



**International Organization  
for Standardization**

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# **CONFORMITY ASSESSMENT and REGULATIONS**

**&**

# **THE ISO/CASCO TOOLBOX**

by Mr. Peter Dennehy  
ISO Head of Conformity Assessment

**WTO Workshop on CONFORMITY ASSESSMENT**

**Geneva, 16<sup>th</sup> – 17<sup>th</sup> March 2006**

# Outline of presentation

- **The WTO TBT provisions & ISO contribution to Conformity Assessment.**
- **What Conformity Assessment is, how it supports Sustainable Development, and may derive from Market & Regulatory requirements**
- **Who & What is ISO/CASCO**
- **What & How Mutual Recognition Works**
- **The ISO/CASCO toolbox of Conformity Assessment Standards and Guides and Work in Progress**
- **ISO Support for Developing Countries**



# Conformity Assessment & the WTO TBT Agreement

“*Recognizing* the important contribution that international standards and **conformity assessment** systems can make in this regard by improving efficiency of production and facilitating the conduct of international trade;”

*Desiring* therefore to encourage the development of such international standards and **conformity assessment systems**; ...

“2.4 Where technical regulations are required and **relevant international standards exist** or their completion is imminent, Members **shall use them**, or the relevant parts of them, **as a basis** for their technical regulations ....”

**... except** when such international standards or relevant parts would be an **ineffective or inappropriate means** for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.”

“2.6 With a view to harmonizing technical regulations on as wide a basis as possible, Members **shall play a full** part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations.”

# ISO and Conformity Assessment

- **World Trade Organization and international acceptance of tests and certificates**
- **Reconciling facilitation of trade and progress in quality, security, health, consumer and environmental protection**
- **International recognition and acceptance to be based on confidence and good practices**
- **The way forward: promoting good practices by implementing the ISO/IEC Standards and Guides, based on a double level of consensus, amongst countries and across stakeholders**



# WHAT IS CONFORMITY ASSESSMENT?

## ISO:

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

[Clause 2.1, ISO/IEC 17000:2004(E): *Conformity assessment* —

*Vocabulary and general principles*]

## WTO:

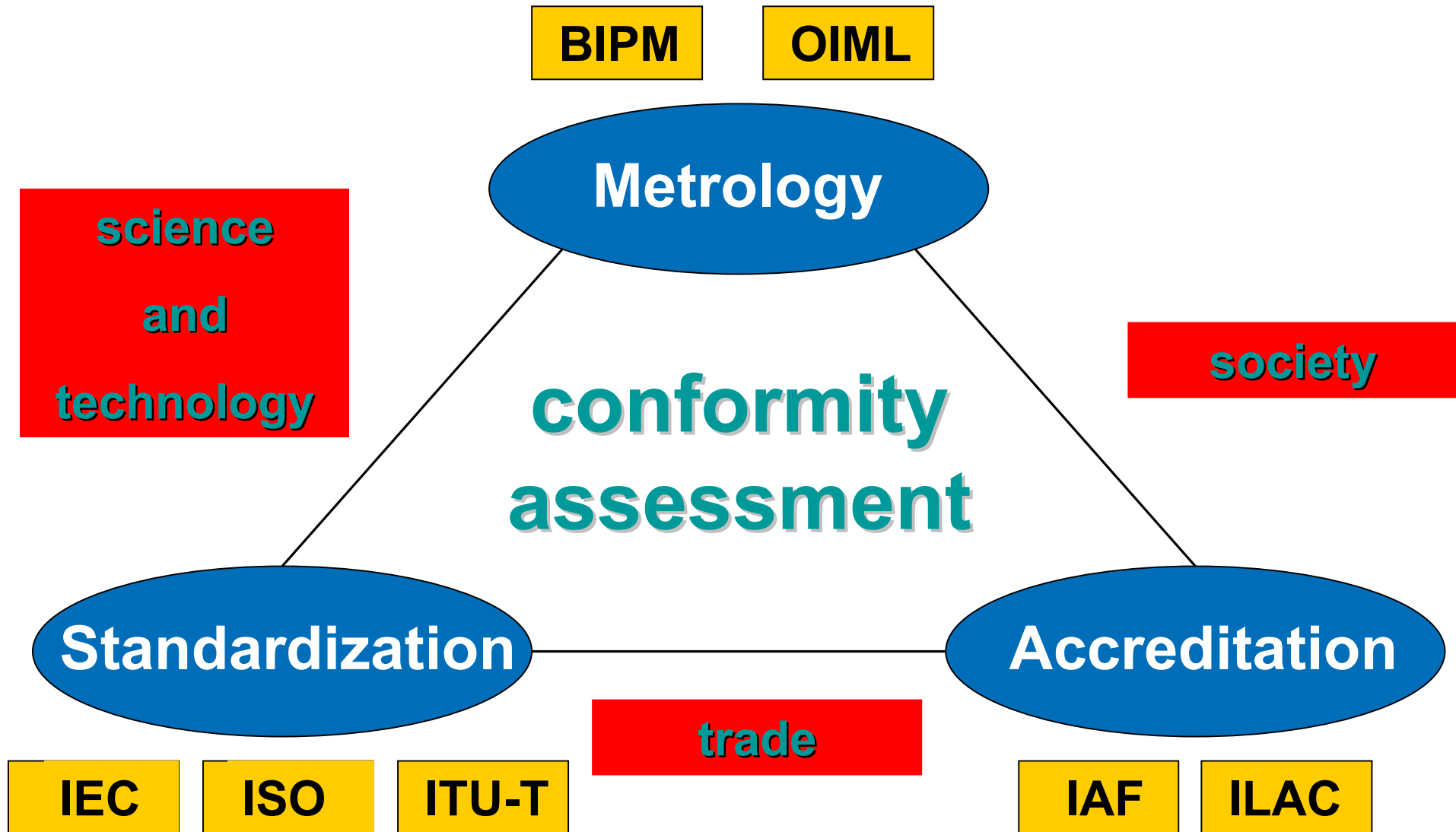
“Any procedure used, directly or indirectly, to **determine** that relevant **requirements** in technical regulations or standards are **fulfilled**.”

[TBT Agreement, Annex 1, paragraph 3]

# CONFORMITY ASSESSMENT: THE 1-1-1 DREAM



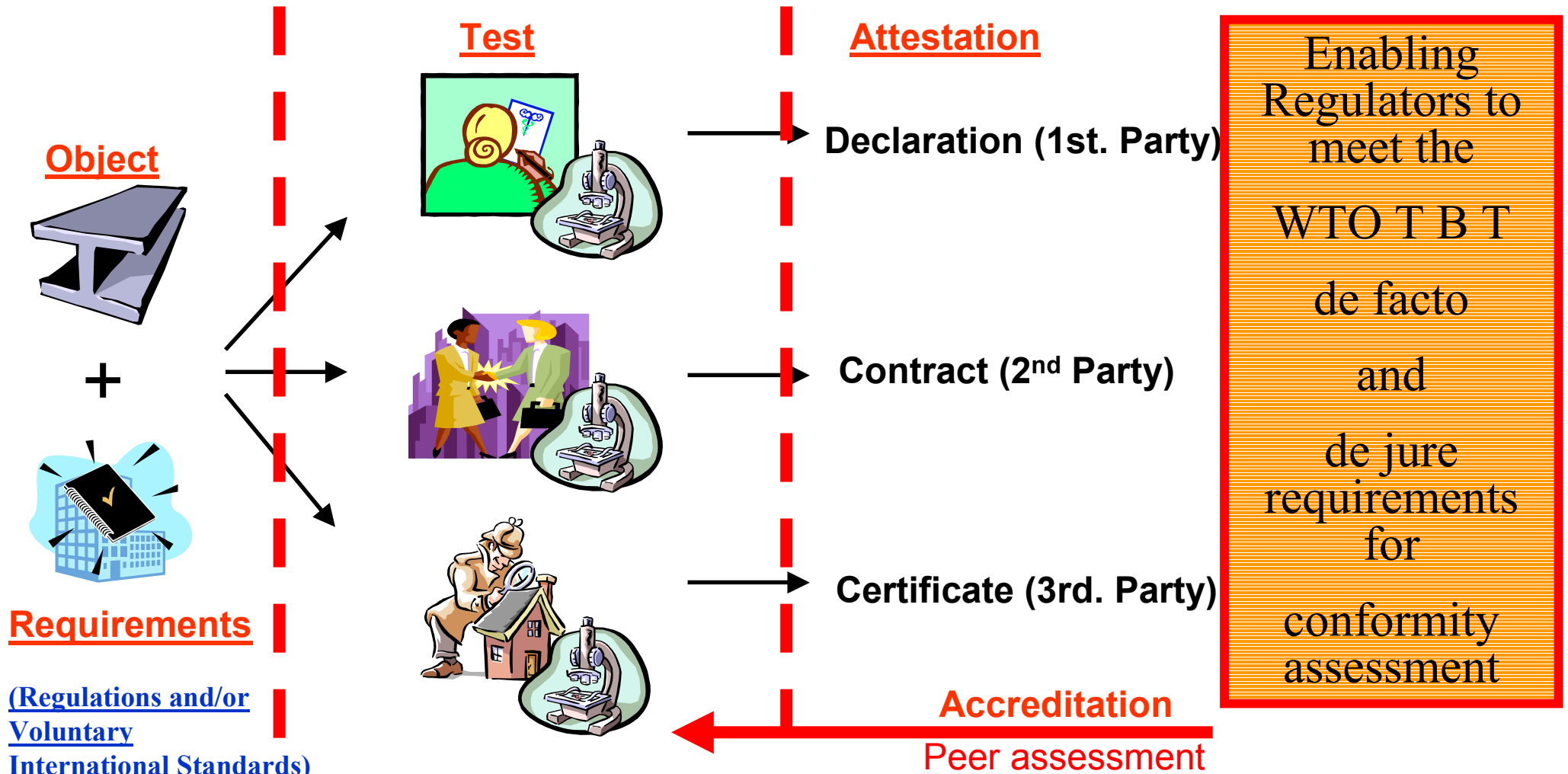
# Conformity Assessment Infrastructure Supporting Sustainable Development





# Basic conformity assessment process

Ex: REGULATORY or MARKET REQUIREMENTS for Products



# ISO/CASCO: The ISO Conformity Assessment Committee

- The **CASCO toolbox** consists of **24** documents covering: vocabulary, principles and common elements of conformity assessment, code of good practice, product certification, system certification, certification of persons, marks of conformity, testing, calibration, inspection, supplier's declaration of conformity, accreditation, peer assessment, and mutual recognition arrangements.
- **100 countries** are involved through **ISO Member Bodies** in CASCO, of which 63 are participating members and 37 observers.
- **9** international organizations are **liaison members** of CASCO: BIPM, IAF, IFAN, IFIA, IPC, IQNet, ILAC, OIML and UIL.

# ISO/CASCO structure

- CASCO has a **structure** that reflects its various roles of policy development, writing of technical documents, promotion of those documents, and monitoring market feedback on the use of those documents.
- A continual **improvement** cycle is in place to ensure CASCO provides globally relevant documents that reflect modern conformity assessment practice.



# World-Wide Conformity Assessment

## So far identified how:

- **International standards will improve trade when used as a means of compliance**
- **TBT has preference for international standards as implementation tool for technical regulation**
- **Regulators should be involved in developing international standards**

## Now consider also that:

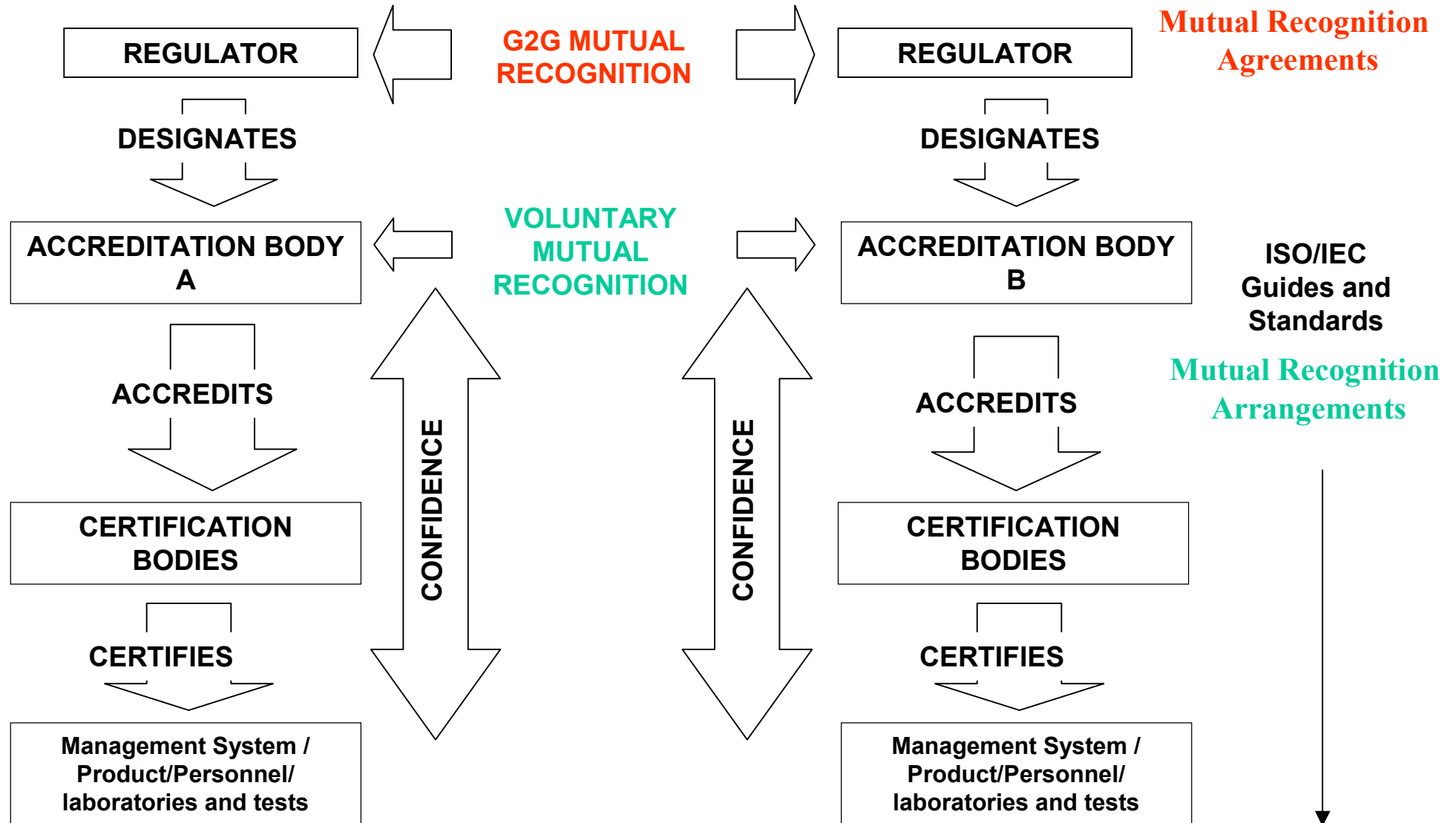
- **TBT makes reference to mutual recognition of conformity assessments**
- **Some factors to consider:**
  - **Risk**
  - **Cost/benefit**
  - **Effects on trade**
  - **The future**

# Mutual Recognition of Conformity Assessment

- **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**

# How mutual recognition works



# ISO/CASCO – Fundamental Documents

- The new [ISO/IEC 17000:2004](#) *Conformity assessment – Vocabulary and general principles* contains the terms, definitions and theoretical basis for conformity assessment – the *functional approach*. This approach identifies three distinct functions: selection, determination, review and attestation.
- The [ISO/IEC Guide 60:2004](#) *Conformity assessment – Code of Good Practice* may be used in conjunction with the WTO-TBT Agreement, to facilitate trade
- CASCO is developing [common elements](#) for conformity assessment that shall be used in all CASCO documents. These common elements include: [Impartiality](#), [Confidentiality](#), [Complaints & Appeals](#), [Disclosure of information](#), and use of [Management Systems](#) in conformity assessment.

# Components of the CASCO Toolbox

## General standards and guides

<b>Subject</b>	<b>Project</b>	<b>Publication date</b>
<b>Accreditation</b>	<b>17011</b>	<b>2004</b>
<b>Peer assessment</b>	<b>17040</b>	<b>2005</b>
<b>Mutual Recognition Arrangements (MRA's)</b>	<b>Guide 68</b>	<b>2002</b>
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<b>Sector Specific CA</b>	<b>14065, - 22003, 28004, - 27003,</b>	<b>Work In Progress</b>



# Components of the CASCO Toolbox

## Technical functions

Subject	Document	Completion date
Suppliers declaration of conformity	17050	2004
Testing & calibration laboratories	17025	2005
	Guide 43	1997
Inspection	17020	1998
Product certification	Guides 28 - 28	2003 - 4
	Guides 65, 67, 53	2000 - 04 - 05
System certification	17021	2006
Person certification	17024	2003

# ISO/CASCO projects in progress

- **ISO/IEC 17021 (CASCO WG 21)**, *Conformity assessment — Requirements for bodies providing audit and certification of management systems*
- **ISO PAS 17005 (CASCO WG 23)**, *Conformity assessment — Use of management systems in conformity assessment — Principles and requirements*
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# Developing Countries and Economies in Transition

- **Improve awareness**
- **Develop capacity**
- **Increase national and regional cooperation**
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- **Increase participation in governance and technical work of ISO**

# Conclusion

- **Technical Barriers to Trade related to Tests, Certificates and similar Requirements can be addressed through the use of ISO/IEC International Standards on Conformity Assessment.**
- **To facilitate this International Regulatory requirements should:**
  - **be performance based**
  - **allow for acceptance of Conformity Assessment based on mutual recognition**
  - **Use, reference and promote the ISO/IEC International Standards and Guides on Conformity Assessment.**
- **Relying on ISO/IEC International Standards on Conformity Assessment to demonstrate compliance with technical regulation, reconciles public objectives such as safety and security with compliance to the commitments in the WTO TBT Agreement.**

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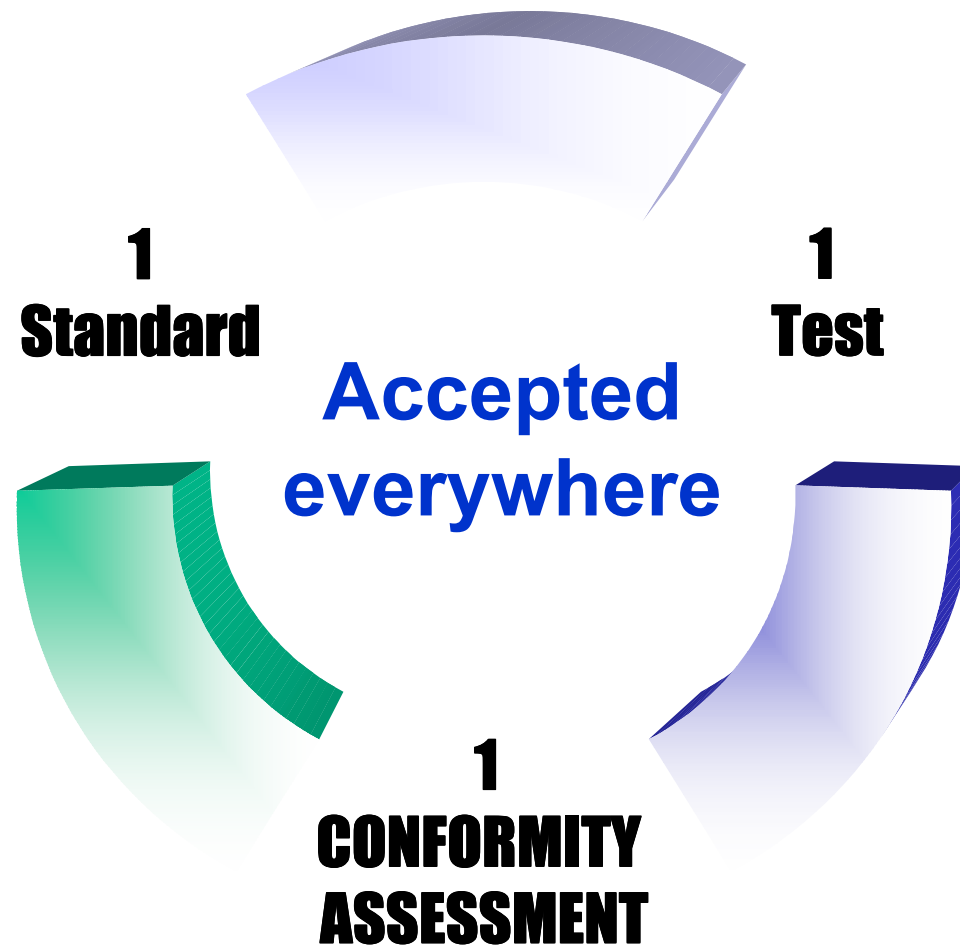
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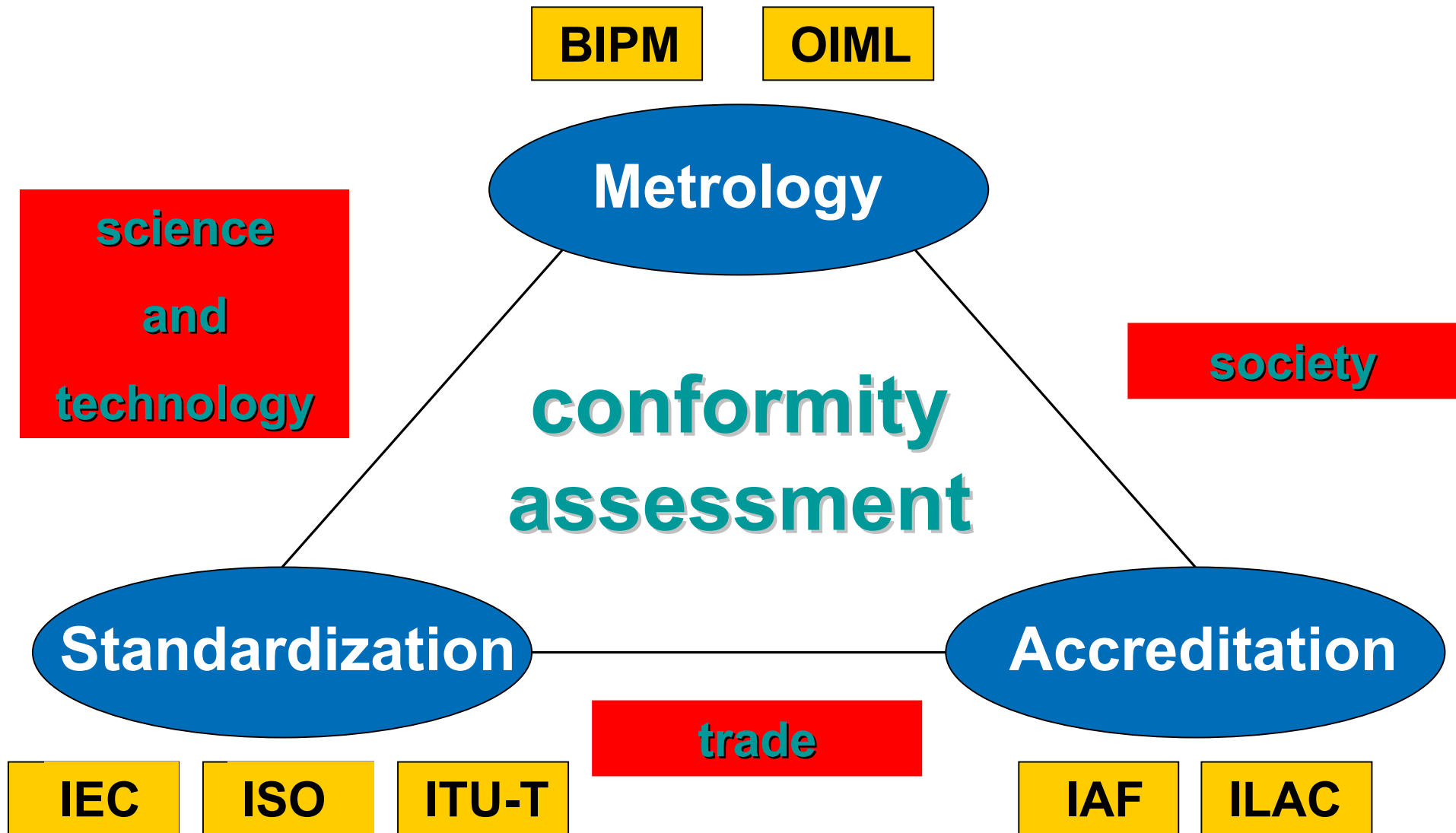
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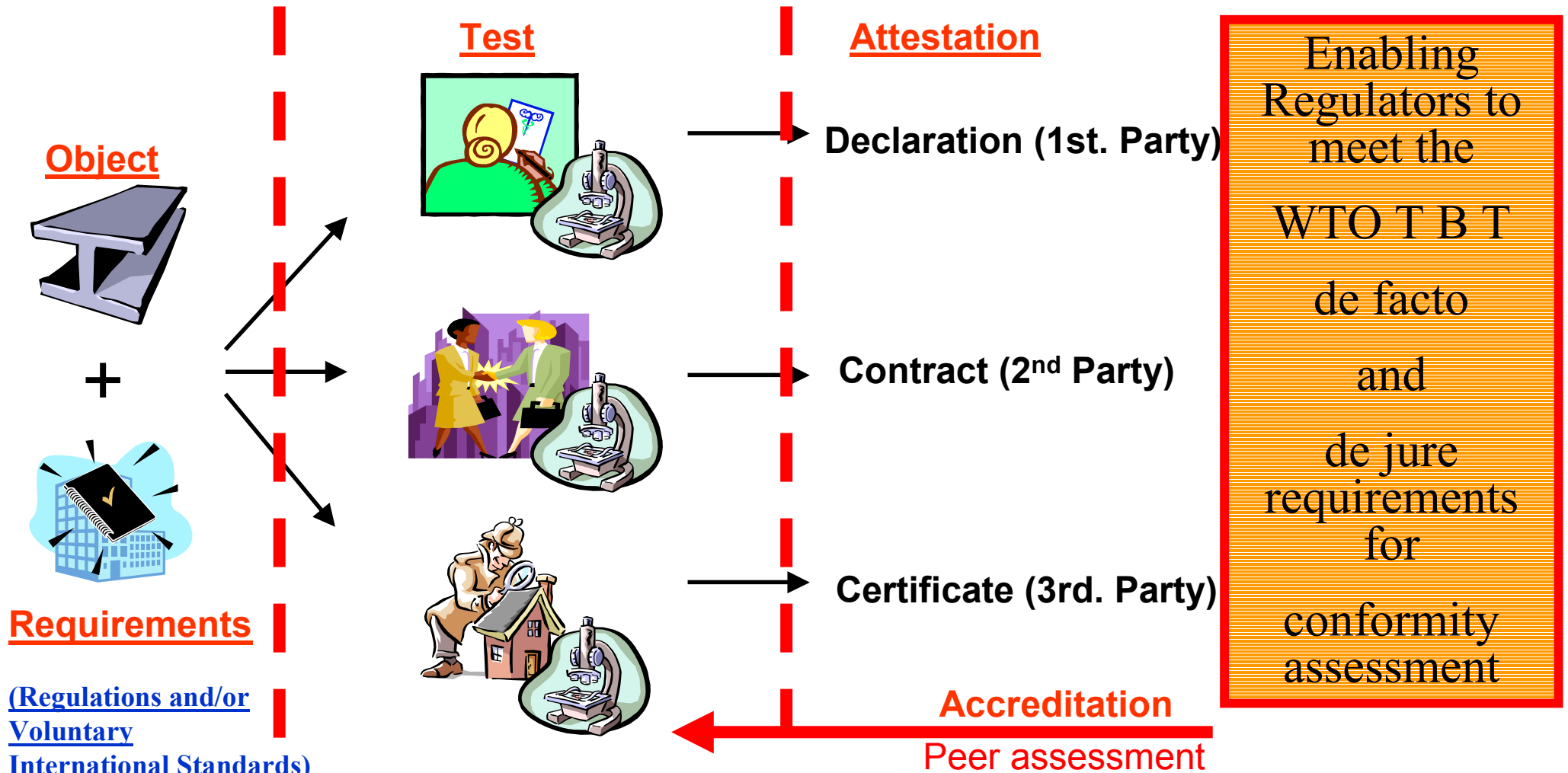


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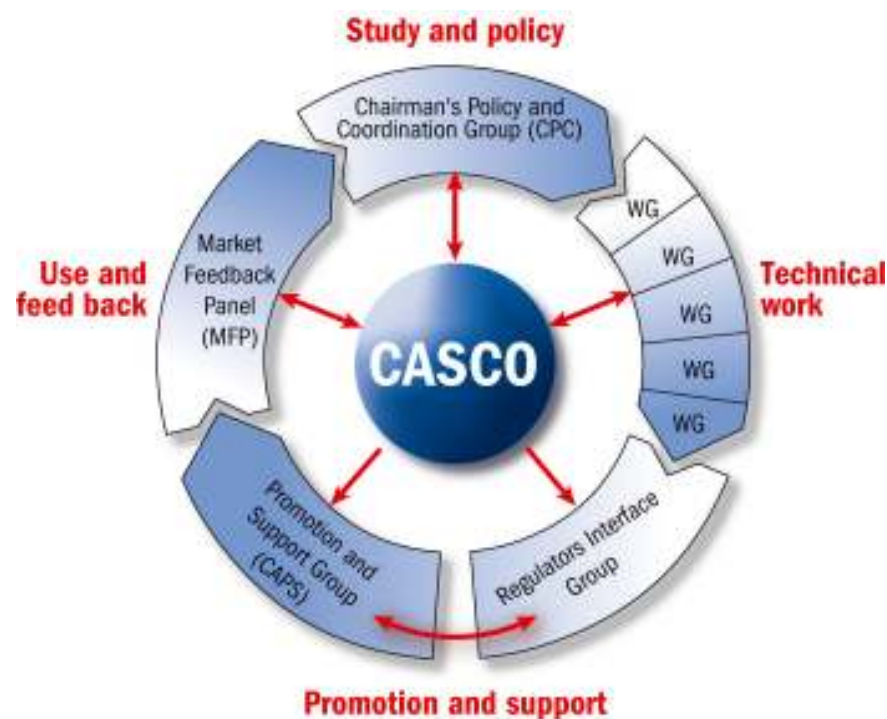


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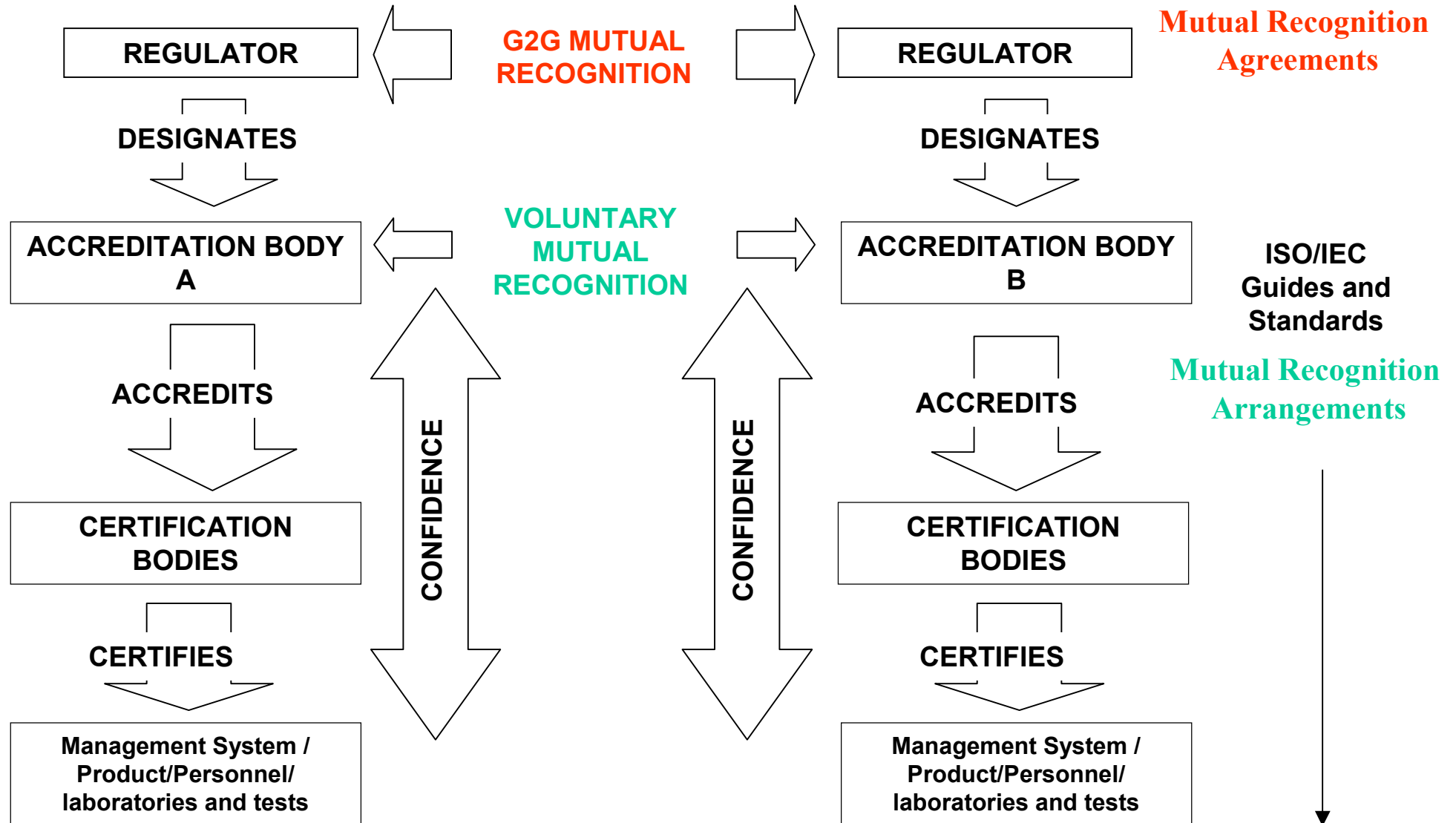
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