

Eurachem Tbilisi 2022 – Scientific Workshop 16-18 May 2022  
Quality Assurance Challenges of Measurements from Field to Laboratory

Revision of Eurachem Guides

in relation to ISO/IEC 17025 -

Developments in the revision of ISO 15189

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# This presentation

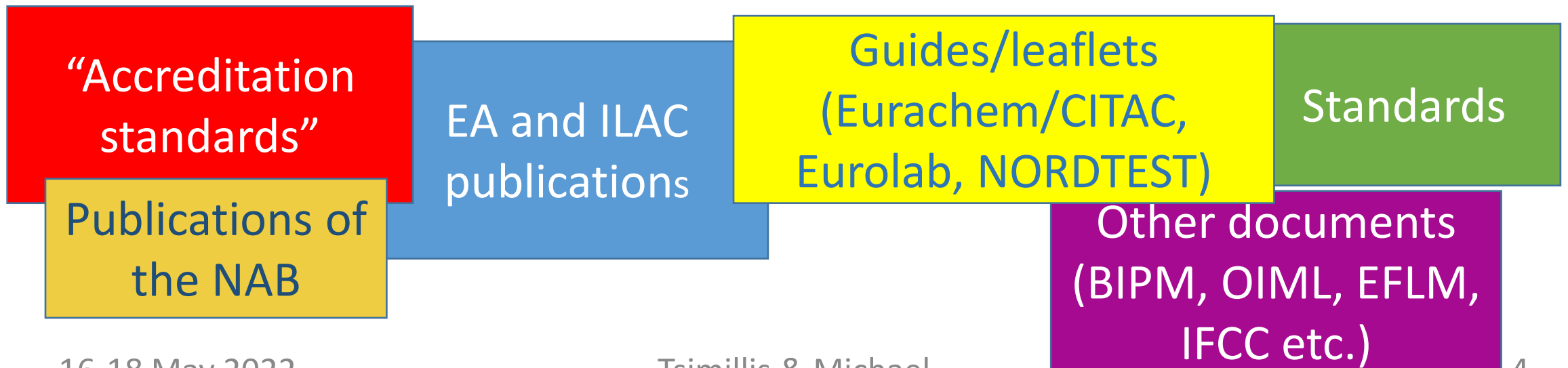
- describes the main elements of the revision of two Eurachem Guides;
- provides a comprehensive reference to the revision of ISO 15189 and its current status (ISO/DIS 15189);
- provides a brief correlation of ISO/DIS 15189 and ISO/IEC 17025.

# Abbreviations

- BIPM *International Bureau of Weights and Measures*
- CITAC *Cooperation on International Traceability in Analytical Chemistry*
- EA *European cooperation for Accreditation*
- EFLM *European Federation of Clinical Chemistry and Laboratory Medicine*
- IFCC *International Federation of Clinical Chemistry*
- ILAC *International Laboratory Accreditation Cooperation*
- NAB *National Accreditation Body*
- Nordtest *Nordic cooperation in conformity assessment*
- OIML *International Organization of Legal Metrology*

# What is required towards accreditation?

In order to better understand the “accreditation standards”, the laboratory needs the support of other documents i.e. standards, guides, EA and ILAC publications (mandatory or guidelines), explanatory documents by the national accreditation body (NAB)



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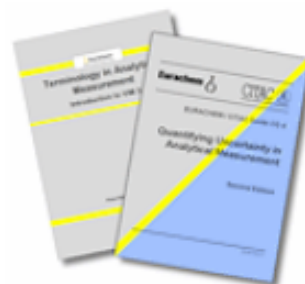
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## Eurachem Publications



Eurachem publishes guidance documents and information leaflets on a range of issues in quality and accreditation for analytical measurement.

### Guides

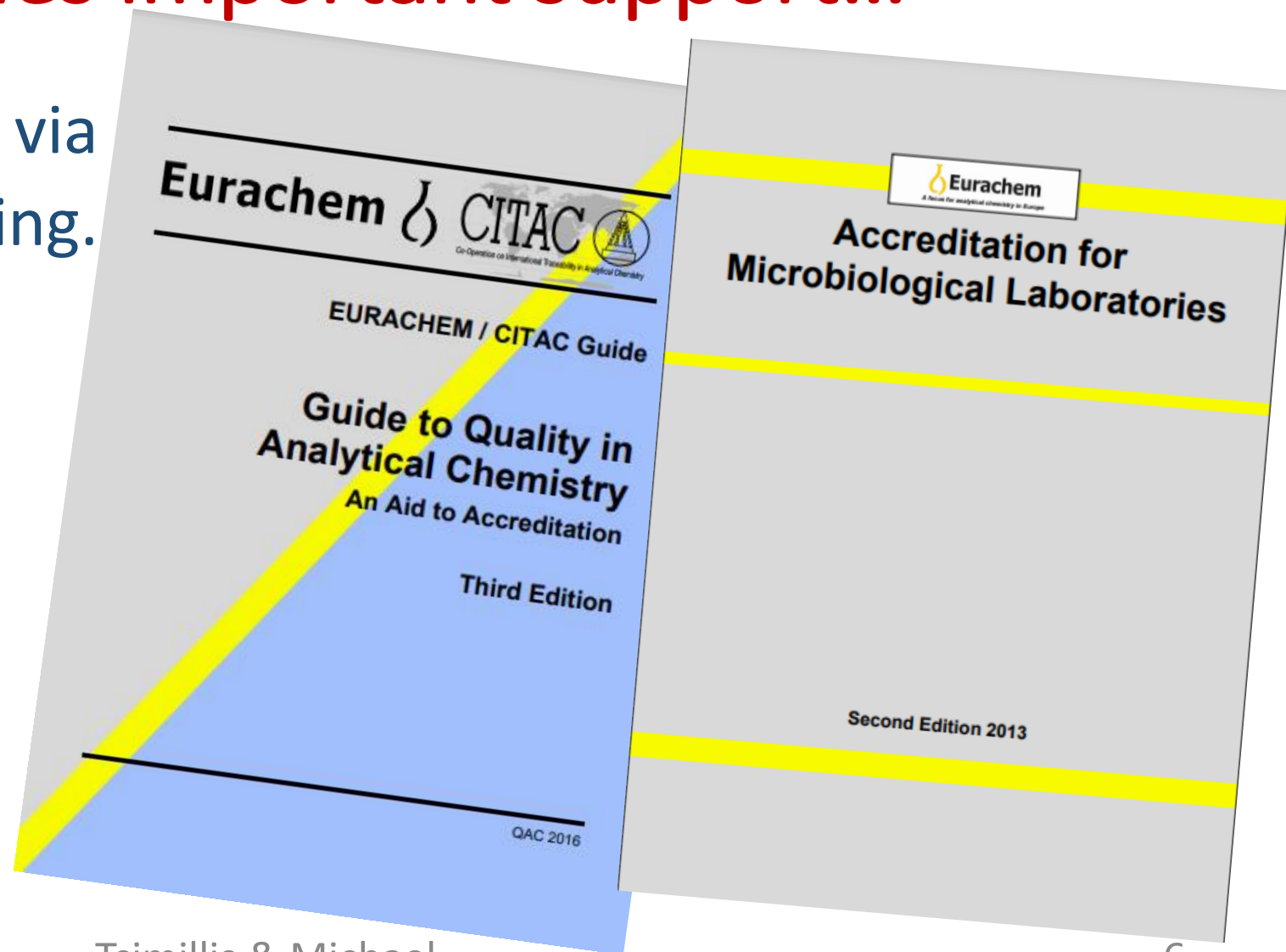


Eurachem guides typically give detailed technical information about a topic. Guides usually include definitions of terms and concepts, practical advice on achieving quality objectives or requirements, and detailed technical information such as statistical methods, performance characteristics for analytical methods or information on typical uncertainties or performance. Guides often include practical examples. Eurachem Guides are normally aimed at laboratory staff responsible for quality in laboratories. Many Eurachem guides are

# Eurachem provides important support...

to laboratories mainly via publications and training.

All aspects referring to the competence of laboratories are addressed in guides drafted by thematic Working Groups.



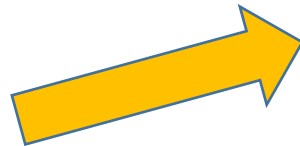
# The two Guides are currently under revision...

by two competent task groups; the objective is to ensure that the revised documents will provide a comprehensive picture of what is changing with the new ISO/IEC 17025 in the life of laboratories, both the analytical (QAC) and the microbiological (AML) ones.

# New aspects in ISO/IEC 17025

- Risk-based thinking
- Uncertainty from sampling
- Use of a decision rule
- Metrological traceability
- Control of data and information management
- Impartiality and liability

A first step:  
Eurachem leaflet  
(2018)



Tsimillis & Michael

**The management system**

Two options for laboratories

Option A  
Clauses 4-7 and 8.2-8.9

OR

Option B  
ISO 9001 (←→ clauses 8.2-8.9) and clauses 4-7  
"technical competence"

There are two management system options (see Fig. 2).  
**Option A:** Compliance with the provisions of clauses 4-7 and 8.2-8.9.  
**Option B:** Laboratories implementing a management system in accordance with ISO 9001 need to comply with clauses 4-7 of ISO/IEC 17025.

Figure 2: Management system options  
Annex B gives more detailed information

**Some other significant changes**

**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 of the accreditation bodies. The structure of the Standard has changed extensively to be in line with the format of the new ISO/IEC 17000 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

**The 2005 Standard**

1. INTRODUCTION
2. SCOPE
3. NORMATIVE REFERENCES
4. TERMS AND DEFINITIONS
5. MANAGEMENT REQUIREMENTS
6. TECHNICAL REQUIREMENTS
7. ANNEXES
8. BIBLIOGRAPHY

**The 2017 Standard**

1. INTRODUCTION
2. SCOPE
3. NORMATIVE REFERENCES
4. TERMS AND DEFINITIONS
5. GENERAL REQUIREMENTS
6. STRUCTURAL REQUIREMENTS
7. RESOURCE REQUIREMENTS
8. PROCESS REQUIREMENTS
9. MANAGEMENT SYSTEM REQUIREMENTS
10. ANNEXES
11. BIBLIOGRAPHY

Figure 1: Comparison of 2005 and 2017 versions of ISO/IEC 17025

**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 98-4 [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 reviews – but in its philosophy as a whole. No reference is made to "preventive actions" – risk-based provisions as well as clauses relating to improvement cover the need.

**Eurachem**  
A FOCUS FOR ANALYTICAL CHEMISTRY IN EUROPE

Role of measurement uncertainty in conformity assessment (available as / uncertainty information in compliance assessment. First Edition (2007) ults (available from [www.lac.org](http://www.lac.org))

Fig Group



# Some of the challenges of ISO/IEC 17025...

namely

- uncertainty from sampling;
- statements of conformity;
- metrological traceability;

have already been extensively addressed in existing Guides.

*However...*

# Some of the additional requirements

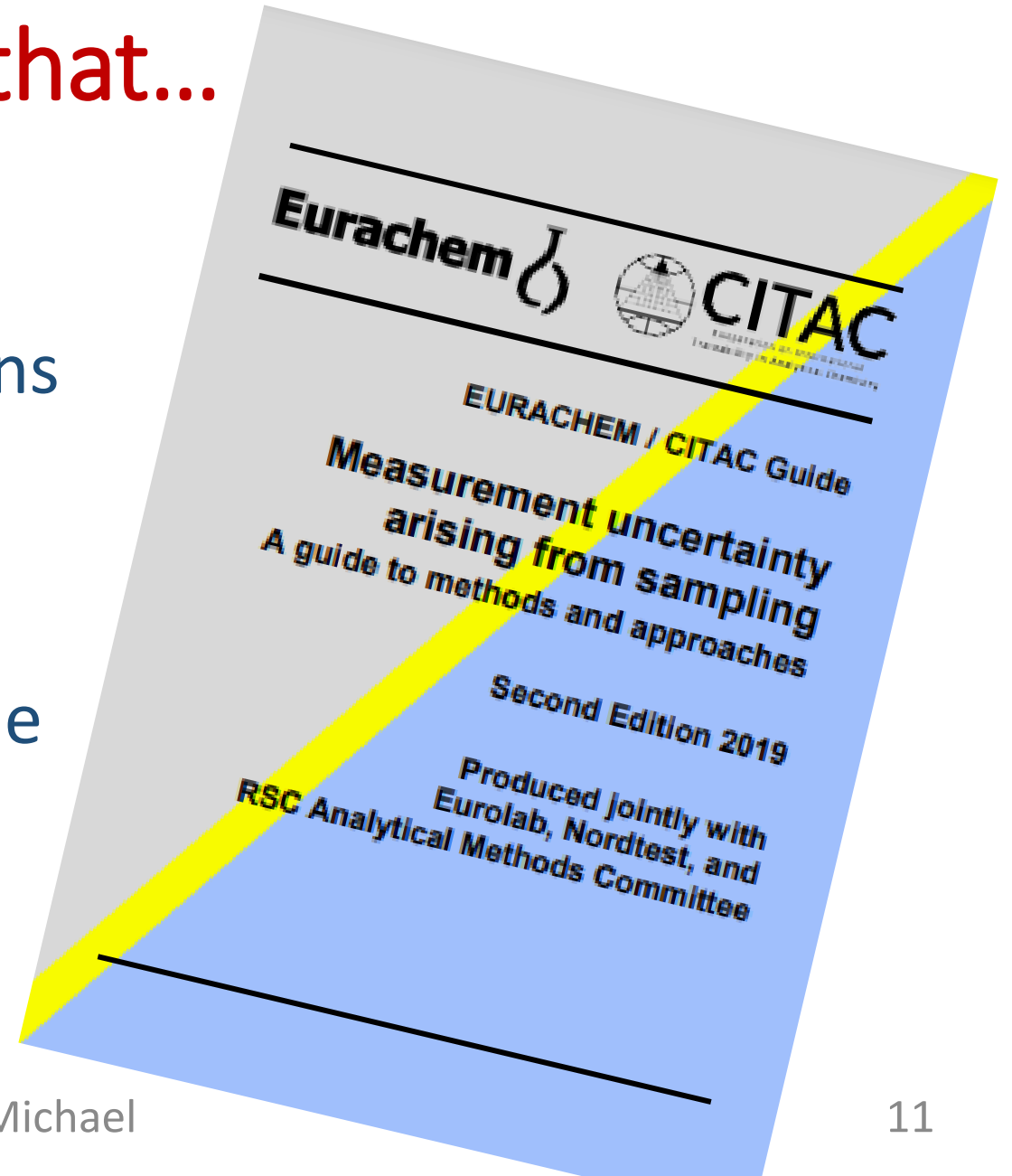
introduced by the said standard namely

- risks and opportunities;
- the use of a decision rule;
- information management etc.

made it necessary to revise the two guides QAC and AML.

# ISO/IEC 17025 specifies that...

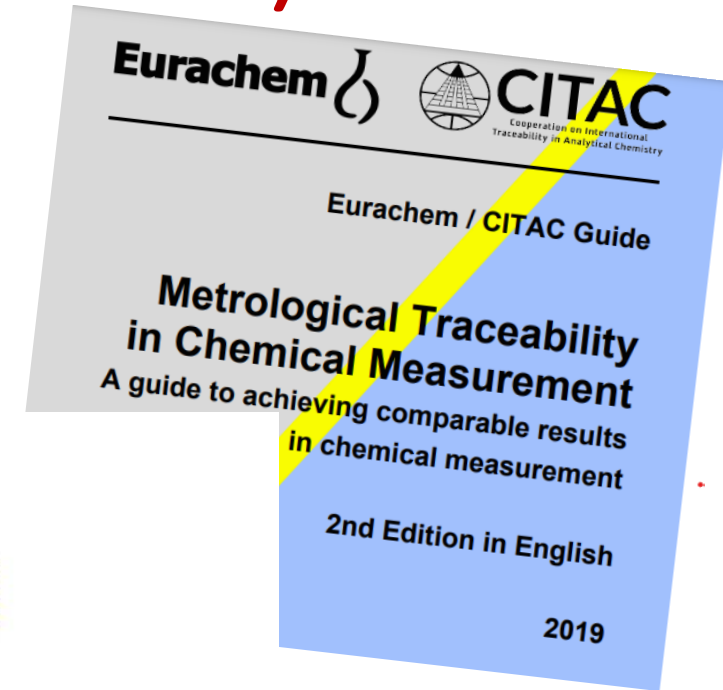
when evaluating measurement uncertainty (MU), all contributions have to be taken into account, including those arising from sampling. This is elaborated in the new Guide with reference to the relevant Eurachem/CITAC Guide.



# Metrological traceability (ISO/IEC 17025)

The laboratory shall establish and maintain metrological traceability of its measurement results (see also Annex A of the standard) through:

- Calibration shall be provided by competent laboratory (ILAC P10)
- Use of certified reference materials (ISO 17034 for competence)
- Direct realisation of the SI units by comparison with national or international standards.



**ILAC Policy on Metrological  
Traceability  
of Measurement Results**

**ILAC-P10:07/2020**

# Structural changes in ISO/IEC 17025\*

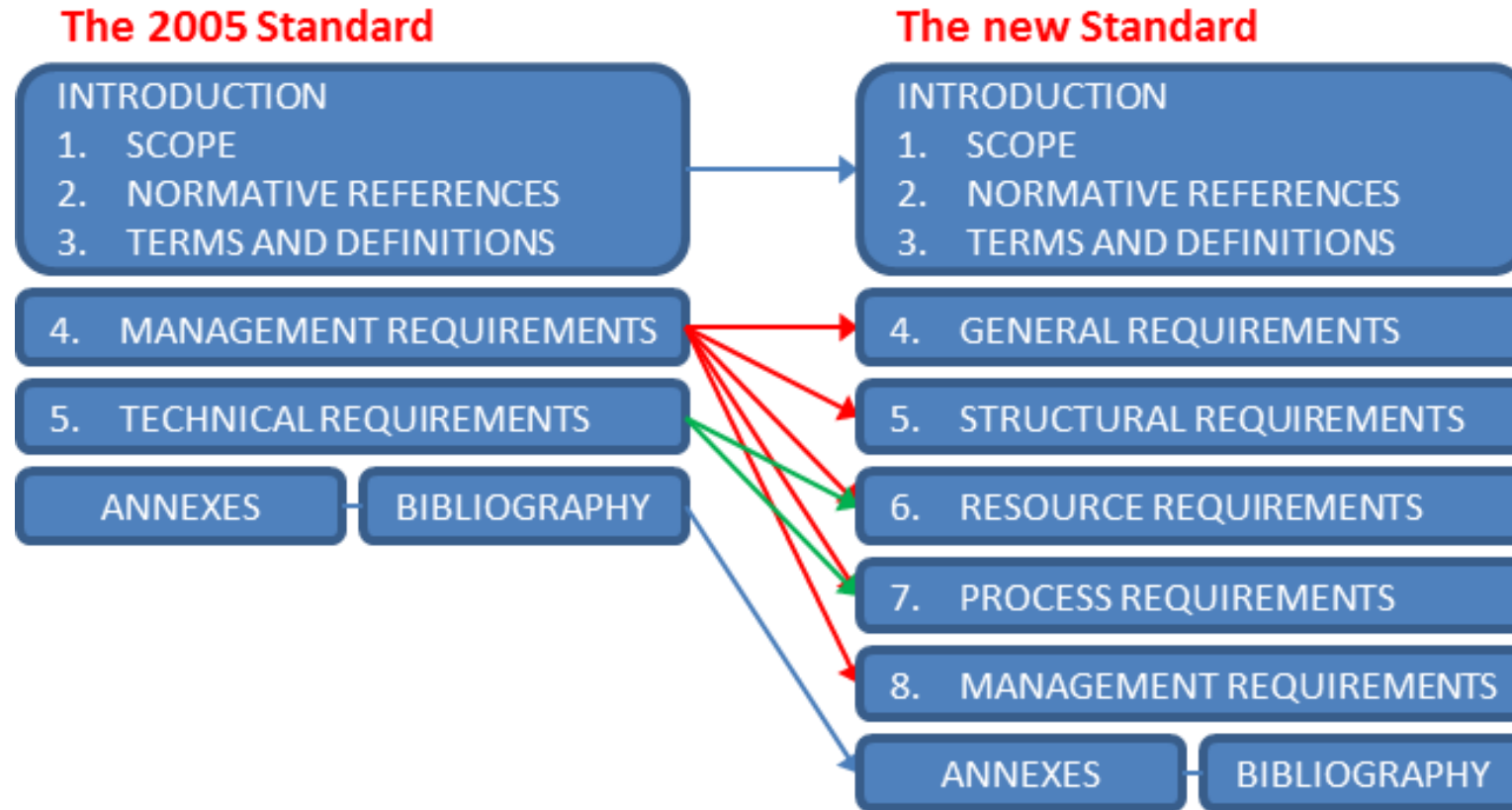


Figure 1: Comparison of 2005 and 2017 versions of ISO/IEC 17025

*\*extract from the Eurachem leaflet "A new ISO/IEC 17025 for laboratories" (2018)*

# The risk-based thinking in ISO/IEC 17025

- The introduction of risk-based thinking is the main change in the philosophy of **ISO/IEC 17025**; it enhances the sense of quality assurance in the laboratory work
- The risk-based thinking is integrated throughout the standard (31 references in the text)
- Emphasis is given to
  - ✓ impartiality
  - ✓ statements of conformity,
  - ✓ management of nonconforming work
  - ✓ management reviews

# Other issues addressed

- the use of a decision rule
- alternative procedures for the internal quality control
- more strict requirements for PT participation
- expression of opinions and interpretations
- control of data and information management taking into account new technology

# The new draft QAC Guide...

- is structured in a way close to the Standard
- includes a number of examples illustrating how to address the risk-based requirements
- reflects changes due to the revisions of other Eurachem Guides
- provides an updated bibliography
- ➔ *Unfortunately there is some delay in the revision process*



# The new draft AML Guide...

addresses the particular needs of this sector; main emphasis is given to:

- measurement uncertainty
- calibration and measurement traceability
- selection of methods - verification and validation
- reporting of results

Different approaches to be followed in food and water microbiology are described as appropriate.

**→ *It is expected that the AML Guide will be dated “2022”***

# What about medical laboratories?

Undoubtedly, the recent period with SARS-CoV-2 provided indeed an unexpected experience. In most countries no laboratories had the relevant tests included in their accreditation scope; there were cases where laboratories accredited to ISO/IEC 17025 undertook testing activities. All aspects are being extensively discussed in the competent EA LC WG “Healthcare”.

# Medical laboratories are waiting...

for the new ISO 15189; the revision of the 2012 version is approaching its completion following the specified ISO stages; to this end and despite the extensive support received, the current ISO/DIS may not necessarily remain unchanged until the publication of the new standard.

*This is why only main features could be referred to in such a presentation.*

DRAFT INTERNATIONAL STANDARD	
ISO/DIS 15189	
ISO/TC 212	Secretariat: ANSI
Voting begins on: 2021-10-19	Voting terminates on: 2022-01-11
<hr/>	
<b>Medical laboratories — Requirements for quality and competence</b>	
<i>Laboratoires de biologie médicale — Exigences concernant la qualité et la compétence</i>	
ICS: 11.100.01; 03.120.10	

*The 20-year route of the Standard ISO 15189 (medical laboratories)*

ISO/IEC 9000, 9001...

ISO/IEC Guide 25:1990

EN 45001:1992

ISO 15189:2003

ISO/IEC 17025:1999

ISO 15189:2007

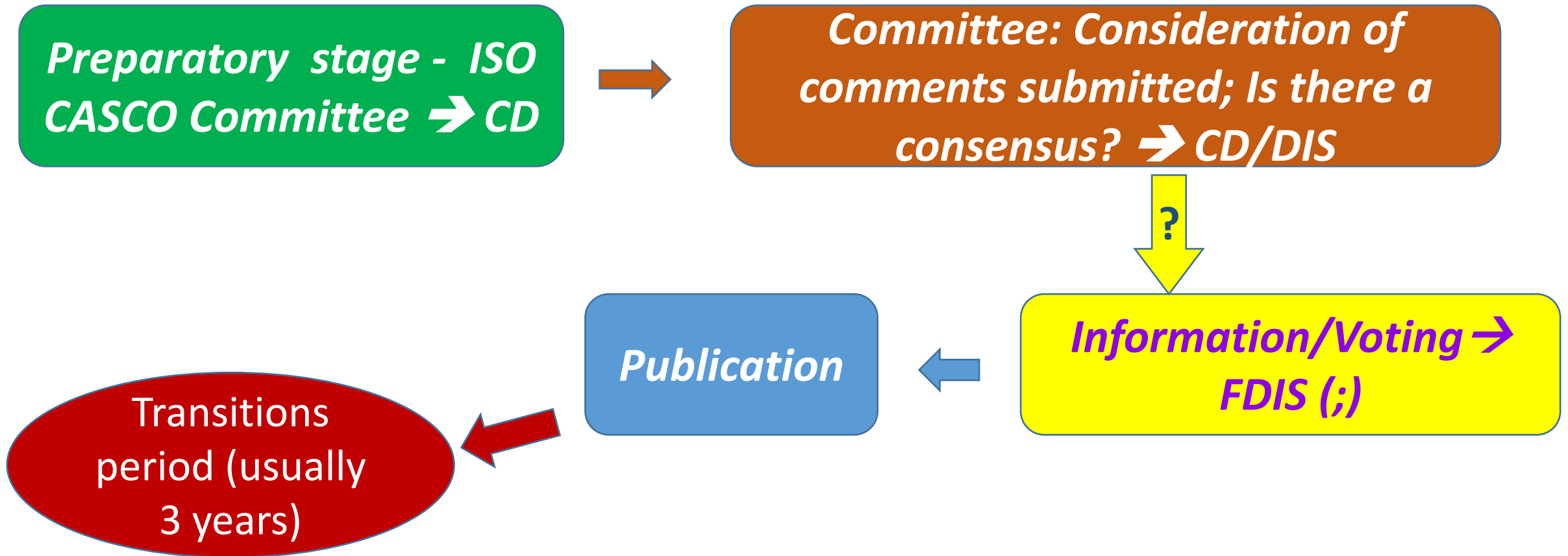
ISO/IEC 17025:2005

ISO 15189:2012

ISO/IEC 17025:2017

ISO 15189:2022

# The revision of ISO 15189:2012 still in progress...



# The objective of the new standard is...

the promotion of the welfare of patients through confidence in the quality and competence of medical laboratories → requirements to plan and implement actions to **address risks and opportunities** (*ISO/DIS 15189, Introduction*). “Risk” appears 81 times in the text!

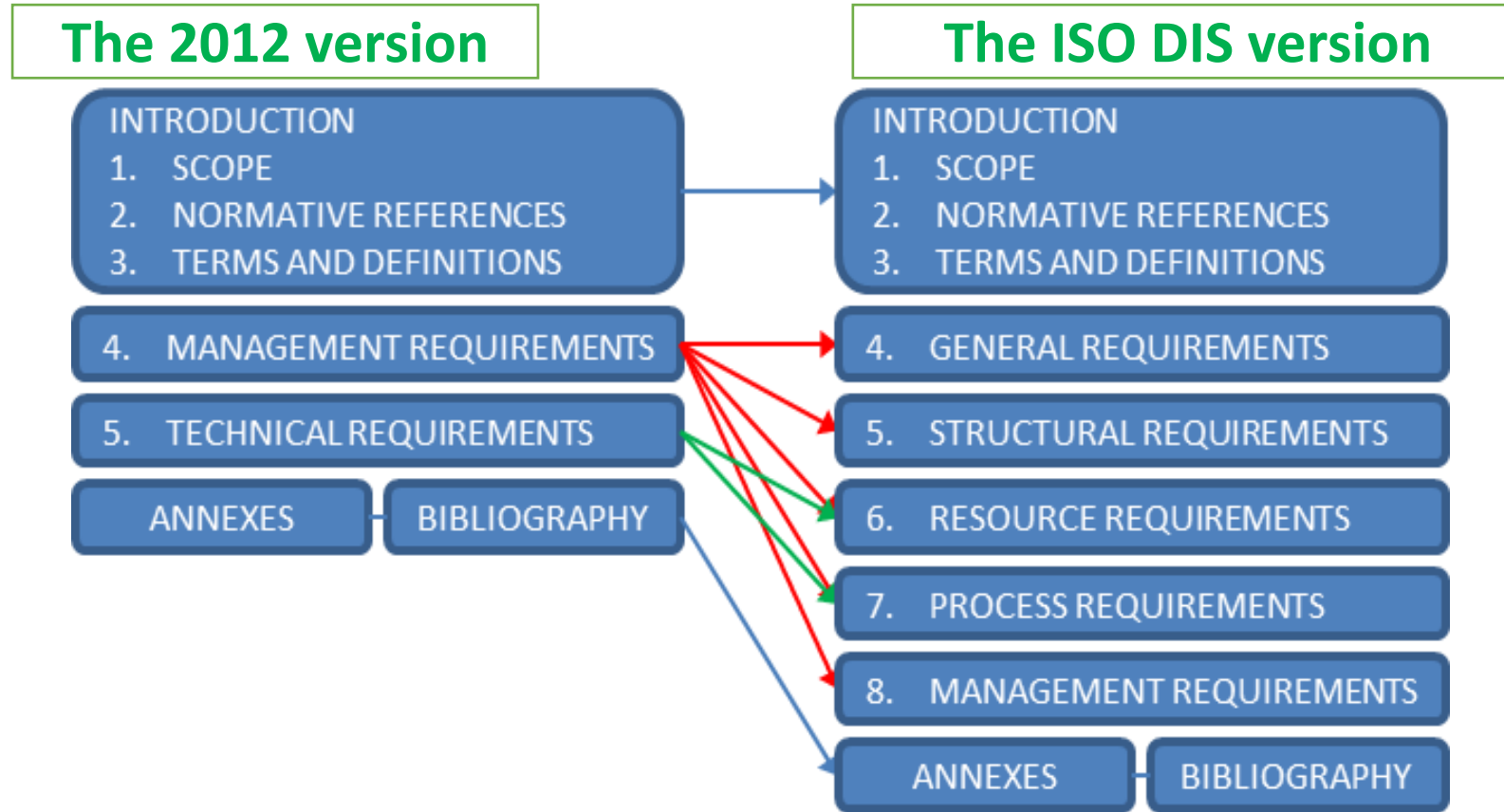
These requirements are aligned with the principles of ISO 22367 (*risk management*), ISO 15190 (*safety*) and ISO/TS 20658 (*collection and transport of samples*). See also ISO 35001 (**biorisk management**).

# What does seem to change?

In general, ISO/DIS 15189 follows basic changes in ISO/IEC 17025...

- the structure: *Yes*, in a way similar to that of ISO/IEC 17025 and other standards in ISO/IEC 17000 series
- distinction between “*shall*”, “*should*”, “*may*” and “*can*”
- the introduction of *risk-based thinking* and *opportunities*
- *metrological traceability*
- *control of data* and *information technology*
- ➔ *PLUS* : the document contains the requirements for *point-of-care testing (POCT)*, thus superseding ISO 22870

# Similar structural changes in ISO/DIS 15189



The figure for ISO/IEC 17025 applies with some differences in the content of the sessions



# ISO 15189 has to address the particular needs...

of medical laboratories; to this end specific requirements are included to cover these needs.

Contrary to ISO/IEC 17025, **sampling is not meant** to be a stand-alone activity within the meaning of ISO/DIS 15189.

Further to this, possibly due to inherent difficulties, **uncertainty arising from sampling** is not taken into account; this issue remains as a challenge for consideration whenever possible!

# However, particular emphasis is given...

to the pre-examination phase with detailed requirements for all relevant aspects, namely

- laboratory information for patients and users
  - requests for providing laboratory examinations
  - primary sample collection and handling
  - sample transportation
  - sample receipt
  - pre-examination handling, preparation and storage
- ➔ *Details referring to sampling have to be included in the report of results*

# ISO/DIS ISO 15189 provides for...

the metrological traceability of

- equipment and method
- measurement results

In general, the requirements are similar to those of ISO/IEC 17025.

Further to the requirements of the Standard, those specified in the European legislative framework apply as well. This refers to *In-Vitro Diagnostic Devices* Directive (98/79/EC) which is repealed by the Regulation (EU) 2017/746 of 5 April 2017 [amended by Regulation (EU) 2022/112 on 25 January 2022].

# This Regulation lays down...

rules concerning the placing on the market, making available on the market or putting into service of *in vitro* diagnostic medical devices for human use and accessories for such devices in the Union.

It will come into force this month (26 May 2022)

# The recently revised ISO 17511:2020

*“In vitro* diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples”

is referred to in the text as a support to laboratories.

## Some other development is expected...

after a proposal by “the ISO/TC 212 Clinical laboratory testing and *in vitro* diagnostic test systems” for a project on a Guidance on the validation and verification of quantitative and qualitative methods. The task is expected to be completed in 36 months.

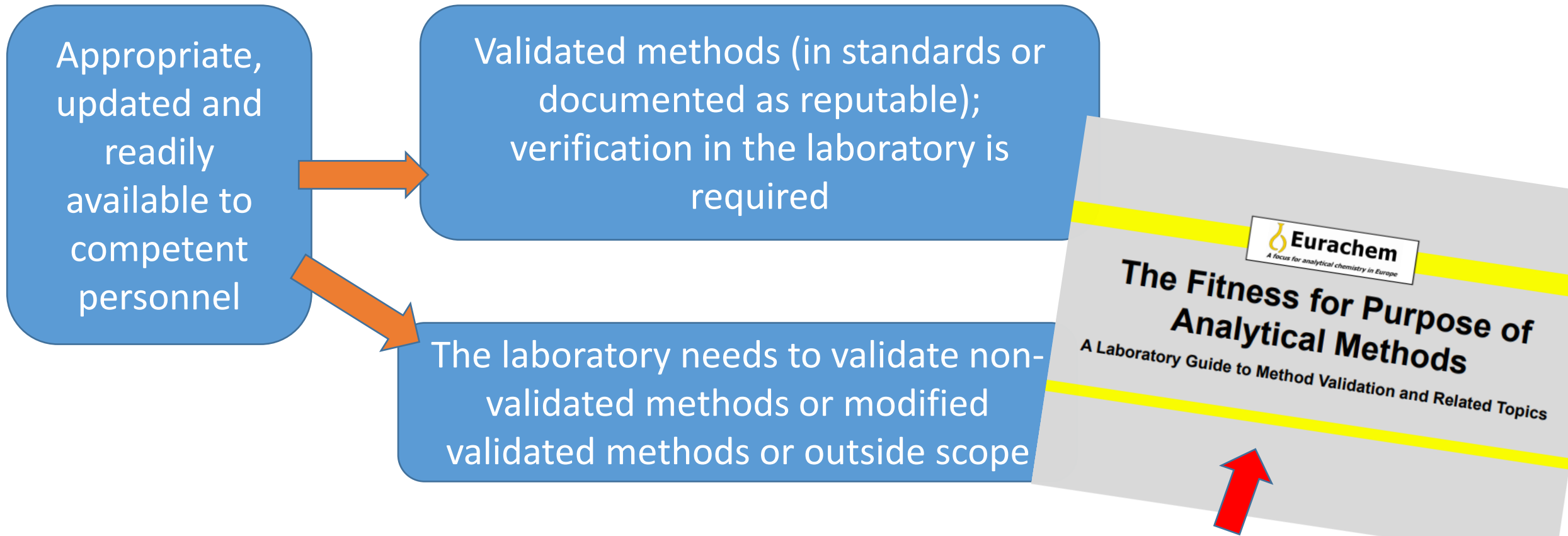
This document will be developed as an International Standard.

# In order to ensure the validity of results...

requirements referring to the following aspects have to be adequately addressed:

- ✓ availability of policies and procedures
- ✓ documented competence of the personnel
- ✓ suitability of equipment
- ✓ adequacy of the environmental conditions
- ✓ metrological traceability
- ✓ measurement uncertainty
- ✓ maintenance of records

# Selection of methods\*/examination procedures\*\*

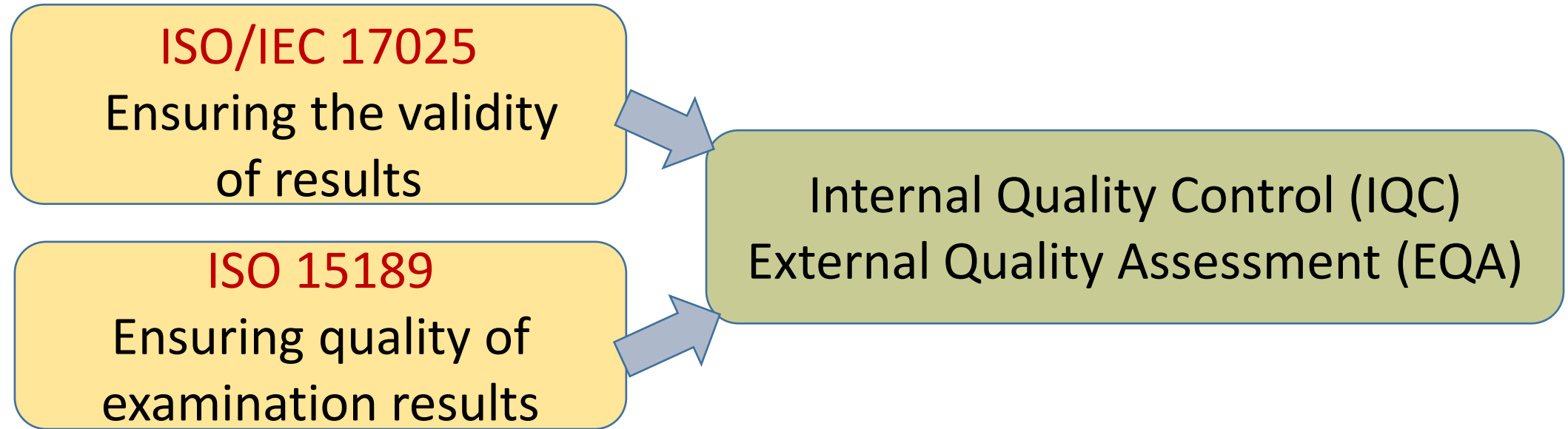


The relevant Eurachem Guide can be of help for medical laboratories as well

**\* ISO/IEC 17025 /\*\* ISO 15189**



# How to ensure the validity of results



More detailed requirements with reference to various alternatives are set in ISO/DIS 15189. ISO 17034 and ISO/IEC 17043 are referred to as means to document competence of Reference Materials Producers and Proficiency Testing Providers respectively. EQA need to adequately mimic patient samples.

# The report of the results needs to be provided...

accurately, clearly and unambiguously. Additional requirements by

- the customer, the legislation or the market (**analytical laboratories**)\*
- the patient or the requesting physician or specific instructions related to the examination procedure (**medical laboratories**)\*\*
- \* plus opinions and interpretations (under conditions)
- \*\* plus professional judgement (under conditions)
- ➔ **Measurement uncertainty** is not normally included; however, relevant information **shall be made available to laboratory users on request.**

# “Laboratory information management system(s)”

includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems (similar to ISO/IEC 17025).

*ISO/DIS 15189 introduces similar provisions to the ones of ISO/IEC 17025, including those for commercially off-the-shelf software, off-site management and contingency plans.*

# Control of data and information management

**Validation** for functioning **before** introduction

**Safeguard** against tampering or loss

Appropriate **environment** (supplier's specification)

**Changes** to the system including software configuration or modification to commercial off-the-shelf software authorized, documented and validated **before** implementation

**Conditions** safeguarding the accuracy of manual recording and transcription

**Protection** from unauthorized access

# Furthermore...

Conditions ensuring the **integrity** of data and information

Recording **failures** – **immediate** and **corrective actions**

Instructions, manuals, and reference data **readily available** to personnel

Calculations and data transfers **checked** in an appropriate and systematic manner

Information system(s) managed/maintained off-site: responsibility of laboratory for ensuring **provider/operator's compliance** with requirements

# Commercial off-the-shelf software...

in general use within its designed application range can be considered to be sufficiently validated.

Changes to the system including software configuration or modification to commercial off-the-shelf software shall be authorized, documented and validated before implementation.

# Risks associated with...

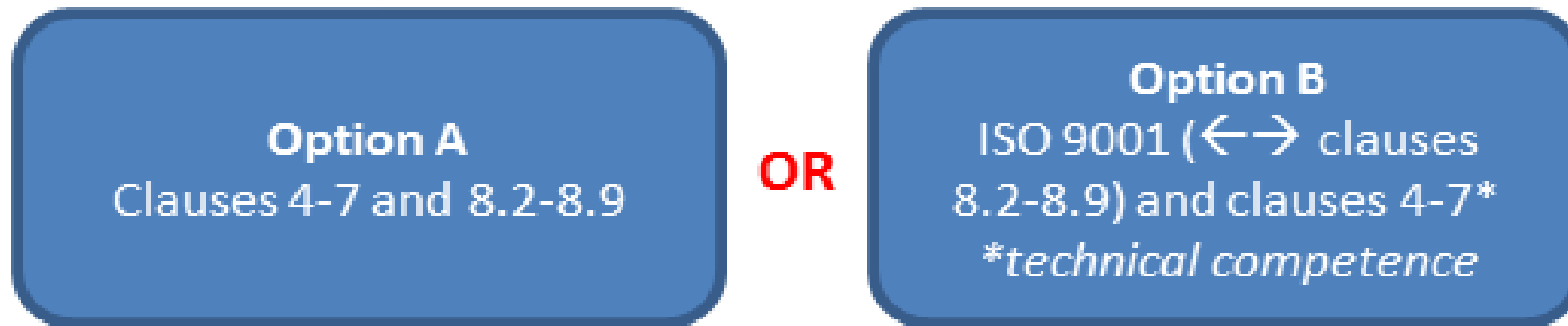
computerized laboratory information systems are discussed in ISO 22367:2020, Clause A.13 Control of laboratory information systems.

→ ISO/IEC 27001:2013, Annex A “Reference control objectives and controls” lists the information security controls, strategies and best practices to ensure the preservation of confidentiality, integrity and availability of information.

## Furthermore, two alternatives are provided...

to meet management requirements. As in ISO/IEC 17025, in case of a quality management system being implemented, e.g. in accordance with ISO 9001, it is considered that specified requirements of ISO 15189 are met; no reference is made to “Option A” and “Option B”.

### Two options for laboratories



*Figure 2: Management system options*

*\*extract from the Eurachem leaflet “A new ISO/IEC 17025 for laboratories” (2018)*



*Thank you for your attention...*