The new standard ISO/IEC 17025:2017
A comparison with ISO 15189:2012
An overview of some critical issues

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The Standard is applicable…

to all laboratories, regardless of the number of personnel.

There had been some discussion on this issue regarding impartiality and independence. It is considered that some tasks e.g. internal audit have to be undertaken by hiring part-time personnel

What is changing in ISO/IEC 17025?

from…

to…

Despite the big differences at a glance…

In practice, these are not too many or difficult to be addressed; however, what is changing refers mostly to the philosophy of the document, thus affecting both the preparation of the laboratory and the assessment by the accreditation body

The new standard…

is written in a less prescriptive form

➔ it is a ***no tick box standard at all!***

- More flexibility is given to laboratories how to address the various issues/requirements
- Not every “shall” leads to a question which, in case of a “NO” answer leads to a nonconformity; assessors need to put more questions
- This means that assessors need to be well trained to meet the challenge! This also underlines the need for harmonisation.

What is changing?

- ❑ The structure
- ❑ The terminology
- ❑ The introduction of new provisions
- ❑ Risk and opportunities
- ❑ The Management System
- ❑ Reference to new standards
- ❑ The Annexes

The structure of the new standard…

is in line with other recent standards in 17000 series; there are five sections:

- General requirements
- Structural requirements
- Resource requirements
- Process requirements
- Management requirements

Sections 4 and 5 of the Standard…

are now presented in more detail under four sectors. A series of notes have been included in the text of the Standard, thus with substantially increased importance. Furthermore

➔Two Annexes, both informative, are included:

- Annex A - Metrological traceability
- Annex B - Management system.

➔ *Notes and Annexes do not provide the basis for raising nonconformities*

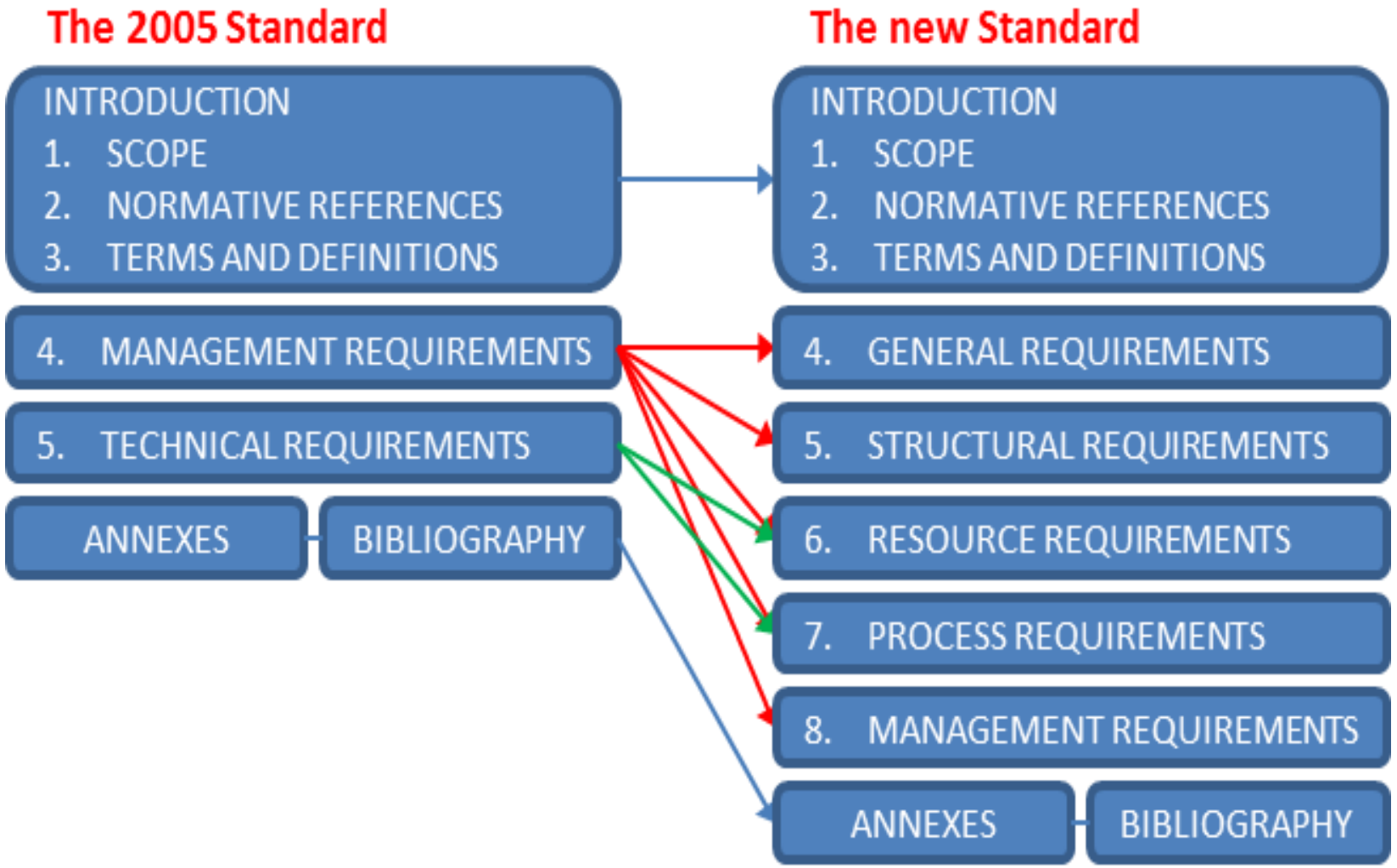


Figure 1: Comparison of 2005 and 2017 versions of ISO/IEC 17025

From the recent Eurachem leaflet "A new ISO/IEC 17025 for laboratories"

Comparison with the 2005 version

❑The main changes compared to the previous edition are:

- The risk-based thinking applied in this edition has enabled reduction in prescriptive requirements and replacement by performance-based requirements
- There is greater flexibility in the requirements for processes, procedures, documented information and organizational responsibilities
- A definition of "laboratory“ is added

Comparison with the 2005 version continues…

The main changes compared to the previous edition are:

- Most of the provisions under clause 5 now appear under clauses 6 and 7
- Specific sub clauses of under the new clause 4 now provide for independence and impartiality. They are more detailed than the equivalent clauses in the 2005 edition
- Externally provided products and services cover both services and supplies, and subcontracting

A laboratory performs…

one or more of the following activities:

- calibration
- testing
- sampling *(associated with subsequent calibration or testing*)*

** Not necessarily carried out in the same entity – this means that sampling as a stand-alone activity is accreditable against this Standard in line with EA Resolution 2015 (35) 20*

➔The term “the laboratory” is used throughout the text without any distinction, *except in cases of different/additional requirements.*

The Standard specifies the meaning…

of the following terms:

- “shall“ indicates a requirement
- “should“ indicates a recommendation
- “may“ indicates a permission
- “can“ indicates a possibility or a capability

Terms and definitions

A series of terms and definitions are added*:

- Impartiality (according to ISO/IEC 17021)
- Complaint (according to ISO/IEC 17000)
- Interlaboratory comparison (according to ISO/IEC 17043)
- Proficiency testing (according to ISO/IEC 17043)
- Intralaboratory comparison
- Laboratory
- Decision rule (how to account measurement uncertainty when stating conformity with a specified requirement)

**Definitions given in ISO/IEC 17000 and ISO/IEC Guide 99 (VIM)*

Roles and names

- Laboratory management used instead of top management
- The term quality manager is not used.

  Relevant responsibilities are to be assigned to competent personnel

Important aspects

- Impartiality and confidentiality
- Sampling as a stand-alone activity
- Risk management and opportunities
- Subcontracting
- The use of a decision rule
- Traceability from calibration certificates
- Ensuring the validity of results
- Control of data
- Opinions and interpretations
- Management options
- The transition period

Other changes

- Additional provisions are now included under control of data – Information management
- Improvement now includes feedback from the customer.
- No need to rewrite the methods! The laboratory has to refer to standard method provided there are no deviations or adjustments

continued…

Other changes (2)

- The issue of liability is more elaborated;

  some of its aspects are addressed under confidentiality
- A new clause 4.1 will now refer only to impartiality. Relevant provisions are more detailed
- Externally provided products and services cover both services and supplies and subcontracting

Examples of notes of the Standard…

which have been transferred in the text of Standard:

- metrological traceability
- sampling
- validation of methods
- reference materials
- proficiency testing

Impartiality and confidentiality

- The new standard makes no reference to independence!* Emphasis is given to impartiality (4.1), defined as “presence of objectivity” (3.1) and confidentiality (4.2).
- In Note 1 to entry, it is explained that “Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the laboratory”.

**As a result, all laboratories (1st, 2nd or 3rd party) can meet the requirements of the Standard, provided that impartiality is demonstrated.*

An accredited laboratory…

uses the accreditation logo on its reports only for results from the activities defined for compliance with the Standard.

Appropriate indication of activities within or outside of the accreditation scope needs to be ensured according to the detailed policy of the national accreditation body.

Note : this is not a new issue, but it is very important with regards to work not carried out in the laboratory, on a permanent basis

Metrological traceability*

- The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference (clause 6.5.1).

* ISO/IEC Guide 99

➔ The above guide indicates that a measurement result is generally expressed as a single measured quantity value including a unit of measurement and a measurement uncertainty

➔ Annex A is informative…

According to Annex A…

Establishing metrological traceability needs:

- The specification of the measurand
- A documented unbroken chain of calibrations going back to stated and appropriate references
- Evaluation of measurement uncertainty according to agreed methods
- Each step to be performed in accordance with appropriate methods (measurement results with associated measurement uncertainties)
- Contributing laboratories supply evidence of their technical competence for the respective steps (A.2)

The laboratory shall ensure…

that measurement results are traceable to SI units. How?

6.5.2 provides for this…

a) calibration provided by a competent laboratory;

➔ *those fulfilling the requirements of this standard are considered to be competent*

b) certified values of certified reference materials by a competent producer with stated metrological traceability to SI;

➔ *producers fulfilling the requirements of ISO 17034 are considered to be competent*

c) Direct or indirect realisation of the SI units by comparison with national or international standards

➔ *see SI brochure (http://www.bipm.org/en/publications/si-brochure/*

Further to this, Annex A also refers…

to how metrological traceability can be established (A.3).

In practice, it briefly reflects the provisions of ILAC P 10 with reference to

- international arrangements (CIPM MRA – KCDB)
- accreditation by bodies under ILAC MRA/regional MLA
- Joint BIPM, OIML, ILAC and ISO Declaration on Metrological Traceability (http://www.bipm.org/utils/common/pdf/BIPM-OIML-ILAC-ISO_joint_declaration_2011.pdf)

In case metrological traceability to SI units…

is not possible, the laboratory shall demonstrate metrological traceability to an appropriate reference e.g.

a) certified values of certified reference materials by a competent producer

b) results of reference measurements procedures, specified methods or consensus standards

(6.5.3)

Additional provisions

- A declaration by the laboratory for the range of its activities conforming with the Standard, excluding activities externally provided *on an ongoing basis*
- Consideration of activities at facilities outside the laboratories permanent control
- Capability of the laboratory to

  - properly perform methods (verification-records)

  - develop new methods-qualified personnel-periodic review

continued…

Additional provisions (2)

- When statement of conformity to a specification/standard is provided, the laboratory shall document the decision rule employed taking into account the level of risk (false accept and false reject) – reference to ISO/IEC Guide 98-4
- Opinions and interpretations are addressed in more detail; the need for documentation of the basis (the results obtained) and the competence of the personnel releasing them – Not to be confused with inspections and product certifications (ISO 17020 and ISO 17065).

continued…

Additional provisions (3)

- The agenda for Management Review meetings is widened to reflect the various changes (include 6 new)
  - **Changes in interval and external issues**
  - **Fulfilment of objectives**
  - **Status of actions from previous management reviews**
  - **Effectiveness of any implemented improvements**
  - **Adequacy of resources**
  - **Results of risk identification**

Options for laboratories

The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results.

In addition to meeting the requirements of Clauses 4 to 7, the laboratory shall implement a management system in accordance of Option A (8.1.2) or Option B (8.1.3)

Options for laboratories (2)

Figure 2: Management system options

A laboratory that has established and maintains a management system in accordance to ISO9001 and that is capable of supporting and demonstrating the consistent requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9

From the recent Eurachem leaflet “A new ISO/IEC 17025 for laboratories”

The transition period

According to ILAC resolution GA 20.15, the transition period is set for three years after the publication of the new standard.

The new standard was published on 30 November 2017.

This means that by 30 November 2020 valid accreditation certificates need to be granted on the basis of ISO/IEC 17025:2017.

After this date, no accreditation certificate to ISO/IEC 17025:2005 will be recognized.

It is not an easy task to compare…

the two documents; some aspects are addressed in a different way and in more than one paragraphs while some new aspects are added.

However, it does not mean that such changes including the “no need for Quality Manual” would lead an accredited laboratory to delete and restart!

What a laboratory has to do?

Is it a matter or moving /exchanging part of the management system or re-numbering of procedures and working instructions?

➔This will really help to some extent; however, it will not be adequate! Further to the position, there are changes in the content of the requirements themselves. However…

➔ Understanding of the philosophy is even most important!

How can laboratories manage smoothly?

- The first priority is not to rewrite documents!
- The starting point is to clearly understand the new text and find out which elements of the existing management system address the restructured sections.
- It is more efficient to keep the Manual trying to renumber its particular parts and corresponding procedures, working instructions and templates.
- Through this process issues to be addressed according to the new published standard will be identified

Are there analogies with ISO 15189?

Some of the new provisions are relevant to those of the standard for medical laboratories. These refer to:

- Risk-based thinking vs risk management
- Control of data and information management vs laboratory information management
- Reference is made to the competence of PT providers and RM producers based on their compliance with ISO/IEC 17043 and ISO 17034 respectively; similarly ISO 15189 refers to ISO/IEC 17043 – ISO 17034 had not been published at the time.

Other aspects

e.g. the use decision rule, metrological traceability, uncertainty from sampling are not addressed as such.

However, these aspects are expected to be of interest for medical laboratories as well. In the case of metrological traceability, some of the new aspects are already covered by ILAC P10 which is a mandatory documents for both laboratories and accreditation bodies.

In the case of management system option B…

according to 8.1.3

A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of clauses 4-7 also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.

It is not clear how these clauses…

are to be assessed by Accreditation Bodies. Clause 7.5.3 of ISO 9001 (Control of documented information) provides for

- availability and suitability for use
- adequate protection (loss of confidentiality/integrity, improper use)
- distribution, access, retrieval and use
- storage and preservation (including protection of legibility)
- control of changes
- retention and distribution
- protection from unintended alterations

Similarly, two management system options...

A and B are provided in ISO/IEC 17020 and ISO 17034 as well.

In all these three types of CABs, those bodies operating according to the management option B, demonstrate their compliance with the accreditation standard via their documentation as required by the relevant clauses of ISO 9001.

With regard to the assessment, the experience with inspection bodies choosing management option B can help...

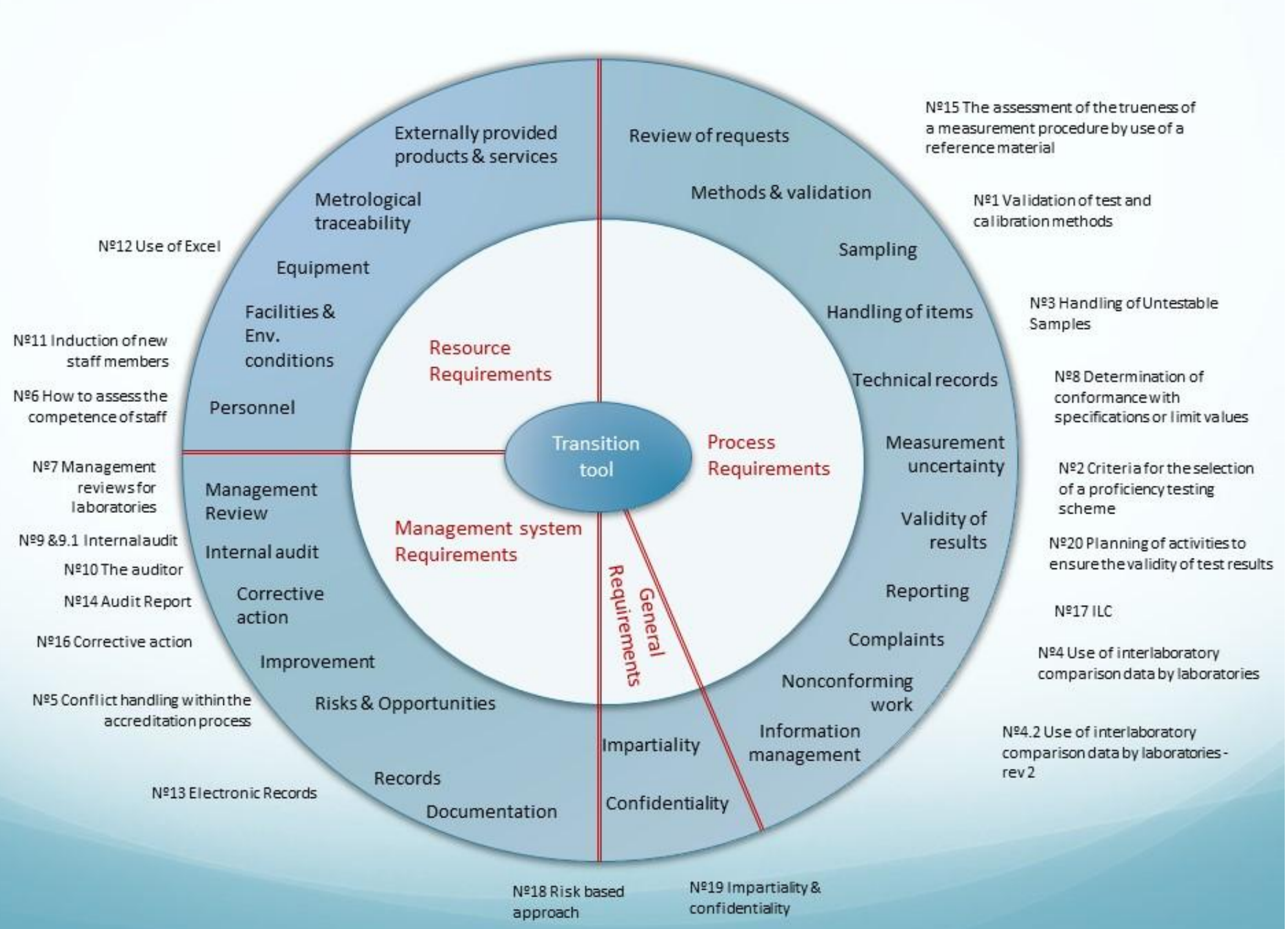
The experience with ISO/IEC 17020:2012

According to ILAC P 15 (8.1.3b)

Option B does not require that the inspection body's management system is certified to ISO 9001. However, when determining the extent of required assessment, the accreditation body should take into consideration whether the inspection body has been certified against ISO 9001 by a certification body accredited by an accreditation body which is a signatory to the IAF MLA, or to a regional MLA, for the certification of management systems.

This means that it is possible that…

a similar approach is followed in the case of laboratories; however, one could notice that among the points considered as already covered by ISO 9001 i.e. 8.2 – 8.9 of ISO/IEC 17025, some of them i.e. 8.5, 8.7-8.9 are more directly related to the operation of the laboratory, thus requiring a technical competence which may not be ensured within the auditors team of the certification body.



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Thank you for your attention

….and your questions