



New publications relating to Quality Assurance

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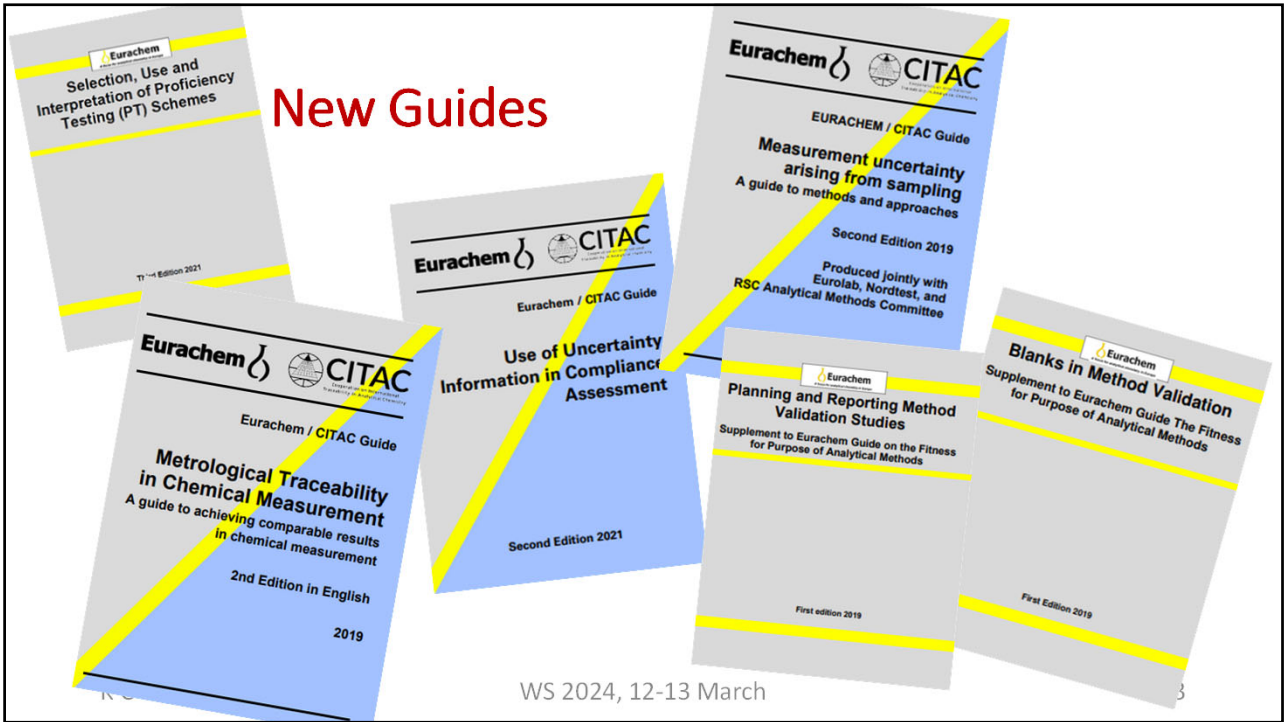
Inactive WGs

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New Guides

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Leaflets on the accreditation standards

A new ISO/IEC 17025 for laboratories

Something is changing in the life of laboratories!

A significant revision has led to the publication of ISO/IEC 17025:2017. A three-year transition period is provided for all parties to fully implement the new version but some effort will be required to ensure a smooth transition. This applies to laboratories and national accreditation bodies. The latter will be supported by regional and international accreditation organisations which need to ensure a harmonised procedure for the implementation of the Standard, the assessment of laboratories and the peer review process for the implementation of the Standard. The structure of the Standard has changed extensively to be in line with the format of the new ISO/IEC 15000 series but the requirements for laboratories remain broadly similar.

What is changing?

- The structure (see Fig. 1)
- Sampling addressed as a standalone activity
- The use of a decision rule
- Risks and opportunities
- The management system
- Reference to new standards
- The Annexes

New definition of "laboratory"

A laboratory is defined as a body performing one or more of the following activities: testing; calibration; and sampling, associated with subsequent calibration or testing. The "subsequent calibration or testing" are not necessarily carried out in the same entity. This means that sampling as a standalone activity can be accredited against the Standard.

The decision rule

A decision rule describes how measurement uncertainty is accounted for when stating conformity with a specified requirement. It is the laboratory's responsibility to document the decision rule, including the statistical basis, and to communicate it to and agree it with the customer. Further information is available in ISO/IEC Guide 99-4 (1) and a guide published by Eurachem/CITAC (2).

Risks and opportunities

It is the laboratory's choice how to address risks. This requires deliberate consideration of what is important for the individual laboratory. The process involves identifying, evaluating and defining measures to control risks and enhance opportunities for the laboratory to achieve its purpose and objectives.

The Standard requires the laboratory to plan and implement actions to address risks and opportunities. This is reflected not only in a number of subclauses – i.e. on impartiality, statements of conformity, management of nonconforming work, and management review – but in its philosophy as a whole. Its reference is made to "preventive actions" – risk-based provisions as well as clauses relating to "improvement over the next".

ISO 15189:2022 – A new task for medical laboratories

A new philosophy in medical laboratories!

The 4th edition of ISO 15189 (the "Standard") was published in December 2022, following a decision by the International Standards Organization (ISO) in December 2021. It seems that the transition period to the new Standard by the medical laboratories is the foundation of a risk-based philosophy. The other major change in its structure, however, there are some differences between the two bodies.

Main changes

- The structure (see Fig. 1)
- Risks and opportunities
- No reference to preventive actions
- Requirements for jobs-of-care testing (JOCT) primarily addressed in ISO 22825 (1) have been incorporated in the Standard
- The management system – the laboratory's quality management system (LQMS) and the laboratory's compliance with ISO 9001 (1) and ISO 13485 (1) are addressed
- The Annexes

A medical laboratory is...

The Standard defines a medical laboratory as an "entity for the examination of materials derived from the human body for the purpose of providing information for the diagnosis, reporting, management, and prevention and treatment of disease, or assessment of health". These activities include pre-diagnostic, diagnostic, and post-diagnostic processes.

Risks and opportunities

The Standard provides for risk management throughout almost all its clauses. This reflects the need for the laboratory to identify potential risks associated with all processes, i.e. pre-diagnostic, diagnostic and post-diagnostic, taking into account their impact on its work, with a focus on the impact on the patient and the safety of the laboratory. The laboratory has to identify, evaluate and define measures to control risks and enhance opportunities for the laboratory to achieve its purpose and objectives. The laboratory's choice how to address risks is reflected in its philosophy as a whole. Its reference is made to "preventive actions" – risk-based provisions as well as clauses relating to "improvement over the next".

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Leaflets and guides (translations)

You talk, we understand – The way out of the tower of Babel

Εσείς μιλάτε και εμείς καταλαβαίνουμε – Η έξοδος από τον Πύργο της Βαβέλ

Du pratar, vi förstår – vägen ut från Babels torn

Terminology in Analytical Measurement Introduction to VIM 3

Ευραχημ

ISO **IEC** **JFCC** **ISO** **IEC** **JFCC** **ISO** **IEC** **JFCC**

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Second Edition 2023

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Reading List for Analytical Scientists

Contents

- Introduction and scope
- Introduction to metrology and terminology
- Traceability of measurement results
- Uncertainty of measurement
- Qualitative analysis
- Sampling
- Statistics
- Validation of analytical methods
- Reference materials
- Proficiency testing
- Internal quality control
- Quality assurance and accreditation

- Websites and web resources
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Revision to address ISO/IEC 17025:2017



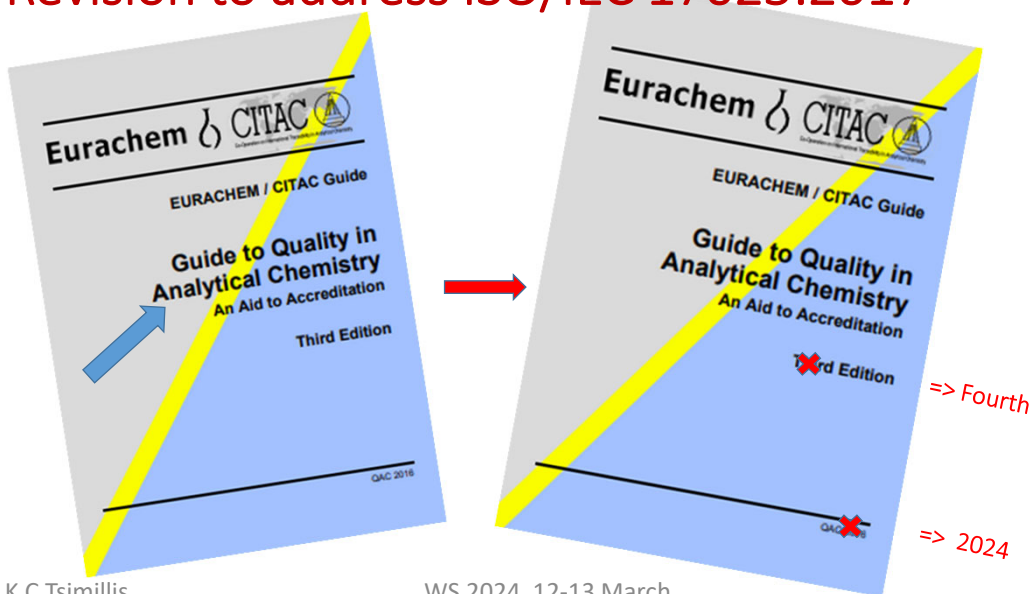
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Revision to address ISO/IEC 17025:2017



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EA and ILAC websites

Accredited laboratories and others seeking accreditation need to be aware of new publications; main sources are

- European accreditation for Cooperation (EA)
www.european-accreditation.org and
- International Laboratory Accreditation Cooperation (ILAC)
www.ilac.org as well as
- the National Accreditation Body (NAB)

Who does the QAC address?

The Guide should/could be used by laboratories, not only analytical ones

- implementing ISO/IEC 17025 or ISO 15189
- complying with the principles of Good Laboratory Practice (GLP)
- involved in education and training
- others not seeking formal recognition

The revision of the Guide (QAC)...

was required after the publication of ISO/IEC 17025:2017

- The existing version (2016) addressed the requirements of the superseded standard (2005)
- A number of more recent publications had to be considered
- The ad hoc committee operating under the E&T WG of Eurachem comprises of scientists, active members of the WG from 10 countries (Austria, Belgium, Cyprus, Germany, Portugal, Romania, Slovakia, Spain, Turkey, UK)

What is changing?

New requirements of the standard had to be addressed.

These refer to

- Terms & definitions (additional)
- Risks & opportunities (with a new Appendix on examples)
- Uncertainty arising from sampling
- Decision rule
- Opinions and interpretation
- ➔ PLUS Reference to the International framework regarding demonstration of competence

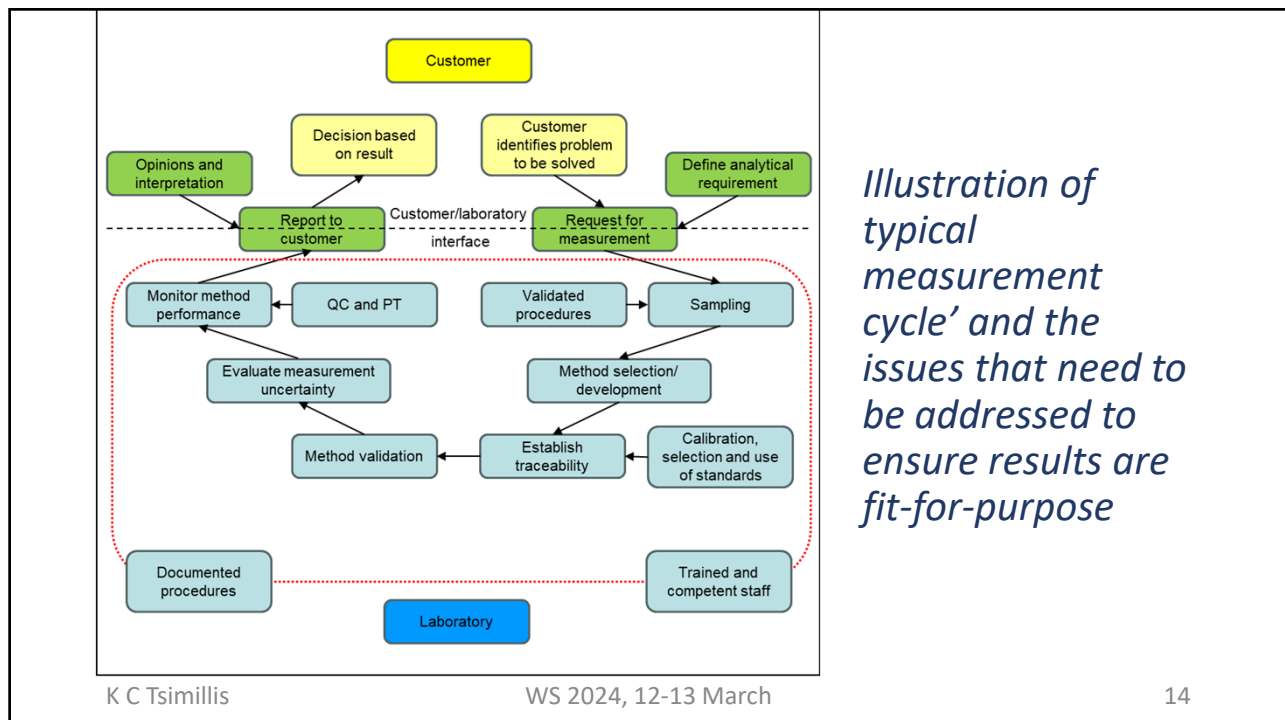
The structure has changed...

The task was not to follow the structure of the Standard; however, this was taken into consideration as well. It seems that the new structure is more functional.

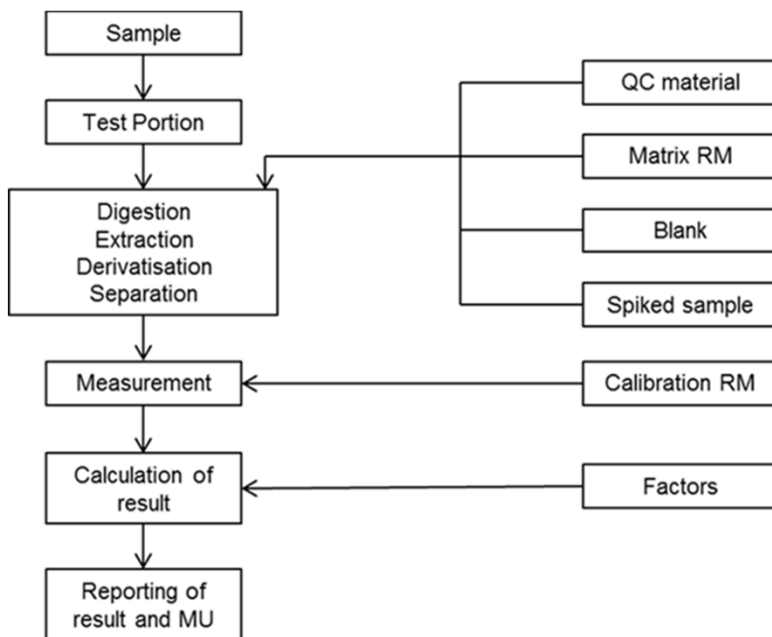
A couple of figures used help the better understanding of some functions.

The draft new QAC takes into account more recent publications

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Example of a typical analytical process, showing the role of RM

Demonstrating competence

- International standards (ISO/IEC 17025, ISO 15189, GLP)
- Introduce concept of scope
- Documentary standards for RM producers and PT providers
- Accreditation vs certification
- Accreditation bodies
- ISO 17011
- Regulation 765/2008
- MLA/MRA

Accreditation process - Structure of ISO/IEC 17025

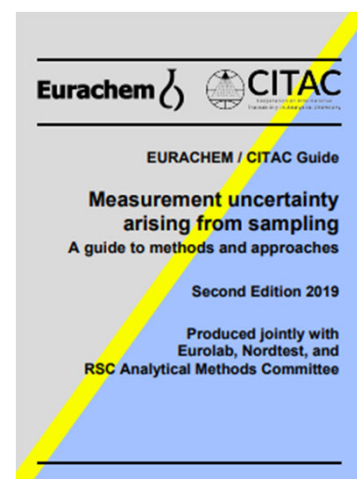
- Scope of accreditation – fixed vs flexible
- Laboratories range of activities vs scope of accreditation
- Mention specific clause but approach applies throughout the standard
- The guide will focus on the “technical” risks
- Guidance on what lab needs to do
- Staff empowerment/engagement - individual staff input in relation to risks and opportunities

Definition of laboratory

Inclusion of sampling in the activities of a laboratory; as a result, sampling is considered as stand-alone activity.



Uncertainty arising from sampling needs to be taken into account



Appendices

- Appendix A – audit check list
- Appendix B – consider what information needs to be retained
- Appendix C (NEW) – Risk register – examples of risk to consider

It is expected that a final draft of QAC...

will be ready by the coming meeting of the Education & Training WG and the General Assembly to be hosted in Vilnius, Lithuania (May 2024)