



International Standards Organisation

Conformity Assessment

Presentation to the

Global Harmonization Task Force

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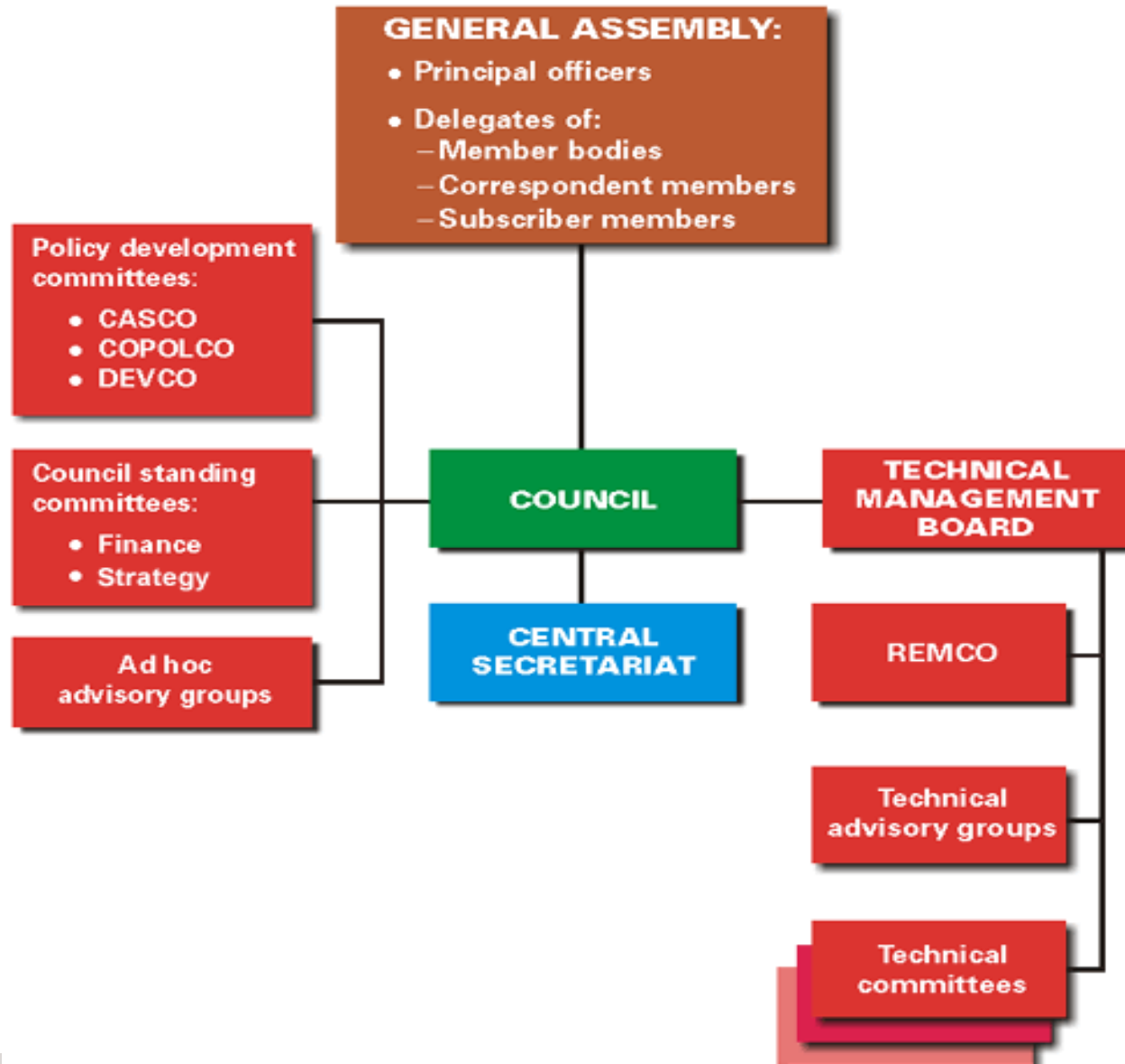
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ISO and conformity assessment

- World Trade Organization and international acceptance of tests and certificates
- International recognition and acceptance to be based on confidence and best practice
- The way forward: implementing the ISO/IEC Standards and Guides, with a double level of consensus, amongst countries and accross stakeholders
- Governments can require that imports must show proof of testing to specific standards and use Conformity Assessment as a means of ensuring products placed on the market are safe
- Developing technical requirements is half the story. After that mandatory or voluntary testing, inspection and assessment of the product, system or service may be required and also a mark of conformity.



ISO STRUCTURE

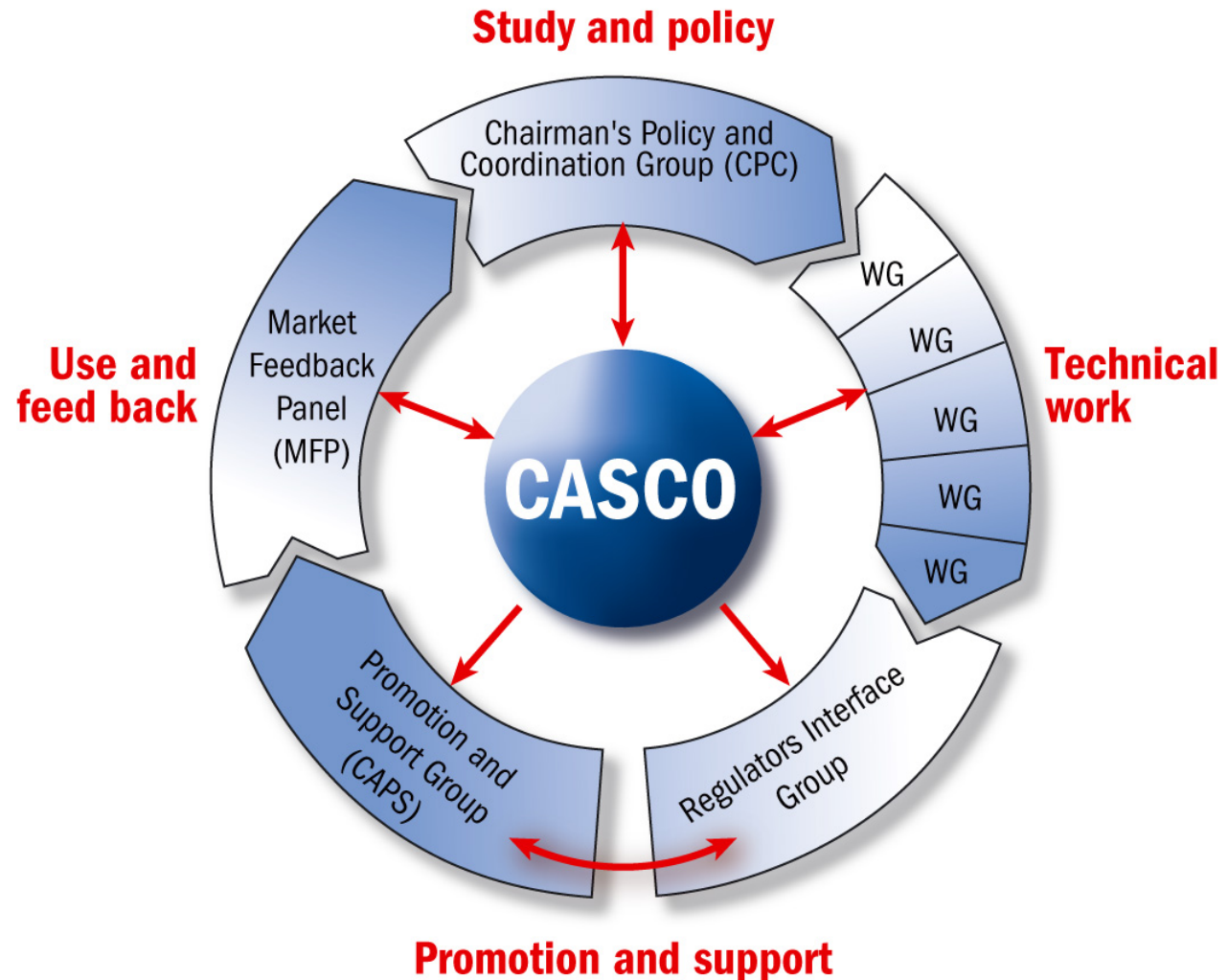


The International Standards Organization (ISO)

- 156 countries which is comprised a mixture of Government, semi-government and private bodies
- Each national member body to represent its government, industry and consumer views
- Develops international policy and reflects this in international standards and guides
- Based on consensus
- Recognition with related bodies include IEC, ITU and sector specific standardizing bodies
- Liaison with a number of international bodies

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.



ISO/CASCO functions

- CASCO undertakes both **policy** and **technical** work
- CASCO **supports** international and national recognition of test results and certificates
- **104 ISO members** participate in CASCO (73 participating members and 31 observers)
- Allow for input from other international organizations through official liaison. Currently has liaison with 9 other international organizations.

Conformity Assessment

- ❖ CASCO provides the technical software (CASCO toolbox) for Governments to have confidence in other countries and their own technical infrastructure
- ❖ CASCO provides the "rules" for achieving harmonized Conformity Assessment. These rules are contained in ISO/IEC documents.

ISO/CASCO Neutrality Policy

- ISO/CASCO has a neutral policy with regard to the application of standards by 1st, 2nd or 3rd parties
- There have been exceptions to this policy (financial planners)
- The application of 1st, 2nd or 3rd party should be decided on by the client (regulator) based on a risk assessment and associated costs and benefits.
- 3rd party (certification) often is associated with significant risk
- 3rd party can be required by technical regulation (mandatory certification) or can be voluntary.
- Regulator can also require use of accredited facilities (laboratories and certification bodies)
- CASCO sets the basis consensus requirements the regulator can then add to these should the circumstances require it.
- Objective of CASCO is to ensure that wherever Conformity Assessment is used, it is used and applied in a consistent manner and the rules are the same.

Some CASCO “Rules”

- ❖ Neutral Approach to Accreditation CASCO documents do not insist that laboratories have to be accredited to 17025 or an organisation must be certified to 9001 by an accredited certification body.
- ❖ This is left up to the market or the purchaser to decide.
- ❖ Do not encourage different sectors developing their own Conformity Assessment Systems:

CA medical example Risk based

- Example:
- Manufacturer of a medical device that needs to be inserted into or used on a human body. The risk is high if there are failures. Therefore the CA activities should be more significant:
- Therefore the client (Regulator) specifies the:
 - Specification to be met
 - The frequency of testing (once off to routine testing)
 - The degree of QMS to be implemented (full or partial system)
 - The amount if any of surveillance activity
 - Who should do all of the above (1st, 2nd or 3rd party)
 - How all of the above should be assessed (need for accreditation)

ISO/CASCO – Fundamental documents

- CASCO provides the “software“ framework for global conformity assessment through its consensus developed documents that give effect to:
 - Product specifications
 - Management system requirements
 - "Rules“ that laboratories and certification bodies must follow for consistency and competency
 - "Rules“ that accreditation bodies must follow to ensure the above occurs
 - The CASCO toolbox consists of 26 documents which gives effect to the soft technical infrastructure.

Components of the CASCO toolbox (1)

General standards and guides

Subject	Document	Publication date
Vocabulary	17000	2004
Code of good practice	Guide 60	2004
Mutual Recognition Arrangements (MRA's)	Guide 68	2002
Peer assessment	17040	2005
Accreditation	17011	2004
Marks of conformity	17030	2003

Components of the CASCO toolbox (2)

Technical functions

Subject	Document	Publication date
Suppliers declaration of conformity	17050	2004
Testing & calibration laboratories	17025	2005
Proficiency testing	Guide 43 (17043 new)	1997
Inspection	17020	1998
Product certification	Guide 28, 67 Guides 65 (17065 new), 67, 53	2004 96 – 04 - 05
System certification Part 1	17021 Part 1	2006
Auditor competence and audit process Part 2 (new)	Part 2 (in preparation)	
Person certification	17024	2003

CASCO and the Regulator

- So how can CASCO infrastructure and processes assist the regulator of today.
- Based on the neutral approach it would be up to each regulator to specify what they require in terms of their issues for a product to be allowed into the market.
- Compliance with the test standard developed by ISO (one test method accepted everywhere)
- Tested for compliance in a competent laboratory determined as competent using ISO standards by an accreditation body that is recognized internationally based on ISO standards
- Manufactured in a plant that has quality management system (ISO standards) in place assessed by a competent certification body against ISO standards
- Market surveillance can be built into the system for conformity assessment again based on the risk
- Regulator can also specify additional requirements either technical requirements unique to their circumstance or additional management requirements. This could include requiring that those involved in the various stages of CA are accredited.

Objectives of Conformity Assessment Schemes

- To provide a global framework for conformity assessment based on risk which will:
 - Increase consumer and regulator confidence
 - Elimination of need for multiple testing, audits and certification (except where national differences exist)
 - Recognition and acceptance of reports
 - Reduced costs

Thank you for your attention !



<http://www.iso.org>