

Comparison ISO/IEC 17011 & Guide 61

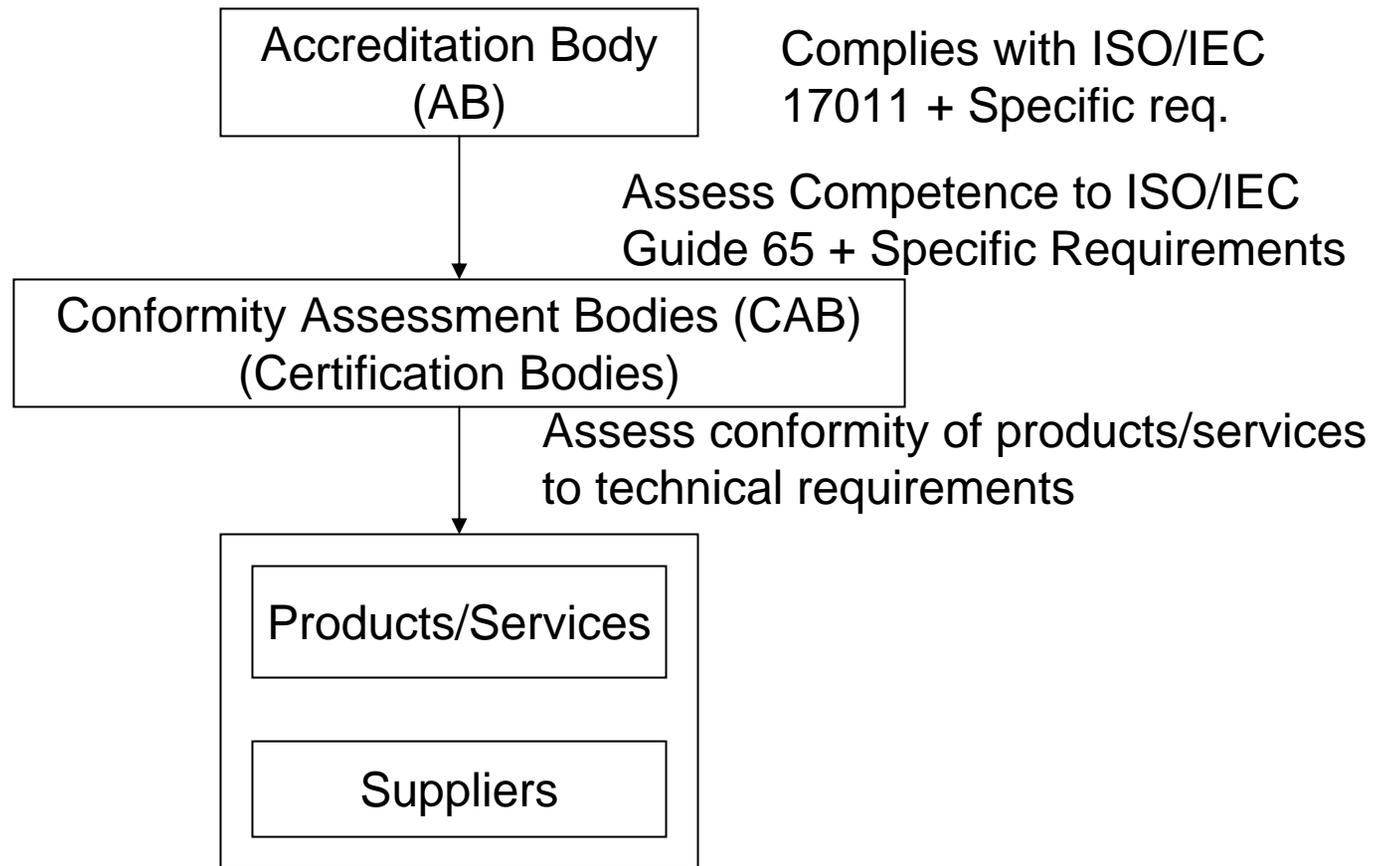
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General Information

- ISO/IEC 17011 published on September 1, 2004
- Replaces
 - ISO/IEC Guide 58:1993; Accreditors of Labs
 - ISO/IEC Guide 61:1996; Accreditors of Certifiers
 - ISO/IEC/TR 17010:1998; Accreditors of Insp. Bodies
- Similar repetitive texts
- Implementation by ABs - January 1, 2006

Product Certification Flow Chart



Scope (1)

- 17011 scopes includes accreditation bodies for
 - Testing & Calibration
 - Inspection
 - Management System Certification
 - Personnel Certification
 - Product Certification
- AB need not operate accreditation in all areas
- This Presentation is limited to:
 - accreditors of certification bodies

Normative References (2)

- Reference to old documents has been replaced by normative references to:
 - ISO/IEC 17000:2004; CA-Vocabulary and general principles
 - ISO 9000:2000; QMS-Fundamentals and Vocabulary
 - VIM 1993; International vocabulary of basic and general terms in metrology

Definitions (3)

- Accreditation Symbol & Mark: Distinction identified
 - Accreditation Symbol issue by an AB to a CAB
 - Mark indicates conformity of an entity against set of requirements
- Appeals & Complaints: Difference clarified
 - Appeal by a CAB against an adverse action by the AB
 - Complaint by person/org against the AB or its accredited CAB
- Assessment: Definition expanded to include competency of the entire operation of CAB
 - Personnel competency
 - Validity of conformity assessment methodology
 - Validity of conformity assessment results

Definitions (3) Continued

- Consultancy: defined in more details
 - Preparing manuals and procedures for a CAB
 - Giving advice or training for development of management systems or operational procedures
- Interested Parties: differentiated between direct & indirect interest
 - Direct interest by those who undergo accreditation
 - Indirect interest by those who rely on accredited CAB services
- Surveillance: monitoring continued compliance with AB requirements
 - On-site assessment
 - Enquiries from AB to CAB
 - Reviewing scope claimed by the CAB
 - AB's request for access to internal audits, complaints/appeals, and management reviews

Accreditation Body (4)

- Legal Responsibility (4.1)
 - Government AB as legal entities based on its Government status
- Structure (4.2)
 - Requires the names, authority & responsibility of the top management
 - Authority and responsibilities of top management include
 - development & implementation of policies
 - decision on accreditation
 - Supervision of finances
 - contractual arrangements
 - delegation of authority to committees and individuals
- Accreditation Activity (4.6)
 - Emphasis on the use of international standards, guides, and normative documents
 - Describes procedures for extending AB's activities

Accreditation Body (4) Continued

- Impartiality (4.3): Strong emphasis on impartiality at all stages of AB operations
 - Formulation of policies with interested parties with balanced interest
 - Accreditation activities
 - Decision on accreditation
 - Not compete with its accredited CABs
 - Not offer consultancy
- Related Bodies (4.3.7): Conflict of interest with *related bodies* to be *analyzed* and avoided. Related bodies may provide prohibited services provided that
 - It has a different top management
 - It uses different personnel from decision makers
 - It ensures that there is no influence on the outcome of the assessment
 - It has different name/logo/symbol

Management (5)

- General (5.1)
 - Emphasis on continual improvement of management system
- Management system (5.2)
 - AB may refer to its obligations under the MRAs (e.g., IAF)
- Document control (5.3)
 - Emphasis placed on distribution and confidentiality of documents
- NCs & corrective actions (5.5), Preventive Actions (5.6)
 - Detailed information provided on dealing with NCs
 - Corrective and preventive actions clauses have more details

Management (5) Continued

- Internal Audits (5.7) & Management reviews (5.8)
 - Detailed information provided on the conduct and follow on actions for internal audits & management reviews
 - Specific time interval has been stated for internal audits (normally once a year)
 - Opportunities for improvement are included
- Complaints (5.9)
 - Determine the validity of the complaint
 - Allow CAB to respond if against another CAB
 - Acknowledge & respond to the complainant

Human resources (6)

- Personnel associated with AB (6.1)
 - Includes internal, external, temporary, full-time and part-time employees
- Personnel involved in the Accreditation Process (6.2)
 - Selected on the basis of their qualifications, training and experience
 - Initial and on-going trainings emphasized
- Monitoring (6.3)
 - Monitoring the performance and competence of accreditation personnel has been expanded.
 - Training needs are identified based on monitoring.
 - Different methods of monitoring have been identified
 - A timeline of 3 years has been specified to observe each assessor on-site.

Accreditation Process (7)

- Application for accreditation (7.2)
 - More attention is paid to multi sited bodies
- Resource review (7.3)
 - Added attention paid to AB's ability to carry out assessment
- Subcontracting technical assessors (7.4)
 - Contracting of individual assessors and technical experts is not considered subcontracting
- Preparation for assessment (7.5)
 - The concept of preliminary visit has been introduced before initial assessment
 - Consultancy to be avoided during preliminary visit
 - AB to have sampling procedures to cover various services provided by CAB
 - For initial assessment of a multi sited CAB, the assessment team to visit all premises
 - For surveillance & reassessment AB to have procedures for sampling the sites covering all premises within a defined timeframe

Accreditation Process (7)

Continued

- Document and record review (7.6)
 - AB may decide not to proceed with the on-site assessment based on NCs found during document review
 - NCs found during document review to be reported to the CAB
- On-site assessment (7.7)
 - Entrance meeting specifically mentioned
 - Conduct assessment at premises where key activities are performed
 - Witness CAB operations at other selected locations
 - Witness performance of representative number of staff of the CAB
- Analysis of findings and assessment report (7.8)
 - Assessment team to seek guidance from the AB where it cannot reach a conclusion about a finding
 - AB has the ultimate responsibility for contents of the final report
 - AB staff to provide a recommendation to the decision-makers

Accreditation Process (7) (continued)

- Appeals (7.10)
 - AB to appoint a person/group to investigate appeal
 - Investigators to establish validity of the appeal
 - AB to advise the CAB about its final decision
- Reassessment and Surveillance (7.11)
 - If based on reassessment alone, 2 years interval
 - If a combination strategy is used, assessment interval every 5 years + surveillance on-site assessment not to exceed 2 years
 - First surveillance should take place no later than 12 months
- Suspending, withdrawing or reducing accreditation (7.13)
 - A CAB may voluntarily withdraw, suspend or ask for scope reduction of its accreditation

Responsibilities of the AB and the CAB (8)

- Reference to accreditation and use of symbols (8.3)
 - More specific information provided on the use of AB's accreditation symbols
 - AB's accreditation symbol to be used only for the premises that have been accredited
 - Specific actions noted that an AB can take against a non-compliant CAB
 - AB can ask the CAB to perform a corrective action
 - Withdraw accreditation
 - Publication of transgression
 - Legal action

Conclusions

- 17011 compared to G-61 is more detailed
- More specific information is provided
- However, there are no new requirements.
- Still there may be few points that are left for interpretation

Thank you for your time and attention

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