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Course Outline

- Introduction Welcome and objectives
- Chapter 1 Background and principles
- Chapter 2 Basic technical requirements
- Chapter 3 Technical measurement requirements
- Chapter 4 Basic management system requirements
- Chapter 5 Active management system requirements
- Chapter 6 Monitoring and measuring the quality system



Chapter Outline

- People (Clause 6.2)
- Facilities and Equipment (Clauses 6.3-4, 6.6)
- Quality Control (Clause 7.7)
- Procedures (Clause 7.1, 7.2)
- Sampling and Sample Handling (Clauses 7.3-4)
- Results (Clause 7.8)



ACCREDITATION 17025 Technical Requirements

Technical Requirements in the 2017 version of 17025 are from the same categories of the ones listed in the 2005 version. See the Principle of Capacity.

- People skills and knowledge (competence)
- Environment, Equipment, Services/Supplies
- QA and QC
- Procedures, including
 - Uncertainty of measurement
 - Traceability of measurement
 - Validation/Verification of methods
 - Sampling and Sample handling
- Reporting Results now with Decision Rule



This is where the new version states each requirement:

| ITEM | CLAUSE(S) |
|---|--|
| Examining own lab Capacity/Competence People with skills and knowledge/competence Environment, Equipment, Services/Supplies QA and QC | 7.1 6.2 6.3, 6.4, 6.6 7.7 |
| Procedures, including Uncertainty of measurement Traceability of measurement Validation/Verification of methods Sampling and Sample handling Reporting Results – now with Decision Rule | 7.6, 7.8.3.1 c) 6.5 7.2 7.3, 7.4 7.8 |

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ACCREDITATION 17025 Technical Requirements

- 1. There are 23 questions in this Chapter.
- 2. What does the standard require?
- 3. Participants select their own answers.
- 4. The whole group is balloted for the most appropriate response.
- 5. <u>Clapping indicates a correctly answered question</u>. Buzzer indicates an incorrectly answered question.
- 6. The citation from the standard is displayed next to the most correct answer.
- 7. The quiz then advances to the next question.

Press





Defining Competence

Competence is defined in Section 3.10.4 from ISO 9000 and from ISO/IEC 17024 as the: "ability to apply knowledge and skills to achieve intended results."

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ACCREDITATION 17025 Technical Requirements

Demonstrating Competence

From the first principle behind ISO/IEC 17025 (See "Capacity" in Section 1.5.1 of the Course Handbook), a lab needs to demonstrate that it has formally examined all aspects of its own competence <u>before</u> it accepts new work.

- How?
 - · Declaring it only does accredited work, or
 - Documenting its formal examination, or
 - Or some other formal means.



7.1 Review of requests, tenders and contracts (Delivering Competence):

The lab **must** determine that it has the **capacity** to do the work whenever it undertakes the review of a request for work that has not been done before.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

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ACCREDITATION 17025 Technical Requirements

7.1 Review of requests, tenders and contracts:

Statements of compliance do not need to consider the uncertainty of the result.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE



7.1 Review of requests, tenders and contracts:

Contract amendments <u>do not need</u> to be resolved or communicated to (or agreed by) the client.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

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INTERNATIONAL 17025 Technical Requirements SERVICE*

Buying Competence – External providers (6.6)

There are 3 types of products and services that are frequently purchased, or externally provided:

- 1. Those provided, in part or full, directly to the customer by the laboratory, as received from the external provider (e.g. testing or calibration subcontracted to another laboratory—see also 7.1.1)
- 2. Those used to support the operation of the laboratory (e.g. calibration services for the lab's reference standards, PT services)
- 3. Those intended for incorporation into the laboratory's own activities (e.g. equipment, consumable materials)



Buying Competence – External providers (6.6)

- 1. The lab must have procedures for
 - Defining, reviewing, approving the requirements for purchased products and services
 - Defining criteria of evaluation, selection, performance monitoring and re-evaluation of external providers
 - Taking action as a result of evaluation and monitoring of external providers
 - Ensuring that products and services meet requirements before they are used
- 2. If the product or service purchased does not materially affect the quality of test or calibration, it need not be covered by 6.6.

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INTERNATIONAL 17025 Technical Requirements SERVICE*

7.1 Buying Competence:

Where external providers are used, the laboratory shall qualify <u>ALL</u> suppliers of <u>ALL</u> services, regardless of what is supplied.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

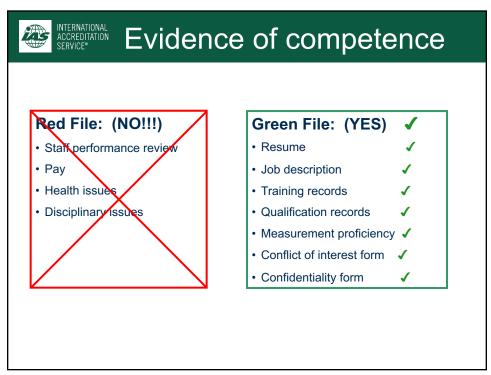


6.2 Personnel:

Labs **must** have job descriptions for all personnel involved in technical work.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

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6.3 Facilities and environmental conditions:

Offsite testing **does not** require control of the testing environment

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

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6.4 Equipment:

Using client testing equipment **does not require** the laboratory to control it.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE



6.4 Equipment:

ALL measurement equipment **MUST** be calibrated.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

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ACCREDITATION 17025 Technical Requirements

6.4 Equipment:

All measurement equipment requiring calibration must have its calibration status clearly marked and visible.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE



7.7 Ensuring the Validity of Results:

Laboratories **must** participate in PT or ILCs.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

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ACCREDITATION 17025 Technical Requirements

7.7 Ensuring the Validity of Results:

Laboratories are **not required** to track trends in the performance of their methods and technical procedures.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE



7.6 **Evaluation** of measurement uncertainty:

Testing and calibration laboratories <u>MUST</u> evaluate the uncertainties associated with their **quantitative** tests and calibrations.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

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ACCREDITATION 17025 Technical Requirements

7.8.3 Specific requirements for test reports:

Testing laboratories **MUST ALWAYS** report the uncertainties associated with their tests.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE



6.5 Metrological Traceability:

Only calibration laboratories which are **competent** can provide traceable calibrations.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

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INTERNATIONAL ACCREDITATION 17025 Technical Requirements SERVICE*

7.2 Selection, verification and validation of methods:

Laboratories **MUST** verify published methods to determine if they can achieve the required performance of the method

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE



7.2 Selection, verification and validation of methods:

Laboratories are not required to validate standard methods that have been modified.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

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INTERNATIONAL ACCREDITATION 17025 Technical Requirements

7.3 Sampling:

The laboratory **cannot insist** on client sampling being conducted in accordance with the lab's instructions.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE



7.4 Handling of test or calibration items:

The laboratory **must accept all** samples, regardless of whether or not they conform to sampling requirements.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

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7.8 Reporting of results:

ALL issued reports **MUST** be maintained as laboratory records.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE



7.8 Reporting of results:

The client who paid for the laboratory work and report <u>MAY</u> reproduce <u>ANY</u> part of the report <u>WITHOUT</u> the approval of the laboratory that produced it.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

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ACCREDITATION 17025 Technical Requirements

7.8 Reporting of results:

When reporting pass/fail statements from laboratory results, the laboratory <u>MUST</u> consider the risk of making such a statement.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE



7.8 Reporting of results:

ONLY specifically-approved persons **MAY** express their opinions on test and calibration reports.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

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INTERNATIONAL ACCREDITATION 17025 Technical Requirements SERVICE*

7.8 Reporting of results:

Amendments to previously issued reports, must make reference to the original.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE



INTERNATIONAL 17025 Technical Requirements SERVICE*

The Decision Rule:

ISO/IEC 17025, Clause 3.7 states:

decision rule - rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

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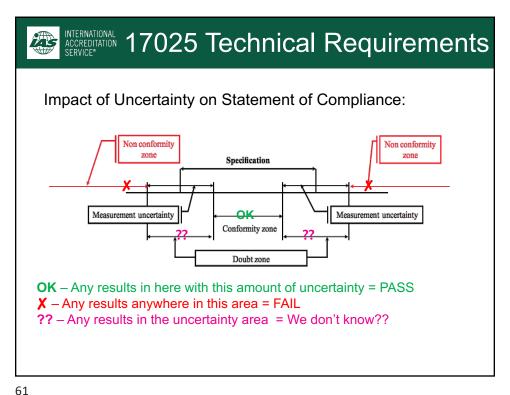


INTERNATIONAL 17025 Technical Requirements SERVICE*

The Decision Rule:

ISO/IEC 17025, Clause 7.1.3 states:

When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance) the specification or standard, and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.



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Decision Rule Resources



- ILAC G8:09/2019 Guidelines on Decision Rules and Statements of Conformity (https://ilac.org/publications-and-resources/ilac-guidance-series/)
- JCGM 106:2012 Evaluation of measurement data The role of measurement uncertainty in conformity assessment (https://www.bipm.org/utils/common/documents/jcgm/JCGM 10 6 2012 E.pdf)
- UKAS LAB 48, Edition 3 June 2020, Decision Rules and Statements of Conformity (https://www.ukas.com/wp-content/uploads/schedule-uploads/759162/LAB-48-Decision-Rules-and-Statements-of-Conformity.pdf)



17025 Technical Requirements

Impact of Uncertainty on Statement of Compliance 2:

This is the uncertainty of the measurement

OK – Any results in here with this amount of uncertainty = PASS

?? – Any results in the uncertainty area = We don't know??

X – Any results in this area at all = FAIL

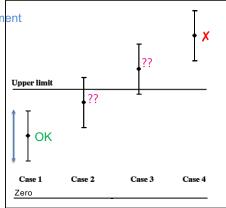


Fig.1 Compliance with specification for an upper limit. Compliance statements may be expanded to explicitly state whether compliance concerns an upper or a lower limit of specification using a coverage probability of 95 %.

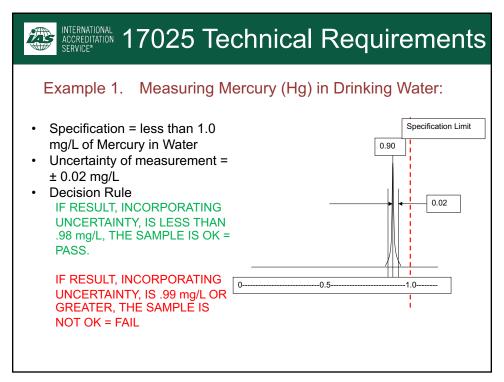
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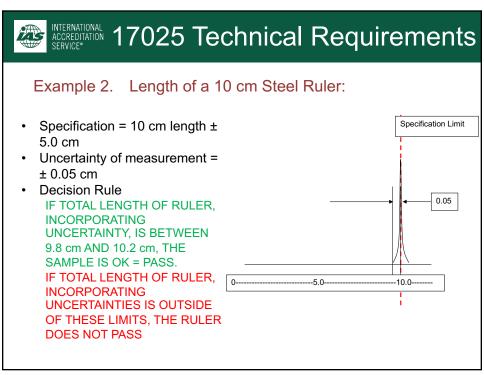


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Examples of Decision Rule

- 1. Measuring Mercury (Hg) in Drinking Water (≤ 1.0 mg/L):
- Uncertainty of measurement = ± 0.02 mg/L
- Decision Rule
 - IF RESULT, INCORPORATING UNCERTAINTY, IS LESS THAN .98 mg/L THE SAMPLE IS OK = PASS.
 - IF RESULT, INCORPORATING UNCERTAINTY, IS .99 mg/L OR GREATER, THE SAMPLE IS NOT OK = FAIL
- 2. Length of a 10 cm Steel Ruler (10 cm ± 0.05 cm):
- Uncertainty of measurement = ± 0.05 cm
- Required Tolerance is ± 5.0 cm
- Decision Rule
 - IF TOTAL LENGTH OF RULER, INCORPORATING UNCERTAINTY, IS BETWEEN 9.8 cm AND 10.2 cm, THE SAMPLE IS OK = PASS.
 - IF TOTAL LENGTH OF RULER, INCORPORATING UNCERTAINTIES IS OUTSIDE OF THESE LIMITS, THE RULER DOES NOT PASS





Decision Rule Resources



- ILAC G8:09/2019 Guidelines on Decision Rules and Statements of Conformity (https://ilac.org/publications-and-resources/ilac-guidance-series/)
- JCGM 106:2012 Evaluation of measurement data The role of measurement uncertainty in conformity assessment (https://www.bipm.org/utils/common/documents/jcgm/JCGM 10 6 2012 E.pdf)
- UKAS LAB 48, Edition 3 June 2020, Decision Rules and Statements of Conformity (https://www.ukas.com/wp-content/uploads/schedule_uploads/759162/LAB-48-Decision-Rules-and-Statements-of-Conformity.pdf)

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Decision Rule Resources (cont.)



- ANSI/NCSL Z540.3:2006: Requirements for the Calibration https://www.ncsli.org/ltemDetail?iProductCode=MS06 04 CALDWEL &Category=MEAS ARTIC&WebsiteKey=d502eebf-7ea1-4ae1-ac05-e2faa9324627
- Handbook for the interpretation of ANSI/NCSL Z540.3 eFile https://www.ncsli.org/ItemDetail?iProductCode=HB Z5403F&Categor y=DOC_STD&WebsiteKey=d502eebf-7ea1-4ae1-ac05-e2faa9324627