

# **MUTUAL RECOGNITION AGREEMENTS/ARRANGEMENTS -- PRINCIPLES**



# How do CABs demonstrate they are competent and impartial?

Conformity assessment bodies (CABs) can demonstrate their competence and impartiality in a number of ways. The 2 most used are :

- A group of them forms **a mutual recognition group (mutual recognition/peer assessment)**.
- They become **accredited** by an accreditation body (AB). Mutual recognition agreements/arrangements (**MRAs/MLAs**) are signed among accreditation bodies (IAF and ILAC).



# Mutual Recognition Arrangement Agreement (MRA)

Mutual recognition reduces costs of trade

Mutual recognition can be G2G\* or voluntary, bilateral or multilateral

- **Between:**

Regulatory bodies (e.g. OIML)

Accreditation bodies (e.g. IAF & ILAC)

Certification bodies (e.g. IEC CB Schemes)

Laboratories (e.g. BIPM)

There are a series of ISO/IEC Guides and Standards that underpin this system.

A number of regional and international accreditation bodies exist that provide the basis for voluntary MRAs.

\* G2G = Government-to-Government



# Mutual Recognition Agreements/Arrangements (MRAs)

How can confidence be achieved?

- Through cross-border cooperation among conformity assessment bodies and also among accreditation bodies.

What is this cross-border cooperation?

- Known as MRAs, whereby the parties involved agree to recognize the results of each other's testing, inspection, certification or accreditation.

What do MRAs achieve ?

- Reduce the multiple conformity assessment that products, services, systems, processes and materials may need to undergo, especially when they are traded across borders.
- Contribute to the efficiency of the international trading system by facilitating the acceptance of goods and services everywhere on the basis of a single assessment in one country.
- Benefit suppliers and customers alike.

ISO/IEC Guide 68: 2002, Arrangements for the recognition and acceptance of conformity assessment results



# Mutual recognition/peer assessment

The group (peers) decides on the **specific rules** for the assessment and re-assessment of the members of the group.

The peer assessment team members should be **highly competent** (both technically and with regard to assessment skills).

Be aware that in peer assessment the members may also be competitors and the impact of this on the process has to be determined. **Confidentiality** is crucial.

**Impartiality** has to be ensured as much as possible in the process.

# Mutual recognition/peer assessment

## Definition - Peer assessment

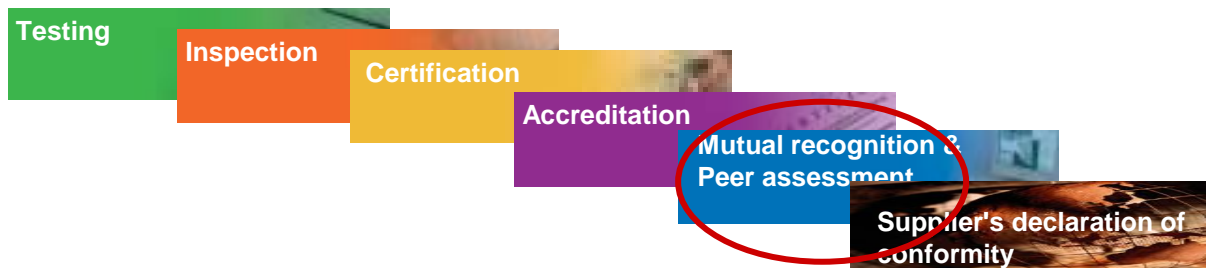
*Assessment of a body against specified requirements by representatives of other bodies in, or candidates for, an agreement group*

**ISO/IEC 17000:2004 (4.5)**

## Definition agreement group

*Bodies that are signatories to which an arrangement is based*

**ISO/IEC 17000:2004 (7.10)**

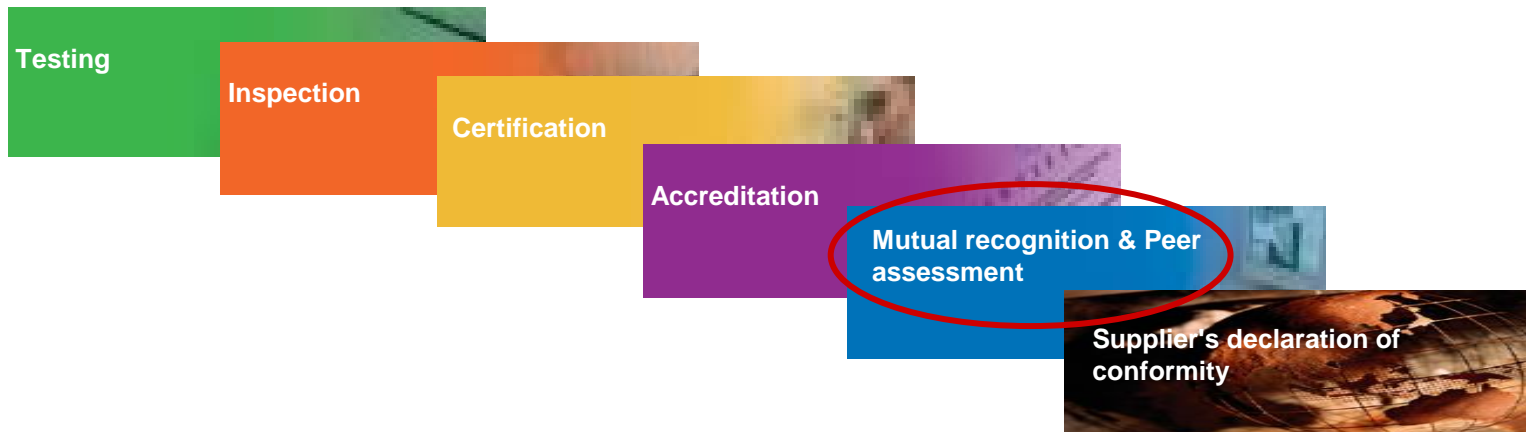


# Mutual Recognition Agreement (MRA)

## Definition - Multilateral arrangement

*Arrangement whereby more than two parties recognize or accept one another's conformity assessment results*

ISO/IEC 17000:2004 (7.9)





# Mutual recognition/peer assessment

**ISO/IEC  
17040  
defines peer  
assessment  
as :**

Assessment of a body against specified requirements by representatives of other bodies in, or candidates for, an agreement group.

**NOTE 1**  
“Candidates” are included to cater for the situation where a new group is being formed, at which time there would be no bodies in the group.

**NOTE 2** The term “peer evaluation” is used by some groups instead of “peer assessment”.

In other word the group itself determines if the requirements are met. The assessment is carried out by members of the group. This enables then to accept the results of the members within the group.





# Mutual recognition/peer assessment

**Peer  
assessment**  
requires the  
following  
elements:

- Competent assessors drawn from members of the group.
- Clearly specified membership criteria decided by the group.
- An assessment of the candidate organization that is looking for membership of the group.
- A report on the candidate organization, indicating where they meet and where they fail to meet the criteria for membership of the group and any other additional information which may impact the decision to allow them to become members.



# Mutual recognition/peer assessment

Peer  
assessments  
are useful:

- to demonstrate competence;
- to ensure quality;
- to create and keep mutual confidence.

Peer  
assessment  
process is:

- carried out by peers or by agreement groups of accreditation bodies or conformity assessment bodies;
- other certification bodies, other laboratories, etc.;
- parties with similar experiences, training, competences.

ISO/IEC  
17040:2005

- **Conformity assessment** — *General requirements for peer assessment of conformity assessment bodies and accreditation bodies*



# Mutual recognition groups

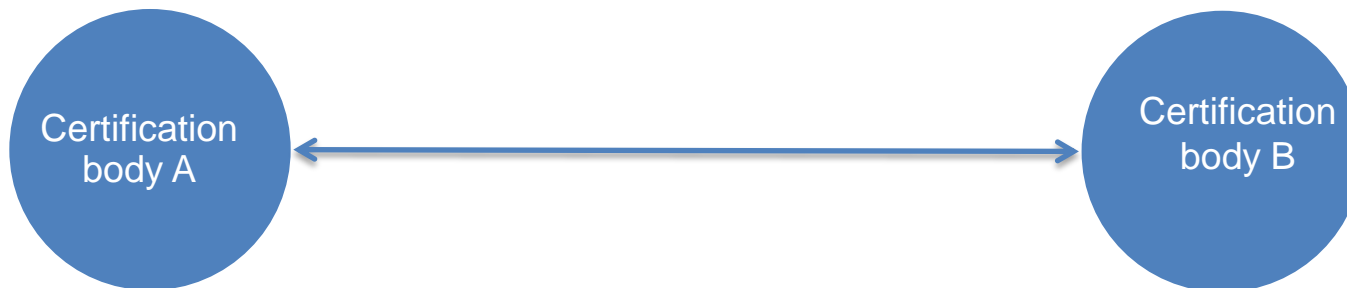
Mutual  
recognition  
groups  
are:

- Used to facilitate acceptance of conformity assessment certificates and cross border trade.
- A group of certification bodies get together and establishes formal recognition arrangements with each other. This can also be bilateral between two certification bodies or a whole group.
- The arrangement needs to establish the competence of each member and thus provide confidence in the conformity assessment results of each member of the group. This is usual done by **peer assessment**.



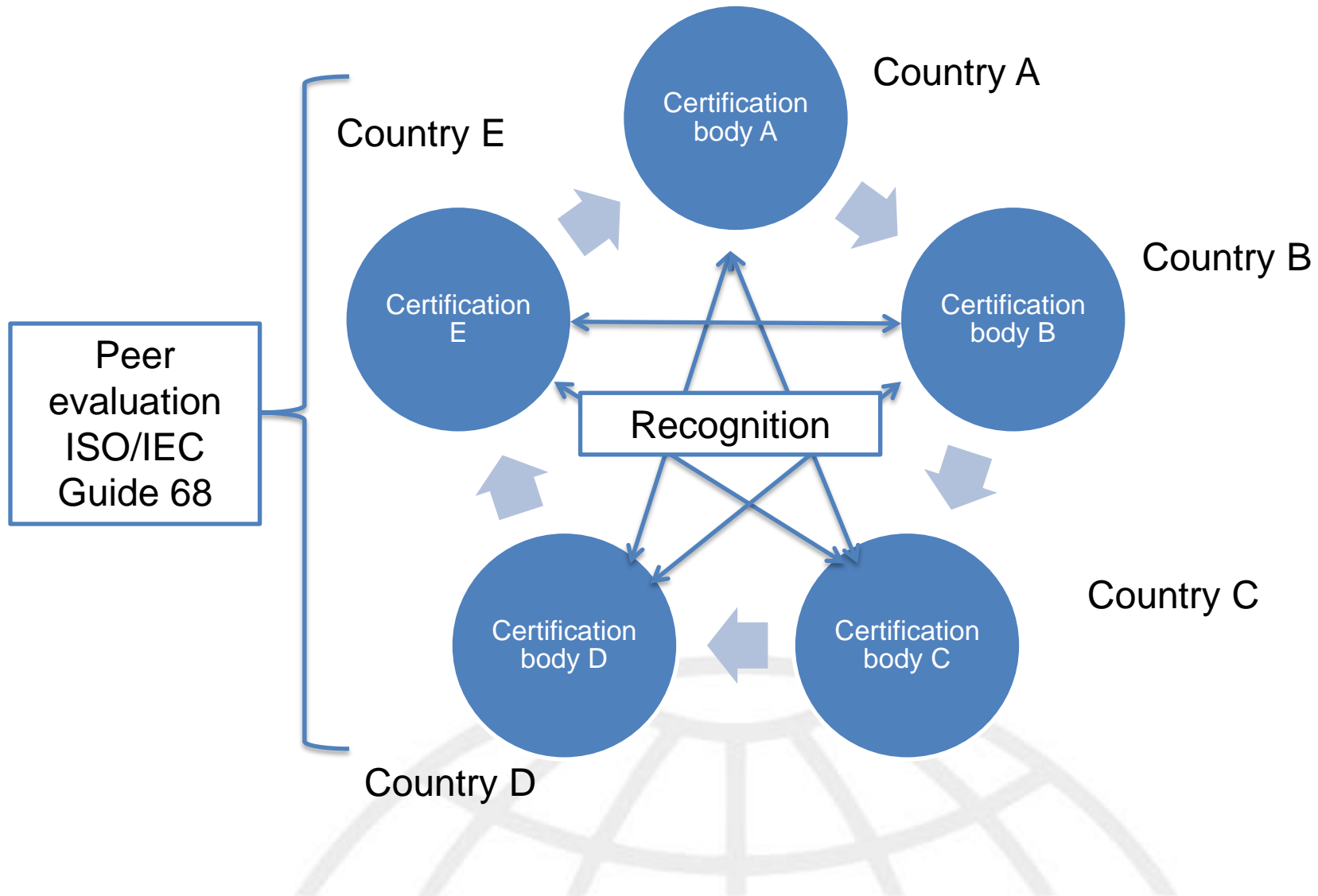
# Certification body (CB) to CB agreement

- Two or more CBs agree to recognize one another CB's certificates.
- Example CB in Canada with joint recognition with Australian CB.
- Does not imply the two programs are the same.
- Recognizes the **equivalence of outcomes**.





# Recognition agreement/arrangement





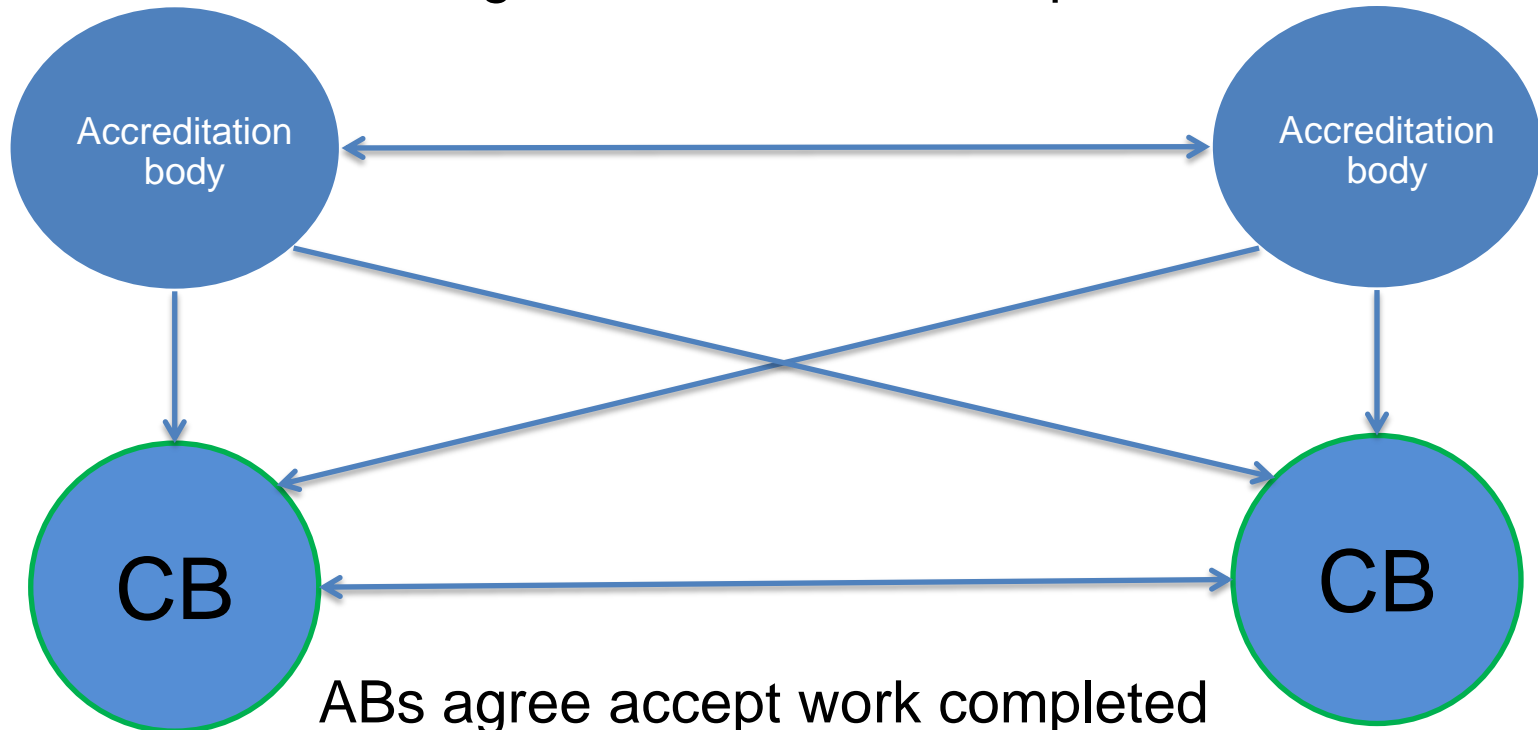
# Accreditation body (AB) to AB agreement

- Allow for a mobile workforce/ product/process that can cross borders with their credential.
- Assure that **accredited CBs** have conducted their programs in a consistent manner and according to best practices as defined by standards.
- **Eliminates duplication** of efforts (recertification and reaccreditation).



# AB to AB agreements

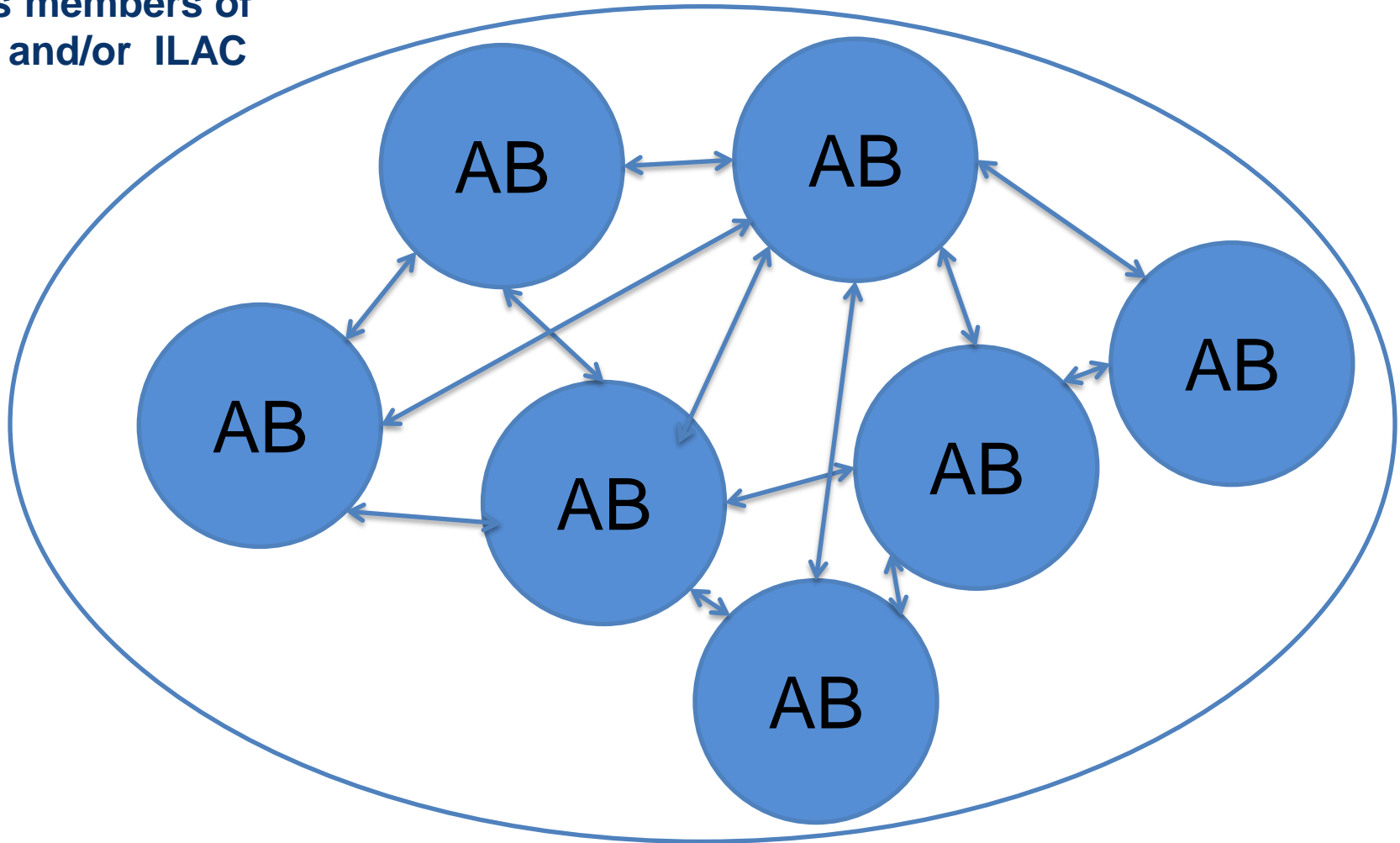
ABs agree to use the same process to accredit



ABs agree accept work completed by another AB in consideration for accreditation

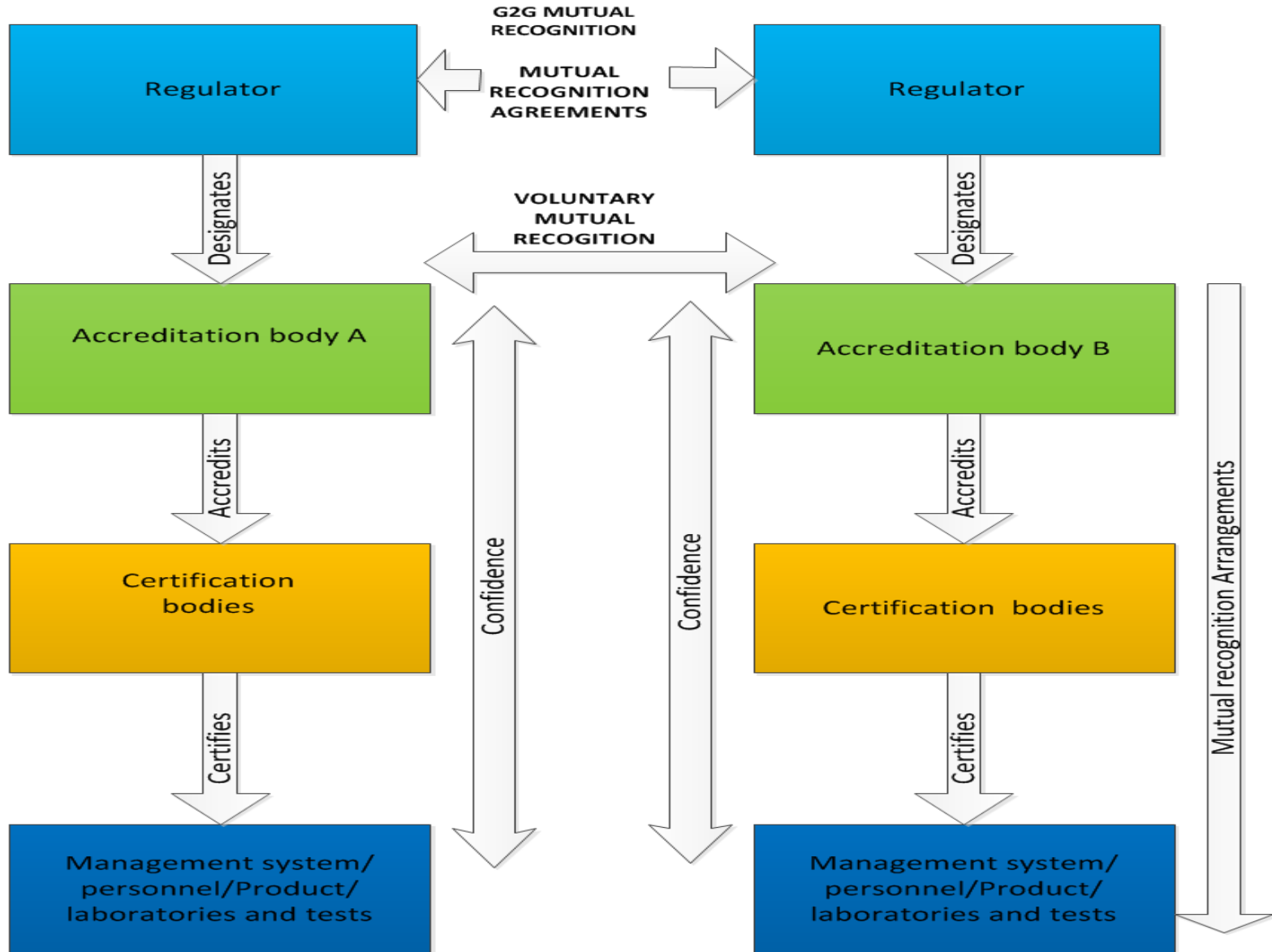
# How are these groups related?

ABs members of  
IAF and/or ILAC





# International Recognition Arrangement/Agreements



# Conformity assessment and regulators

### 3. WTO and standards

WTO requires members to :

- Use international standards, guides and recommendations, or relevant parts as basis for national technical regulation and conformity assessment procedures.
- Play a full part (within resources) in international standards development by international standardizing bodies.



# Standards supporting technical regulations

Reflect best experience of industry, researchers, consumers and regulators worldwide.

ISO standards are adopted at regional and national level.

One important basis for removal of Technical Barriers to Trade (TBT).

Organization for Economic Cooperation (OECD) also recognizes role of international standards in support of regulation.



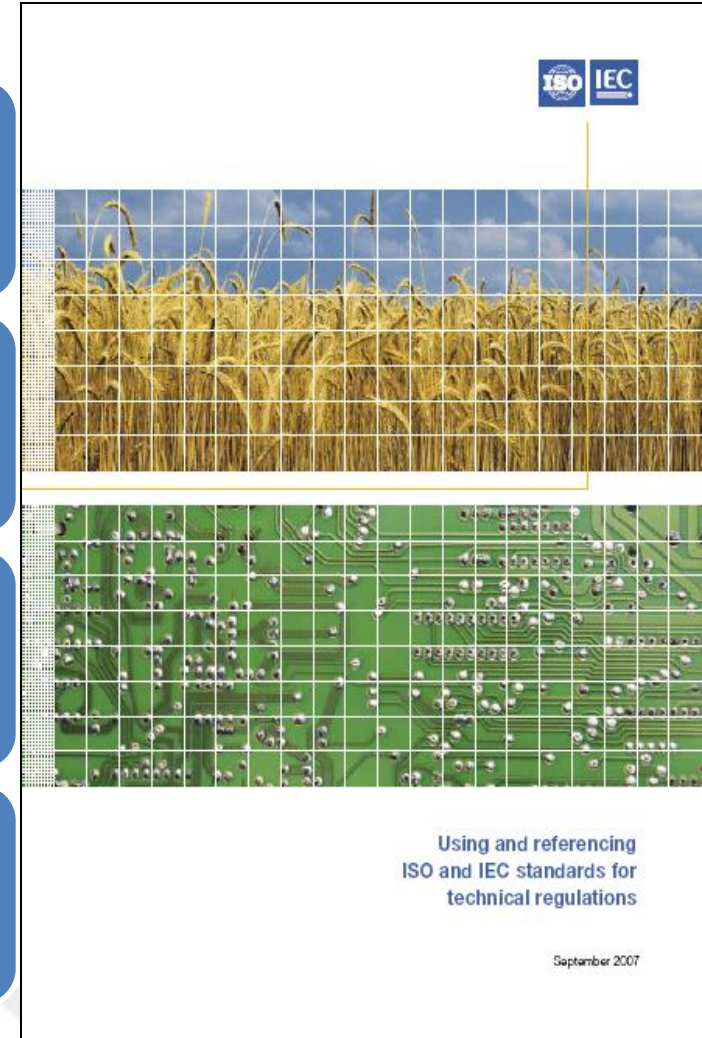
# Conformity assessment standards and good regulatory practice

Use of standards in regulation supports **national, regional** and **global** policies.

**National adoption** may be an important element encouraging the use of ISO or IEC standards in national technical regulation.

National adoption process can give confidence that the international solution is **fully acceptable to the national situation.**

Standards published by **other organizations** may also be referenced in regulations





# ISO/IEC standards & good regulatory practice

How do  
standards  
get  
incorporated  
in  
regulations?

- Direct reference to specific standard (dated or undated)
- Indirect reference to ISO standards
- Some regulators reproduce text of standard directly in regulation



# ISO/IEC standards & good regulatory practice

How do standards get incorporated in regulations?

- **Direct reference - reproduced directly in regulations**
  - Statute directly references standard (title & identification number), avoiding reproduction of standard in legal text and copyright issues.
  - Allows for specific parts of standard to be referenced where regulation only requires part of standard.
  - Regulation's legal certainty given by dated reference.
  - Undated references allow more flexibility when required. Example: waste emissions shall be less than clause 4 of ISO XXXXX:2011, TITLE



# ISO/IEC standards & good regulatory practice

How do standards get incorporated in regulations?

- **Indirect references to ISO & IEC standards use**
- Involves official recognition of standards external to regulatory text
- Regulator compiles and publishes list of suitable standards by official process and controls
- If standard amended or revised no need to change legal text – only the list





# Standards – regulation comparison

Standards	Regulations
<b>Standards</b> development process.	<b>Regulatory</b> development process.
Standards development organizations ( <b>SDOs</b> ) facilitate development of standards in response to requests.	<b>Governments</b> lead in developing regulations.
SDOs <b>seek consensus</b> on content of standards.	Governments consult interested parties, <b>not necessarily seeking consensus</b> . Regulations may reference standards or require use of accredited conformity assessment bodies .
<b>Conformity</b> assessment.	<b>Compliance</b> assurance.
Certification bodies and testing labs ( <b>conformity assessment</b>	<b>Governments</b> enforce regulations themselves or <b>remain accountable</b>



# European Union (EU) approach to conformity assessment

European legislation designed to remove technical barriers to trade and to facilitate trade within Europe.

It specifies a series of conformity assessment modules to be used by legislators when drafting legislation to align the laws of the various member bodies relating to safety.

Legislation is in the form of an EU Directives and the modules are chosen according to the risk of non conforming product.

For low risk the suppliers declaration of conformity (SDoC) is sufficient whereas for higher risk products it requires third party assessment etc.

The modules can be combined in various ways to give choice of complying whilst maintaining the level of conformity assessment needed.

The modules cover:

- self assessment by the manufacturer
- type assessment by an independent body (notified body)
- quality assurance assessment by a notified body
- inspection of production items by a notified body



# Conformity assessment standards and good regulatory practice

## Objectives of the WTO/TBT Agreement

- ensure that national technical regulations, standards and conformity assessment procedures do not constitute unnecessary barriers to international trade
- achieve a balance between allowing WTO Members to take regulatory measures to protect legitimate interests and ensuring that national technical regulations, standards and CA procedures do not become unnecessary obstacles to international trade

## Harmonization is central to the TBT Agreement and is articulated in particular in two requirements:

- WTO members shall use international standards, guides and recommendations, or relevant parts of them, as a basis for their national technical regulations and conformity assessment procedures
- WTO members shall play a full part in the preparation of international standards, guides and recommendations by participating in international standardizing bodies

The WTO also has specific policy areas where international standards are being discussed: trade in services (GATS), food safety (SPS) and trade and the environment (CTE)

