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Requirements for Accreditation Bodies and Testing Laboratories

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PRESENTATION OVERVIEW

- Conformance Testing
- Requirements for Accreditation Bodies
- Requirements for Testing Laboratories

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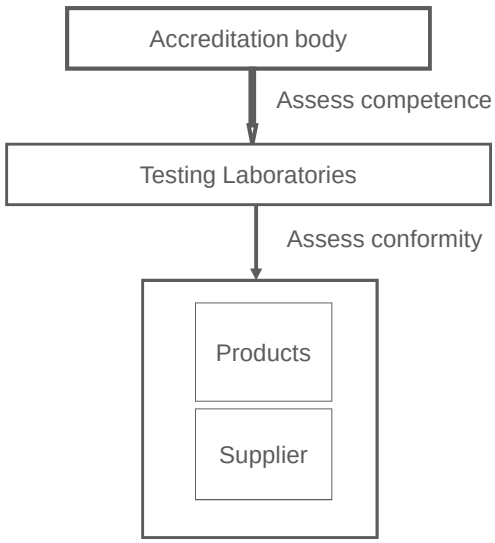
Conformance Testing



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Conformance Testing

- ISO and IEC jointly develop international standards through the ISO Committee on Conformity Assessment (CASCO). These documents are referred to as the CASCO toolbox
- CASCO toolbox consists of documents covering vocabulary, principles and common elements of conformity assessment, code of good practice, product certification, system certification, certification of persons, marks of conformity, testing, calibration, inspection, supplier's declaration of conformity, accreditation, peer assessment and mutual recognition arrangements

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Conformance Testing

CASCO Toolbox (1) includes:

ISO/IEC 17000:2004 Conformity assessment –Vocabulary and general principles
ISO/IEC 17011: 2004 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
ISO/IEC 17020: 1998 General criteria for the operation of various types of bodies performing inspection
ISO/IEC 17021: 2011 Conformity assessment – Requirements for bodies providing audit and certification of management systems

Conformance Testing

CASCO Toolbox (2) includes:

ISO/IEC 17024: 2003 Conformity assessment – General requirements for bodies operating certification of persons
ISO/IEC 17025:2005/Cor 1:2006 General requirements for the competence of testing and calibration laboratories
ISO/IEC 17030: 2003 Conformity assessment – General requirements for third-party marks of conformity
ISO/IEC 17040: 2005 Conformity assessment – General requirements for peer assessment of conformity assessment bodies and accreditation bodies

Conformance Testing

CASCO Toolbox (3) includes:

ISO/IEC 17050: 2004 Conformity assessment – Supplier's declaration of conformity
ISO/IEC Guide 65:1996 General requirements for bodies operating product certification systems
ISO/IEC Guide 68:2002 Arrangements for the recognition and acceptance of conformity assessment results

Requirements for Accreditation Bodies (ISO/IEC 17011)

- Accreditation body
- Management
- Human resources
- Accreditation process
- Responsibilities of the accreditation body and the Conformity Assessment Bodies (CAB)

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Accreditation body

- A registered legal entity
- Structure
  - Authority (generally derived from government) and be responsible for decisions on accreditation
  - Duties, responsibilities and authorities of senior management documented, including decisions on accreditation; finance; policies; contracts etc
  - Access to expertise related to accreditation (committees)
  - Rules for appointment, terms of reference and operation of committees

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Accreditation body (cont'd)

- Impartiality
  - Assessors do not make decisions on accreditation
  - Do not offer conformity assessment services or consultancy
- Confidentiality
  - Safeguard the confidentiality of information gathered in the process of accreditation
- Liability and financing
- Accreditation activities
  - Described and referring to relevant international standards and guides

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Management

- Management system
  - Policies including a quality policy and objectives defined and documented
- Document control
  - Procedures to control all documents
    - Documents approval
    - Updates and review
    - Change and version control

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Management (cont'd)

- Records
  - Procedures to identify, collect, index, access, file, store, maintain and dispose records
- Nonconformities and corrective actions
  - Procedures to identify and manage nonconformities
- Preventive actions
  - Procedures to identify opportunities for improvement and to take preventive actions
- Internal audits
  - Procedures for internal audit to verify conformity to 17011
  - At least once a year

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Management (cont'd)

- Management review
  - Senior management to review management system at least once a year
  - Review includes results of audit; results of peer evaluation; new areas of accreditation; trends in nonconformities; status of preventive and corrective actions; appeals and analysis of complaints
- Complaints
  - Procedures to deal with complaints
    - Validity of complaints
    - Complaints concerning an accredited CAB to be first addressed by the CAB

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Human resources

- Personnel associated with the accreditation body
  - Competent with necessary education, training, technical knowledge, skill and experience
  - Access to assessors
- Personnel involved in the accreditation process
  - Qualification, experience and competence stated for each activity
  - Procedures for selecting, training and approval of assessors and experts
  - Assessors with relevant accreditation assessor training and knowledge of assessment methods

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Human resources (cont'd)

- Monitoring
  - Procedures to monitor the performance and competence of personnel
  - Evaluate performance of assessors. On-site observation every three years
- Personnel records
  - Maintain records of qualifications, training, experience and competence of persons involved in accreditation
  - Maintain up-to-date records on assessors and experts

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Accreditation process

- Accreditation criteria and information
  - Criteria for accreditation of CABs documented
  - Information on assessment and accreditation processes, requirements for accreditation, fees, procedures for lodging complaints and appeals,
- Application for accreditation
- Resource review
  - Ability to carry out the assessment
  - Ability to carry out initial assessment in a timely manner

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Accreditation process

- Subcontracting the assessment
  - Decision-making cannot be subcontracted
  - Contracting of external assessors is not subcontracting
  - Takes full responsibility subcontracted assessments
  - Written consent of CAB to use a particular subcontractor

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Accreditation process

- Preparation for assessment
  - Preliminary visit before initial assessment
  - Appoints assessment team with lead assessor
  - Team members cannot provide consultancy to CAB
  - Names of team members supplied to CAB in advance to allow the CAB to object
  - Task of assessment is to review documents collected from CAB and to conduct on-site assessment
  - Assessment team witness a representative number of samples of the conformity assessment services
  - Visits to all premises of the CAB which perform key activities covered by the scope of accreditation.

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Accreditation process

- Document and record review
  - Assessment team reviews all documents and records provided by the CAB
  - If nonconformities are found during review, on-site visit may not go ahead and nonconformities are reported to CAB in writing.

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Accreditation process

- On-site assessment
  - Opening meeting to define purpose of assessment and accreditation criteria and to confirm schedule and scope of assessment
  - Conduct assessment at premises from which one or more key activities are performed
  - Witness the performance of a representative number of staff of CAB

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Accreditation process

- Analysis of findings and assessment report
  - Review of documents and on-site assessment to determine competence and conformity of CAB with requirements of accreditation
  - If assessment team cannot reach a conclusion, it will refer back to accreditation body for clarification
  - Assessment team meets with CAB prior to leaving the site and provides a written and or oral report on its findings
  - Written assessment report provided to the CAB for comments
  - Assessment team to provide detail report on assessment to accreditation decision-makers

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Accreditation process

- Decision-making and granting accreditation
  - Can use results of assessment of another accreditation body as long as it is 17011 compliant
  - Accreditation certificate with logo of accreditation body, unique accreditation number of the accredited CAB, effective dates, scope of accreditation
  - Unique information on the CABs e.g. For testing laboratories, the tests performed, products tested and methods used
- Appeals
  - Procedures to address appeals
  - Appoint competent and independent person to investigate appeals

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Accreditation process

- Reassessment and surveillance
  - Reassessment is similar to initial assessment
  - Surveillance – monitor the continued fulfillment of the accredited CAB of requirement of accreditation, includes surveillance on-site assessments and other surveillance activities such as enquires, review of declarations of CAB on scope, request to CAB for documents and records

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Accreditation process

- Reassessment and surveillance (cont'd)
  - Reassessment at least every 2 year
  - If reassessment and surveillance are used, reassessment is done at least every 5 years and surveillance on-site assessment is at least every 2 year.
  - First surveillance on-site assessment no later than 12 months from initial accreditation

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Accreditation process

- Extending accreditation
  - Extension of scope of accreditation may require reassessment
- Suspending, withdrawing or reducing accreditation
  - Accreditation of CAB can be suspended, withdrawn or reduced if the CAB persistently failed to meet the requirements of accreditation or to abide by the rules of accreditation

Requirements for Accreditation Bodies (ISO/IEC 17011)

❖ Accreditation process

- Responsibilities of the accreditation body
  - Give notice of changes to its requirements for accreditation
  - Make public information on the current status of the accreditations it has granted to CABs
- Responsibilities of the CAB
  - Fulfill continually the requirements for accreditation
  - Cooperate with accreditation body to verify fulfillment of requirements for accreditation
  - Inform accreditation body of changes relevant to its accreditation

Requirements for Testing Laboratories (ISO/IEC 17025)

- General
- Organization and Management
- Management requirements
- Technical requirements

Requirements for Testing Laboratories (ISO/IEC 17025)

- General

- ISO/IEC 17025 addresses both management system elements and technical competence in a systematic and consistent way
- Quality systems elements in line with ISO 9001
- Emphasis on responsibility of senior management
- Explicit requirements for continued improvement of the management system
- Emphasizes communication with customers

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Organization and Management

Organization

- The laboratory must be part of an organization that is an entity which can be held legally responsible
- Responsible for meeting requirements of:
  - ISO/IEC 17025
  - The needs of its clients
  - Regulatory authorities
- The management system shall cover work at:
  - Permanent facilities
  - Sites away from permanent facilities
  - Associated temporary or mobile facilities

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Organization and Management

Lab requirements

- Have managerial and technical personnel with authority and resources needed to carry out their duties including:
  - implementation, maintenance and improvement of the management system
- Have policies and procedures for the protection of client's confidential information, proprietary rights including:
  - Electronic storage and transmission of results

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Organization and Management

Lab requirements

- Define organization and management structure including:
  - Relationship within a larger organization
  - Relationship between qualify management, technical operation and support services
- Define the responsibility, authority and inter-relationship of personnel involved in management, performance or verification of work affecting the quality of tests and/or calibrations

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Organization and Management

Lab requirements

- Technical management with overall responsibility for:
  - Technical operation
  - Provision of resources needed to meet the required quality of laboratory operation

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Management system

- Document policies, procedures and instructions on the laboratory's scope of activities
- Quality policy defined in a quality manual and issued under authority of top management with:
  - Statement on standard of service
  - Quality objectives must be measurable
- Roles and responsibility of technical management and quality manager defined in the qualify manual

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Document control

- Establish and maintain procedures to control all documents as part of it management system
- Document approval and issue:
  - Documents reviewed and approved by authorized personnel
  - A master list established and readily available
  - Authorized editions of documents available at all locations where operations essential to effective operation of the laboratory are performed

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Document control

- Document approval and issue:
  - Documents reviewed and revised periodically for suitability
- Documents changes:
  - Changes to documents reviewed by the same function that performed the original review
  - Procedures and authorities for hand written amendment defined
  - Procedures to describe to make and control changes in computerized systems

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Review of request, tenders and contracts

- Procedures for review to ensure that:
  - Requirements including methods to be used are adequately defined and understood
  - Capability and resources to meet the requirements
  - Appropriate tests or calibrations are selected capable of meeting the customer's requirements
- Any differences between the request or tender and the contract be resolved before commencing work
- Maintain records of review and discussions with customers

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Subcontracting

- Subcontracting work be placed with a competent laboratory (e.g. one which is ISO/IEC 17025 compliant)
- Advise in writing the customer of subcontracting of tests and, where appropriate obtain their approval
- Responsible to the customer for the subcontractor's work

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Purchasing services and supplies

- Have procedures for selecting and purchasing of services and supplies affecting quality of work
- Purchased supplies not to be used until they have been verified as complying with requirements
- Purchasing documents adequately describe the services and products ordered and they are reviewed and approved for technical content before being released

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Service to customer

- Seek feedback both positive and negative from customers
- Analyse feedback for improvement to the management system

Complaints

- Procedure for resolution of complaints
- Maintain records of all complaints, investigations and corrective actions taken

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Control of nonconforming testing

- Have policy and procedures to be implemented in the case of the testing does not conform to its own procedures or customer's requirements
- Policy and procedures ensure that:
  - Responsibilities and authorities for taking action are designated
  - Corrective action is taken immediately with decision on the acceptability of the nonconforming work
  - Customer is notified and work is recalled

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Corrective actions

- Have procedures for corrective action and appropriate authorities designated to implement corrective action
- Corrective action procedures include:
  - Root cause analysis
  - Selection and implementation of corrective actions
  - Additional audits to ensure compliance with own policies and procedures or compliance with ISO/IEC 17025

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Preventive actions

- A proactive process to identify opportunities for improvement, not a reaction to the identification of problems
- Plans to be developed, implemented and monitored to identify improvement opportunities or required preventive actions

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Control of records (General)

- Have procedures to identify, collect, index, access, file, maintain and dispose quality and technical records
- Specify retention times for records
- Records to be readily retrievable and stored in a manner to prevent damage and loss
- Records to be held secure and in confidence
- Procedures to back up records stored electronically and to prevent unauthorized access to or amendment of such records

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Control of records (Technical)

- Records retained for a defined period of time including:
  - Original observations
  - Derived data
  - Sufficient information to establish audit trail
  - Staff records
  - Copy of test report or calibration certificate issued
  - Calibration records

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Control of records (Technical)

- Test or calibration records contain sufficient information to enable:
  - Identification of factors contributing to measurement uncertainty
  - Identification of personnel responsible for the sampling and checking of results
- Mistakes in records be crossed through but still legible with the correction entered next to the original information
- Alteration signed or initialled by person making the correction

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Internal audits

- Conducted periodically and within a predetermined schedule and procedure
- Quality manager responsible for planning and carrying out internal audits
- Covers all elements of management system including testing activities
- Records kept of the area of activity audited, the audit findings and corrective actions
- Conduct follow up to the audit to verify the implementation and effectiveness of corrective actions taken

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Management reviews

- Management reviews are conducted periodically (typically once per year) with a predetermined schedule and procedure to:
  - Review the effectiveness and suitability of its management system and/or testing or calibration activities
  - Introduce necessary changes or improvement

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Management requirements

Management reviews

- Management reviews cover:
  - Reports from managerial and supervisory personnel
  - Outcome of recent internal audits
  - Corrective and preventive actions
  - Assessments by external bodies
  - Customer feedback
  - Complaints
  - Recommendations for improvement

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

General

- Factors which determine the correctness and reliability of tests include:
  - Human, environmental conditions, test method and method validation
  - Measurement traceability, sampling and handling of test items
- Take into account of these factors when developing tests, procedures, training and qualification of personnel and selection of equipment

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Personnel

- The laboratory shall:
  - Ensure the competence of all who operate equipment, perform tests, evaluate results and sign test reports and calibration certificates
  - Have policies and procedures for training programs and evaluation of their effectiveness
- Management to authorize specific personnel:
  - To perform particular types of sampling and tests
  - To issue test reports and calibration certificates
- Maintain records of relevant authorizations, competence, qualifications and experience for all personnel including those under contracts

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Accommodation and environmental conditions

- Laboratory facilities (energy source, lighting, environmental) be suitable for performing tests correctly
- Document technical requirements for accommodation and environmental conditions that can affect results
- Effective separation between incompatible activities
- Control access to and use of areas affecting quality of testing

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Test and calibration methods and method validation

- Use appropriate methods and procedures for all tests in its scope
- Deviation from test methods documented, technical justified, authorized and accepted by the customer
- Test methods published in international, regional or national standards are preferred
- Use of non-standard method shall:
  - Be subject to agreement with the customer
  - Include a clear specification of the customer's requirement and the purpose of the test or calibration
  - Be validated appropriately before use

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Estimation of uncertainty of measurement

- Procedures for estimation of uncertainty for types of tests and calibrations
- If test method may preclude rigorous analysis, the laboratory shall:
  - Attempt to identify all components of uncertainty
  - Make a reasonable estimation based on knowledge of the performance of the method and on the measurement scope

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Control of data

- Calculation and data transfers subject to appropriate checks
- Computer software suitably validated
- Procedures for protecting data including integrity and confidentiality of data collection, data storage, data transmission and data processing

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Equipment

- Furnished with equipment for correct performance of tests
- Equipment used outside of its permanent control meets appropriate requirements of ISO/IEC 17025
- Equipment which has been subject to overloading or mishandling or found to be defective shall be:
  - Taken out of service
  - Isolated or clearly marked as being out of service until it has been repaired and calibrated

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Equipment

- Equipment to be labelled with its calibration status
- When for whatever reason, equipment goes outside the control of the laboratory, check its function and calibration status before it is returned to service
- Conduct intermediate checks when required according to defined procedure

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Measurement traceability

- Calibrate all equipment which have a significant effect on test results
- For calibration, establish traceability of equipment to the International System of Units (SI) (Systeme international d'unites) by means of an unbroken chain of calibrations or comparison linked to relevant primary standards, typically through national metrology institutes

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Sampling

- Have sampling plan and procedures available at locations where sampling is undertaken
- Record deviations, additions or exclusion from the documented sampling procedure with appropriate sampling data
- Record sampling procedure, identification of the sampler, environmental conditions, diagram and if appropriate statistics upon which sampling is based

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Handling of test and calibration items

- Procedures for identification, transportation, receipt, handling, protection, storage, retention and disposal of test items
- Consult customer before proceeding when there is doubt about the suitability of an item for test or test required is not specified in sufficient detail

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Reporting the results

- Report results accurately, clearly, unambiguously and objectively and in accordance with any specific instructions in the test method
- Test reports include information requested by the customer and necessary for interpretation of the test results

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Test reports and calibration certificates

- Test report, as a minimum contains:
  - A title (e.g. "Test Report" or "Calibration certificate")
  - A unique identification such as the serial number
  - Name and address of customer
  - Identification of test methods used
  - Description of condition and unambiguous identification of test item
  - Date of receipt of test item where this is critical to the validity and application of the results
  - Date of test or calibration
  - Test or calibration results with, where appropriate the unit of measurement

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Test reports

- Test report also contains where necessary for interpretation of test results:
  - Deviations from, additions to, or exclusions from the test method
  - Where relevant, a statement of compliance/non-compliance with requirements
  - Where applicable, a statement on the estimated uncertainty of measurement
    - This statement is applicable when required for the validity or application of results, when the customer requires it or when it affects compliance to a specification limit

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Test reports

- In addition, if sampling is used, report includes:
  - Date of sampling
  - Unambiguous identification of samples
  - Location of sampling, including diagrams, sketches or photographs
  - Reference to sampling plan and procedures used
  - Details of any environmental conditions during sampling that may affect interpretation of results
  - Any standards or specifications for sampling methods
  - Any deviations, additions or exclusions from the specification concerned

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Calibration certificates

- Calibration certificates contains:
  - Conditions under which calibrations were made
  - Uncertainty of measurement and/or statement of compliance
  - Evidence that measurements are traceable

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Opinion and interpretation

- When opinions and interpretations are included, the laboratory shall:
  - Document the basis on which they were made
  - Clearly mark as such in the report

Testing and calibration results obtained from subcontractors

- When test report contains results of tests performed by subcontractors, these results shall be clearly identified

Requirements for Testing Laboratories (ISO/IEC 17025)

❖ Technical requirements

Amendments to test reports & calibration certifications

- Material amendments to test report after issue shall be made only in the form of a further document or data transfer
- It includes the statement:
  - "Supplement to Test Report (or Calibration Certificate), serial number…." or equivalent wording
- A new report shall be uniquely identified and contain a reference to the original that it replaces

Requirements for Accreditation Bodies and Testing Laboratories

Thank you

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