Training Course

April 11, 2014
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Preparation by: Reinaldo Figueiredo

**Certification of Products,
Processes and Services
ISO/IEC 17065**

Are you ready for accreditation?

Objective

- Present the conformity assessment concepts for the certification of products, process and services as defined in ISO/IEC 17065
- Provide the certification body and others with the understanding of the requirements presented in ISO/IEC 17065

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Agenda

- Introduction and History
- Concepts and Definitions
- Scheme Terminology and Understanding
- Clause by Clause Understanding
  - Review by Example
- Conclusion - ANSI
- TCB Perspective
- A2LA Transition, Explanations, Information
- Panel Discussion

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Introduction

- ISO/CASCO - WG 29 Revision of ISO/IEC Guide 65
- ANSI/ICAC
- Timeline revision of ISO/IEC Guide 65 to ISO/IEC 17065
- Purpose of the Revision ISO/IEC Guide 65 to ISO/IEC 17065

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ISO/CASCO structure

- **124 ISO members** are represented in CASCO (76 participating members and 48 observers).
- Fifteen international organizations are **liaison members** of CASCO: BIPM, CEOC, CODEX Alimentarius, EOQ, Eurolab, IAF, IFAN, IFIA, IIOC, ILAC, IPC, IQNet, ITU-T, OIML, UILI.
- Both policy and technical work
- Continual improvement cycle
- CASCO Secretary acts as Secretary for ISO 9000 Advisory Group (IAG)

Promotion   Study and policy

Strategic Alliance and Regulatory Group (STAR)

Chairman's Policy and Coordination Group (CPC)

KMG

CASCO

WG

WG

WG

WG

WG

Technical Interface Group (TIG)

Technical support   Technical work

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ANSI
ICAC - International Conformity Assessment Committee

- Serve as the ANSI Committee responsible for working with the International Organization for Standardization (ISO) Committee on Conformity Assessment (CASCO) including providing U.S. representatives to working groups (from candidates proposed by ICAC and CAPC members), contributing to the technical development of international CA guides, reviewing ISO CASCO documents, recommending their approval by ANSI, providing ANSI representation at ISO CASCO meetings, and liaison with delegations from other countries to ISO CASCO Plenary meetings.

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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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Members of the WG-29 From the US

- Patricia Gleason – SEI
- Shahin Moinian – ICC-ES
- Gordon Gillerman – NIST
- Paul Moliski – Intertek and IAF- WG on Product Certification
- Keith Mowry – UL (Member of Drafting Group)
- Reinaldo B. Figueiredo – ANSI (Member of the Drafting Group)

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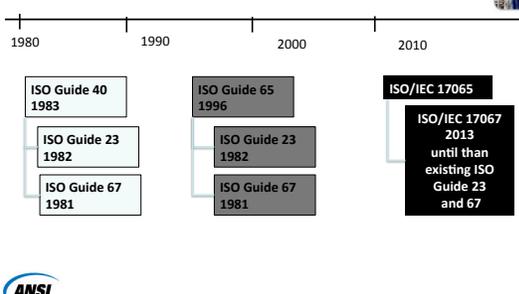

History and Relationship

1980   1990   2000   2010

ISO Guide 40
1983

ISO Guide 23
1982

ISO Guide 67
1981

ISO Guide 65
1996

ISO Guide 23
1982

ISO Guide 67
1981

ISO/IEC 17065

ISO/IEC 17067
2013
until than
existing ISO
Guide 23
and 67

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Purpose of Revision ISO Guide 65 to ISO/IEC 17065
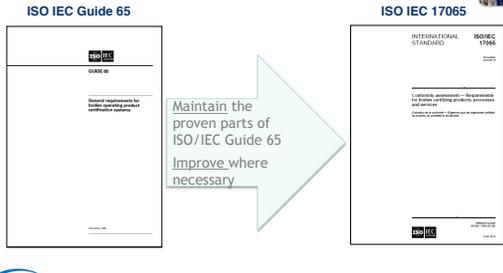
ISO IEC Guide 65

ISO IEC 17065

Maintain the proven parts of ISO/IEC Guide 65

Improve where necessary

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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 will NOT mandate how CBs develop schemes.
- More specifically addresses process and service certification.

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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/IEC 17065

- New concept: ISO/IEC 17065 had to be applicable to both simple organizations and complex CBs. This allows a mechanism to deliver services. How can requirements be written for a multinational corporation for certification decisions.
- Cohesive process
- The CB shall look at the scheme requirements
- It does not constrain the scheme requirements

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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

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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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Overview Changes – ISO/IEC Guide 65

- restructuring of the standard
- modifications based on ISO/PAS 17000 series
- introduction of the ISO/IEC 17000 functional approach in the process
- information on the application to processes and services
- revision of the terms and definitions
- improvement of the impartiality requirements
- consolidation of the management system requirements
- inclusion of principles for product certification bodies and their activities
- improvement by taking into account IAF Guidance and interpretations;
- inclusion of a reference to certification schemes

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Compared to ISO/IEC 65

- See CASCO website:
  - *www.iso.org/iso/ppt_presentation_17065.ppt*
- Our purpose in this class is to focus on the requirements and the implementation/assessment processes.
  - Presentations on comparisons are available.

Please ask questions as we work through the new standard

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After Publication of ISO/IEC 17065

- Communication after Publication
- Targeted Communication with IAF
- ---- Transition period – Defined by IAF
- ---- Avoid Guidelines
- # of ISO/IEC 17065 and ISO/IEC Guide 65
- Published article in ISO Focus Magazine (October 2012)
- Articles in Member bodies newsletters
- PPP on 17065 that can be used by experts , CB AB (ISO Website)
  (http://www.iso.org/iso/conformity-assessment_resources)
- Comparison documents between 17065/ 65/ IAF Guidance (ANSI developed a Cross reference table)
- Discussion with everybody for selling the new standard
- Transition period for the CBs – 3 Years (Approved by IAF Plenary) (September 2012 to September 2015)

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ISO/IEC 17065

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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General

- 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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Concepts

- Section 3
  - ISO/IEC 17000
    - Concepts
    - Functional Approach
    - Body versus Scheme
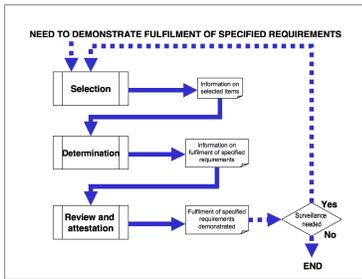
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Functional Approach

Figure A.1 — A functional approach to conformity assessment

NEED TO DEMONSTRATE FULFILMENT OF SPECIFIED REQUIREMENTS

Key/Légende/Легенда

shape A/forme A/контур A

shape B/forme B/контур B

Selection — Information on selected items

Determination — Information on fulfilment of specified requirements

Review and attestation — Fulfilment of specified requirements demonstrated

Surveillance needed — Yes / No

END

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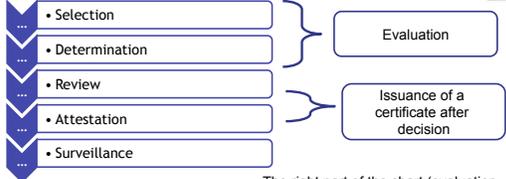
Functional Approach

The functional approach is described in ISO/IEC 17000 (left part of the chart below)

- Selection
- Determination
- Review
- Attestation
- Surveillance

Evaluation

Issuance of a certificate after decision

The right part of the chart (evaluation – Issuance of certificate) is the terminology used in ISO/IEC 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 will be provided in the future ISO/IEC 17067 "Fundamentals of product certification and product certification schemes"

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Relationship of certification body and scheme owner
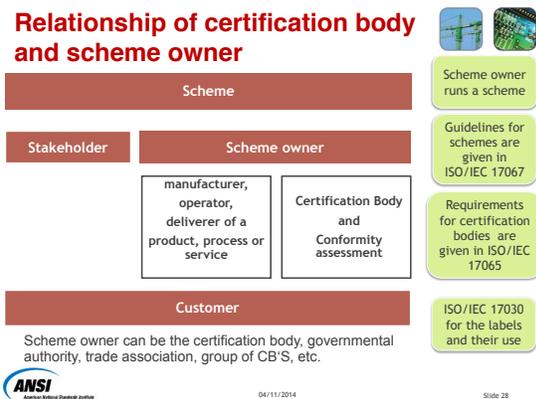
Scheme

Stakeholder	Scheme owner

manufacturer, operator, deliverer of a product, process or service	Certification Body and Conformity assessment

Customer

Scheme owner can be the certification body, governmental authority, trade association, group of CB'S, etc.

- Scheme owner runs a scheme
- Guidelines for schemes are given in ISO/IEC 17067
- Requirements for certification bodies are given in ISO/IEC 17065
- ISO/IEC 17030 for the labels and their use

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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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Section 4 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
- Use of license, certificates & marks of conformity
  - Exercises control as specified by the scheme

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4.2 Management of Impartiality

- No commercial, financial or other pressures to compromise impartiality
- 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
- Applies to internal/external personnel & committees

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CB - Ownership - Management

- Review 4.2.6 – Legal Entity or any part of the same entity shall not…. See list in standard
- Review 4.2.7 – CB and activities of separate legal entity
- Review 4.2.8 –
  - Management, Review, Certification Decision
  - CB and other legal entity – not the same management

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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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Section 5 Structural Requirements

5.1 Organizational structure and top management

5.2 Mechanism for safeguarding 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

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5.2 Mechanism for safeguarding impartiality

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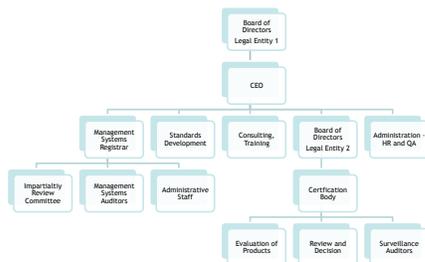- Ability to take independent action if proposals are ignored.

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Example

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CB's Impartiality Risk Management

Use of ISO 31000 is not required

Process Elements – Example

•Step 1 - Identify the threat to impartiality
•Step 2 - Determine the effect of impartiality, What is acceptable risk?
•Step 3 - Evaluate the risks and decide on precautions (Control Measures to Mitigate Risk)
•Step 4 - Record your findings and implement Control Measures
•Step 5 - Review your assessment periodically and update if necessary

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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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Section 6 Resource Requirements

6.1 Certification body personnel

6.2 Resources for evaluation

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Management of Competency

- The CB must apply uniform procedures
  - 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 used for testing, inspection and auditing

```
                    ┌─────────────────┐
                    │  Certification  │
                    │      body       │
                    └────────┬────────┘
        ┌──────────┬─────────┼──────────┬──────────┐
┌───────────┐ ┌───────────┐ ┌───────────┐ ┌───────────┐
│ Testing   │ │ Use       │ │ Test      │ │           │
│ with own  │ │ equipment │ │ reports   │ │   Full    │
│ ressource/│ │ from      │ │ from      │ │outsourcing│
│ equipment │ │Manufacturer│ │bodies or  │ │           │
│           │ │(under the │ │parties    │ │           │
│           │ │CB control)│ │other than │ │           │
│           │ │           │ │the CB     │ │           │
└───────────┘ └───────────┘ └───────────┘ └───────────┘
```

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

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Examples of Resources Personnel

```
                 ┌────────────────────┐
                 │ Certification Body │
                 └──────────┬─────────┘
        ┌──────────────────┼──────────────────┐
┌──────────────┐   ┌──────────────┐   ┌──────────────┐
│ Own Personnel│   │ Free Lancer  │   │Related Company│
└──────┬───────┘   └──────┬───────┘   └──────┬───────┘
   ┌───────────┐      ┌──────────┐        ┌───────────┐
   │Work Contract│    │ Contract │        │ Agreement │
   └───────────┘      └──────────┘        └───────────┘
```

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

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6.2 Resources for Evaluation

- EVALUATION ACTIVITIES – ONLY
  - Internal
    - Subcontracting
  - External (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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Management of Functional Competency

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

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Section 7 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

Process Requirements

- Complaints & Appeals
  - Documented Process
  - Record & Track
  - Information Gathering
  - Investigated by person outside the process
  - Decision & actions taken
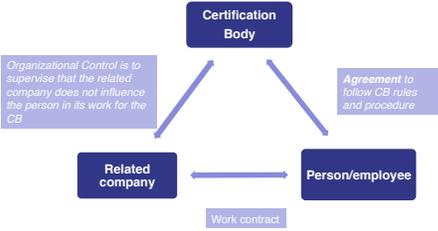 - Challenge
  - Levels of Appeal – ANSI PRO-PR-141

Possible Arrangement for Organizational Control

```
                    Certification
                       Body

Organizational Control is to                    Agreement to
supervise that the related                      follow CB rules
company does not influence                      and procedure
the person in its work for the
CB

    Related                            Person/employee
    company
                    Work contract
```

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

Confidentiality

- 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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Procedures

- 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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Records

- 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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FCC TCB

Scheme	Selection	Determination	Review Attestation	Surveillance	Other
FCC Telecommunications and Radio Equipment (R&TCB)	TCB Roles and Responsibilities KDB641163 6 47 CFR Parts 0 through 101 FCC Rules	47CFR Parts 0 through 101 FCC Rules; TCB Roles and Responsibilities KDB641163	FCC Rules; TCB Roles and Responsibilities KDB641163	FCC Surveillance Paper 47 CFR 2 KDB 610077 TCB Program Roles and Responsibilities KDB641163	FCC Knowledge Database (KDB)

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Section 8 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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Conclusion

- IAF
- ANSI
- Summary
- Remaining Questions

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Transition

- IAF Deliberations
  - Time frames and obligations
- ANSI Accreditation Transition
  - ANSI Accreditation Process for products since 1972
    - Policies and procedures
    - Transition period (ISO/IEC Guide 65 to ISO/IEC 17065)
    - PRO-NT-114 release April 2013

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ANSI Implementation Underway

- Gap Analysis performed since July 2013
- Full Assessment to ISO/IEC 17065 for some CB's
- Explanations maintained
  - Task Group formed "Matters related to ISO/IEC 17065"
    - 6 members
    - Publish Explanations on ANSI Standards Action
      - https://www.ansica.org/wwwversion2/outside/PROISOIEC17065Explanations.asp?menuID=1
    - Not Interpretation, guidance or clarification
    - Interpretations handled through ANSI-ICAC and ISO/CASCO/WG-29 Maintenance Group
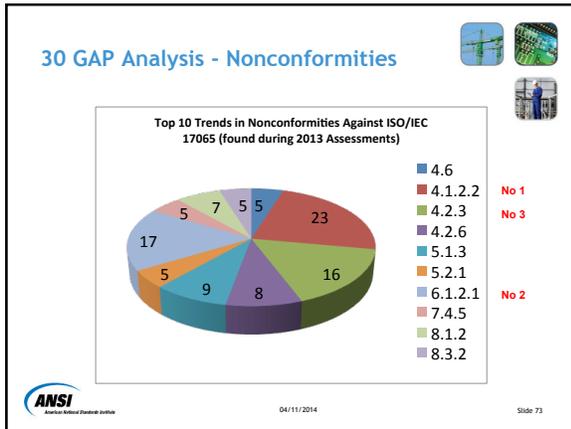
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30 GAP Analysis - Nonconformities

Top 10 Trends in Nonconformities Against ISO/IEC 17065 (found during 2013 Assessments)

- 4.6
- 4.1.2.2 — No 1
- 4.2.3 — No 3
- 4.2.6
- 5.1.3
- 5.2.1
- 6.1.2.1 — No 2
- 7.4.5
- 8.1.2
- 8.3.2

23, 16, 8, 9, 5, 17, 5, 7, 5, 5

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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, 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

- TCB - Gap Analysis for FCC program
  - PRO-NT-114 indicates July 1 2014 is being extended awaiting decision from FCC
  - Notice of Proposed Rulemaking in ET Docket No. 13-44 (FCC 13-19)
  - TCB Program Roles and Responsibilities, April 4, 2014
  - Other TCB programs require review

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