The event will start at 15:00 IST.

TIC COUNCIL

THE INDEPENDENT VOICE OF TRUST

TIC Council Webinar
Shaping India's Medical Devices Regulatory Framework:
Global Best Practices and Priorities
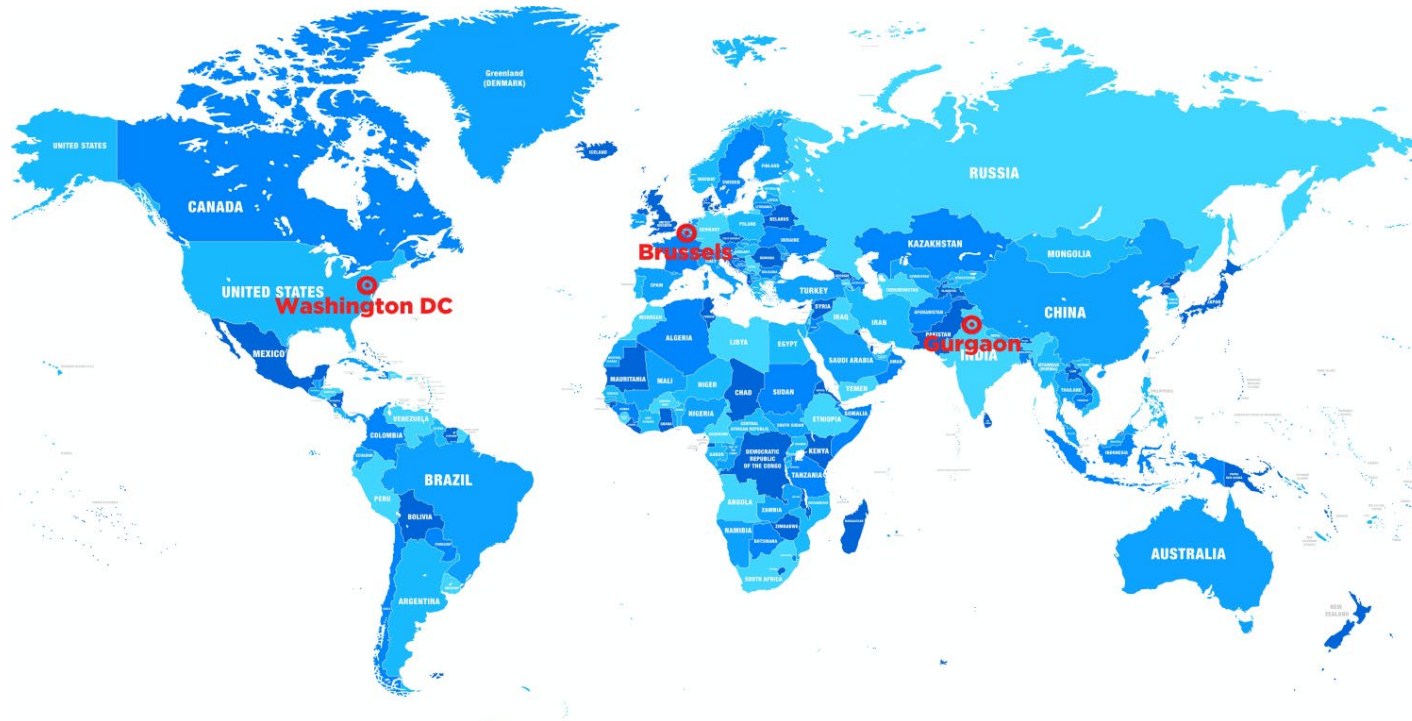
28-29 October 2021

TIC Council
The Independent Voice of Trust

- Born from the merger of IFIA and CEOC

- ~90-member companies & organizations active in more than 160 countries (HQ mapped)

- TIC Council has its head office in Brussels. It is also present in Washington DC, China and India.
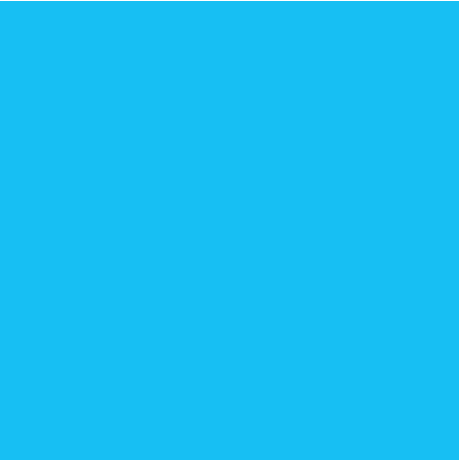
TIC Council Mission

As the voice of the global independent testing, inspection and certification industry, the TIC Council engages governments and key stakeholders to advocate for effective solutions that protect the public, support innovation and facilitate trade.

The TIC Council works with its members to promote best practices in safety, quality, health, ethics and sustainability.

Inaugural session

Welcome and

Opening Remarks

Special Address

**Suresh
Sugavanam,**
Chairman TIC
Council India

Hanane Taidi
Director General
TIC Council

Technical Session: The Global Trends on Regulations: Perspectives from EU, US and Asia

Chairperson

Moderator

Anupam Kaul
Strategic Advisor
(Quality and
Standards)

Karthik Venkataraman
UL India

Technical Session: The Global Trends on Regulations: Perspectives from EU, US and Asia

Speakers

Claire Dyson
Global Vice President,
Dekra, UK

Reinaldo Figueredo
ISO-CASCO Chair

Kimberly Trautman
Medical Device, IVD and
Combination Product
Regulatory & Quality
Expert, USA

Closing Session

Concluding Remarks

Sudhir Zutshi
Chair, Public Affairs
Sub Committee,
TIC Council, India

Claire Dyson
Global Vice President,
Dekra, UK

UKCA – the new route to market

UKCA – the new route to market

1. What is UKCA?

2. Where will UKCA-marking be required?

3. UKCA-certification for medical devices

What is UKCA?

DEKRA

UKCA (UK Conformity Assessed) marking - a new UK product marking

Used for goods being placed on the market in Great Britain.

Covers most goods where CE-marking was required.
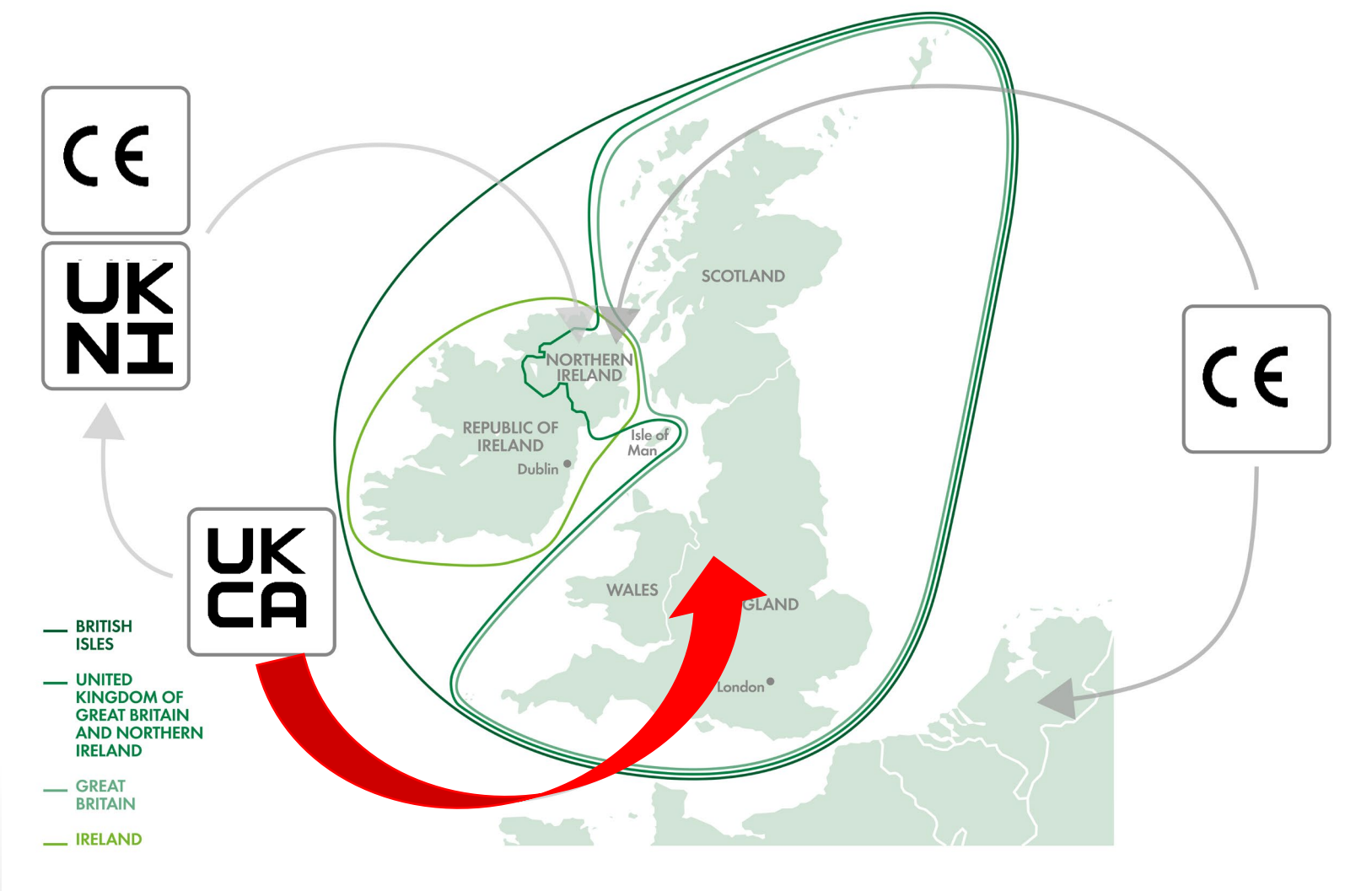
Came into effect on 1 January 2021.

Transition period in place until
- 1 January 2023 (most products)
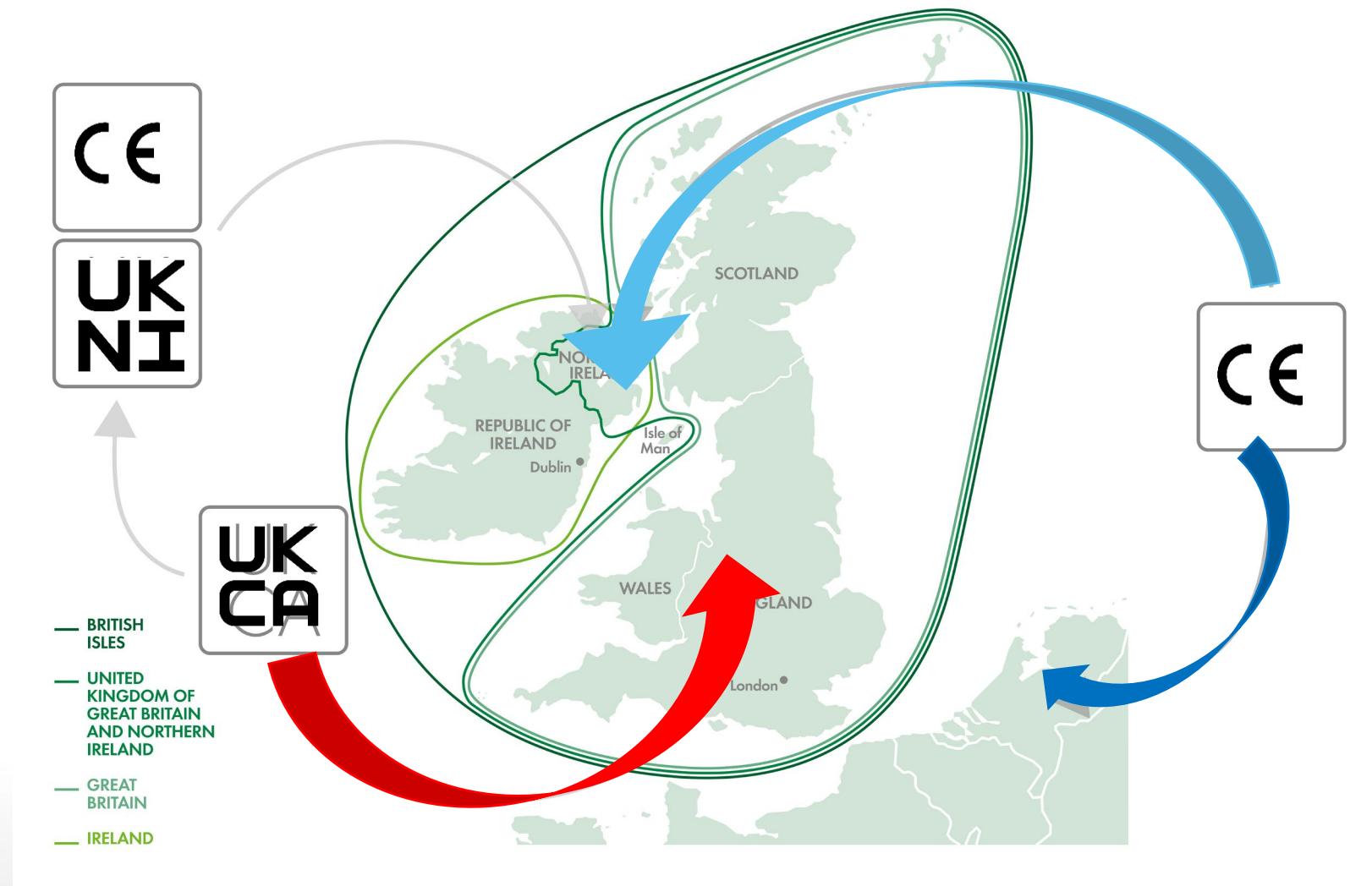- 1 July 2023 (medical devices, including in vitro diagnostics)

https://www.gov.uk/guidance/using-the-ukca-marking

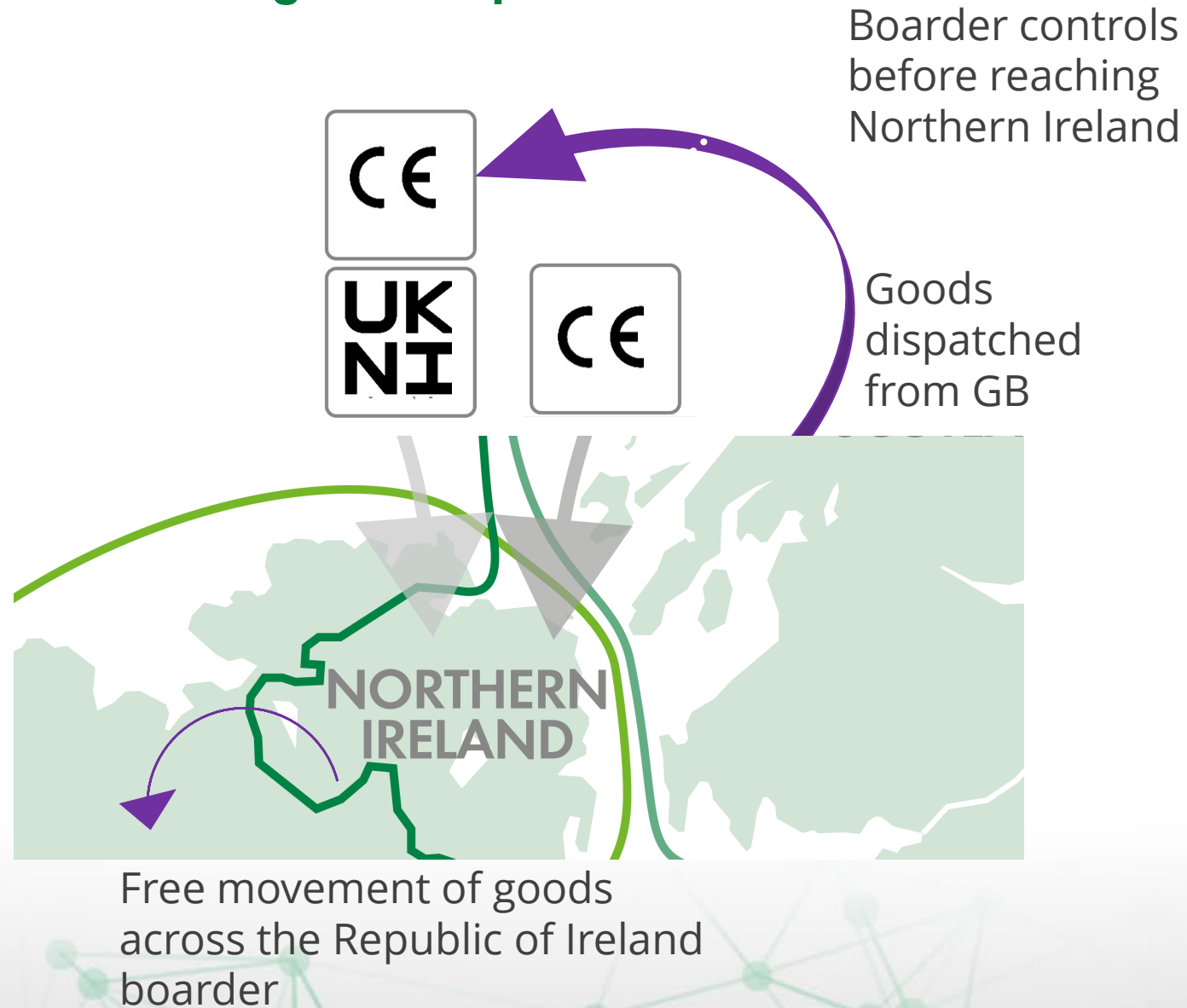# Where will UKCA-marking be required?

Where will UKCA-marking be required?

Where will UKCA-marking be required?

Where will UKCA-marking be required?

Where will UKCA-marking be required?

Boarder controls before reaching Northern Ireland

Goods dispatched from GB

NORTHERN IRELAND

Free movement of goods across the Republic of Ireland boarder

17

UKCA-certification for medical devices

UKCA-certification for medical devices

UKCA-certification for medical devices

13/06/2002

Changes to legislation: There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medical Devices Regulations 2002. Any changes that have already been made by the team appear in the content and are referenced with annotations.

View outstanding changes

Essential requirements for general medical devices

8.—(1) Subject to regulation 12, no person shall place on the market or put into service a relevant device unless that device meets those essential requirements set out in Annex I which apply to it.

(2) Subject to regulation 12, no person shall supply a relevant device—

    (a) if that supply is also a placing on the market or putting into service of that device; or

    (b) in circumstances where that device has been placed on the market or put into service,

unless that device meets those essential requirements set out in Annex I which apply to it.

UKCA-certification for medical devices

UKCA-certification for medical devices

UKCA-certification for medical devices

UKCA-certification for medical devices

EXISTING MEDICAL DEVICE CERTIFICATION LOCATIONS ▷ DEKRA

UKAB

Germany
- **Notified Body 0124**
- Designated by Competent Authority in Germany
- MDD, MDR, IVDR
- MDSAP via NoBo 0344

The Netherlands
- **Notified Body 0344**
- Designated by Competent Authority in the Netherlands
- MDD, AIMD, IVDD, MDR, IVDR, MDSAP

Japan
- **Branch Office**
- Under NoBo 0344
- MDD, AIMD, IVDD, MDR, IVDR, MDSAP

USA
- **Branch Office**
- Under NoBo 0344
- MDD, AIMD, IVDD, MDR, IVDR, MDSAP

China
- **Branch Office**
- Under NoBo 0344
- MDD, AIMD, IVDD, MDR, IVDR, MDSAP

Israel
- **Branch Office**
- Under NoBo 0344
- MDD, AIMD, IVDD, MDR, IVDR, MDSAP

THANK YOU
FOR TAKING CARE OF SAFETY!

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DEKRA

Reinaldo Figueredo
ISO-CASCO Chair

Shaping India's Medical Devices Regulatory Framework: Global Best Practices & Priorities

Use of CASCO Standards to harmonize the medical device regulatory framework

CASCO Chair: Reinaldo B. Figueiredo
27th October 2021

Today

- What is ISO/CASCO?

- Why is important to participate

- CASCO's Toolbox of Standards

- How can we help?

ISO snapshot

We are an independent, non-governmental organization.

We are a global network of national standards bodies with one member per country.

Our job is to make International Standards.

We are coordinated by a Central Secretariat in Geneva, Switzerland.

164 members

100 new standards each month

> 22,000 International Standards

> 250 technical committees

ISO STRATEGY 2030

Making lives easier, safer and better

Our vision and goals

ISO standards used everywhere

Meeting global needs

All voices heard

Vision
Making lives easier, safer and better

ISO GENERAL ASSEMBLY 2021 -

LONDON DECLARATION

https://www.iso.org/ClimateAction/

LondonDeclaration.html

ISO governance structure
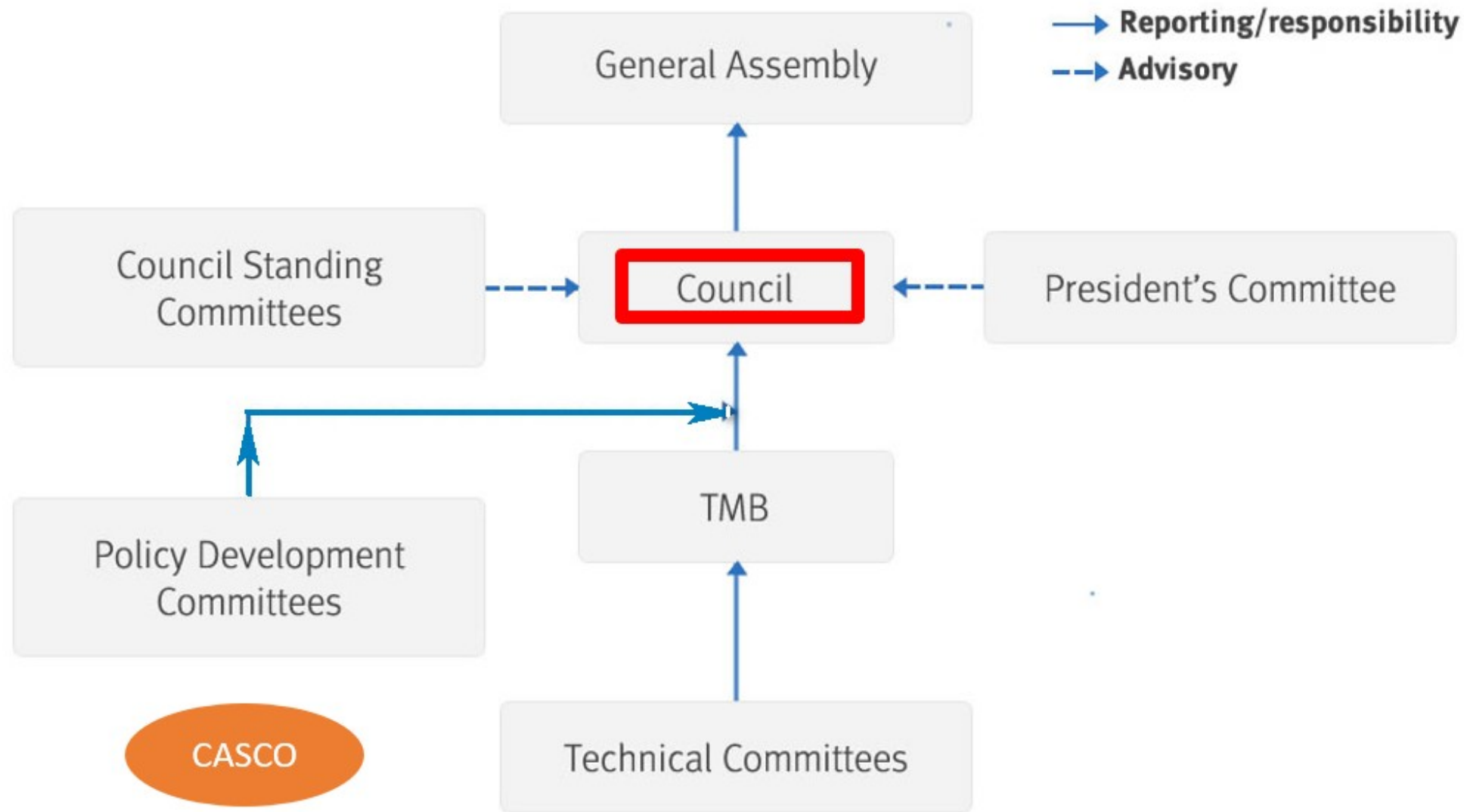
❑ The Role of CASCO as ISO Policy development Committee on Conformity Assessment
- To Study means of assessing the CA of Product/process/services/MS/Persons to standards and other technical specification
- To prepare International Standards relating to practice of conformity assessment
- To promote mutual recognition and acceptance of national , regional and International conformity assessment systems
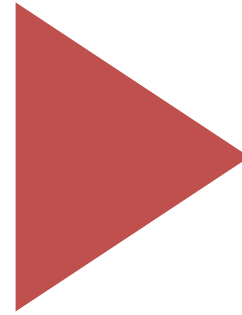
Advise ISO Council

Develop standards & policy for conformity assessment

Coordinated by a Secretariat in ISO CS

142 members and 24 organizations in liaison

ISO

Conformity assessment is

a vital link between

standards and the reality

Conformity assessment and the need for harmonized approach

Non acceptance of test reports and certificates is a major non tariff obstacle to trade

A harmonized approach to conformity assessment standards facilitates international trade

This is the role of the ISO committee on conformity assessment (CASCO) to develop CA standards using a double level of consensus

CASCO
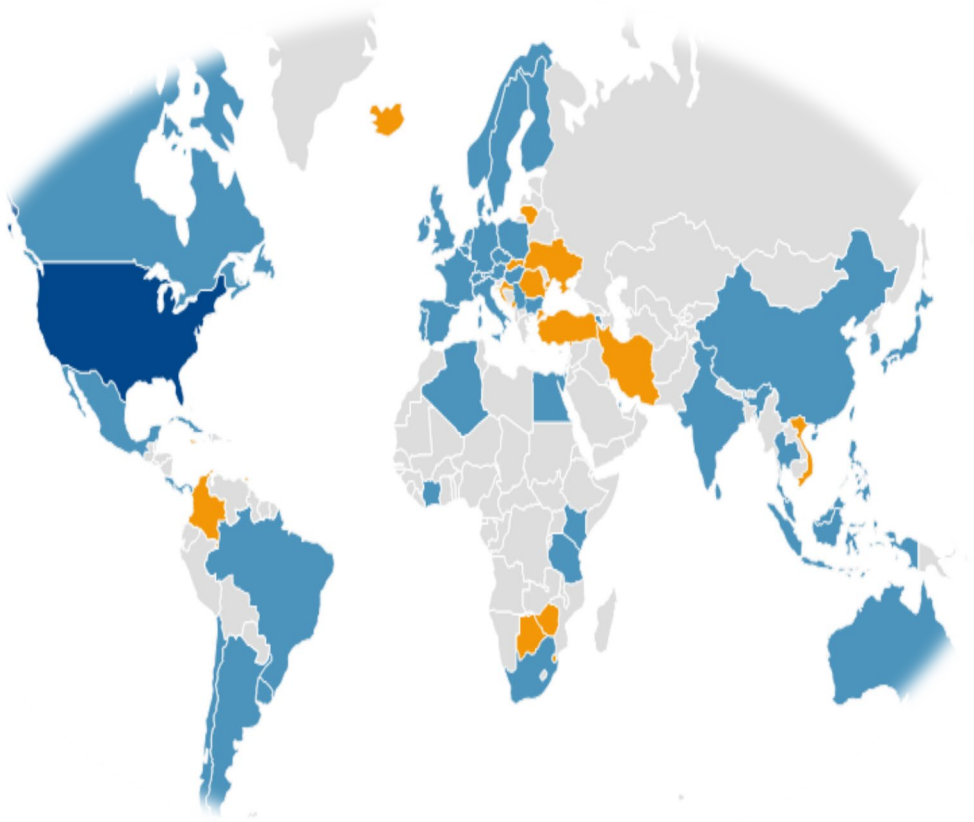
ISO committee on conformity assessment that develops

➢ generic conformity assessment standards

➢ policies related to conformity assessment practices

CASCO has 142 members and 23 organizations in liaisons

37 published standards and 3 under development

Initiatives

Mentorship Programme

Future of toolbox

Information sessions

Stakeholder consultation
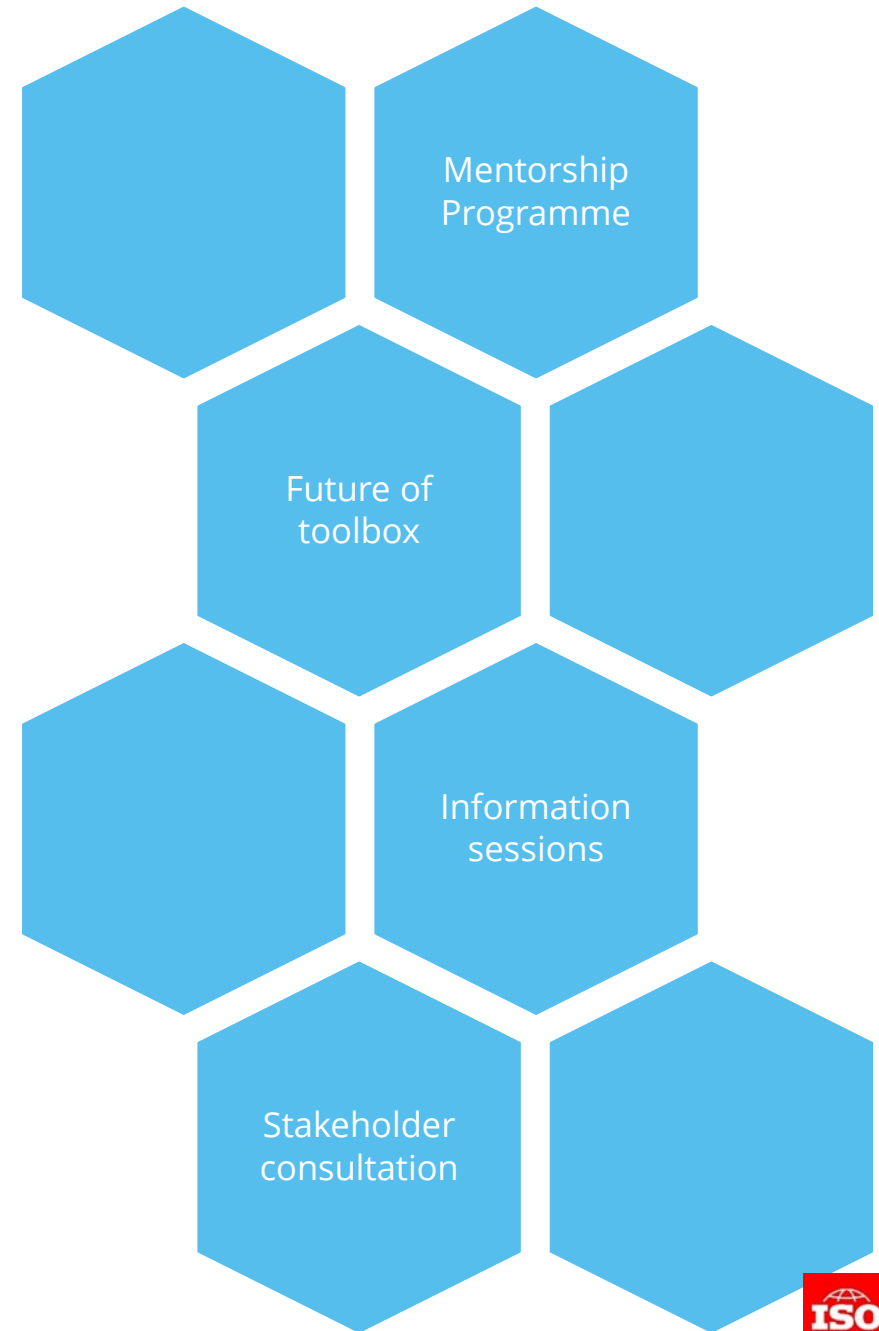
How does CASCO operate?

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

Chairman's policy and coordination group (CPC)

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

Liaises with other ISO technical commitees (TCS)

Technical interface group (TIG)

WG WG WG WG WG WG

Working Group (WG)

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

Strategic Alliance and Regulatory Group (STAR)

ISO

NEED TO DEMONSTRATE FULFILMENT OF SPECIFIED REQUIREMENTS
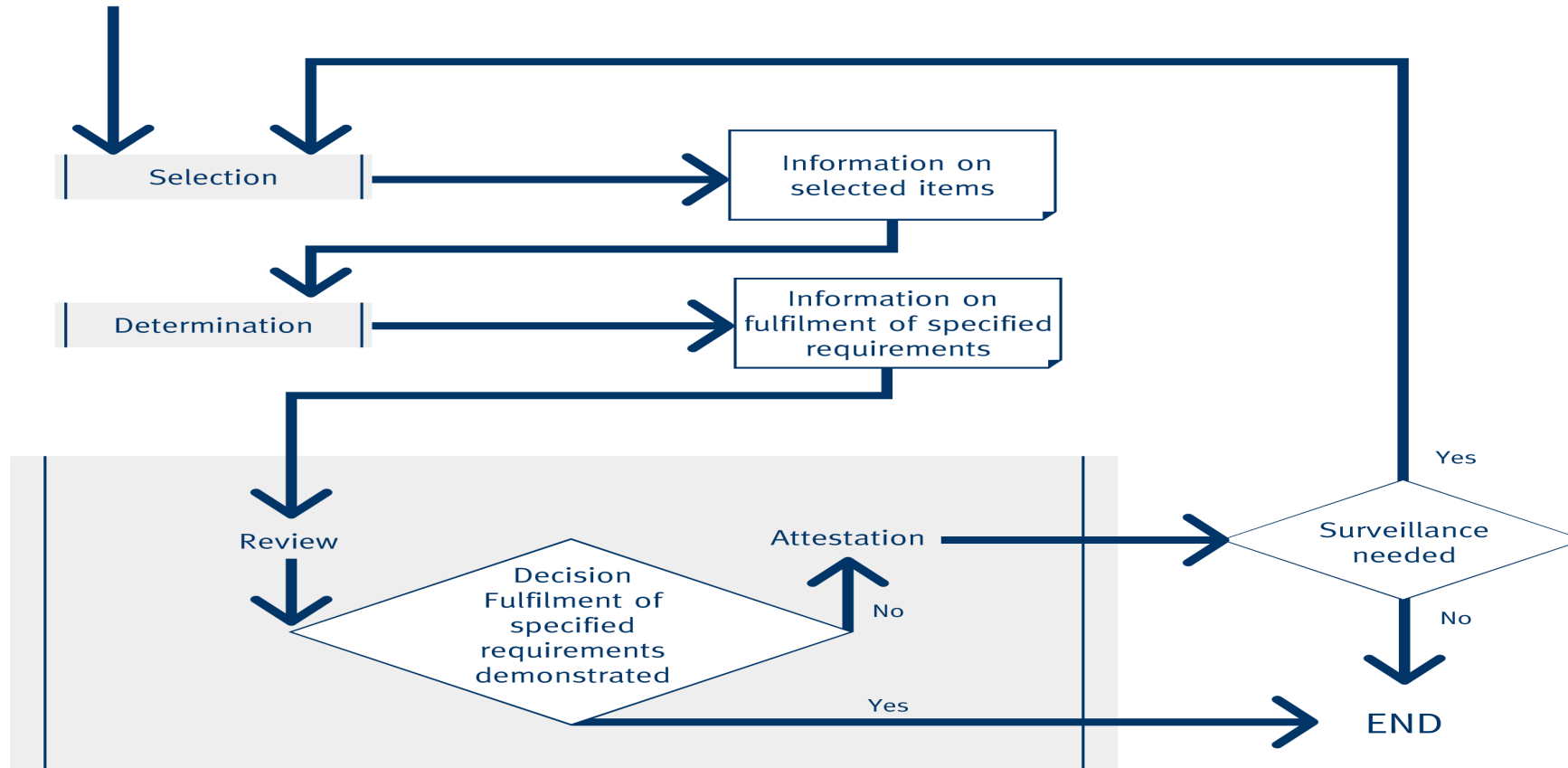
KEY
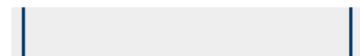
Shape A conformity assessment function

Shape B output form a function or input to the next function

Shape C decision point

What is CA toolbox

37 standards for

- CA principles
- CA bodies
- CA methodologies
- accreditation bodies
- peer evaluation
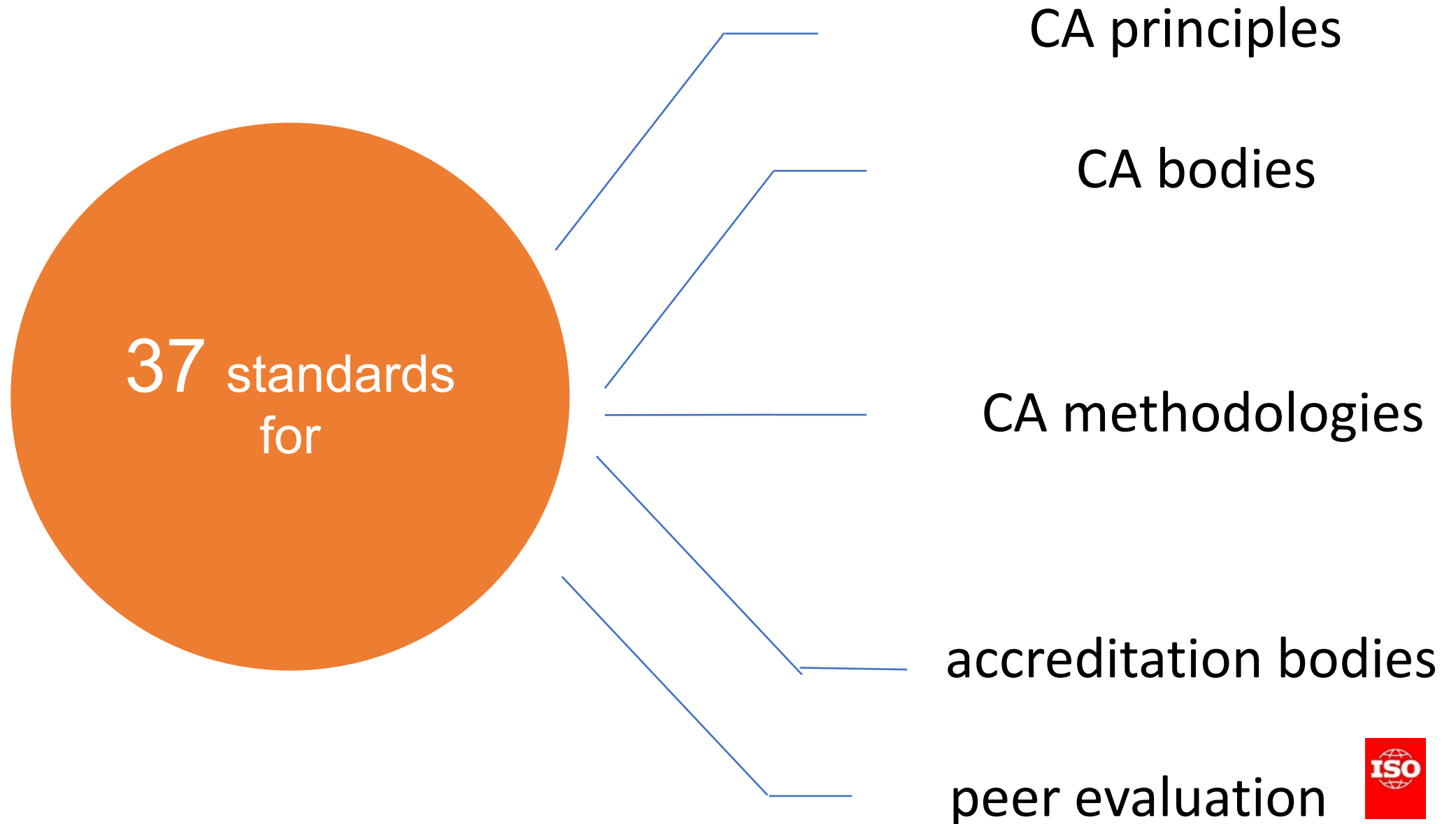
Applications of CA Toolbox
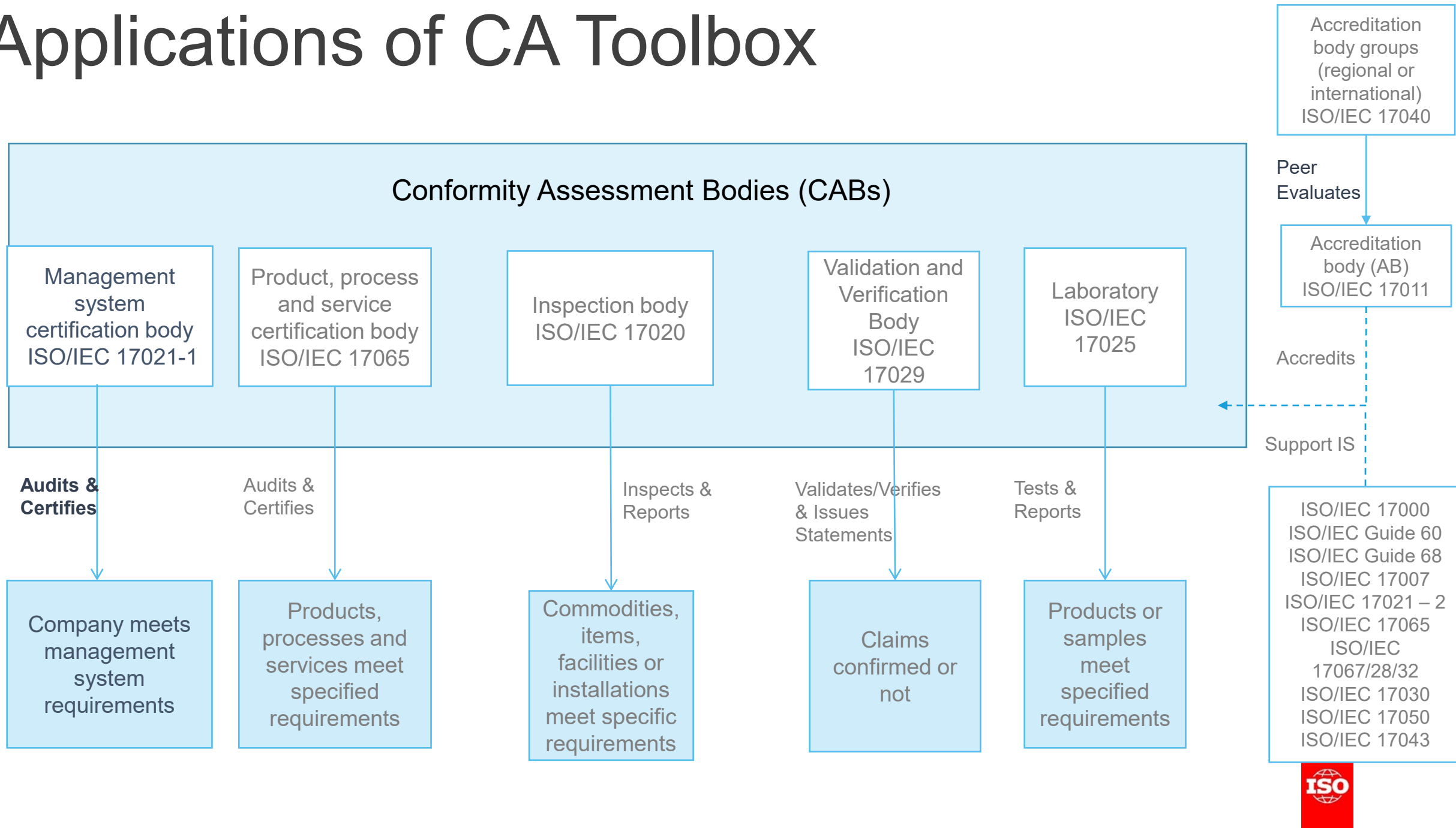
Looking Ahead

➢ Development of CASCO strategy

➢ Review of CASCO structure

➢ Future stakeholder engagement plan to focus on sustainability and circular economy

➢ CASCO toolbox in view of future needs and challenges in the areas of conformity assessment

Why to engage with CASCO

ISO/CASCO
National Mirror Committees

Resources

ISO CASCO resources page

Conformity Assessment and **regulators** – online resource provides tools to support public policy with examples

Conformity assessment for standards writers – Do's and Don'ts
https://www.iso.org/publication/PUB100303.html

Educational Toolbox explaining some basic conformity assessment Concepts

Published **brochures**

ISO - Publications

ISO - The ISO Survey

ISO - Building trust - The Conformity Assessment Toolbox

Conformity Assessment tools for regulators

ISO - Resources for Conformity Assessment

ISO'S COMMITTEE ON CONFORMITY ASSESSMENT (CASCO)

ISO - CONFORMITY ASSESSMENT DURING COVID-19

CASCO Chair 2020 to 2021 – Reinaldo Figueiredo (ANSI) (rfigueir@ansi.org)

Kimberly Trautman
Medical Device, IVD
and Combination
Product Regulatory &
Quality Expert, USA

TIC Council Webinar

Global Medical Devices:
Medical Device Single Audit Program - Key Learnings

Kimberly Trautman

Medical Device, IVD and Combination Product Expert

KIM TRAUTMAN, M.S.

Medical Device, IVD and Combination Product Expert

E ktrautman_mdis@msn.com

EXPERIENCE

Kimberly A. Trautman is an experienced Medical Devices, InVitro Diagnostics, and Combination Product Expert with over 30 years of experience. She worked at the US Food and Drug Administration (FDA) for 24 years and continues to work with Regulatory Agencies around the globe. Industry experience as well as regulatory agency experience. Demonstrated history of working collaboratively with industry, regulators and patient groups for the betterment of public health. Executes several medical device regulatory services and developed a formal Education/Training business. Established an Authorized Medical Device Single Audit Program (MDSAP) Auditing Organization and a new Notified Body for EU IVDR/MDR Designation.

Expert in global medical device regulations, wrote and harmonized the current US FDA Quality System Regulation and was on the international authoring group of ISO 13485 since inception. Conceived and developed the Medical Device Single Audit Program and its consortium of five Global Regulators. Twenty-year veteran of the Global Harmonization Tasks Force (GHTF) and foundational member of the International Medical Device Regulators Forum (IMDRF).

EDUCATION

M.S. of Biomedical & Medical Engineering, University of Virginia, Charlottesville, VA
B.Sc. of Molecular Cell Biology and Engineering Sciences, Pennsylvania State University, State College, PA

Key Takeaways

Explore the way multiple medical device Regulatory authority schemes are moving towards harmonization with MDSAP.

Discuss FDA upcoming rulemaking to harmonize with ISO 13485:2016. Discuss how FDA might use additional aspects of MDSAP.

Understand recent changes in EU and UK global Regulatory Authority schemes utilization of MDSAP

International Medical Device Regulators Forum (IMDRF)
Medical Device Single Audit Program (MDSAP)

IMDRF MDSAP:

International Convergence Effects since 2011

IMDRF and MDSAP

➤ The International Medical Device Regulators Forum (IMDRF) recognized the value in developing a global approach to auditing and monitoring the manufacturing of medical devices to ensure safe medical devices

➤ The IMDRF, at its inaugural meeting in Singapore in 2012, identified a Work Group to develop specific documents for advancing the concept of the Medical Device Single Audit Program (MDSAP)

The International consortium of countries for MDSAP:

Therapeutic
Goods
Administration
(TGA)

Agência Nacional
de Vigilância
Sanitária
(ANVISA)

Health Canada
(HC)

Pharmaceuticals
and Medical
Devices Agency
(PMDA)

U.S. Food and
Drug
Administration
(FDA)

MDSAP International Consortium

➢ 2014 Added Observers:
- World Health Organization (WHO) Diagnostic Prequalification Program
- European Union

➢ 2019 Added Affiliates:
- ANMAT – Argentina's National Administration of Drugs, Foods and Medical Devices
- Republic of Korea's Ministry of Food and Drug Safety

MDSAP Audit Criteria

The MDSAP audit process was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the quality management system requirements:

- ➤ ISO 13485:2016
- ➤ Brazilian Good Manufacturing Practices (ANVISA RDC 16)
- ➤ Japanese requirements (MHLW MO 169)
- ➤ FDA's Quality System Regulation (21 CFR Part 820)

MDSAP Audit Criteria

AND other specific requirements of medical device regulatory authorities participating in the Pilot MDSAP program such as:

- registration
- licensing
- adverse event reporting and more

Concept

RA: Regulatory Authorities; *AO*: Auditing Organizations; *Mfr*: Manufacturers
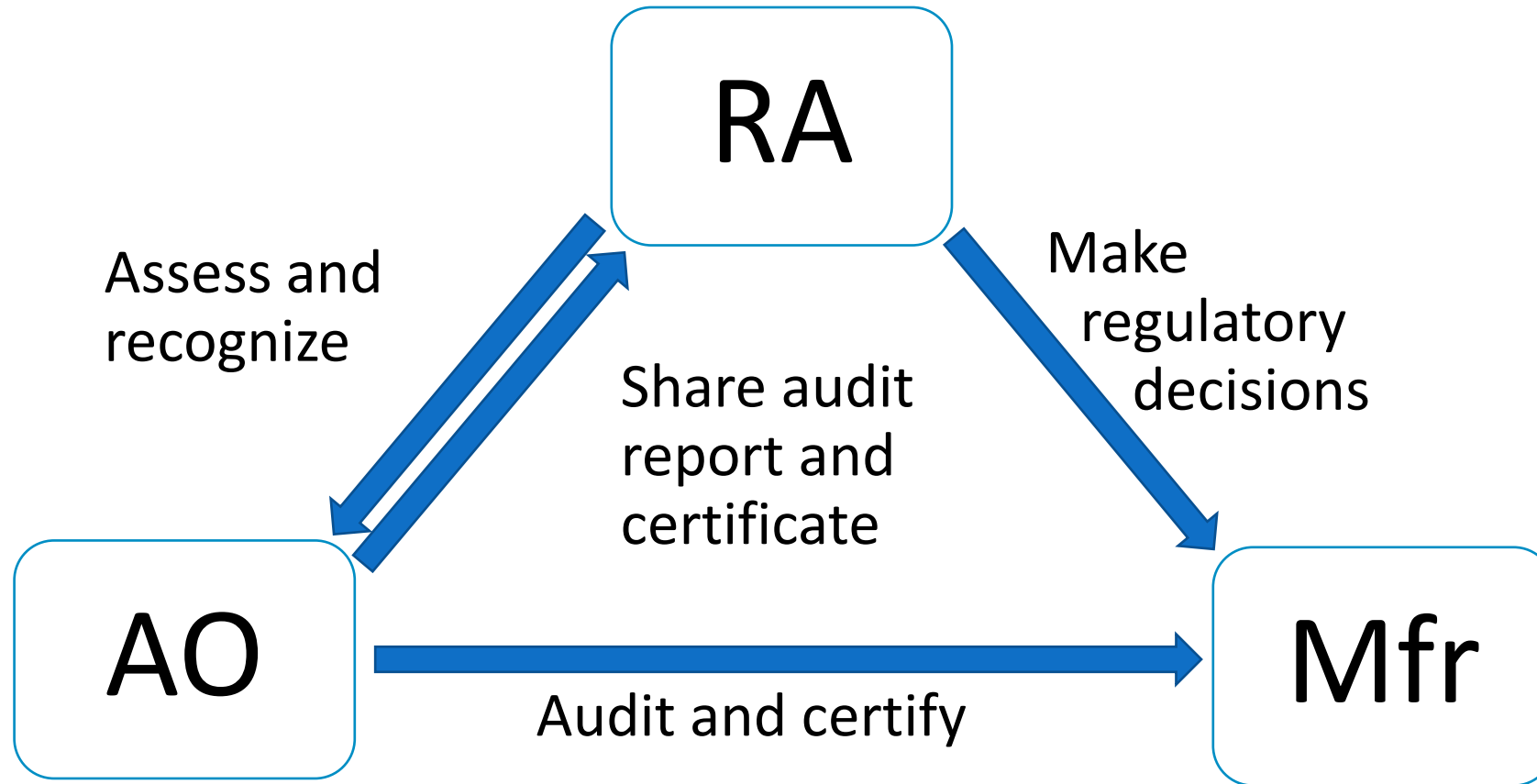
Assessment Process
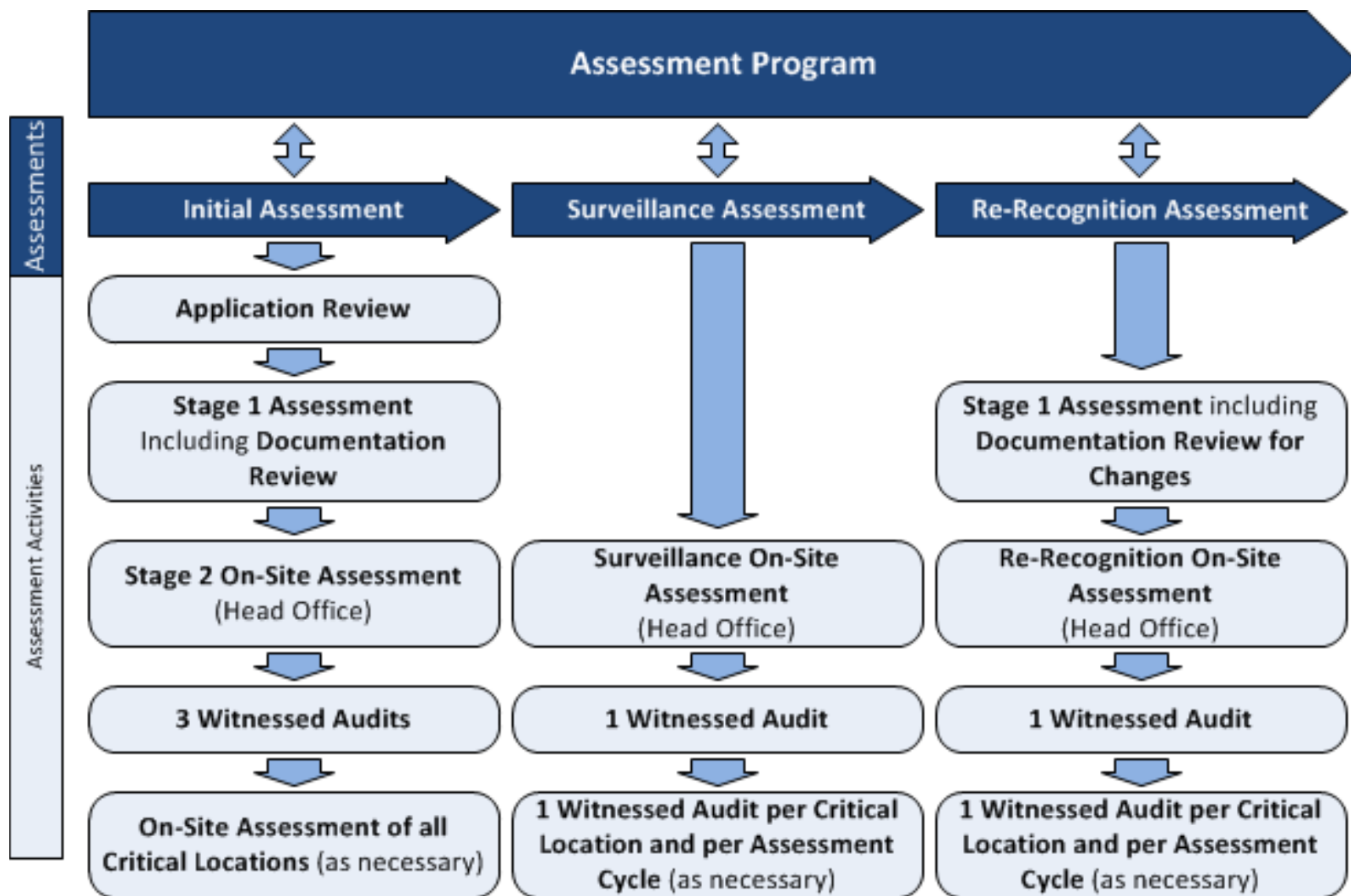
Outputs of an MDSAP Audit

Australia:

Where regulations do not require a TGA CAC, TGA will accept MDSAP certificates as evidence of compliance with ISO 13485 where the standard has been used to demonstrate partial compliance with the requirements of an Australian Conformity Assessment Procedure.

Where regulations require a TGA CAC, TGA will take into account MDSAP certificates when deciding to issue or maintain a TGA CAC. Under some circumstances, a manufacturer may avoid routine TGA inspections.

Outputs of an MDSAP Audit

Brazil:

ANVISA may use MDSAP audit reports in lieu of premarket inspections by ANVISA to grant ANVISA's GMP Certificates

ANVISA can also use MDSAP audit reports to renew ANVISA GMP Certificates bi-annually as an alternative to an ANVISA comprehensive inspection.

Canada:

Health Canada will accept MDSAP certificates as evidence of conformity in accordance with section 32(2)(f), (3)(j), 4(p), 34, and 43.1

Outputs of an MDSAP Audit
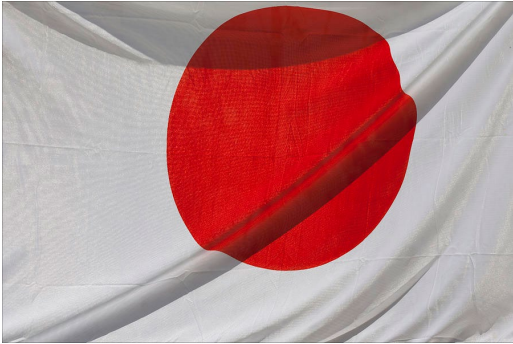
<u>Japan:</u>

MHLW and PMDA can use MDSAP audit reports to: Exempt a manufacturing site from on-site inspection (restrictions apply)

Substitute considerable part of the documentation to be supplied by the Marketing Authorization Holder for inspection with the MDSAP audit report.

<u>US FDA</u>:

CDRH will accept MDSAP audit reports as a substitute for FDA routine inspections.

Third Parties and Regulatory Authorities

MDSAP:

The development of MDSAP includes the use of third-party auditors, much like some current regulatory audit programs, as well as regulatory inspectorates. Use of third-party auditors, in addition to Regulatory Authority Inspectorates, allows greater coverage in auditing manufacturers around the globe.

MDSAP and EU MDR/IVDR

International Workgroup (Joint NBO/International ad-hoc TF) created guidance for MDCG 2020-14 to support "*taking into consideration*" the MDSAP Regulatory report.

- Examples cited for Supplier Control, PMS, Clinical Evaluation
- CEN/TR 17223

In MDCG guidance on remote audits during COVID-19 indicates that notified bodies can "take account of" MDSAP audit reports.

Success may be is possible with:

- Audit planning alignment
- Audit report documentation to support the needs of both schemes.

MDSAP AFFILIATES

MDSAP Affiliate Program

Launched in June 2019, 2 countries have joined

- ANMAT – Argentina's National Administration of Drugs, Foods and Medical Devices

- Republic of Korea's Ministry of Food and Drug Safety

AOs will not be auditing to any of the affiliate members regulations, mentioning them in the audit reports or including them in any certificates.

MDSAP Affiliate Program

Manufacturers can share their audit reports directly with the affiliates. It is not up to the RAs or AOs to provide.

Affiliates members may be an observer during an audit by invitation of the client but are not to be perceived as part of the audit.

The AOs will not engage in any decision related to the presence of the Affiliate as an observer during the audit.

Thank you for participating!

Q&A

Questions?

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Wikipedia page:
Testing, inspection and
certification

TIC-Council.org