

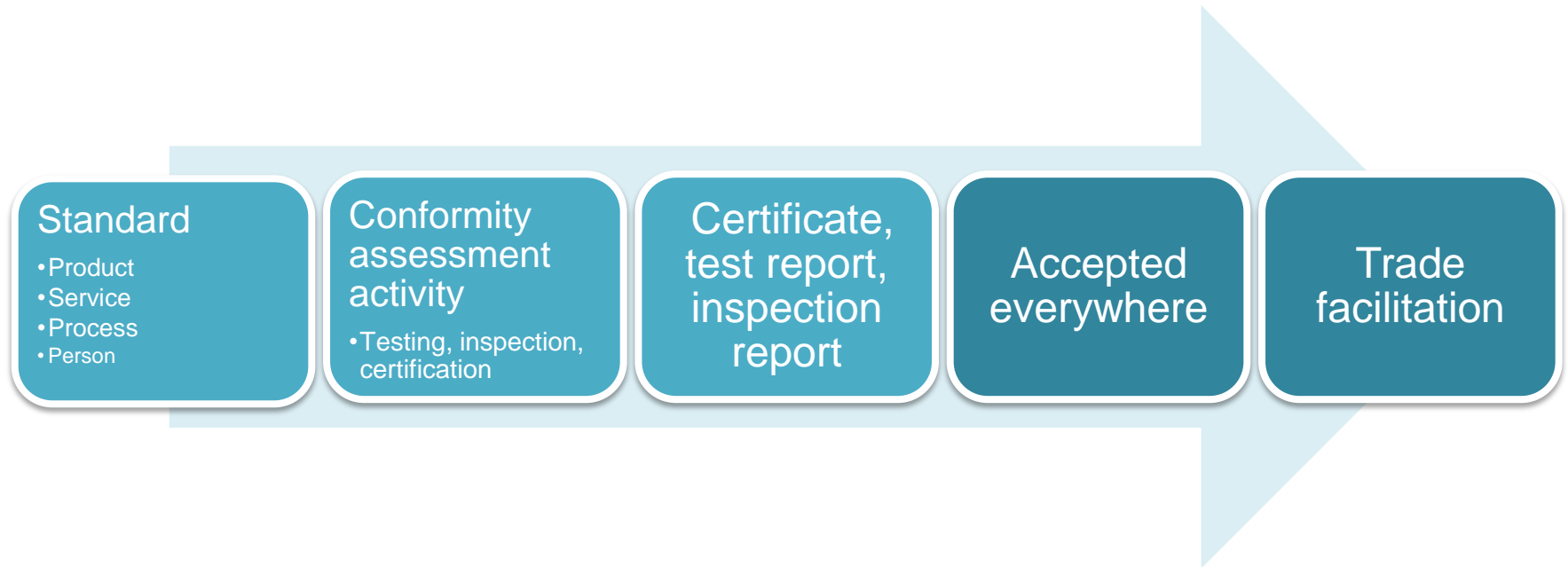
ISO CASCO

Thematic session on conformity assessment
procedures

WTO 28 March 2017

Sean MacCurtain

Conformity assessment dream



CASCO structure

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

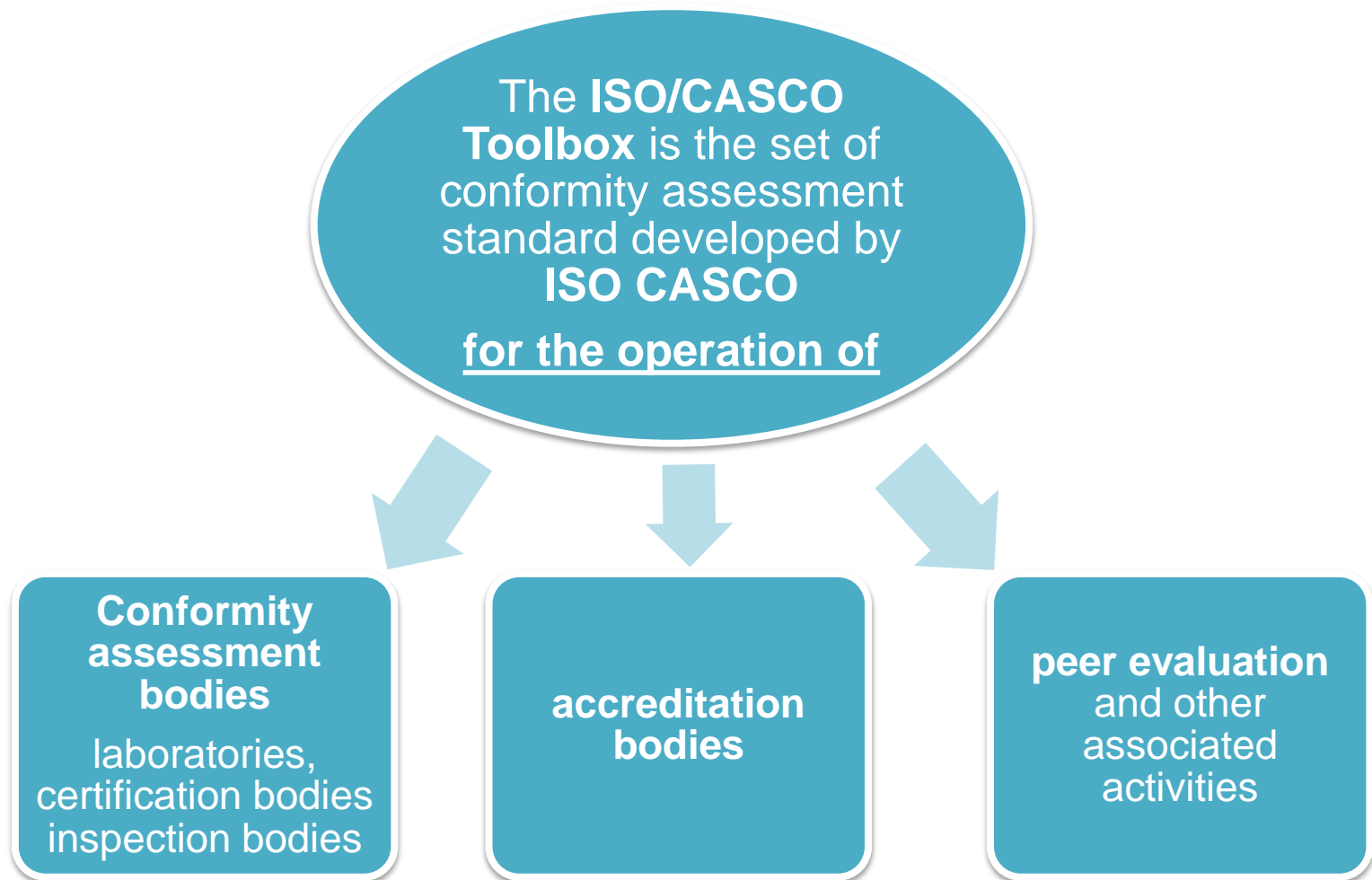


Working Group (WG)

CASCO

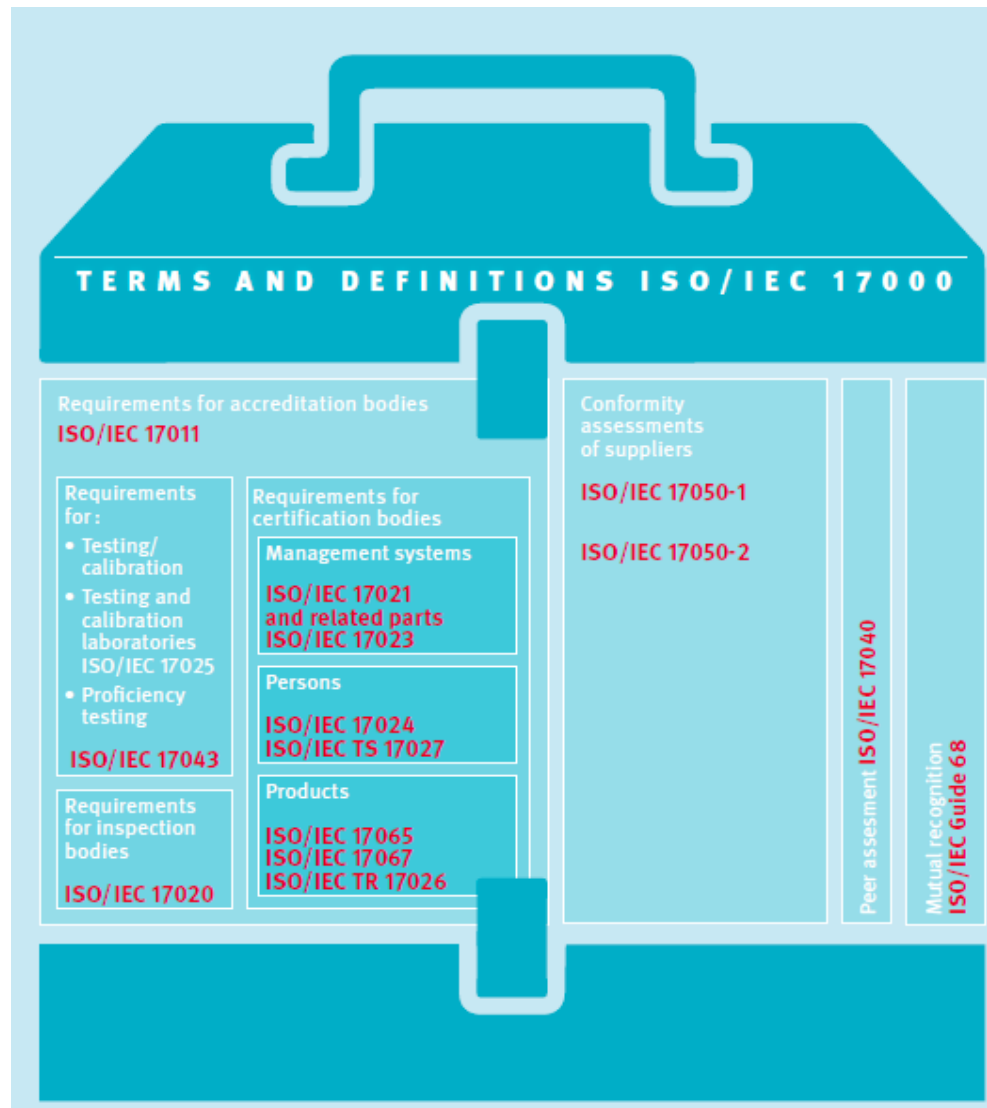
ISO / CASCO
On conformity assessment

CASCO Toolbox






CASCO Toolbox 27 published standards and guides



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

www.iso.org



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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](#).



Sean MacCurtain
CASCO Secretary
ISO CENTRAL SECRETARIAT
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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

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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


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

Welcome

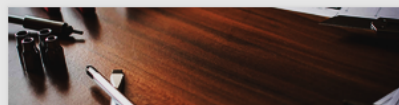
Whether you are a regulator or a standards' development or conformity assessment body, this on-line support will help you identify existing conformity assessment tools, consider possible conformity assessment routes and select the solution that better suits your goals.

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](#)

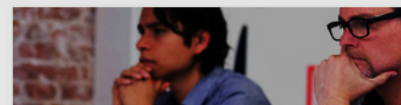

Conformity assessment concepts

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.



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...](#)



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Conformity Assessment tools to support public policy

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

Suggested steps for using conformity assessment in regulations

When considering the use of conformity assessment in regulations the following suggested steps can be used. These steps are suggestions only, and the actual process used to consider and use conformity assessment in regulations will depend on the legal system in each country. In many countries a regulatory impact analysis (RIA) may be required to justify the selected option.

STEP 1

Purpose and scope

STEP 2

Check jurisdiction

STEP 3

Risk assessment

STEP 4

CA options

STEP 5

Confirm CA approach and responsibilities

STEP 6

Communication

STEP 7

Surveillance

STEP 8

Review and management of changes



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Conformity Assessment tools to support public policy



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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...](#)

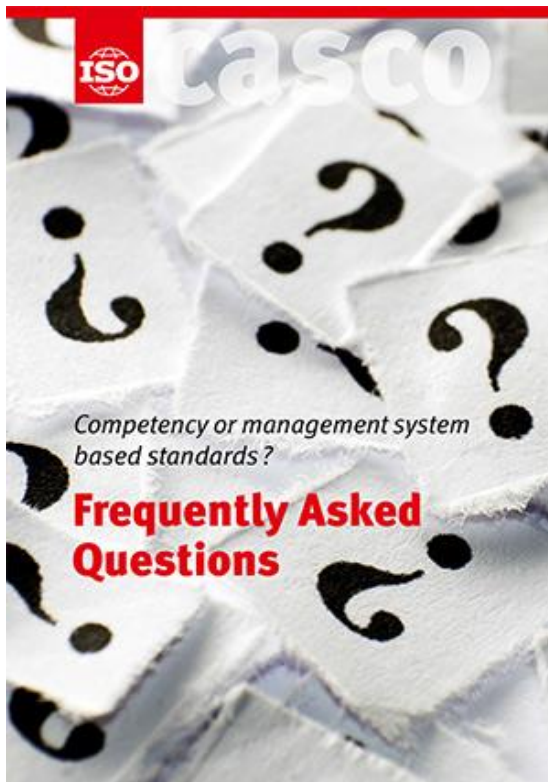
Energy efficiency

Mexico - Energy Efficiency (EE) products certification

[See more...](#)




CASCO do's and don'ts





ISO Survey on certifications




International Organization for Standardization

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Benefits | Standards in action | Popular standards | Certification & conformity




Standards | Certification & conformity | The ISO Survey

ISO Survey

Every year we perform a survey of certifications to our management system standards. The survey shows the number of valid certificates to ISO management standards (such as ISO 9001 and ISO 14001) reported for each country, each year.

ISO does not perform certification. Organizations looking to get certified to an ISO standard must contact an independent certification body. The ISO Survey counts the number of certificates issued by certification bodies that have been accredited by members of the International Accreditation Forum (IAF).

Learn more about [how to get certified](#).



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Year	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
TOTAL	660132	773843	896905	951486	980322	1063751	1076525	1009845	1017279	1022877	1036321	1033936
Africa	4865	6763	7441	7446	8534	8435	7667	8164	9674	9816	10143	12154
Central and South America	17016	22498	29382	39354	37458	35549	49260	51685	51459	52466	50165	49265
North America	49962	59663	61436	47600	47896	41947	36632	37530	38586	48579	41459	46938
Europe	320748	377172	414208	431479	455303	500286	530039	459367	469739	458814	453628	439477
East Asia and Pacific	240938	266100	320320	354056	366491	408498	396492	402453	396398	387543	414801	422519
Central and South Asia	13856	27966	44923	50379	44171	44432	37596	33577	32373	44847	44790	40822
Middle East	12747	13681	19195	21172	20469	24604	18839	17069	19050	20812	21335	22761

ISO Survey 2015

A total of 1,519,952 certificates were issued worldwide the previous year, an increase of 3 %.

This year we added a new management system standard *Information technology – Service management – Part 1: Requirements*, after recommendations from international experts that we consult annually. This brings the total of standards surveyed to 9.

Read the overview in the [Executive summary](#) [PDF].

Despite our best efforts to display consistent results, there are fluctuations in the number of certificates from year to year due to:

- The variability in numbers of certificates reported each year by individual certification bodies
- Inconsistent participation of some certification bodies that contribute to the survey one year but not the next
- The participation of new certification bodies

[ISO 14001](#)
[ISO 50001](#)
[ISO/IEC 27001](#)
[ISO 22000](#)
[ISO/TS 16949](#)
[ISO 13485](#)
[ISO 22501](#)
[ISO 20000-1](#)



New rights pilot for ISO correspondent and subscriber members

Who?

ISO correspondent and subscriber members
To date 34 out of 43 correspondent + subscriber members take part in the programme

What?

Participate as P-members in up to 5 technical committees, including ISO/CASCO

Why?

Learn and gain experience in ISO standards development work
Members can demonstrate to stakeholders the advantages of increased and active participation

When?

2014-2019

How?

Support and training through ISO CS plus
3 sponsorships per year

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 center has a green wristband. The background is blurred, suggesting an outdoor event or stadium setting.

**Great things happen
when the world agrees**