Technical requirements for competency of laboratory : ISO/IEC 17025 standard

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Business Card

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Outline

- Introduction: How to prove technical competency ?
- Main elements of a technical competency
- ISO/IEC 17025 standard and requirements for technical competency
- Overview of technical requirements of the ISO/IEC 17025 standard
- Conclusion

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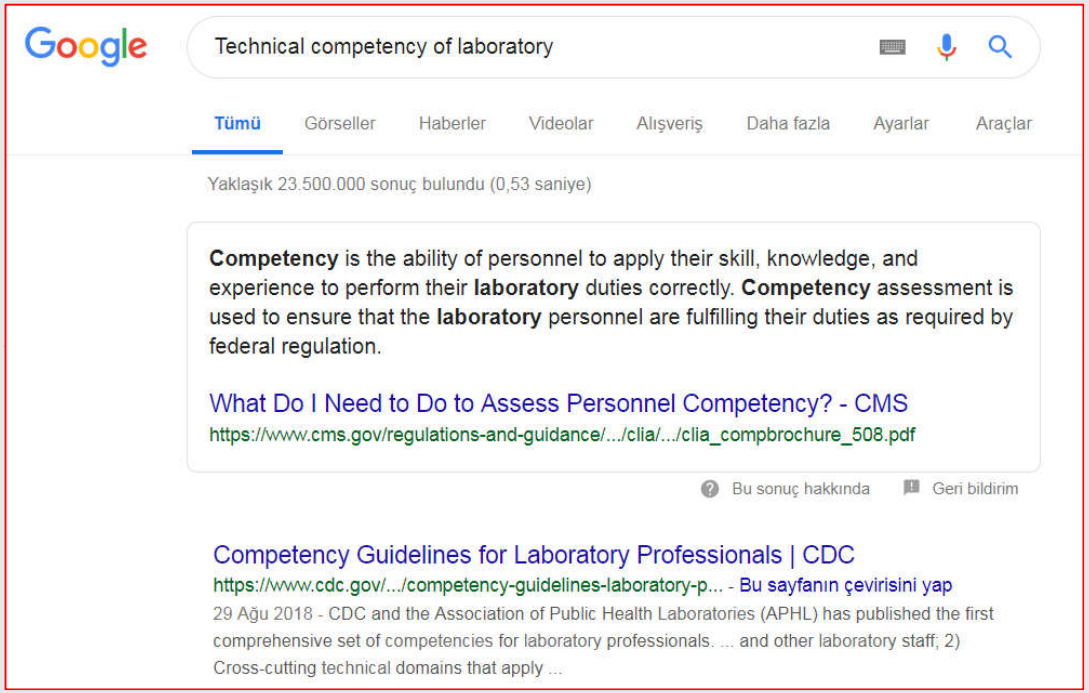
How to prove technical competency ?



- Number of items found: around 23 500 000
- Majority of items are irrelevant
- No specific recommendations…
- Some measures for staff competency

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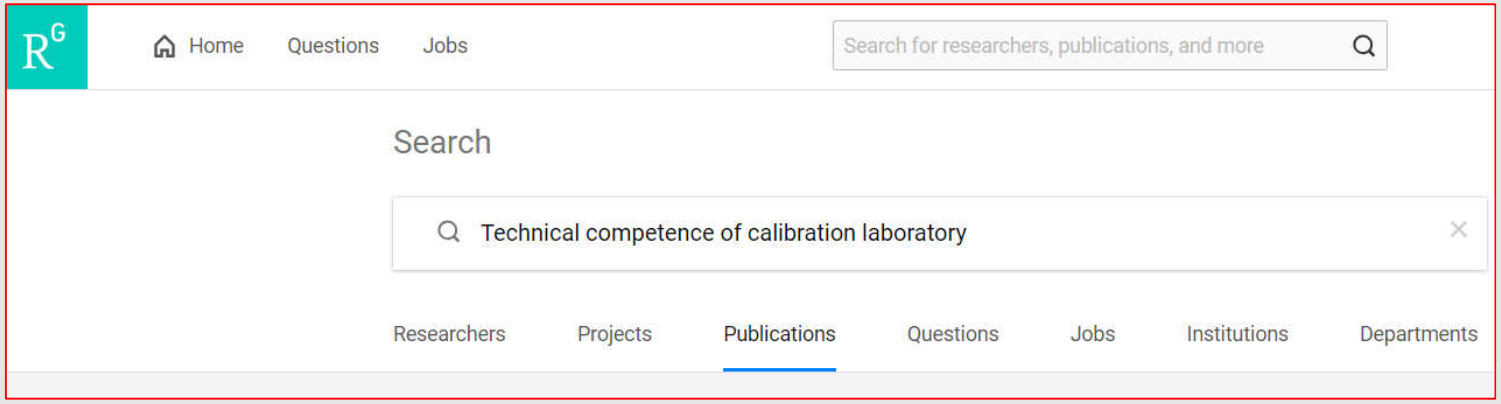
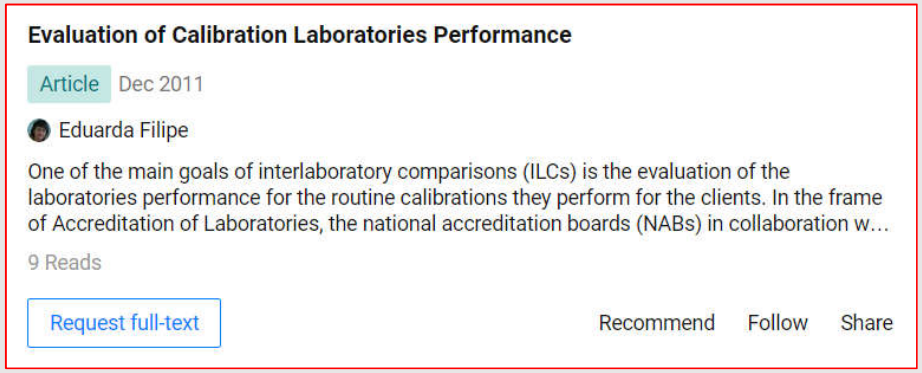
How to prove technical competence ?





- Many items are still irrelevant
- ILC is mentioned as a tool for measurement of laboratory performance

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How laboratory could prove it’s competence ?

- Accreditation
- Certification
- Peer visits / peer reviews
- Internal audits
- Assessment by customers
- Extensive participation to interlaboratory comparisons
- Others ?

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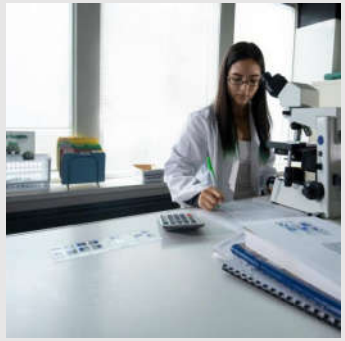
Main elements of technical capability of laboratory

- Personnel
- Accommodation, physical facilities
- Equipment
- Calibration/measurement/testing methods
- Metrological traceability
- Measurement uncertainty
- Use of internal and external quality control



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ISO/IEC 17025 standard

General requirements for the competence of testing and calibration laboratories

Date of publication: November 2017
Edition: 3

ISO/IEC 17025:2017 specifies the general requirements for the competence, impartiality and consistent operation of laboratories. ISO/IEC 17025:2017 is applicable to all organizations performing laboratory activities, regardless of the number of personnel.

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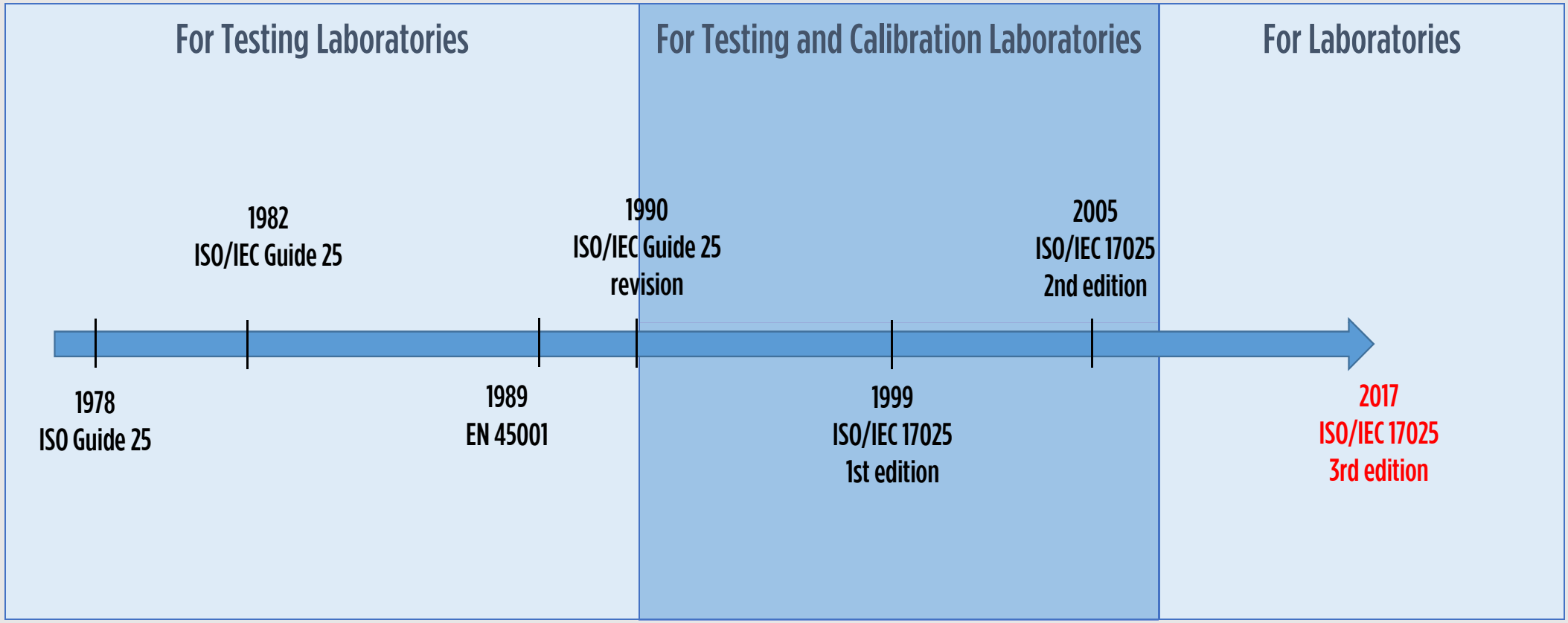
History of the ISO/IEC 17025 standard



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Structure of ISO/IEC 17025 standard

ISO/IEC 17025:2005

- Scope
- Normative references
- Terms and definitions
- Management requirements
- Technical requirements
- Cross reference to ISO 9001:2000
- Guidelines for establishing applications for specific fields

ISO/IEC 17025:2017

1. Scope
2. Normative references
3. Terms and definitions
4. General requirements
5. Structural requirements
6. Resource requirements
7. Process requirements
8. Management requirements

Annex A Metrological traceability

Annex B Management system

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ISO/IEC 17025 standard: technical requirements

Chapter 6. Resource Requirements

6.2 Personnel

6.3 Facilities and environmental conditions

6.4 Equipment

6.5 Metrological traceability

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ISO/IEC 17025 standard: technical requirements

Chapter 7. Process Requirements

7.2 Selection, verification and validation of methods

- 7.2.1 Selection and verification of methods
- 7.2.2 Validation of methods

7.3 Sampling

7.5 Technical records

7.6 Evaluation of measurement uncertainty

7.7 Ensuring the validity of results

7.8 Reporting of results

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6.2 Personnel

6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.

6.2.2 The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills, and experience.

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6.2 Personnel

6.2.5 The laboratory shall have procedure(s) and retain records for:

a) determining the competence requirements;
b) selection of personnel;
c) training of personnel;
d) supervision of personnel;
e) authorization of personnel;
f) monitoring of competence of personnel.

Summary:

Appropriate number of staff
Training
Authorization
Keeping records
Monitoring of competence

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6.3 Facilities and Environmental Conditions

6.3.1 The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results.

6.3.2 The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented.

6.3.3 The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.

Summary:

- Required physical space
- Controlled environment
- Separation of spaces
- Keeping records

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6.4 Equipment

6.4.1 The laboratory shall have access to equipment including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus which is required for the correct performance of laboratory activities and which can influence the result.

6.4.2 In those cases where the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.

Summary:

- To be equipped with necessary standards/devices
- Calibration programme
- Intermediate checks
- Labelling
- Keeping records

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6.5 Metrological traceability

6.5.1 The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations each contributing to the measurement uncertainty, linking them to an appropriate reference.

Note 1: See JCGM 200:2012 for the definition of metrological traceability

Note 2: See Annex A for additional information on metrological traceability.

Summary:

- To establish and maintain calibration programme for reference standards and devices
- Use appropriate providers of calibration services
- Traceability to own primary realizations or to other NMIs/DIs is accepted within the scope of the CIPM MRA

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7.2 Selection, Verification and Validation of Methods

7.2.1 Selection and verification of methods

- Use appropriate methods and procedures for:
  - All laboratory activities
  - Evaluation of measurement uncertainty
  - Statistical techniques for analysis of data
- Use of "method" for laboratory activities synonymous with "measurement procedure" in Guide 99/VIM

Summary:

- Use internationally recognized, standard methods
- Even standard methods have to be verified
- Records of verifications have to be retained
- In case of laboratory developed methods, validation prior to use is required.
- Written procedures/instructions for all laboratory technical activities

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7.6 Evaluating Measurement Uncertainty

7.6.1 Laboratories shall identify the contributions to the measurement uncertainty. When evaluating the measurement uncertainty all contributions which are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

7.6.2 A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.

Summary:

- Detailed uncertainty budget for each calibration/measurement
- All contributions have to be considered
- Uncertainty estimations should be realistic
- Evidence for each value in uncertainty budget should be available.

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7.7 Assuring the validity of the results

7.7.2 The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to a selection from the following list:

a) participation in proficiency testing;
b) participation in interlaboratory comparisons other than proficiency testing.

Summary:

- Establish and implement plan for participation in comparisons
- Analyze the results of comparisons
- Do not worry if you failed in comparison !
- Keep records for all stages of comparisons

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Conclusion

- Criteria described in the ISO/IEC 17025 standard could be used for evaluation of technical competence of calibration laboratory
- Evaluation of laboratory performance and its technical competence should be made preferably by third parties:
    - Accreditation body
    - Peer evaluators (e.g. within RMO peer review project)
- Evaluation should be made on periodical basis (once for 4-5 years) to prove sustainability of technical competence

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Many thanks for your attention !

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