New publications relating to Quality Assurance

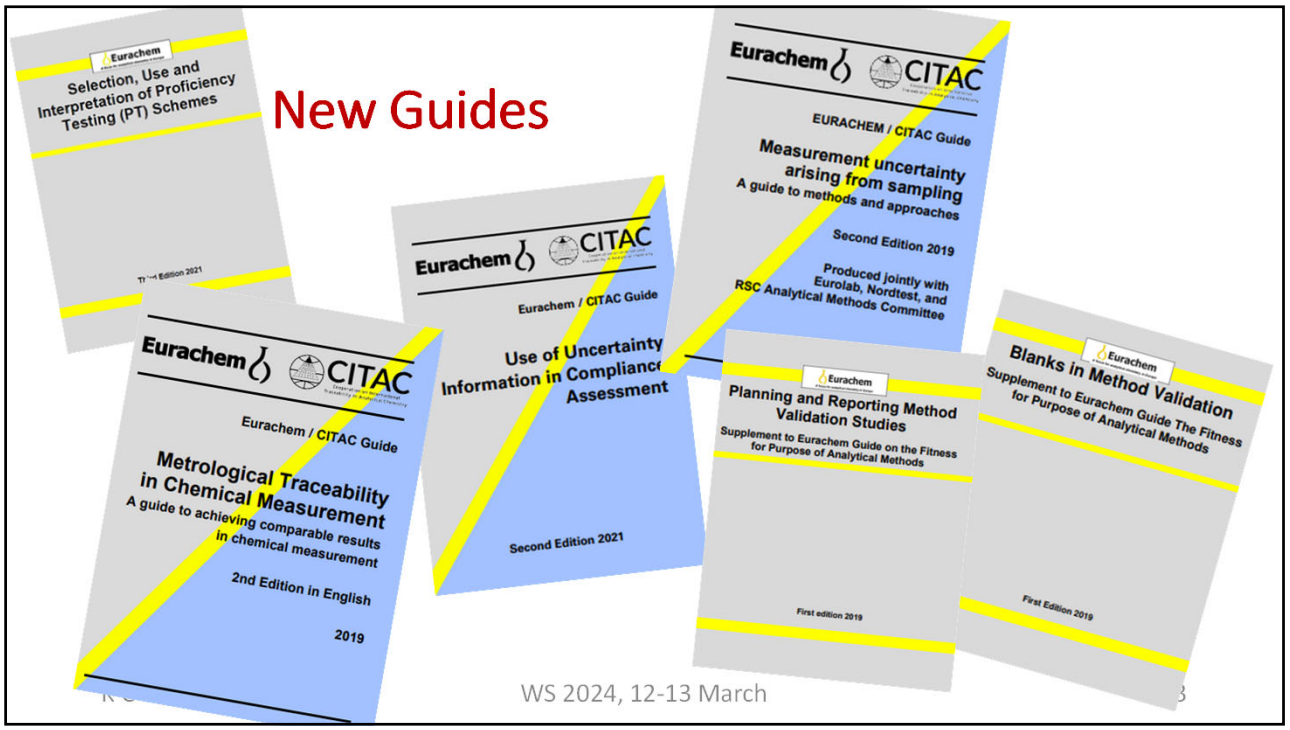
Dr Kyriacos C. Tsimillis

12-13 March 2024

1

www.eurachem.org

2



3

Leaflets on the accreditation standards

4

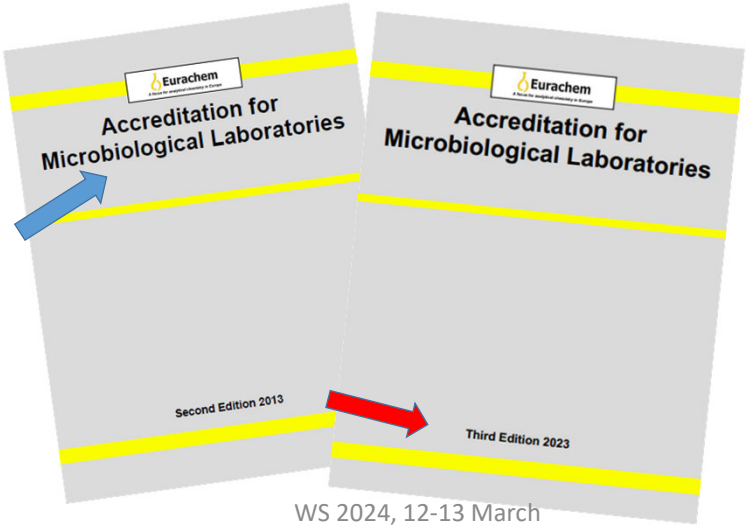
Leaflets and guides (translations)

Reading List for Analytical Scientists

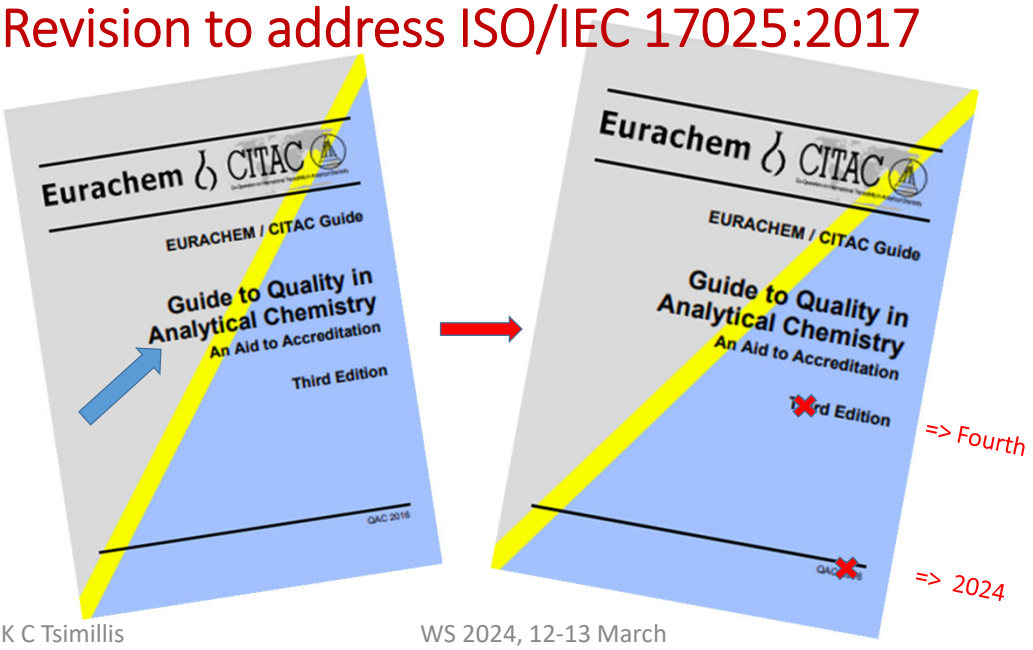
Contents

- *Websites and web resources*
- *Standards*
- *Guides*
- *Books*
- *Articles and reports*
- *Leaflets*
- *Software*

Revision to address ISO/IEC 17025:2017



Revision to address ISO/IEC 17025:2017



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- The existing version (2016) addressed the requirements of the superseded standard (2005)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

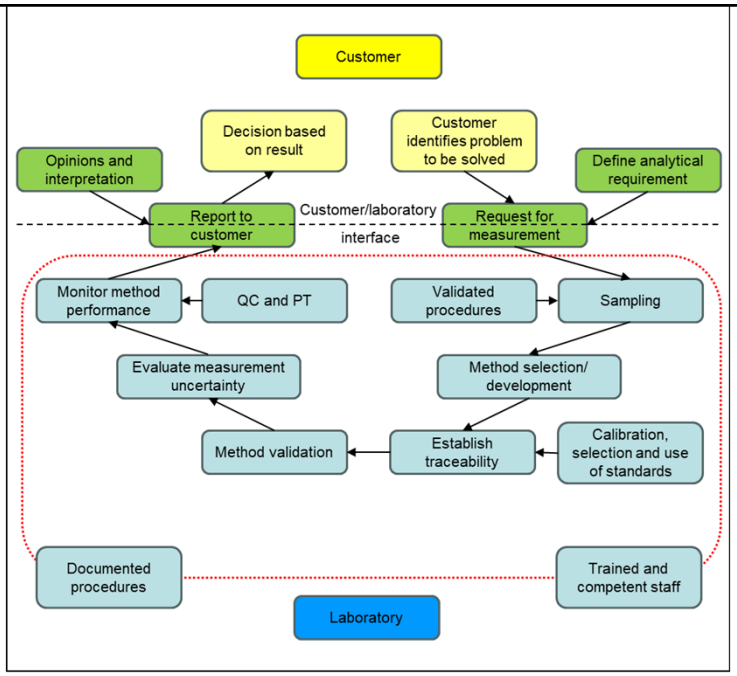
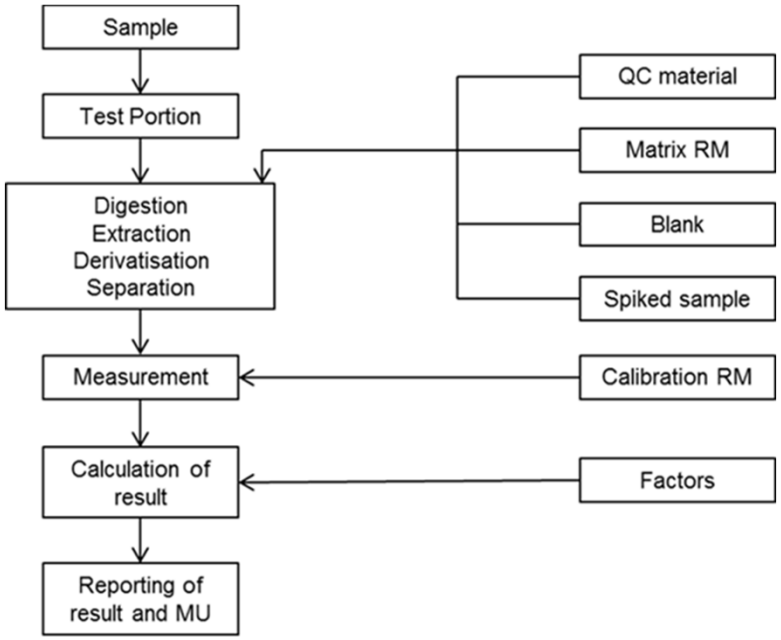


Illustration of typical measurement cycle' and the issues that need to be addressed to ensure results are fit-for-purpose



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

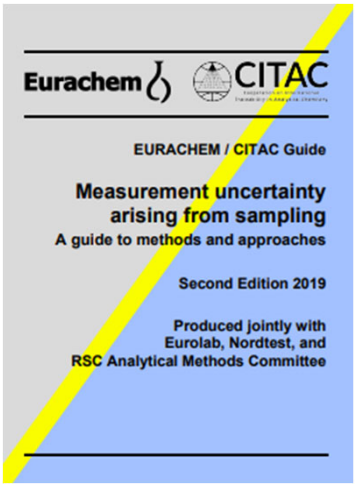
Accreditation process - Structure of ISO/IEC 17025

- 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)