Transition to ISO/IEC 17025
Main changes in the version 2017

Présentation

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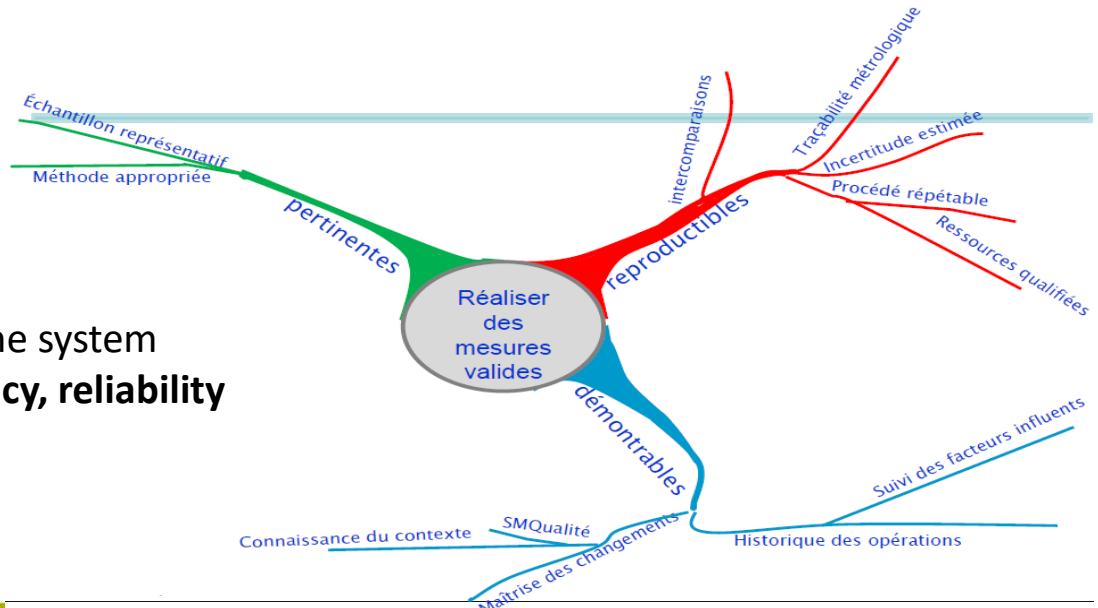
EPPO Worshop – 13 février 2019

Introduction

The international Standard ISO/IEC 17025 is used for the accreditation of competence of testing and calibration laboratories worldwide. It includes requirement for laboratories in order to:

1. Demonstrate competence **in issuing valid results.**
This requires people, knowledge, methods, equipments, consumables and a process.
« make appropriate choices »
« quality replaced by validity»



2. Prove their competences in operating the system
including ensuring impartiality, consistency, reliability
« once right ... Always right »

Principaux changements de la nouvelle version 2017

This third edition cancels and replaces the ISO Standard ISO 17025:2005, with hte following main modifications :

- A new structure for the document which takes into account requirements from du CASCO (Conformity ASsessment COmmittee): this structure is similar to ISO 17020 and ISO 17065 ;
- An **applied risk-based approach** that has reduced prescriptive requirements (resource requirements) and replaced them with performance-based requirements
- Equivalence with the management system to ISO 9001: 2015. A laboratory that meets the requirements of this ISO 17025 standard shall be considered as meeting the requirements of 9001:2015 (maintenance of the ISO-EA-ILAC tripartite agreement) ;
- Taking into account new information technologies
- An update of the **vocabulary**.

Main changes in the new version 2017

Structure of the Standard

ISO 17025 v2005

1 Scope of application
2 Normative references
3 Termes et définitions

4 Management requirements
5 Technical requirements

Annexe A – Nominal cross-references to ISO 9001:2000
Annexe B – Guidelines for establishing applications for specific fields

ISO 17025 v2017

1 Scope of application
2 Normative references
3 Termes et définitions
4 General requirements
5 Structural requirements
6 Ressource requirements
7 Process requirements
8 Management system requirements

Annexe A – Metrological traceability
Annexe B – Management system options

Main changes in the new version 2017

What happens to the requirements of the 2005 version?

2017 version / 2005 version	4. General requirements	5. Structural requirements	6. Resource requirements	7. Process requirements	8. Management system requirements
4 - Management requirements	4.1	4.1 - 4.2	4.6	4.4 - 4.5 - 4.7 4.8 - 4.9 - 4.13	4.1 - 4.2 - 4.3 4.7- 4.10 - 4.11 4.12 - 4.13 4.14 - 4.15
5 – Technical requirements			5.2 - 5.3 5.5 - 5.6	5.4 - 5.7 - 5.8 5.9 - 5.10	

There are very few technical changes to the requirements to be met by laboratories. Where changes have been made, they correspond to additional requirements that allow for a better interpretation of the requirement.

Main changes in the new version 2017

The 24 procedures (version 2005)

P Impartiality
P Confidentiality
Management of staff competence
Facility Maintenance
Intermediate checks / controls
Calibration correction factors
Handling of measuring instruments
Traceability of measurement
P Purchasing
P Contract review
Sampling
Handling of test and calibration objects
Validation of methods
Estimation of measurement uncertainties
Quality or Validity of results
P Complaints
P Control of nonconfirming work
Data protection
Documentation
Handwritten amendments
Recordings
P Corrective actions
Internal audit
Management reviews

P = political

Main changes in the new version 2017

Management of staff competence

Intermediate checks / controls

Handling of measuring instruments

Purchasing

Contract review

Handling of test and calibration objects

Estimation of measurement uncertainties

Quality or Validity of results

Complaints (documented process)

Control of nonconfirming work

9 procedures
And a documented process
(2017 version)

Policy on the Competence, Impartiality and Consistency of Laboratory Activities

Main changes in the new version 2017

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 (§ 8.1.1)
The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document (§ 8.4.1)

The objective is to have documented information: the support can be a process, a procedure, an operating mode, a recording, a powerpoint, a photo...

Procedure = documented disposition

Management of staff competence
Intermediate checks / controls
Handling of measuring instruments
Evaluation of the measurement uncertainty
Purchasing
Contract review
Handling of test objects
Validation of results
Complaints (documented process)
Control of nonconforming work

Main changes in the new version 2017

Challenges and changes of version 2017

The risk-based approach	**Products and services provided by external service providers (including subcontracting)**	Metrology traceability
Reduction of prescriptive requirements	**Control of data and information management**	Decision rules
Impartiality	Management System Options A & B	…
Complaints	Range of laboratory activities	

Main changes in the new version 2017

Risk ↗ ↗(explicit)

«The laboratory shall plan and implement actions that take into account risks and opportunities»

«It is the responsibility of the laboratory to determine the risks and opportunities that need to be taken into account. »

Impartiality ↗ ↗(developed)

«The laboratory must regularly identify risks that may affect its impartiality»

- Risks related to the organization and the organization's relationships
- Risks related to people's relationships and activities

Confidentiality ↗(developed)

«through legally enforceable commitments, the laboratory must be responsible for managing all information obtained or generated during its activities. »

- Protect
- Communicate in a controlled way

Main changes in the new version 2017

Organisation , structure ➔ (↘ best endeavour obligation, ↗ working field)

More formal requirement to appoint a quality manager More formal requirement to appoint alternates

"The laboratory shall define and document the scope of the laboratory activities for which it complies with this document."

Staff➔ (↘ simplification ↗ impartiality)

"All laboratory personnel (whether internal or external) who could influence laboratory activities must act impartially, be competent and work in accordance with the laboratory's management system. »

- the determination of competency requirements;
- staff selection;
- staff training;
- staff supervision;
- staff authorization;
- monitoring of staff skills.

Main changes in the new version 2017

Equipment ➔ (↘ possession)

"The laboratory must have access to the equipment"

- Equipment requirements
- Requirements for measuring equipment

Sampling ➔ (↗ definition)

"Laboratory: an organization that performs one or more of the following activities:

Calibration; testing; sampling associated with one (or more) subsequent test(s) or calibration(s). »

"Laboratory activities" refers to the three activities mentioned above.“

Traceability ↗ (↘ deletion of notes, ↗ annexe, ↗ report)

Annex echoing ILAC P10 document mentioning recognised ways to ensure metrological traceability

"calibration certificates shall include a statement indicating how the metrological traceability of measurements is ensured"

Principaux changements de la nouvelle version 2017

Purchase ↘ (more generic)

Merge of "purchasing services and supplies" and "subcontracting of tests and calibrations" into "Externally provided products and services".

Process ↗ (↗ client relationship and information)

- Purchases for its own account or for the customer
- Compliance decision rule shared with the customer
- Information on sampling (including information influencing measurement uncertainty)
- Information provided by the client included in the reports

Control of data and information management↗ (↗ extension of the scope of application)

"Also concerns the information management system"

"When a laboratory's information management system is managed and maintained off-site or by an external service provider"

Specific requirements for calibration certificates↗ (↗ content)

«where appropriate, opinions and interpretations"

Principaux changements de la nouvelle version 2017

Ensuring the validity of results↗ (↗ possibilities)

- The "validity of the results" beyond the "quality of the results
- 13 examples of monitoring methods
- A focus on comparing results with those of other laboratories
- Internal AND external monitoring

Complaints ↗ (↗ formalism)

«The conclusions to be communicated on the complainant must be made, or reviewed, and approved by a person or persons who were not involved in the laboratory activities initially involved »

Management system ↗ (↗ compatibility 9001, ↗ risk)

Option A / Option B (9001) The laboratory must plan:

- the actions to be implemented in response to risks and opportunities,
- how: integrate and implement these actions within the management system
- evaluate the effectiveness of these actions.

No imposed method for managing risks and opportunities