

INTERNATIONAL
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Welcome!!

- Aims of this Course
 - To provide regulatory and accreditation body staff with a good understanding of the requirements in ISO/IEC 17020
- Expected Results of this Course
 - Your ability to better appreciate all aspects of the inspection body standard.
 - Your ability to better maintain a quality system conformant to ISO/IEC 17020



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Our Contract

Introductions

- We wish to see you succeed.
- We work for you.

We owe you:

- Deference
- Respect
- Honesty
- Some knowledge of the subject matter

We want.....?????



Your Objectives

Please introduce yourself:

- Your name
- Your role / appointment within your org
- What you seek from this training.



Objectives



Course Grading

- Based on the results of the End-of-Course Quiz
- Evaluating your facilitator.

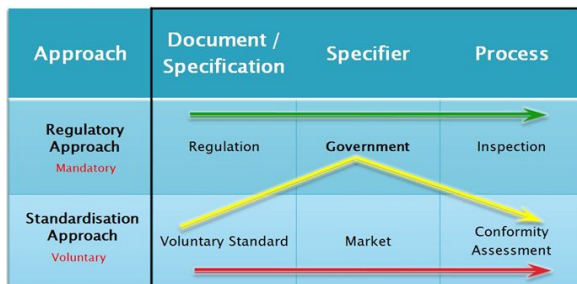
Outline

- Introduction
- Chapter 1 – Background
- Chapter 2 – Program Integrity Requirements
- Chapter 3 – Organizational Requirements
- Chapter 4 – Infrastructure Requirements
-
- Chapter 5 – Inspection Process Requirements
- Chapter 6 – Management System Requirements

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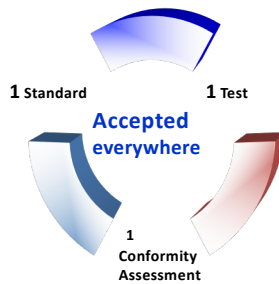
Standards vs Regulations





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Aim of Conformity Assessment





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ISO/CASCO Standards (1)

Non-Technical Conformity Assessment Standards

| Subject | Document | Publication date |
|-------------------------------------|----------|------------------|
| Vocabulary | 17000 | 2004 |
| System certification | 17021 | 2012 |
| Marks of conformity | 17030 | 2003 |
| Personnel certification | 17024 | 2003 |
| Suppliers declaration of conformity | 17050 | 2004 |



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ISO/CASCO Standards (2)

Technical Conformity Assessment Standards

| Subject | Document | Publication date |
|--|------------------|------------------|
| Accreditation | 17011 | 2017 |
| Testing & calibration laboratories | 17025 | 2017 |
| Proficiency Testing | 17043 | 2010 |
| Inspection | 17020 | 2012 |
| Product certification | 17065 | 2013 |
| Product certification Schemes | Guide 23, 28 | 2003, 2004 |
| | Guides 53, 17067 | 2005, 2015 |
| Reference Material Production (from REMCO, not CASCO) | 17034 | 2016 |

ISO/CASCO Standards (1)

Common Elements in Conformity Assessment Standards

| Subject | Document | Publication date |
|---|----------|------------------|
| Impartiality | 17001 | 2005 |
| Confidentiality | 17002 | 2004 |
| Complaints and Appeals | 17003 | 2004 |
| Disclosure of Information (Transparency) | 17004 | 2005 |
| Use of Management Systems | 17005 | 2008 |
| All now withdrawn and part of ISO CASCO Directives Part 2 | | |

Hierarchy of Standards

17065

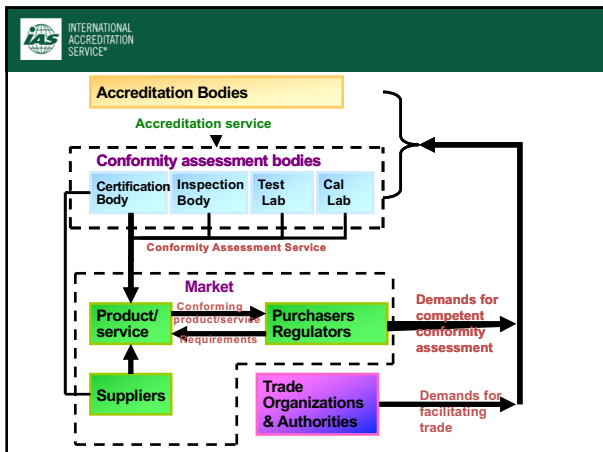
Knowledge of the science and use of professional judgment to determine conformance – some is subjective.

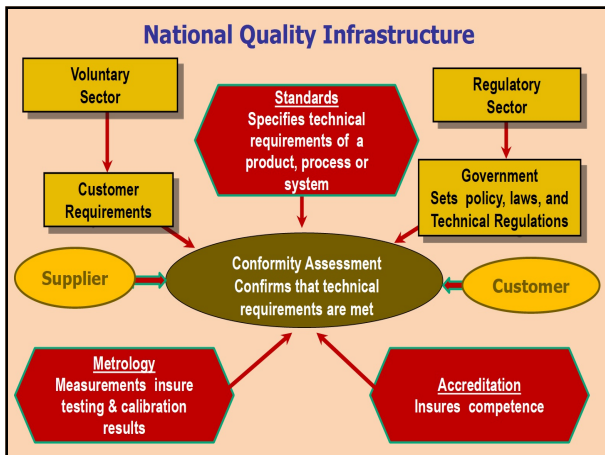
17020

Knowledge of the science and use of professional judgment to determine conformance – primarily objective.

17025

Knowledge of the science – objective test and calibration results.

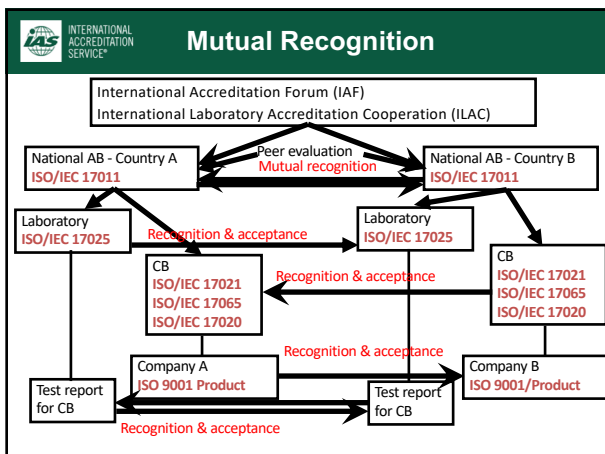




Part of the National Quality Infrastructure

The National Quality Infrastructure describes the main NQI components important for each nation. These are:

- Metrology – A national metrology institute signatory to the international agreements on metrology. Calibration.
- Standardization – This means the use of standards and technical regulations.
- [Conformity Assessment – Testing, calibration, inspection, certification, proficiency testing, reference materials, and accreditation.](#)
- Accreditation – Accreditation of conformity assessment bodies and internationally recognised by ILAC, IAF and their regions.





Conformity Assessment Principles

Lets review the Conformity Assessment Principles on page 8 of the Course Handbook.

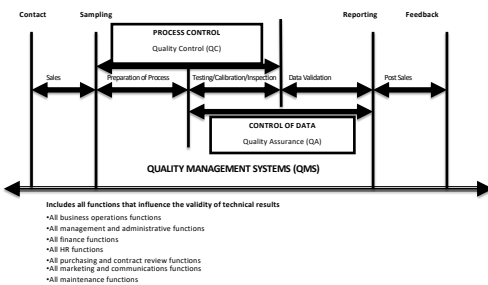


ISO/IEC 17020:2012

- “Conformity assessment — Requirements for the operation of various types of bodies performing inspection”
- Principles and requirements for the competence, consistency and impartiality of the inspection bodies inspecting **designs, products, processes, services and installed plant.**



The Scope of IB Operations



Inspection

- More involved than testing and calibration.
- Less involved than product, service or process certification
- Includes examination of installed plant (eg: medical gas piping systems)
- Requires full determination of conformance to requirements (technical standards and laws).
- Same quality system approaches as for product certification and calibration/testing.
- Inspection requirements are primarily driven by regulatory needs. The alternatives can be draconian.

Inspection Body Examples

- Welding inspection
- Building materials inspection
- Food safety (meat and plant) inspection
- Construction inspection
- Crime Scene Investigation
- Non-destructive inspection
- Software and Hardware inspections on electronic gaming devices
- Billboard structural inspection
- Plant inspection
- Air Quality inspection
- Label inspection

Inspection Processes

