

# The Role of National Quality Infrastructure in Promoting Risk-Based Solutions

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*Consultation on public policy, regulation and standardization*

“Risk-Based Consumer Protection Workshop”

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Dakar, SENEGAL

# Outline

- Introduction
- National Quality Infrastructure
- US principles and practices in NQI
- Use of NQI for risk-based consumer protection, and to promote trade
- Ongoing efforts for improving quality infrastructure
  - UNIDO, World Bank Group, ISO, Standards Alliance
- Conclusions and recommendations

# Background

- Deytec, Inc. is a consulting company and active member of ANSI (AIF, AIC, IPC)
- Nuclear engineering/nuclear safety
- Development of US public policy and safety regulations
- Fire safety of nuclear installations/fire safety engineering
- Public safety risk assessment/engineering analytical methods

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# Expert in ISO Standardization System

- Convenor in *TC 92 SC 4 - Fire safety engineering* (5 yrs.)
- Focus on inclusion of conformity assessment
- Member ANSI-ICAC (mirror committee to ISO CASCO)
- ISO Convenors training and workshops – ISO mission
- ISO, IEC, WTO conferences and training – Policy, TBT
- Participation in DEVCO (ANSI), ISO General Assembly
- **Business focus on developing economies: trade and competitiveness**

# Standards for a better world



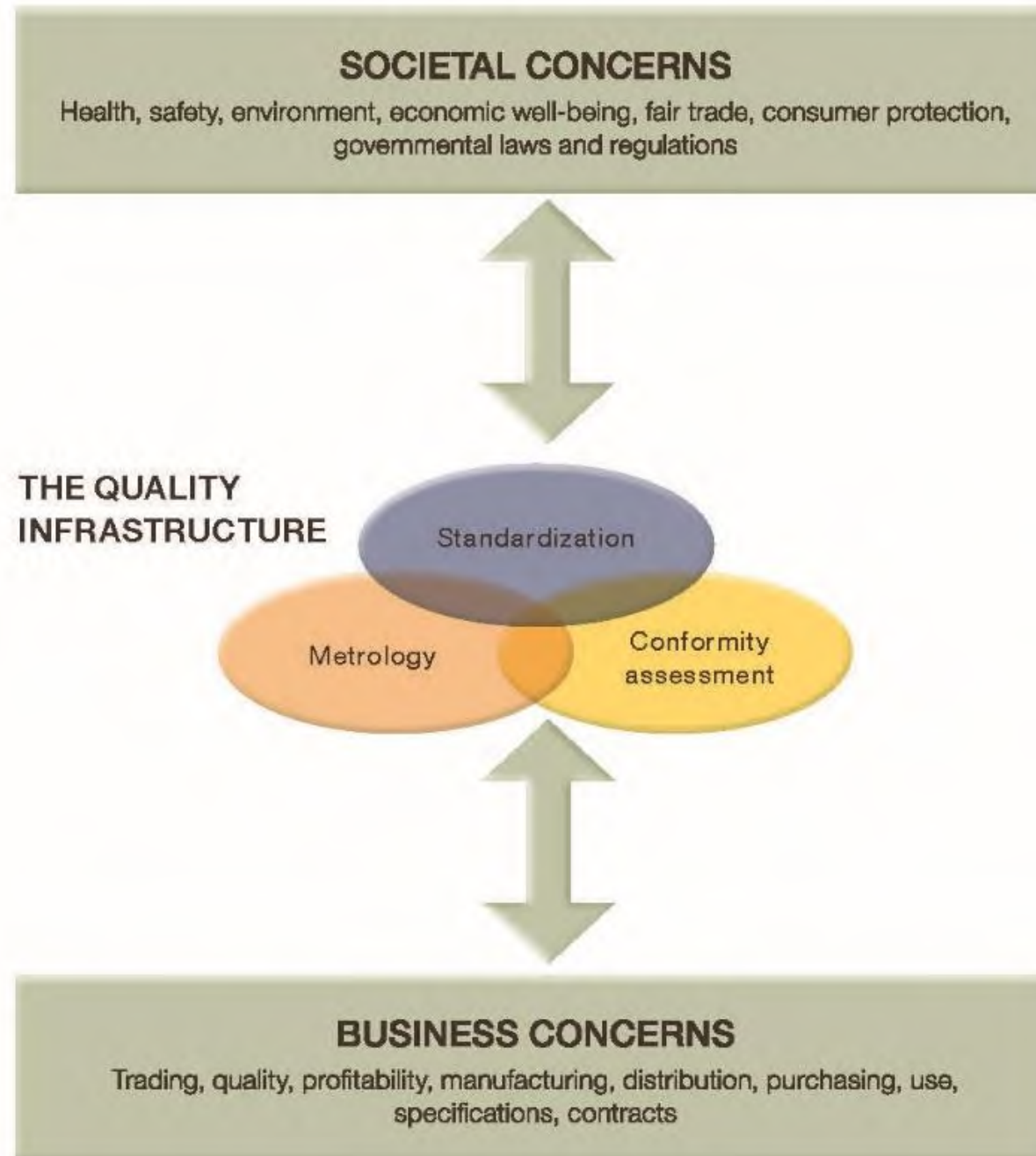
For more about ISO's work programme as it affects consumers, see the ISO Directory for consumer interest participation: [www.iso.org/COPOLCO\\_interest](http://www.iso.org/COPOLCO_interest)  
 \*In collaboration with IEC.

Illustration: Vera Kozlovskaya

ISO 26000: 2010: 2.1.1.1.1

Prepared by Alexey Sidorov

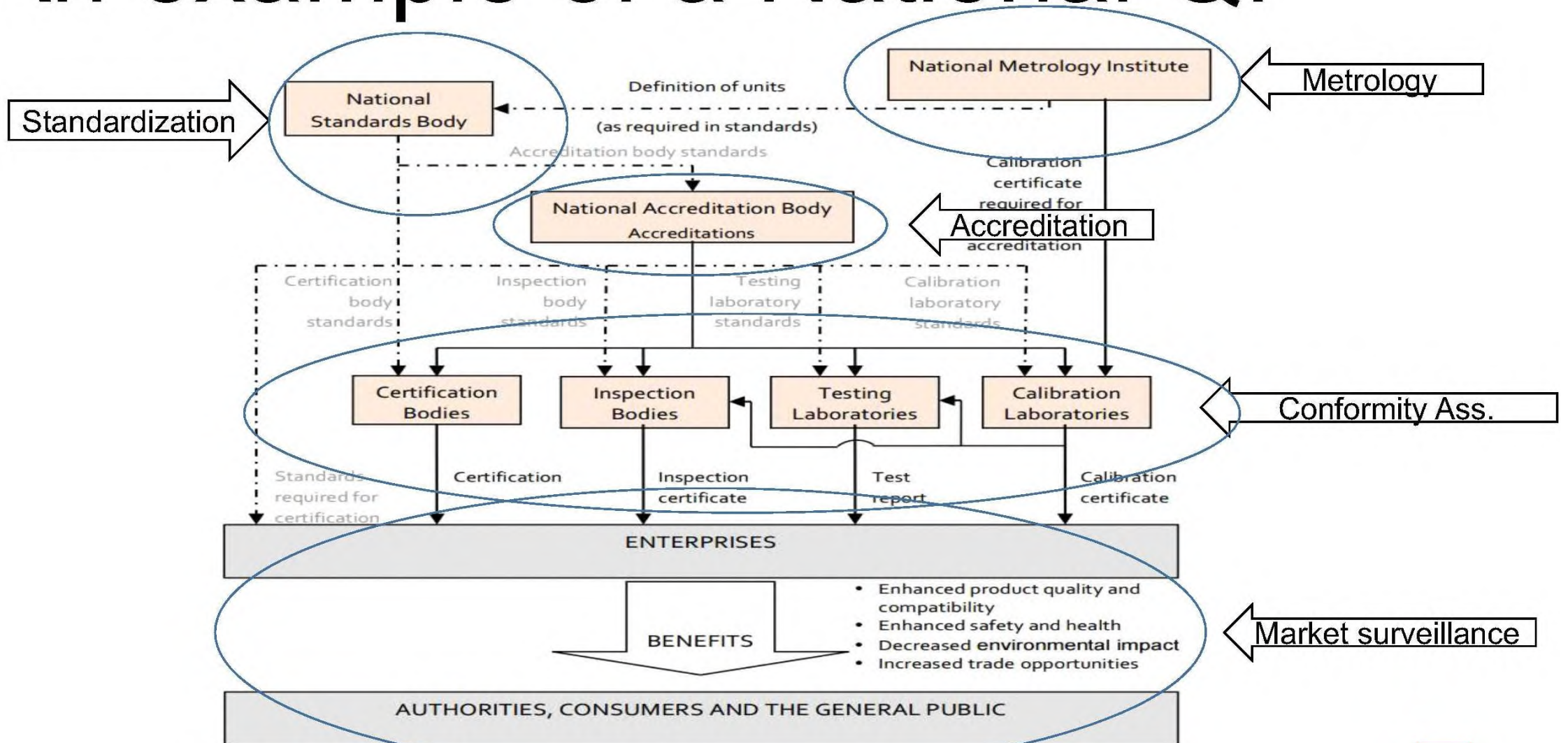
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# Quality infrastructure definition

- The organizations public and private that establishes and implement standardization, metrology, accreditation, conformity assessment and market surveillance
- The definition has been agreed by the BIPM, IAF, ILAC, ISO, IEC, ITU, ITC, OIML, UNIDO and UN/ECE
- Required for effective operation of domestic markets, and international recognition to foreign markets
- Critical element in sustaining economic development and environmental and social wellbeing

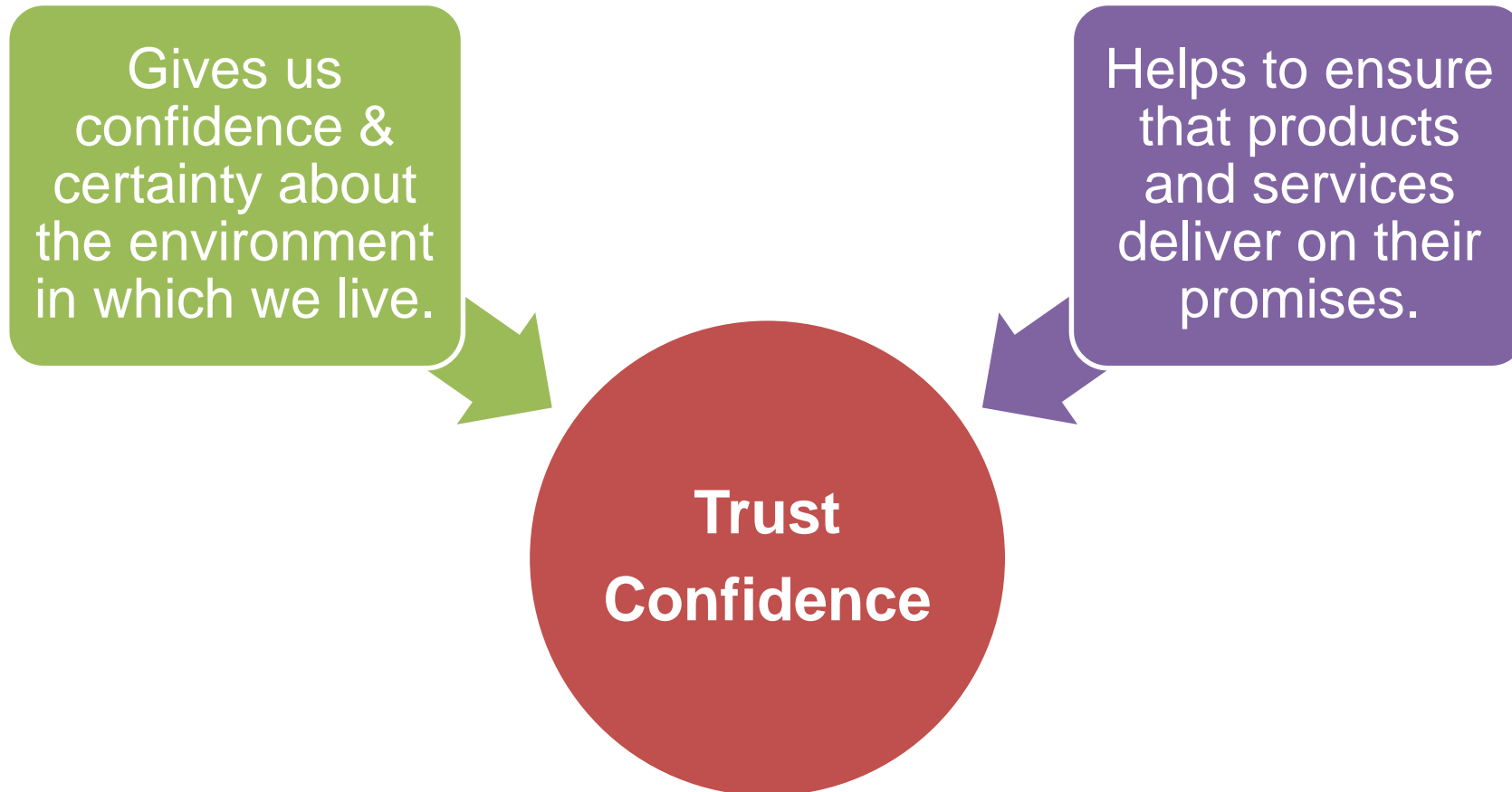
# An example of a National QI



Source: World Bank 2007.



# Conformity assessment



# Conformity assessment

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

(ISO/IEC 17000, Clause 2.1)

# Conformity assessment techniques



## Testing

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



## Evaluation

the process of **gathering evidence** about whether a product, process or service meets specified requirements. It is also sometimes used in the context of person certification.



## Inspection

can include a visual examination, measurement or testing of physical items based on the **professional judgment** of the inspection bodies' personnel.



## Examination

often used interchangeably to cover a number of techniques, but is used in a more specific way for certifying the **competence of a persons**.



## Auditing

an audit is a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.



## Assessment

process of determining whether an organization fulfils requirements related to its **technical competence**. Assessments are carried out during accreditation and peer assessment.

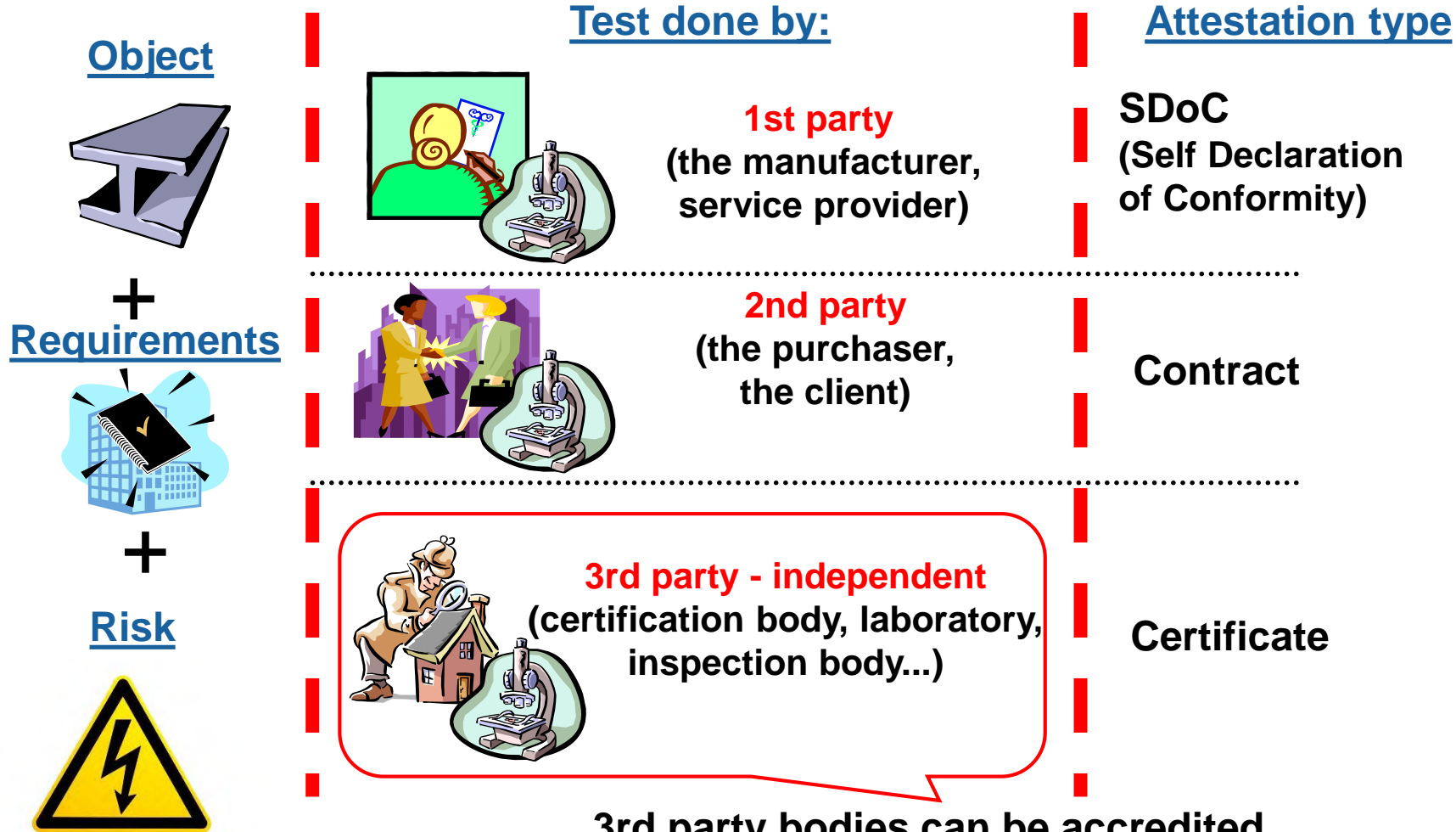
# Conformity assessment bodies (CABs)

Conformity assessment activities are carried out by different types of **CABs**:

- testing laboratories
- inspection bodies
- certification bodies.

After the application of one or more conformity assessment techniques, a **claim of conformity** can be made.

# Conformity assessment claims



3rd party bodies can be accredited.  
Accreditation bodies are assessed by their peers

# Third-party claims of conformity Certification

- **third party assurance** that a product, (services), process, personnel, organization or management system conforms to specific requirements.
- made by **independent** organizations of the person or organization that provides the object.

**Examples** include independent and impartial testing laboratories, inspection bodies or certification bodies.

# Recognition of CABs

## Accreditation

- A specific conformity assessment activity carried out by Accreditation Bodies (ABs) involving the **independent third-party** assessment of CABs with specified requirements.
- third-party attestation related to a CAB conveying formal demonstration of its **competence**.



# TOOLBOX

## Terms and definitions ISO/IEC 17000

### Requirements for accreditation bodies – ISO/IEC 17011

Requirements for Testing/ calibration Testing and calibration laboratories ISO/IEC 17025 Proficiency testing ISO/IEC 17043	Requirements for inspection bodies  ISO/IEC 17020	Requirements for certification bodies <table border="1"><tr><td>Management systems  ISO/IEC 17021 and related parts ISO/IEC 17023</td><td>Persons  ISO/IEC 17024 ISO/IEC TS 17027</td><td>Products  ISO/IEC 17065 ISO/IEC 17067 ISO/IEC TR 17026</td></tr></table>	Management systems  ISO/IEC 17021 and related parts ISO/IEC 17023	Persons  ISO/IEC 17024 ISO/IEC TS 17027	Products  ISO/IEC 17065 ISO/IEC 17067 ISO/IEC TR 17026	Conformity assessments of suppliers ISO/IEC 17050-1 ISO/IEC 17050-2	Peer assessment ISO/IEC 17040	Mutual recognition ISO/IEC Guide 68
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# US Strategy and Principles

- United States standards strategy – ANSI publication
- US conformity assessment principles – ANSI publication
  - supplement language of TBT to clarify and focus of conformity assessment for US
  - foster increased acceptance of U.S. products in international markets through use of international standards as feasible
- NIST Special Publication 2000-01 ABC's of Conformity Assessment – Draft

# Conformity Assessment Standards

(from NIST 2000-01 Draft)

	SDoC	Testing	Inspection	Certification	Management System Certification
Arrangements	N/A	Mutual Recognition Arrangement	Mutual Recognition Arrangement	Multilateral Recognition Arrangement	Multilateral Recognition Arrangement
Accreditation	N/A	Accreditation Bodies (ISO/IEC 17011)	Accreditation Bodies (ISO/IEC 17011)	Accreditation Bodies (ISO/IEC 17011)	Accreditation Bodies (ISO/IEC 17011)
Standard	ISO/IEC 17050 – Part 1 ISO/IEC 17050 – Part 2	Testing & Calibration Labs (ISO/IEC 17025)	Inspection Bodies (ISO/IEC 17020)	Certification Bodies (ISO/IEC 17065)	Registrars (ISO/IEC 17021)

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# ANSI Accreditation Services

- Product certification programs - ISO/IEC 17065
- ANSI-ASQ ANAB joint accreditation program for laboratory and inspection bodies - ISO/IEC 17065, 17025, 17020
- Credentialing programs – Certification ISO/IEC 17024, certificate ANSI/ASTM E2659
- Greenhouse gas validation/verification bodies - ISO 14065
- Accreditation for food safety – ISO/IEC 17065

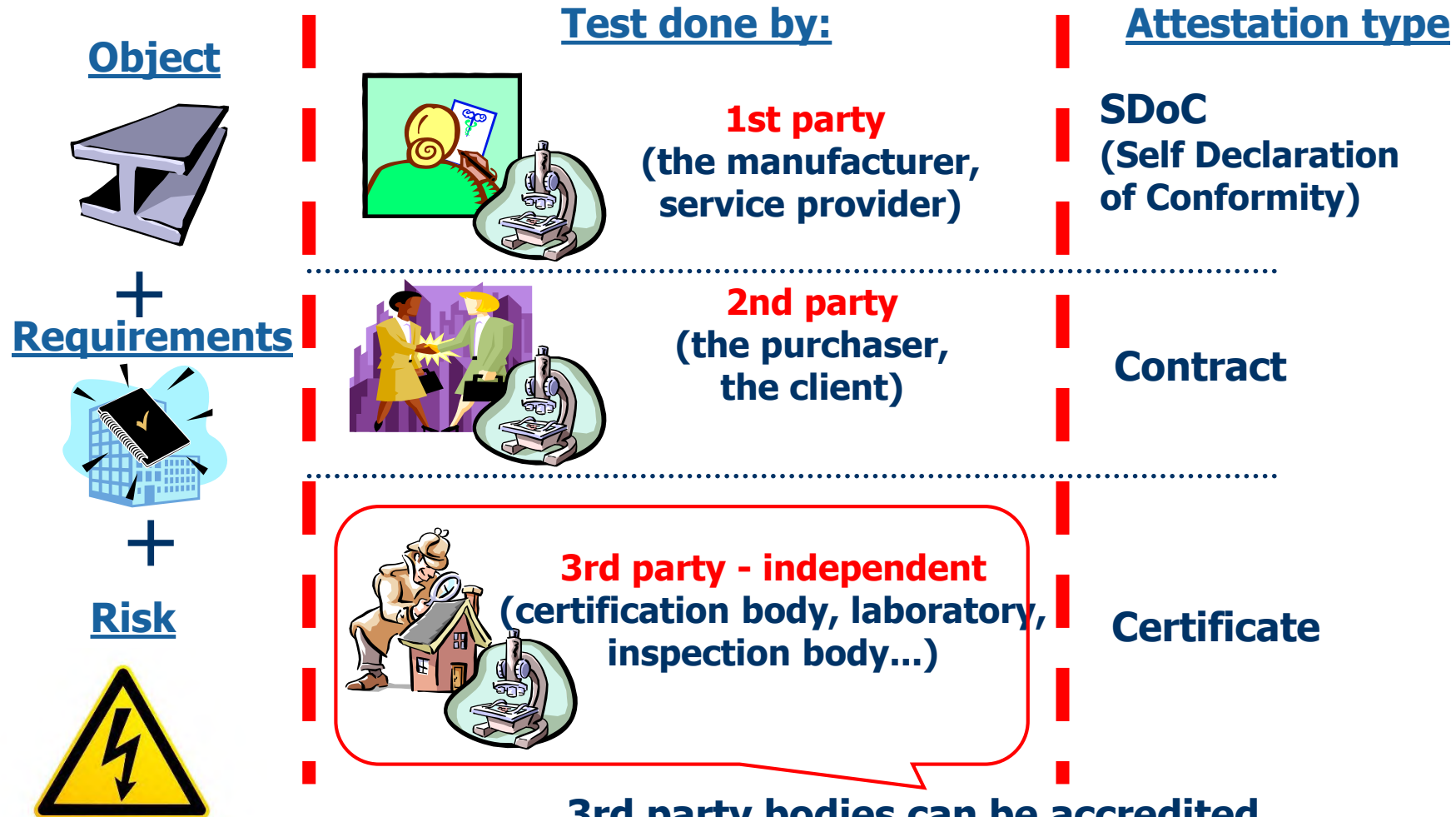
# Use of NQI for Consumer Protection

- Pre-market controls
  - Establish regulations that refer to international standards
  - Follow work of international consumer organizations, e.g. ISO COPOLCO, Consumers International
- Post-market controls
  - Consumer protection agency
  - Establish framework for risk-informed decision making

# Use of Regulations and International Standards

- Establish regulations for consumer products, including conformity assessment, based on risk (TBT)
  - Initiative of Mauritius Standards Bureau (2017)
  - Safety of household electrical appliances - 20 IEC standards referenced in regulation
- Evaluate substandard products entering market
- Proactively evaluate international experience
  - Minimize missed opportunities – furniture tipping/child safety

# Conformity assessment claims



**3rd party bodies can be accredited.  
Accreditation bodies are assessed by their peers**

# Work of COPOLCO

- Determine most effective areas of focus for consumer protection in standards
  - Food safety and labeling
  - Safety of household appliances (microwave ovens, vacuum cleaners, dishwashers and clothes washing machines)
  - Safety of toys, guidelines for child safety
  - Second-hand goods
- Promote evaluation of national issues in COPOLCO



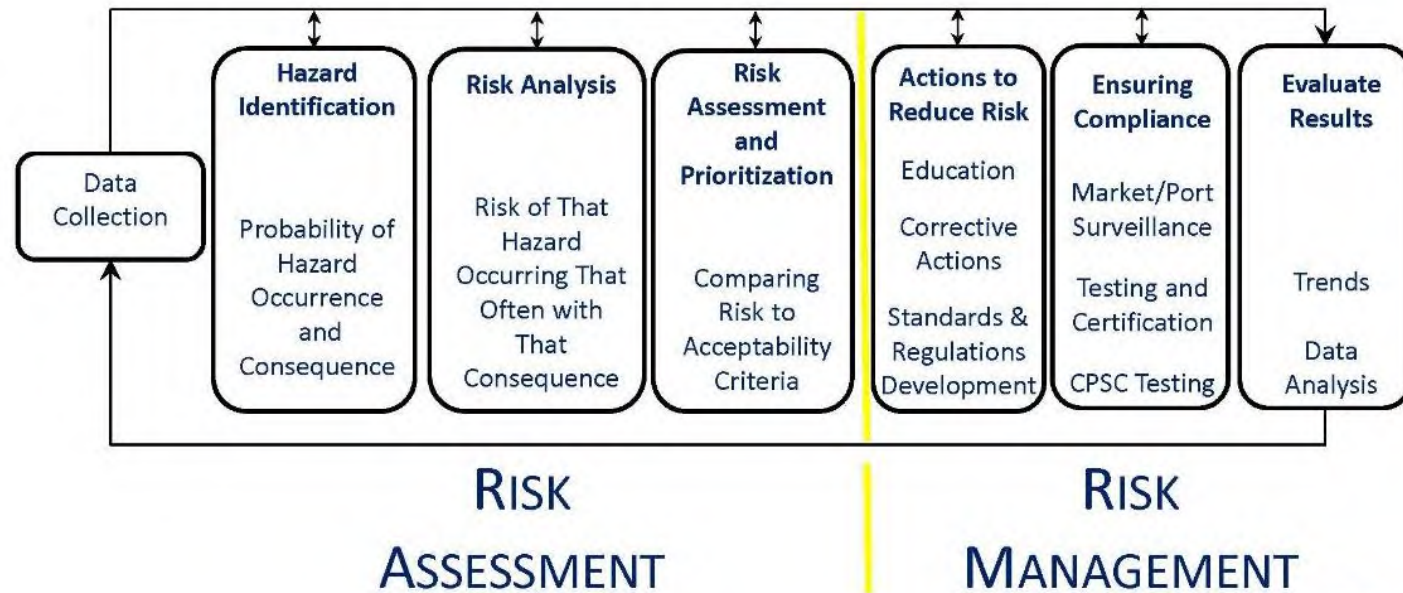
# Post-Market Controls

- Consumer Protection Agency, e.g. US Consumer Product Safety Commission
- Risk-Informed Decision Making (CPSC)
  - Use best available information in a formal or informal risk assessment to inform decision makers
  - Prevent or reduce unreasonable risk, account for uncertainty
  - Costs must bear a reasonable relationship to benefits

# Risk-Based Analysis

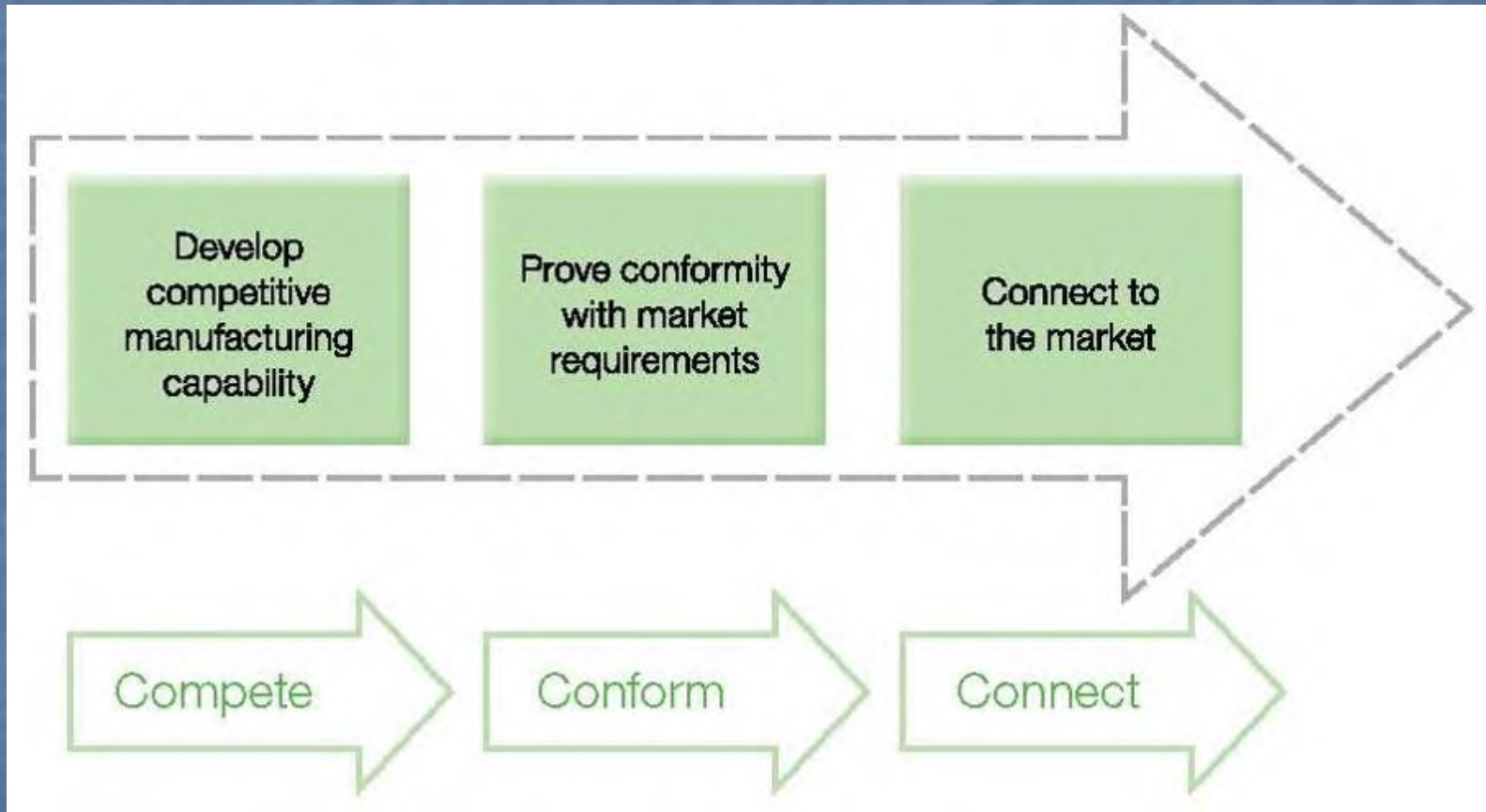
- Information used (CPSC):
  - Frequency and severity of injuries
  - Causality of injuries
  - Chronic illness and future injuries
  - Cost and benefit of action
  - Unforeseen nature of the risk (“hidden” hazard?)
  - Vulnerability of the population at risk
  - Probability of exposure to the hazard
- Collection and use of data in analysis important

# CPSC RISK MANAGEMENT PROCESS



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# Trade Competitiveness



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# International Programs

- Tools, data for:
  - trade and industry competitiveness analysis
  - data on quality infrastructure constraints
  - product refusals/notifications tool
- Projects:
  - building the components of a quality infrastructure (UEMOA)
  - building an integrated quality infrastructure (UEMOA)
  - Southern Africa Development Community (SADC)

# The Value of Quality Infrastructure

- QI determines quality and affects trade, innovation, productivity, jobs, safety, and competitiveness
- 44% of firms had to conduct significant duplication of testing procedures to meet foreign requirements
- 30% of firms had to conduct complete duplication of testing procedures
- 68% of firms cited testing and certification costs as an important reason for not exporting

# Issues Recognized in TBT

- TBT recognized conformity assessment activities can expedite or seriously hinder free flow of goods
- Most trade disputes are about conformity assessment
- TBT requires conformity assessment procedures not create unnecessary obstacles to international trade
- Use guides issued by international standardizing bodies
- Meet TBT's code of good practice
- Conformity assessment presently key issue in TBT Comm.

# Quality Infrastructure is Critical for Trade, Innovation and Competitiveness



## Increase Market Access

- Increase exports
- Increase product diversification
- Improve investment opportunities
- Benefit from trade agreements

## Improve Firm's Productivity

- Reduce cost of trade and cost of doing business
- Benefit from economies of scale due to improved working methods and standardization
- Enhance innovation and technology transfer

## Protect Public Good

- Public health and safety
- Consumer protection
- Social protections and labor conditions
- Environmental protection



# Our QI Reform Approach

## Identify

- Priority sector(s)
- Target market(s)
- Technical regulations

## Diagnose

- Demand for QI service
- Supply of QI services
- QI service capacity

## Prioritize

The relevant and necessary QI reforms to serve countries' priorities

## Develop

The QI reform program and plans

## Implement and Review

The QI reform project(s)

## Key Principles

- Market-Drive Approach
- Establishing the Process for QI reforms, *we are not scientists!*
- Ensure transparency and availability of services
- Identify market failure that may justify public intervention/funding
- Engage with all the stakeholders (private sector, development partners, academia)

# Ethiopia World Bank NQI Project

- Financed by World Bank Group for implementing National Quality Infrastructure Development Project (NQIDP)
- Objective is to improve delivery of quality assurance services to enterprises in targeted sectors
  - (i) leather and leather products; (ii) textile and garments; and (iii) agro-processed products
- Strengthen Ethiopian Standards Agency (ESA), Ethiopian National Accreditation Office (ENAO), and Ethiopian Conformity Assessment Enterprise ( ECAE)

# Potential Exports from Senegal

- Establish quality assurance services for exports:
  - Fish
  - Petroleum products
  - Precious metals
  - Food products
- Are the necessary elements of NQI available?

# ANSI-USAID Standards Alliance

- Capacity building for implementation of TBT agreement
- Establish opportunities for bilateral trade
- Identify priority sectors, target markets & regulations
- Diagnose need & availability for QI service & capacity
- Prioritize, develop and implement reforms
- Role of ASTM and UL standards in bilateral trade

# Conclusions and Recommendations

- Assess NQI and any need for reform
  - National quality policy and standards strategy
  - Engage and promote national issues in ISO, IEC, WTO
  - Most trade issues are conformity assessment related
- Utilize ISO resources and CASCO toolbox
- Education and development of young professionals
- Regional/Sub-regional involvement important
- Build on past successes - UEMOA

# Recommendations – Cont'd

- Support for capacity building: ISO, UNIDO, UNECE, Standards Alliance
- Participation in World Bank Group (WBG) – Trade and Competiveness financed project
  - Toolkit provides methodic process of enhancing NQI
  - Donor programs or loans available
  - Investment will pay off and benefit future generations
- Future programs in ANSI-USAID Standards Alliance

# Thank you!

Questions:

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