



Training Program

June 21 and 22, 2014
Trainers:
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**Certification of Products,
Processes and Services
ISO/IEC 17065**

Lesson Learned




Programme Overview

- Materials Needed For Training
 - ISO/IEC 17000, current edition
 - ISO/IEC 17065, current edition
 - ISO/IEC 17025, current edition
 - ISO/IEC 17020, current edition
 - ISO/IEC 17021, current edition
 - ISO/IEC 17067, current edition




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Objective




- Provide lessons learned regarding assessments to ISO/IEC 17065
 - Relationship with other ISO/IEC standards
 - Relationship with scheme requirements
 - Common Non-conformances
- Present examples of assessment application of ISO/IEC 17065
- Share information on implementation




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Agenda - Day 1 - June 21




- Course Overview and Introduction
- Concepts and Definitions
- Introduction to ISO/IEC 17065 and related standards
- General Requirements Section 4
- Structural Requirements Section 5
- Resource Requirements Section 6
- Process Requirements Section 7
- Management System Section 8




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Agenda - Day 2 - June 22





- Application of Standards to Certification
- Exercise certification process
- Application of ISO/IEC 17067
- Presentation on status of participants
- IAF CASCO Interpretations
- Assessing certification body
- Questions & Wrap-up



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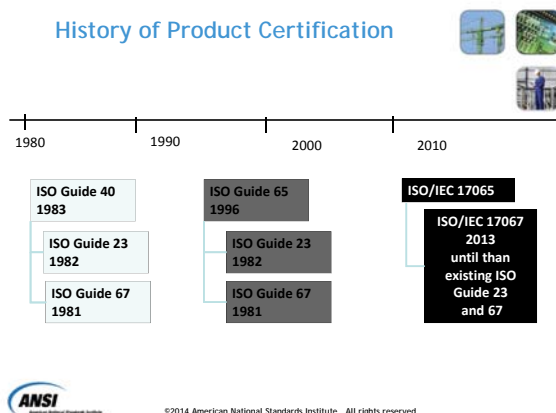
Introductions

- Trainers
- Participants


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History of Product Certification



Timeline showing the evolution of ISO/IEC standards:

- 1980-1983: ISO Guide 40 (1983), ISO Guide 23 (1982), ISO Guide 67 (1981)
- 1981-1982: ISO Guide 23 (1982), ISO Guide 67 (1981)
- 1982-1996: ISO Guide 65 (1996), ISO Guide 23 (1982), ISO Guide 67 (1981)
- 2010-2013: ISO/IEC 17065 (2013), ISO/IEC 17067 (2013) until then existing ISO Guide 23 and 67



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Purpose of Revision ISO Guide 65 to ISO/IEC 17065

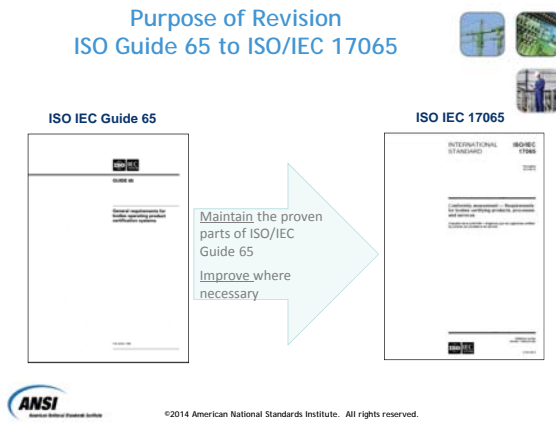




Diagram illustrating the revision process:

- ISO IEC Guide 65 (left)
- ISO IEC 17065 (right)
- Transition text: Maintain the proven parts of ISO/IEC Guide 65. Improve where necessary.




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ISO/IEC 17065




- Background
 - There has been a major change from the early 1990s to the present. Earlier, CBs were single-nation, single-legal entities, and ISO/IEC Guide 65 was based on that situation.
 - Today, CBs are embedded in multinational companies. The intent of ISO/IEC 17065 will be to apply to a range of entities - from simple companies to complex CBs.
 - WG recognized the ISO neutrality principle. Requirements had to be written to be used by anyone (auditors, scheme owners, product certification bodies). The goal was to minimize the need for IAF guidance. People can now ask for guidance from the ISO and the scheme itself rather than the IAF.




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ISO/CASCO WG 29
Revision of ISO/IEC Guide 65 – Product Certification




Resolution 7/2006 – CASCO Plenary
(Buenos Aires, Nov. 2006)

CASCO
notes the majority support expressed by the CASCO members to revise ISO/IEC Guide 65:1996 reported in CASCO 32/2006; and
agrees to revise Guide 65 and **instructs** the Secretariat to call for Working Group nominations from the members; and
decides that the first task of the WG is to draft a proposal for the scope and structure of the future standard ISO/IEC 17065, taking into account the functional approach described in ISO/IEC 17000. The proposal will be circulated for comment and approval to the CASCO members.




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ISO/CASCO




- ISO/CASCO can accept requests for clarification. There will be key WG members who will serve as a maintenance team and provide answers to questions, and that mechanism should be available on the web site.




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After Publication of ISO/IEC 17065 


- Presentation on 17065 that can be used by experts (<http://www.iso.org/iso/conformity-assessmentresources>)
- Comparison documents between 17065/ 65/ IAF Guidance
- Transition period for the CBs - 3 Years (Approved by IAF Plenary)
(September 2012 to September 2015)
- *IAF Informative Document for the Transition of Product Certification Bodies to ISO/IEC 17065:2012 from ISO/IEC Guide 65:1996, February 2014*

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Concepts 

- Principles
- Terms and Definitions
- Functional Approach
- Body versus Scheme


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ISO/IEC 17065 


- The intent of the ISO WG on 17065 was to create a document that is current with today's marketplace reality;
Scope
- The ISO/IEC 17065 involves certification bodies only, and it does not address [the worthiness of product requirements and schemes](#). In the real world, it is possible to have a fully compliant CB that operates an inadequate scheme and does comply with requirements.

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ISO/IEC 17065




The intent of ISO/IEC 17065 requirements will be to contribute to [the consistency, competence, and compliance of product certification bodies](#). While it makes every effort to assure that the product CB operates consistently, competently, and in compliance, it does not guarantee maximum confidence.




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ISO/IEC 17065




- The primary focus in ISO/IEC 17065:
 1. The difference between the product scheme and the product CB.
 2. ISO/IEC 17065 does not restrict the role of scheme owners, because there can be no discrimination allowed on the basis of type.
- ISO/IEC 17065 does NOT mandate how CBs develop schemes.




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ISO/IEC 17065




- In regard to process certification, there are two approaches:
 - (1) certification process itself (e.g., galvanizing steel) with its related process requirement (purity, etc.); or
 - (2) assessment of the process to ensure that output is suitable to the requirements.
- ISO/IEC 17065 allows both approaches to assess process.




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ISO/IEC 17065




- This IS specifies requirements, the observance of which is intended to ensure that the CBs operate certification schemes in a competent, consistent and impartial manner
- This IS does not set requirements for schemes and how they are developed and is not intended to restrict the role or choice of scheme owners, however scheme requirements should not contradict or exclude any of the requirements of this IS

Annex A – Principles Discussion




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Terms & Definitions




- ISO/IEC 17065 - General
 - every word matters!
 - requirements are independent - they do NOT cancel each other out - general AND specific
 - each requirement only once - but perhaps not where you expected
 - Scope 2nd Par & Annex B - requirements for process and service certification bodies




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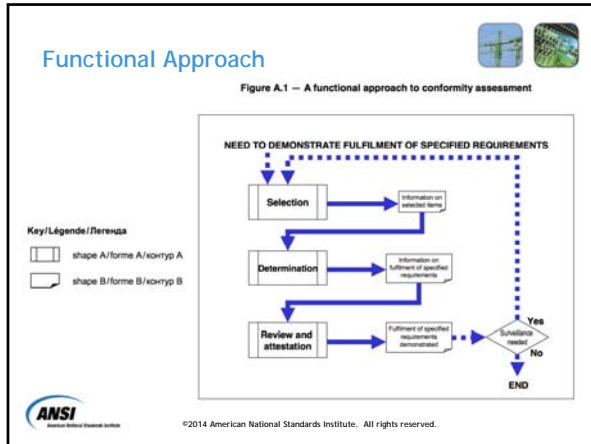
Terms & Definitions

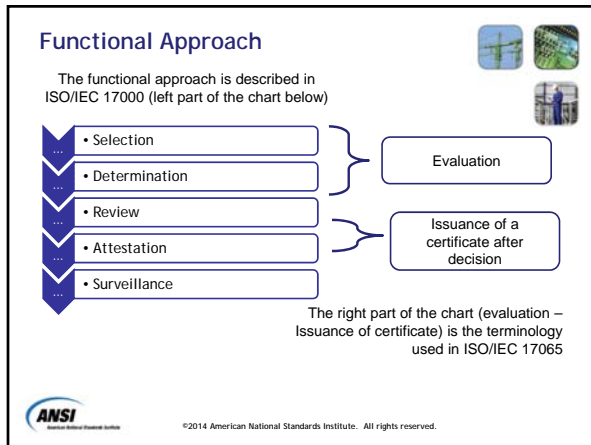


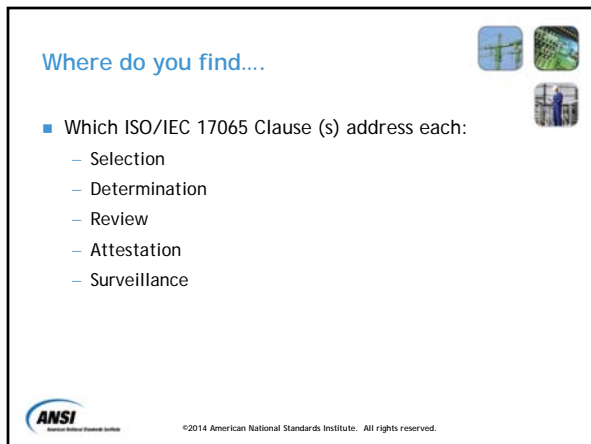
- ISO/IEC 17000 Plus ISOIEC 17065
 - Certification body (17065/17000)
 - Product (17065/17000)
 - Certification scheme (17065)
 - Consultancy (17065)
 - Impartiality (17065)
 - Review (17000)
 - Certification requirement (17065)
 - Product requirement (17065)



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Certification Scheme vs Certification Body



- The Scheme is all the activities and details of the process described generally by the Functional Approach
- The Body is the organization of people, facilities, equipment, etc. that carry out the scheme
 - Schemes by definition always exist
 - Bodies fill in what Schemes leave out
 - Conflicts between Schemes and ISO/IEC 17065
 - Process used by body to address differences



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Schemes must be understood



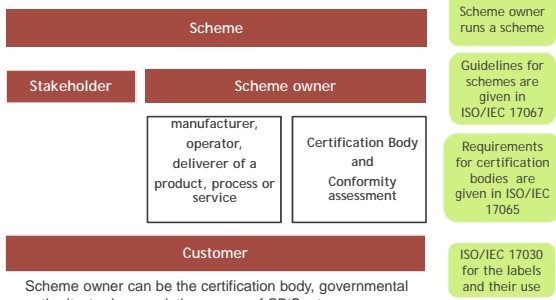
Certification schemes are mandatory part of product certification (ISO/IEC17065). The requirement to operate one or more certification schemes is contained in clause 7.1.1. The term "scheme" replaces the term "system" used in ISO/IEC Guide 65

ISO/IEC 17065 does not contain detailed requirements on certification schemes. Guidelines for understanding, developing, establishing, maintaining or comparing certification schemes for products, processes and services are provided in ISO/IEC 17067 "Fundamentals of product certification and product certification schemes"



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Relationship of certification body and scheme owner



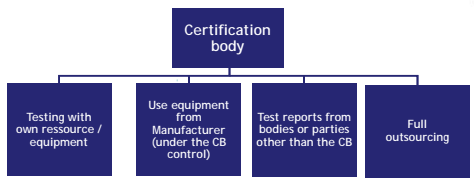
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ISO/IEC 17065 and Related Standards

- EVALUATION ACTIVITIES - ONLY
 - Internal Resources
 - Subcontracting or contracted personnel or services following procedures of CB
 - External Resources (Outsourcing)
- Meet applicable requirements of relevant International Standard and of other documents specified by the scheme.
 - Testing = ISO/IEC 17025
 - Inspection = ISO/IEC 17020
 - Management System auditing = ISO/IEC 17021

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Examples of resources used for testing, inspection and auditing



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graph TD
    CB[Certification body] --> T[Testing with own resource / equipment]
    CB --> E[Use equipment from Manufacturer (under the CB control)]
    CB --> R[Test reports from bodies or parties other than the CB]
    CB --> O[Full outsourcing]
          
```

All those examples are covered in Clauses 6 of ISO/IEC 17065

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Relationship with other standards

- ISO/IEC 17025 - Testing
- ISO/IEC 17020 - Inspection
- ISO/IEC 17021 - Management system auditing

What about other evaluation activities ?


Which standards from the above are applicable?

Can the CB use other standards if more relevant?


- Construction analysis
- Materials determination and analysis
- Toxicity determination
- Engineering judgment on changes
- Do you know of others?

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ISO/IEC 17065 Sections




1. Scope
2. Normative references
3. Terms and definitions
4. General requirements
5. Structural requirements
6. Resource requirements
7. Process requirements
8. Management system requirements




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Clause by Clause



- Section 4 General Requirements
- Section 5 Structural Requirements
- Section 6 Resource Requirements
- Section 7 Process Requirements
- Section 8 Management System Requirements

Please ask questions as we work through the standard



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General Requirements



- 4.1 Legal and contractual matters
- 4.2 Management of impartiality
- 4.3 Liability and financing
- 4.4 Non-discriminatory conditions
- 4.5 Confidentiality
- 4.6 Publicly available information



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4.1 Legal and contractual matters



- CB must be a legal entity
- Certification Agreement -
 - Client must agree to 11 specific items
 - Referenced or included in agreement?
 - Signed by one or both parties?
- Use of license, certificates & marks of conformity
 - Exercises control as specified by the scheme



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4.3 Liability and financing



- Adequate resources to cover liabilities
 - Insurance
 - Reserves
- Funding
 - Sustainable Operations
 - Source



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4.4 Non-discriminatory conditions




- CB policy & procedures shall not be used to impede or inhibit access by applicants
- CB makes services accessible to all applicants
- Access not conditional upon size of the client, membership or prior work submitted
- Business decision exceptions allowed



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4.5 Confidentiality



- Contractual agreements
 - Clients
 - Personnel - Internal & External
 - Subcontractors
 - Committee Members
- Subpoena Obligations

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4.6 Publicly available information



- Information about the certification scheme
- Disclosure of how the CB obtains financial support and fees charged
- Rights and Duties of applicants & clients
- Information on procedures for handling complaints & appeals.

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**Structural Requirements
Impartiality Requirements**



- 5.1 Organizational structure and top management
- 5.2 Mechanism for safeguarding impartiality
- 4.2 Management of impartiality

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5.1 Organizational structure and top management



- Document organizational structure of personnel & Committees. Show duties, responsibility and line of authority.
- Formal rules for the appointment of Committees
- Agreements between legal entities for services



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5.2 Mechanism for safeguarding impartiality



- Provides oversight on the management of impartiality
- Balanced interest representation
- Full access to information
- Ability to take independent action if proposals are ignored.



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Assessment Criteria




- Is there objective evidence that:
 - A process is followed
 - CB determines acceptable risk level
 - The conclusions are reasonable



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4.2 Management of impartiality

- No commercial, financial or other pressures to compromise impartiality (also 4.2.10)
- CB shall identify risks to impartiality on an ongoing basis.
- CB shall demonstrate how it eliminates/reduces risk
- Interrelationship with related legal entities
- Marketing & Sales (4.2.9)
- Applies to internal/external personnel & committees (4.2.12)

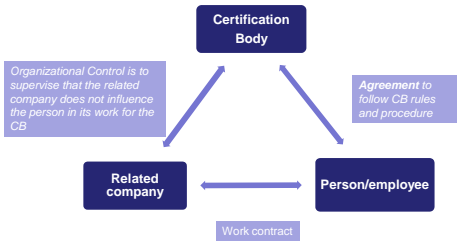
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CB - Ownership - Management

- 4.2.6 - Legal Entity or any part of the same entity shall not.... See list in standard
- 4.2.7 - CB and activities of separate legal entity
- 4.2.8 - Management, Review, Certification Decision
 - CB and other legal entity - not the same management if consultancy in other legal entity
- Organizational or business risks to impartiality often overlooked
 - Personnel impartiality usually very complete

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Possible Arrangement for Organizational Control




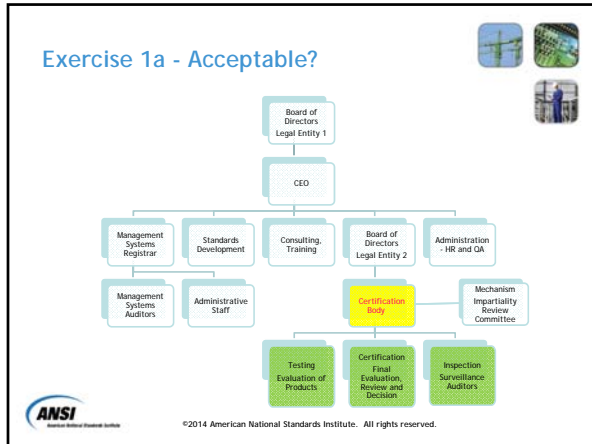
Organizational Control is to supervise that the related company does not influence the person in its work for the CB

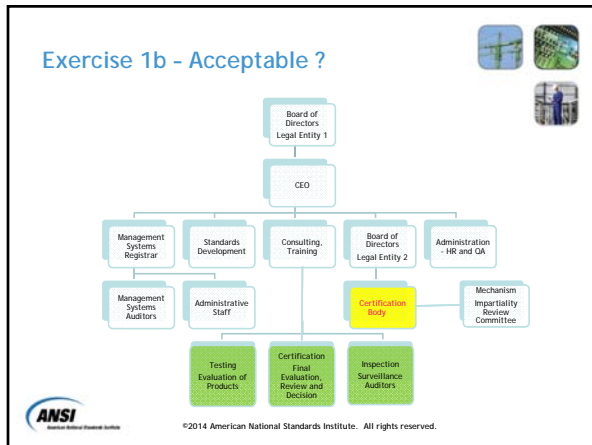
Agreement to follow CB rules and procedure

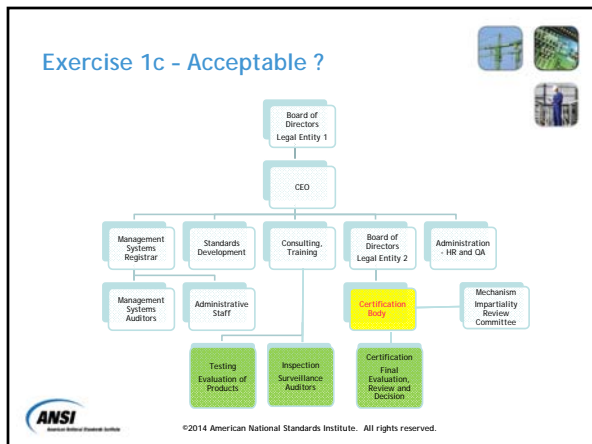
Work contract

This relates to Clause 7.6.4 of ISO/IEC 17065.
This is one possibility for organizational control among many


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Resource Requirements



- 6.1 Certification body personnel
- 6.2 Resources for evaluation

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Management of Competency



- The CB must apply procedures (6.1.2.1)
 - Determine competency criteria of each certification function
 - Identify the training requirements for each functional criteria
 - Have a means to determine demonstrated competency for the certification function
 - Have a process to appoint individuals for specific certification functions
 - Monitor the individual's functional performance

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Examples of Resources Personnel




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graph TD
    CB[Certification Body] --> OP[Own Personnel]
    CB --> FL[Free Lancer]
    CB --> RC[Related Company]
    OP --> WC[Work Contract]
    FL --> C[Contract]
    RC --> A[Agreement]
  
```


All those examples are covered in Clause 6 of ISO/IEC 17065

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Competency 


- The Certification Body personnel shall be competent for the functions they perform - 6.1.1.2
 - Technical judgments
 - Defining policies and implementing them
- Includes:
 - CB employees and related body employees
 - Contract workers
 - Subcontractors

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Management of Functional Competency 


- Determine Criteria for Functional Competence
- Education & Training needs to meet criteria
- Objective Evidence that personnel meet the criteria
- Authorize personnel for functions in the Certification Process and show Competency Matrix
- Monitor Functional Competence

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Functional Competency 

Which of these activities are part of the certification process?


| | |
|--|--|
| - Quoting, Sales, Marketing | - Corrective action review |
| - Agreement | - All evaluation activities completed report/records |
| - Application assistance by CB personnel | - Review |
| - Application review | - Decision |
| - Selection of evaluation activities (plan) | - Issuance of Certification Documentation |
| - Evaluation Activities (testing, inspection, management system auditing, other items needed for determination of conformance) | - Surveillance |
| - Report on evaluation | - Termination/Withdrawal |
| | - Suspension |
| | - Extending/Reducing Scope |
| | - Complaints/Appeals |

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Records




- Personnel in process (6.1.2.2)
 - Employer (often overlooked)
 - Competence assessment
 - Authorizations (new item for most)
- Contract with personnel in process (6.1.3)
 - Internal resource
 - External resource (discussion)




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Exercise 2 - Situation 1




- The CB establishes & maintains a procedure for management of technical competencies.
- Identify the requirement clause and present the possible objective evidence
 - The technical competency for each function in the certification process
 - The criteria for competence for each function in the certification process
 - The objective evidence that individuals have the required competencies
 - The authorization of personnel to perform functions in the certification process
 - The CB monitoring of the performance of the technical staff




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Exercise 2 - Situation 2



- Medical devices are certified by the CB for electrical shock, fire and mechanical hazard.
- The standard was revised to include clinical essential performance, risk management and required conformity to corollary (required) standards.
- The CB staff has demonstrated a strong background in electrical shock, mechanical and fire hazards.

Does the CB have the competence to perform this revised standard? What can they do?
(Identify clause and your rationale)



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Exercise 2 - Situation 3



- The scheme has no criteria for competency
- The CB competency for the reviewer (7.5) and decision maker (7.6) is defined as:
 - Understanding and knowledge of certification activities
 - Five years experience in certification body
 - Management system auditing experience
 - Education in college or university
 - (no technical qualifications, such as food specialist, engineering, other sciences are designated)
- Is this acceptable?



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Process Requirements



- 7.1 General
- 7.2 Application
- 7.3 Application review
- 7.4 Evaluation
- 7.5 Review
- 7.6 Certification decision
- 7.7 Certification documentation
- 7.8 Directory of certified products
- 7.9 Surveillance
- 7.10 Changes affecting certification
- 7.11 Termination, reduction, suspension or withdrawal of certification
- 7.12 Records
- 7.13 Complaints and appeals



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Process Requirements




- Application - provides the necessary info to complete the certification process
- Application Review - Justification to Certify
 - Identify differences in understanding
 - Confirm Scope of Certification
 - Agreement on Standards & normative documents
 - Adequate means to evaluate the product
 - CB has competence & capability to Certify
 - New & innovative products - justification 7.3.3
 - Modifications & Transfers - 7.3.5




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Process Requirements




- **EVALUATION**
 - Evaluation Plan defines tasks
 - Sampling, testing, inspection, audit
 - Quality Management
 - Construction - Drawings
 - Assignment of Staff, Competency
 - Information available to perform tasks
 - Document Evaluation Results - Opinion




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Process Requirements




- **REVIEW**
 - CB shall assign person
 - Review by person not involved with evaluation process
 - Recommendation for certification documented
 - Reviewer can make the decision on certification




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Process Requirements



- **Decision on Certification**
 - Certification Body responsible for its Decision on Certification
 - Can be committee not involved with the evaluation process
 - Performed by employee or contractor or an entity under the organizational control of the CB
 - CB's organization control: whole or majority ownership by the CB; majority participation on the Board of another entity; documented authority over another entity linked by ownership or board of director control



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Process Requirements




- Certification Documentation
 - After certification agreement signed
 - Certification Requirements fulfilled
 - The decision to grant certification has been made
 - Expiration date
- Directory of Certified Products
 - CB or Scheme Owner
- Surveillance
 - Mark of Conformity
 - Product, Service or Process - Handling of Variations




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Process Requirements




- Changes affecting Certification
 - Driven by the Scheme
 - CB responsible for communicating changes to its clients
 - CB shall verify implementation by client
 - Product changes
 - Contract Terms - Design Changes
 - Evaluation, Review, Decision, Certification Documents
 - Management changes
 - Key staff
 - Location




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Process Requirements




- Termination
- Reduction
- Suspension
- Certification
- Records
 - Confidentiality
 - Retention




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Process Requirements




- Complaints & Appeals
 - Documented Process
 - Record & Track
 - Information Gathering
 - Investigated by person outside the process
 - Decision & actions taken
 - Challenge

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Confidentiality Clauses




- 4.5 Confidentiality
- 5.2.3 Safeguarding impartiality
- 6.1.1.3 Personnel keep information confidential
 - 6.1.3 Contract with personnel
- 6.2.2.3 Outsourcing
- 7.12 Records remain confidential
- 8.4.2 Records control
- Annex A (Informative)

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Procedure Clauses



- 4.6 Information about procedures for certification
- 6.1.2 Management of competencies
- 6.2.2.4.c Qualifications and monitoring personnel
- 8.4 Records control
- 8.5 Management review
- 8.6 Internal audits
- 8.7 Corrective actions
- 8.8 Preventive action

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Record Clauses



- 6.1.2.2 Personnel records
- 7.3.3 Justification for decision to undertake certification
- 7.10.3 Record of rationale for excluding any activity
- 7.12 Records required
- 7.13 Complaints and appeals
- 8.4 Control of records



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Exercise 3 - Background



- A certification body has acquired a company in another country. It plans to offer certification services from the new location.
- The CB has formal staff technical competency requirements
- The local staff in the new country has not achieved competency
- Staff in training can conduct project management. A fully qualified coach is providing technical training and assistance to the staff in training
- The Reviewer is fully competent technically.



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Exercise 3 - Situation 1



- The project manager meets the technical competency requirements
- The reviewer verifies the technical aspects of the project
- The person making the decision on certification verifies that all the certification process elements are fulfilled (non technical)

Determine if the situation complies with ISO/IEC 17065:
Identify the Clause(s)



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Exercise 3 - Situation 2



- The project manager meets the technical competency requirements.
- The reviewer verifies the technical aspects of the project and that all the certification process elements are fulfilled.
- The reviewer makes the Decision on Certification

Determine if the situation complies with ISO/IEC 17065:
Identify the Clause(s)



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Exercise 3 - Situation 3



- The project manager is in training and the Coach signs the evaluation report.
- The Coach is fully competent and performs the role of the Reviewer.
- Another person makes the decision on certification after verification that all the certification process elements are fulfilled.

Determine if the situation complies with ISO/IEC 17065:
Identify the Clause(s)



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Exercise 3 - Situation 4




- The laboratory sends a report to the CB which includes a statement that the results comply with the standard.
- The report goes directly to the Reviewer who verifies that the technical requirements have been met.
- Another person makes the decision on certification after verification that all the certification process elements are fulfilled.

Determine if the situation complies with ISO/IEC 17065:
Identify the Clause(s)




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Management System Requirements




- 8.1 Options
- 8.2 General management system documentation
- 8.3 Control of documents
- 8.4 Control of records
- 8.5 Management review
- 8.6 Internal audit
- 8.7 Corrective actions
- 8.8 Preventive actions




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Section 8.1.3 - Options




- Management system requirements
 - internal process for self-assuring fulfillment of ISO/IEC 17065
- Option A
 - Sections 8.2 to 8.8
- Option B
 - an ISO 9001 QMS that takes account of the specific requirements in the sections 8.2 to 8.8 of ISO/IEC 17065 is an option
 - annex to ISO/PAS 17005:2008 shows how the ISO 9001 requirements would need to be read for meeting 8.1.3
 - 6 pages of commentary (based on ISO 9001:2000)
 - ISO 9001 current version is 2008




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General Management System



- Documentation
 - Commitment to ISO/IEC 17065
 - Authority and responsibility for meeting ISO/IEC 17065
 - All information documented and linked to management system
 - Access to documents by all personnel




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Requirements more prescriptive




- Document Control
- Record Control
- Management Review
- Internal Audit
- Corrective Action
- Preventive Action




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End Day 1




- Day 2 - Coming Tomorrow
 - Applications of related standards in process
 - Scheme requirements
 - Status of implementation by participants
 - IAF CASCO interpretations
 - Common non-conformances




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Application of Related Standards




- ISO/IEC 17025
- ISO/IEC 17020
- ISO/IEC 17021




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ISO/IEC 17025




- Testing part of evaluation
 - Remember: General requirements for the competence to carry out tests and calibrations using standard methods, non-standard methods and laboratory developed methods.
- The CB must review the test data in order to perform an evaluation of the information provided and ensure it is appropriate for the product evaluation.




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ISO/IEC 17025




- Are the following applicable?
 - Equipment calibration at manufacture's site
 - Quality control testing during or end of production
 - Testing of product by manufacturer
 - "go" "no-go" testing (yes/no, on/off, presence/absence)




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ISO/IEC 17020




- Inspection part of evaluation
 - What about auditing - Is it inspection?
 - What if scheme defines audit/inspection but not ISO/IEC 17020 based?
 - What if CB defines audit/inspection not using ISO/IEC 17020?
 - Inspection performed remotely
 - One time for life of certification




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ISO/IEC 17021




- Management system auditing part of evaluation
 - What if not ISO/IEC 9000 requirements
 - CB defines management system elements not based on ISO/IEC 9000
 - Scheme defines system elements not based on ISO/IEC 9000




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Relevant requirements




- ISO/IEC 17065 indicates relevant requirements of related standards.
 - Who determines what is relevant?
 - Does the assessor write a nonconformance if he/she does not agree with what is relevant as determined by the scheme? by the CB?
 - Does the AB need a process to accept or not the decision of the CB or the scheme?




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Exercise 4 - Situation 1



- A CB does not have the internal competency to perform technical evaluation or review of the test report submitted by an accredited ISO/IEC 17025 lab.
- Should the CB: (select one of the following)
 - Accept the laboratories assessment of compliance
 - Refuse to certify the product due to its internal technical limitations
 - Subcontract with an external technical expert or firm having the required technical competencies
 - Develop an independent contractor arrangement with a person having the required technical competencies
- For your selection, what are the risks to impartiality and how are they safeguarded?
- What objective evidence would you expect to see in order to satisfy clause 6.1.3? (Internal and external resource)



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Exercise 4 - Situation 2



- The test data is generated prior to application for certification.
 - Can the test data be used for certification?
 - What process must be used by the CB for acceptance of the test data?
 - What are the applicable clauses of ISO/IEC 17065



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Exercise 4 - Situation 3



- What if test data is from:
 - 1. accredited test laboratory to ISO/IEC 17025
 - 2. test data generated and witnessed by CB personnel
 - 3. test laboratory with self declaration to ISO/IEC 17025
 - 4. manufacturer's laboratory accredited to ISO/IEC 17025
 - 5. manufacturer's quality control laboratory
 - How should each of these be handled by the CB?
 - Identify ISO/IEC 17065 Clause to support you rationale



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Application of Scheme ISO/IEC 17067




- Elements of Scheme
- Assessment to Scheme requirements
- AB review and acceptance of Scheme
- Scheme contradicts or excludes ISO/IEC 17065 requirements




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Schemes - Assessment




- CB scheme
 - Must have document that defines scheme requirements to address ISO/IEC 17065 requirement
 - Not addressed as clearly in ISO/IEC Guide 65
- Non-CB schemes
 - Scheme does not address ISO/IEC 17065 requirement
 - Scheme contradicts requirement
- The next several slides present where in the standard scheme requirements are found




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Scheme Elements




- 4.1.2.2.f - Withdrawal, suspension, termination
- 4.1.2.2.g - Certification documents
- 4.1.2.2.h - Reference to product certification
- 4.1.2.2.i - Use of mark, product information
- 4.1.3.1 - Control over license, certificates, mark
- 4.1.3.2 - Incorrect use
- 4.2.6.e - Scheme may specify management system requirement
- 4.2.10 Note 1 Period specified for consultancy
- 4.6.a - Public information on certification




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Scheme Elements




- 5.2.1.c Note 2 and 3 - Impartiality
- 5.2.4 Note 2 - limited interests
- 6.1.1.1 - Personnel
- 6.1.1.3 - Confidential information
- 6.1.2.1.a - Personnel competence criteria
- 6.1.2.1.b - Personnel training
- 6.2.1 - Internal Resources
- 6.2.2.1- External Resources
- 6.2.2.4 Note - qualifications of outsourced bodies




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Scheme Elements




- 7.1.1 - Operate scheme
- 7.2 - Application
- 7.3.2 - Identify scheme
- 7.4.1 Note - Plan, general or specific
- 7.4.4 - Evaluation activities
- 7.4.5 - Evaluation results before application
- 7.4.9 Note 1 and 2 - Evaluation results
- 7.7.f - Information
- 7.8 - Directory
- 7.9.1 - Surveillance




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Scheme Elements




- 7.10.1 - Changes affecting certification
- 7.10.3 - Documentation of revised surveillance activities
- 7.11.3 - Termination
- 7.11.4 - Suspension
- 7.11.5 - Suspension
- 7.12 - Records
- 7.12.3 - Re-evaluation
- 8.2.1 - Management system
- 8.5.2 Note - Scheme owners as interested party




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Schemes




- What actions must the AB consider when:
 - Scheme contradicts ISO/IEC 17065
 - Scheme indicates certain clauses are not applicable
 - Not all requirements are implemented to meet ISO/IEC 17065
 - Scheme does not update or reference ISO/IEC 17065




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Transition




- Accreditation Body Transition Policy
 - Communicated to certification bodies
 - Communicated to schemes
- When schemes do not make transition
 - When and what is communicated
 - The next slides present some possibilities




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Gap Analysis or Full Assessment




- Full ISO/IEC 17065 not performed if scheme owner has not updated to ISO/IEC 17065.
 - For example, SQF, BRC, AECO, TCB, Energy Star, WaterSense, WaterMark, SFI/PEFC, etc.
 - The Scheme owner needs to decide what to do
 - Guidance or criteria from scheme owner related to ISO/IEC Guide 65 is used during the assessment so scheme requirements for ISO/IEC 17065 are not available




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Gap Analysis or Full Assessment




- If the scheme belongs to the CB or scheme is updated to ISO/IEC 17065 - Then full assessment
- The CB must complete necessary changes and implement ISO/IEC 17065 - Then full assessment
 - CB shall change all the documents,
 - CB contact clients about the changes and request their comments,
 - CB must implement the new requirements or changes as appropriate
- Otherwise - Gap Analysis ???




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Presentations




- Please share...
 - Status of program
 - Lessons learned to date on transition
 - Scheme issues




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IAF CASCO Interpretation





- Available on IAF CASCO website
 - Interpretations
 - Maintenance Committee established
- AB providing explanations
 - Process defined for explanation development
 - Posted on website of AB



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ADD SLIDE ON INTERPRETATIONS

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Assessing a CB to ISO/IEC 17065

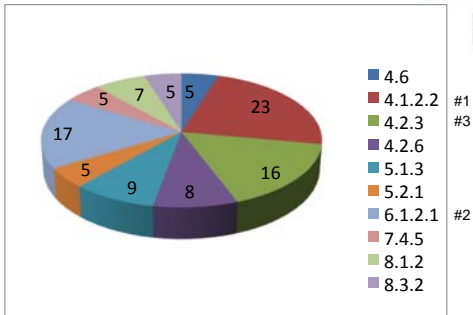


- Outcome depends on CB experience
 - Accredited to ISO/IEC 17021 - have impartiality mechanism
 - One legal entity with no relationships except testing and inspection bodies
 - Multinational CBs with over 100 legal entities - many for tax purposes but must be identified



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Common Non-conformances ANSI 2013



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Questions

- Any questions on any of the elements in ISO/IEC 17065?



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