ISO/IEC 17025 and ISO/IEC 17065 in International Quality Infrastructure and MRA

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About the Presenter

- Deputy Director of TAF (Lab/IB/PTP Accreditation in EE field)
- M.Sc. in Electrical Engineering
- ISO/IEC 17025 Lead Assessor for over 12 years
- Over 10 years experience on EMC, RF, Telecommunication technology standardization and government/private Lab/CB management
- Involved with accreditation programs such as US EPA Energy Star, Bluetooth SIG, US CTIA, IECEE, IECRE, ISA Secure cyber security
- Represents TAF with APEC, APAC, ILAC
- APAC ISO/IEC 17011 Evaluator
- APEC TEL MRA Task Force chair(2013 ~2015)
- APAC Liaison at APEC TEL WG and SCSC (2017~)

Roger SHENG
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Overview

Quality Infrastructure

Accreditation in QI

ISO/IEC 17025
ISO/IEC 17065

Competence of CB and Lab

International Quality Infrastructure

UN Sustainable Development Goal 9: "Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation".

INetQI(International Network on Quality Infrastructure): BIPM, IAF, IEC,IIOA, ILACI, QNET, ISO, ITU, ITC, UNIDO, OIML, UNECE, WBG and WTO

MISSION	OBJECTIVES	**SYSTEM**
• support and enhance the quality, safety and environmental soundness of goods, services and processes.	• Reduce Technical Barriers to Trade • Facilitation of digitalisation and innovation • Safety of industrial production sites • Protection of consumers from unsafe products	• Governance • metrology • standardization • accreditation • conformity assessment • market surveillance

QI System

Regulatory Agency
Legal Framework
Quality Policy

BIPM
APMP (Asia Pacific)
Calibration Laboratory

ISO/IEC
JIS/CNS

GOVERNANCE

METROLOGY

STANDARDIZATION

ILAC/IAF
APAC
IAJapan/JAB/
VLAC/TAF

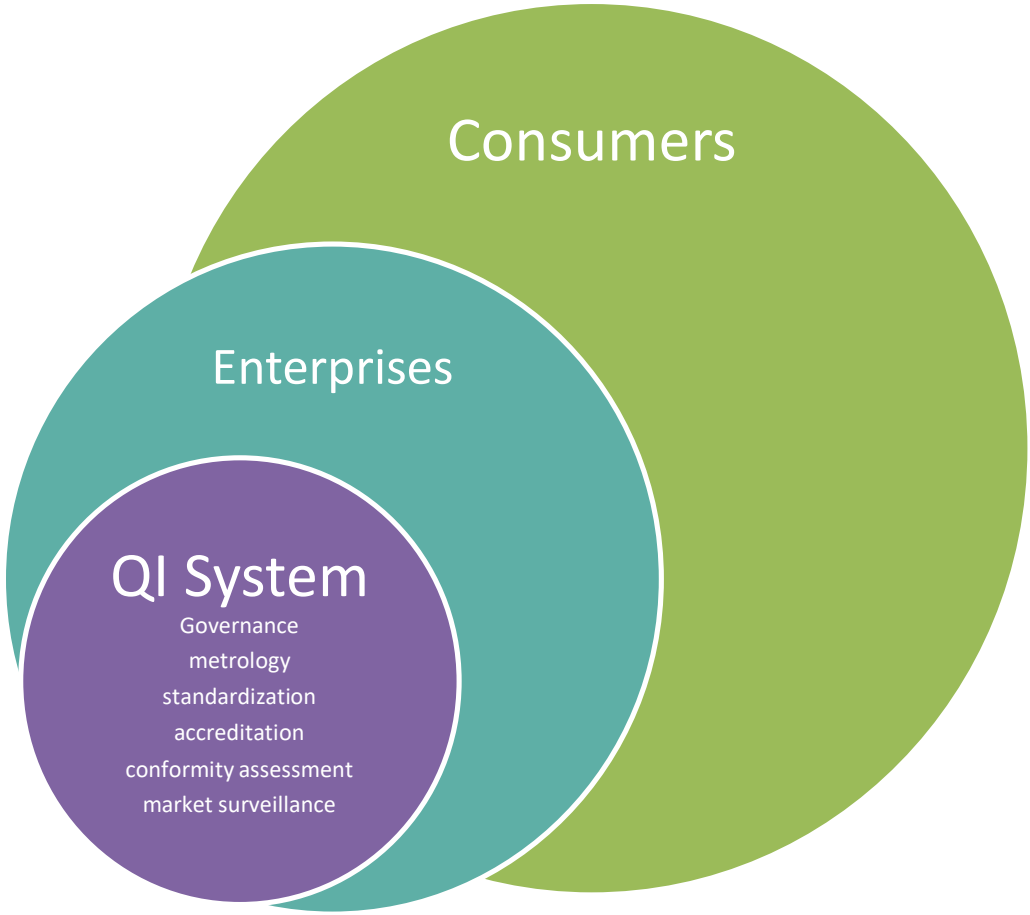
ACCREDITATION

CONFORMITY ASSESSMENT

MARKET SURVEILLANCE

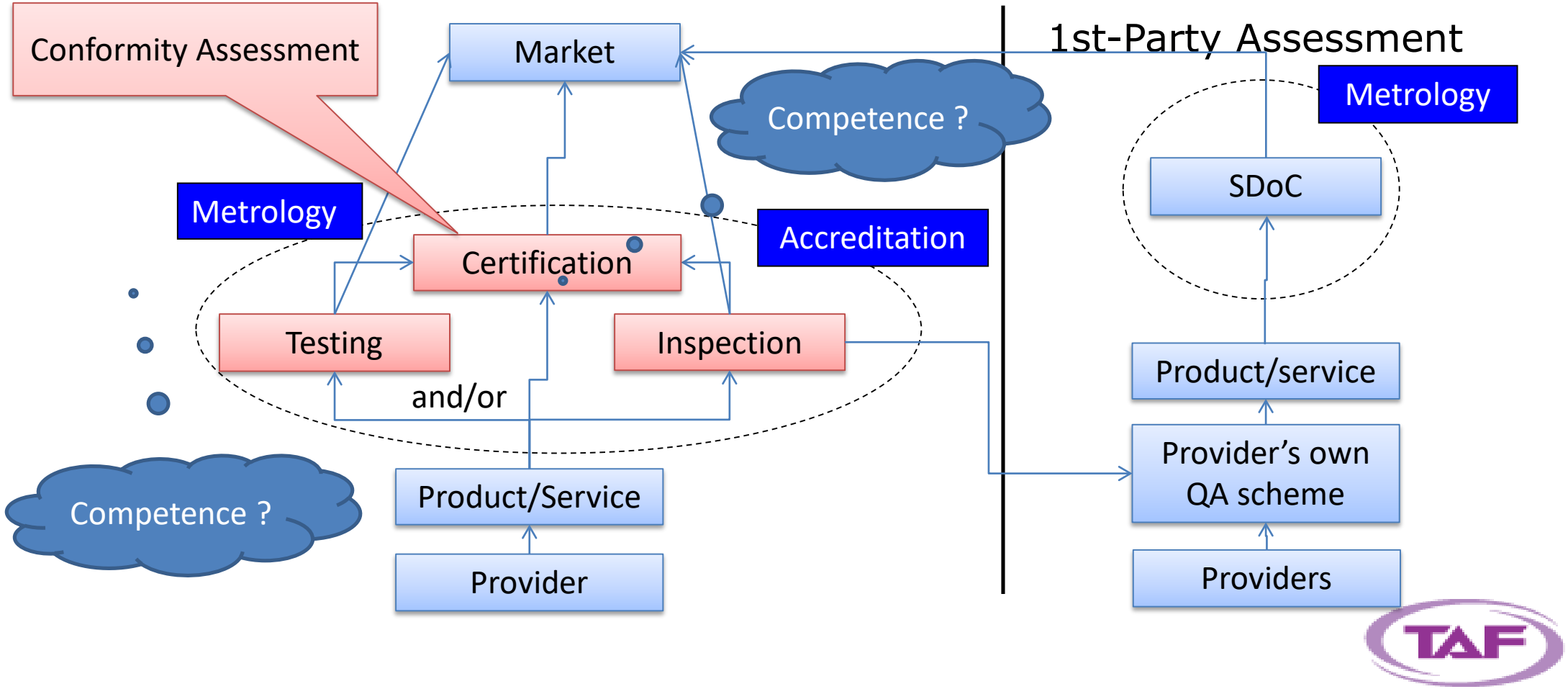
Testing Laboratory
Inspection Body
Certification Body

Regulatory Agency
Enforcement Department
Conformity Assessment Body



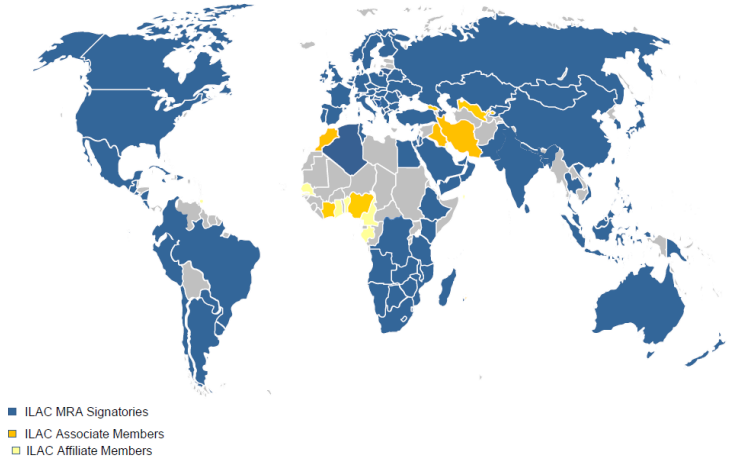
Example of Quality Infrastructure

Regulators: Policies, Law, Acts, Policies, and legal and regulatory framework
Practices: Testing, Inspection, Certification

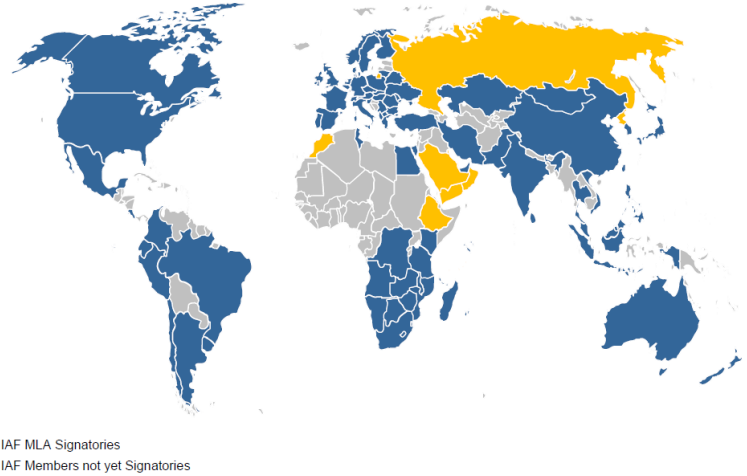


A GLOBAL ACCREDITATION SYSTEM
SUPPORTING INTERNATIONAL QI SYSTEM

Coverage of the ILAC MRA (2 March 2021)



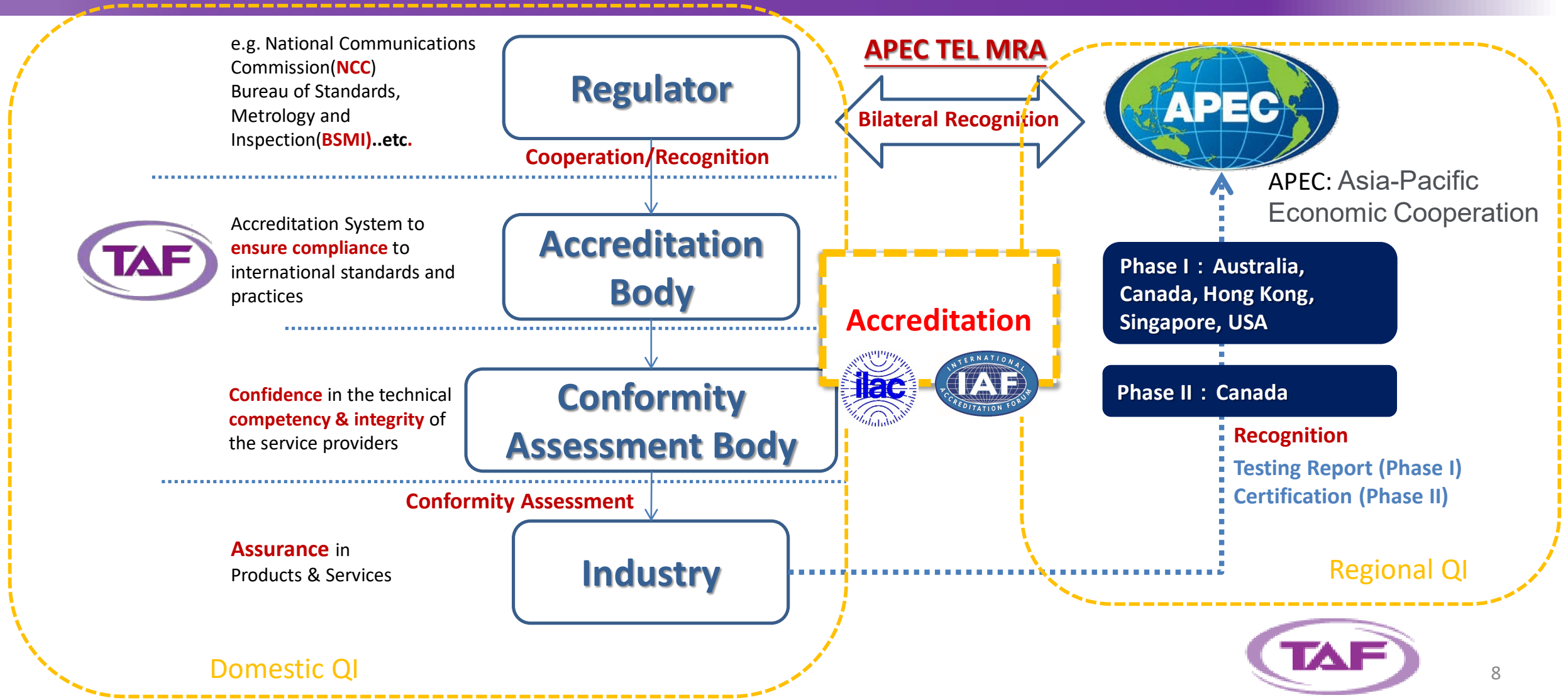
Coverage of the IAF MLA (July 2021)



International Laboratory Accreditation Cooperation (ILAC)

International Accreditation Forum (IAF)

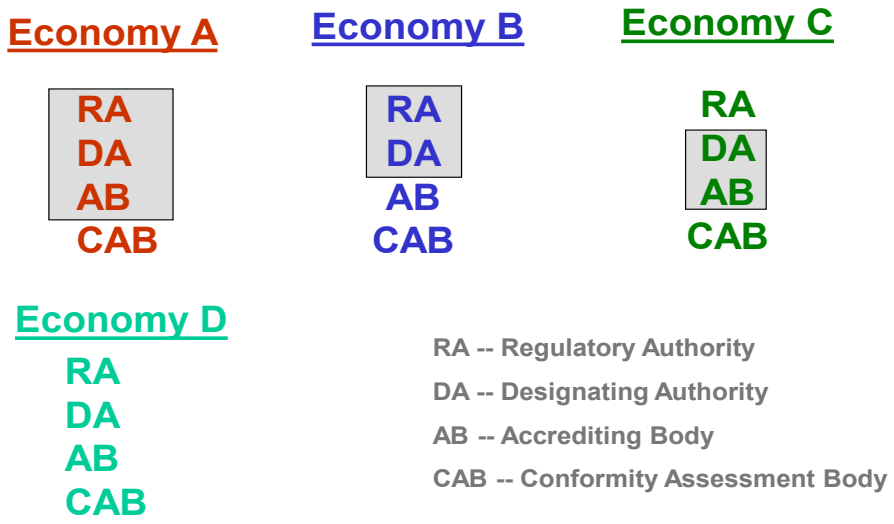
Accreditation in Regional and Domestic QI: APEC and Taiwan Case



APEC Approach: APEC TEL/EE MRA

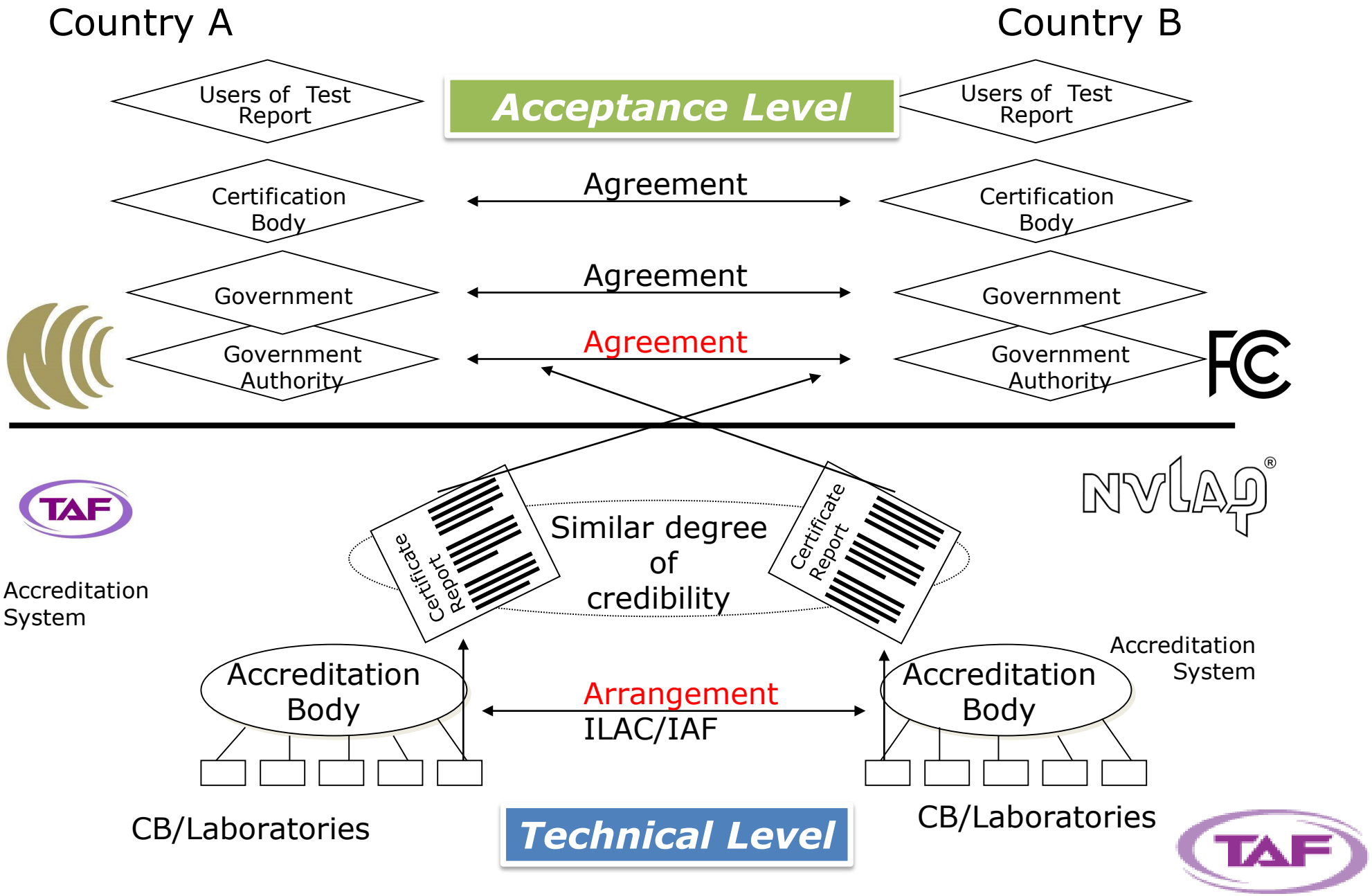
- Use APEC TEL MRA/EE MRA to reduce Technical Barriers to Trade
- Scope (to ICT products) of MRA:
  - Electromagnetic Compatibility
  - Telecommunications regulations
  - Electrical Safety/SAR
  - Cyber security
- MRAs to conformity assessment procedures (MRA-CA)
  - Phase I(testing);
  - Phase II (certification)
- MRAs to technical Requirement (MRA-ETR)

APEC: Asia-Pacific Economic Cooperation

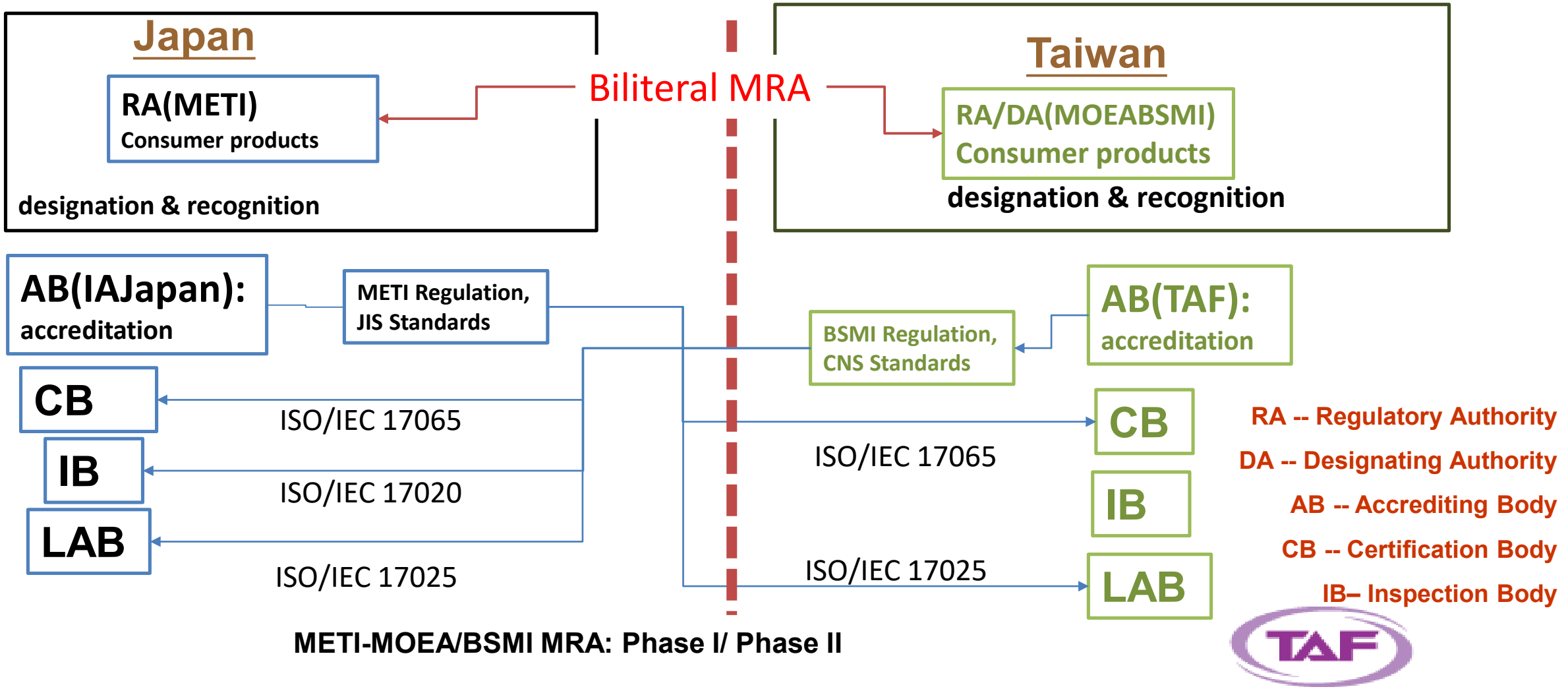


Source: INFORMATION MANAGEMENT GUIDE FOR THE APEC TELECOMMUNICATIONS MUTUAL RECOGNITION ARRANGEMENT

Accreditation in Multilateral/Bilateral MRA



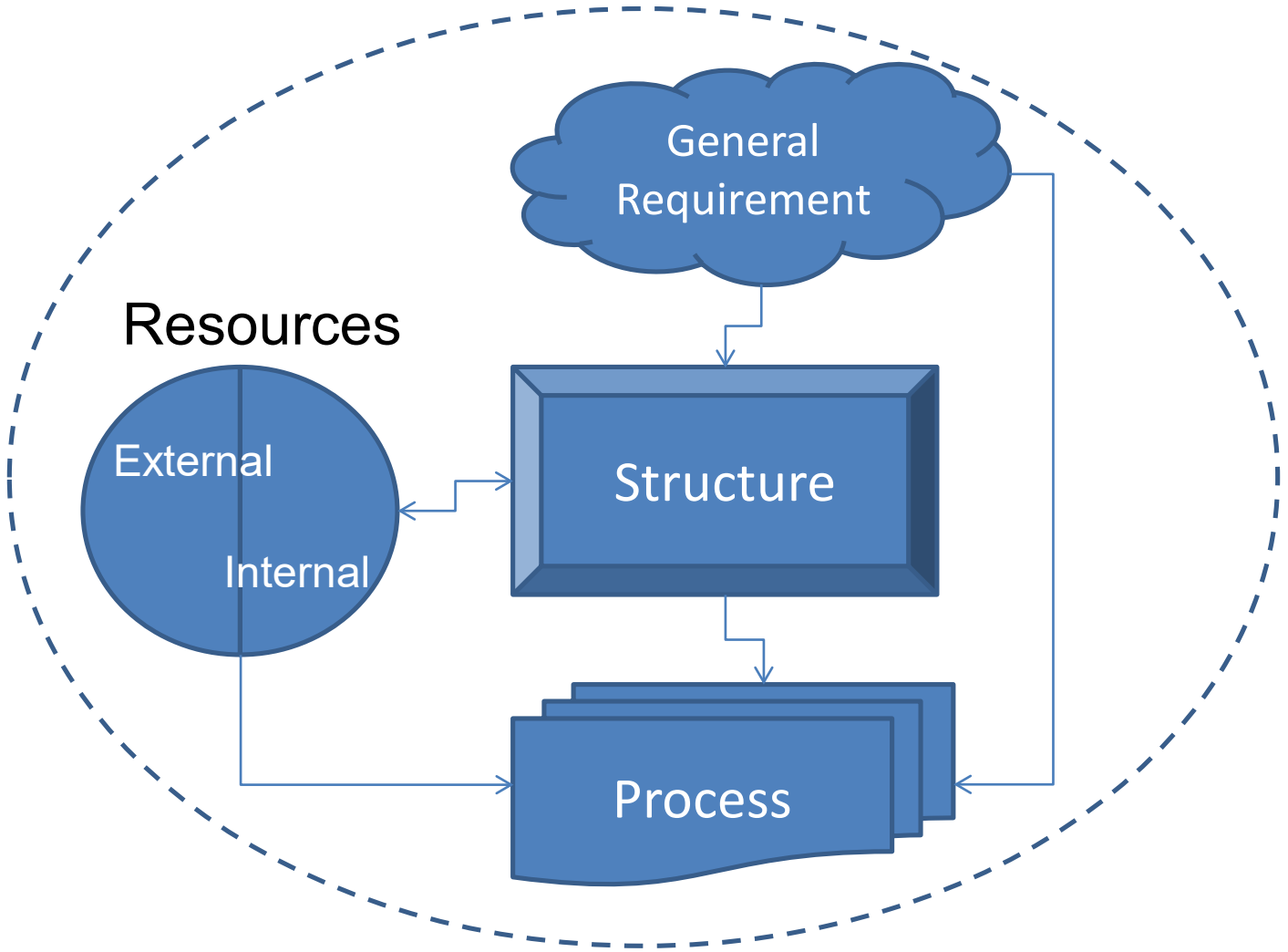
Special Case
Japan(METI)-Taiwan(MOEA) MRA



ISO/IEC 17025: 2017

To promote confidence in the operation and results of Laboratories

ISO/IEC 17025: 2017



Impartiality
Competence
Consistent Operation

Management System
(Option A or ISO 9001)

ISO/IEC 17025:2017

- General Requirements
  - 4.1 Impartiality
  - 4.2 Confidentiality
- Structure Requirements
  - 5.1 Legal entity
  - 5.2 Management
  - 5.3 Range of activities
  - 5.4 Stakeholder responsibilities
  - 5.5 Org. Relationships & Procedures
  - 5.6 Authority & Resources
- Resource Requirements
  - 6.1 General
  - 6.2 Personnel
  - 6.3 Laboratory & Environment
  - 6.4 Equipment
  - 6.5 Metrological Traceability
  - 6.6 External Products & Services
- Process requirements
  - 7.1 Review of RTC
  - 7.2 Selection, V&V of Methods
  - 7.3 Sampling
  - 7.4 Handling of test/Cal Items
  - 7.5 Technical Records
  - 7.6 Evaluation of MU
  - 7.7 Ensuring Validity of Results
  - 7.8 Reporting of Results
  - 7.9 Complaints
  - 7.10 Nonconforming Work
  - 7.11 Control of Data and info management
- Management System Requirement
  - 8.1 Options (A/B)
  - 8.2 MS Documentation
  - 8.3 Control of MS Documentation
  - 8.4 Control of Records
  - 8.5 Risks & Opportunities
  - 8.6 Improvements
  - 8.7 Corrective Actions
  - 8.8 Internal Audits
  - 8.9 Management Reviews

ISO/IEC 17025: Process-oriented

ISO/IEC 17025:2017

1 Scope
2 Normative References
3 Terms & Definitions

4 General Requirements
5 Structural Requirements
6 Resource Requirements
7 Process Requirements
8 Management Requirements

Annex A – Metrological Traceability

Annex B – Management System

Bibliography

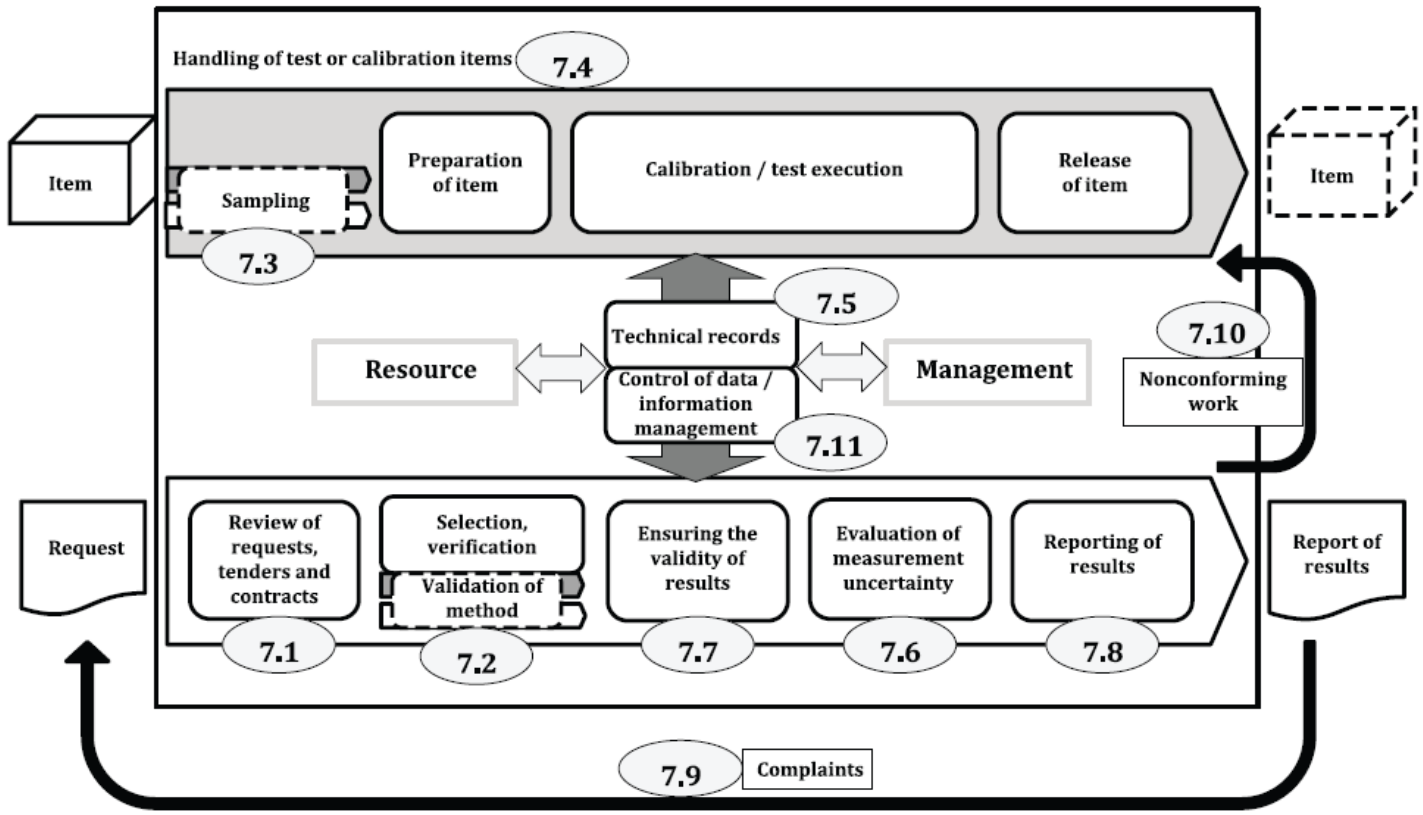


Figure B.1 — Possible schematic representation of the operational processes of a laboratory

Key Technical Requirement in ISO/IEC 17025

METROLOGICAL TRACEABILITY

MEASUREMENT UNCERTAINTY

PROFICIENCY TEST

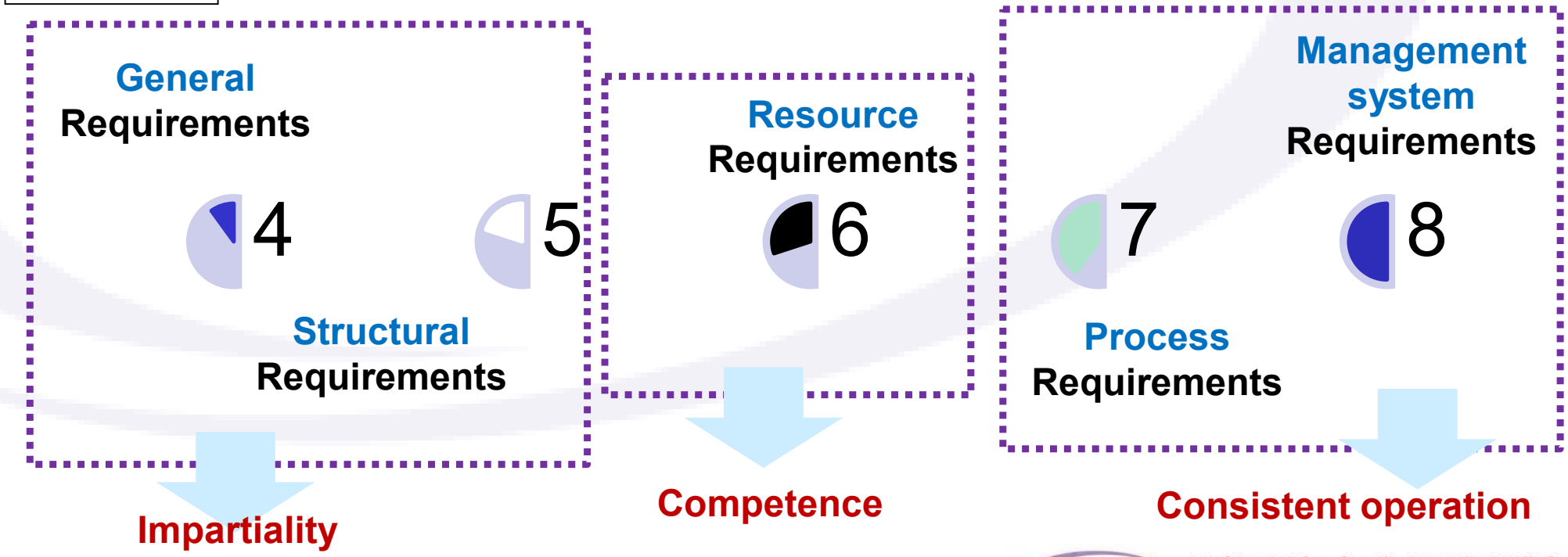
DECISION RULE

ISO/IEC 17065:2012

To promote confidence in the operation of Certification Bodies

Structure of ISO/IEC 17065

- 8 chapters and 2 informative annex
- Chapters 1 to 3 are general information, including "scope", "normative reference", "terms and definitions"
- **Requirements** for the certification bodies (CBs) are stipulated in **Chapter 4 to 8**



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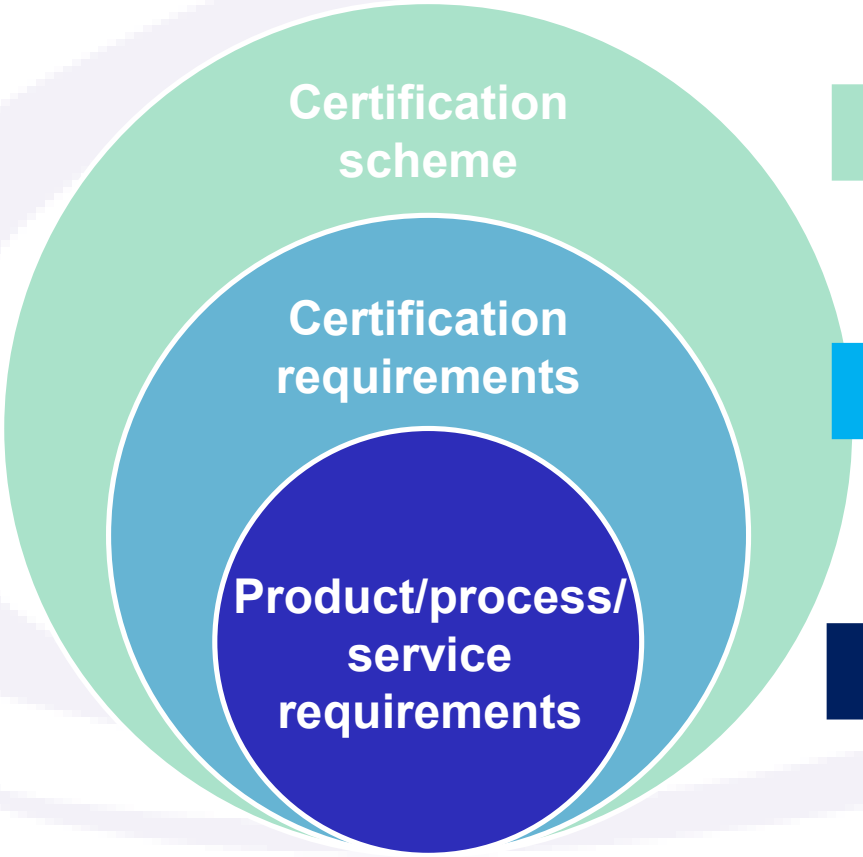
Taiwan Accreditation Foundation

Concept of certification



Certification system related to specified product/process/service, to which the same specified requirements, specific rules and procedures apply
e.g. GLOBAL G.A.P.

Specified requirement, including product/process/service requirement, that is fulfilled by the client as a condition of establishing or maintaining certification
e.g. providing information about changes to the certified product

Requirement that relates directly to a product/process/service, specified in standards or in other normative documents identified by the certification scheme
e.g. IEC 62368-1, CISPR 32

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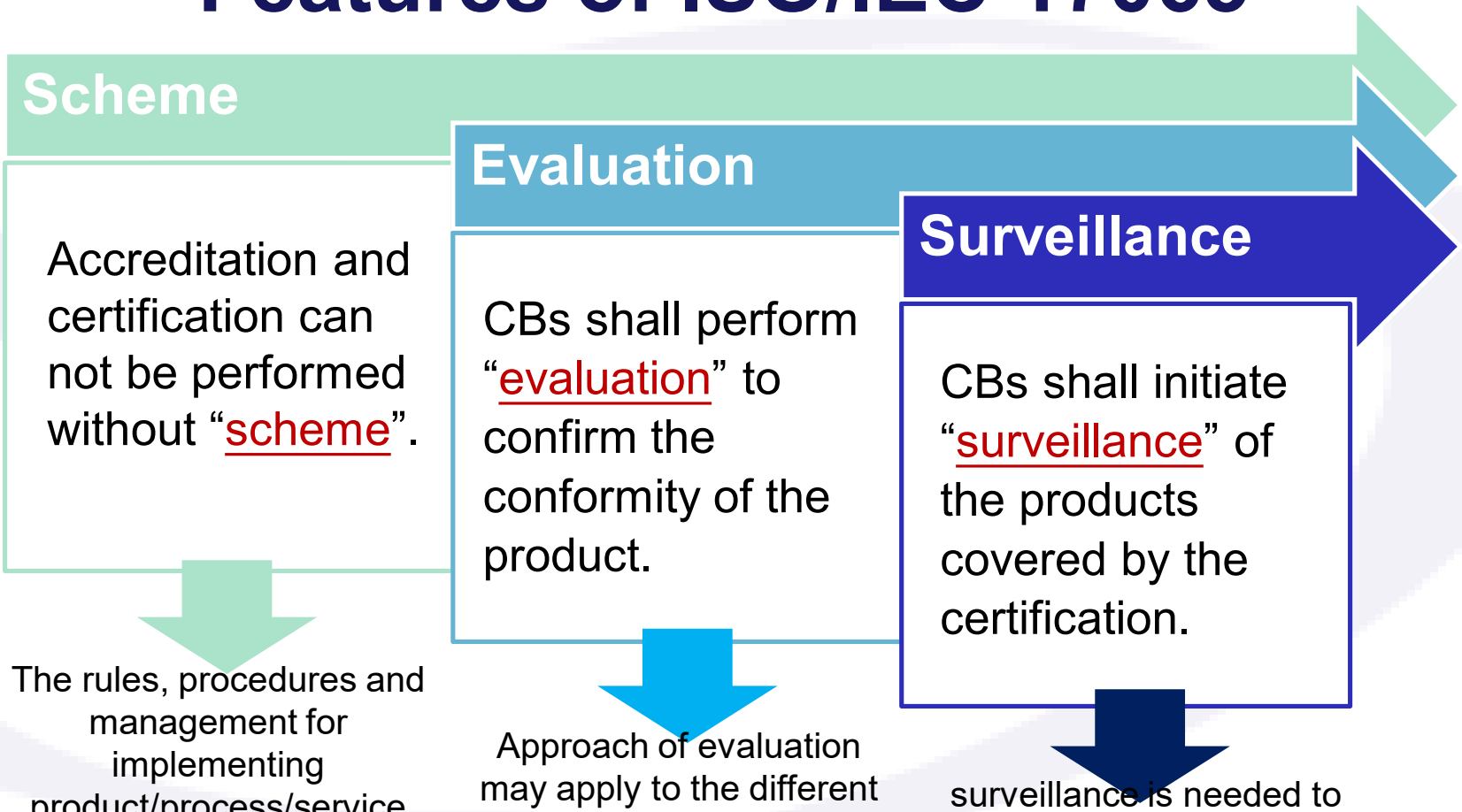
Features of ISO/IEC 17065



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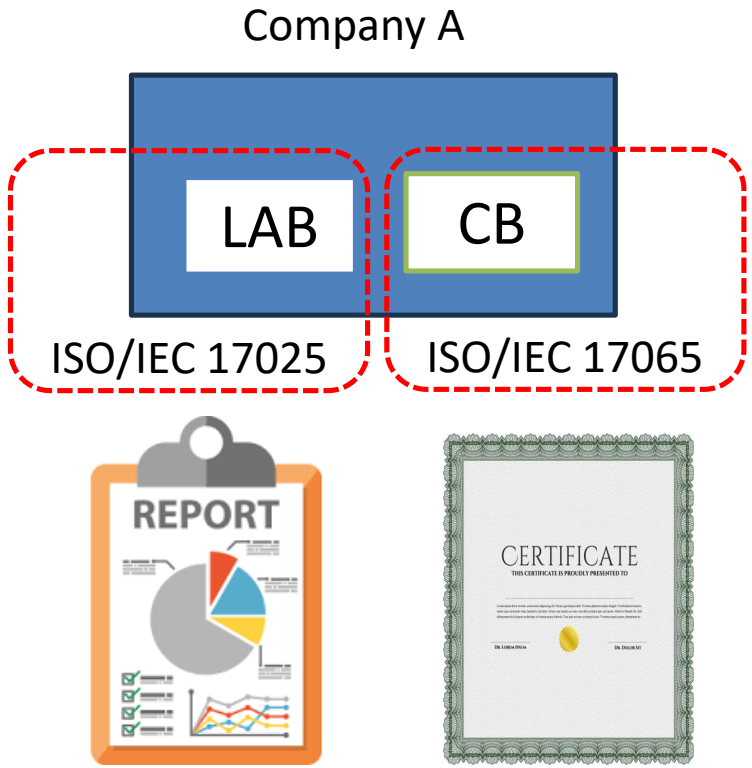
Distinguish Competence between CBs and Labs

- Accreditation: third-party attestation related to a CAB's competence
- CB or Lab's competence?
  - Impartiality(CB>Lab)
  - Market Surveillance(CB)
  - Knowledge of Product Types/ Design(CB>Lab)
  - Certification Decision Making(CB)
  - Knowledge of testing Methods(Lab>CB)
  - Knowledge of regulations(CB)
- Don't mix "Reporting opinions and interpretation in ISO/IEC 17025" and "Statements of Product Certification in ISO/IEC 17065"!!

Case Study:
Multiple Product Models in Report /Certificate

- Competence in distinguishing Products: Product Functions and Required Tests
- Product CB competence of understanding Certification Requirement is in ISO/IES 17065 accreditation scope
- Laboratory competence of Reporting opinions and interpretation is usually not in ISO/IES 17025 accreditation scope



Key Takeaway:

What is Quality Infrastructure?

How Accreditation works in QI?

Key requirements of ISO/IEC 17025 ISO/IEC 17065

Distinguish the different competences between CB and Lab

Thank you for Listening

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