Outline

• Quality Infrastructure: concept and definition
• The role of National Standards Bodies
• The role of ISO
Quality Infrastructure (1)

The term was introduced in the early 2000s by the PTB (Physikalisch-Technische Bundesanstalt) international development cooperation unit. The term was then used by the German government and gradually spread through the international community.

Original reference to QI:

“Quality Infrastructure refers to all aspects of metrology, standardization, testing, and quality management including certification and accreditation. This includes both public and private institutions and the regulatory framework within which they operate”.

Quality Infrastructure (2)

The concept is implicitly clear – although there is no definition of QI agreed at the international level (among the key player of the international system).

The proposal submitted by ISO, IEC, ITU an ITU-T to DCMAS* is presented in the following two slides.

* = DCMAS: The Network on Metrology, Accreditation and Standardization for Developing Countries, comprising BIPM, IAF, ILAC, ISO, IEC, ITU, ITC, OIML, UNIDO and UN/ECE
Quality Infrastructure: (draft) definition

The system comprising the organizations (public and private) together with the policies, legal (regulatory and legislative) 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 to enable access to foreign markets. It is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing.

...
Quality Infrastructure: definition (ctnd)

... It *relies on* the **scientific and technical foundations** of
- metrology (scientific, industrial and legal), and
- standardisation,

*to underpin*
- accreditation,
- conformity assessment (supplier’s declaration, certification, testing, verification, and inspection),
- calibration, and
- market surveillance.
Metrology

• A broad field divided into three basic, overlapping activities:
  – Definition of internationally accepted units of measurement
  – Realization of these units of measurement in practice
  – Application of chains of traceability linking measurements made in practice to reference standards

• With three primary sub-fields that use the three basic activities to varying degrees:
  – Scientific or fundamental metrology
  – Applied, technical or industrial metrology
  – Legal metrology
Metrological system

- BIPM (Bureau International des Poids et Mesures)
- National metrology institutes or designated national institutes
- Calibration laboratories, often accredited
- Industry, academia, regulators, hospitals
- End users

The national metrological infrastructure

Uncertainty increases down the traceability chain
National measurement system

“The national measurement system is the technical infrastructure which makes it possible to obtain accurate and reliable measurements which are fit for purpose in the country and are accepted worldwide.

A comprehensive national measurement system includes several areas of responsibility:
- maintaining measurement standards for the units of measurement
- calibration and testing
- continuous development of measurement standards to meet future needs
- laboratory accreditation
- training in metrology
- legal metrology
- relevant documentary standards.”

Source: EURAMET (European Association of National Metrology Institutes)
National metrology institute

• “An essential and indispensable component of any national measurement system is the national metrology institute (NMI). The NMI is the institute which is by national decision responsible for:

  • developing and maintaining national measurement standards
  • providing internationally recognized traceability to the SI
  • ensuring the suitability of these standard for national needs, and
  • providing metrological expertise and knowledge to national users through high level calibration services, advice, training and other assistance.”

Source: EURAMET (European Association of National Metrology Institutes)
Standardization

- activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context

Note 1  In particular, the activity consists of the processes of formulating, issuing and implementing standards.

Note 2  Important benefits of standardization are improvement of the suitability of products, processes and services for their intended purposes, prevention of barriers to trade and facilitation of technological cooperation.

Standardization areas usually very important for developing countries

- Food safety (food processing, testing, traceability, etc.)
- Agriculture (equipment, fertilizers, pesticides, irrigation, etc.)
- Buildings and built infrastructure (buildings, roads, bridges, etc.): materials, codes of design and execution, …
- Electrical infrastructure (generators, power lines, transformers, etc.)
- Water infrastructure (equipment, water management, water treatment, etc.)
- Fire safety
- Medical devices
- Safety and energy efficiency of cook-stoves
- Safety and energy efficiency of electric and gas appliances
- Extractive industries (processing, health and safety of workers, environmental protection, etc.)
- Priority sectors for the local economy and export (e.g. raw materials, textiles, machinery equipment, chemicals, …)
Conformity assessment and accreditation

**Conformity assessment**: involves a set of processes that show your product, service or system meets the requirements of a standard. The main forms of conformity assessment are **testing, certification, and inspection**.

Source: ISO

**Accreditation** – the formal recognition by an independent body, generally known as an accreditation body, that an organization is competent to conduct specified conformity assessment services (that is, testing, inspection, or certification).

Source: The World Bank

[According to ISO: “…that a certification body operates according to international standards.”]
National Quality Infrastructure

Why is the quality infrastructure so important?

**Market access**

- Export markets

**Contribution of the Quality infrastructure**

- Ensure comparability of results (traceability of measurement units and calibration of instruments; availability of test labs at reasonable distance and affordable costs)
- Support the continual improvement of exporters’ products and processes
- Provide up-to-date and reliable information to exporters re: target markets
- Enable exporters to achieve compliance with regulations (mandatory requirements) of target markets
- Help exporters to meet expectations (quality requirements) of target markets
Why is the quality infrastructure so important?

**Market access**
- Participate in global supply chains

**Contribution of the Quality infrastructure**
- Ensure comparability of results (same as in previous slide)
- Support domestic participants to integrate in more complex production systems, requiring:
  - harmonization of processes, materials and instruments; as well as tools and methods used in R&D and production, with those of the other participants in the chain (and notably the buyers)
- Help domestic participants to build trust with the other participants in the chain, concerning:
  - reliability of the legal and technical system within which they operate
  - demonstration of compliance with international standards and other standards or proprietary requirements set by buyers
Why is the quality infrastructure so important?

Consumer and environment protection

Contribution of the Quality infrastructure

- Ability to measure properties and impact of materials and products, concerning in particular health and safety aspects
- Ability to measure environmental impact of production processes, products and services
- Ability to set suitable technical regulations (and/or to support the adoption and use of voluntary standards, whenever appropriate)
- Support the enforcement of technical regulations in a cost-effective way (for all parties)
- Protect domestic producers (especially SMEs) from illegal practices adopted by foreign companies entering the market
National Standards Body (NSB) in developing countries

• In many countries, the NSB is the first of the Quality Infrastructure institutions to be formally established by Government

• Other QI activities, and sometimes institutions, such as accreditation or legal metrology, are often established within the NSB before being spun-off

• Expectations from Government, industry, consumers, and generally other stakeholders are often very high (sometimes too high)

• The NSB’s success depends significantly on the legal and institutional framework, as well as the governance, under which it operates
NSB in developing countries: institutional set-up

• There is no single model specifying how a NSB should be constituted. It depends on what other QI institutions and services already exist in the country, and what roles are conferred to them by the policy-maker.

• A decision needs to be made whether the NSB will cover standardization activities, conformity assessment services (testing certification or inspection), metrology functions, accreditation functions: noting that certain functions are incompatible according to recognized international good practice.

• It could be advisable to have the NSB set up under an Act of law

• NSBs (and more generally NQI bodies) should join international organizations in their respective fields
NSB in developing countries: two fundamental aspects

- Understand, promote and take advantage of the **voluntary nature** of standardization:
  - Using standards and participating in standards development **brings value** to organizations and society – even when compliance is not required

- Use standards and related practices (such as conformity assessment) to implement measures **supporting and ensuring compliance**:
  - Following recognized international good practices
  - Ensuring separation of functions and avoiding conflict of interest
Role of NSB in the quality infrastructure

- NSBs should support the development or improvement of the NQI by:
  - Evaluating gaps, coordinating with other NQI institutions, engaging relevant stakeholders
  - Implementing Good Standardization Practice (strengthening the NQI «standardization pillar»)

- NQI bodies should be supported by a legal framework:
  - Either a comprehensive national quality policy, with related legal provisions, or
  - Specific laws covering standardization, metrology and accreditation bodies
Separation of functions – avoiding conflict of interest

- NSBs can carry out several functions of the QI, however, conflict of interest must be avoided
- Testing/certification **should not** be combined with accreditation
- Consultancy on management systems **should not** be combined with certification of those systems
- However, training in management systems may be combined with their certification, since training is not specific to one company and does not specify actions to be undertaken in a particular company
Separation of functions – avoiding conflict of interest (2)

- **NSB should not be responsible for developing technical regulations** (TRs) – however, TRs should be based on international standards, where they exist (WTO/TBT Agreement, Article 2.4)

- A regulatory body may ask the NSB to develop (or nationally adopt) standards to be used as a basis for technical regulations – regulators should be fully involved in the standards development process

- Regulatory bodies can enforce TR through:
  - Premarket approval of products
  - Market surveillance
Quality infrastructure supporting development in Africa: some concrete issues

• How increased cooperation among the African regional (and sub-regional) standards organization can help to:
  − Reduce bureaucratic layers (within the various countries) creating obstacles to trade
  − Improve the way to deal with sub-standard products (at domestic and export level)
  − Improve the way to deal with major environmental challenges (e.g. toxic waste)

To be debated by the CEOs joining the CEO Forum for Africa on 30 June!
The role of ISO

- Developing and providing International Standards covering a broad variety of sectors and issues relevant for developing countries
- Developing and providing International Standards for Conformity Assessment – recognized as international good practices in the field
- Providing technical assistance and training to developing countries, aiming to strengthen their ability to operate as effective NQI institutions
Conformity Assessment: the CASCO toolbox

The **Toolbox** is the set of conformity assessment standards developed by ISO/CASCO for the operation of:

- **Conformity assessment bodies** (laboratories, certification bodies and inspection bodies)
- **Accreditation bodies**
- For **peer evaluation** and other associated activities

ISO/CASCO has more than 29 published standards and guides
Conformity Assessment: the CASCO toolbox

Terms and definitions ISO/IEC 17000

Requirements for accreditation bodies – ISO/IEC 17011

- Requirements for Testing/calibration: ISO/IEC 17025
- Testing and calibration laboratories: ISO/IEC 17025
- Proficiency testing: ISO/IEC 17043

ISO/IEC 17020

Requirements for inspection bodies

- Management systems: ISO/IEC 17021 and related parts
- ISO/IEC 17023

ISO/IEC 17024

Requirements for certification bodies

- Persons: ISO/IEC 17024
- ISO/IEC TS 17027

ISO/IEC 17065

ISO/IEC 17067

ISO/IEC 17026

Conformity assessments of suppliers
ISO/IEC 17050-1
ISO/IEC 17050-2

Peer assessment ISO/IEC 17040

Mutual recognition ISO/IEC Guide 68
ISO resources on conformity assessment

- ISO website
  [http://www.iso.org/iso/home/about/conformity-assessment/casco.htm](http://www.iso.org/iso/home/about/conformity-assessment/casco.htm)

- Conformity Assessment tools for regulators:

- Subscribe to CASCO's newsletter

- Publications
  [http://www.iso.org/iso/home/about/conformity-assessment/conformity-assessment_resources.htm](http://www.iso.org/iso/home/about/conformity-assessment/conformity-assessment_resources.htm)

- CASCO Toolbox
Thank you!
Merci!
Baarka!