

# How Laboratory Accreditation Community Demonstrates Its Competence and Responsibility in Meeting Regulator's MRA Needs

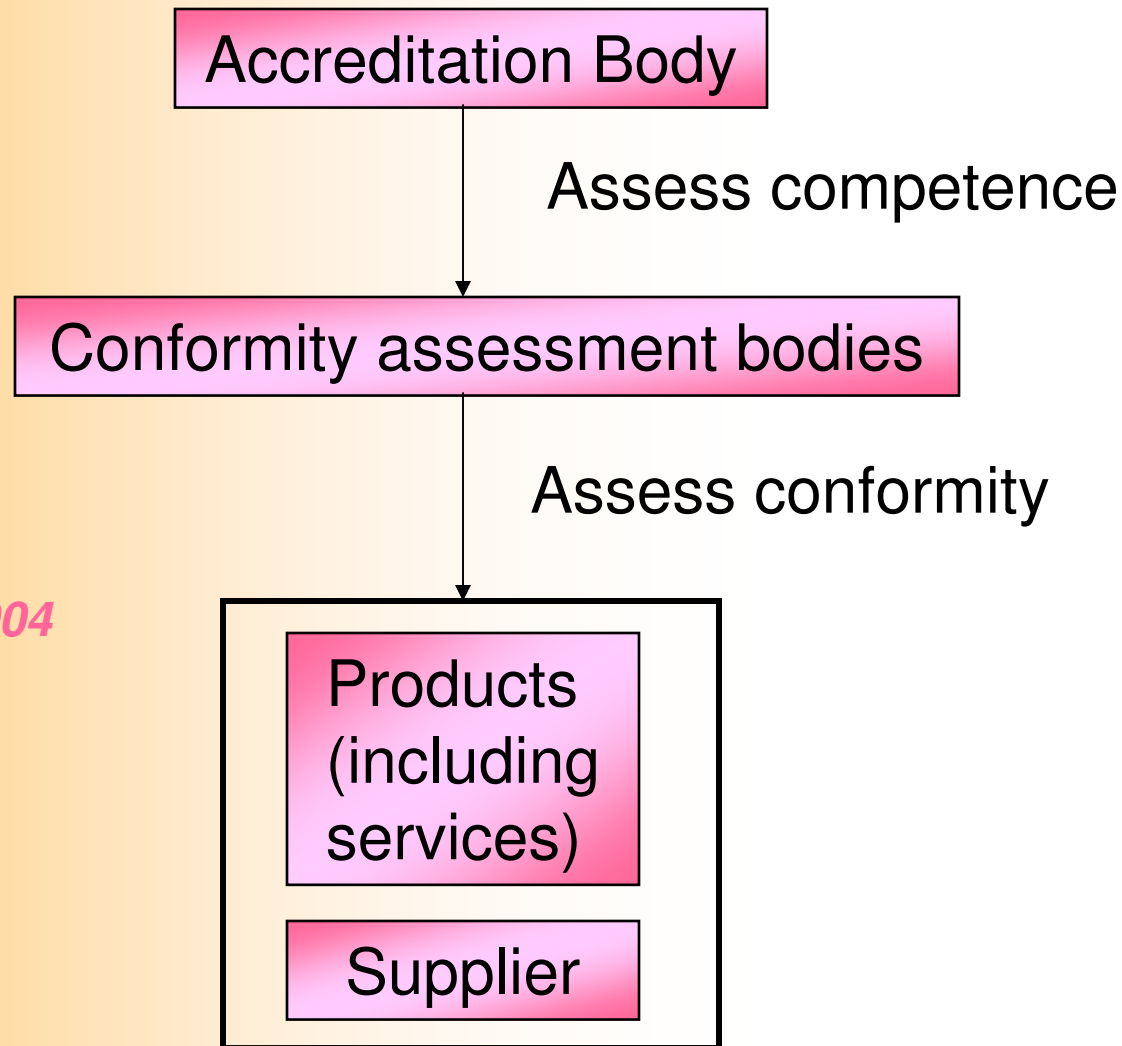
**Nigel Jou**  
**TAF**

# Outline

- Background
- International / regional accreditation cooperation's responsibilities
- Local accreditation body's responsibilities
  - Taking TAF as an example
- Conformity assessment body's responsibilities and liability
- Conclusion & suggestion

# Background

# Accreditation Flowchart



*ISO/IEC 17011:2004*



## Competence

a core  
principle of  
what  
accreditation  
delivers

# Technical and operational competence,

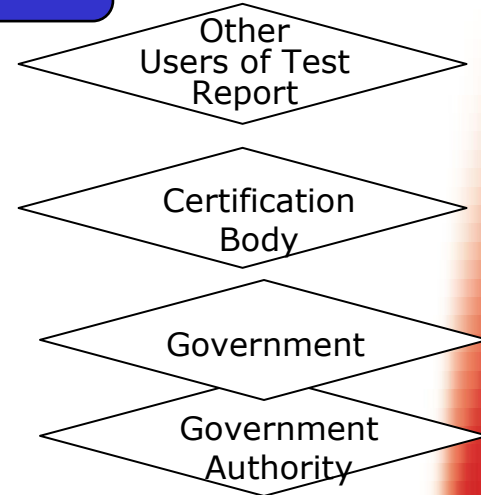
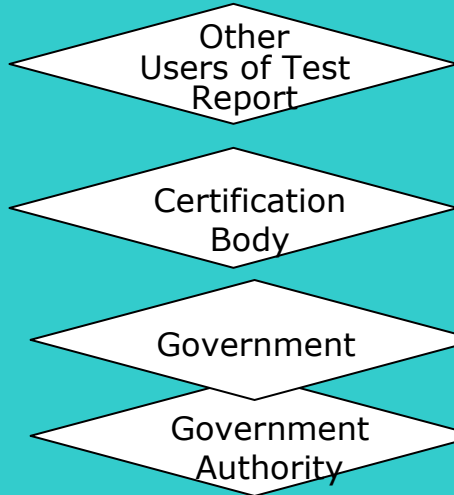
**as it relates to an organisation's ability to  
provide the market with its products and  
services, is determined by accreditation.**

# Types of Agreements

Country A

*Acceptance Level*

Country B

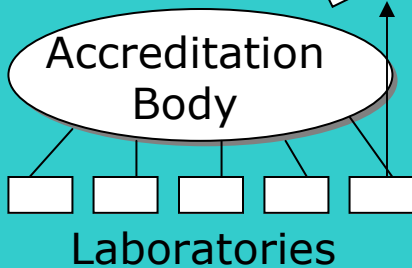


Agreement

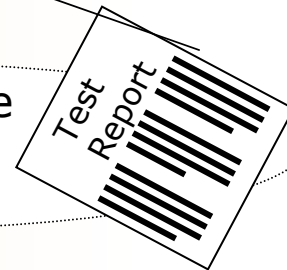
Agreement

Agreement

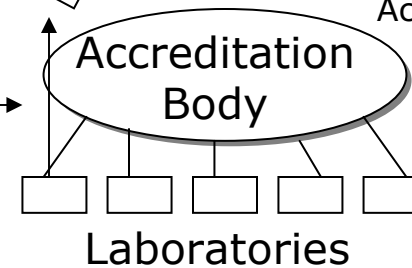
Accreditation System



Similar degree of credibility



Accreditation System



Agreement

*Technical Level*

# **International / regional accreditation body's responsibilities**



# Cooperation



*BIPM, CIPM, ICSCA, IEC, ISO, OECD,  
UNIDO, WADA, WTO TBT*

International

**ILAC / IAF**

Regional

**APEC**

**EU / EFTA**

**NAFTA**

**APLAC / PAC**

**EA**

**IAAC**

**SADCA**

National

**TAF**

**COFRAC**

**A2LA**

**SANAS**

ABs

# ILAC Combined MRA Mark

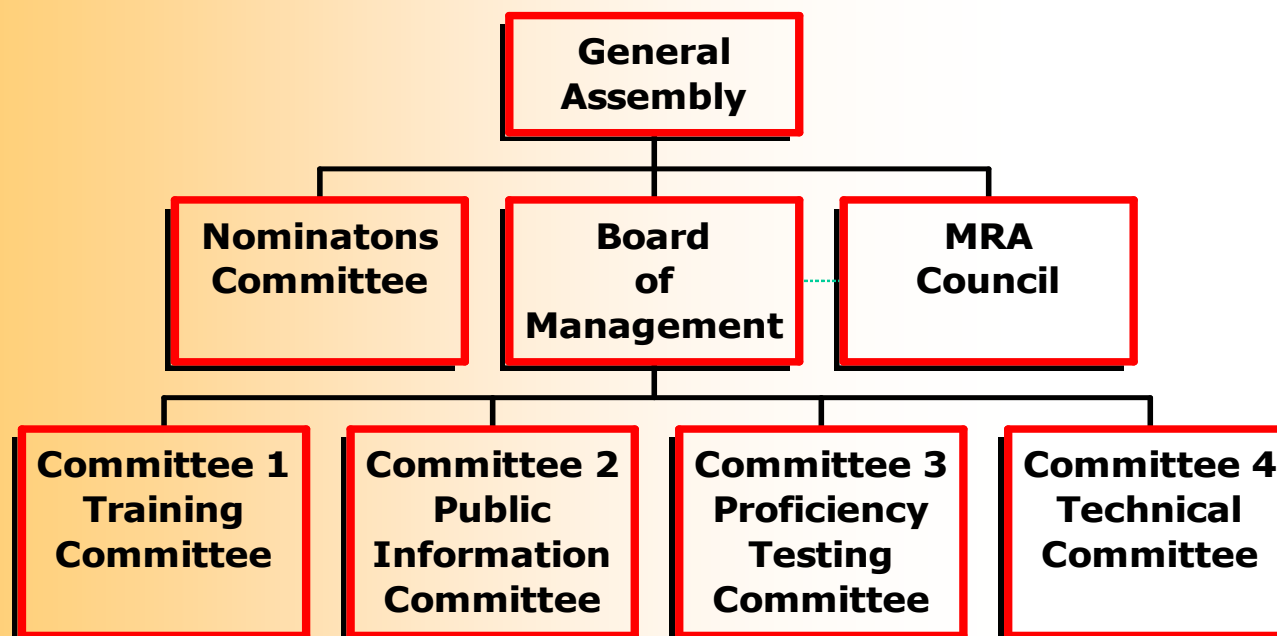


**Testing Laboratory**  
**0000**

# APLAC

- What is APLAC?
- The Role of APLAC
- Structure of APLAC
- Accreditation
- APLAC Mutual Recognition Arrangement
- APLAC MRA - supporting G2G MRAs and trade in the APEC region

# APLAC's Structure



*e.g. APLAC Subcommittee on APEC TEL MRA*

# Accreditation

- Assessment of laboratory, inspection body and RMP performance against international criteria (ISO/IEC 17025; ISO/IEC 17020; ISO Guide 34)
- Means of determining competence of laboratories, inspection bodies and RMPs to perform specific measurements, calibrations, tests or inspections, or to certify reference materials competently
- Formal recognition of that competence

## Accreditation ctd

- 3<sup>rd</sup> party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks (ISO/IEC 17000)
- Key phrases
  - competence
  - specific.... tasks

# Accreditation ctd

- Demonstrated competence
  - Specific tests
  - Defined measurements
  - Types of calibrations
  - Particular testing techniques
  - Specific types of inspections
  - Specific types of reference materials

# Accreditation ctd

- Technical competence
- Integrity
- Transparency (as defined by WTO TBT)
- Fairness
- Scope of accreditation
  - products; types of test parameters types of inspections; matrices
  - measurement techniques, range, accuracy
  - test specification; test method



# APLAC MRA Signatories

## 18 Economies, 28 Accreditation Bodies

- NATA (Australia)
- CALA (Canada)
- SCC (Canada)
- CNAS (China)
- HKAS (Hong Kong China)
- NABL (India)
- KAN (Indonesia)
- JAB (Japan)
- IAJapan (Japan)
- VLAC (Japan)
- KOLAS (Korea)
- DSM (Malaysia)
- ema (Mexico)
- IANZ (New Zealand)
- PAO (Philippines)
- SAC (Singapore)

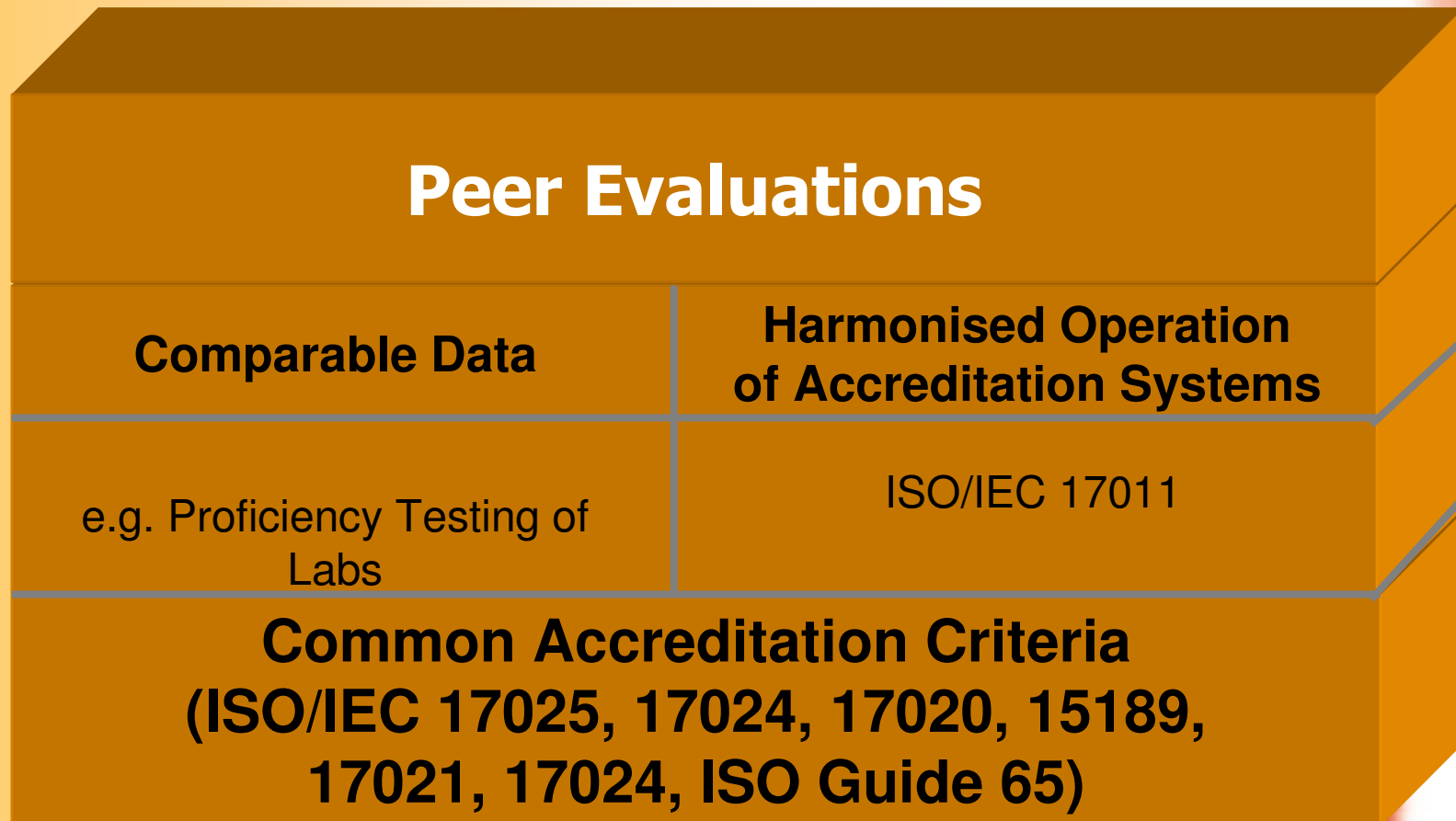
# APLAC MRA Signatories ctd

- TAF (Chinese Taipei)
- DSS (Thailand)
- DMSc (Thailand)
- NSC-ONAC (Thailand)
- A2LA (USA)
- ACLASS (USA)
- IAS (USA)
- L-A-B (USA)
- NVLAP (USA)
- PJLA (USA)
- BoA (Vietnam)
- JAS-ANZ (Australasia)

***Among which, 14 Economies are participants in Part I of the MRA***

# Mutual / Multilateral Recognition

## The Building Blocks of Confidence

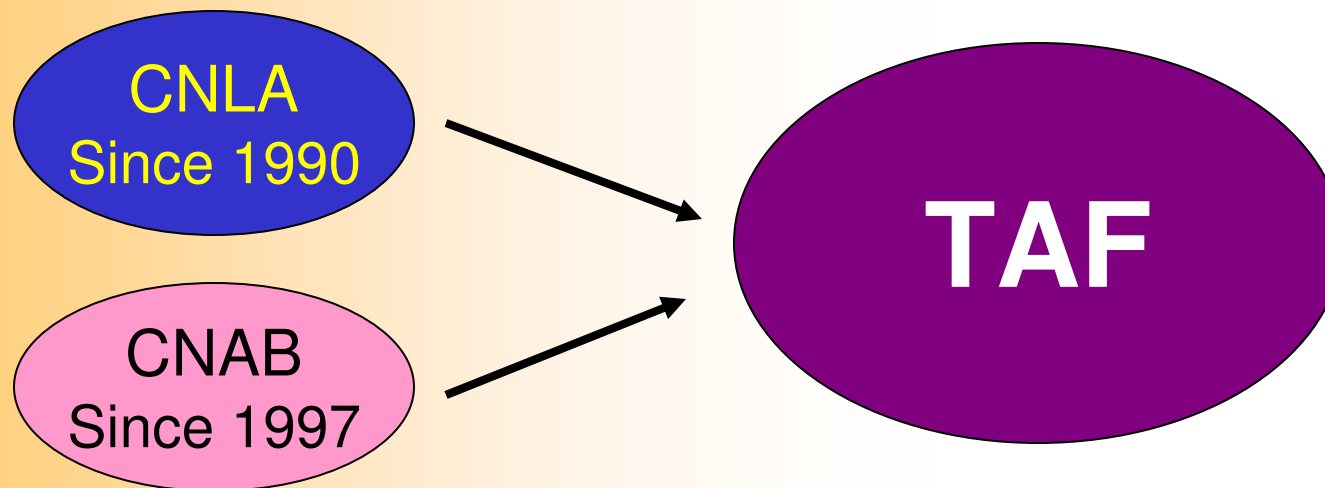


# Local accreditation body's responsibilities

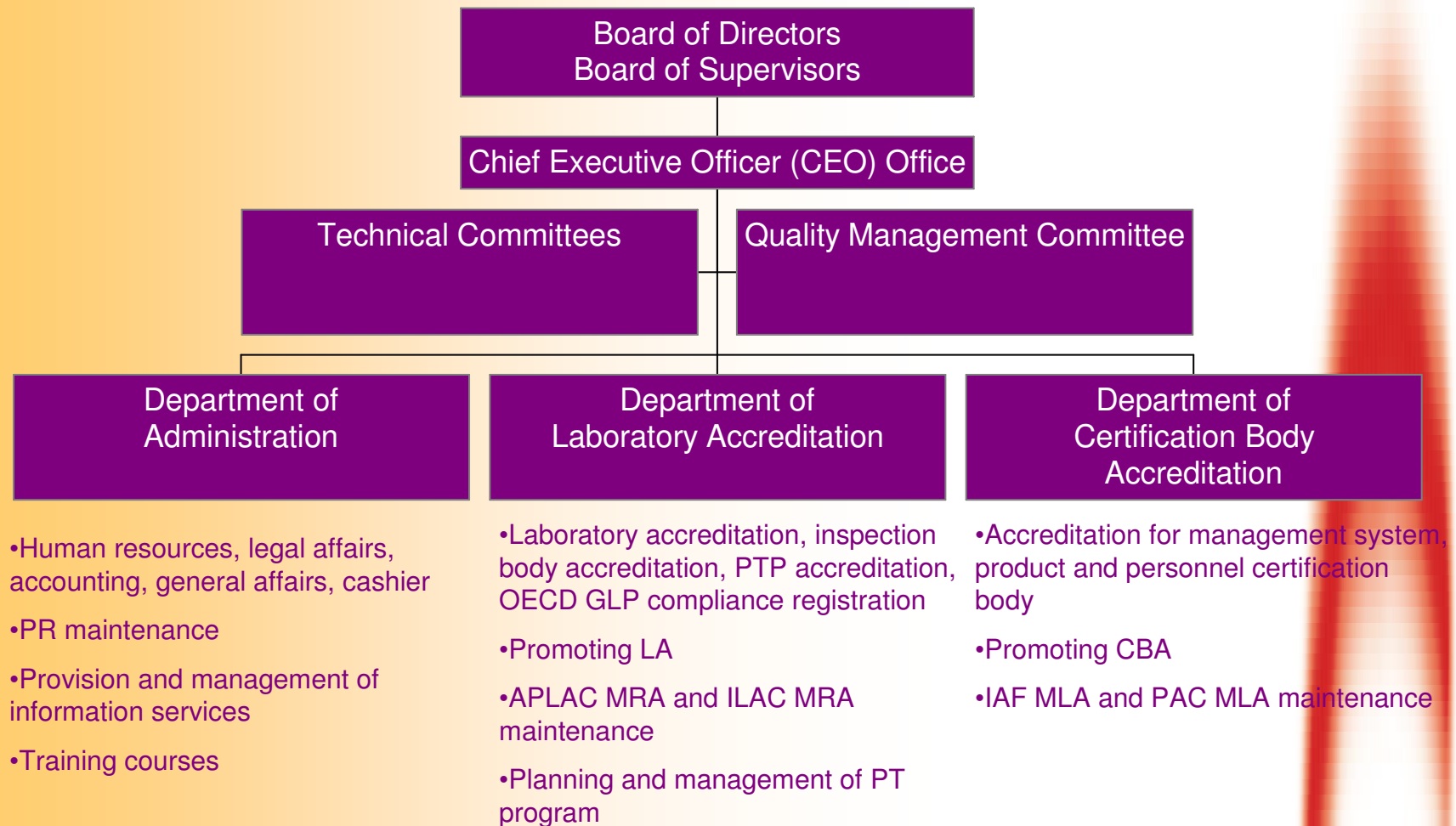
Taking TAF, Chinese Taipei as an example



## Non-profit Organization Founded in September 2003



## Organisational Flow Chart



Field	Sub-Fields	No.
Calibration (11)	Acoustics & Vibration, Chemical, Electricity, Electromagnetic, Flow, Ionizing Radiation, Length, Mass / Force, Pressure / Vacuum, Temperature / Humidity, Time & Frequency	180
Testing (9)	Acoustics & Vibration, Biological, Chemical, <b>Electrical</b> , Ionizing Radiation, Mechanical, Non-destructive, Optical, Temperature & Heat	750
Civil Engineering (2)	Chemical, Construction Engineering	196
Medical (10)	Anatomical pathology, Clinical biochemistry, Transfusion medicine, Hematology, Clinical immunoserology, Clinical microbiology, Clinical toxicology, Clinical microscopy, Cytogenetics, Genetics and molecular pathology	127

Field	Sub-Fields	No.
Hospital (9)	RPR/VDRL test · TPHA/TPPA test · Hepatitis B virus surface antigen/HBs Ag · HIV antibody—Screening, Ova examination · Identification of morphology · Amoebic smear/stain examination · Chest X ray examination · The process and moving path for health examination	60
Inspection Body (4)	Non-destructive Inspection, Factory Inspection, Metrology Instrument, Safety Inspection	14
Proficiency Testing Provider		3
OECD GLP Compliance Monitoring Program		3



Fields	No.
Management System Certification Body (QMS 、 EMS 、 FSMS 、 ISMS 、 OHSAS 、 GHG 、 Green Product)	37
Product Certification Body	43
Personnel Certification Body	1

# Distribution of TAF accredited organisations

## Kinmen 3

Lab: 3

## Matsu 1

Lab: 1

## Penghu 2

Lab: 2

## North 711

Lab: 646

MS: 33

Product: 23

Personnel: 1

IB: 10

## Central 242

Lab: 238

MS: 1

Product: 1

IB: 2

## South 300

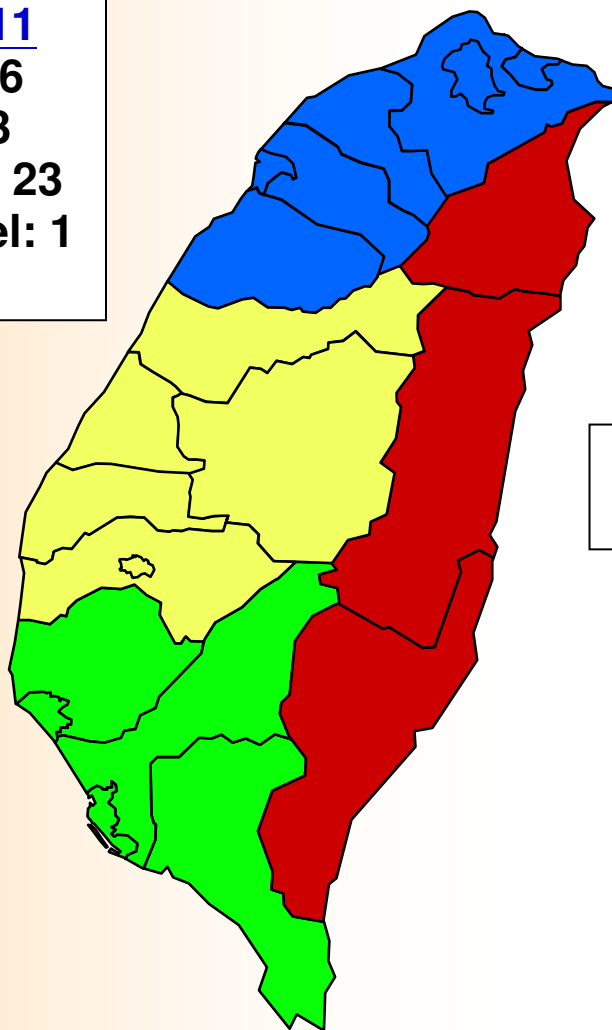
Lab: 297

Product: 3

IB: 2

## East 47

Lab: 47



# Cooperative relationships with regulators

## - specific accreditation programs:

- National Communication Commission (NCC)
- Central Weather Bureau (CWB)
- Center for Disease Control (CDC)
- **Bureau of Standards, Metrology and Inspection (BSMI)**
- National Treasury Agency (NTA)
- Public Construction Committee (PCC)
- Environmental Protection Administration (EPA)
- Atomic Energy Council (AEC)

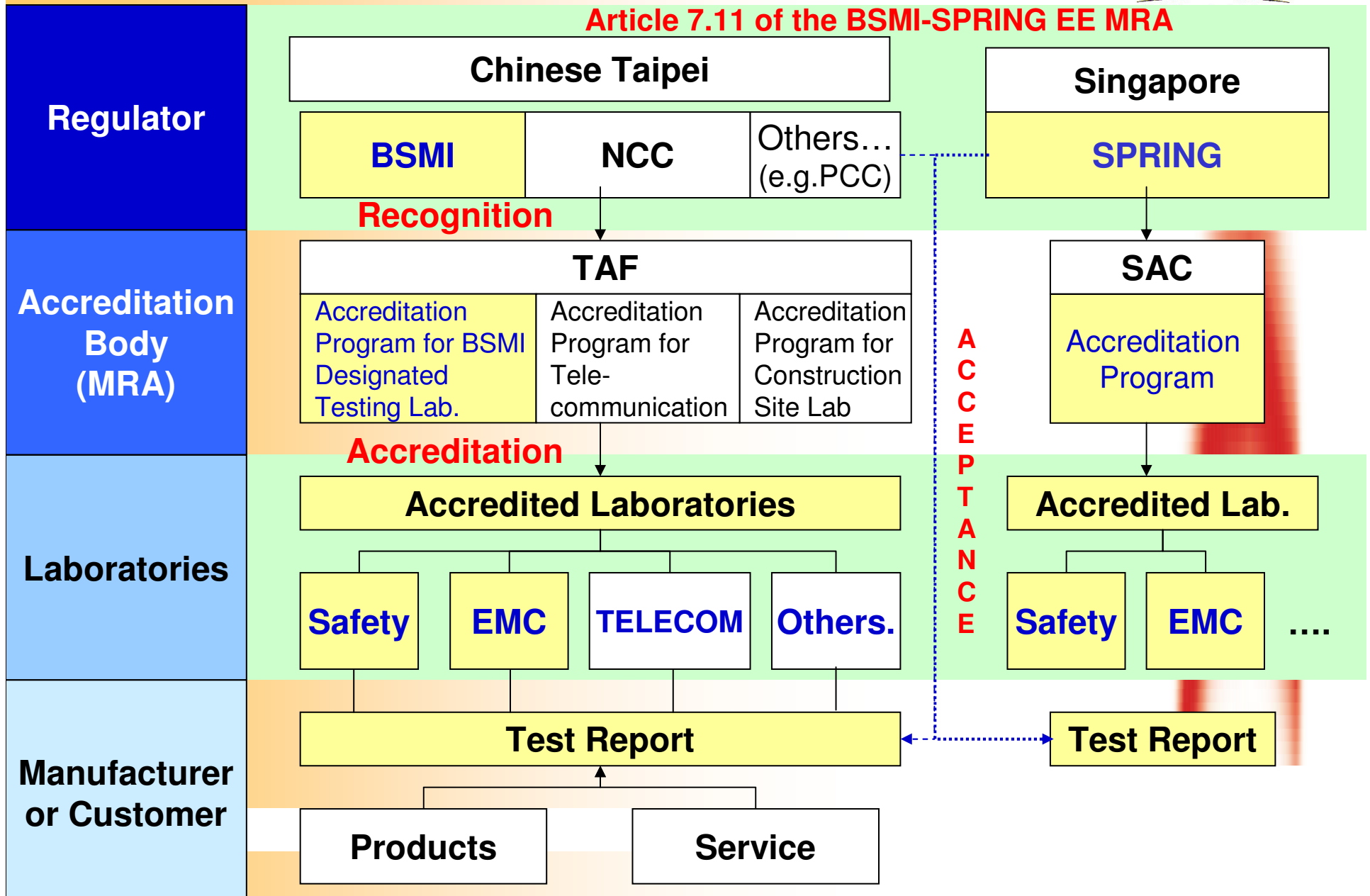
# TAF accreditation in electrical testing

- **175** labs
- Specific accreditation programs with regulator “Bureau of Standards, Metrology and Inspection”
  - **93** are accredited to the *Accreditation Program for Designated Testing Laboratory for Commodity Inspection*
  - **30** are accredited to the *Accreditation Program for Laboratories Recognized by BSMI under the Mutual Recognition Arrangement*

# Model of regulator using accredited labs



Article 7.11 of the BSMI-SPRING EE MRA



## A recent cooperative event between regulators

On 13 May 2009, under the framework of the “MRA between BSMI and SPRING”, Mr SIM Geok Seng, Head of Consumer Product Safety, SPRING Singapore, delivered a speech in Taipei on:

- The Singapore Consumer Protection (Safety Requirements) Registration Scheme (CPS Scheme)
- Test requirements for CPS controlled goods
- Certification requirements for CPS controlled goods

# Conformity assessment body's responsibilities and liability

## Legal liability

**- depends on the legislation in any particular country**

- AB's responsibility
- CAB's responsibility & liability
- Client's responsibility
- Report end user's responsibility
- Regulator's responsibility



## AB's responsibilities on CAB

- Assess technical competence
- Rights and obligations (legal liability)
- Professional insurance (financial risk)

## **CAB's responsibilities & liability**

- Responsible for test / calibration results
- not to falsify reports
- not to make misleading claims about their scope of accreditation
- follow requirements for accreditation

## Taking Chinese Taipei as an example

### - In consultation with TAF's lawyer

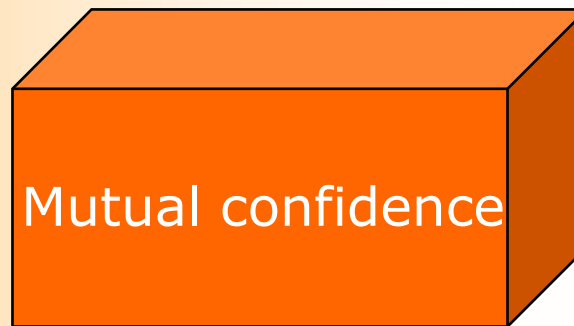
- TAF grants accreditation to incompetent CAB
  - Responsibility by TAF (professional insurance, legal liability against Civil Law)
- CAB issues reports with faults
  - legal liability against Civil Law
- CAB falsifies reports
  - legal liability against Criminal Law

***Case by case...***

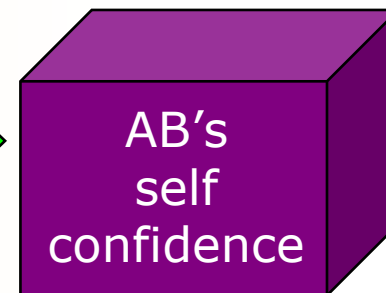
# Conclusion & suggestion

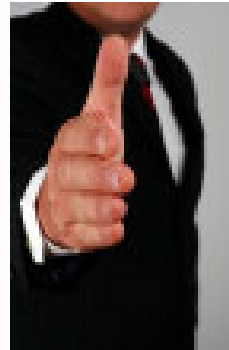
# Building confidence

Regional



National





## AB's self-confidence

- Comes from **COMPETENCE**:
  - Appropriate staff
  - Appropriate assessment manpower
  - Understanding the requirements of performing certain job
  - Establishing procedures
  - Following accreditation criteria

# Mutual confidence between ABs

- Supported by **PEER EVALUATION**
  - Verification and confirmation of “same level of competence” between two different accreditation bodies
  - For APLAC MRA, each signatory accreditation body is peer evaluated every four years:
    - Peer review
    - Balance of skills and technical expertise
    - Evaluators
      - experienced in laboratory accreditation
      - technical expertise
      - proficiency testing experience
      - free from conflict of interest



## Mutual confidence between ABs (ctd)

- MRA partners would recommend third parties to accept endorsed test and inspection results obtained by accredited organisations of one another.



## Regulator's confidence in AB

- AB provides necessary conditions to meet regulator's needs and earn trust:
  - Exchange of information
  - Assessors with full comprehension on regulations (by training)
  - Assessment check-list
  - Invite regulators to observe or participate in an assessment
  - Periodic and non-regular review procedures

## Suggestion

- More communications between APEC EE & APLAC
  - E.g. APLAC subcommittee on APEC EE MRA
- Joint training
  - E.g. APLAC invites APEC EE to hold a seminar for AB
- Joint PT programs for EE requirements
- Encouraging direct activities between local regulators and AB

# Thank you for your attention!



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