# Session 3 - The Quality Infrastructure (QI)


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# Definition of the QI



## Quality Infrastructure

- Whether it is for the internal or external market we all have to demonstrate our products and services are **safe and reliable** and we need **technical expertise** within the country to do this.
- **Harmonization** of these structures at regional and global levels is critical to facilitate trade. Governments want to be sure that a countries' quality or technical infrastructure is adequate and comparable in order to accept goods.
- Most countries have **established appropriate bodies and international relationships** to support their QI infrastructure.

# Quality Infrastructure

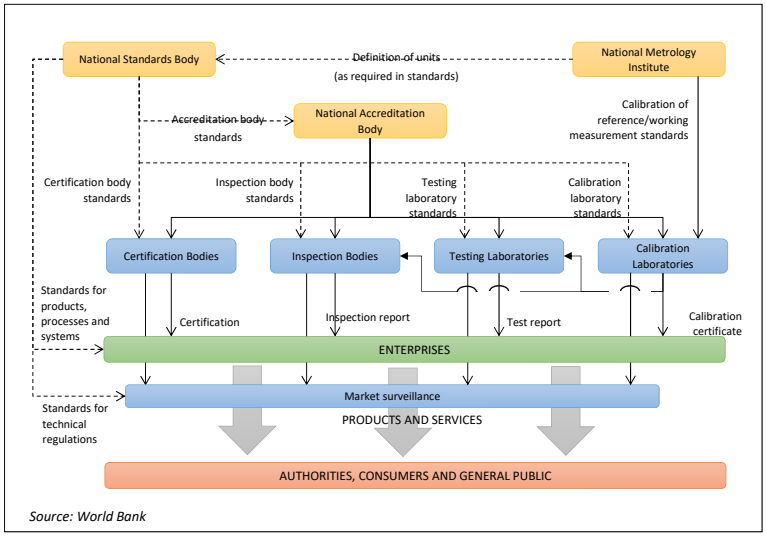
- Is a system comprising the organizations together with the policies, relevant legal and regulatory framework and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes.
- Is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing.
- Institutions of this framework represent the scientific and technological basis for the whole infrastructure.

# Quality Infrastructure

In simple terms is the organizations (public and private) that establish and implement …

- standardization
- metrology
- accreditation
- conformity assessment
- market surveillance

# National Quality Infrastructure




*Source: World Bank*



# National Quality Policy (NQP)

# Quality Policy - What is meant

- The policy adopted at national or regional level to develop and sustain an efficient and effective quality infrastructure.
- The National Quality Policy (NQP) provides the policy framework, endorsed by the highest political level, of the way in which the country wishes to establish and maintain its Quality Infrastructure. The policy has to clearly address the organizational structures, responsibilities and coordination amongst the entities of the QI. It should provide guidance regarding the governmental responsibilities viz. a viz. those of the private sector. It should provide the connection between other government policies and the need for an effective and efficient QI

# Quality Policy - How can it be demonstrated?

- The NQP should be a formal document approved by the Cabinet or Parliament as relevant for implementation.
- The National Quality Policy should be publicly available, i.e. on the relevant Ministry website or in hard copy.
- The activities, business plans and budgets of the QI entities should be aligned with the National Quality Policy to ensure its implementation.
- The NQP should be accompanied by an Implementation Plan and concomitant budget with detailed responsibilities for actions and outcomes.

## Quality Policy - Typical content

| NQP Section | Subsections and comments |
|---|---|
| Foreword | The relevant minister (for example, Trade and Industry) expresses political support for the implementation of the policy |
| 1- Introduction | ▪ International and regional context<br>▪ Trade as a driver for development and poverty reduction<br>▪ Definition of the national quality infrastructure and technical regulation framework<br>▪ Policy environment |
| 2- Review of the current situation | ▪ National quality infrastructure (QI)<br>▪ Technical regulation framework (TRF)<br>▪ Compliance with WTO TBT Agreement and related regional obligations<br>▪ Gap analysis |
| 3- Vision | Where the country wishes to be in time (5 or 10 years) |
| 4- NQP objectives | ▪ QI that meets country needs and is accepted internationally<br>▪ A technical regulation regime common across all authorities compliant with international and regional obligations |

## Quality Policy - Typical content

| NQP Section | Subsections and comments |
|---|---|
| 5- The future NQI | ▪ Organization and responsibilities of the NSB, NMI, and NAB<br>▪ Provision of calibration, inspection, testing and certification services<br>▪ Role of government in relation to the private sector |
| 6- The TRF | ▪ The necessity of regulatory impact assessments (RIAs)<br>▪ Use of standards as the basis for technical regulation<br>▪ Conformity assessment for regulatory purposes<br>▪ Regulatory authorities, their responsibilities, and activities<br>▪ Coordination of the technical regulation system |
| 7- . Education & training, awareness & communication | ▪ The role of education institutions<br>▪ Registration of quality-system professionals |
| 8- Information network | ▪ National TBT Inquiry Point<br>▪ Cooperation with the trade promotion organization |
| | |

Quality Policy - Typical content

| NQP Section | Subsections and comments |
|---|---|
| 9- Role of other stakeholders | ▪ Private sector<br>▪ Nongovernmental organizations<br>▪ International development partners<br>▪ Academia |
| 10- International and regional liaison | ▪ Liaison with international and regional organizations<br>▪ Commitment for active participation in international and regional technical committees |
| 11- Financing the NQI and TRF | ▪ Government responsibility for standards, metrology, and accreditation<br>▪ Conformity assessment: “user pays” principle<br>▪ Technical regulation |
| 12- Legal framework | ▪ Review of current legislative instruments<br>▪ Development of new legislative instruments |
| 13-Implementation | ▪ Lead ministry<br>▪ The private sector as one of the key drivers of the NQP<br>▪ Interministerial and private sector coordination committee<br>▪ Implementation plan or strategy (five years) |

# Components of the QI

# Technical regulations

Government policy and regulation can address the following:

- Public health and safety
- Market failure (including externalities)
- Interconnectivity and interoperability
- Economic transactions
- Trade and market access
- Quality excellence and technically credible results

- Organisational improvement
- Regulatory compliance
- Supply chain entry
- Access to funding
- Risk management

- Market differentiation
- Better regulatory practice
- Consumer protection
- Sustainable development

# Standardization

- Development and publication of a formal document by a recognized body, generally by consensus, containing the requirements that a product, process or service should comply with. Standards can be the basis of technical regulation, contractual obligations or market expectations. Standards are developed on a number of levels, namely
  - International standards
  - Regional standards
  - National standards
  - Private standards
- Voluntary and mandatory standards

# Metrology

- Legal metrology approves measurement devices used in daily commerce and includes scales used in shops, gas and electricity meters, breath analysis and speed measurement. Legal metrology is coordinated by the International Organization of Legal metrology (OIML).
- Scientific and technical metrology ensures world-wide uniformity of measurements and their traceability to the International System of Units (SI). International coordination of measurements is provided through the International Bureau of Weights and Measures (BIPM) .
- The international framework for providing reliable measurements is coordinated at the national level by National Measurement Institutes (NMI) which provide reliable measurement.

# Metrology in daily life

Video from VSL Dutch Metrology Institute (2min)
https://www.youtube.com/watch?v=vRnT8hIxjqk

# Conformity assessment

- ISO and IEC have jointly developed standards (ISO/IEC 17000 series) covering:
  - Principles and terminology
  - Code of conformity assessment practice
  - Testing
  - Inspection
  - Validation and verification
  - Suppliers declarations of conformity
  - Certification – Product, Management systems and Persons
  - Accreditation
  - Peer assessment
  - Mutual recognition underpinned by peer evaluation

# Market surveillance

- Market surveillance is a set of activities carried out and measures taken by regulators or designated authorities to ensure that products comply with mandatory requirements and do not endanger any aspect of public interest protection.
- Examples of market surveillance activities
  - **Pre market:** a regulator or owner may require that prior to selling medical devices the factory has a quality management system (QMS) in place which has been certified by an accredited certification body.
  - **Post market:** a regulator may go to the market place and purchase a medical devices, take it to an “accredited” laboratory and have it tested to determine if it meets the requirements.

# Examples of QI institutions at the national level

## QI at the national level - Switzerland

| 1- Public Policy, Regulation, Contracts | 2- Measurement (metrology and physical standards) | 3- Documentary standards, Methods of test | 4- Claims of conformity, Validation, Verification, Certification | 5- Accreditation, Peer assessment |
|---|---|---|---|---|
| • Governments, industry groups, consumer groups | • METAS, Swiss Metrology Institute | • SNV, Swiss Association for Standardization and other standards' writers and professional bodies | • Various government, not-for-profit and commercial bodies | • SAS, Swiss Accreditation Service |

# QI at the national level - Pakistan

| 1- Public Policy, Regulation, Contracts | 2- Measurement (metrology and physical standards) | 3- Documentary standards, Methods of test | 4- Claims of conformity, Validation, Verification, Certification | 5- Accreditation, Peer assessment |
|---|---|---|---|---|
| • Technical regulations are developed and administrated by a number of competent authorities at federal and provincial level<br>• Coordination of the technical regulation system will be conducted at the federal level | • National Physical and Standards Laboratory (NPSL) is e sole custodian of National Standards of Measurement in the country<br>• Legal metrology is a collective responsibility shared between the federal and provincial governments | • Pakistan Standards and Quality Control Authority (PSQCA)<br>• PSQCA registers Standards Development Organizations to develop national standards | • Testing and inspection services, or the certification of product and management systems for the implementation of technical regulations may be provided by laboratories, inspection bodies and certification organizations in both the private and public sector | • Pakistan National Accreditation Council (PNAC) as an independent entity under the Ministry of Science and Technology |

# Examples of QI institutions at the regional level

# QI at the regional level

| 1- Public Policy, Regulation, Contracts | 2- Measurement (metrology and physical standards) | 3- Documentary standards, Methods of test | 4- Claims of conformity, Validation, Verification, Certification | 5- Accreditation, Peer assessment |
|---|---|---|---|---|
| • Regional intergovernmental regulatory body, e.g. MERCOSUR, APEC, SADC, EU | • Regional metrology reference laboratories e.g. APLMF, COOMET, EMLM, SMIIC | • Regional SDOs, e.g. COPANT, CEN-CENELEC, EASC, ARSO | • Process used to claim conformity (Auditing, Calibration, Evaluation, Examination, Inspection, Testing)<br>• 1st, 2nd and 3rd party claims of conformity and marking | • Regional accreditation cooperative organisations, e.g. EA, APAC, IAAC, SADCA, AFRAC, ARAC |

# Example of the Caribbean regional approach to metrology

The slide that follows shows how the region has established a regional Caribbean reference laboratory (CaRL) policy to provide traceability to the national labs in states without the resources to establish and maintain the required standards. The standards maintained by the national labs are used to disseminate traceability through the working standards used by inspectors to the instruments used in measurement in trade.

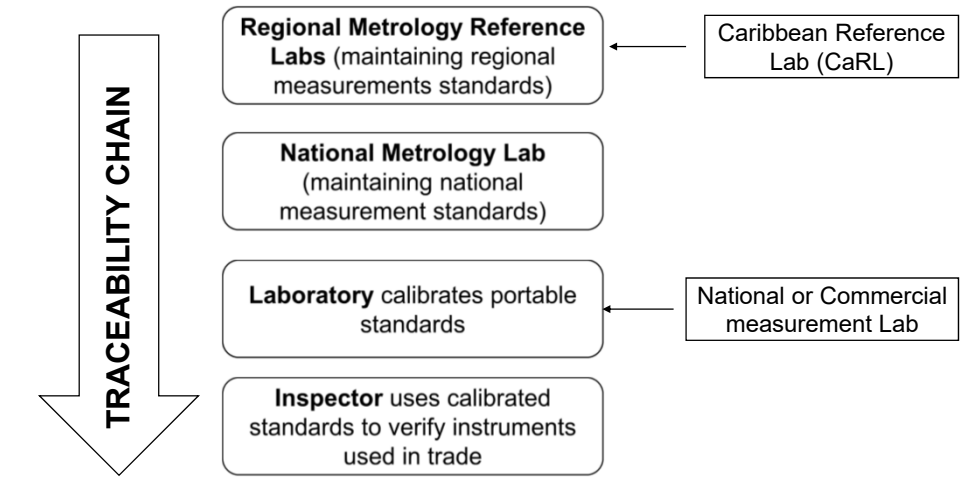
**Insitutins**

ISO KN1

## Slide 26

**KN1** KHAMMASH Nesreen; 2019-08-11

# Traceability chain in Caribbean SIDS




*SIDS = Small Island Developing States*

# Points to remmeber

# Don’t forget that …

QI components and organizations can vary from one country to another but the following elements make up an acceptable system:

- Capability to develop standards or at least adopt them as national
- Access to physical, chemical and biological standards of measurement (physical standards)
- Provision of a legal metrology system
- Availability of inspection, testing and calibration services required by the level of industry needs
- Availability of third party conformity assessment services such as product certification to meet the requirements of the regulators and others
- Mechanism to ensure all service providers are competent, such as accreditation that is recognised via a mutual recognition arrangement or agreement.

# Video

Quality Infrastructure supporting Nigeria to overcome the trade barriers of dried beans
*from United Nations Industrial Development Organization (UNIDO)*

https://youtu.be/-L35Zz1F-YQ

# Individual/Group Activity #2

## Individual/Group Activity #2

**Discuss in Groups (10 minutes) and complete individually (10 minutes)**

1. Using the chart below, fill in the different institutions/components of QI in your country? Which of the institutions are not (fully) operational and what do you do to compensate for this?
2. Do you belong to a regional grouping for any of the different components of the QI?

# Individual/Group Activity #2

| 1- Public Policy, Regulation, Contracts | 2- Measurement (metrology and physical standards) | 3- Documentary standards, Methods of test | 4- Claims of conformity, Validation, Verification, Certification | 5- Accreditation, Peer assessment |
|---|---|---|---|---|
| | | | | |