What do laboratories need to know about ISO/IEC 17011:2017?

Eurachem Guides for analytical and microbiological laboratories

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According to European Regulation no 765 (2008)

conformity assessment body shall mean a body that performs conformity assessment activities including calibration, testing, certification and inspection" (Article 2.13)

conformity assessment shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled (Article 2.12)

Conformity assessment bodies (CAB)

According to ISO/IEC 17011

- a CAB is a "body that performs conformity assessment activities and that can be the object of accreditation" (sub-clause 3.4)
- conformity assessment activity is given a more wide context with the addition of provision of proficiency testing, production of reference materials etc (Note 1 to sub-clause 3.5)

Requirements for the competence

of conformity assessment bodies (CABs) are included in a series of standards. These standards do not refer to accreditation themselves; however, these are the ones used by accreditation bodies in the assessment of laboratories for their accreditation.

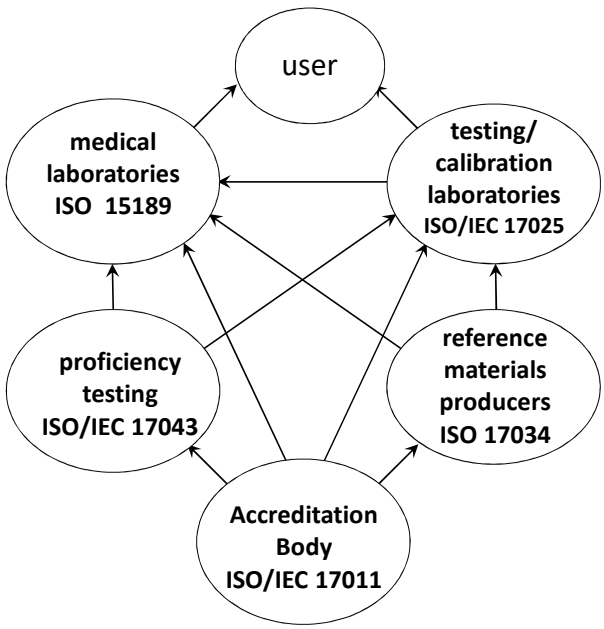
This is why the term "accreditation standards" is used throughout this presentation.

The Accreditation Standards…

of interest to laboratories are mainly those referring directly to the requirements for their competence, namely

- ISO/IEC 17025 (2017) General requirements for the competence of testing and calibration laboratories
- ISO 15189 (2012) Medical laboratories – Requirements for quality and competence

HOWEVER, THESE ARE NOT THE ONLY ONES…



Interaction between a laboratory and other bodies

Other accreditation standards of interest

to laboratories are

- ISO/IEC 17043 (2010) Conformity assessment – General requirements for proficiency testing
- ISO 17034 (2016) General requirements for the competence of reference material producers

PLUS

➔*ISO/IEC 17011 (2017) Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies*

➔*Eurachem/CITAC Guide on R&D and non-routine analysis (under revision)*

Both ISO/IEC 17025 and ISO 15189

refer to the competence of PT providers and RM producers based on their compliance with the requirements of the two standards respectively.

=> No reference is made to their accreditation.

=> In case they are not accredited, it is upon the laboratory to document this compliance, provided that it is aware of the relevant requirements included in the said standards.

This is an issue to be assessed by the Accreditation Body.

Are ISO/IEC 17043 and ISO 17034 really…

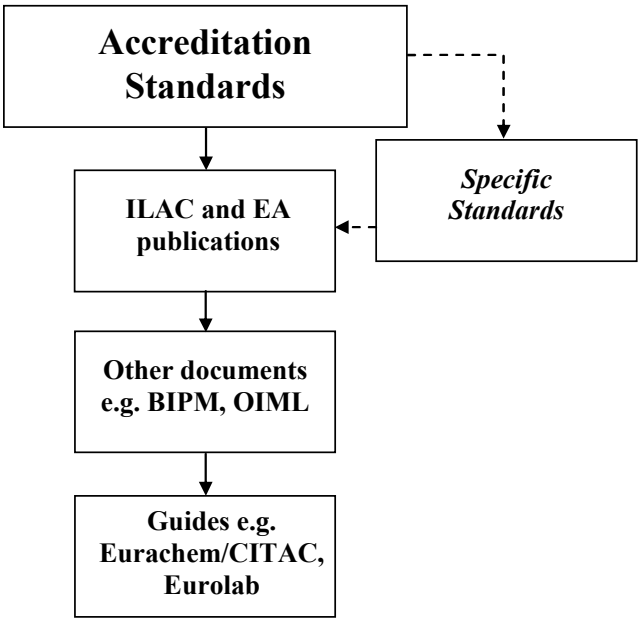
of interest to laboratories or not?

Are laboratories aware of the main provisions of…

- ISO/IEC 17043 (2010)
- ISO 17034 (2016)
- ISO/IEC 17011 (2017) (or the 2004 version)

Accreditation standards

are generally applicable; they do not address all specific needs in each field of laboratory work. Additional documents are necessary to set some specific requirements while other documents provide guidance and explanations to laboratories…



Order of documents to be considered by a laboratory

There are other documents of interest

- Normative references
- Standards and other documents referring to particular issues, i.e. measurement uncertainty, sampling, sectoral needs
- Other documents referring e.g. to traceability (BIPM, OIML)
- Publications by EA and ILAC
- Publications by Eurachem/CITAC, Eurolab etc.

What about normative references?

- ISO/IEC 99 : International vocabulary of metrology – Basic and general concepts and associated terms (VIM)[1,2]
- ISO/IEC 17000 : Conformity assessment – Vocabulary and general terms[1,2]
- ISO IEC Guide 2 : Standardization and related activities – General vocabulary[2]

➔Are these necessary to be included in the external document list?

[1] ISO/IEC 17025, [2] ISO 15189

EA and ILAC documents*…

are not only very useful but, a number of them are compulsory for the accreditation bodies for which they have been drafted; they are also important for laboratories and other CABs as appropriate bearing in mind that…

Laboratories need to be aware of the documents describing requirements to be used during their assessment by the accreditation body.

*available from www.european-accreditation.org and www.ilac.org

The accreditation body

- Shall follow the requirements of EA* e.g. EA 4-02 M, EA 4-16 G as well as those of ILAC i.e. P 10, P 14, G 17. Such documents comprise the basis for the EA MLA/ILAC MRA.
- Further to these, the national accreditation body may prepare additional documents, both regarding their policy (mandatory) and informative/guidance to the laboratories in the country.

** or, other regional bodies*

This is not the case with guides…

and other documents drafted by Eurachem, CITAC, Eurolab etc. except in cases where reference is made to them.

In any case, they are very useful! Following relevant statistics, it is illustrated that their use is increasing.

All these guides, leaflets and other information are freely downloadable from relevant websites (www.eurachem.org, www.eurolab.org, etc)

What about the new ISO/IEC 17011?

- This Standard specifies the "Requirements for accreditation bodies accrediting conformity assessment bodies"
- It provides for all operational matters and technical competence of accreditation bodies
- Many of these requirements affect laboratories which are expected to be adequately aware and well prepared in the perspective of their assessment by the accreditation bodies towards their accreditation.

Structure and terminology

- The structure of the Standard is extensively changed in line with the format of the ISO 17000 series.
- It is stated that the following verbal forms are used:
  - *"shall"* indicates a requirement;
  - *"should"* indicates a recommendation;
  - *"may"* indicates a permission;
  - *"can"* indicates a possibility or a capability.

Risk and risk-based thinking

The introduction of the concept of risk and risk-based thinking is reflected in a number of sub-clauses i.e. the ones dealing with

- impartiality (4.4.6 – 4.4.9, 4.4.13) - financing and liability (4.5.2)
- determination of competence criteria (6.1.2.4)
- competence management (6.1.3.4)
- preparation for assessment (7.4.6) - accreditation cycle (7.9.3)
- extending accreditation (7.10) - improvement (9.10)
- management reviews (9.8.2)

➔*As a result, no reference is made to preventive actions*

New definitions

- "accreditation scheme" rules and processes including ISO/IEC 17025, ISO 15189, ISO/IEC 17043, ISO 17034 etc. (sub-clause 3.8 and Note)
- "flexible scope of accreditation" allows CABs to make changes to methodology and other parameters within their competence as confirmed by the accreditation body (sub-clause 3.7)
- "remote assessment" (sub-clause 3.26)
- "assessment programme" (sub-clause 3.27);

As already mentioned, the Standard is …

much more detailed than the relevant provision of the European Regulation for Accreditation (no 765/2008); according to this Regulation:

- "conformity assessment": the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled (Article 2.12)
- "conformity assessment body": a body that performs conformity assessment activities including calibration, testing, certification and inspection (Article 2.13).

Other definitions added

conformity assessment activity (sub-clause 3.5)
accreditation activity (3.9) - impartiality (3.10)
accreditation process (3.11) - accreditation decision (3.13)
granting of accreditation (3.14) - maintaining of accreditation (3.15)
reassessment (3.23) - assessment technique (3.24)
assessment plan (3.28) - accreditation body personnel (3.29)

Legal entity - accreditation agreements

Clause 4 (previously partly in clauses 4 and 8) is undoubtedly very important both for the accreditation body and the laboratories!

It provides for…

- The legal entity (4.1)
- The accreditation agreement (4.2)
- The use of accreditation symbols and claims (4.3)
- Impartiality issues (4.4)
- Financing and liability (4.5)
- Establishing accreditation schemes (4.6)

Structural requirements

Clause 5 (previously in 4.2) provides, among other issues, for

- Safeguarding impartiality (5.1)
- Organizational structure - lines of authority and responsibility (5.2)
- Relation with a larger entity - legal status (5.3+5.4)
- Authority for accreditation decisions (5.5)
- Duties, responsibilities and authorities of top management (5.6+5.7)
- Rules for the appointment, terms of reference of committees involved in the accreditation process and interested parties

Resource requirements

"Human resources" remains under clause 6 with a different title.

- Competence of personnel (6.1)
- Personnel involved in the accreditation process (6.2)
- Personnel records (6.3)
- Outsourcing (6.4)

Process requirements

"Accreditation process" remains under clause 7 with a different title.

- Accreditation requirements (7.1)
- Application for accreditation (7.2)
- Resource review (7.3)
- Preparation for the assessment (7.4)
- Review of documented information (7.5)
- Assessment (7.6)

continued

Process requirements (2)

- Accreditation decision-making (7.7)
- Accreditation information (7.8)
- Accreditation cycle (7.9)
- Extending accreditation (7.10)
- Suspending, withdrawing or reducing accreditation (7.11)
- Complaints (7.12)
- Appeals (7.13)
- Records on conformity assessment bodies (7.14)

Information requirements

are specified in clause 8 (previously in clauses 4.4 and 8.2) in a more elaborated way.

- Confidential information (8.1)
- Publicly available information (8.2)

Management system requirements

are included in clause 9 (previously in clause 5).

- General (9.1)
- Management system (9.2)
- Document control (9.3)
- Records control (9.4)
- Nonconformities and corrective actions (9.5)
- Improvement (9.6)
- Internal audits (9.7)
- Management reviews (9.8)

Annex A (informative)

provides for “Knowledge and skills for performing accreditation activities”. Table 1 provides a list of aspects with reference to the relevant sub-clause in the text.

According to Note 3 conformity assessment scheme requirements include ISO 9001, ISO 14001, ISO 9096, WADA ISL, Energy STAR”.

The familiarization of the laboratory

for the provisions of ISO/IEC 17011 is of high importance because this is the only way to know the framework within which the accreditation operates, its rights and its obligations. This is the basis for the communication with the accreditation and in case of a problem the origin for a complaint.
This is not undermined by the existence of any kind of information provided by the accreditation body (website, leaflets etc.) which may not always be adequately comprehensive.

The deadline for the transition…

to the new ISO/IEC 17011 is approaching!

- According to a Resolution of the Joint General Assembly of ILAC and IAF...
  "...all peer evaluation activities to be carried out after 1 July 2018 will use ISO/IEC 17011:2017 as the requirements document. Details of this transition plan are described in the document entitled "ISO/IEC 17011:2017 Transition Plan" dated 29 October 2017 available from ILAC website (www.ilac.org). The transition period in November 2020.

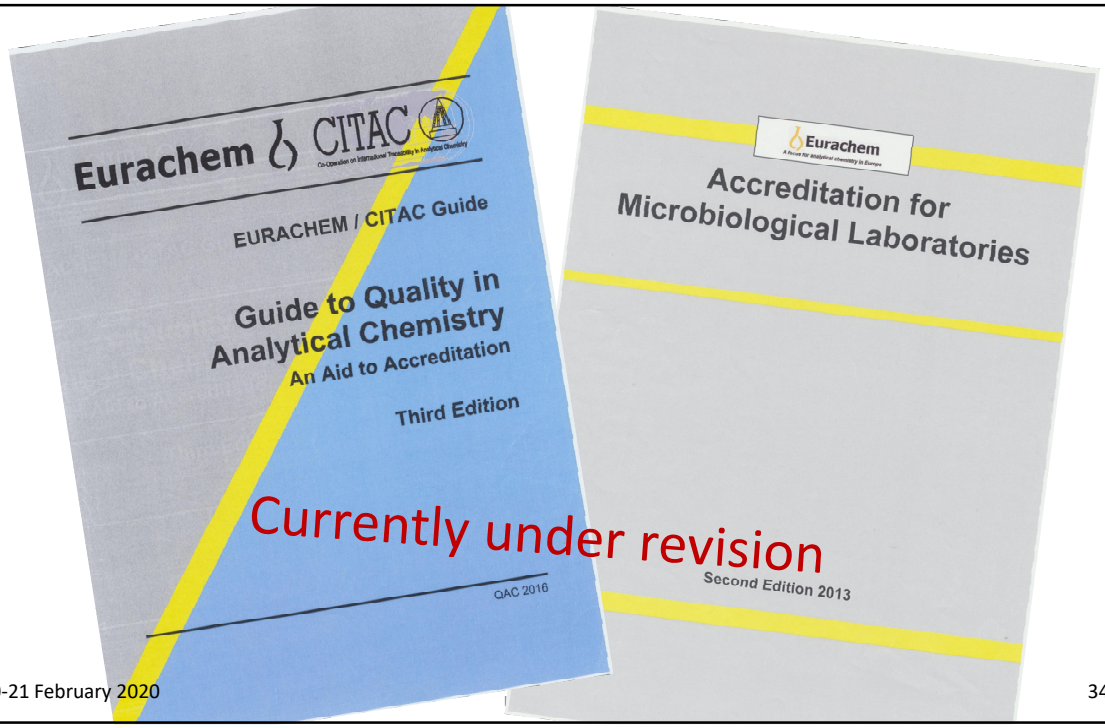
Two guides are, among others…

under revision, namely…

Eurachem/CITAC *Guide to Quality in Analytical Chemistry - An Aid to Accreditation*

Eurachem *Guide - Accreditation for Microbiological Laboratories*

All additional elements of ISO/IEC 17025 will be addressed in the revised documents providing guidance to the user on how to smoothly adjust to the new needs.

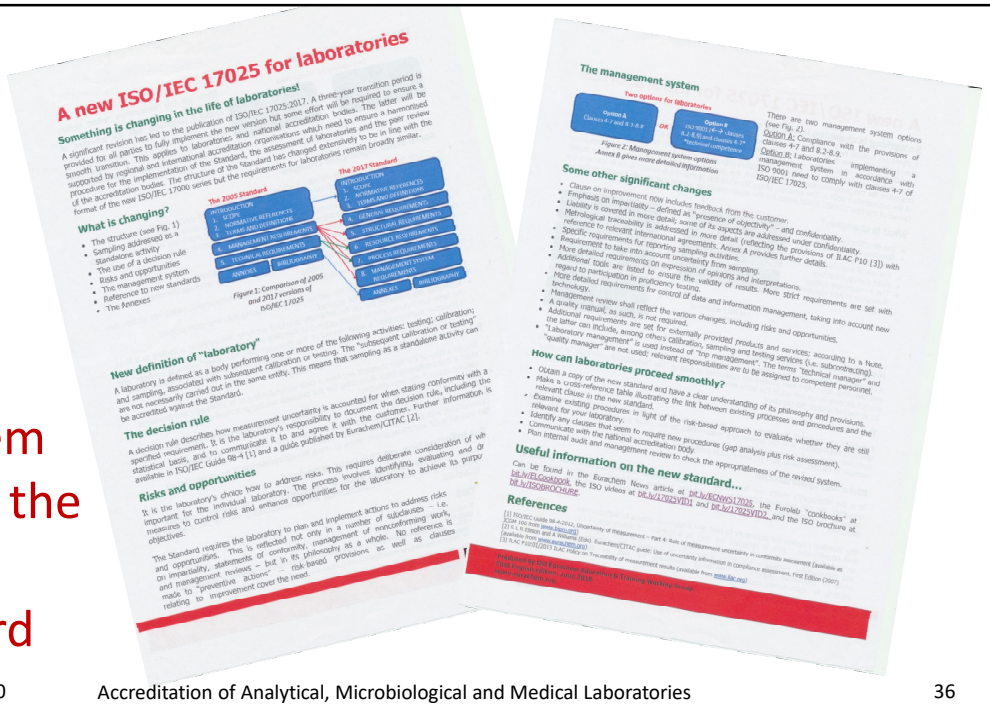


The guide for analytical laboratories…

has been quite recently revised (2016); however it was known that, soon later, it would have to be revised again to be in line with the then expected new ISO/IEC 17025.

The Guide refers mostly to the technical issues of the operation of a testing or calibration laboratory. Each chapter is linked to a particular sub-clause of the standard with references to other publications accordingly.

Eurachem leaflet on the new Standard



Main aspects to be considered are

- reference to sampling as a stand-alone laboratory activity
- the risk-based thinking and opportunities
- the uncertainty arising from sampling as appropriate
- the use of a decision rule
- the additional requirements for traceability
- the compliance of PT providers and RM producers to the relevant standards
- adjustment of the wording “shall”, “should” etc.
- review of the reference list

Microbiological laboratories’ Guide

The Guide was published in 2013 as a revision of the previous version which appeared as an EA document (EA 4/10) although it had been prepared by Eurachem and the Laboratory Committee of EA.

The Guide provides support…

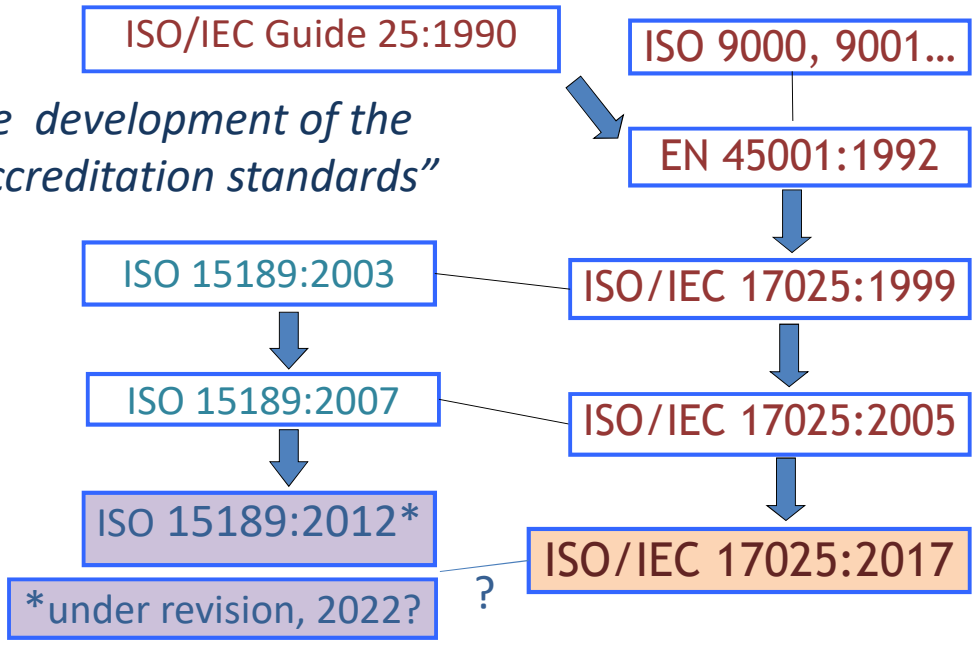
- to laboratories carrying out microbiological testing - guidance on how to fulfill the requirements of ISO/IEC 17025
- to medical laboratories (ISO 15189)
- to those involved in R&D (see also relevant guide by Eurachem/CITAC, currently under revision as well)
- to GLP, GMP and GCP

A final comment

Despite the differences between the two standards reflecting the specific needs each of them is addressing, their development has followed similar paths until now.

It is expected that some of the new elements of ISO/IEC 17025 are to be taken into account during the revision of ISO 15189 e.g. management issues, metrological traceability, additional tools to ensure the validity of results, the meaning of “shall”, “should”, “may”, “can”. It is not expected that uncertainty from sampling will be taken on board in the case of medical laboratories.

The development of the "accreditation standards"



Thank you

for your attention

and your questions…