Understanding ISO/IEC 17025:2017 Chapter 1 - Background and Principles

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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

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- Chapter 4 – Management system requirements
- Chapter 5 – Continual improvement requirements
- Chapter 6 – Monitoring and measuring the quality system

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Timings for this course

- 09:00 – 10:30 Training
- 10:30 – 10:45 Break
- 10:45 – 12:00 Training
- 12:00 – 13:00 Lunch
- 13:00 – 14:30 Training
- 14:30 – 14:45 Break
- 14:45 – 16:30 Training
- 16:30 – End of Day

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Welcome!

- Aims of this Course
  - To provide laboratory staff with a good understanding of the requirements in ISO/IEC 17025
- Expected Results of this Course
  - Your ability to better appreciate all aspects of your own quality system.
  - Your ability to better maintain your own quality system.

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Our Contract
(We work for you)

- We owe you:
  - ☐ Deference
  - ☐ Respect
  - ☐ Honesty
  - ☐ Some knowledge of the Subject Matter
- We want from you
  - ☐ ?

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Your Objectives

- Understanding of what the assessor assesses during an assessment.
- Learning what does, and does not apply, to us from 17025.

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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

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- Chapter 4 – Basic management system requirements
- Chapter 5 – Active management system requirements
- Chapter 6 – Monitoring and measuring the quality system

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Why a laboratory needs or wants a quality system?

- Improve the consistency (and/or quality) of lab results.
- Demonstrate competence to a client or a regulatory agency.
- Meet a market specification from laboratory clients (market) or a regulatory agency to stay in business.

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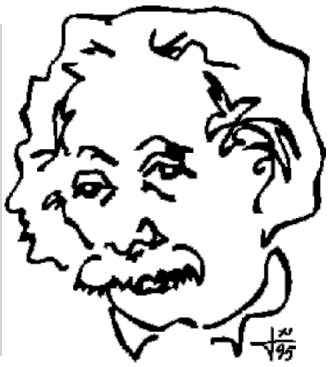
Consistency is the Aim



"We can produce consistent results, day after day, within the ninety-five percent confidence region. Day after day."

Drawing by Iutta Waloschek.
From the website of the University of St. Andrews, Scotland. www-gap.dcs.st-and.ac.uk/~history/PictDisplay/Einstein.html

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What is a Perfect Lab?

"An organisation that produces consistent results, day after day after day after day….. at specified uncertainties within the 95% confidence region."

- Sounds boring to the marketing types but not to lab people.
- It is about the science
- It is about consistency
- It is about technical competence

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Rationale for ISO/IEC 17025

1. There is only one question.
2. What does the standard require?
3. Participants select their own answers.
4. The whole group is balloted for the most appropriate response.
5. Clapping indicates a correctly answered question. 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 Continue

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Rationale for ISO/IEC 17025

Introduction:

ISO/IEC 17025 is primarily to allow laboratories to satisfy customer requirements.

A. TRUE
B. FALSE
C. NOT APPLICABLE

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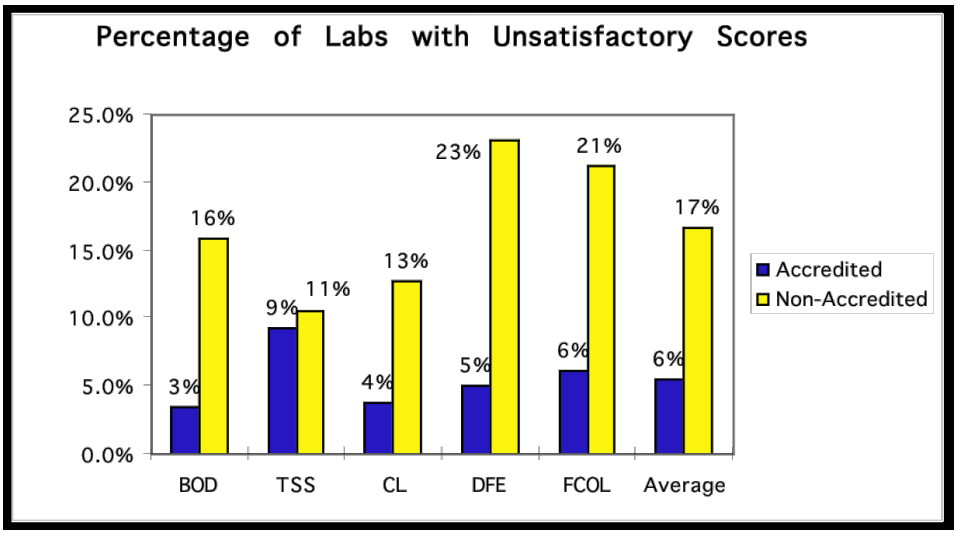
17025 Labs produce Consistent Results. Proof is in PT Scores.



Morris, A. and D. Macey. 2004. Laboratory accreditation: Proof of performance for environmental laboratories-2001 study. Accreditation and Quality Assurance 9:52-54.

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Competent Lab

The laboratory with:

- The People with the Skills and Knowledge
- The Environment with the Facilities and Equipment
- The Quality Control, and
- The Procedures

All aimed at producing technically valid results.

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Competence

Ask your clients and regulators which is most important:

A. Labs conform to an international standard
B. Labs are competent
C. Labs produce valid (correct) results

They will respond in this priority:

1. Correct results
2. Competence
3. Conformance to a standard

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Competence

- Laboratory clients and regulators want labs to be correct and that it is telling them the truth. They want to trust that **both** of these conditions exist whenever a lab produces a result. Instead of facing all of the labs and asking them if (and how) they would do this, many have come to trust an organisation whose recognition of the laboratory indicates that both conditions are being met.

- That type of organisation is a recognised accreditation body.

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Standards vs Regulations

Approach	Document/Specification (What is it?)	Specifier (Who wants it?)	Process (How do they get it?)
(1) Regulatory Approach (Mandatory)	Regulation	Government	Inspection
(2) Standardisation Approach (Voluntary)	Voluntary Standard	Market	Conformity Assessment

- Red = Govt Regulation, ENFORCED by Inspectors through INSPECTION
  - FDA Lab Licensing Fail to comply? Jail or fines
- Black = Govt Regulation, MONITORED through Audits for CONFORMANCE
  - Most Lab Accreditation Fail to conform? Lose registration
- Blue = Market Demand, MONITORED through Assessments for COMPETENCE
  - ISO 9000. Fail to demonstrate competence? Lose accreditation

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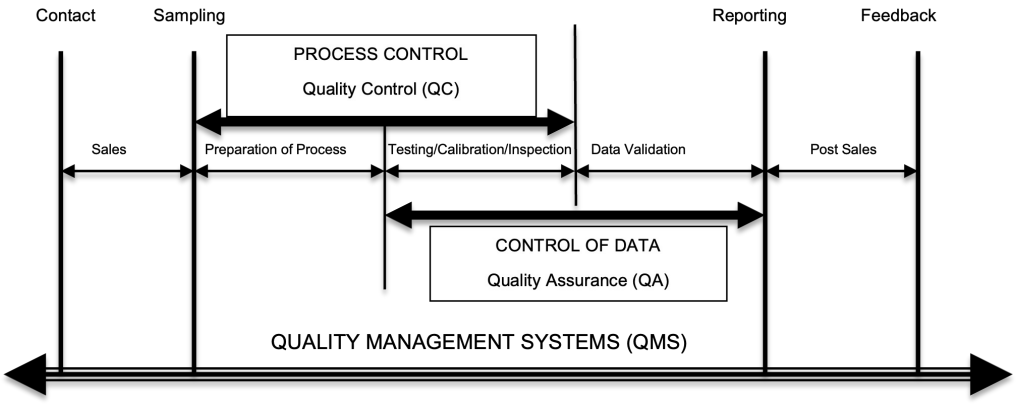
The Scope of Lab Operations



Includes all functions that influence the validity of technical results

- All business operations functions
- All management and administrative functions
- All finance functions
- All HR functions
- All purchasing and contract review functions
- All marketing and communications functions
- All maintenance functions

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Quality Control and Quality Assurance

- Quality control activities are aimed at ensuring the processes continue to be fit for purpose.
- Quality assurance activities are aimed at ensuring the results of the processes continue to be fit for purpose.
- A quality management system covers both of these disciplines and the other supporting procedures used to ensure that a laboratory produces technically valid results.

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The Documents that Govern

- ISO/IEC 17025 and accreditation body Interpretations of the Requirements in 17025
- Accreditation body criteria documents will normally include:
  - Traceability
  - Uncertainty
  - Method Validation and Verification
  - Decision Rule
  - Detection Limits (LOQ and LOD)
  - Acceptable range of measurement
  - Internal Audit / Management Review
  - Use of IT

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Where to Start?

- **ISO/IEC 17025** - General Requirements for the Competence of Testing and Calibration Laboratories.

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Principles behind ISO/IEC 17025

- These principles are about the standard - they are not the standard. They are a guide to understanding “WHY” a particular requirement exists within the standard.
- These principles do not replace any requirement or groups of requirements in the standard.
- These principles are just one more way of looking at the basis of the requirements.

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Principles behind ISO/IEC 17025

- Capacity
- Exercise of Responsibility
- Scientific Method
- Objectivity of Results
- Impartiality of Conduct
- Traceability of Measurement
- Repeatability of Test
- Transparency of Process

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Capacity

Concept that a laboratory has the resources (PEOPLE with the required skills and knowledge, the ENVIRONMENT with the required facilities and equipment, the QUALITY CONTROL, and the PROCEDURES) in order to undertake the work and produce competent results.

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Exercise of Responsibility

Concept that persons in the organisation have the authority to execute specific functions within the overall scope of work – and that the organisation can demonstrate accountability for the results of the work.

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Scientific Method

Concept that the work carried out by the organisation is based on accepted scientific approaches, preferably consensus-based, and that any deviations from accepted scientific approaches can be substantiated in a manner considered generally acceptable by experts in that field.

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Objectivity of Results

- Concept that the results produced within the scope of work of the organisation, are mainly based on measurable or derived quantities.
- Concept that subjective test results are produced only by persons deemed qualified to do so and that such results are noted as being subjective or are known by experts in the field of testing to be mainly subjective.

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Impartiality of Conduct

Concept that the pursuit of competent results through the use of generally accepted scientific approaches is the primary and overriding influence on the work of persons executing tests - all other influences being considered secondary and not permitted to take precedence.

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Traceability of Measurement

- Concept that the results produced, within the scope of work of the laboratory, are based on a recognised system of measurement that derives from accepted, known quantities (SI system) or other intrinsic or well-characterised devices or quantities.
- Concept that the chain of comparison of measurement between these accepted, known quantities or intrinsic devices or quantities, and the device providing the objective result, is unbroken for the transfer of measurement characteristics, including uncertainty, for the whole of the measurement chain.

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Repeatability of Test

Concept that the test which produced the objective results, will produce the same results, within accepted deviations during subsequent testing, and within the constraints of using the same procedures, equipment and persons used during a previous execution of the test.

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Transparency of Process

Concept that the processes existent within the laboratory producing the objective results, are open to internal and external scrutiny, so that factors which may adversely affect the laboratory's pursuit of objective results based on scientific method, can be readily identified and mitigated.

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