Conformity Assessment, Regulation and Standards and Trade

Catholic University

Strategic Standardization

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Activity Overview

- Assist US Federal Government Agencies including the Department of Homeland Security and the Department of Justice in developing standards and conformity policies and administrative infrastructure
- Design and assist in the implementation of homeland security related conformity assessment programs
- Assist in the development of standards for homeland security
  - Coordinate and network with standards development organizations
  - Promote use of available international and national standards
  - Identify standards suitable for homeland security procurement and grant guidance
  - Participate in the development of key standards

Conformity Assessment

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

ISO/IEC 17000

Helpful Terminology

The parties – who done it?

Conformity Assessment can be conducted by:

first party – seller or manufacturer

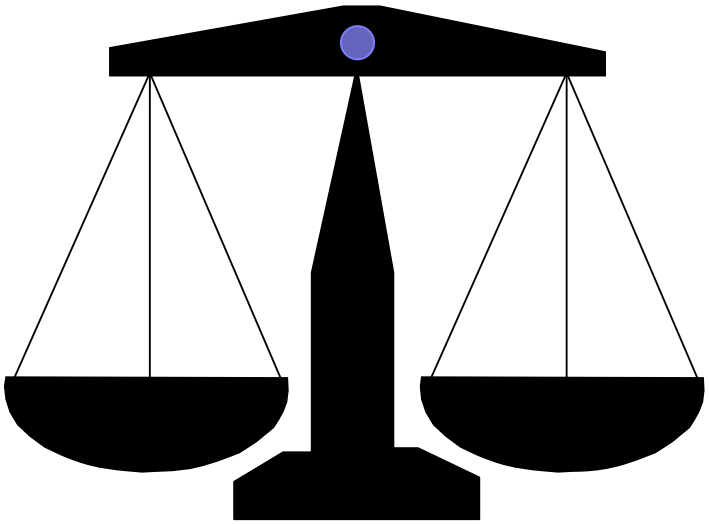
second party – purchaser or user

third party – an independent entity that has no interest in transactions between the 1st and 2nd parties

government – has a unique role in regulation, but is the second party in procurement

Types of Conformity Assessment

- Supplier's Declaration
- Inspection
- Testing
- Certification
- Registration
- Accreditation



Typical Use – Testing (1st, 2nd or 3rd Party CA)

- Used when the critical characteristics can be evaluated via measurement under specified conditions.
- Type test is a test carried out on samples that represent production for the purpose of determining conformity.
- May be an element of a suppliers' declaration or certification system.

Typical Use – Suppliers Declaration (1st Party CA)

Generally used:

- when the risk associated with noncompliance is low
- there are adequate penalties for placing noncompliant products on the market
- there are adequate mechanisms to remove noncompliant products from the market

Typical Use – Inspection (1st, 2nd or 3rd Party CA)

- Used when the critical characteristics can be evaluated via physical examination or measurement.
- May be an element of a certification system.
- May be used to ensure that all parts of a system have been properly installed (ex. code inspection)

Typical Use –Certification (3rd Party CA)

- Used when the risks associated with non-conformity are moderate to high.
- Includes evaluation, compliance decision, attestation of conformity and some form of *surveillance* or follow up.
- Always conducted by a third party.

Management System Registration (3rd Party CA)

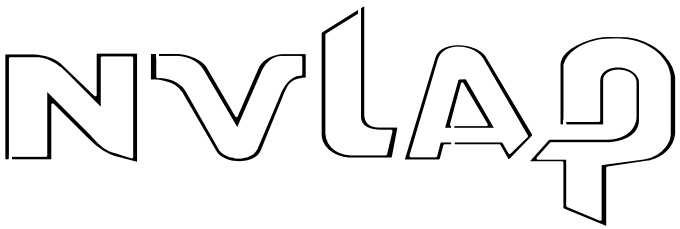
- Used to provide an assurance that a process meets requirements
- Not a silver bullet for product or service quality or compliance
- In the US registration is associated with third party certification of management systems.
- This process includes initial assessment of written management system procedures and implementation
- Audits are typically used for surveillance
- Scope of management system is key
- Useful for process critical applications, quality (ISO 9000) and environmental (ISO 14000) management systems.
- Sector specific applications are generally the most effective such as ISO 13485 (medical devices) and TS 9000 (automotive).

Surveillance

- Used to ensure/enhance ongoing conformity.
- Key part of certification or registration system.
- For products pre-market and post-market
- Announced or unannounced
- Inspection, testing and audits are among commonly used methods
- Frequency and rigor should be balanced with the costs (direct and indirect) and confidence needs.
- Typically resource intensive

Typical Use - Accreditation

- Used to assess and ensure/enhance ongoing conformity assessment body and program for competence, management and technical requirements.
- Used to attain needed confidence in laboratory testing operation and results.
- Used to attain needed confidence in certification system.

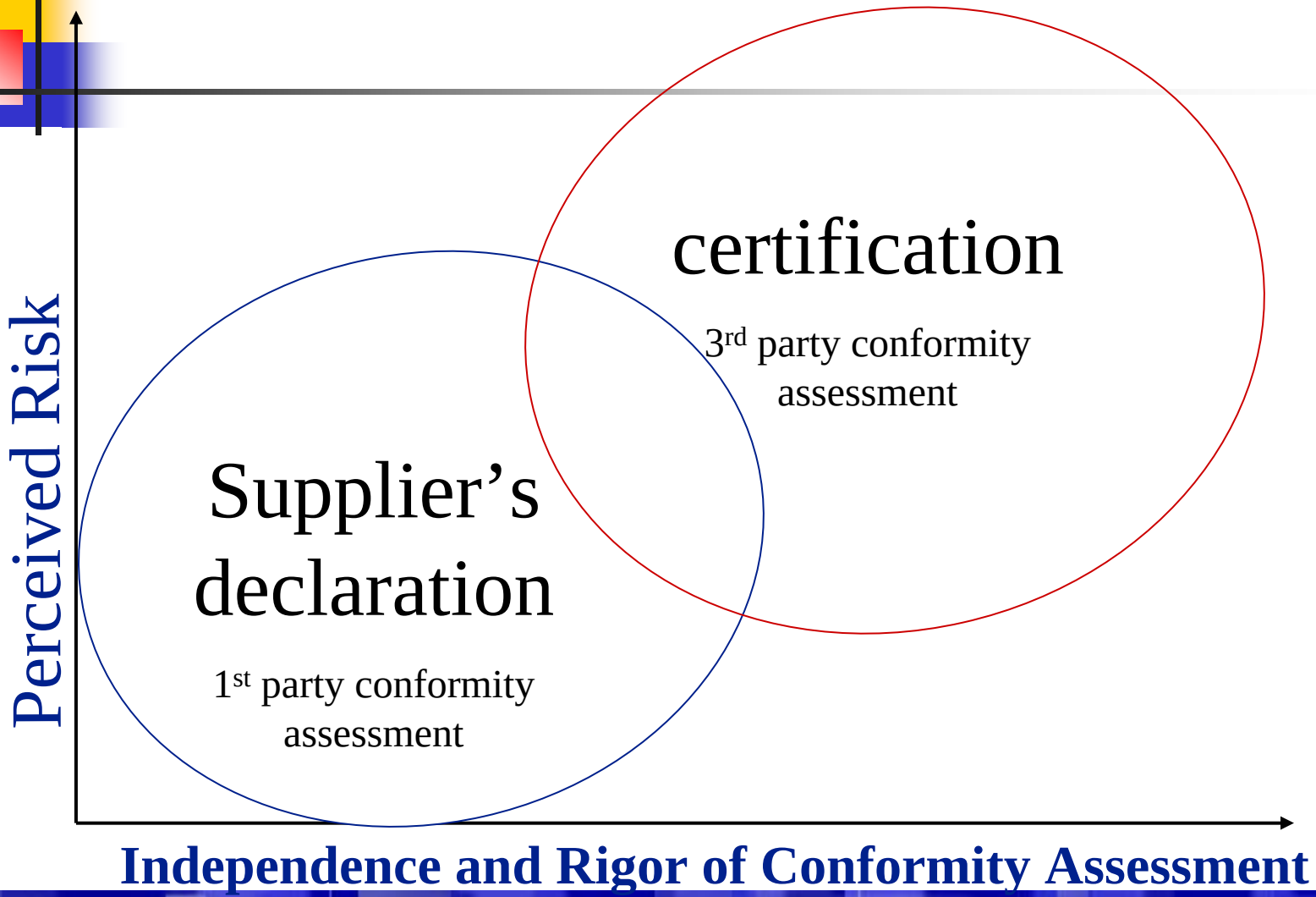


Factors in CA System Design

- **The risks associated with non-compliance should be proportional to the rigor and independence of the CA system.**
- System over-design will add too much cost.
- System Under-design will result in too little confidence of compliance.
- Penalties associated with non-compliance may reduce the needed rigor and independence of the conformity assessment system.
- Timely mechanisms that effectively remove non-compliant products from the market may also reduce the needed rigor and independence of the system.

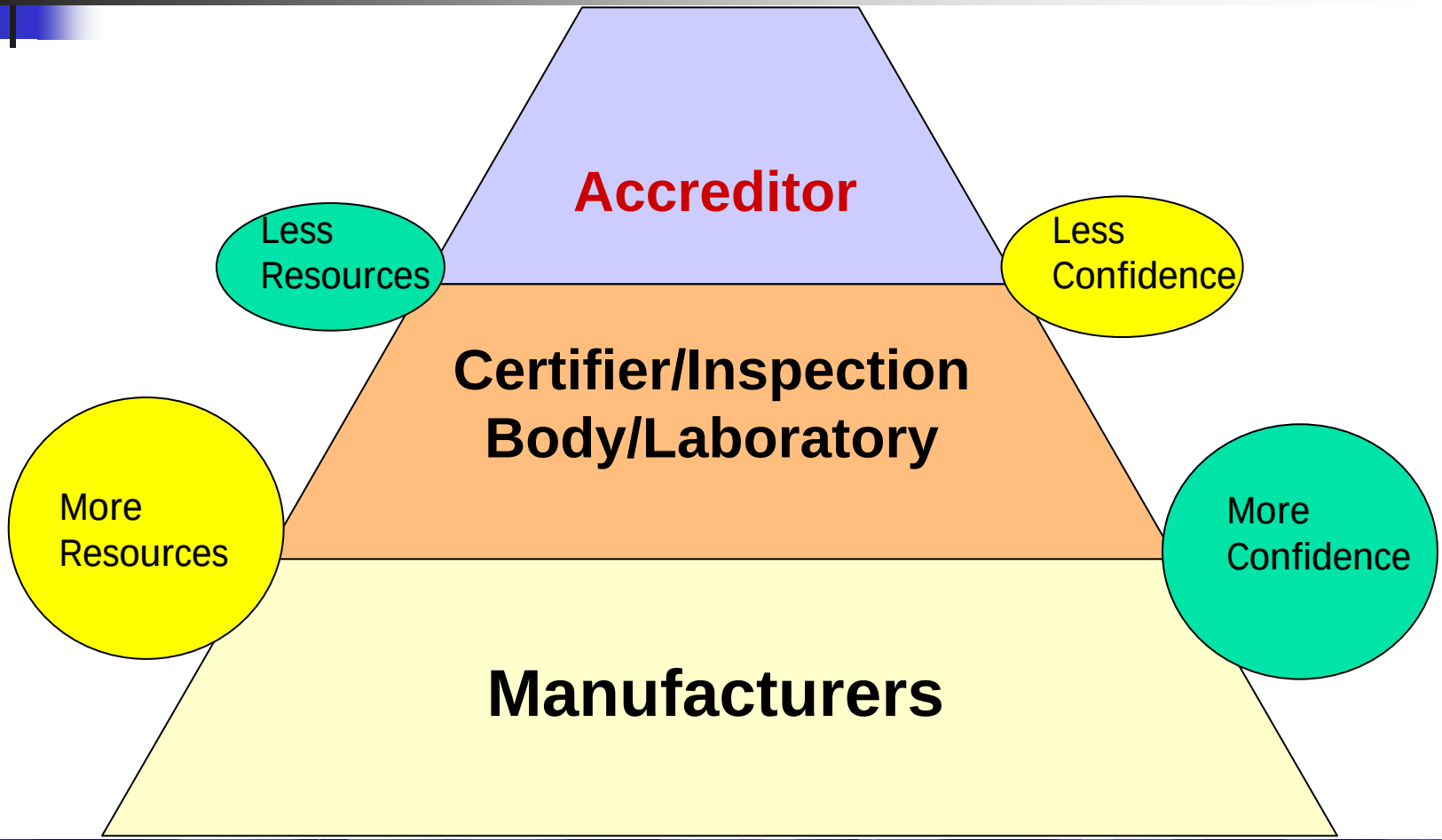
Risk and Conformity Assessment

How much confidence is needed?

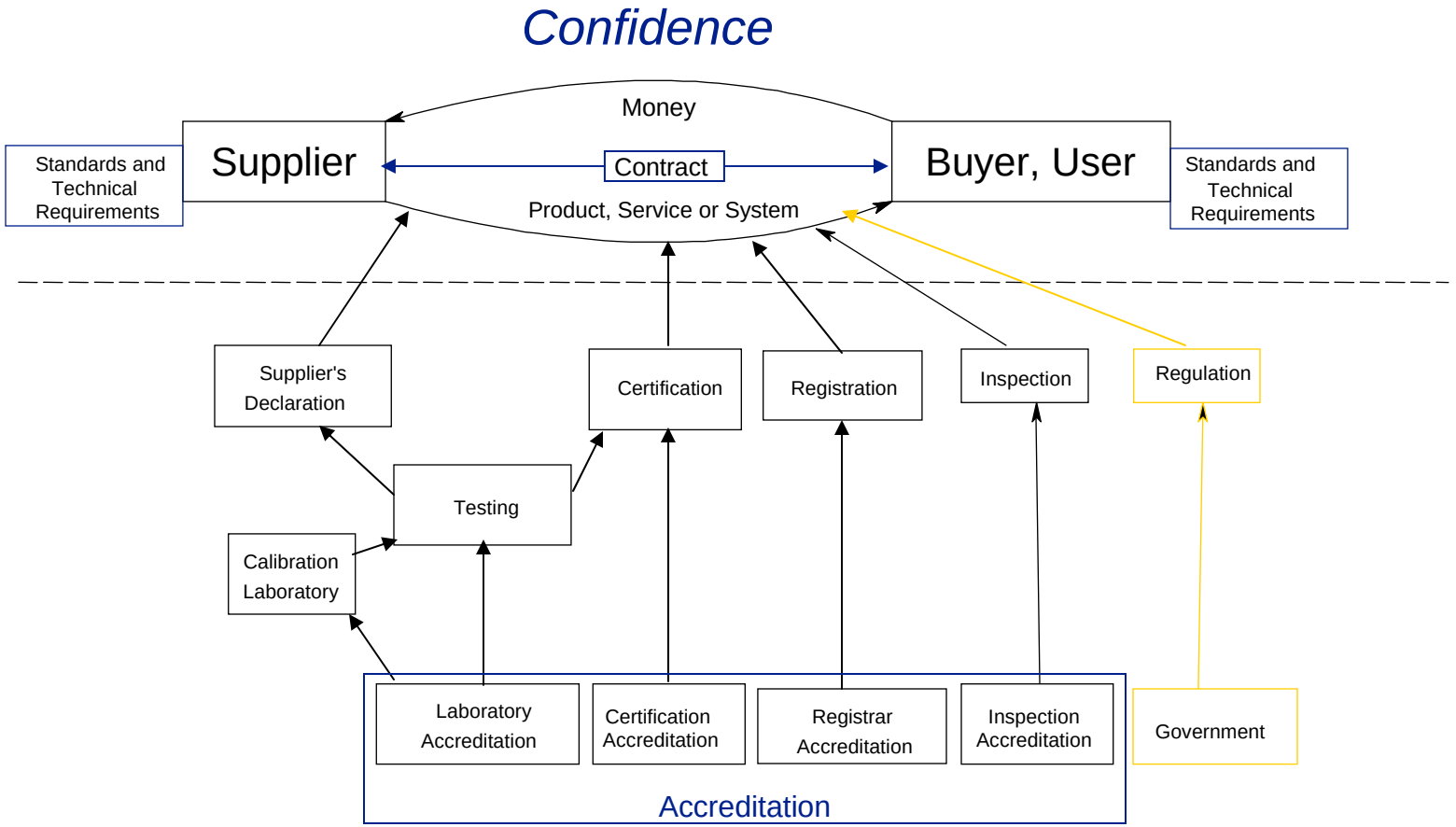


Conformity Assessment Hierarchy

Who watches the watchers?



Conformity Assessment's Role



Regulatory System - USA

- Diversity in use of standards and conformity assessment by different government agencies and within government agencies
- Reliance on private sector standards supported by the National Technology Transfer and Advancement Act and OMB Circular A119
- Regulation based on locale of use for many products with overlap
  - CPSC – homes, schools and places of public enjoyment
  - DoL OSHA – the workplace
- Extensive use of supplier's declaration – formal and informal
- Moves to use of accredited private sector conformity assessment for regulatory purposes
  - FDA Accredited Persons Programs
  - FCC Telecommunications Certification Bodies
- In some sectors private sector programs preceded government regulation and are still effective – products for fire protection, roofing, electrical safety.
- Some regulatory systems not standards based – FDA 510(k) pre-market clearance
- Established national standards and unique safety concerns make harmonization with "international" standards (ISO and IEC) a challenge
- State and local regulation in addition to federal regulation from principles of Federalism

Regulatory System - EU

- Movement to the “New Approach” based on European Commission Directives replacing member state regulations
- New Approach motivated by desire to facilitate internal EU free trade and to create a market to compete with major trade countries such as US not to improve safety, health and environment
- European Commission develops directives with “essential requirements” – very few specific technical requirements
- European SDOs (CEN, CENELEC) develop European Norm (EN) standards to support essential requirements
- Compliance with appropriate EN Standards provides presumption of conformity with essential requirements – other approaches are technically allowed, but difficult
- CE marking placed on products declared to comply with essential requirements of directives
- Generally, the CE marking is not a certification mark and is based by supplier’s declaration and required technical file
- For high risk sectors the use of Notified and/or Competent Bodies (3rd party conformity assessment organizations) is required before declaring conformity and placing the CE marking on the product
  - Examples: medical devices, electrical products for use in hazardous environments
- Post market surveillance left to member states without resources from European Commission
- Supplier’s responsibility entity required in EU

Regulatory System - Mexico

- Mexico has mandatory (NOM) standards and voluntary (NMX) standards
- Many Mexican Standards are based on ISO and IEC Standards with additional labeling requirements (Spanish)
- Products covered by NOM Standards are required to be certified by accredited Mexican certification body (NOM Mark)
- Accreditation performed by private sector Mexican accreditation organization (EMA)
- Testing can only be done by an EMA accredited Mexican laboratory or laboratory in a country that has a free trade agreement with Mexico and a data exchange agreement with Mexican certifier and is EMA accredited
- Laboratories may be 1st or 3rd parties
- Re-test (type test) required every year or two years for manufacturers that have a quality management system (ISO 9000) registered by a Mexican Registrar
- Responsible Mexican entity required

Regulatory System - China

- China's national standards are referred to as "GB" Standards
  - Based on IEC/ISO Standards with Chinese National Differences
  - Safety and EMC Standards
- Products on compulsory list are required to be certified and bear the CCC Mark
- Type testing at a CNCA accredited laboratory and certification including annual factory surveillance by a CNCA accredited certifier is required
- Chinese government agency (CNCA) accredits laboratories and certifiers
- Only wholly owned Chinese organizations can be accredited at this time
- Previously China had two separate systems one for domestically produced products and a separate more onerous one for imports
- China's entry into the World Trade Organization (WTO) and compliance with the Agreement on Technical Barriers to Trade (TBT) motivated the development of one system for both

Mechanisms to Facilitate Trade

- Supplier's Declaration of Conformity
- Mutual recognition of laboratory accreditation
- National treatment for conformity assessment organizations
- Private sector data exchange agreements among certifiers
- Equivalency
- Government to Government Mutual Recognition Agreements/Arrangements

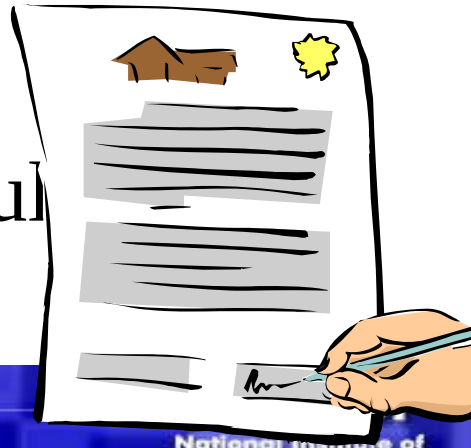
Market Access – Regulatory requirements (gov't and/or private sector mechanisms effective)

Market Acceptance – Expectations of the purchasers (private sector mechanisms effective)

Supplier's Declaration of Conformity

Export/Import Issues

- Sometimes a representative of the supplier is required in the market
- Test data to support declaration may need to come from an accredited and/or 3rd party lab (accreditation MRA may be useful



Mutual Recognition of Laboratory Accreditation

- Can facilitate market access and acceptance
- Must take into account the technical aspects of other markets' requirements to be effective and accepted
- Can reduce the accreditation burden – keep costs down
- Typically relies on peer assessment for confidence

Examples

- Asia Pacific Laboratory Accreditation Cooperation MRA
- Pacific Accreditation Cooperation
- European Cooperation for Accreditation
- Inter-American Accreditation Cooperation
- National Cooperation for Laboratory Accreditation

National Treatment for Conformity Assessment Organizations

- Foreign conformity assessment organizations are accredited or recognized under same terms as domestic organizations
- Facilitates conformity assessment acceptance in other markets
- Does not require harmonized requirements
- May add to accreditation burden
- High level of confidence for importing country's authority

Example

- US and Canada based on NAFTA (maybe Mexico in the future)

Data Exchange Agreements

- Usually between and/or among private sector certifiers
- Facilitates the acceptance of test data for certification and market access/acceptance in other markets
- Surveillance from multiple certifiers may still be needed
- Peer assessment typically used to facilitate confidence between organizations

Example

- IECEE National Certification Body Scheme (CB Scheme) is a multilateral data exchange agreement for certification to IEC based standards

Equivalency

- Standards, technical requirements, regulations and/or conformity assessment processes are determined to provide an equivalent level of safety, fitness for use, interoperability……(any relevant characteristic)
- May be of requirements only
- Usually relies on significantly harmonized standards

Example

- US/EU Mutual Recognition Agreement Marine Craft Annex uses equivalent standards, but not accept other party's certification mark or certificate

Mutual Recognition Agreements

- Government to Government Agreement
- May be bilateral or multilateral
- Covers regulated aspects of products
- Recognizes conformity assessment organizations to provide conformity assessment to other party's regulatory requirements

Examples

- US/EU Mutual Recognition Agreement
- APEC Telecom Mutual Recognition Arrangement*

* Arrangement implies participation level determined by each party

Where is the confidence?