increasing need to adopt new ways of thinking about issues as they emerge and use these, together with developments in technology for instance, to leapfrog rather than follow others. A classic example of such an approach is the widespread adoption of cellular technology for communication in Africa. This generated rapid growth in this area and superseded the need to follow the landline technology and infrastructure approach used historically in more developed countries to address a similar need.

#### Don't reinvent the wheel (DRW)

It is important to encourage innovative approaches where appropriate and where value can be created, using existing tools and services that are known to work. Optimization means using limited resources to achieve maximum results. A national QP should identify what quality goals are most important for the country and then prioritize its resources to best achieve those goals. Integrating the use of recognized and respected global CA services into quality policy, especially when those services are free of cost, is a resource optimization approach. It is important to appreciate that many of the accepted and trusted global services that are currently in use at the international level are best practices resulting from many years of practical experience, interaction with the market, learning and refinement. Examples are those offered by ILAC and IAF for accreditation methodology, OIML services for international legal metrology, and those WTO recommended services offered by the IEC for CA of products and services for household products, office equipment, IT products, industrial equipment, renewable energy projects, and much more.

#### 4.3.4.4 Benefits

The benefits of an optimized QP/QI system are as follows:

- » All QI aspects, including relevant technical regulation, are appropriately, cost-effectively and efficiently addressed within a coherent, tailored, fit-for-purpose and efficient system that meets current and future TBT, SPS and TFA-related needs of government, regulatory authorities and private enterprise by addressing more immediate priorities whilst creating a suitable foundation for future QI capacity and capability as the country/region moves further along its chosen development trajectory.
- » Using existing recognized and respected global CA services creates value for a QP/QI at no cost. This is the highest possible level of optimization.
- » The availability of a QP/QI infrastructure not only assists enterprises in accessing local and foreign markets, but also simultaneously addresses the need to minimize or avoid threats to public health, safety and the environment.
- Access to a proactively defined QP/QI infrastructure encourages the use of a value chain approach that assists in aligning/matching CA supply and demand, identifies a set of national priority sectors/products/produce/services, and focuses efforts on addressing specific QI implementation and maintenance needs, including technical and professional capacity and capability that are appropriate for each of the selected areas.

A QP provides vital direction to assist a country in refocusing its QI activities to cost-effectively and efficiently address the requirements, including those of any regional trading blocs they are members of, to promote greater intra-regional trade. Opportunities can also arise for better understanding of global quality needs and any further strengthening of the national and regional QI systems required to satisfy the associated requirements and standards.

#### 4.3.5 SUSTAINABILITY

#### 4.3.5.1 Definition

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

### **4.3.5.2** Why is Sustainability important?

An analysis of the finances of OI institutions worldwide indicates that many, if not most, governments retain the responsibility for funding fundamental aspects of the QI system, namely standards, metrology and accreditation. Although governments are obliged to fund the QI institutions that form part of their own departments or statutory organizations, they also frequently provide funding for other QI-related activities through specific agreements between the state and designated institutions. These fundamental activities are considered as public good activities, given that they are intended to benefit all the citizens of the country and not a particular, well-segmented grouping. In some cases, governments also retain the responsibility for funding international liaison activities and the costs associated with obtaining and maintaining international recognition for their QI institutions.

It is important that the QP enables the government to clearly articulate its commitment to long-term funding of the QI activities that cannot be funded by others, to provide the necessary assurance and associated stability that such organizations require to establish and maintain national, regional and international trust in these activities under its mandate. In the case of those QI institutions that are encouraged to earn income from some of the services they provide, the QP should clarify that the government may specifically identify funding for certain activities that are in the wider public interest.

#### 4.3.5.3 Associated sub-principles

#### Follow demand-driven approach (DDA)

The QP should encourage a market-driven approach to the supply of QI capability and capacity that directly links the current operations and future planning to the national strategies and regional demands for quality produce and products. The QP/QI system needs to adequately address, and appropriately balance, national and market-driven needs related to competitively servicing CA needs for the local market and accessing regional or international markets on the one hand, and addressing health, safety and environmental protection needs on the other. It is important that the need for appropriate government intervention following good regulatory and standardization practice is also recognized and appropriately elaborated in the QP to address issues, including market failure. QP/QI-related remedies should allow the appropriate use of the private sector in finding solutions that address issues such as increased trade and investment, enterprise competitiveness/business environment reform, gender and environmental impacts, including climate change-related needs.

#### Ensure financial and resource sustainability (FS)

The optimum arrangement of a QP/QI system at the national level is both a government policy and funding issue, as well as a market-related service provision concern. Financing QI in a sustainable way is a complex exercise. With respect to regulations, although these are formulated using public consultation processes, they are often perceived to be unilaterally imposed by the state, especially if this is done to meet the demands of other trading blocs with insufficient information or education of those who are impacted locally. Due to difficulties associated with implementation of such requirements, partial cost recovery initiatives have developed over time where the producers and/ or suppliers now carry part of the financial burden associated with them. This is an equitable solution in which the costs incurred are allocated directly to those that need to be monitored by the state instead of having to be funded by all taxpayers using state coffers.

To move from an unstructured and uncoordinated QI approach to the creation and maintenance of a more cohesive, relevant and cost-effective QP/QI system, it is essential that the QP stipulates the need for government to provide appropriate ongoing support, including funding. Any pressure on QI institutions to provide conformity assessment or calibration services below cost will compromise their long-term financial sustainability. National sectors that need such strategic support should be funded in other, more transparent ways, e.g. by refunding SMEs some of the costs associated with CA or calibration services on presentation of a positive report or certificate.

Another problem to be addressed is the tendency of some government departments to seek/demand CA services from other public QI institutions without payment. This negatively impacts the financial support received from the institution's line ministry for fundamental services. The QP should therefore require government departments and their agencies to allocate a suitable budget for the CA services they require, and reimburse institutions accordingly.

An aspect that needs to be urgently addressed through the QP is the evolution in some countries of separate QI systems, i.e. one to address TFA, one for TBT-related needs, another for SPS issues and yet another one for the market place. This creates unnecessary duplication of effort, increased cost and inherent inefficiency. The QP should encourage the creation of a single, coherent and internationally recognized and appropriately public funded QI system to cost-effectively and efficiently address the needs of regulatory authorities and the local, regional and international market place.

#### Periodically monitor and review (PMR)

Given that externally funded QP/QI projects have a finite life, it is imperative that post QP/QI project monitoring and review mechanisms are continued by the lead ministry to ensure that the benefits of such projects, as well as other national QI-related initiatives, are achieved in the longer term.

The identification in the QP of an appropriate set of key success indicators and the creation of supporting data collection mechanisms are vital given their foundational role in subsequent monitoring and review activities. The results of such monitoring and review activities can then be used to identify gaps and areas for future improvement, including the formulation of new QI related projects.

#### **Ensure effective implementation (EEI)**

Manufacturers, exporters and suppliers utilize standards, metrology, accreditation, calibration and CA services to demonstrate conformity of their products and services with their contractual obligations and target market preferences. It is important to therefore determine on an ongoing basis if their targeted needs are being successfully addressed. The QP needs to promote an appropriate feedback mechanism, using appropriate market surveillance and risk analysis involving risk evaluation, risk management and risk communication, to provide a feedback loop for improvement of regulatory processes, including decision making, and guide the future development of QI activities.

#### Promoting information and awareness (PIA)

Disseminating information and fostering awareness of quality improvement principles and practices across all stakeholder groups is a key cross-cutting demand driver and supply enabler for the development of a quality conscious culture in society. It is one of the major ways in which the psychological expectation of quality, as an inherent right, can ultimately be ingrained at the individual level and be neutral of national borders. Therefore, as inherent consumers of all types of products and services, citizens come to accept nothing less than the quality they are willing to pay for. Also, as the same producers of socio-economic value, it is important that their behaviours also reflect quality cognizant and socially responsible attitudes.

#### 4.3.5.4 Benefits

The benefits of a sustainable QP/QI system are as follows:

- » The availability of a QP/QI infrastructure encourages a market-driven approach to the supply of QI capability and capacity that directly links the current operations and future planning to the national strategies and regional demands for quality produce and products.
- » A cohesive, relevant and cost-effective QP/QI system allows government to provide appropriate and targeted, ongoing support, including funding, whose impact on supporting national priorities is much easier to assess.
- » The QP/QI monitoring and review activities that are created can be used to identify gaps and areas for future improvement, including the formulation of new QI-related projects.



# Moving to action

The QI in a large number of countries has evolved over many years, often in an unstructured way due to the absence of an overarching set of national policy principles for the area of QI. Many have now developed to the point where there are complications and unnecessary process intricacies and restrictions that actively hinder, rather than support and promote, trade and insufficiently protect against unintended consequences associated with imported produce and products. Countries therefore increasingly see a need to fundamentally review and adapt their national QI system to connect more effectively with the international trading system and gain even more benefit from inter and intraregional trade agreements. This is particularly true for smaller economies with a need to satisfy the requirements of much larger, better developed trading partners who already have established and well-developed QI systems.

The development and implementation of an appropriate QP can substantially assist in establishing well-grounded and much needed government policy guidance. It can also provide the impetus for the

alignment of the country's QI system with that of their major trading partners. The set of principles described in paragraph **4.3** are intended to help those tasked with developing a QP in a holistic, and country and/ or regional needs-focused, way. Such an approach encourages the development of solutions that also fit into the broader context of regional integration and the alignment of the QI system with international and regional TBT, SPS and TFA-related processes and coordination activities.

Many good practices have evolved related to QI systems that support trade whilst simultaneously protecting the safety and health of people, fauna and flora and the environment. Some of these practices are contained within the WTO TFA, TBT and SPS Agreements, while others reside in the mandatory and other requirements of international recognition arrangements of organizations such as ISO, IEC, ITU, BIPM, OIML, ILAC and IAF. A list of resources from these and other organizations that can provide insights and information on the creation and implementation of a QP/QI system is given in Annex B.

### Glossary

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

#### Accreditation

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

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

#### Attestation

issue of a statement, based on a decision following review, that fulfillment of specified requirements has been demonstrated

[SOURCE: ISO/IEC 17000:2004, 5.2]

#### Calibration

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

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

#### Certification

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

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

#### **Circular economy**

economy that is restorative and regenerative by design, and which aims to keep products, components and materials at their highest utility and value at all times, distinguishing between technical and biological cycles

#### **Conformity assessment**

evidence that specified requirements relating to a product, process, system, person or body are fulfilled [SOURCE: ISO/IEC 17000:2004, **2.1**, modified]

#### Industry 4.0

terminology used to describe the emerging era of industrialization in which the use of computers and automation will be harnessed in new and innovative ways, such as the creation of smart factories where cyber-physical systems monitor the physical processes of the factories and make decentralized decisions

#### Inspection

examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements

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

#### **Lead ministry**

specific ministry mandated to take the leadership role and primary responsibility in overseeing the quality policy implementation process

#### **Mandatory requirement**

compulsory requirement contained in a standard (usually denoted by the word "shall") and/or a mandatory document that governs the activities of the membership of an international organization (e.g. IAF/ ILAC A Series documents, IAF MD series documents and ILAC P series documents)

#### Producer

depending on context, a manufacturer of components or goods, including agricultural produce, or a provider of services

#### **Quality infrastructure**

system comprising the organizations (public and private) and functionalities, together with the policies, relevant legal and regulatory frameworks, principles, practices and promotion campaigns, used to support and enhance quality competitiveness, innovation, productivity, safety, health and environmental soundness of goods, services and processes

#### **Quality policy**

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

#### Stakeholder

person or organization that can affect, be affected by, or perceive itself to be affected by the quality policy

#### Standard

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

Note - According to ISO/IEC Guide 2: 2004, a standard may be Mandatory. Under the WTO TBT Agreement a standard is a voluntary document, while a document of mandatory compliance is a technical regulation [SOURCE: ISO/IEC Guide 2: 2004, 3.2]

#### **Mandatory standard**

**Standard** the application of which is made compulsory by virtue of a general law or **exclusive reference** in a **regulation.** 

#### **Technical regulation**

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

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

The WTO Agreement on Sanitary and Phytosanitary Measures calls regulations which fall under its mandate simply "measures" (See Annex A). The Guiding Principles apply to SPS measures as well.

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

#### Testing

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

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

# ANNEX A

#### How QP/QI components underpin the UN SDGs

The following six examples illustrate how the components of a QP/QI system, including metrology, standards, accreditation, and CA, are linked to, and underpin, the UN Sustainable Development Goals (SDGs).

#### Goal 3: Good Health and Well Being.

Population growth, longer life expectancy, increasing international travel and trade, as well as innovations in modern medicine, are placing an ever-growing demand on healthcare systems. Government authorities mandated to protect the health and safety of citizens can, when working under a QP, more rationally and collaboratively align their QI capability and capacity needs with national strategic imperatives and work together with others to fulfil their assigned regulatory and international responsibilities. Policies, guidelines, and regulations that cover health and safety-related equipment and methods can only be relied on if the measurements used to verify their compliance are accurate, traceable to internationally agreed reference measurement standards, and performed using approved and correctly calibrated instruments. The appropriate use of metrology, standards, accreditation and competent CA bodies to underpin health and safety-related requirements and regulations is therefore critical.

#### **Goal 6: Clean Water and Sanitation.**

Few challenges are more global than water demand and supply. Rivers and lakes cross national boundaries while oceans are shared resources. Droughts, floods and climate change cut across continents. The need for improved management of water demand and supply, including universal and equitable access to safe drinking water, can only increase. This implies increased promotion and implementation of water efficient production methods and clean technologies, nationally, regionally and globally. National and international strategies in this area need to be addressed in a QP to ensure that all associated QIrelated needs are appropriately coordinated and mutually supportive. International harmonized standards for water also assist in providing global tools to help manage these shared water resources. increase the efficiency of water distribution services, and reduce leakages, preventing unnecessary water losses. Water quality standards for the safe and efficient use of waste water for irrigation can also ease the strain on water resources, particularly important when agriculture accounts for about 70% of the world's

freshwater consumption. The appropriate use of a QP/ QI system provides an important enabling and qualityassured way of addressing these challenges.

#### Goal 7: Affordable and Clean Energy.

Energy, especially electricity, is one of the golden threads that impact most of the 17 SDGs and, indeed, the development of every nation and economy. For example, IEC standards enable all forms of power generation, including on-grid and off-grid use of good quality renewable solar, wind, marine and hydro energy generation. Such standards also provide the basis for rural electrification, microgrids, low voltage direct current (LVDC) applications and safer, more reliable, more efficient devices, bringing sustainable electricity and light to all cities and economies. The ITU and others have developed several standards for monitoring and assessing energy efficiency for telecommunication networks and equipment and related infrastructure. ISO and others have also published many energyrelated standards, including energy performance indicators, energy efficiency assessment and energy data management for buildings. There are also such standards that address emerging technologies such as solar power and biofuels.

The provision of energy involves complex supply chains and processes, often involving cross-border trade and the transportation of volatile substances. Increased use of renewables also creates challenges for distribution grids in terms of grid stability, but also due to the requirements of commerce for an electricity supply that is free from momentary voltage interruptions or interference sources. Measurements play an increasingly critical role at every stage of the energy challenge. Accreditation of those performing such measurements and other related CA activities provides valuable support for governments and organizations as they seek to enhance energy efficiency, and economic performance, whilst preventing unsafe, unhealthy or environmentally harmful products from entering the market place. All of this promotes the need for a fit-for-purpose and strategically-focused QP/QI infrastructure.

# Goal 9: Industry, Innovation and Infrastructure.

High-performance products and manufacturing systems require accurate measurements for a wide range of parameters and production environments. In order to control manufacturing processes and guarantee the

quality of their products, companies need to access a suitable QI infrastructure, including cost-effective access to CA services. Industry in developing countries usually begins by producing basic goods for local markets, then adding the ability to assemble products, before graduating to the design, development, testing, inspection and certification of truly home-produced products that are suitable for export. Effective QP/QI infrastructure facilitates this "added value" journey and promotes a culture of quality consciousness. Industrialization has become one of the main drivers of sustained growth and sustainable development. Industrial competitiveness and innovation are also key to successfully accessing the global marketplace. The economic success of nations can therefore hinge on their ability to manufacture, and trade, precisely-made and tested products and components that are accepted by trading partners and meet destinationmarket regulatory and consumer requirements. As innovators and potential employers, SMEs are often crucial players. To allow them to be successful exporters, they need appropriate and affordable access to QI services that provide a cost-effective way to access the quality assurance and CA capability and capacity required for their products and services to be trusted and accepted. Internationally-recognized CA results from accredited service providers enable consumers, suppliers, purchasers and regulators to have confidence that products placed on the market are safe and meet the manufacturers' claims, while helping avoid the need to duplicate CA in target markets that could also jeopardize competitiveness.

### Goal 12: Responsible Consumption and Production.

An estimated 41.8 million tons of electronic and electrical equipment was discarded in 2014, only onefifth of which was recycled. A number of international standards open the way to a significant reduction of e-waste and creation of a circular economy. Producing and supplying agricultural products in a way that minimizes wastage can also be a daunting task, even for the local market, especially in developing countries. Quality and metrology standards are an important source of knowledge, even for smaller producers. Translating this increased knowledge into the capacity to increase the quality of production for even the local market decreases losses during the production process, as well as post-harvest losses, during storage and transport. This provides higher earnings to farmers and can contribute to food security and dietary improvements for the national population. When trying to address the needs of export markets, the challenges are much greater. Exporters' produce can be rejected in the foreign market due to non-conformity of the production and distribution systems with that market's requirements. A suitable QP/QI system can ensure that control systems meet obligations under the WTO SPS Agreement, align with international standards for quality assurance and accurate, reliable and traceable measurements, and prove conformity with importer regulations and requirements, including those addressing food safety.

**Goal 13: Climate Action** acknowledgesthe United Nations Framework Convention on Climate Change as the primary international, intergovernmental forum for negotiating the global response to climate change. Integrating the QP into national and regional climate change policies and associated implementation could also assist countries in effectively managing climate change data and reporting, leading to improved transparency, education and enhanced climate ambition. A QP could therefore also ensure continual improvement in the design and implementation of climate actions and create the space needed for effective climate policy development and integration into national sustainable development planning and implementation.

# ANNEX B

#### **Further resources**

Further information is available on the following topics at the websites detailed below.

#### WTO TFA, TBT and SPS agreements

TFA: https://www.wto.org/english/tratop\_e/ tradfa\_e/tradfa\_e.htm#I

TBT: (Annex 1) https://www.wto.org/english/ docs\_e/legal\_e/17-tbt\_e.htm#annexl

SPS: https://www.wto.org/english/tratop\_e/sps\_e/ spsagr\_e.htm#fnt4

Further information on good regulatory practices can be found in the 2012 OECD *Recommendation of the Council on Regulatory Policy and Governance*, as well as relevant discussions in the WTO TBT Committee (https://www.wto.org/english/tratop\_e/tbt\_e/tbt\_e. htm).

#### **Standards**

IEC: www.iec.ch ISO: https://www.iso.org ITU: www.itu.int

#### Metrology

BIPM: www.bipm.org CIPM MRA: https://www.bipm.org/en/cipm-mra/ KCDB: https://kcdb.bipm.org/ OIML: www.oiml.org

#### Accreditation

IAF: www.iaf.nu ILAC: http://ilac.org/

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ISO / IEC Guide 2: 2004, Standardization and related activities - General vocabulary

JCGM 200:2012, International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM) 3rd edition (https://www.bipm.org/en/ committees/cc/wg/jcgm-wg2.html) OECD. Recommendation of the Council on Regulatory Policy and Governance, OECD: Paris. 2012 (<u>https://www. oecd.org/governance/regulatory-policy/49990817.</u> pdf).

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