INTERNATIONAL ACCREDITATION SERVICE®

- Introduction – Welcome and objectives
- Chapter 1 – Background and Principles of Certification
- Chapter 2 – Certification process Overview
- Chapter 3 – Safeguarding Integrity of Certification
- Chapter 4 – Certification body Organisation
- Chapter 5 – Certification body Resources
- Chapter 6 – Certification Processes
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INTERNATIONAL ACCREDITATION SERVICE®

Introduction and Welcome!!

- Aims of this Course
  - To provide accreditation body staff, regulatory staff, conformity assessment scheme designers, and assessors with a good understanding of the requirements in ISO/IEC 17065
  - Now let's get your objectives.
- Expected Result of this Course
  - Your ability to better appreciate all aspects of the international requirements for certification body operations, including those required by certification schemes.

Objectives

Our Contract (We work for you)

- We owe you:
  - ☐ Deference
  - ☐ Respect
  - ☐ Honesty
  - ☐ Some knowledge of the Subject Matter
- We want from you
  - ☐ ?

Written Materials

- The following materials are available to assist participants in this course. Lets examine the binders.
- Course Notes Binder
  - Tab 1 – Course Handbook
  - Tab 2 – Presentations (these slides)
  - Tab 3 – Reference Materials
    - » Generic ISO/IEC 17065 checklist
  - Tab 4 – Samples for Class Use
  - Tab 5 – Facilitator evaluation form and Quiz

Written Materials, (cont'd)

- All participants are requested to check mark each ISO/IEC 17065 clause examined during the course of these two days.
- After lunch on day 2, we will see what has not been touched to ensure all parts of the standard are covered.

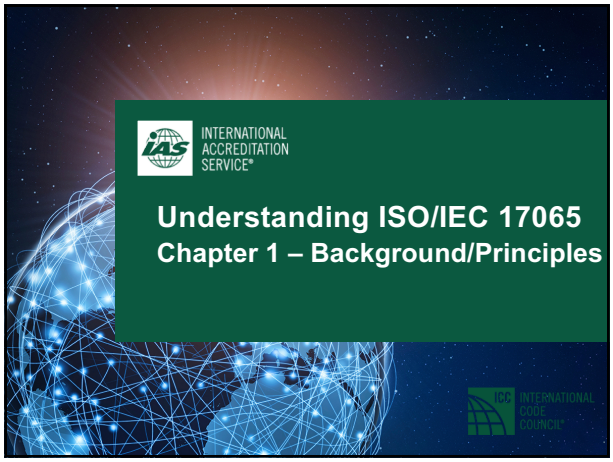
Applicant for Certification

Before proceeding, it is important to recognise that the product, process or service to be evaluated and certified is the "object for certification." The organisation and people who submit it for such evaluation is the client is for certification. We will refer to them as the "Applicant" and that term includes the following.

- applicant for certification;
- manufacturer using the process, or supplying the product that is the object of certification, and
- supplier of the product, process or service that is the object of certification.

Your Grade and My Grade

- Participants who wish to receive a Certificate of Successful Completion must participate in the discussion activities in each chapter and obtain 70% on the end-of-course quiz.
- We will score them collectively.
- You are all asked to evaluate the facilitator and this course. What happens to the evaluation? See the feedback on www.motiva-training.com.

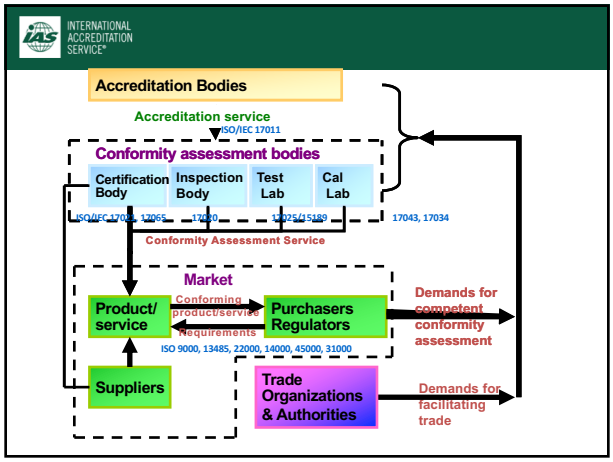


Rationale for Certification

- Public trust directly from stakeholders.
- Regulatory requirement (also aimed at public trust).
- Safety

Standards vs Regulations

Approach	Document / Specification	Specifier	Process
Regulatory Approach Mandatory	Regulation	Government	Inspection
Standardisation Approach Voluntary	Voluntary Standard	Market	Conformity Assessment



Consensus to Establish Trust

CBs ensure that all interested parties are part of the solution (from Annex A to 17065):

- the clients of the certification bodies;
- the customers of the organizations whose products are certified;
- governmental authorities;
- non-governmental organizations; and
- consumers and other members of the public.

Principles to Establish Trust

Annex A list and clauses affected in 17065

- Impartiality - 4.2, 4.4, 5.2, 7.6
- Competence – 6.1, 6.2, 7.1.3, 7.4.2
- Confidentiality and openness
  - Confidentiality - 4.5
  - Openness - 4.4
  - Access to information – 4.6, 5.2.2, 7.8
- Responsiveness to complaints and appeal – 7.13
- Responsibility - 4.1, 5.1, 6.1.2, 6.2.2.4, 7.4.5, 7.6, 7.7.2, 8.1, 8.2.3, 8.2.5

Certification Schemes

- Certification schemes are defined in ISO/IEC 17067.
- Certification schemes contain the requirements for the certification of products, processes and services.
- Scheme owners can be:
  - certification bodies;
  - governments and regulators;
  - non-government organisations;
  - industry and retail associations; and
  - consumer organisations.

Certification Schemes

Scheme owners can establish requirements for:

- pre-requisites for certification bodies;
- pre-requisites for the certification of conformant products, processes and services;
- scheme owner participation in the processes leading to either of the above;
- surveillance of products, processes and services for continued certification;
- sanctions to all other parties for failure to conform to their requirements, and
- supporting requirements such as cost recovery, legal liability, and conflict resolution.

Certification Scheme Types

Scheme types can be (from ISO/IEC Guide 67 & 17067):

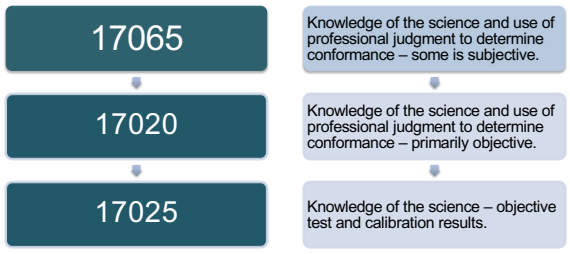
- Type 1a (Certification of specific samples only)
- Type 1b (Certification by lot number, such as aircraft type certification)
- Type 2 (Certification through continuing after-market testing)
- Type 3 (Certification through continuing production line testing)
- Type 4 (Certification through continuing comprehensive re-testing)
- Type 5 (Certification through continued audit of the manufacturer and products)
- Type 6 (Certification of processes and services)
- Review the list on page 10 of the Course Handbook

Certification Scheme Types

Minimum Certification Scheme Requirements:

- Determination of characteristics (evaluation)
  - testing,
  - inspection,
  - design appraisal,
  - assessment of services
- Technical Review (independent of evaluation)
- Decision on certification
- Surveillance (as required depending on scheme)

Hierarchy of the Standards



Commonality of Standards

All developed based on the ISO/PAS series of standards (now incorporated into ISO/CASCO Rules):

- ISO/PAS 17001 Impartiality;
- ISO/PAS 17002 Confidentiality;
- ISO/PAS 17003 Complaints and appeals;
- ISO/PAS 17004 Disclosure of information, and
- ISO/PAS 17005 Use of management systems in conformity assessment.

Commonality of Standards

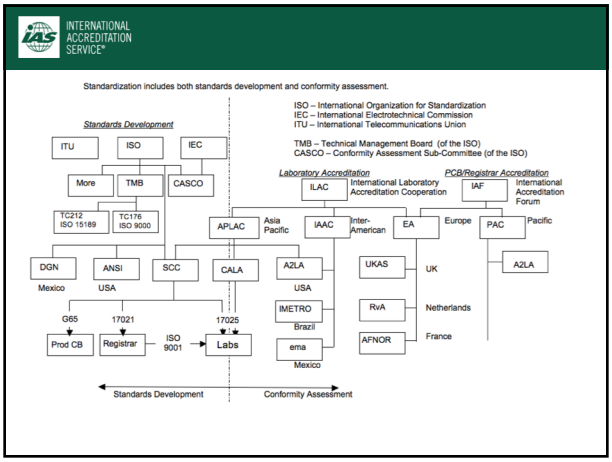
Common elements in all standards

- Organisation requirements;
- Management system requirements, responsibilities, confidentiality, impartiality, personnel and training, etc;
- Document control and control of records
- Feedback, including complaints;
- Disputes and appeals (where applicable);
- Handling of non-conformances through to corrective action (as appropriate);
- Handling of potential non-conformances and opportunities for improvement through to preventive action (as appropriate);
- Internal audit, and
- Management review

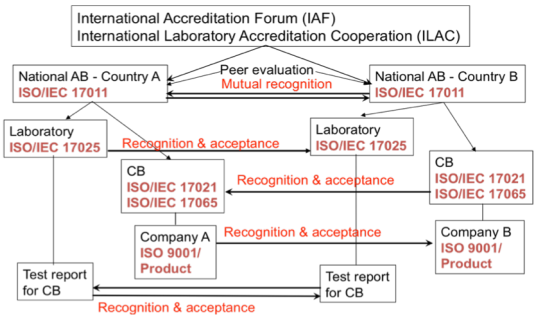
Commonality of Standards

Common look and feel

- Informative Preliminary Sections (Intro etc)
- Normative General Sections
- Normative Technical Sections
- Informative Supplementary Sections



International Application



Five levels of IAF Recognition

- Level 1 - ISO/IEC 17011, specifies the criteria for the Accreditation Body (AB).
- Level 2 - Accreditation Activities, in which the AB has demonstrated competence to perform accreditation as specified by the IAF endorsed generic accreditation normative documents listed in Level 3. IAF MLA accreditation activities are:
  - Management system certification
  - Product certification
  - Certification of persons

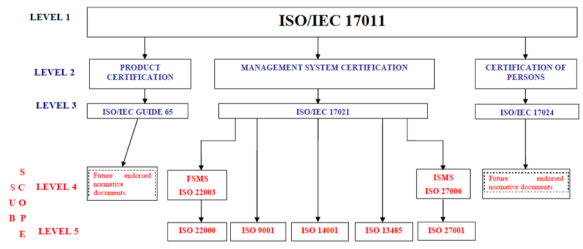
Five levels of IAF Recognition

- Level 3 - IAF endorsed generic accreditation normative document used by the AB to assess the Conformity Assessment Body (CAB) competence for each accreditation activity. For example:
  - For management system certification - ISO/IEC 17021
  - For product certification - ISO/IEC 17065
  - For certification of persons - ISO/IEC 17024

Five levels of IAF Recognition

- Level 4 – IAF endorsed sector specific normative documents which specify internationally recognized applications of the generic normative document listed in Level 3. The documents are used by the AB, in combination with the generic normative document listed in Level 3 to assess the CAB competence in the relevant sector. For example:
  - Normative document to be used in combination with ISO/IEC 17021:
    - For certification of food safety management systems (FSMS) – ISO/TS 22003;
    - For certification of information security management systems (ISMS) - ISO/IEC 27006.
  - Normative documents to be used in combination with ISO/IEC 17065:
    - None currently endorsed
  - Normative documents to be used in combination with ISO/IEC 17024:
    - None currently endorsed

Five levels of IAF Recognition

- Level 5 – IAF endorsed conformity assessment normative document used by CABs. For example:
  - Normative document used by Management System Certification Bodies
    - For certification of Quality Management Systems (QMS) - ISO 9001);
    - For certification of Environmental Management Systems (EMS) – ISO 14001;
    - For certification of Food Safety Management Systems (FSMS) - ISO 22000;
    - For certification of Information Security Management Systems (ISMS) - ISO/IEC 27001.
  - Normative document used by Product Certification Bodies
    - None currently endorsed

Five levels of IAF Recognition