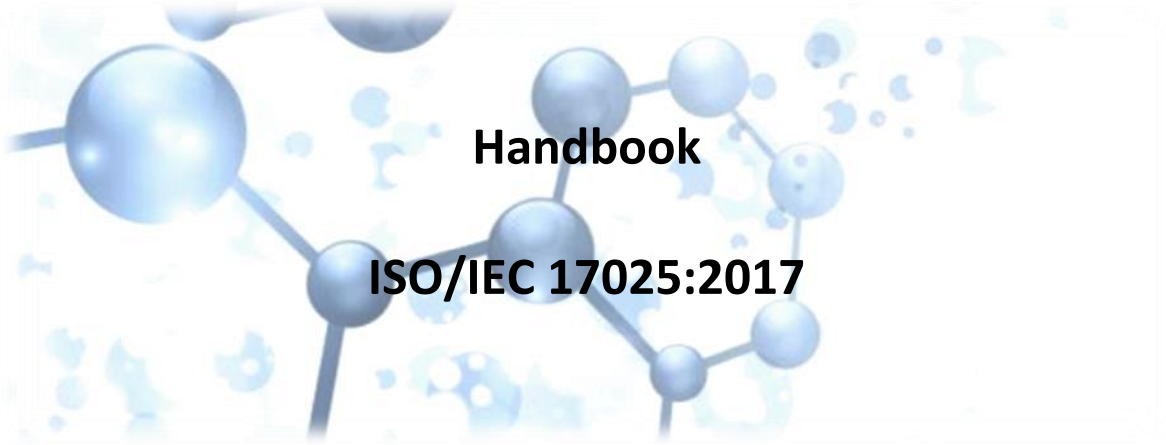

Handbook

ISO/IEC 17025:2017

General considerations

This new standard ISO/IEC 17025 includes some noteworthy changes related to its structure and scope that should be mentioned before we go into greater details of each section of the standard.

- **Structure:**

The new structure of the standard is no longer based on the two main chapters (four for Management requirements, and five for Technical requirements) we were used to; to be harmonized with the rest, this one follows the CASCO guidelines for conformity assessment standards, and the structure is more process oriented:

  - Structure requirements
  - Resource requirements
  - Process requirements
  - Management system requirements

The standard also includes two Annexes that were not included in the previous version:
  - Informative Annex A, related to metrological traceability
  - Informative Annex B, related to the different options of the laboratory management system

- **Wording:**

A stronger process orientation and the implementation of risk-based thinking are reflected in a changed way of formulating the requirements. While in the previous edition of ISO/IEC 17025 specific provisions for the implementation in the laboratory have been expressed, the new choice of words is more performance-based and therefore much more abstract. The result or the purpose of certain processes is now embedded in the formulations (performance-based requirements), while the concrete design of the processes (the "how") is left up to the users; consequently, the description of individual process steps has been abandoned.

- **Scope:**

A new definition of the term “laboratory” and its activities has been included. In the new version, a laboratory has been defined as an organization that can perform testing, calibration and/or sampling associated with subsequent testing or calibration. The term “laboratory activities” has been introduced. The resulting new definition of the term “laboratory” makes clear that laboratory activities do not only include testing and calibration but also sampling, provided that this is in connection with a subsequent test or calibration. For the user, it is important that the appropriate requirements are applied to all three activities whenever the standard speaks of laboratory activities.

In the following, this handbook identifies the major innovations of ISO/IEC 17025:2017, often in comparison to the previous version, gives suggestions on how to implement the novelties, and recommends further readings on the particular clauses, especially to the CookBooks.

RISK BASED THINKING

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
Introduction	"Risk based approach"	N/A	N/A

Identification of changes

This document requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed.

Suggestions on how to implement the novelties

The objectives of risk assessments in the laboratory (8.5) are to:
“a) give assurance that the management system achieves its intended results;
b) enhance opportunities to achieve the purpose and objectives of the laboratory;
c) prevent or reduce undesired impacts and potential failures in the laboratory activities; and
d) achieve improvement.”

Risk based thinking in a laboratory is not a novelty, but it is promoted in the new standard, although the standard does not stipulate a complete risk management system (RMS), for example conforming to the requirements of ISO 31000. The laboratory is expected to plan and implement actions for addressing risks and opportunities. It is therefore useful to get an overview of the specific risks as well as the corresponding opportunities for the laboratory and to document the results of the risk analysis. Both the risks of producing invalid results including the provision of an invalid statement of conformity (7.8.6) and impartiality risks should be considered (4.1.4). Additionally, risk levels regarding non-conforming work (7.10) and invalid statements (7.8.6.1), such as false accept and false reject as well as statistical assumptions, should be defined for instance by a three-stage quotation system. An acceptable risk should be classified as such.

This risk analsysis as well as adequateness of the resulting actions shall be implemented in the management system; it is therefore recommended to address this during the management review (8.9.2).

Further readings

- CookBook Nº18 An introduction to risk consideration
- CookBook Nº8 Determination of Conformance
- CookBook Nº7 Management Reviews
- ISO 31000 Risk management -- Guidelines

4. GENERAL REQUIREMENTS
IMPARTIALITY AND CONFIDENTIALITY

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
4.1	Impartiality	4.1.4/4.1.5	Organization
4.2	Confidentiality	4.1.5 c)	Organization

Identification of changes

New harmonized text has been included, so these are completely new clauses.

Suggestions on how to implement the novelties

- **Regarding impartiality (4.1)**

It is recommended to write down a document in which, depending on the needs, the following steps should be included:

- Analysis of potential impartiality risks, including risks arising from the laboratory activities, its relationships and the relationships of its personnel
- Measures to eliminate or minimice risks **concerning impartiality**
- Action plan: design and implement pertinent actions
- Commitment of the laboratory to its integrity, through the signature of a statement by the top management

This analysis should be reviewed at the Management review and, if necessary, revised.

- **Regarding confidentiality (4.2)**

The customer should be informed in writing if the laboratory intends to make publicly available any information about an assignment. This information should be provided before starting the activities. and should therefore be included in the offer/contract or other similar document used by the laboratory. It is common practice that information about customer assignments are kept confidential.

The laboratory personnel, providers, external personnel etc. should also sign a confidentiality declaration.

Further readings

- CookBook Nº11 Induction of New Staff Members
- CookBook Nº19 Impartiality and Confidentiality

5. STRUCTURAL REQUIREMENTS

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
5	Structural Requirements	4	Organization

Identification of changes

The requirements have been restructured. The most important changes are:

- The term “quality manager” is not mentioned, even though the functions are still included in the standard. (5.6)
- The term “technical manager” is not mentioned, even though the functions are still included in the standard. (5.2)
- It is no longer necessary to have deputies for key positions.
- The laboratory is obliged to write down the range of activities (5.3, 5.4). The range of activities does not include those activities that have been permanently subcontracted.
- Following the new ISO 9001:2015 clause 5.7. a) requires adequate communication processes regarding the effectiveness of the management system.

Suggestions on how to implement the novelties

It is suggested to adapt existing documents in the laboratory and to write down a brief summary of the activities fulfilling ISO/IEC 17025. If there are any other activities (permanently subcontracted activities etc.), they can also be included in this document, but they have to be clearly marked.

Regarding the communication requiremements, it is suggested to communicate the results of the management review addressing the effectiveness of the MS to the personnel concerned.

Further readings

6. RESOURCE REQUIREMENTS
6.2 PERSONNEL

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
6.2	Personnel	4.1.5 f) -h) 5.2	Organization / Personnel

Identification of changes

There are no substantial changes. The most prominent are:

- The need to supervise (before authorisation) and to monitor (after authorisation) the personnel (6.2.5 c and f) has been taken up.
- The need to assess the efficiency of training has been erased.
- The need to document job descriptions has been erased. However, it is required to define competence requirements for each function (not only managerial functions but all of those that have an impact on the results of the laboratory).

Suggestions on how to implement the novelties

In 6.2.5, the standard includes a list from a) to f) which should be considered in chronological order.
It is suggested to adjust existing documents in the laboratory to this new situation.
Usually laboratories already have a monitoring plan for the personnel.

The most frequently used supervision/monitoring methods are:

- measuring samples known: Reference standards, Intercomparison samples, etc.
- blind samples
- inter/intralaboratory comparisons
- exams (for intellectual knowledge)

It is recommended to record these activities.

Further readings

- CookBook Nº6 How to Assess the Competence of Staff
- CookBook Nº11 Induction of New Staff Members

6. RESOURCE REQUIREMENTS
6.3 FACILITIES AND ENVIRONMENTAL CONDITIONS

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
6.3	Facilities and environmental conditions	5.3	Accommodation and environmental conditions

Identification of changes

There are no significant changes. When tests are performed in facilities outside its permanent control, the new standard requires that environmental and facilities related requirements be met.

Suggestions on how to implement the novelties

It is advisable to adapt formats to the environmental requirements, if any.

Further readings

6. RESOURCE REQUIREMENTS
6.4 EQUIPMENT

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
6.4	Equipment	5.5	Equipment

Identification of changes

- Standards, reference materials, reagents, and software are now also considered as equipment (6.4.1).
- Conditions to calibrate equipment are set (6.4.6):
  - if accuracy or uncertainty affect the validity of results
  - if calibration is needed to establish metrological traceability
- Reference to ISO 17034 has been included to emphasise the competence of RM producers.

Suggestions on how to implement the novelties

Adapt and extend the equipment control system to reagents, standards, reference materials, auxiliary equipment, and software.
This implies at least the following:

- identification
- inventary and storage
- calibration/verification, modification of maintenance plan, as applicable
- record of malfunction and reparations

Before new software (developed by the laboratory or by an external provider) is used by the laboratory, it has to be validated, except if it is standard off the shelf software. The validation activities of new software have a lot in common with method validation and acceptance test of new equipment. In short, the validation shall demonstrate that the software is fitted for its intended use. When software is included (built-in) in test equipment the validation should be included in the acceptance test and also be considered during calibration. However, in many cases built-in software could be considered as standard off the shelf software.

Further readings

- CookBook Nº12 Use of Excel For Data Handling in Laboratories

6. RESOURCE REQUIREMENTS
6.5 METROLOGICAL TRACEABILITY

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
6.5	Metrological traceability	5.6	Measurement traceability

Identification of changes

Most of the notes have been erased, and a new Informative Annex on metrological traceability has been created. In Annex A, possibilities have been included on how to establish and demonstrate traceability:

- through the use of a NMI
- accredited calibration laboratory
- others

Suggestions on how to implement the novelties

Whenever possible and cost-efficient, it is easier for the laboratory to use accredited calibration laboratories or NMIs; however, if this is not possible, it is advisable to assess their competence based on ISO/IEC 17025.

The main aspects of the assessment are:

- traceability of used standards
- used calibration procedure
- uncertainty evaluation procedure

If the results cannot be traced to SI the laboratory can use other recognised methods (reference laboratories, reference standards/materials, reference procedures, etc.)

Further readings

- ILAC P10:01/2013 ILAC Policy on Traceability of Measurement Results
- ISO 17034 General requirements for the competence of reference material producers (or ISO Guide 34 as predecessor during transition period)

6. RESOURCE REQUIREMENTS
6.6 EXTERNALLY PROVIDED PRODUCTS AND SERVICES

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
6.6	Externally provided products and services	4.5 and 4.6	Subcontracting of tests and calibrations Purchasing services and supplies

Identification of changes

This new item includes the previous concept of subcontracting, so purchasing and subcontracting are now compiled in one clause.

The laboratory should have a system to select, assess, monitor, and reassess external providers.
The laboratory shall ensure that all purchased products and services fulfil the requirements.
The laboratory shall make the following clear to the provider:

- what is to be bought,
- acceptance criteria,
- personnel competence needed, and
- activities that the laboratory intends to perform in the provider's facilities

Three different ways (6.6.1 a, b and c) describe which products and services can be provided externally.
The procedure for reviewing requests, tenders, and contracts shall include the laboratory's information to the customer of externally provided activities, and the customer shall approve the involvement of external providers before starting laboratory activities.

Suggestions on how to implement the novelties

The laboratory shall ensure that the system to assess and control providers fulfils the standard.
When standardised off the shelf software is purchased, this software can be considered as validated.

Further readings

7. PROCESS REQUIREMENTS
7.1 REVIEW OF REQUESTS, TENDERS, AND CONTRACTS

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
7.1.1	Review of requests, tenders, and contracts	4.4	Review of requests, tenders, and contracts

Identification of changes

When subcontracting a laboratory activity (7.1.1d) it is necessary to obtain the customer's approval.
If the customer requires a conformity statement, then the decision rule has to be clear, and it has to be communicated to and agreed upon by the customer.

Suggestions on how to implement the novelties

Modify commercial documents to include new requirements.

Further readings

7. PROCESS REQUIREMENTS
7.2 SELECTION, VERIFICATION, AND VALIDATION OF METHODS

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
7.2	Selection, verification, and validation of methods	5.4.1. / 5.4.2	Test and calibration methods and method validation - General / Selection of methods

Identification of changes

In 7.2.1.5, the concept of "method verification" is introduced which is the activity to verifiy that the laboratory can achieve the required performance.

“When method development is required, this shall be a planned activity (7.2.1.6) and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized.”

Following 7.2.1.7, the customer has to accept deviations from the methods. Deviation in this context should be understood as a planned change or modification of the method.
The content of5.4.3 and 5.4.4 of the previous version regarding own developed methods and non-standardized methods have been erased.
A “new” way to validate methods has been included as 7.2.2.1 c). This technique provides that method robustness is tested through variation of controlled parameters such as incubator temperature, volume dispensed, etc.

The previous Note 3 in the previous standard is now the requirement 7.2.2.2
7.2.2.4 precises more thoroughly the need of records as a validation result.

Suggestions on how to implement the novelties

It is recommended to document verifications when using standardized methods.

Further readings
CookBook Nº1 Selection, Verification and Validation of Methods
CookBook Nº15 Assessment of the trueness of a measurement procedure by the use of a reference material

7. PROCESS REQUIREMENTS
7.3 SAMPLING

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
7.3	Sampling	5.7 5.8 Note 2 5.10.2 h 5.10.3.2	Sampling

Identification of changes

Sampling is now highlighted as a laboratory activity as is testing and calibration. The whole standard is also applicable to sampling activities.

The way in which the standard handles sampling has not changed much. Nevertheless, when evaluating the uncertainty of measurement, the sampling contribution has to be included (7.6.1).

Suggestions on how to implement the novelties

Adapt procedures on uncertainty evaluation to include the sampling component when necessary.

Further readings

Nordtest “Uncertainty from sampling. A Nordtest handbook for sampling planners and sampling quality assurance and uncertainty estimation.” (2007), NT tec 604/TR604 (www.nordicinnovation.net)

Eurachem Guide “Measurement uncertainty arising from sampling” (2007); https://www.eurachem.org/images/stories/Guides/pdf/UfS_2007.pdf

7. PROCESS REQUIREMENTS
7.4 HANDLING OF TEST OR CALIBRATION ITEMS

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
7.4	Handling of test or calibration items	5.8	Handling of items

Identification of changes

When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation (7.4.3)

Suggestions on how to implement the novelties

Modify the report formats to include a disclaimer.

Further readings

CookBook Nº3 Handling of Untestable/Deviating Samples

7. PROCESS REQUIREMENTS
7.5 TECHNICAL RECORDS

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
7.5	Technical records	4.13.2	Technical records

Identification of changes

The handling and recording of mistakes and errors have been updated. The previous 4.13.2.3 addressing the crossing out and initialling of mistakes has been erased. Now it is a requirement that modifications of technical records shall be tracked to previous versions and to the original. All versions shall be kept indicating what has been changed and who is responsible for the alteration (7.5.2).

Suggestions on how to implement the novelties

In case of using electronic records, the laboratory has to have a system allowing versions and their tracking and the identification of responsibilities.

Further readings

CookBook Nº 13 Technical records

7. PROCESS REQUIREMENTS
7.6 EVALUATION OF MEASUREMENT UNCERTAINTY

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
7.6	Evaluation of measurement uncertainty	5.4.6	Estimation of uncertainty of measurements

Identification of changes

This clause has remained almost unchanged, but there is a new Note 2 in 7.6.3 specifying that if the laboratory uses a method with which the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result, if the laboratory can demonstrate that the identified critical influencing factors are under control.

Suggestions on how to implement the novelties

Define and control the critical influencing factors (usually through the assurance of the validity of results of measures).

Further readings

- ISO/IEC Guide 98-3 (GUM), ISO/IEC Guide 98-3/Suppl 1, ISO/IEC Guide 98-3/Suppl 2,
- ISO 5725 -x series
- ISO 21748 Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation
- Further guidance : see Eurachem reading list https://www.eurachem.org/index.php/publications/mnu-rdlst/128-rdl-uncert

7. PROCESS REQUIREMENTS
7.7 ENSURING THE VALIDITY OF RESULTS

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
7.7	Ensuring the validity of results	5.9	Assuring the quality of results

Identification of changes

The validity of results can be monitored in different ways; the laboratory should have a strategy on how to use the different measures.
This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:

a) use of reference materials or quality control materials;
b) use of alternative instrumentation that has been calibrated to provide traceable results;
c) functional check(s) of measuring and testing equipment;
d) use of check or working standards with control charts, where applicable;
e) intermediate checks on measuring equipment;
f) replicate tests or calibrations using the same or different methods;
g) retesting or recalibration of retained items;
h) correlation of results for different characteristics of an item;
i) review of reported results;
j) intra-laboratory comparisons;
k) testing of blind sample(s).

Additional measures are possible.
There is a specific point (7.7.2) with requirements for the participation in interlaboratory comparisons, in which PTs and other types of intercomparisons find mention.

Suggestions on how to implement the novelties

Adapt the validity ensurance plan to new options if needed. In the laboratory´s strategy/policy and plan for validating results participation and non-participation should be motives, preferably with a risk analysis as a basis.

Further readings

- CookBook Nº2 Criteria for The Selection of a Proficiency Testing Scheme
- CookBook Nº17 Interlaboratory Comparison_The Views Of Laboratories
- CookBook Nº4 Use of Interlaboratory Comparison Data by Laboratories
- CookBook Nº4.2 Use of Interlaboratory Comparison Data by Laboratories rev 2
- CookBook Nº 20 Planning of Activities to Ensure the Validity of Test Results

7. PROCESS REQUIREMENTS
7.8 REPORTING OF RESULTS

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
7.8	Reporting of results	5.10	Reporting of results

Identification of changes

7.8.1 General:
7.8.1.3 The requirements for simplified reports are no longer for internal customers only, but for any customer, if agreed upon

7.8.2 Common requirements:
7.8.2.1 The following has been included:
j) The date of issue of the report;
Note 1 (paging of reports) from the previous standard has been erased.
o) instead of a signature the identification of the person(s) authorizing the report
7.8.2.2 is new and includes two disclaimers: one regarding the information provided by the customer, and the other one regarding sampling when the laboratory does not cover it.

7.8.5 Reporting sampling - specific requirements -
In comparison to the previous 5.10.3.2 a new point f) under 7.8.5 is added:
f) Information required to evaluate measurement uncertainty for subsequent testing or calibration

7.8.6 Reporting statements of conformity
Two new subclauses are added:
7.8.6.1 “When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.”
7.8.6.2 “The laboratory shall report on the statement of conformity, such that the statement clearly identifies:
a) to which results the statement of conformity applies;
b) which specifications, standards or parts thereof are met or not met; c) the decision rule applied (unless it is inherent in the requested specification or standard).”

7.8.7 Reporting opinions and interpretations
This is more detailed now. There has to be authorised personnel to provide opinions and interpretations (7.8.7.1), and opinions and interpretations have to be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.

7.8.7.3 “When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.”

7.8.8 Amendments to reports
7.8.8.1 has been added. “When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change shall be included in the report.”

Suggestions on how to implement the novelties

Include the definition of decision rule and link it with the evaluation of measurement uncertainty.
When sampling is made, the contribution of this activity to the measurement uncertainty has to be clear. Therefore, procedures have to be developed for this.
The laboratory shall develop decision rules together with its customer when conformity assessment has to be made based on the results.
The laboratory shall officially authorise the personnel in charge of giving opinions and making interpretations.
The laboratory should adapt the report format to include all new requirements and reissuing/modification requirements.

Further readings

- CookBook Nº 8 Determination of Conformance with Specifications unsing Measurement Uncertainty – Possible Strategies
- EUROLAB Technical Report No. 01/ 2017 Decision rules applied to conformity assessment http://www.eurolab.org/documents/EUROLAB%20Technical%20Report%20No.1-2017_Final.pdf

7. PROCESS REQUIREMENTS
7.9 COMPLAINTS

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
7.9	Complaints	4.8	Complaints

Identification of changes

This clause has been refined and contains requirements for the procedure:
7.9.2 Complaints procedure shall be made available to any interested party on request.

7.9.3 The content of the procedure is detailed here.

7.9.5 The laboratory shall acknowledge the complaint and report the progress to the complainant.

7.9.6 “The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.”

7.9.7 “Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.”

Suggestions on how to implement the novelties

It is advisable to adapt the complaints handling procedure to the new requirements.
The definition of the term complaint (3.2) as an “expression of dissatisfaction by any person or organization to a laboratory (3.6), relating to the activities or results of that laboratory, where a response is expected” is a good definition of complaint.

It is important that this is not limited to written complaints.

According to 7.9.6, decisions made within the complaint process, especially the decision about the outcome of a complaint, must be communicated by personnel not involved in the activity in question.

Further readings

7. PROCESS REQUIREMENTS
7.10 NONCONFORMING WORK

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
7.10	Nonconforming work	4.9	Control of nonconforming test and/or calibration work

Identification of changes

This clause is more detailed, and a new item has been included that is to be taken into account in the nonconforming work procedure.

b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;

A novelty on the extension analysis has also been included in point c (previously b)):

c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;

Suggestions on how to implement the novelties

The laboratory should adapt its procedure of nonconforming work handling to include:

- different levels of risk
- extension analysis

Further readings

7. PROCESS REQUIREMENTS
7.11 CONTROL OF DATA AND INFORMATION MANAGEMENT

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
7.11	Control of data and information management	4.13	Control of records

Identification of changes

The entire chapter has been rewritten and adapted to handle electronic information.

The laboratory might have an information management system applicable to electronic and conventional information. The system has to be validated and protected.

Suggestions on how to implement the novelties

- The requirements for information management systems are not restricted only to computerized systems (LIMS) but to any kind of system handling information.
- Test the system in place to check integrity, potential unauthorised access, protection against tampering and test backups!
- The system has to be maintained in a correct manner and kept in a suitable environment.
- If needed, validate the system!
- Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.
- The staff shall have access to instructions to the LIMS.
- Calculations and data transfers shall be checked.

Further readings

- CookBook Nº 12 Use of Excel For Data Handling in Laboratories
- CookBook Nº 13 Technical records

8. MANAGEMENT SYSTEM REQUIREMENTS
8.1 OPTIONS

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
8.1	Options		

Identification of changes

The entire chapter is new, and there are two options:

Option A includes the minimum content for the management system.
Option B states that the minimum requirements are considered fulfilled if the laboratory has an ISO 9001 system and also fulfills clauses 4 to 7.

Suggestions on how to implement the novelties

It should be considered that the objectives of the ISO 9001 can be different from the ISO/IEC 17025, and the system should be adapted accordingly (the scope of the ISO 9001 should be checked to ensure that the activities of the laboratory are included).

Laboratories which are part of bigger organizations with ISO 9001 in place can benefit from this.

Further readings

Annex B of the standard

8. MANAGEMENT SYSTEM REQUIREMENTS
8.2 MANAGEMENT SYSTEM DOCUMENTATION

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
8.2	Management system documentation (Option A)	4.2	Management system

Identification of changes

Requirements have been softened.

The need of a Quality Policy as well as a Quality Manual has been erased (as in the revised ISO 9001:2015).

Suggestions on how to implement the novelties

Adapt the system to the novelties.

Further readings

ISO 9001 Quality management systems -- Requirements

8. MANAGEMENT SYSTEM REQUIREMENTS
8.3 CONTROL OF MANAGEMENT SYSTEM DOCUMENTS

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
8.3	Control of management system documents (Option A)	4.3	Document control

Identification of changes

The clause has been simplified even though the requirements are basically the same.

Suggestions on how to implement the novelties

Further readings

8. MANAGEMENT SYSTEM REQUIREMENTS
8.4 CONTROL OF RECORDS

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
8.4	Control of records (Option A)	4.13.1	Control of records – General -

Identification of changes

The clause has been simplified even though the requirements are basically the same.

Suggestions on how to implement the novelties

Further readings

8. MANAGEMENT SYSTEM REQUIREMENTS
8.5 ACTION TO ADDRESS RISKS AND OPPORTUNITIES

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
8.5	Actions to address risks and opportunities (Option A)		

Identification of changes

The clause is completely new and replaces the concept of preventive actions.

- 8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:
    - give assurance that the management system achieves its intended results;
    - enhance opportunities to achieve the purpose and objectives of the laboratory;
    - prevent, or reduce, undesired impacts and potential failures in the laboratory activities; and
    - achieve improvement.
- 8.5.2 The laboratory shall plan:
    - actions to address these risks and opportunities;
    - how to:
        - integrate and implement the actions into its management system;
        - evaluate the effectiveness of these actions.
- 8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

Suggestions on how to implement the novelties

The laboratory is recommended to develop a specific document (procedure or any other name) where risks and opportunities are identified, as well as a plan to implement action to minimize risks and maximize opportunities.

This procedure as well as the updated action plan should be analyzed during the management review (8.9.2), and the efficacy of the actions taken should be assessed.

The document identifying the risks should include, at least, the following:

- 4.1.4 risks to impartiality (arise from its activities, or from its relationships, or from the relationships of its personnel.)
- 7.8.6.1 the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule.
- 7.10.1 The laboratory should establish different levels of risk, and assess arisen nonconformities using these levels, and act in consequence (8.7.1)

Further readings

- CookBook Nº 18 An Introduction to Risk Consideration

8. MANAGEMENT SYSTEM REQUIREMENTS
8.6 IMPROVEMENT

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
8.6	Improvement (Option A)	4.7.2 / 4.12	Service to the customer / Preventive action

Identification of changes

Requirements have been reduced. There is no need of having a procedure in place or of assessing the efficiency.

Suggestions on how to implement the novelties

Adapt the system to new situation.

Further readings

8. MANAGEMENT SYSTEM REQUIREMENTS
8.7 CORRECTIVE ACTION

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
8.7	Corrective actions (Option A)	4.11	Corrective action

Identification of changes

The writing of the clause has been modified, and some further items have been included:

- b) determining if similar nonconformities exist, or could potentially occur
- e) update risks and opportunities determined during planning, if necessary

Aditional internal audits have been erased.

Suggestions on how to implement the novelties

Update the procedure.

Further readings

CookBook Nº 16 Corrective Action

8. MANAGEMENT SYSTEM REQUIREMENTS
8.8 INTERNAL AUDITS

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
8.8	Internal audits (Option A)	4.14	Internal audits

Identification of changes

This clause has been made more flexible:

- There is no need to conduct internal audits every year, but at planned intervals.
- The relevance of the activities to be audited, changes in the laboratory and the results of previous audits have to be taken into account in the program of each audit.

Suggestions on how to implement the novelties

Adapt the procedure.

When programming and planning the audit, it is recommended to consider the relevance of the activities to be audited, as well as the particular context of the laboratory, the result of previous internal and external audits, etc.. Depending on this, the frequency as well as the focus of the internal audits could be revised.

Further readings

- CookBook Nº 9 Internal audits
- CookBook Nº 10 Internal audits - the auditor
- CookBook Nº 14 Internal audits - audit report

8. MANAGEMENT SYSTEM REQUIREMENTS
8.9 MANAGEMENT REVIEWS

Cross reference

ISO/IEC 17025:2017		ISO/IEC 17025:2005	
Clause	Title	Clause	Title
8.9	Management reviews (Option A)	4.15	Management reviews

Identification of changes

This clause has been rewritten.

The recommendation of performing the management review every 12 months has been erased.

Some inputs have been changed:

- "customer feedback" has been modified to "customer and personnel feedback"
- Instead of "recommendations for improvements", it has been modified to: "effectiveness of any implemented improvements "

Some inputs have been added:

a) changes in internal and external issues that are relevant to the laboratory;
b) fulfilment of objectives;
d) status of actions from previous management reviews;
l) adequacy of resources;
m) results of risk identification

The outputs have been detailed:

a) the effectiveness of the management system and its processes;
b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;
c) provision of required resources;
d) any need for change.

Suggestions on how to implement the novelties

Adapt the procedure.

Further readings

CookBook Nº 7 Management reviews for laboratories

Tool for Transition to ISO/IEC 17025

In view of the content of the new standard ISO/IEC 17025:2017, EUROLAB has created a tool to help the laboratories properly implement the transition.

CookBook Wheel

To help the laboratories with further readings and hints to implement a proper transition, EUROLAB has revised and adapted the CookBooks considering the requirements of the new standard.

This wheel has been made interactive in the EUROLAB webpage to make access even easier.