

## Training Course on Conformity and Interoperability, Tunis-Tunisia, 22-26 May 2017





### Overview of ISO 17025 standard

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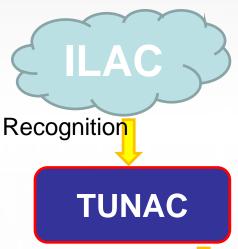
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## Definition

#### accreditation

Procedure by which an authoritative body gives formal recognition that an organization or individual is **competent** to perform specific tasks

## Laboratory recognition



accreditation ISO 17025

Formal recognition of the technical competence

**Tunisian** authorities

**European** authority

**Notification** 

Authorization to perform the compliance check

Test reports recognized by the authorities

# Accreditation Repositories

Activity	repository
testing laboratories, analysis or calibration	ISO / IEC 17025
Inspection Bodies	ISO / IEC 17020
quality systems and technical business skills	EN 45012 / ISO Guide 62
Environmental Management Systems	ISO Guide 66
personal	EN 45013 / ISO Guide 17024
certification	ISO / IEC 17065
Services	IN 45011
environmental verifiers	EMAS

## The accreditation process





Technical documents: As part of an initial accreditation and extensions = technical scope + technical procedures



Evaluation Team



Evaluation report



**Decision** 

permanent structure



#### Analyze

- Formalization of the request
- •Examination of the admissibility of the file
- •Establishment of an agreement

#### **Assess**

- •Define the evaluation program
- •Establishment of an evaluation team
- Evaluation

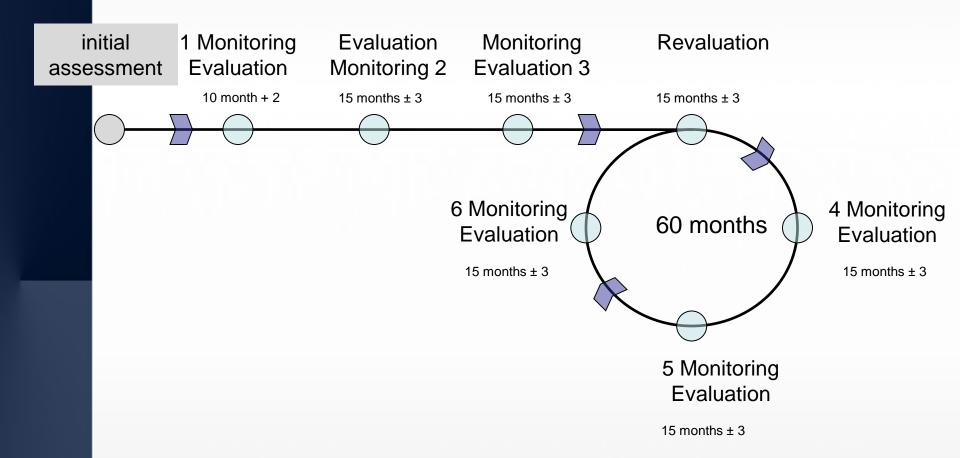
#### Decide

- •Review of the evaluation report
- •Formulation of a opinion for a decision

#### accredit

- decision by the director of the accrediting
- •Issuance of a certificate specifying the scope and duration of accreditation

# The accreditation cycle



The laboratory accreditation According to the standard EN ISO / IEC 17025

# Accreditation body

- In Tunisia, laboratory accreditation is carried out by TUNAC according to standards:
  - EN ISO / IEC 17025
    - managerial requirements (≈ ISO 9001)
    - technical requirements
  - Reference Document TUNAC
  - Analysis of technical Standards

#### MANAGEMENT REQUIREMENTS

- 1) Organization
- 2) Management System
- 3) Control of documents
- 4) Review of applications,appealsand supply contracts
- 5) Subcontracting of tests and calibrations
- 6) Purchases of services and supplies
- 7) Customer services

- 8) Claims
- 9) Control of test work and / or calibration
- 10) Improvements
- 11) Corrective Actions
- 12) Preventive actions
- 13) Control of records
- 14) Internal audits
- 15) Management review

# managerial requirements

- Organization and Management
- quality system
- Mastery of documentation
- Complaints, nonconformities and corrective and preventive action
- recordings
- Management reviews
- → ISO 9001 Requirements

### specific managerial requirements (1)

- The staff must have technical supervision authority and the resources necessary to perform its functions and identify any gaps
- Arrangements are made to ensure that the management and staff do not have commercial pressure
- The laboratory ensures confidential data protection and customer ownership
- A organizational chart of laboratory structure

### specific managerial requirements (2)

- It takes a quality manager who must have (irrespective of other functions) a authority to ensure that the quality system is implemented and observed at all times. It must have access to management.
- Must appoint substitutes for supervisors
- Staff should be aware of the importance of its activities and how it contributes to achieving the objectives of laboratory

### TECHNICAL REQUIREMENTS

- 1) General
- 2) Personal
- 3) Equipment and environmental conditions
- 4) Methods of testing and calibration and validation methods
- 5) Equipment
- 6) Measurement Traceability
- 7) Sampling
- 8) Manutentions of test and calibration items
- 9) To ensure the quality of test and calibration results
- 10) Test report

# technical requirements

- Staff competence
- Ambient conditions
- Test method and calibration

# Staff competence

- Qualified
  - Studies
  - formations
  - Experience
  - Skills
  - Training Policy
- set jobs
  - Job description



### Ambient conditions and facility

- Monitoring and mastery of environmental conditions
- Separation of incompatible activities
- limited access / regulated

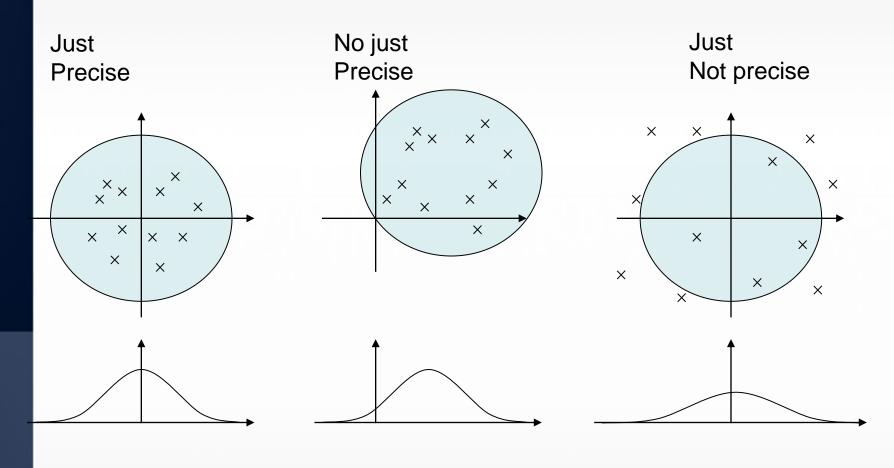
## **Facilities**

- In operating condition
  - Commissioning
  - metrological connection
  - Calibrations
  - Maintenance, preventive maintenance
- Customized
- Used by a competent and authorized

### Test methods

- selected methods from
  - Standards
    - international
    - regional
    - national
  - eminent scientific organizations
- methods developed and validated by the laboratory
- Methods specified by the client

### Uncertainty of test methods

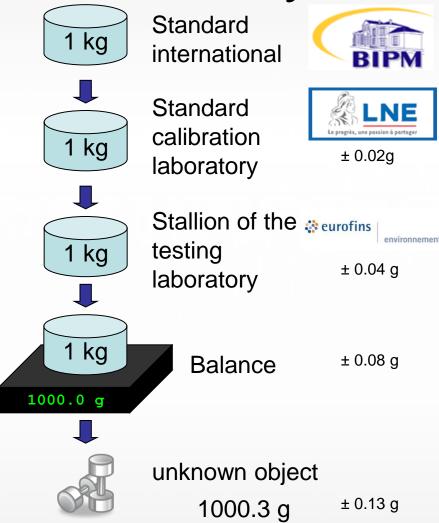


The precision determines the uncertainty (eg 3V / m ± 5%)

# Measurement Traceability

#### Definition

Property of a measurement or standard that can be connected to stated references, usually national standards or international through uninterrupted chain comparison with all of the reported uncertainties.



# Proficiency tests





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