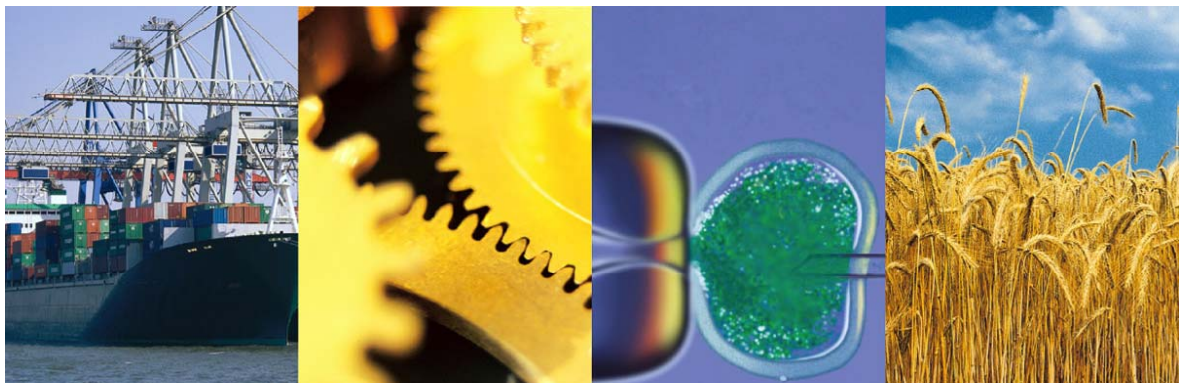




OIML Seminar on Conformity to Type (CTT)

29-30 June 2011, Utrecht, the Netherlands

Conformity Assessment and the CASCO Toolbox



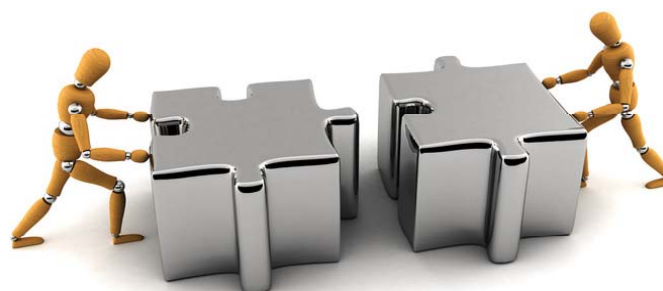
Sean Mac Curtain
CASCO Secretary
OIML Seminar on Conformity to Type (CTT)
29 – 30 June 2011 Netherlands

Standards for a better world



ISO's Mission

ISO develops **high quality voluntary** International Standards which **facilitate** international exchange of goods and services, **support** sustainable and equitable economic growth, **promote** innovation and **protect** health, safety and the environment



Standards – they simply help economies thrive!

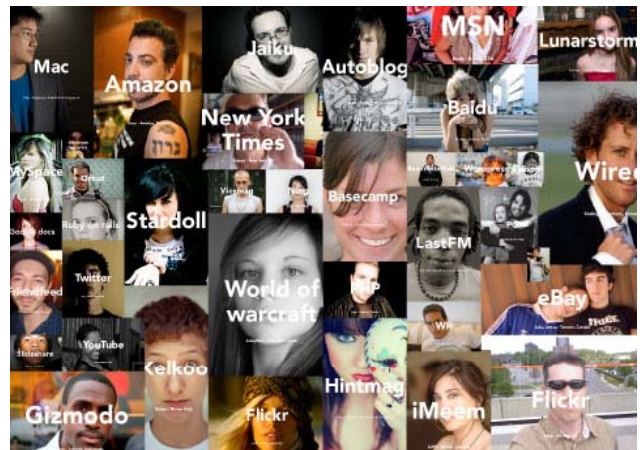
- Are an important link in **global supply chains**
- Underpin international trade - **access to markets**
- **Reduce technical barriers** to trade - support Multilateral trade
- Help **renew confidence** and promote economic recovery



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... for consumers

- safer, healthier, more environmentally sound products and services
- products with improved quality and reliability
- compatibility within and between products
- greater consistency in the delivery of services
- improved choice and access to goods and services
- lower costs
- better product or service information



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The World Standards Cooperation (WSC)

The leading international standardization organizations



- Multi-discipline and cross-sector



- For electrotechnology



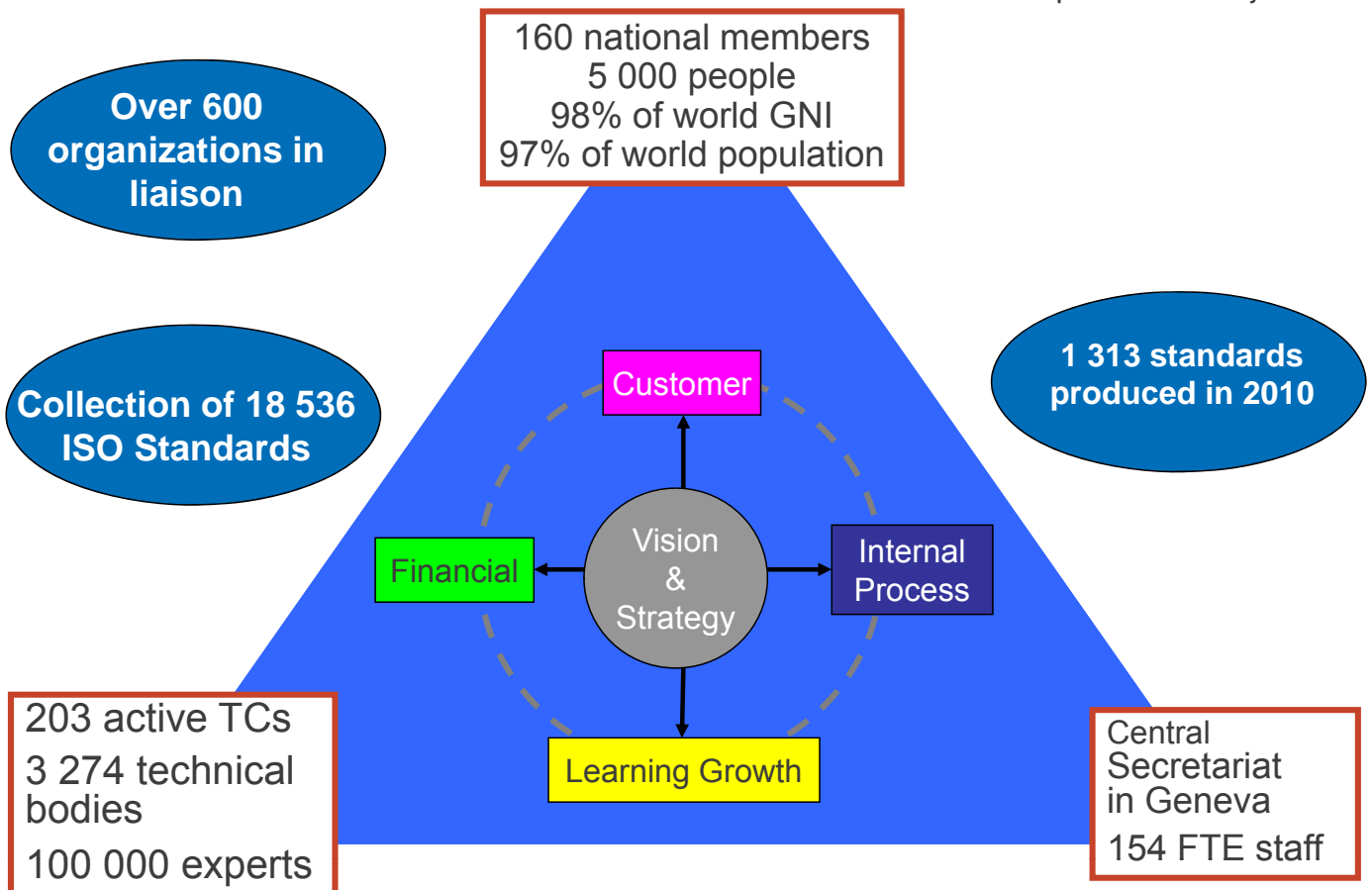
- For telecommunications

Collaborate to meet the challenges of converging technologies

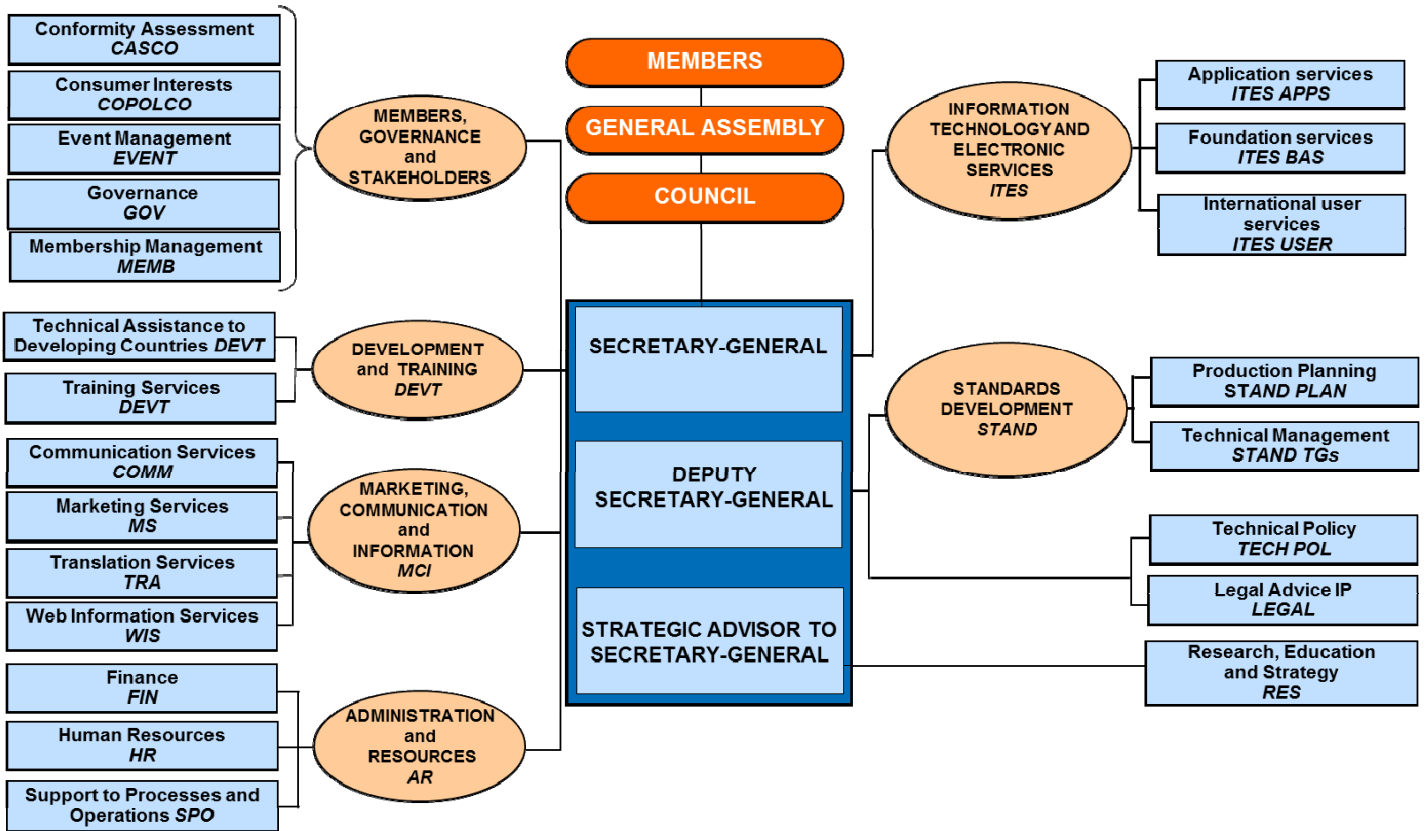
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ISO – A Global System

Updated on 7 February 2011



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ID 1769805 – March 2011

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Double layer of consensus for ISO standards

- At the level of **delegates/experts** who participate in technical committees, sub-committees, working groups, i.e. industry specialists, technologists, users, consumers, etc.
- Then, at the level of **countries** through their national standards bodies (NSBs), involving all stakeholders in national mirror committees

ISO - Responding to market needs

Over 40 new technical bodies established since 2005

- Information and societal security
- Response to **climate change**
- **Energy** efficiency and renewable resources
- Sustainable building design and operation
- **Water** services
- Nanotechnologies
- Intelligent transport systems
- **Food safety** management
- Health informatics
- Social responsibility
- Tourism and related services
- Fisheries and aquaculture
- **Carbon footprint**
- Services
- Biotechnology
- Finance



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What is conformity assessment

What is Conformity Assessment?

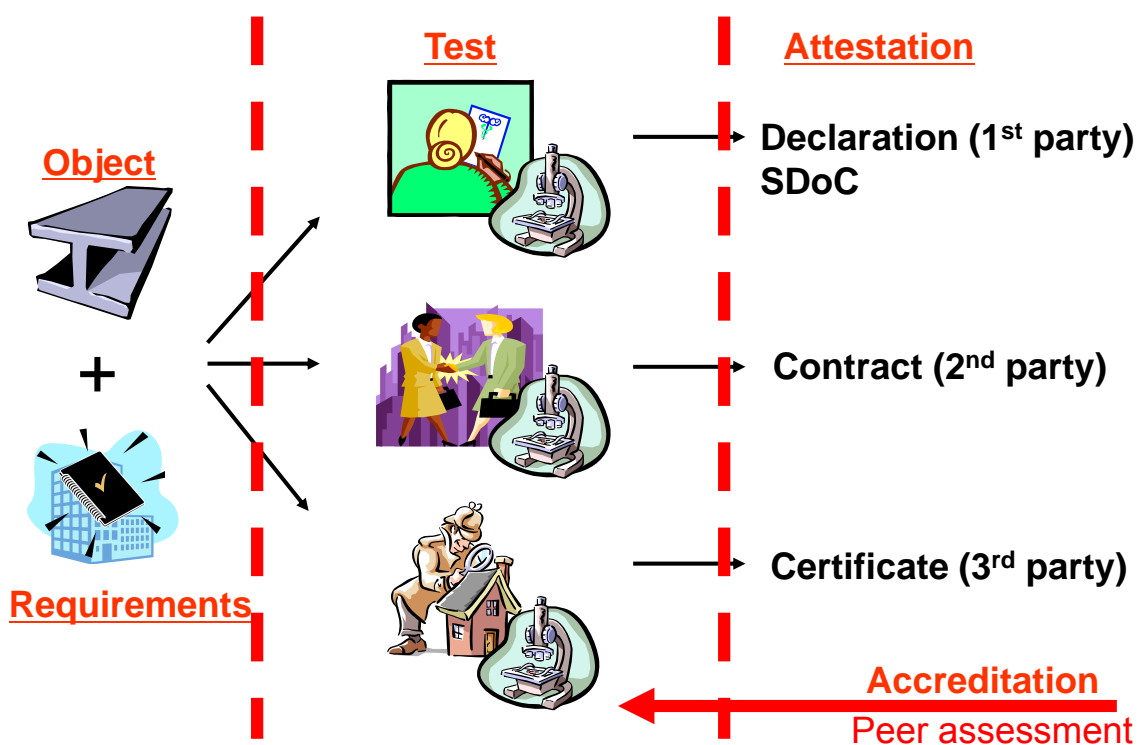
Conformity Assessment:

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*]

The Conformity Assessment processes



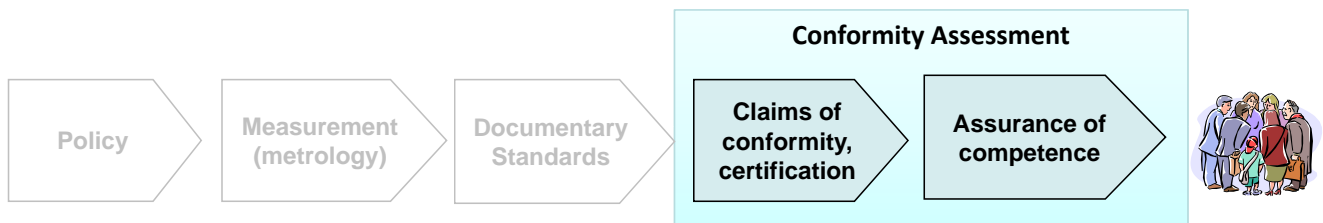
TWO CASCO PRINCIPLES

- The ISO Directives identifies two major principles applied in the development of Conformity Assessment documents:
 - **Principle of neutrality**
 - This policy states that all documents containing requirements for products, processes, services and persons shall be written such that conformity can be assessed by a manufacturer or supplier (1st party), a user or purchaser (2nd party), or an independent body (3rd party).
 - **Sector Policy**
 - This policy states that ISO/CASCO does not encourage the unnecessary poliferation of sector documents however where there is a geniune need by a sector for such a document CASCO will assist in its development. An example is the Food industry and motor industry.

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The CASCO Toolbox

International standards and guides on conformity assessment are jointly published by ISO and IEC, and are developed by ISO/CASCO

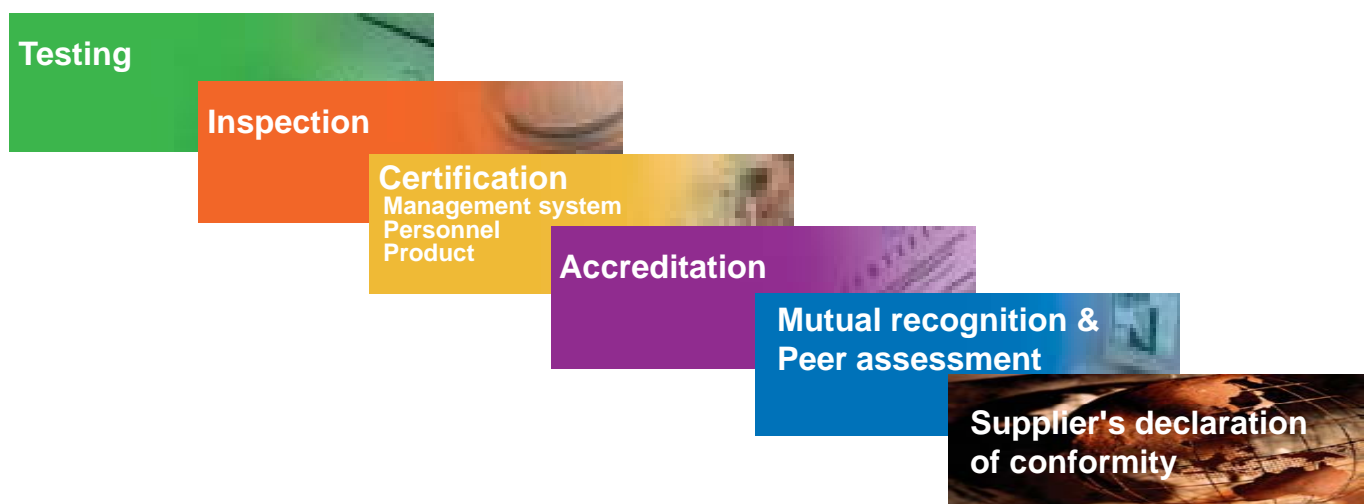


The ISO/CASCO toolbox refers to 26 International Standards and Guides produced by the *ISO Policy Committee on Conformity Assessment (ISO/CASCO)* covering:

- Principles and terminology
- Common elements
- Code of conformity assessment practice
- Writing specified requirements
- Testing
- Inspection
- Suppliers declarations of conformity
- Certification
 - Product
 - Management systems
 - Persons
- Accreditation
- Peer assessment
- Mutual recognition

1
7

The ISO/CASCO toolbox provides specific standards and guides on each conformity assessment activity



The decision to use one type of conformity assessment, depends on the customer's requirements, the level of risk associated with the product/service and regulatory requirements

Mechanisms for performing CA - Testing

- Definition from ISO/IEC 17000 (4.2) – Testing
 - Determination of one or more characteristics of an object of conformity assessment, according to a procedure.
 - NOTE “Testing” typically applies to materials, products or processes.
- ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*
- ISO 15189:2007, *Medical laboratories - Particular requirements for quality and competence*
- ISO/IEC 17043:2010, *Conformity assessment -- General requirements for proficiency testing*



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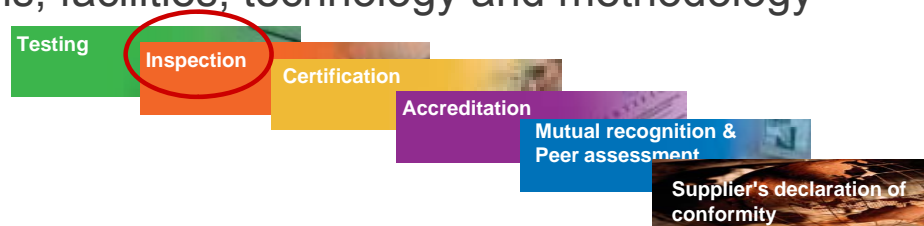
Mechanisms for performing CA - Testing

- Common form of conformity assessment
- Provides the **basis for other types of conformity assessment** like inspection and product certification
- Product is tested against a **specified set of criteria**
- Used to make **decisions on the performance of the product**
- Depending on specific requirements from customers and the risk associated with the product, the **testing laboratory may choose to be accredited**

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Mechanisms for performing CA - Inspection

- Definition - Inspection
 - Examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the **basis of professional judgement**, with general requirements
 - NOTE Inspection of a process may include inspection of persons, facilities, technology and methodology



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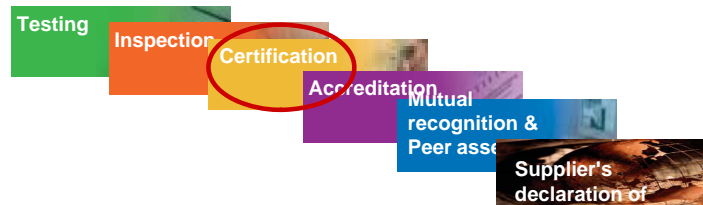
Mechanisms for performing CA - Inspection

- Inspection bodies
- Examine
 - a huge range of products, **materials, installations, plants, processes, work procedures and services**, in the private as well as the public sector, and report on such parameters as quality, fitness for use and continuing safety in operation
- Overall aim
 - to **reduce risk** to the buyer, owner, user or consumer of the item being inspected
- ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection*

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Mechanisms for performing CA - Certification

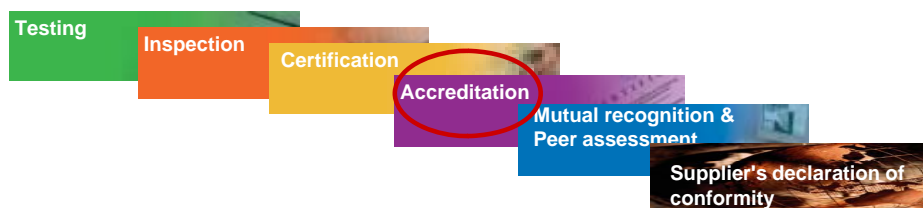
- Definition from ISO/IEC 17000 (5.5)
 - Third party attestation related to products, processes, systems or persons”
 - NOTE 1 Certification of a management system is sometimes also called registration
 - NOTE 2 Certification is applicable to all objects of conformity assessment except for conformity assessment bodies themselves, to which accreditation is applicable
- Definition of Attestation from ISO/IEC 17000 (5.2)
 - Issue of a statement based on a decision following review that fulfillment of specified requirements have been demonstrated



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Mechanisms for performing CA - Accreditation

- Definition in ISO/IEC 17000 (5.6)
 - Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks



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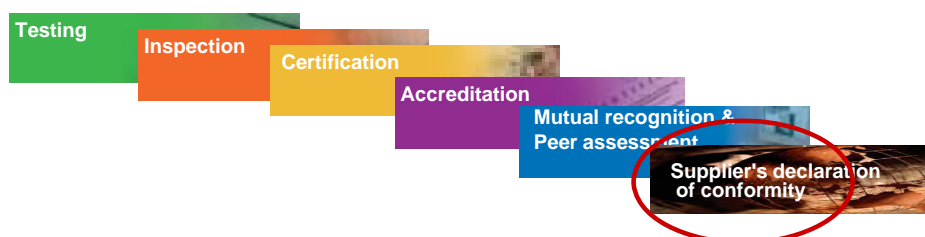
Mechanisms for performing CA - Accreditation

- Accreditation is the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks
- Accreditation of testing laboratories, product certification and inspection bodies is independent verification that they are competent to perform the activities for which they are accredited
- ISO/IEC 17011, *Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies*

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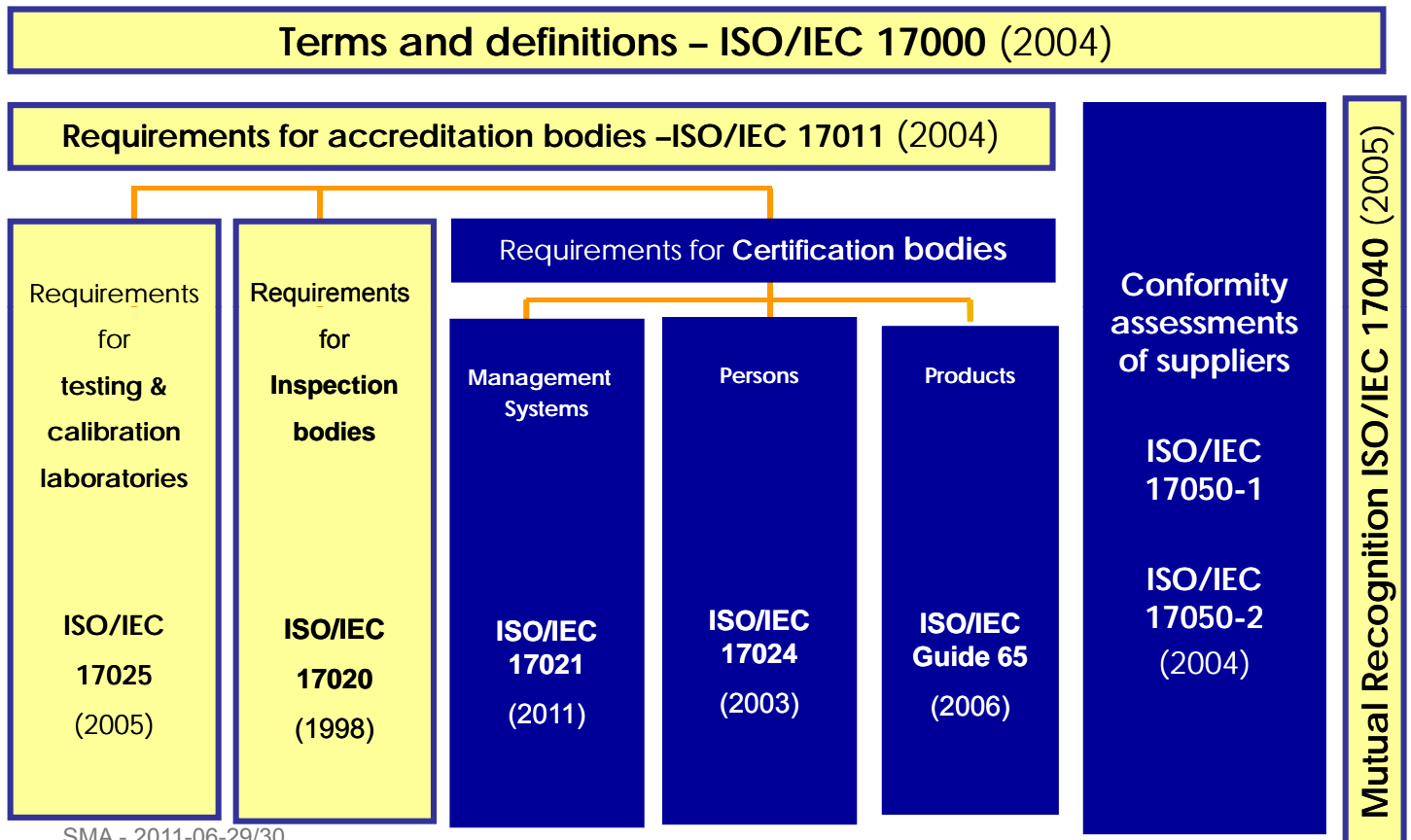
Mechanisms for performing CA - Supplier's Declaration of conformity (SDoC)

- Most widely used claim of conformity in the market
- ISO/IEC 17050-1:2004, *Conformity assessment -- Supplier's declaration of conformity -- Part 1: General requirements*
- ISO/IEC 17050-2:2004, *Conformity assessment -- Supplier's declaration of conformity -- Part 2: Supporting documentation*



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The “CASCO Toolbox” relationships...



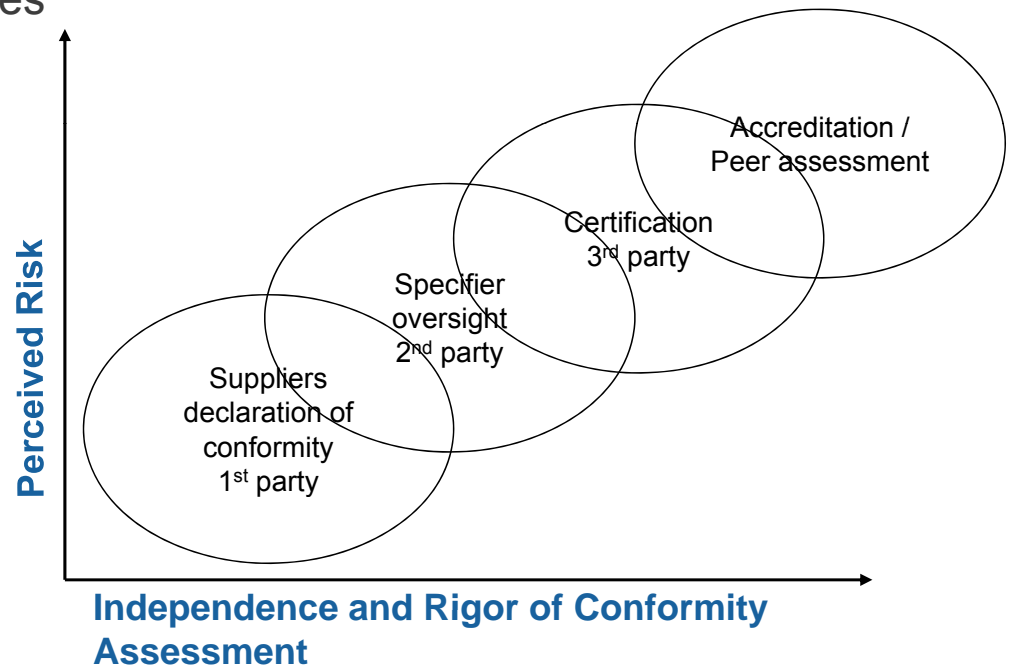
CASCO Standards in Progress

- ISO/IEC **17021:2011** (CASCO WG 21), Conformity assessment — Requirements for **3rd party certification auditing of management systems** (Published 01 February 2011)
- ISO/IEC **17065** (CASCO WG 29), Conformity assessment — Requirements for certification bodies **certifying products, processes and services** (DIS – Expected publication 2012)
- ISO/IEC **17024** (CASCO WG 30), Conformity assessment — General requirements for bodies operating **certification of persons** (DIS- Expected publication 2012)
- ISO/IEC **17020** (CASCO WG 31), Conformity assessment — General criteria for the operation of various types of **bodies performing inspection** (DIS- Expected publication 2012)
- ISO/IEC **17067** (CASCO WG 32), Conformity assessment – Fundamentals of **product certification** (Product scheme development) (WD 2)
- ISO/IEC TS **17022** (CASCO WG 33), Conformity assessment – Third party management system **audit reports** (PDTs Expected publication 2012)

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Application of conformity assessment activities is sometimes expressed in relation to managing risk

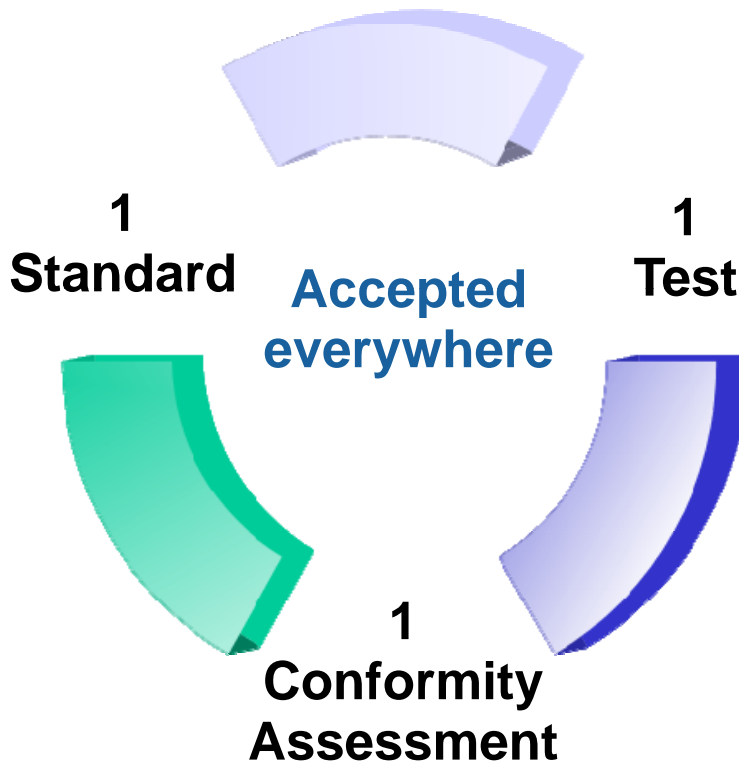
- Confidence in safety, health, environment, fair commerce
- Regulations based on risk
- Choice of activities
 - Testing
 - Inspection
 - SDOC
 - Certification
 - Accreditation



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CASCO Structure and operation

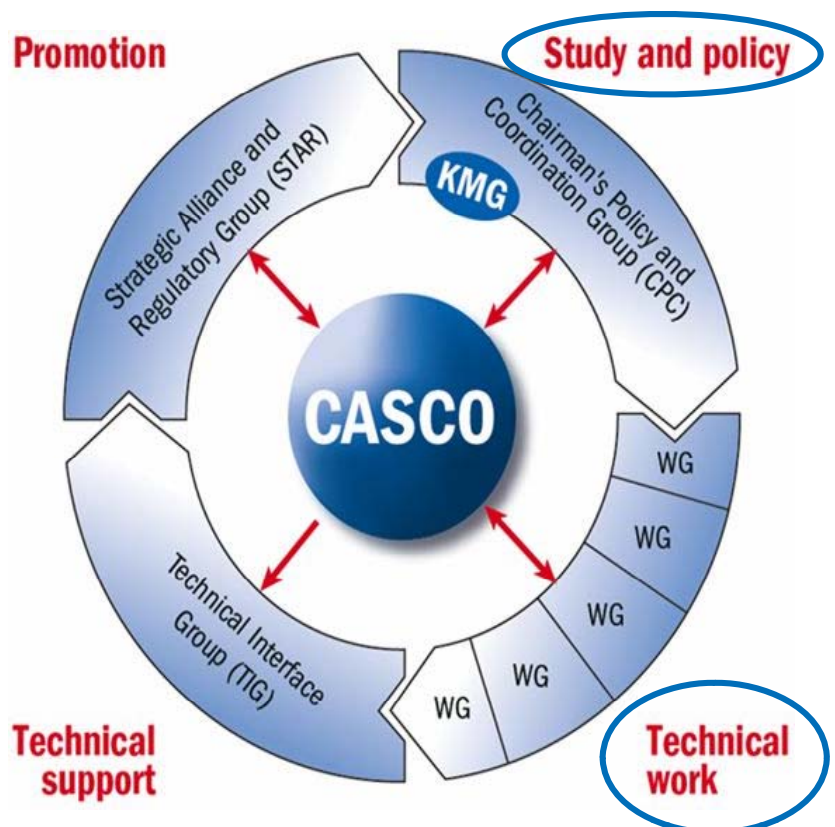
The 1-1-1 dream of Conformity Assessment



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ISO/CASCO structure

- 112 ISO members are represented in CASCO (70 participating members and 42 observers).
- 18 international organizations are **liaison members** of CASCO: BIPM, CEOC, CAC, EFAC, EOQ, Eurolab, IAF, IFAN, IFIA, IIOC, ILAC, INLAC, IPC, IQNet, ITU-T, OIML, UILI, UNFCCC and IEC.
- Both policy and technical work
- Continual improvement cycle



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CASCO Interpretation Process

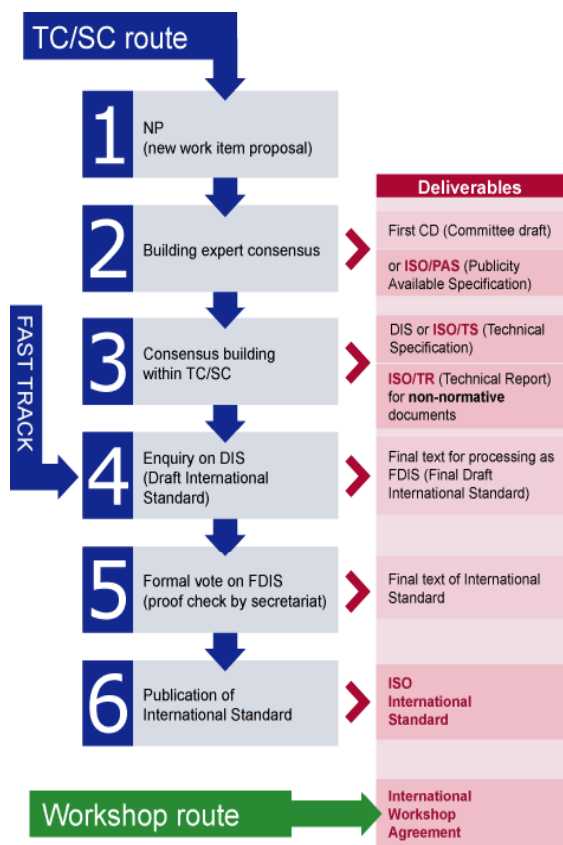
- Provides a uniform consistent approach to interpretation and maintenance of existing standards and guides
- Responses are available on ISO website
- Accepted as the official interpretation structure
- Ten interpretations done to date
 - ISO/IEC Guide 65
 - ISO/IEC 17021
 - ISO/IEC 17011

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Developing CASCO Standards

Conformity Assessment Standards

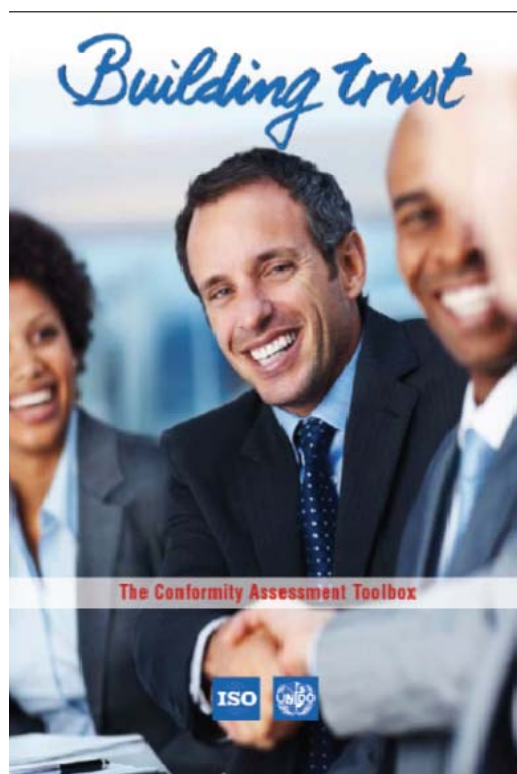
- Standards generation



- **ISO Standard**
 - A normative document, developed according to consensus procedures, which has been approved by the ISO membership and P-members of the responsible committee in accordance with Part 1 of the ISO/IEC Directives as a draft International Standard and/or as a final draft International Standard and which has been published by the ISO Central Secretariat
- **ISO/PAS Publicly available specification**
 - A normative document representing the consensus within a working group.
- **ISO/TS Technical specification**
 - A normative document representing the technical consensus within an ISO committee
- **ISO/TR Technical report**
 - An informative document containing information of a different kind from that normally published in a normative document.
- **International Workshop Agreement (IWA)**
 - An IWA is an ISO document produced through workshop meeting(s) and not through the technical committee process.
- **ISO Guide**
 - Guides provide guidance to technical committees for the preparation of standards, often on broad fields or topics

CASCO Working Groups

- ISO/CASCO P Members nominate to the WG.
- **A-Liaison** members nominate to WG. **D-Liaison** can be established between an organization and a WG.
- They are nominated as experts and required to input as **experts. WG group members act as independent experts not as national delegates.**
- The WG develops a Working draft document (**WD**). It evolves into a Committee Draft (**CD**) document.
- The CD goes to member bodies who distribute to **NMC** (NMC) for CASCO.
- At this stage no longer the experts but the national consensus comments.
- Responsible for the development of the document (Standard/Guide) (DIS and FDIS and publication).



Topical issues in CASCO

- 1) **Market Suveillance** – Information booklet to be developed on regulatory Good Practice aimed to assist developing economies
- 2) **Interpretation Panel** – Completion of 8 requests for interpretation – process is functioning well
- 3) **CASCO Newsletter** developed and 3rd edition released
- 4) **IAF-ISO Action plan** on monitoring the effectiveness of Accredited Management System Certification – progress is on schedule.
- 5) **Web conferencing** being used relatively extensively for workshops and WG meetings. Facilitates participation from developing economies
- 6) Composition of the **CPC structure** –more efficient
- 7) **Communication** strategy
- 8) **Open day** 5th October

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The End at last!

**Thank you
and
any questions**

- http://www.iso.org/iso/resources/conformity_assessment.htm
 - [ISO video](#)
 - maccurtain@iso.org
 - chalet@iso.org
 - bleeker@iso.org