

**Topic:** AIF Support Series #16: *Conformity Assessment in ISO standards*

**Date:** June 22, 2021

**Presenters:** Dr. Cynthia Woodley (Professional Testing Inc.) & Kristen Califra (ANSI staff)

### 1. Opening of the meeting

- A presentation (see AIF N442-2021) was given on Conformity Assessment (CA) in ISO standards. We want to hear from you to learn how we can best support you throughout your U.S. TAG and committee work. Submit any inquiries or comments to ANSI's ISO Team (isot@ansi.org).

### 2. Key points from the presentation

#### What is Conformity Assessment?

- Conformity Assessment (CA), as defined in ISO/IEC 17000 (2020) Clause 2.1, is the demonstration that specified requirements are fulfilled
- A number of activities make up any individual conformity assessment. Some examples of these activities are accreditation, certification, inspection, validation, verification, testing, etc.
- Conformity Assessment activities can be performed by different parties:
  - 1<sup>st</sup> party – provider of the “object of conformity” (e.g., the product, service, management system, a person, etc.)
  - 2<sup>nd</sup> party – person or organization with a user interest in the “object”
  - 3<sup>rd</sup> party – person or organization independent from the provider and of user interests in the “object”
- ISO's Neutrality Principle does not allow conformity assessment standards to require third party conformity assessment. The Neutrality Principle states that 1st, 2nd, or 3rd parties shall be able to fulfill/utilize the CA content of an ISO standard (see Clause 33 of the ISO/IEC Directives part 2)

#### What is ISO/CASCO?

- ISO/CASCO is ISO's committee on Conformity Assessment. The committee studies CA, writes CA standards and guides and promotes mutual recognitions of results of CA activities
- There are three policy level groups in ISO/CASCO:
  - The Chairman's Policy and Coordination Group (CPC) coordinates the technical work of CASCO and assists the CASCO Chair in identifying strategic conformity assessment issues.
  - The Technical Interface Group (TIG) liaises with other ISO technical committees (TCs) in order to ensure a consistent and harmonized approach to conformity assessment in those TCs.
  - The Strategic Alliance and Regulatory Group (STAR) provides a forum for industry sectors and regulators to interact with CASCO.
- There are also a number of technical Working Groups (WGs) and Joint Working Groups (JWGs) that work on the development of a specific deliverable

#### How does CASCO interact with ISO TCs and SCs?

- The CASCO TIG and its volunteer experts liaise with other ISO committees to provide input related to Conformity Assessment. TIG experts observe/participate in ISO TC and SC meetings to advise when TC or SC is “treading” into a CA area

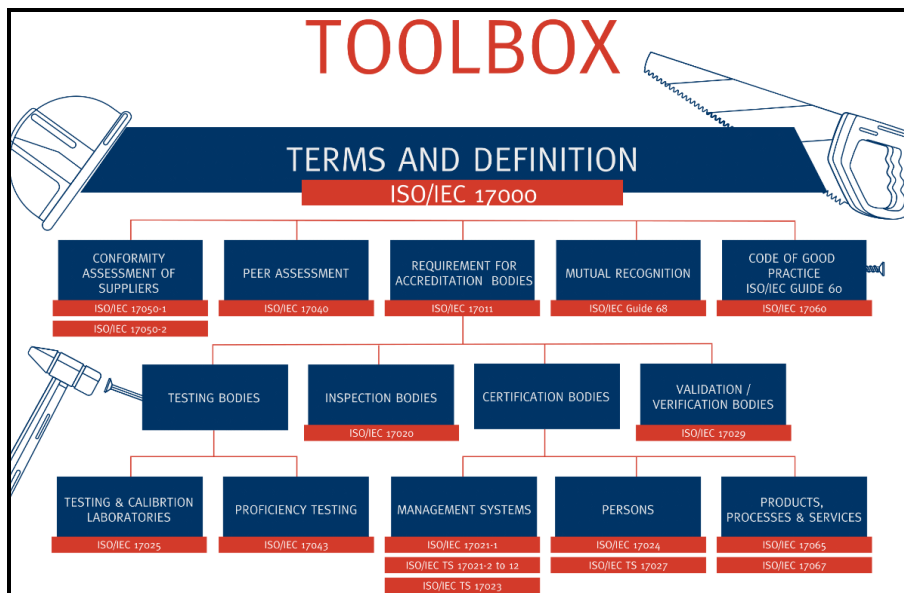
- If the standard will have CA as a major part of it, a JWG is set up under ISO/CASCO to develop that particular standard. Two convenors are named, one representing the TC/SC and one representing CASCO.
- **It is of utmost importance that TCs and SCs developing CA in their standards consult with ISO/CASCO as early on in the process as possible to minimize edits requiring to be made later in the standards development process.**

**Relevant Directives/Standards**

- [ISO/IEC Directives, Part 2](#), Rules for the structure and drafting of International Standards sub clause 33, Aspects of conformity assessment provides info on:
  - ... when an ISO TC/SC wishes to develop a document specifying arrangements for conformity assessment, the TC/SC must consult with CASCO
  - ... the ISO neutrality principle
  - ... test methods
  - ... schemes
    - Conformity Assessment Scheme – set of rules and procedures that describes the objects of conformity assessment, identifies the specified requirements and provides the methodology for performing conformity assessment (the CA activities)
    - ISO TCs and ISO CASCO formulate and publish the Standards; Standards can be used as the “specified requirements the “object” must fulfill”; Standards can also provide the methodology for performing conformity assessment but the Neutrality Principle must be respected
    - The scheme owner is responsible to select the conformity assessment activity desired, so it’s important for scheme owners to understand the CA standards
- ISO/IEC 17000:2020, Conformity assessment-- Vocabulary and general principles, in particular, Annex A
- ISO/IEC 17007:2009, Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment

**Available Resources**

- **CASCO Toolbox-** A collection of ISO/CASCO standards:



- **CASCO common elements**- Document used by ISO/CASCO WGs in the development of ISO/CASCO standards and other deliverables specifying requirements for bodies performing conformity assessment. It defines the wording for the obligatory and recommended elements of “impartiality”, “confidentiality”, “complaints and appeals”, “competence” and “use of management systems”
- A set of public, educational presentations on the 17000 series can be found [here](#)
- [CASCO Communiques](#)
- [Resources for Conformity Assessment](#)
- [Conformity Assessment Do's and Don'ts](#)
- [Building Trust- The Conformity Assessment Toolbox](#)
- [ISO/CASCO webpage](#)

### **What should you know as a TC/SC?**

- When an ISO TC/SC wishes to develop a document specifying arrangements for conformity assessment (the methodology for the Scheme), the TC/SC must consult with ISO/CASCO to ensure compliance with Clause 33
- It is important to liaise with ISO/CASCO prior to the commencement of the work or as early on as possible to avoid reaching the end and having to go back and redo work

### **Session Questions and Answers**

1. **I developed a standard that took us 5 years to complete because we consulted with ISO/CASCO very late in the process. The standard was finally published as a TS. I'm now looking into how to transform the TS into an IS. Can someone advise the easiest way to do this?**

**Answer:** Yes, this is why we want to remind our stakeholders to get CASCO involved as early as possible. For process questions related to transforming a TS into an IS, please email [isot@ansi.org](mailto:isot@ansi.org)

2. **What is ISO/CASCO doing for non-tangible products that do not necessarily fit under “services”? In our committee we are developing standards for digital services and want to be able to certify as both an MSS and product/service certifications.**

**Answer:** While CASCO is currently working on a guidance deliverable that will be a decision tree for which CASCO standard to use in any given situation, speaking offline about this specific situation would be most helpful.

3. **Can you provide more information on Management System Standards (MSS)?**

**Answer:** Yes, here is a link to the ISO site with more information on MSS:  
<https://www.iso.org/management-system-standards.html>

# AIF Support Series #16

## Conformity Assessment in ISO Standards

Welcome!

- We will mute all lines. Please stay muted so everyone can hear each other and the presentation.
- If your sound quality is low, try using the call back feature.
- Please disable video.
- To ask a question, please use the Q&A or Raise Your Hand features. We will closely monitor both.

# Conformity Assessment in ISO standards

AIF Support Series #16



# Housekeeping Items

- All participants will be muted until the end of the presentation
- Use the Q&A function to “All Panelists” / Raise Your Hand to ask questions
- If we don’t get to your question today, reach out via email [isot@ansi.org](mailto:isot@ansi.org)
- Follow-up/repeat sessions will be held if necessary
- Slides and one-page summary to be circulated after the call
- Keep us informed of your experiences!

# Session Overview

- Agenda
  - What is Conformity Assessment?
  - What is ISO/CASCO?
  - How does CASCO interact with ISO TCs and SCs?
  - Relevant Directives/Procedures
  - Available Resources
  
- Speakers
  - Dr. Cynthia D. Woodley, Chief Operations Officer, Professional Testing, Inc.
  - Kristen Califra, Program Manager, ANSI

# Draft Outline

- What is Conformity Assessment?
- What is ISO/CASCO?
- How does CASCO interact with ISO TCs and SCs?
- Relevant Directives/Standards
- Available Resources
- Q&A/ Open Dialog



# What is Conformity Assessment?

- Conformity Assessment (CA) is defined as demonstration that specified requirements are fulfilled.
  - (ISO/IEC 17000 [2020], Clause 2.1)
- A number of activities make up any individual conformity assessment
- Some examples of CA activities are: accreditation, certification, inspection, validation, verification, testing

# Who Performs Conformity Assessment

- Conformity Assessment activities can be performed by different parties:
  - 1<sup>st</sup> party – provider of the “object of conformity” (e.g., the product, service, management system, a person, etc.)
  - 2<sup>nd</sup> party – person or organization with a user interest in the “object”
  - 3<sup>rd</sup> party – person or organization independent from the provider and of user interests in the “object”
- ISO’s Neutrality Principle states that 1st, 2nd, or 3rd parties shall be able to fulfill/utilize the CA content of an ISO standard

# What is ISO/CASCO?

- ISO committee on Conformity Assessment
- Study conformity assessment; write International Standards and Guides; promote mutual recognition of results of CA activities
- CASCO membership is open to interested member bodies as participating (P) or observer (O) members and to interested correspondent members as observer (O) members
- Does NOT perform conformity assessment activities



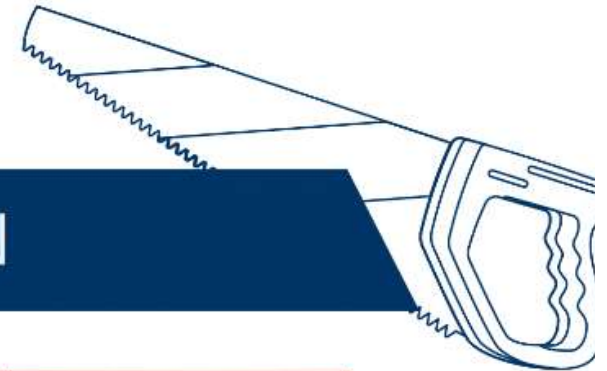
# How ISO/CASCO Interacts with ISO TCs/SCs

- The CASCO TIG and its experts liaise with other ISO committees to provide input related to Conformity Assessment
  - TIG experts observe/participate in ISO TC and SC meetings to advise when TC or SC is “treading” into a CA area
- If the standard will have CA as a major part of it a JWG is set up to develop that particular standard
  - JWG is under CASCO lead with 1 convenor from CASCO and another convenor from TC/SC
- Important for ISO TCs and SCs to approach ISO/CASCO as early on as possible

# Relevant ISO Documents

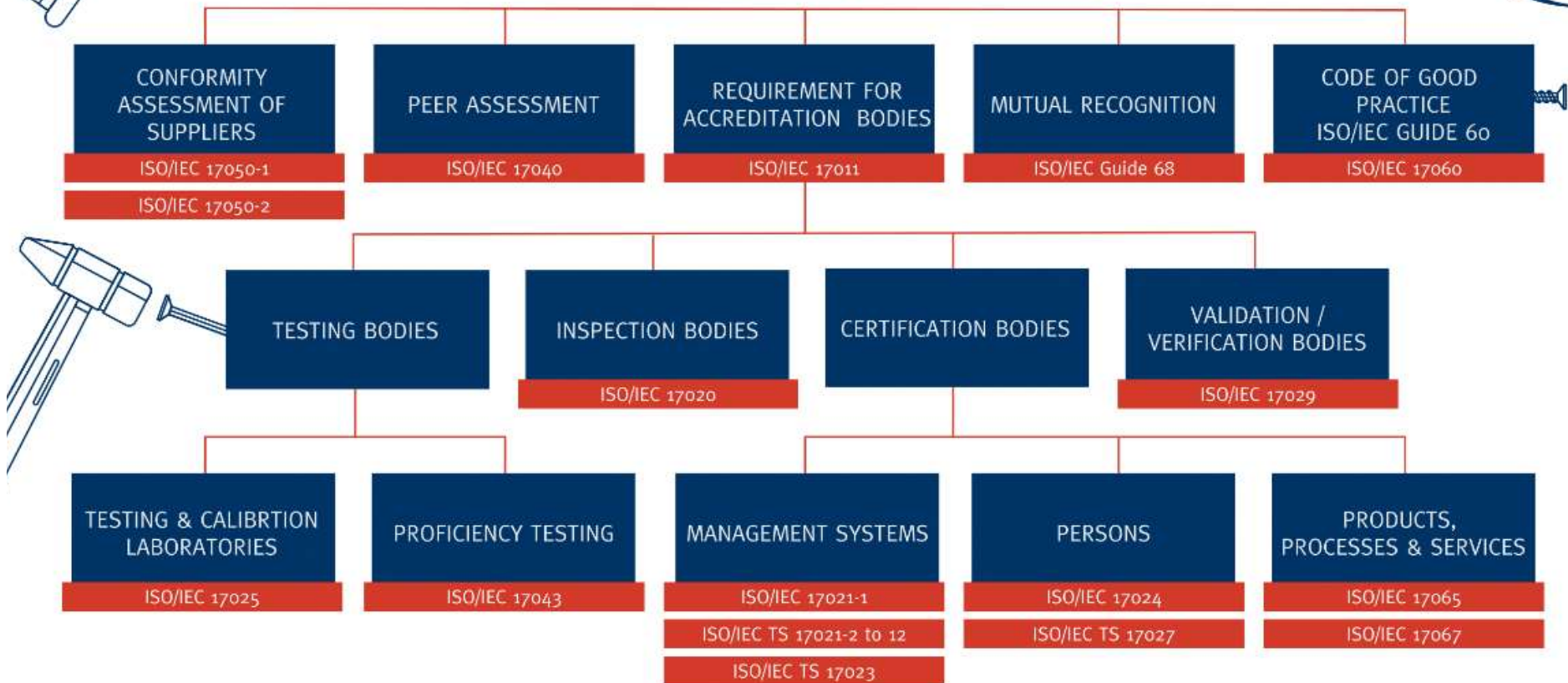
- ISO/IEC Directives, Part 2, *Rules for the structure and drafting of International Standards* sub clause 33, *Aspects of conformity assessment*.
- ISO/IEC 17000:2020, *Conformity assessment-- Vocabulary and general principles, in particular, Annex A*
- ISO/IEC 17007:2009, *Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment*

# TOOLBOX



## TERMS AND DEFINITION

### ISO/IEC 17000



# CASCO common elements

1. Impartiality
    - (presence of objectivity)
  2. Confidentiality
  3. Handling of Appeals
  4. Handling of Complaints
  5. Competence
  6. Management Systems
    - (Option A for ISO 9001 certification; Option B for inclusion of the specified list of requirements)
- ISO CASCO WGs are required to include the obligatory wording and can accept or reject the recommended wording for the common elements



# Directives Clause 33...

- ...states that when an ISO TC/SC wishes to develop a document specifying arrangements for conformity assessment, the TC/SC **must** consult with CASCO
- ...notes the neutrality principle
- ... provides info on test methods
- ... provides info on schemes

# Schemes and Scheme Owners

- Conformity Assessment Scheme – set of rules and procedures that describes the objects of conformity assessment, identifies the specified requirements and provides the methodology for performing conformity assessment (the CA activities)
- ISO TCs and ISO CASCO formulate and publish the Standards; Standards can be used as the “specified requirements the “object” must fulfill”; Standards can also provide the methodology for performing conformity assessment but the Neutrality Principle must be respected
- The scheme owner is responsible to select the conformity assessment activity desired, so its important for scheme owners to understand the CA standards.

# What should you know as a TC/SC?

- When an ISO TC/SC wishes to develop a document specifying arrangements for conformity assessment (the methodology for the Scheme), the TC/SC must consult with ISO/CASCO to ensure compliance with Clause 33
  - The ISO Committee Manager and ISO Chair should liaise with their TPM and ISO CASCO Secretariat
- **It is important to liaise with ISO/CASCO prior to the commencement of the work or as early on as possible to avoid reaching the end and having to go back and redo work**

# Q&A / Open Dialogue

(please use the Q&A or Raise Your Hand functions to join the queue)

# Additional Resources

- <https://www.iso.org/casco.html>
- A set of public, educational presentations on the 17000 series can be found [here](#)
- [CASCO Communiques](#)
- [Resources for Conformity Assessment](#)
- [Conformity Assessment Do's and Don'ts](#)
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# Thank you!

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