

Eurachem Workshop
Uncertainty from sampling and analysis for accredited laboratories

Uncertainty from Sampling: Could the requirements of ISO/IEC 17025:2017 be adopted in medical laboratories?

Kyriacos C. Tsimillis¹ and Sappho Michael²

¹*Division of Quality Assurance, Pancyprian Union of Chemists*

²*Ministry of Health
Nicosia, Cyprus*

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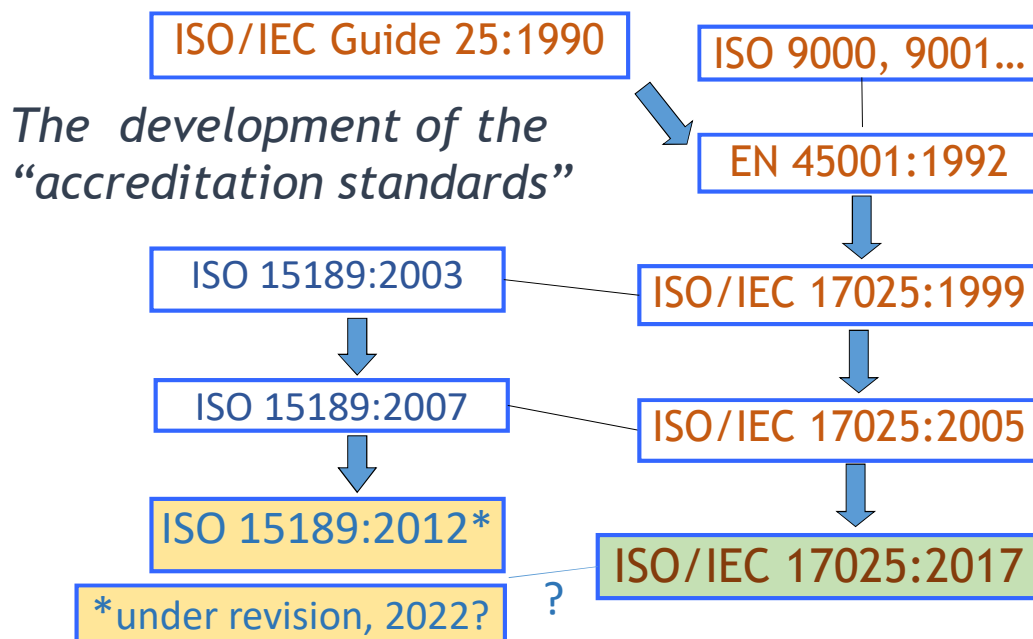
ISO/IEC 17025:2017¹ and ISO 15189:2012²

specify the requirements for the competence of
1 testing and calibration laboratories and sampling
2 medical laboratories

Despite the differences between the two standards reflecting the specific needs each of them is addressing, the development of the two documents follows similar paths.

What to discuss?

- The requirements of ISO/IEC 17025 referring to sampling and the uncertainty arising from it, where applicable
- A comparison with the ISO 15189 with regard to its requirements for sampling
- Could an approach on uncertainty from sampling similar to the one introduced by the new ISO/IEC 17025 be included in a future revision of ISO 15189?



The new ISO/IEC 17025:2017...

has introduced a number of changes not only in the text itself but in the philosophy as well.

Some of the additional provisions are quite new, e.g. the inclusion of sampling in the accreditable activities of a laboratory, the use of a decision rule, some management aspects.

Are there analogies with ISO 15189?

Some of the new provisions of ISO/IEC 17025:2017 are similar to those of the standard for medical laboratories i.e.

- Risks and opportunities (risk-based thinking ⇔ risk management)
- Control of data and information management: More detailed requirements, addressing new technology tools
- Competence of PT providers and RM producers based on their compliance with the relevant standards (ISO/IEC 17043 and ISO 17034 respectively)

Transition period will be soon over!

As the transition of all parties to the new standard ISO/IEC 17025 needs to be completed by 30 November 2020,

- laboratories try to find their way to adequately address all the new requirements
- accreditation bodies need to ensure their readiness to assess all laboratories against the new standard, considering the new philosophy
- EA and other regional bodies need to ensure that peer evaluation procedures are carried out in a homogeneous way.

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ISO 15189:2012 is currently under revision

The revision of the standard has recently started; the task is expected to be finalised in 2022.

However, some comments on the possible outcome can be made.

It is considered that some of the new provisions of ISO/IEC 17025:2017 will be reflected in the revised edition of the standard for medical laboratories.

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What about sampling?

The inclusion of sampling as a stand-alone laboratory activity, although not expressed in this way, represents one of the main changes of the new ISO/IEC 17025 compared with its 2005 version.

This is reflected in a number of other provisions of the standard, including the evaluation of measurement uncertainty.

Contribution of uncertainty arising from sampling

- Clause 7.6.1 specifies that all contributions of significance including those arising from sampling shall be taken into account
- Clause 7.8 specifies the requirements for reporting of results; sub-clause 7.8.2 includes common requirements for all reports – test, calibration or sampling

Requirements for reporting of sampling...

are specified in sub-clause 7.8.5.

Information required to evaluate measurement uncertainty for subsequent testing or calibration to be included in the report is referred to in 7.8.5 (f)

Other required information is referred to in 7.8.5 (a)-(e).

What does ISO 15189 provide for sampling?

Great emphasis is given to the pre-examination processes including self collected and otherwise collected primary samples and their handling.

This is due to the fact that a number of factors leading to a high percentage of failures do occur during this phase. These factors contribute to the measurement uncertainty, thus the measurement result (and its significance) might be compromised.

The medical laboratory shall have...

documented procedures and information for pre-examination activities, including

- Information to patients and users of its services (sub-clauses 5.4.2 and 5.4.3)
- Procedures for
 - the proper collection and handling of primary samples (sub-clause 5.4.4)
 - the transportation of samples (sub-clause 5.4.5)
 - sample reception (sub-clause 5.4.6)
 - sample handling, preparation and storage (sub-clause 5.4.7)

However, with regard to uncertainty...

ISO 15189 is focusing only on contributions arising from the examination phase (see sub-clause 5.5.1.4) thus excluding those arising from the pre-examination processes and sample collection in particular.

Note 1 to the said sub-clause indicates that:

The relevant uncertainty components are those associated with the actual measurement process, commencing with the presentation of the sample to the measurement procedure and ending with the output of the measured value.

It is expected that...

some of the new elements of ISO/IEC 17025:2017 are to be taken into account during the revision of ISO 15189:2012, e.g.

- management issues
- metrological traceability
- additional tools to ensure the validity of results
- the meaning of “shall”, “should”, “may”, “can”

In the medical sector...

sampling is often an activity carried out in the medical laboratory; this is especially the case of small private laboratories.

This is not the case in hospital laboratories where the sample collection is out of the control of the medical laboratory.

Could we expect that sampling

could be considered as a stand-alone activity in the medical sector?

Why not?

A similar definition to the one given in ISO/IEC 17025 could apply

What about uncertainty from sampling?

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For testing laboratories

some approaches providing guidance how to address the issue of uncertainty arising from sampling are described in the Eurachem/Eurolab/CITAC/Nordtest/RSC AMC (2019) Guide “Uncertainty arising from sampling. A guide to methods and approaches”.

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Could these approaches be used...

in medical laboratories as well?

What about some inherent difficulties mainly due to the nature of the samples which, according to ISO 15189, are “materials derived from the human body”?

The main difficulties refer to...

- the nature of biological samples (biological variation)
- the process for their collection e.g. repeated blood samples from one or both arms could give some indication – sampling variation
- ethical issues with regard to the patient concern
- not easily quantifiable factors during transportation from the collection site to the laboratory

Replicate sampling

which can be used by testing laboratories is rather unrealistic in the medical sector.

Based on the above, it is questionable whether an approach on uncertainty from sampling similar to the one introduced by the new ISO/IEC 17025 could be included in the expected revision of ISO 15189.

There is a number of publications

which do address the issue but not in a practical way to quantify the uncertainty arising from sampling.

Hopefully, the discussion during this event will give food for thought.

Thank you for your attendance...

and your questions and comments