



BIPM Paris training session

October 2017

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International Organization for Standardization

- Founded in 1947
- Independent
- Non-governmental organization
- Global network of national standards bodies*
- One member per country
- ISO membership comes with **rights, benefits, obligations and good practice**

163 members

21 100 +
International Standards

100
new standards each month

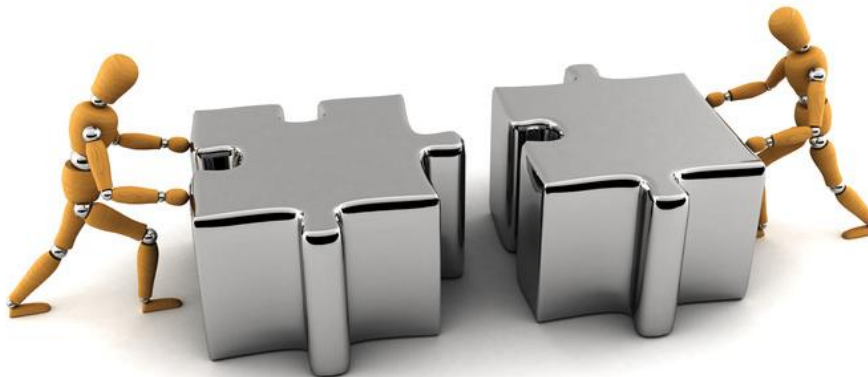
More than
100 000 experts

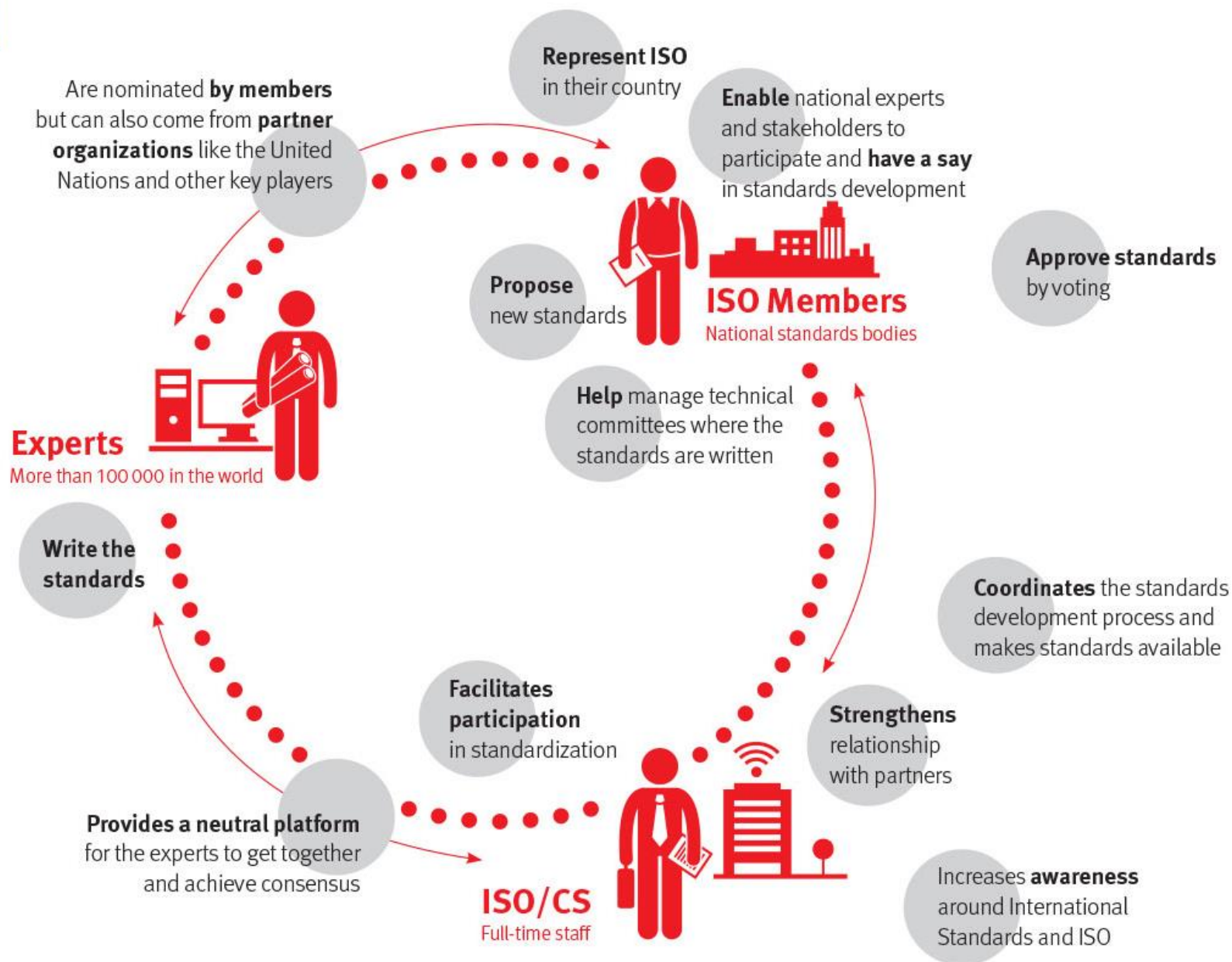
238
technical committees

*National standard body = national body most representative of standardization

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 for a better world



For more about ISO's work programme as it affects consumers, see the ISO Directory for consumer interest participation: www.iso.org/COPOLCO_interest
 * In collaboration with IEC.



Breadth of ISO's work in recent years

2011

- Project, programme & portfolio mgt
- Additive manufacturing
- Facilities management
- Outsourcing
- Risk management
- Bionics
- Fireworks
- Coal bed methane
- Carbon capture and storage
- Fine bubble technology
- Water re-use
- Occupational Health & Safety MS requirements
- Clean cookstoves and cooking solutions
- Collaborative business relationship management – Framework
- Chain of Custody of Forest Based Products – Requirements
- Educational organizations management systems - Requirements with guidance for use

2012

- Railway applications
- Sustainable development in communities
- Plastics and rubber machines
- Compliance programs
- Forensic sciences
- Customer contact centres
- Light and lighting

2013

- Sludge recovery, recycling, treatment and disposal
- Biotechnology
- Sustainable purchasing
- Anti-bribery management system – Requirements
- Innovation process: interaction, tools and methods
- Management consultancy

2014

- Brand evaluation
- Online reputation
- Domestic gas cooking appliances
- Security
- Feed machinery

2015

- Security
- Forensic sciences
- Asset management
- Bamboo and rattan
- Waste management, recycling and road operation services
- Rare earth
- Robots and robotic devices
- Solid recovered fuels
- Guidance on unit pricing
- Audit data collection

New ISO groups touching upon sustainability pillars:

Environment

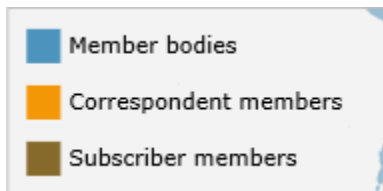
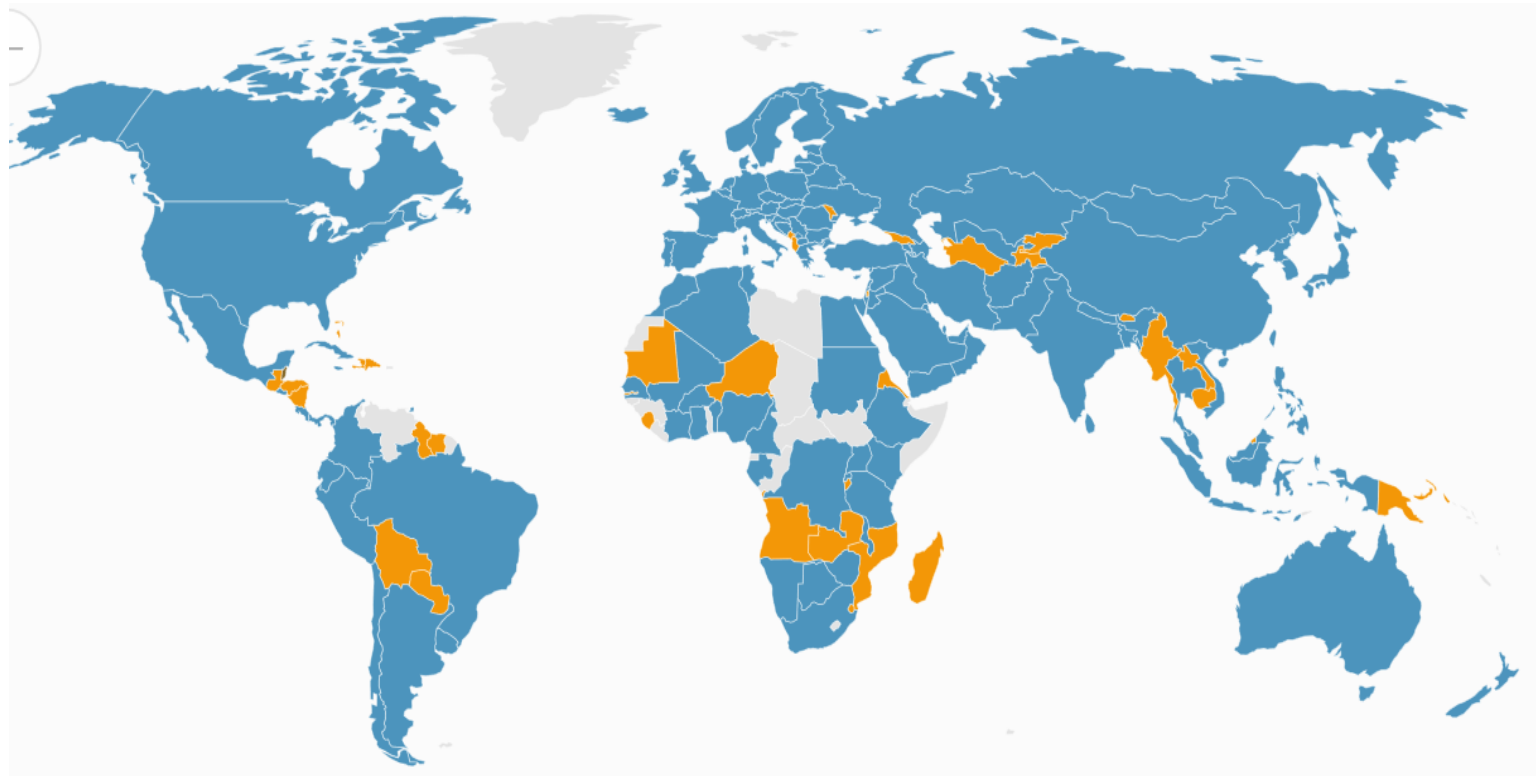
Economic

Societal





ISO members



As of April 2017



General ISO Member Rights

Full members (Member Bodies)

Participation in any policy or technical body

Voting & commenting rights

Adoption of ISO standards

May sell ISO Publications

Correspondent members

Participation in any policy or technical body as
observers

No voting nor commenting rights

Adoption of ISO standards

May sell ISO Publications

Subscriber members

Observer status at the General Assembly

No voting nor commenting rights

Can't adopt ISO standards

Can't sell ISO Publications



Membership of ISO committees

Participating members

- Active role
- Voting obligation
- Identify experts
- Provide national delegations
- Stakeholder engagement

Observing members

- Those who wish to follow
- No voting rights
- Can make contribution
- But do not want to commit
- Open to Member Bodies

External liaisons

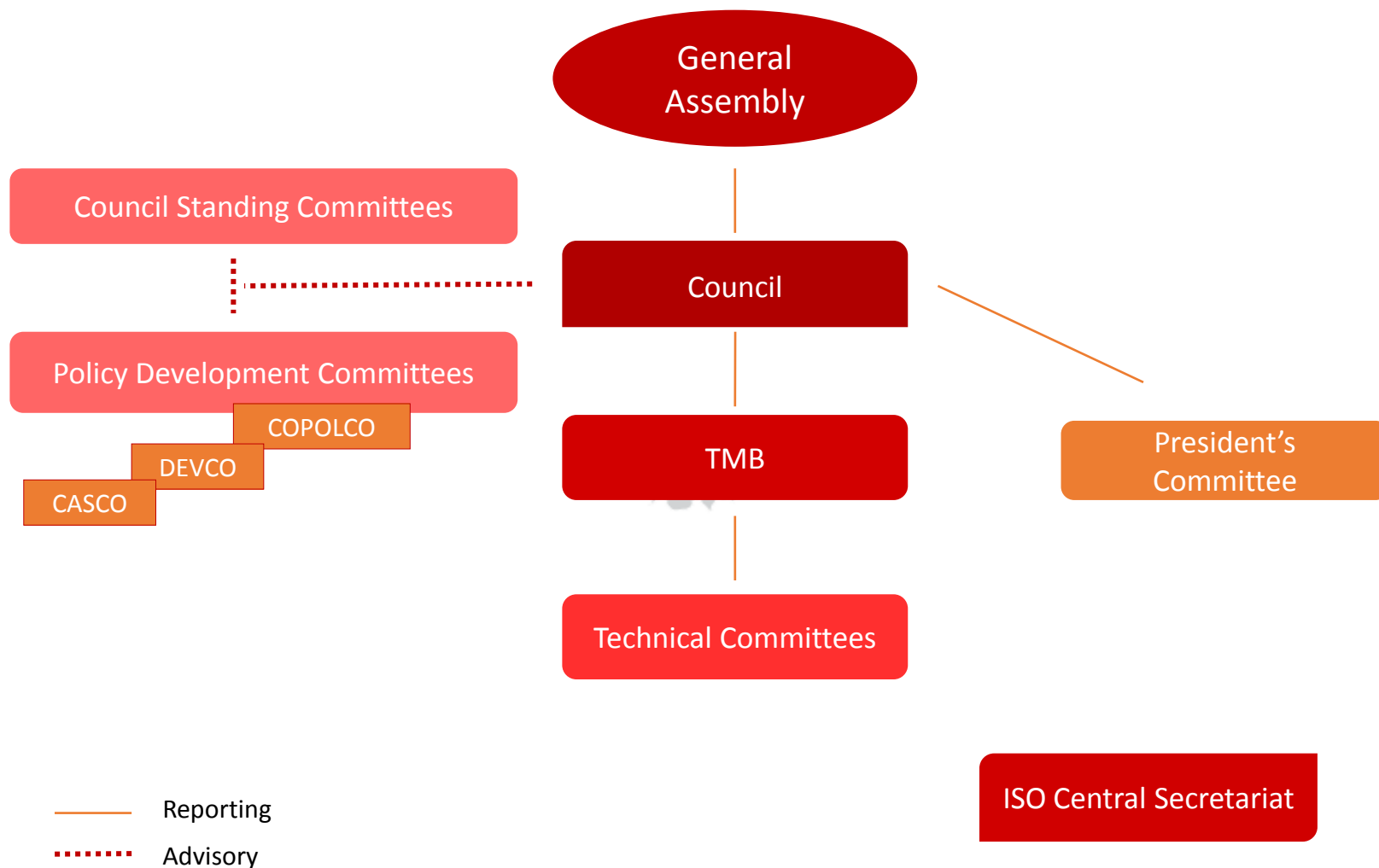
- For international & regional organizations
- No voting rights
- Participation or information
- Help to ensure wider acceptance
- Bring expertise

Internal liaisons

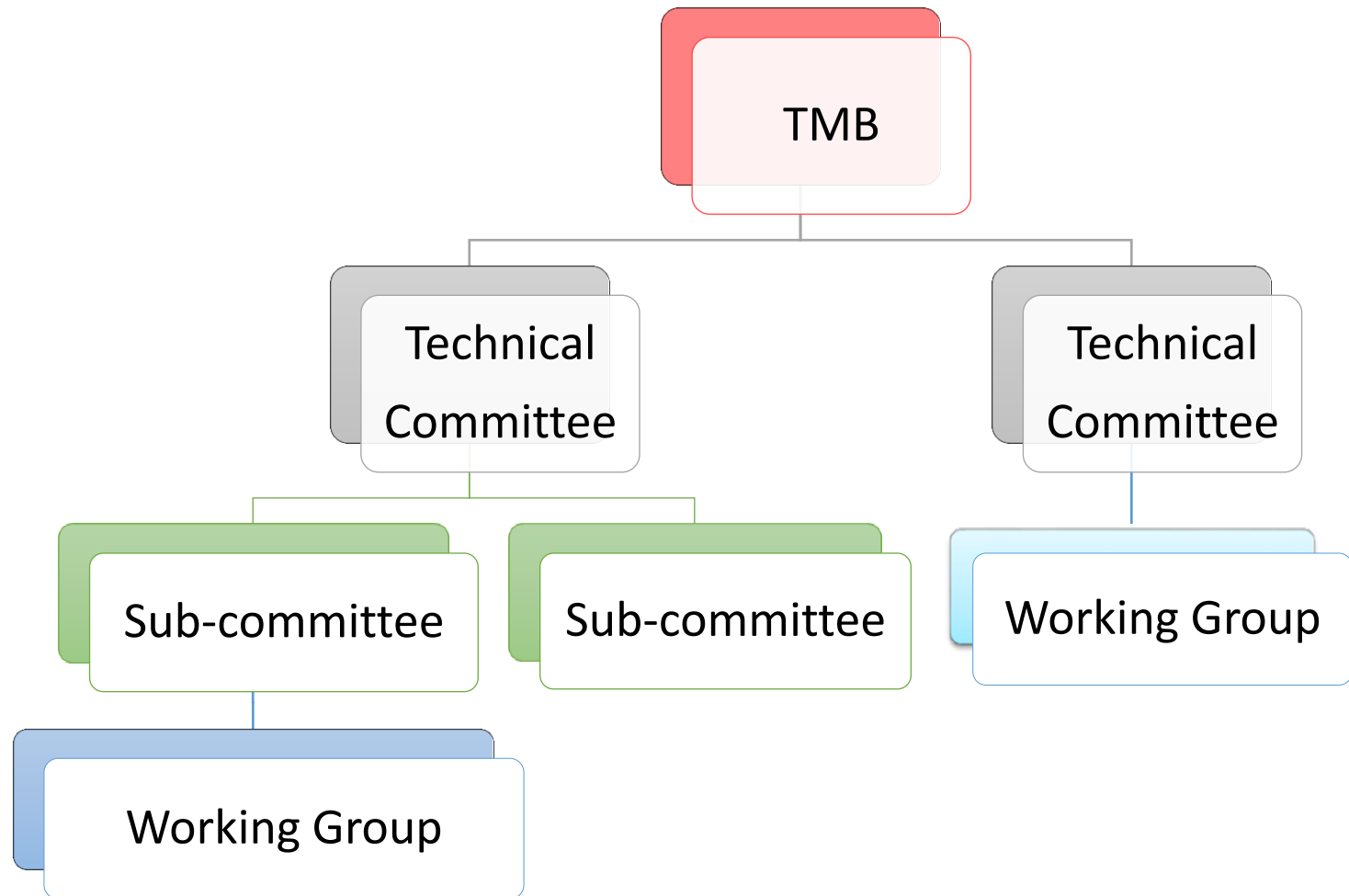
- With ISO and IEC committees
- No voting rights
- Participation or information



ISO management structure



Who does the technical work in ISO?



P-members voting obligation

CIB

NP/CD
DTS/DTR

If 20% failure
+ at least 2
CIB votes

**DIS
FDIS**

if 1 missed
vote

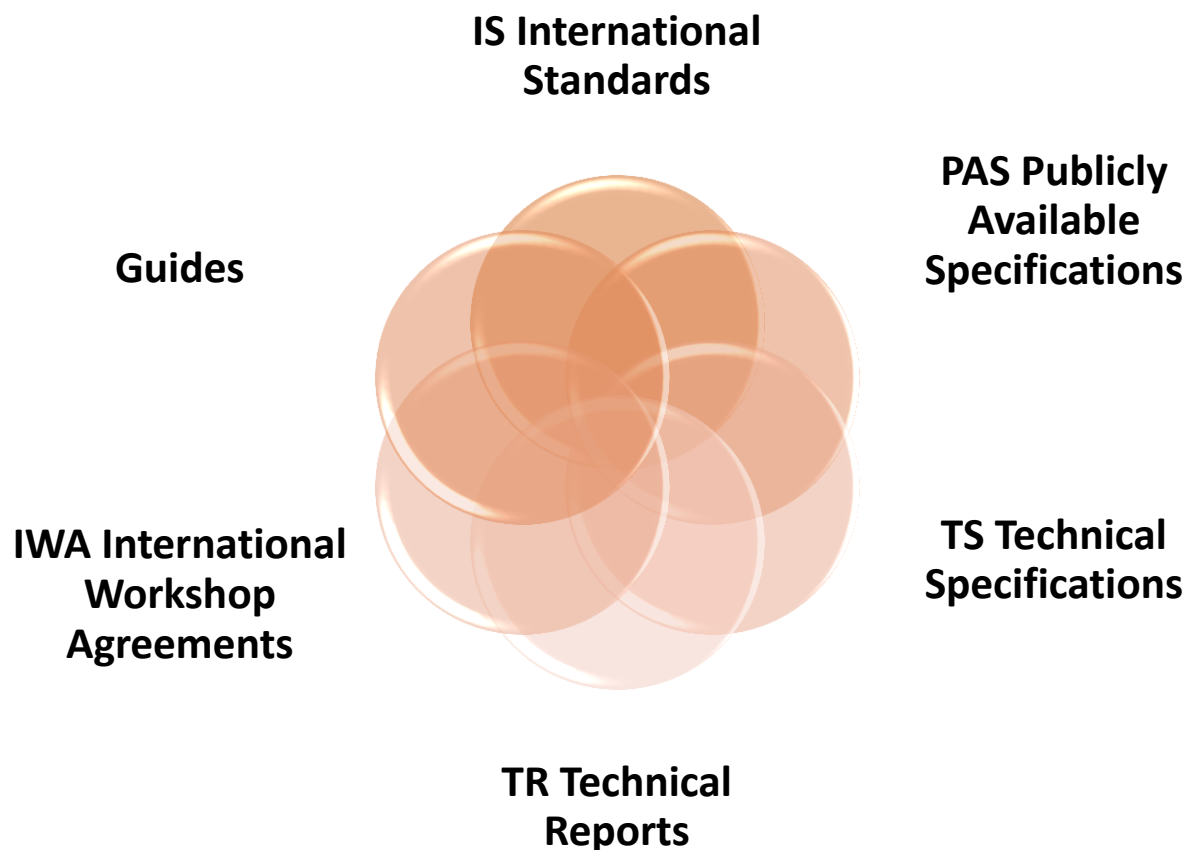
SR

If 1 missed
vote

2017-01-01

Downgraded to O-member
For 1 year => no experts in WGs

ISO-IEC deliverables





ISO & IEC Deliverables

International Standard – IS	Technical Specification – TS	Publicly Available Specification – PAS	Technical Report – TR
Normative	Normative	Normative	Informative No requirements
Consensus in a committee + members	Consensus in a committee	Consensus in a WG	Consensus in a committee
2/3 of P-members approval 75% of member approval	2/3 of P-members approval	Simple majority of P-members	Simple majority of P-members
	Good when you can't get to an IS	Good when you can't get to an IS	Good when TC has collected relevant information e.g. test results
Review every 5 years	Review every 3 years Max life = 6 years (recommended)	Review every 3 years Max life = 6 years	No life limit



Development of a new ISO International Standard

	6 stages	Action
1	Proposal NP	Proposal to start a new project
2	Preparatory WD *	Expert consensus within working group
3	Committee CD *	Committee consensus
4	Enquiry DIS	ISO MB consensus
5	Approval FDIS *	YES or NO vote
6	Publication	ISO International Standard

* OPTIONAL

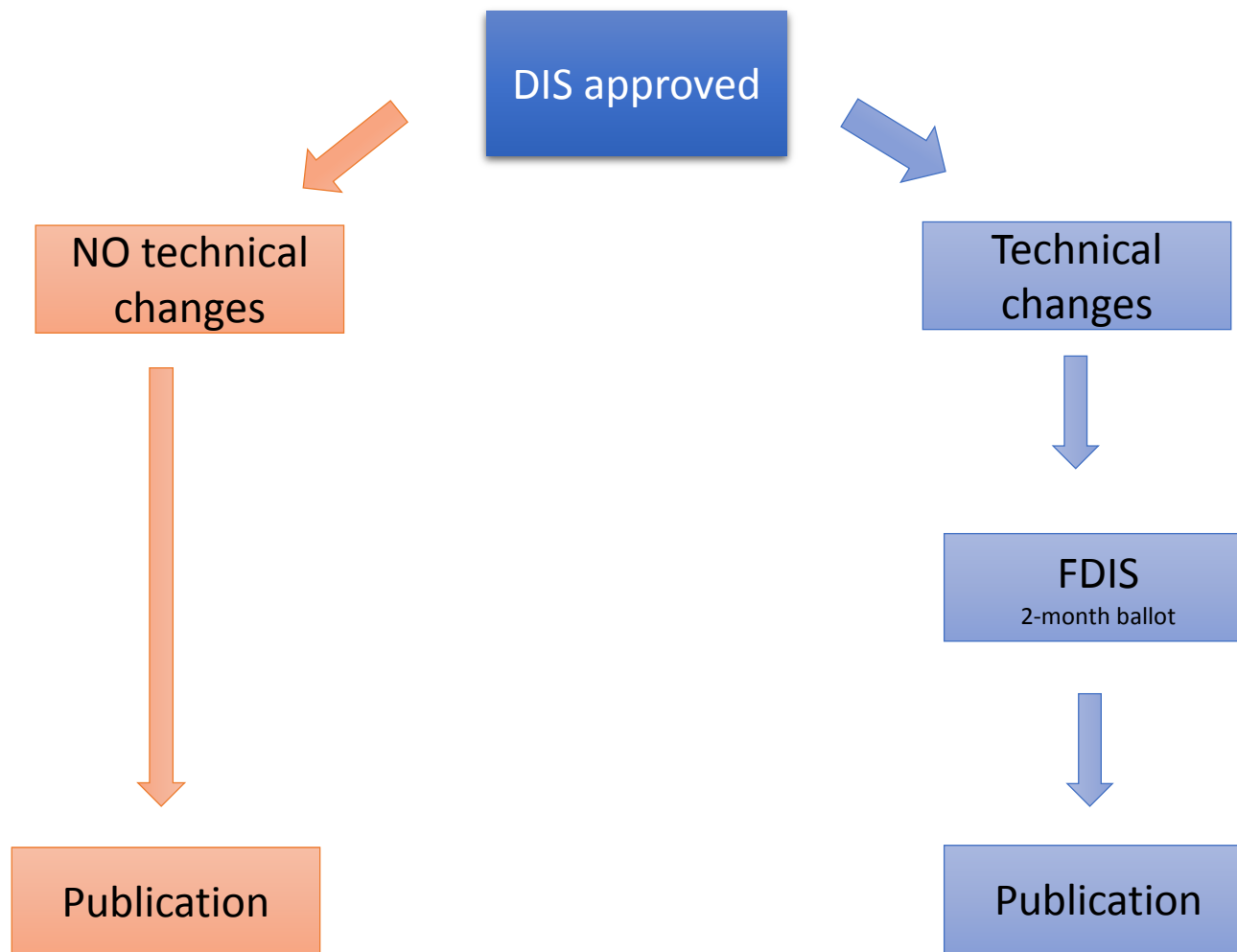
At publication ISO International Standards represent the state-of-the-art in terms of global expertise and know-how

Commenting is sometimes more important than voting!

- Influencing content from the start
- Early input = better, more relevant Standard
- Easier national adoption and use

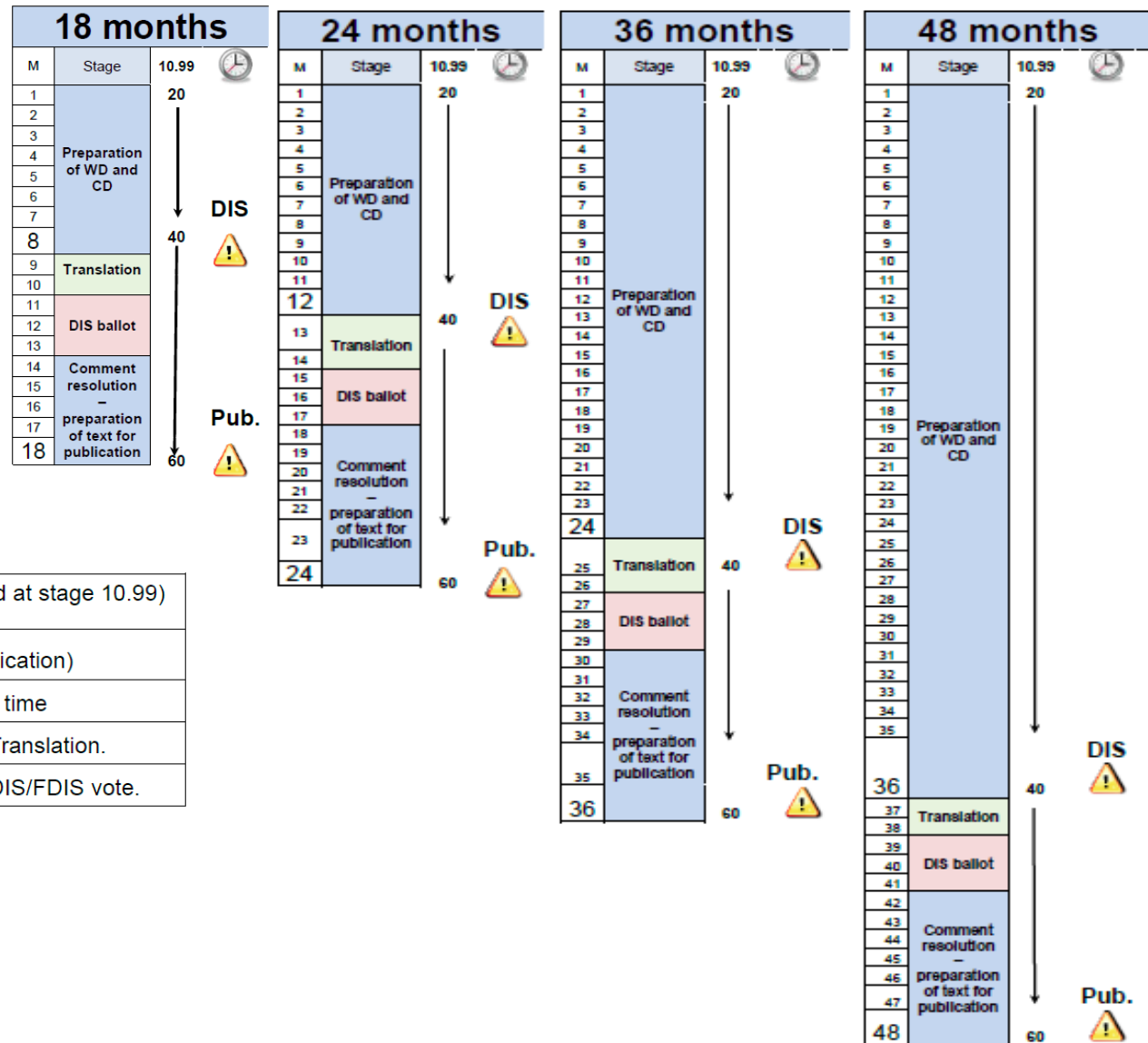


Follow up of an approved DIS ballot





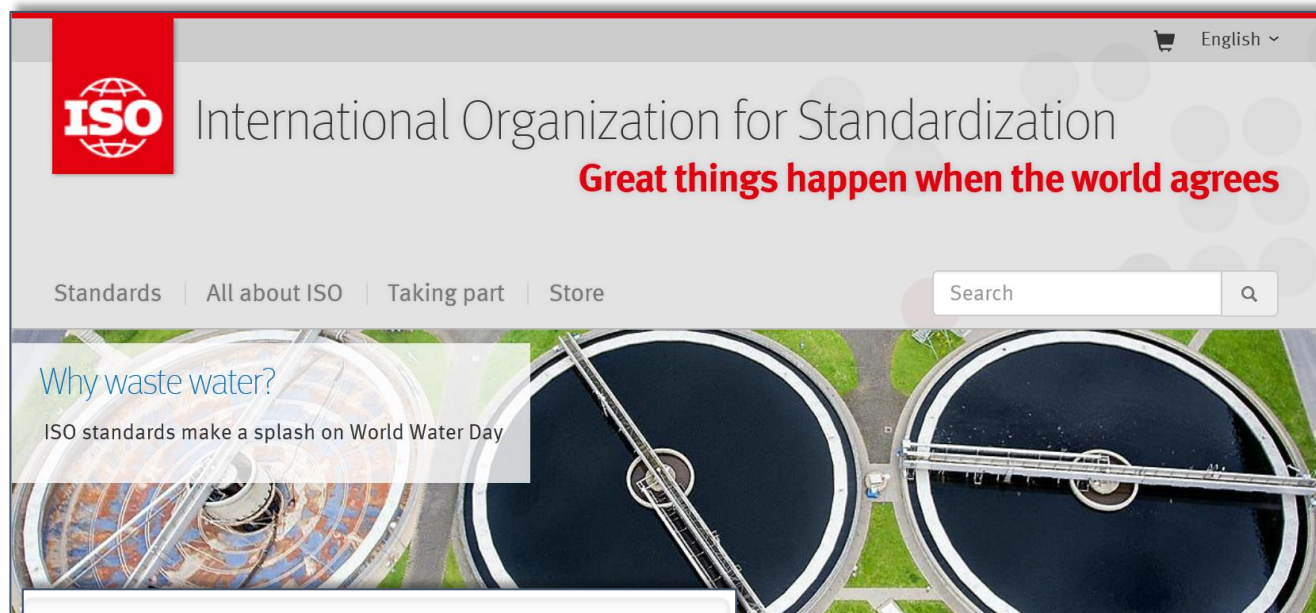
Development timeframes of an IS



	Clock starts (NP approved at stage 10.99)
	Limit dates (DIS and Publication)
	ISO Technical Committee time
	ISO Member body time: Translation.
	ISO Member body time: DIS/FDIS vote.



Available on www.iso.org



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ISO/CASCO

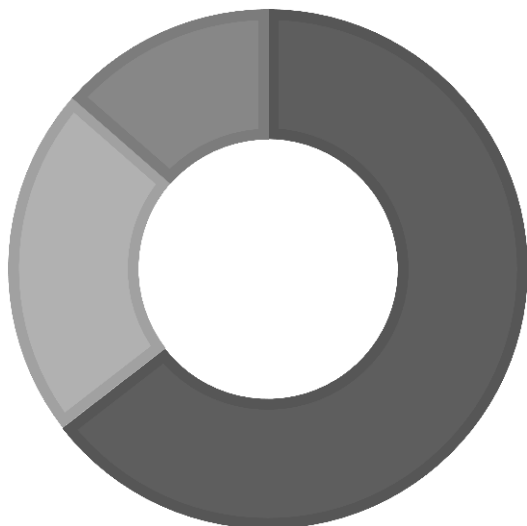


ISO/CASCO Members

ISO committee that develops

- generic conformity assessment standards
- policies related to conformity assessment

139 National Members

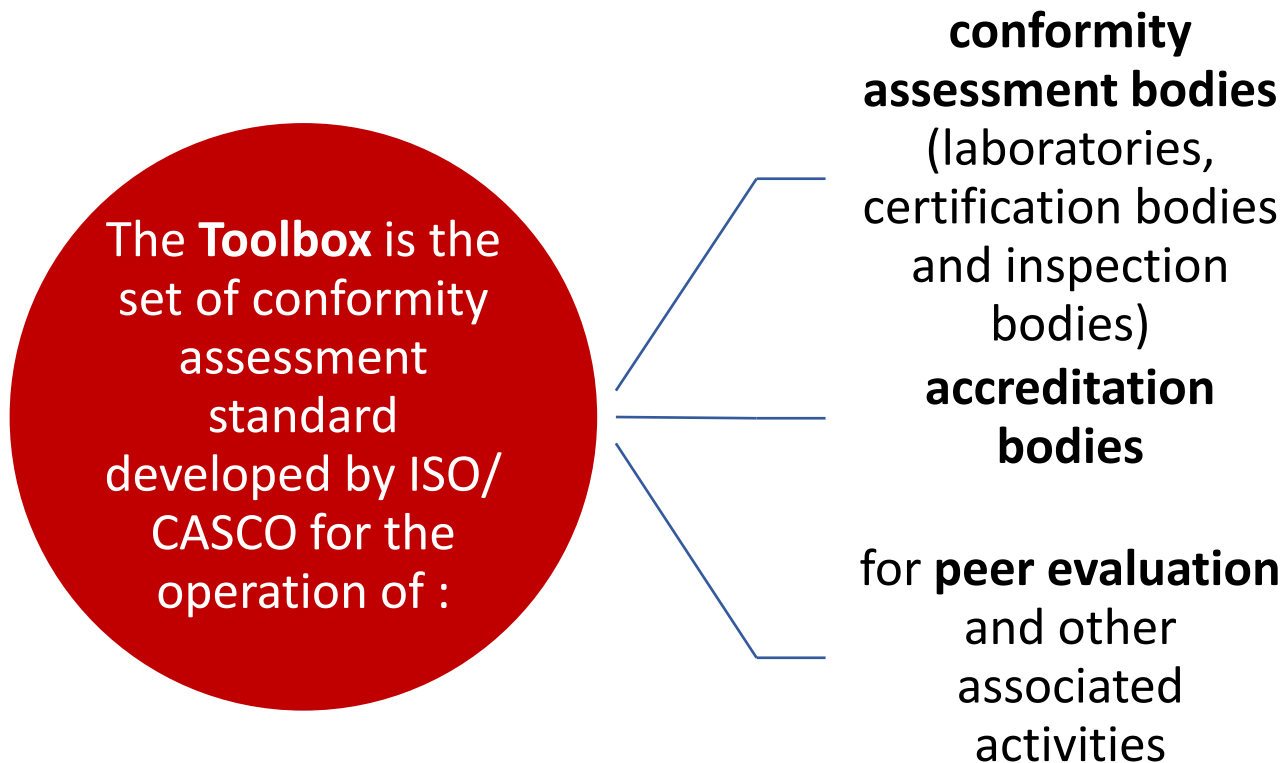


- 103 P Members

- 36 O Members

22 Organisations in liaison

ISO/CASCO TOOLBOX



ISO/CASCO has more than 29 published standards and guides



Functional structure of CASCO

Policy groups :

work on *conformity assessment policies*

Coordinates the technical work of Casco and assists the Casco Chair in identifying strategic conformity assessment issues

Chairman's policy and coordination group (CPC)

Liaises with other ISO technical committees (TCS)

Technical interface group (TIG)

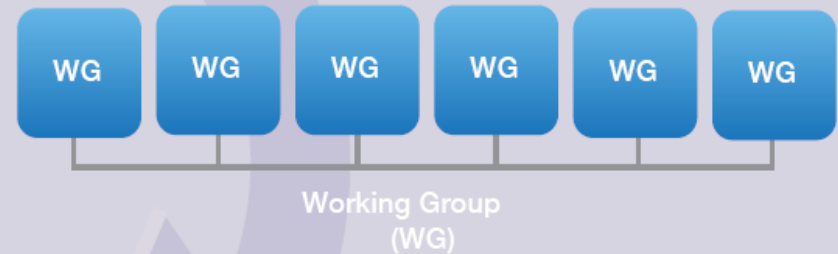
Provides a forum for industry sectors and regulators to interact with CASCO

Strategic Alliance and Regulatory Group (STAR)

Technical working group :

development of *conformity assessment standards*

Standards' development work is carried out by working groups made up of experts put forward by the ISO Member Bodies

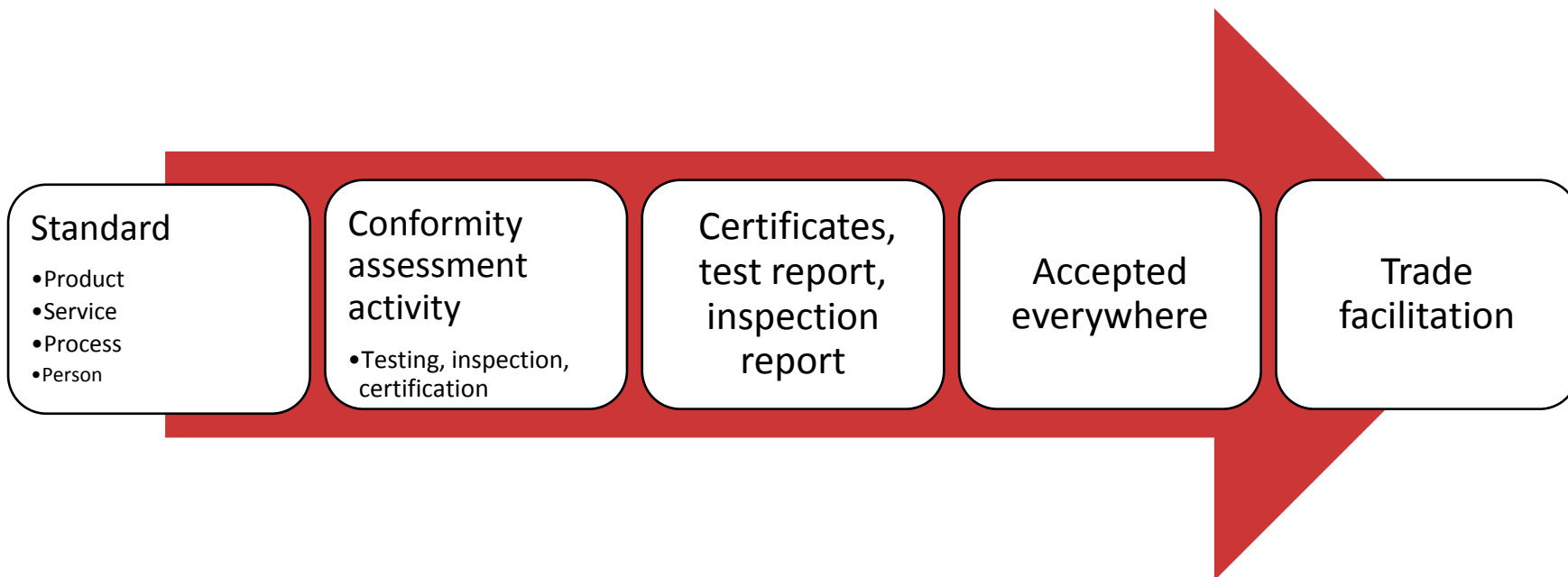


CASCO

ISO / CASCO
On conformity assessment



Conformity assessment dream





TOOLBOX

Terms and definitions ISO/IEC 17000

Requirements for accreditation bodies – ISO/IEC 17011

Requirements for
**Testing/
calibration**
Testing and
calibration
laboratories
ISO/IEC 17025
Proficiency
testing
ISO/IEC 17043

Requirements for
**inspection
bodies**

ISO/IEC 17020

Requirements for certification bodies

**Management
systems**

ISO/IEC 17021
and related parts
ISO/IEC 17023

Persons

ISO/IEC 17024

Products

ISO/IEC 17065
ISO/IEC 17067
ISO/IEC TR 17026

**Conformity
assessments
of suppliers**
ISO/IEC 17050-1
ISO/IEC 17050-2

Peer assesment ISO/IEC 17040

Mutual recognition
ISO/IEC Guide 68

ISO/IEC 17022 Audit reports



TECHNICAL
SPECIFICATION

ISO/IEC
TS
17021-2

Conformity
Requirements
audit and
certification —
systems —

Part 9:
Competence
auditing and
certification of
management
systems

*Évaluation de la conformité — Exigences pour les organismes
procédant à l'audit et à la certification des systèmes de
management —*

*Partie 9: Exigences de compétence pour l'audit et la certification des
systèmes de management*



INTERNATIONAL
STANDARD

ISO/IEC
17021-2

First edition
2016-12-01

Conformity assessment —
Requirements for bodies providing
audit and certification of management
systems —

Part 2:
Competence requirements for
auditing and certification of
environmental management systems

*Évaluation de la conformité — Exigences pour les organismes
procédant à l'audit et à la certification des systèmes de
management —*

*Partie 2: Exigences de compétence pour l'audit et la certification des
systèmes de management environnemental*



Reference number
ISO/IEC 17021-2:2016(E)

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CASCO TECHNICAL WORK

Key ISO/CASCO working groups

- **WG 42** Revision ISO/IEC 17011, Requirements for accreditation bodies accrediting conformity assessment bodies (To be published soon)
- **WG44** Revision ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories
- **WG46** ISO/IEC 17029, General requirements for bodies performing validation and verification activities WD 2
- **WG49** Revision of ISO/IEC 17000:2004, Vocabulary and general principles 2 meetings
- **WG 23** Revision of the common elements
- **WG 52** ISO/IEC 1732 TR for Scheme for processes

Key changes to ISO/IEC 17025

- Structure of document
- Mandatory wording
- Process approach
- Concept of risk and opportunities
- Decision rule (pass/fail)
- Information management
- Management system options
- Metrological traceability (informative)

Structure of ISO/IEC 17025

ISO/IEC 17025 :2005

- Scope
- Normative references
- Terms and definitions
- Management requirements
- Technical requirements
- Cross reference to ISO 9001:2000
- Guidelines for establishing applications for specific fields

ISO/IEC 17025 :2017

1. Scope
 2. Normative references
 3. Terms and definitions
 4. General requirements
 5. Structural requirements
 6. Resource requirements
 7. Process requirements
 8. Management requirements
- Annex A Metrological traceability
- Annex B Management system



Mandatory wording or common elements of CASCO

- Impartiality
- Confidentiality
- Complaints ~~and Appeals~~
- Managements systems (Option A or B)

Relationship to ISO 9001

- Laboratories that conform to this International Standard will also operate **generally** in accordance with the principles of ISO 9001.

Scope of ISO/IEC 17025

This *International* Standard specifies the general requirements for the **competence, impartiality and consistent operation** of **laboratories** as defined in the standard.

Definition of Laboratory (3.6)

- body that performs one or more of the following activities:
 - calibration
 - testing
 - sampling, associated with subsequent calibration or testing

Management system (8)

- Allows for a choice between 2 options
- In addition to meeting the requirements of clauses 4 to 7 of this International Standard the laboratory shall implement a management system in accordance with option A or option B.

Option A (8.1.2)

As a **minimum** the management system of the laboratory shall address the following:

- management system documentation (see 8.2)
- control of management system documents (see 8.3)
- control of records (see 8.4)
- actions to address risks and opportunities (see 8.5)
- improvement (see 8.6)
- corrective action (see 8.7)
- internal audits (see 8.8)
- management review (see 8.9)

Option B (8.1.3)


A laboratory that has established and maintains a management system,

- in accordance with the requirements of ISO 9001,
- and that is capable of **supporting** and demonstrating the consistent **fulfilment of the requirements of clauses 4 to 7** of ISO/IEC 17025

also fulfils at least the intent of the management system section requirements (8.2 - 8.9).

**CASCO on line resources for use by members
stakeholders and others**



 International Organization for Standardization
Great things happen when the world agrees

Standards

All about ISO

Taking part

Store

Search

Q

Benefits ▾Standards in actionPopular standardsCertification & conformity ▾


StandardsCertification & conformityResources

Resources for conformity assessment

The CASCO Toolbox

CASCO has produced a number of standards related to conformity assessment practices. These are referred to as the CASCO Toolbox and cover topics such as the operating of testing laboratories, marks of conformity, accreditation and the mutual recognition of conformity assessment results.

Learn more by consulting the full list of [CASCO Standards](#).



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CASCO Secretary
ISO CENTRAL SECRETARIAT
casco@iso.org

Presentations on CASCO standards

For some of the recently published CASCO standards, the experts of the Working Groups who developed them have done a Powerpoint presentation to highlight the main elements of the document and show the differences with the former version. The slides can be used by anyone doing a presentation or simply to learn about the new standard.

All presentations are available [here](#).

CASCO Clarification Process

People working in conformity assessment sometimes have questions about how to interpret ISO/IEC standards on this topic. In order to ensure consistency in the implementation of its standards, CASCO has set up a clarification process (replacing the former interpretation process). The clarification is done by the maintenance group responsible for the specific ISO/IEC conformity assessment standards (17000 series) and the clarification decision represents a consensus position on the intent of the working group. Clarifications cannot be considered as new requirements. These are considered for inclusion in the relevant standards only when they are revised. Until they are included in a standard they have no binding effect and are implemented at the discretion of interested parties.

All clarification requests that have been addressed are available [here](#).

How to make a clarification request

All the details on how to submit a clarification request can be found in the document [Casco Clarification Process \(PDF\)](#). Once you have read the process and that you fulfill the criteria for requesting a clarification please use this [form \(DOC\)](#).

Please note: Interpretation/Clarification requests for standards developed by other Committees in ISO should be referred directly to the secretary of the committee in question.

Workshops

CASCO annually holds workshops in conjunction with its plenary meetings. These workshops are designed to allow a fruitful exchange of experience and practice in the fields covered. All past presentations and related documents can be found [here](#).

For more information on these workshops and how to get involved please contact casco@iso.org.

CASCO communiqués


CASCO has issued a number of important joint communiqués with regard to the transition

Want to keep up to date with ISO's work on conformity assessment?

Subscribe to CASCO's newsletter


Subscribe

2,790



Conformity Assessment tools for regulators

Designed for standards developers, conformity assessment bodies and regulators, this online resource provides tools to support public policy.



Building trust - The Conformity Assessment Toolbox

A handbook covering all aspects of conformity assessment and its role in international trade


[See all conformity assessment publications »](#)

ISO survey - 2015

Find out how many certificates to ISO management standards are awarded in each country, each year.







CASCO

Conformity Assessment tools to support public policy

[Introduction](#) [Conformity assessment -](#) [CASCO Toolbox](#) [Key considerations](#) [Path forward](#) [Examples](#)

Welcome

Whether you are a regulator or a standards' development or conformity assessment body, this on-line support will help you identify existing conformity assessment tools, consider possible conformity assessment routes and select the solution that better suits your goals.


This online support is made of different sections that cover the basics of conformity assessment, the ISO/CASCO toolbox and offer examples from around the world, including Brazil for toy safety, Singapore for electrical products, New Zealand for public utilities and Australia for agricultural production. Users of this tool can easily navigate the material via the links provided at their own pace. Some topics have links to relevant standards and other documents containing more detail, or further sources of information.

[Download the full content of this website](#)
[Download](#)




Conformity assessment concepts

This section describes the basic concepts of conformity assessment, conformity assessment techniques and how they can be combined to create a scheme. It outlines possible claims of conformity and explains who can perform conformity assessment activities and what the outcomes are.



Conformity assessment in practice


When considering the use of conformity assessment in regulations some key considerations should be kept in mind and a number of **suggested steps** can be used.



Conformity assessment case studies

This section provides concrete examples of referencing the International Standards and Guides contained in the CASCO toolbox in regulation, and using conformity assessment schemes in various regulated sectors.







CASCO

Conformity Assessment tools to support public policy

[Introduction](#) [Conformity assessment -](#) [CASCO Toolbox](#) [Key considerations](#) [Path forward](#) [Examples](#)

Key considerations for using Conformity Assessment in regulatory practice

There are a number of key considerations that should be kept in mind when using conformity assessment in regulatory practice. Some of these considerations are interrelated and can be applied more than once during the development of regulation that uses conformity assessment. For example, risk management can be used when identifying the characteristics of products that should be subject to conformity assessment or deciding what conformity assessment techniques (e.g. audit, test, inspection) to apply or confirming the frequency and nature of the surveillance activities.

Good regulatory practice

Good regulatory practice includes consideration of a number of compliance options.
[See more...](#)

Functional approach to conformity assessment

It may be helpful to structure the policy development and discussion about the design of the conformity assessment options around the functional approach.
[See more...](#)

Identifying controlled products and requirements

It is appropriate to have a clear justification why the regulator considers an object of conformity needs to be regulated.
[See more...](#)

Conformity assessment scheme design and ownership

Regulators can develop and mandate the use of conformity assessment schemes.
[See more...](#)

Investment and costs of conformity assessment options

When deciding on the appropriate conformity assessment approach, it helps to be aware of the amount of investment and cost associated with each alternative approach.
[See more...](#)

Conformity assessment and competition

An important aspect to consider when designing a conformity assessment approach is competition between conformity assessment bodies.
[See more...](#)

Risk management

Another important aspect is taking into account risk.
[See more...](#)



Access to competent resources

Competence is another consideration in using conformity assessment in regulation.
[See more...](#)

Surveillance

Surveillance can be considered in at least two ways: market surveillance activities that the regulator may undertake; and surveillance that may be undertaken that is associated with the conformity assessment activity.
[See more...](#)





CASCO

Conformity Assessment tools to support public policy

- Introduction
- Conformity assessment -
- CASCO Toolbox
- Key considerations
- Path forward
- Examples

Using Conformity Assessment in regulatory practice

ISO and IEC provides guidance on how to reference standards in regulations in their website on [Using and referencing ISO and IEC standards to support public policy](#). The following are examples of referencing the International Standards and Guides contained in the CASCO toolbox in regulation, and using conformity assessment schemes in various regulated sectors.

For more examples, please visit the [Public Sector Assurance](#) website. It provides case studies from around the world in key policy areas that show how different conformity assessment tools help government officials and regulators deliver results.

Agriculture

Australia - Livestock Disease Control Regulations 2006
[See more...](#)

Building and construction

New Zealand - Accreditation of Building Consent Authorities
[See more...](#)

Dangerous goods and hazardous substances

New Zealand - Hazardous Substances (Compressed Gases) Regulations 2004
[See more...](#)

Public utilities

Singapore - Public Utilities (Water Supply) Regulations.
[See more...](#)

Medical devices

Canada
[See more...](#)

Testing services

Mexico – Testing laboratory accreditation
[See more...](#)

Transport

United States - Code of Federal Regulations for Energy
[See more...](#)

Health

Australia – Access to funding for medical testing
[See more...](#)

Equipment used in environments with an explosive atmosphere

UNECE and US Coast Guards
[See more...](#)

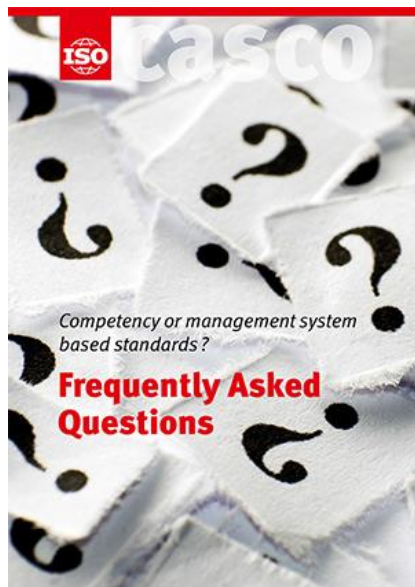
Toy safety

Brazil - Toy Safety Certification Scheme
[See more...](#)

Energy efficiency

Mexico - Energy Efficiency (EE) products certification
[See more...](#)

CASCO do's and don'ts





Resources on conformity assessment

- **ISO website** <http://www.iso.org/iso/home/about/conformity-assessment/casco.htm>
- [Clarifications process](#)
- **Conformity Assessment tools for regulators:**
<http://www.iso.org/sites/cascoregulators/index.html>
- **Subscribe to CASCO's newsletter**
- **Publications** http://www.iso.org/iso/home/about/conformity-assessment/conformity-assessment_resources.htm
- **CASCO Toolbox**
http://www.iso.org/iso/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=54998&published=on&inclusesc=true

Thank you for your attention !

casco@iso.org

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A close-up photograph of a large group of people's hands and forearms raised and clasped together in a gesture of unity or agreement. Many individuals are wearing red wristbands with white polka dots, and one person in the foreground wears a yellow wristband with a red and white geometric pattern. The background is blurred, showing a crowd of people in an outdoor setting.

**Great things happen
when the world agrees**

Any questions...

