

**Workshop for Maghreb countries to promote the  
development and implementation of Conformity  
Assessment programmes  
Tunis-Tunisia,  
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**PART 2  
Requirements for Accreditation Bodies  
and Testing Laboratories**

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## **PRESENTATION OVERVIEW**

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

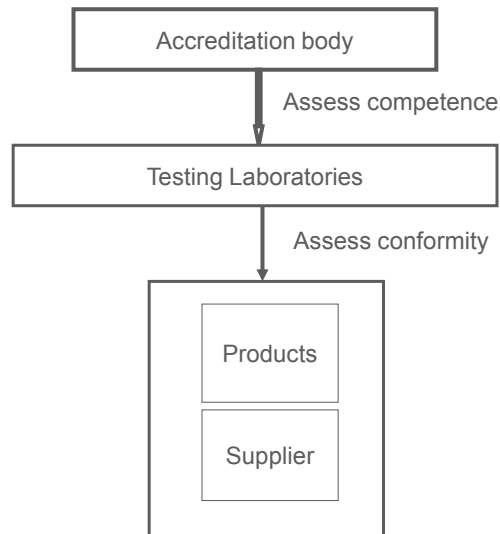
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## Conformance Testing



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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: 2012 | 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: 2012           | 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: 2010  |
| Conformity assessment – Supplier’ s declaration of conformity                    |
| ISO/IEC 17065:2012   |
| General requirements for bodies operating product certification systems          |
| ISO/IEC Guide 17068:2013   |
| Arrangements for the recognition and acceptance of conformity assessment results |

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## 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)

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## 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



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## 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



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## 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

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## 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

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## **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

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## **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

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## **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

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## **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

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## **Requirements for Accreditation Bodies (ISO/IEC 17011)**

### **❖ Accreditation process**

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

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## **Requirements for Testing Laboratories (ISO/IEC 17025)**

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

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## 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



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## 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 quality manual



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## Requirements for Testing Laboratories (ISO/IEC 17025)

### ❖ Management requirements

#### Document control

- Establish and maintain procedures to control all documents as part of its 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

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## 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 must be resolved before commencing work
- Maintain records of review and discussions with customers

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## 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

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## 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

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## 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

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## 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

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## 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

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## 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

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## 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

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## 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) (Système international d'unités) by means of an unbroken chain of calibrations or comparisons linked to relevant primary standards, typically through national metrology institutes

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## 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

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## 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

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## 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

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## 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

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## 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

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## 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

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# Requirements for Accreditation Bodies and Testing Laboratories

**Thank you for your attention**

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