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Trends & Challenges in Ensuring Quality in Analytical Measurements

Ensuring Quality: A key element in analytical and medical/clinical laboratories

Kyriacos C.Tsimillis and Sappho Michael

Definitions according to ISO 9000:2015

3.6.2 ***Quality***
degree to which a set of inherent characteristics of an ***object*** fulfils ***requirements***

3.6.1 ***Object***
entity, item, anything perceivable or conceivable
i.e. product, service, process, person, organization, system, resource

3.6.4 ***Requirement***
need or expectation that is stated, generally implied or obligatory

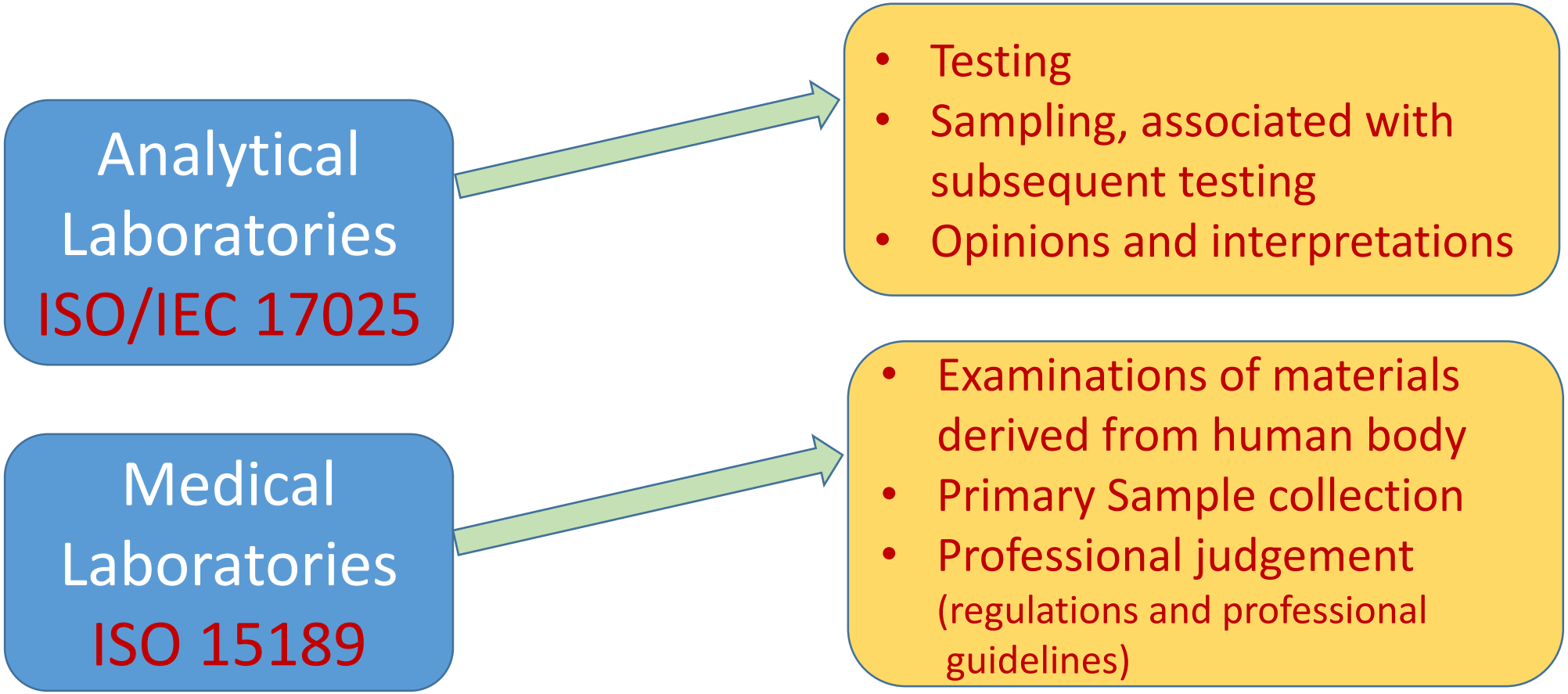
Quality refers to the overall service provided

It is governed by policies and procedures addressing both management and technical issues related to the operation of the laboratory.

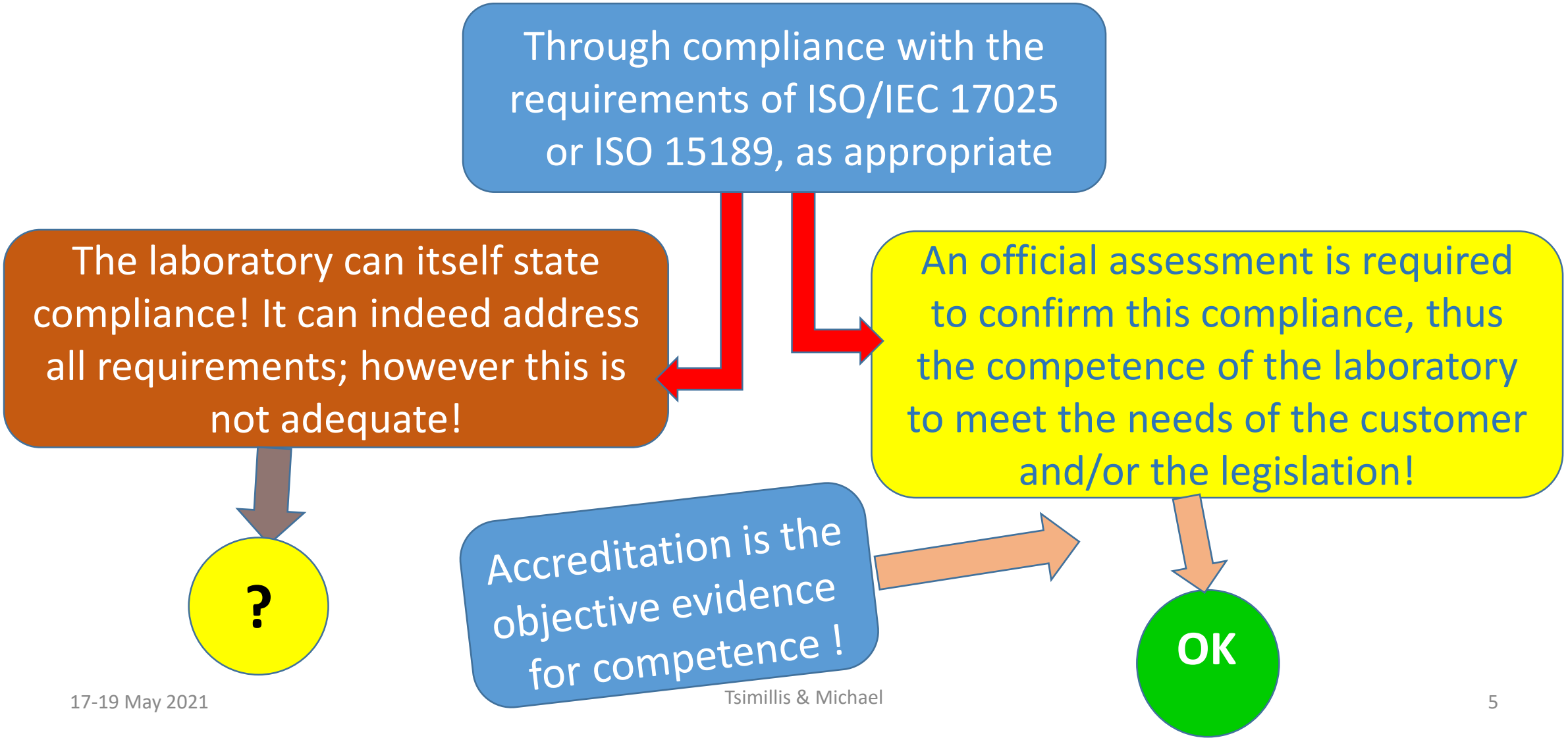
Management issues may include time-schedules, agreements and contract reviews, communication with the customer/user of the results, handling of complaints, management of nonconformities, consideration of risks and opportunities etc.

In the case of medical laboratories, these aspects may be even more important.

Services provided by laboratories



How can laboratories document competence

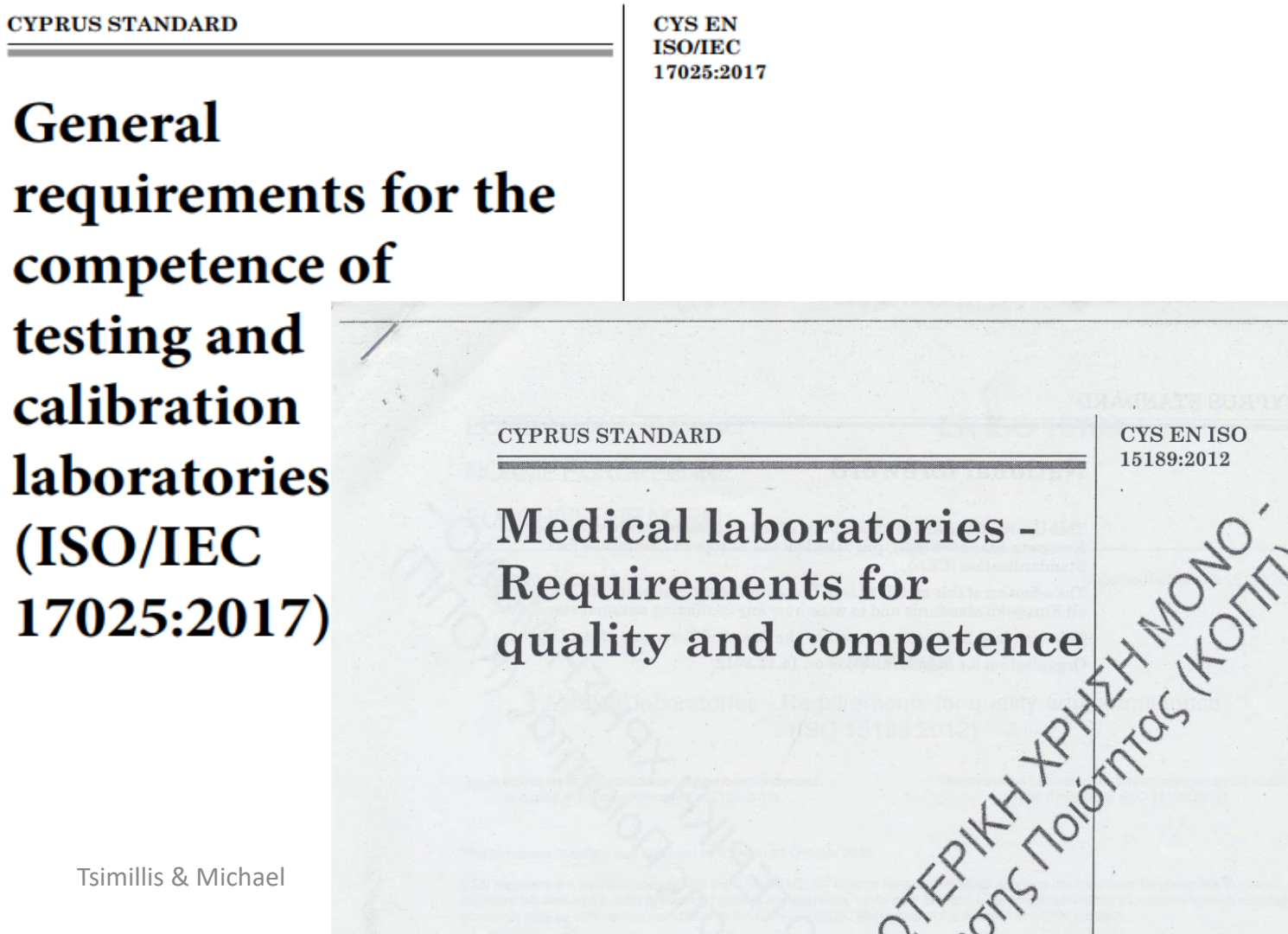


ISO/IEC 17025 and ISO 15189 are the basis…

for assessment towards accreditation. However, they do not refer to accreditation!

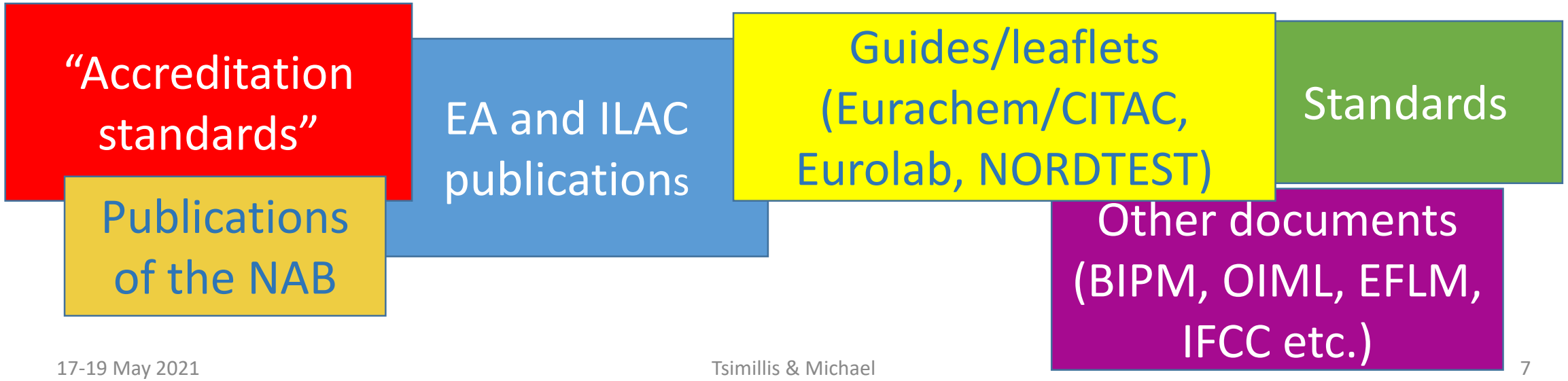
They only set requirements for quality and competence.

Even non-accredited laboratories may fully comply with the relevant "Accreditation Standard".



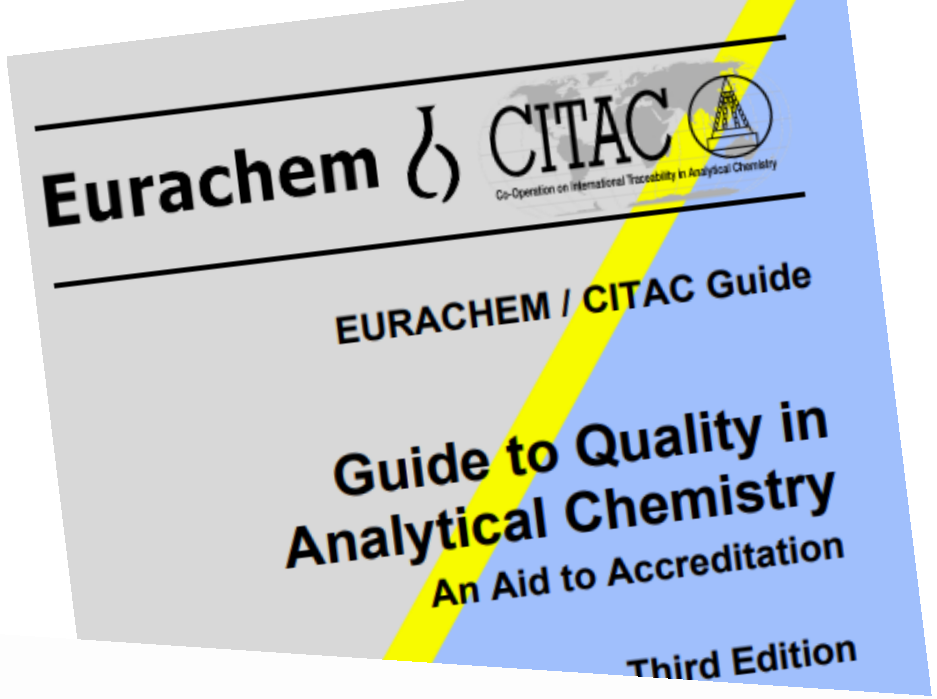
Further to the “accreditation standards”…

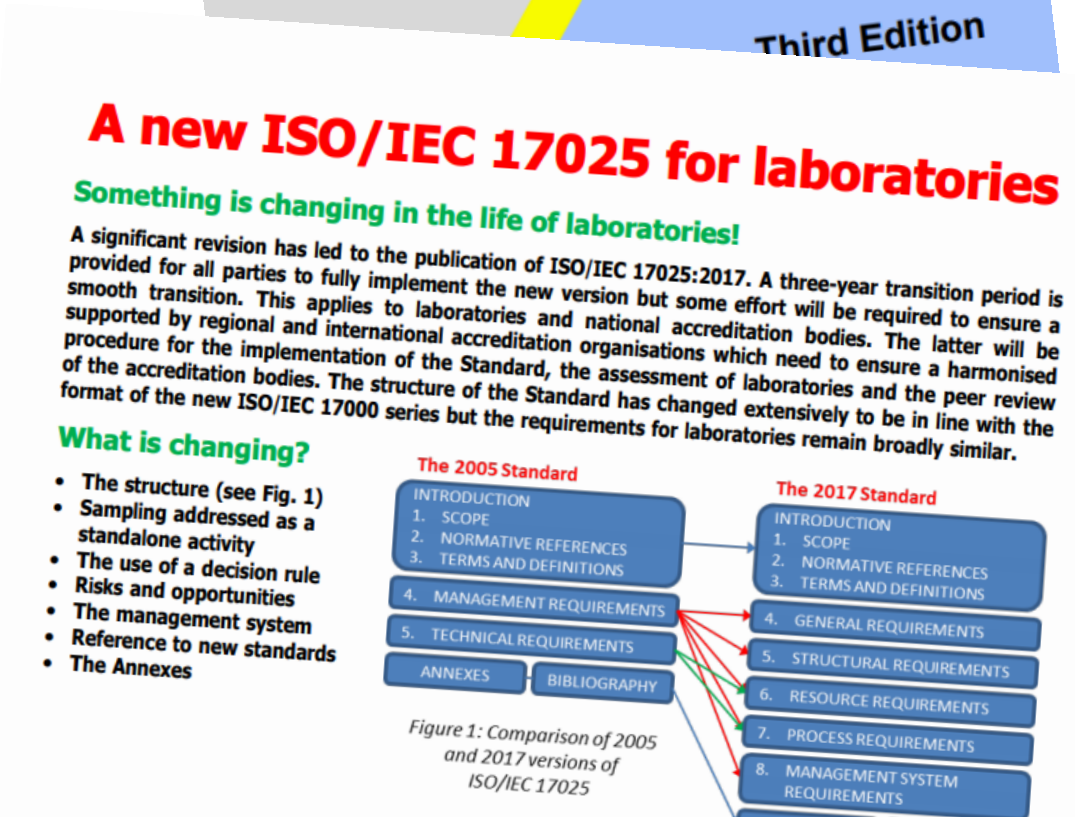
the laboratory needs the support provided by other documents i.e. standards, guides, EA and ILAC (mandatory or guidelines), explanatory documents by the national accreditation body (NAB)



New aspects in ISO/IEC 17025

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





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

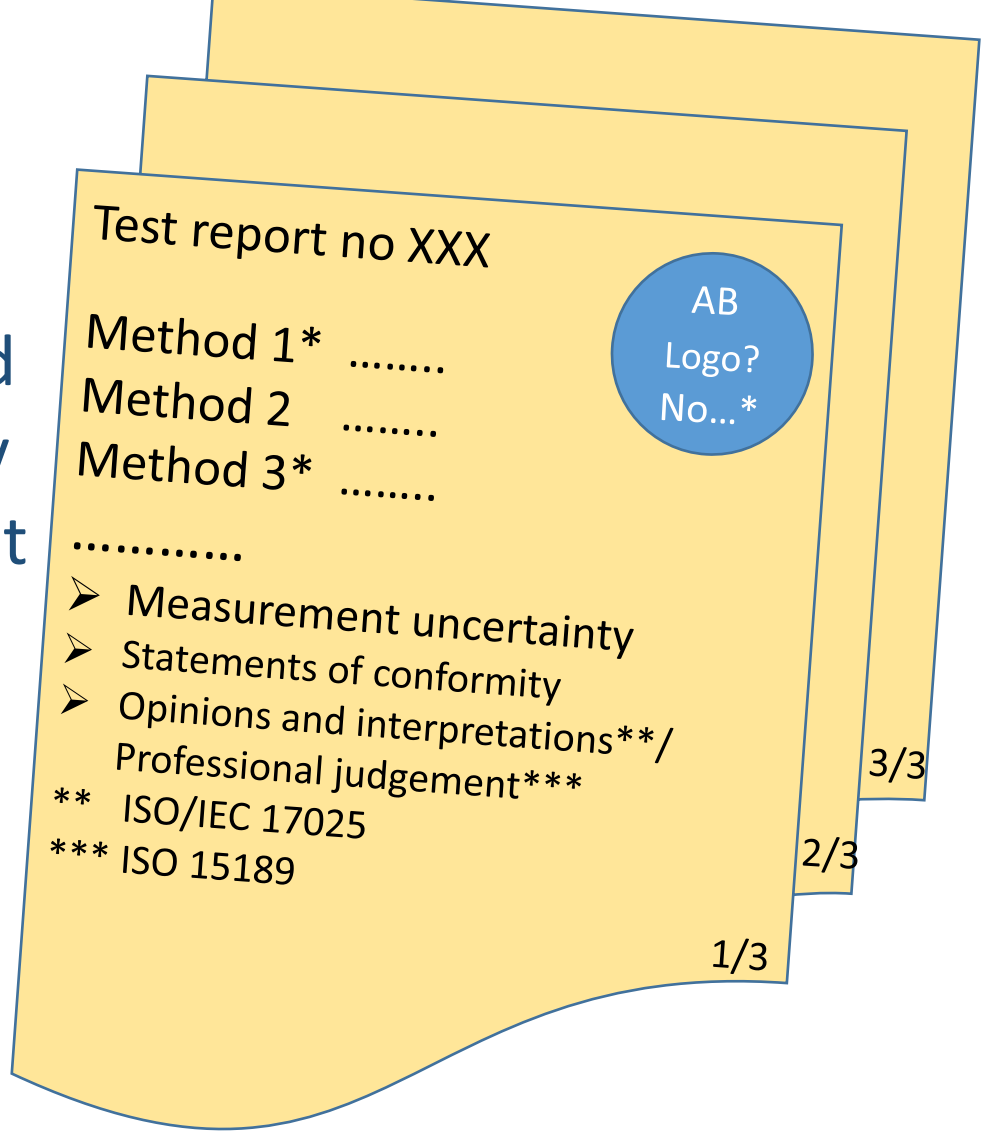
Figure 1: Comparison of 2005 and 2017 versions of ISO/IEC 17025

The report of 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 (medical laboratories) or specific instructions related to the examination procedure

➔ other requirements refer to the overall service provided for which details have to be reviewed and agreed or communicated.

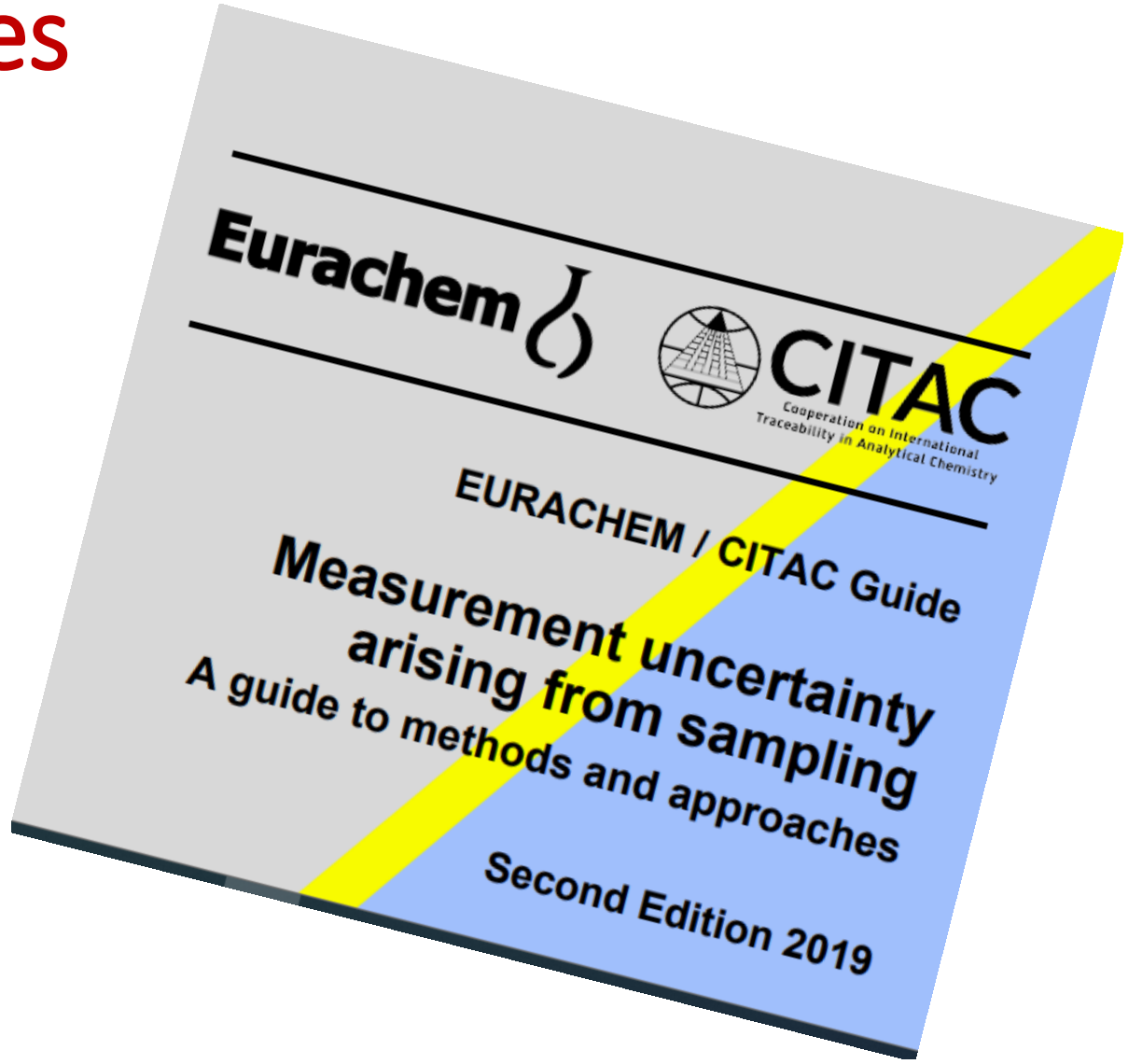


Some of the EA publications are relevant…

In analytical laboratories

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 not the case in medical laboratories…



ISO 15189 clarifies that…

uncertainty components are those associated with the actual measurement process; this is not expected to be changed in the current revision of the standard. This does not disregard the critical importance of the pre-examination phase (including sampling), for which the standard does specify very detailed requirements.

It is important that the user of the results…

fully understands the meaning of MU stated on test/examination reports. MU contributes in confidence and reliability. It shall be presented

- when it is relevant to the validity or application of test results or required by the customer or it affects conformity to a specification limit (ISO/IEC 17025)
- upon request (ISO 15189)

The decision rule describes…

how MU is accounted when reporting statements of conformity, taking into account the level of risk associated with it; this is not required when the decision rule is prescribed by the customer, regulations or normative documents.

The risk-based thinking in ISO/IEC 17025

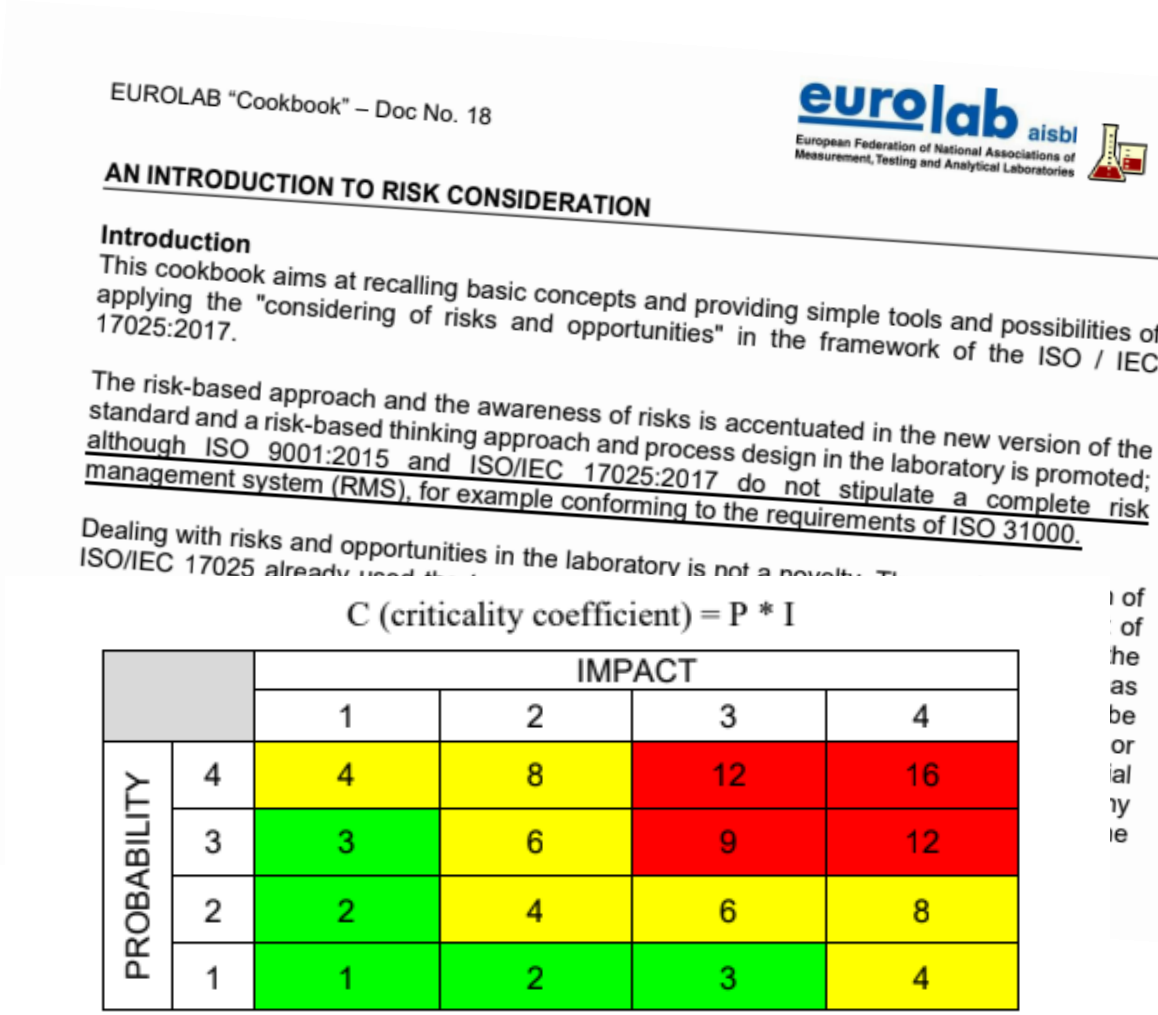
- The introduction of risk-based thinking is the main change in the philosophy of ISO/IEC 17025; it enhances the sense of quality assurance in the laboratory work.
- The risk-based thinking is integrated throughout this standard (31 references in the text).
- Emphasis is given to
  - ✓impartiality
 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

The laboratory is expected

to make its considerations based on the correlation of the probability of a risk and its impact.

Risks with high probability and high impact shall be given much more emphasis.

SWOT analysis is also a useful tool to analyse strengths and weaknesses, opportunities and threats *(see Eurolab Cookbook No 18)*.



EUROLAB "Cookbook" – Doc No. 18

eurolab aisbl
European Federation of National Associations of Measurement, Testing and Analytical Laboratories

AN INTRODUCTION TO RISK CONSIDERATION

Introduction

This cookbook aims at recalling basic concepts and providing simple tools and possibilities of applying the "considering of risks and opportunities" in the framework of the ISO / IEC 17025:2017.

The risk-based approach and the awareness of risks is accentuated in the new version of the standard and a risk-based thinking approach and process design in the laboratory is promoted; although ISO 9001:2015 and ISO/IEC 17025:2017 do not stipulate a complete risk management system (RMS), for example conforming to the requirements of ISO 31000.

Dealing with risks and opportunities in the laboratory is not a novelty. The ISO/IEC 17025 already used the

C (criticality coefficient) = P * I

		IMPACT			
		1	2	3	4
PROBABILITY	4	4	8	12	16
	3	3	6	9	12
	2	2	4	6	8
	1	1	2	3	4

Risk consideration in ISO 15189

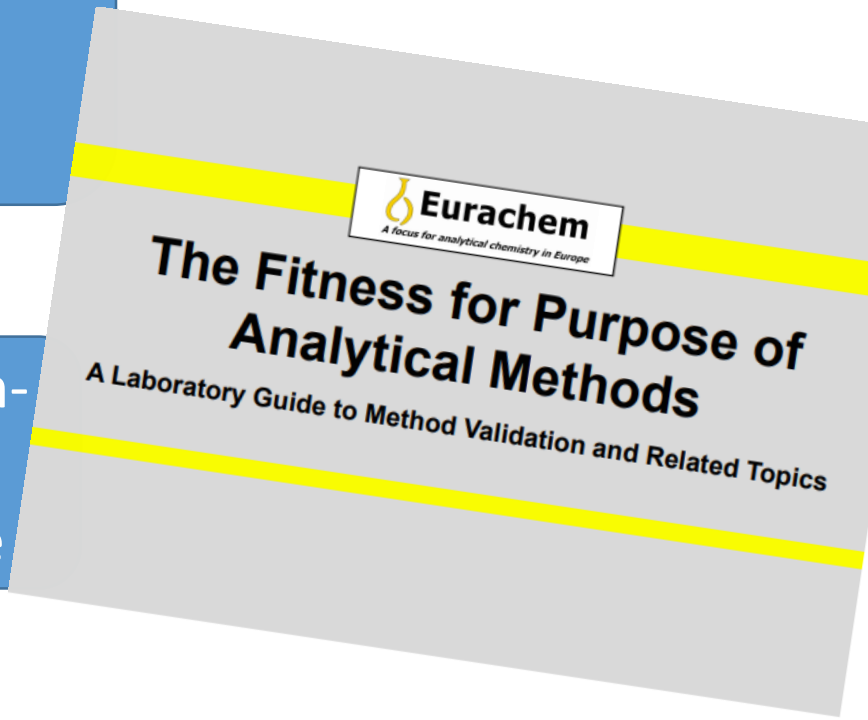
- Risk management had earlier been addressed in ISO 15189 but with reference only to activities which may affect the examination results.
- This aspect may change during the coming months in the perspective of the revision of the said standard, currently under way. The new standard is expected to be published by the end of 2022 or the beginning of 2023.
- ISO/IEC 17025 provides for a broader consideration to be made by the laboratory.

Selection of methods/examination procedures

appropriate, updated and readily available to competent personnel

Validated methods (in standards or documented as reputable); verification in the laboratory is required

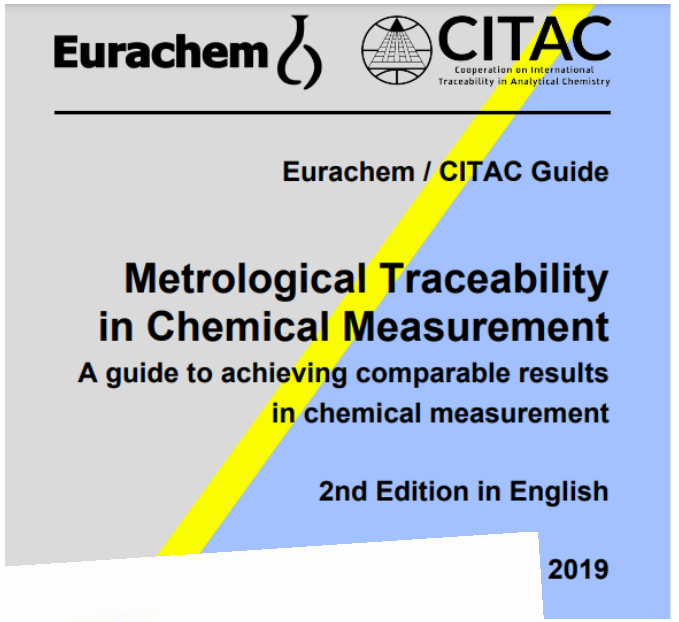
The laboratory needs to validate non-validated methods or modified validated methods or outside scope

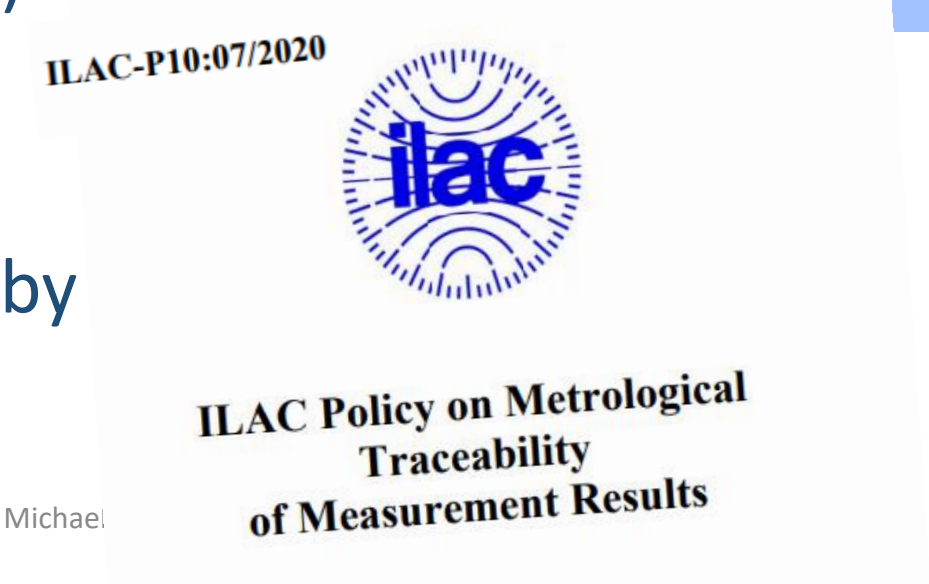


Metrological traceability (ISO/IEC 17025)

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

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





Metrological traceability (ISO 15189)

In medical laboratories, the requirements are similar.

In Europe, further to the requirements of the Standard, those specified in the legislative framework for *in vitro diagnostics* apply as well.

This refers to In-Vitro Diagnostic Devices Directive (98/79/EC) while the European In Vitro Diagnostic Regulation (IVDR 2017/746) will come into force in May 2022.

“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 (ISO/IEC 17025).

➔ *A similar definition is given in ISO 15189 for “information systems”.*

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.

In order to ensure the validity of results…

requirements referring to the following aspects have to be adequately addressed

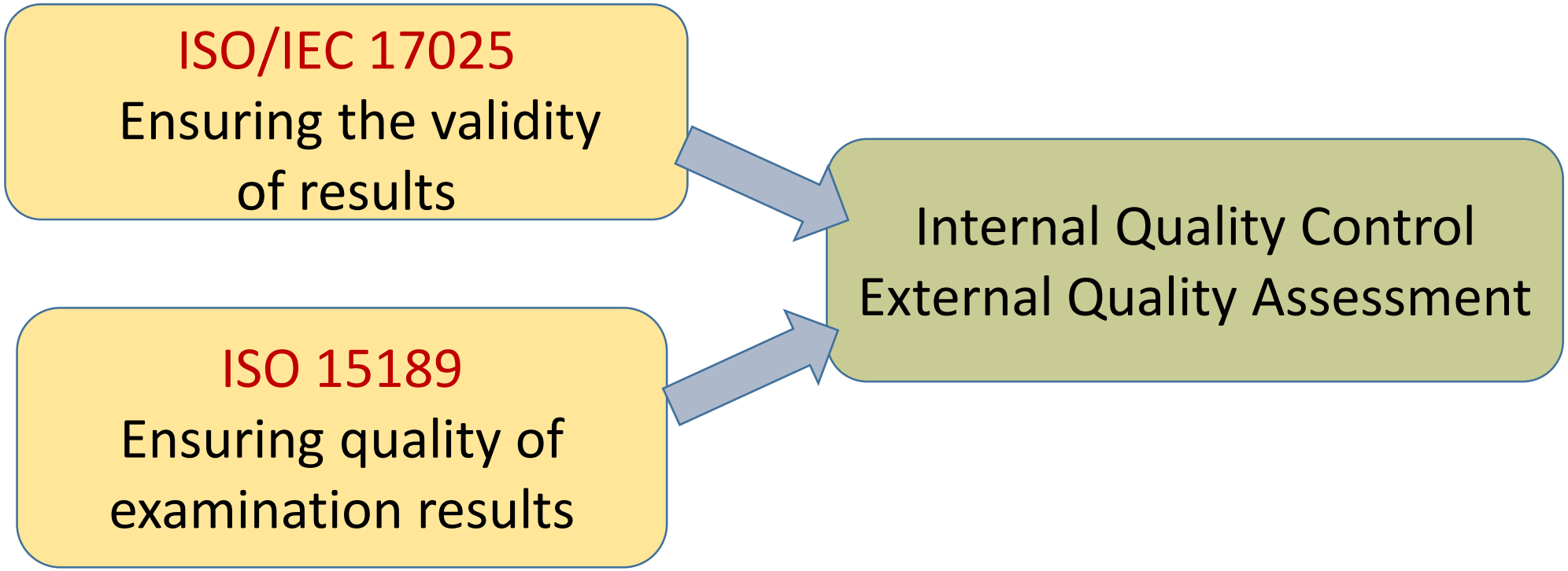
- ✓availability of policies and procedures
- ✓documented competence of the personnel
- ✓suitability of equipment
- ✓adequacy of the environmental conditions
- ✓metrological traceability
- ✓measurement uncertainty
- ✓maintenance of records

Are these adequate?

No!

Even with all these aspects being systematically and adequately addressed, the validity of results may still be under question; to this end the laboratory needs to monitor the validity of its results.

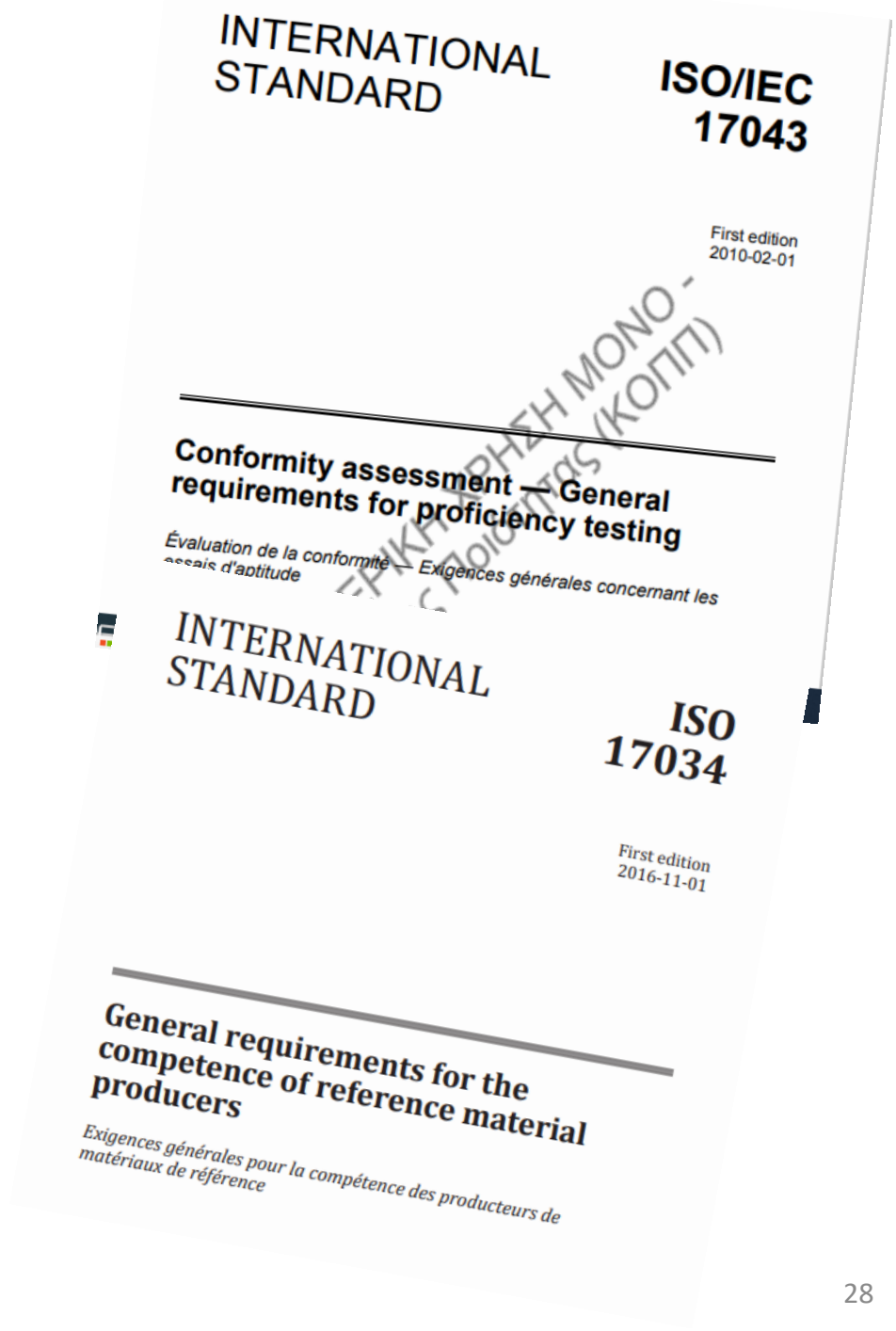
How to ensure the validity of results



This is achieved via both

- internal quality control, mainly with, but not limited to the use of reference materials (RM) and
- external quality assessment with the participation in proficiency testing (PT) schemes or other interlaboratory comparisons.

ISO/IEC 17043 and ISO 17034 specify requirements for the competence of PT suppliers and RM producers



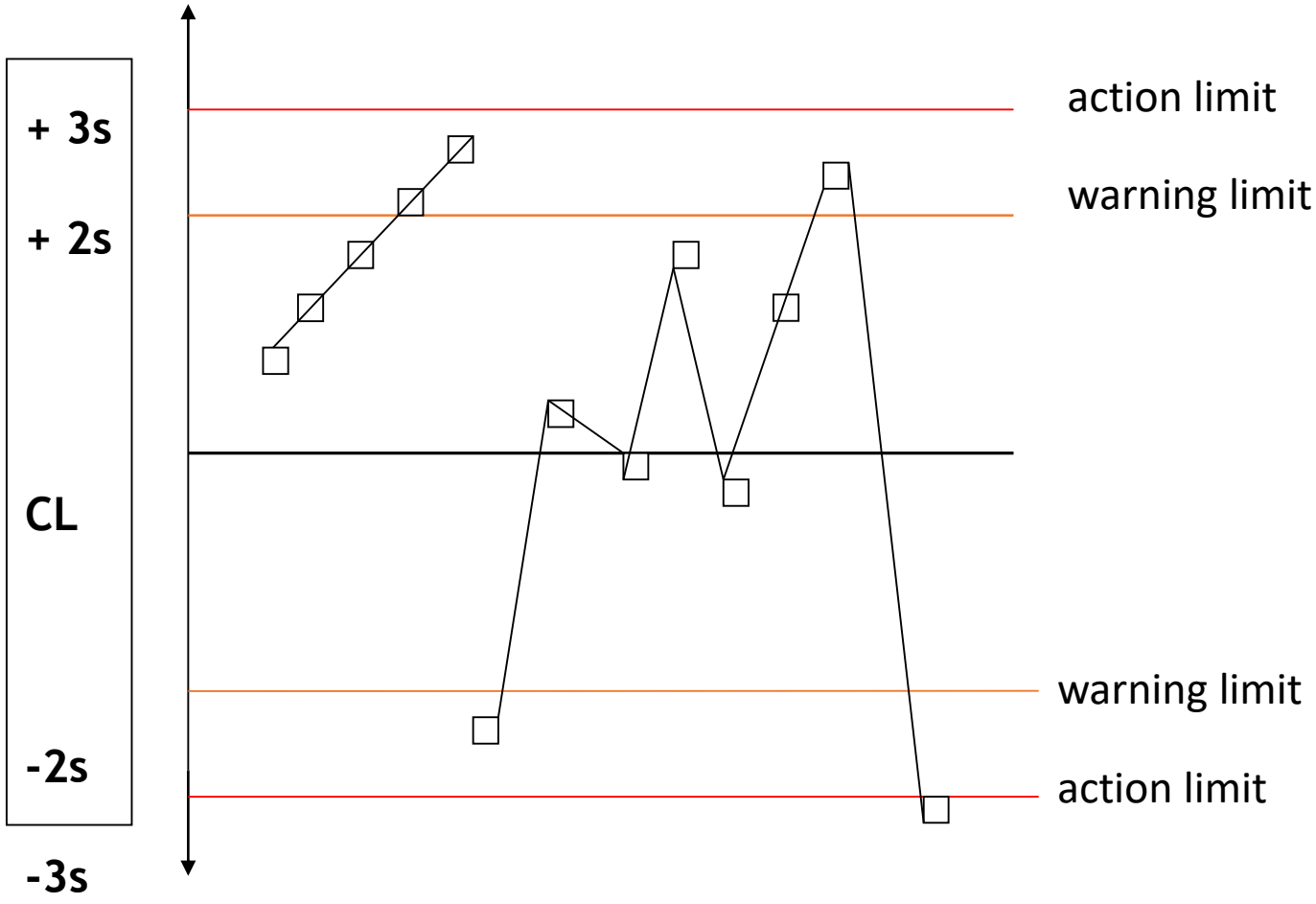
Internal quality control

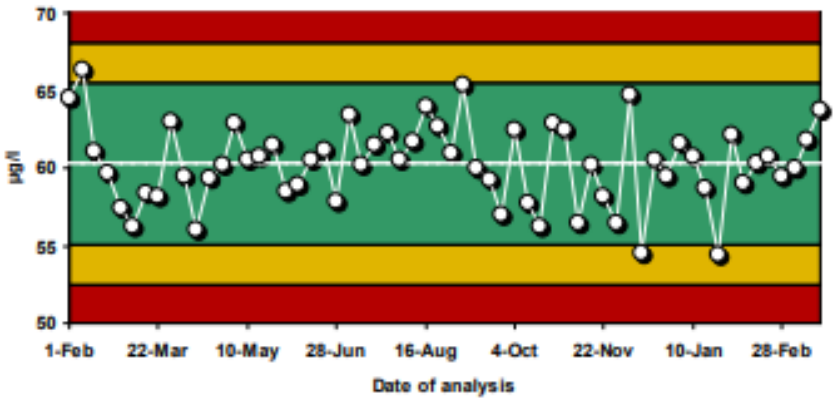
The task is to detect the trends and take appropriate actions. An extended list of alternative means appears in the new ISO/IEC 17025; this monitoring shall be planned and reviewed.

Among others, the following are included: the use of RMs/control materials, alternative instrumentation, control charts, replicate tests , retesting, intralaboratory comparisons.

ISO 15189 underlines that quality control materials shall react similarly to patient samples. The use of pooled samples can serve this purpose.

Internal quality control

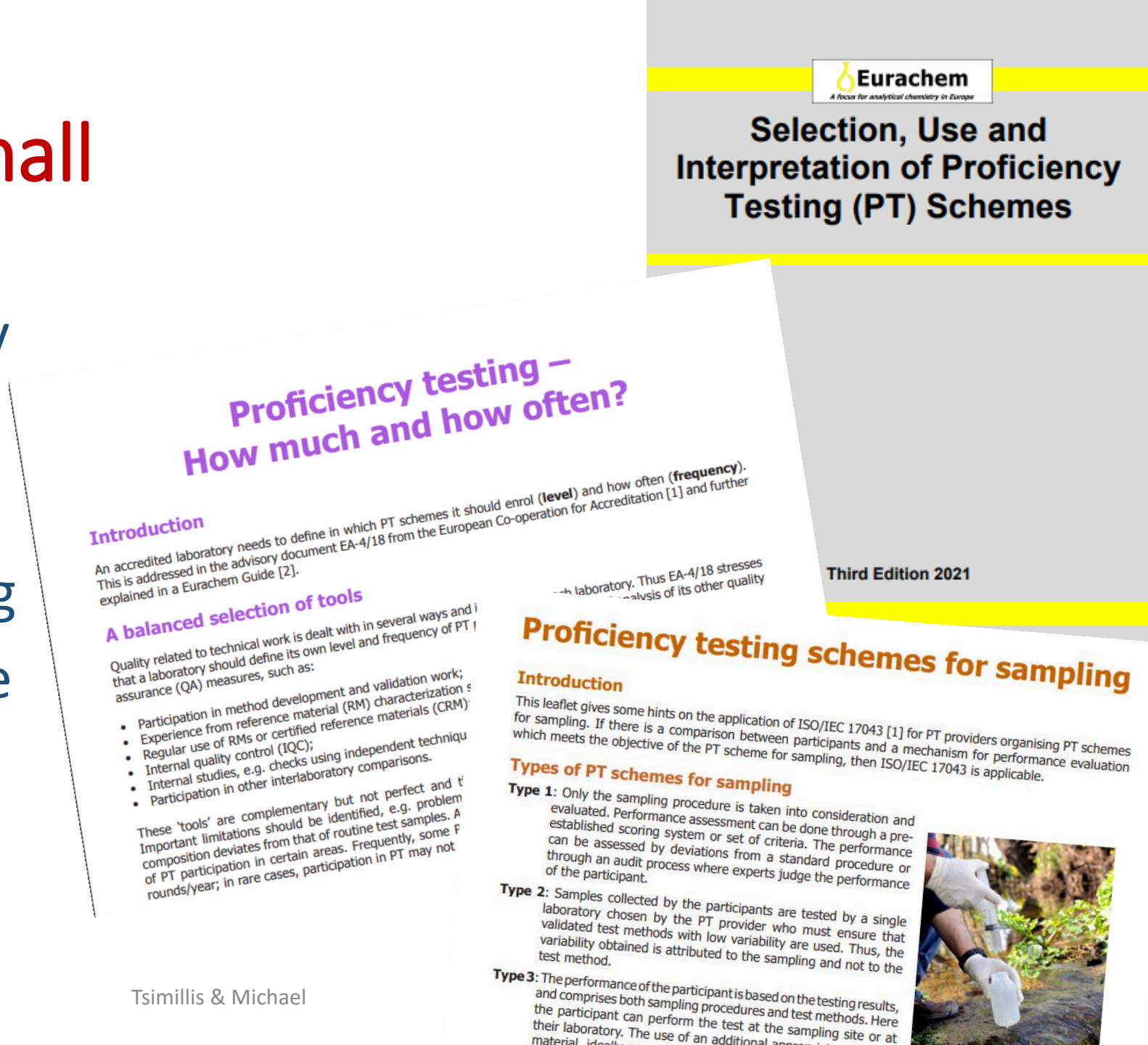




The laboratory shall

plan for the frequency and type of proficiency testing schemes to participate.

PT providers complying with ISO/IEC 17043 are considered competent *(see Eurachem publications)*

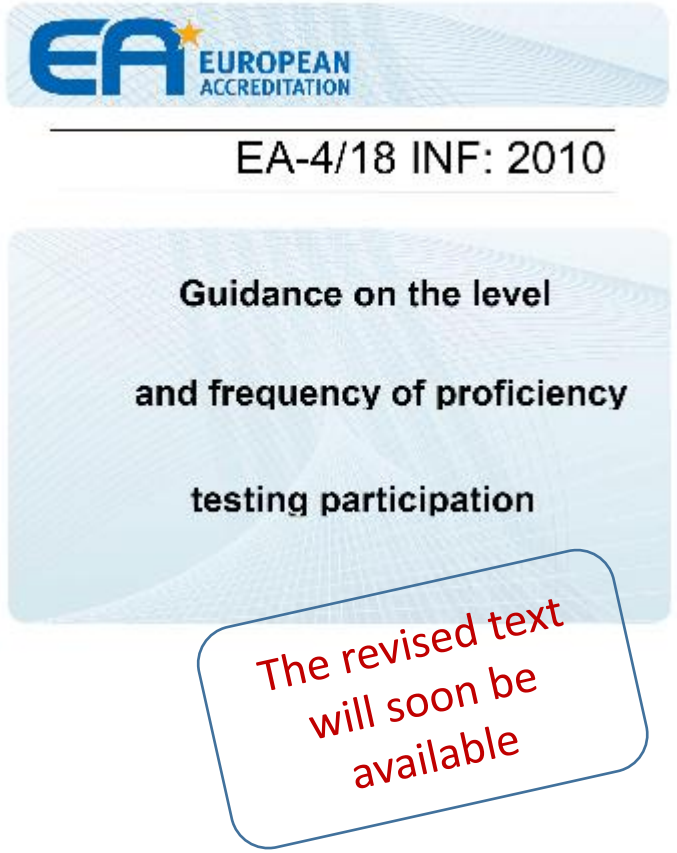


In all cases, participation in PT schemes…

(or other interlaboratory comparisons) needs to be decided by the laboratory based on

- ➢ the measurement process
- ➢ the characteristic
- ➢ the product

Further to these a series of factors have to be considered within risk-based thinking

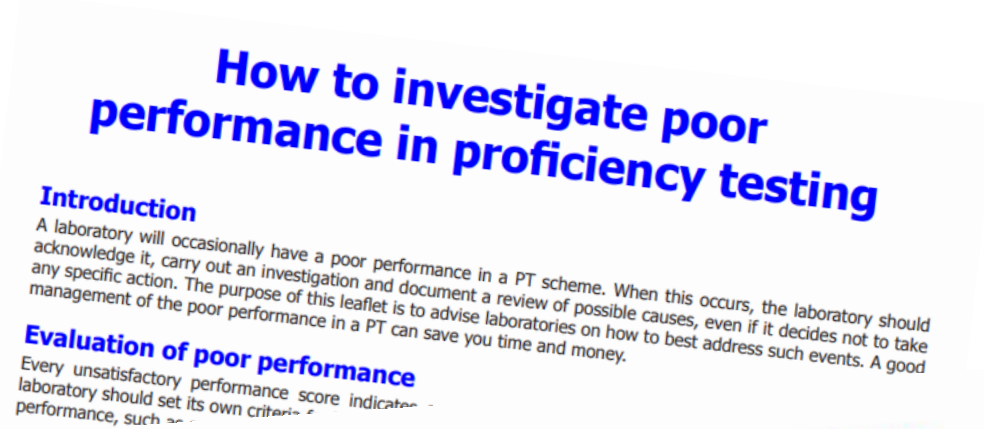


The results of the participation in PT schemes…

provide a useful feedback for appropriate actions.

➔All personnel authorised for specific tasks should participate, in rotation, in the respective schemes.

➔The surplus PT items are not to be wasted; they can be used.



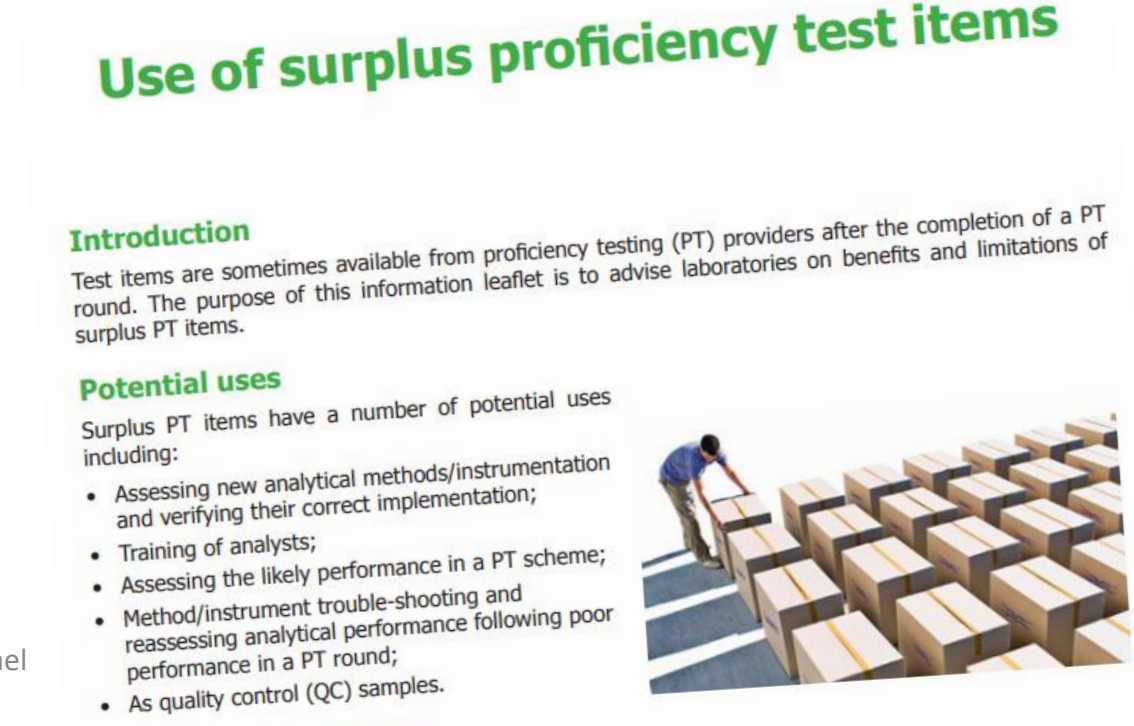
How to investigate poor performance in proficiency testing

Introduction

A laboratory will occasionally have a poor performance in a PT scheme. When this occurs, the laboratory should acknowledge it, carry out an investigation and document a review of possible causes, even if it decides not to take any specific action. The purpose of this leaflet is to advise laboratories on how to best address such events. A good management of the poor performance in a PT can save you time and money.

Evaluation of poor performance

Every unsatisfactory performance score indicates
laboratory should set its own criteria
performance, such as



Use of surplus proficiency test items

Introduction

Test items are sometimes available from proficiency testing (PT) providers after the completion of a PT round. The purpose of this information leaflet is to advise laboratories on benefits and limitations of surplus PT items.

Potential uses

Surplus PT items have a number of potential uses including:

- Assessing new analytical methods/instrumentation and verifying their correct implementation;
- Training of analysts;
- Assessing the likely performance in a PT scheme;
- Method/instrument trouble-shooting and reassessing analytical performance following poor performance in a PT round;
- As quality control (QC) samples.

In medical laboratories

All necessary equipment and materials (reagents, kits, controls and calibrators) are usually provided by the same supplier of the equipment; this means that we have a “closed” system which needs to be monitored by an external source. Therefore the need for an external quality assessment is imperative.
As a result, the frequency of participation is much higher in the case of medical laboratories compared to analytical ones.

Thank you for your attention…