ISO/IEC 17025

Overview of Differences Between ISO/IEC 17025:2005 & ISO/IEC 17025:2017

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Overview of Differences Between ISO/IEC 17025:2005 & 2017

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ISO/IEC 17025:2017

In meeting the current industry needs, the changes to ISO/IEC 17025:2017 include

- A new chapter on risk-based thinking has been added
- Greater flexibility in the guidelines for processes, procedures, documented information, and organizational responsibilities
- Terminology has been updated
- The standard now recognizes and incorporates the use of computer systems, electronic records, and the production of electronic results and reports
- The scope has been revised to cover all laboratory activities. This includes testing, calibration, and the sampling associated with subsequent calibration and testing.

ISO/IEC 17025:2017 - Structure

The new structure, closely aligned with all recent 17000-series standards

- The 2005 edition was split into Management requirements and Technical requirements, appearing in that order. The 2017 Standard has five sections;
- Management System Options (A&B)
- Strong emphasis on “risk-based thinking”. The word “risk” appears over 30 times in the document, compared to only four appearances in the 2005 edition

The Structure of ISO/IEC 17025:2017

1 Scope
2 Normative references
3 Terms and definitions
4 *General requirements*
4.1 Impartiality
4.2 Confidentiality
5 Structural requirements
6 Resource requirements
6.1 General
6.2 Personnel
6.3 Laboratory facilities and environmental conditions
6.4 Equipment
6.5 Metrological traceability.
6.6 Externally provided products and services
7 Process requirements
7.1 Review of requests, tenders and contracts
7.2 Selection, verification and validation of methods
7.3 Sampling
7.4 Handling of test or calibration items
7.5 Technical records
7.6 Evaluation of measurement uncertainty
7.7 Assuring the quality of results
7.8 Reporting of results
7.9 Complaints
7.10 Management of nonconforming work
7.11 Control of data – Information management
8 Management requirements
8.1 Options
8.2 Management system documentation (Option A)
8.3 Control of management system documents (Option A)
8.4 Control of records (Option A)
8.5 Actions to address risks and opportunities (Option A)
8.6 Improvement (Option A)
8.7 Corrective action (Option A)
8.8 Internal audits 8.9Management reviews (Option A)

4.1 Impartiality

Impartiality = presence of objectivity

In ISO 17025:2005 Impartiality mostly mentioned in notes and conflict of interest is only mentioned once. 4.1.4, 4.1.5 b ,d,e,f

ISO/IEC 17025:2017 there is a new section 4.1 dealing with impartiality

Highlights

- The laboratory management shall be **committed** to impartiality
- The laboratory **shall identify risks** to its impartiality on **an on-going basis**
- If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it **eliminates or minimizes** such risk.

4.2 Confidentiality

17025:2005

- 4.1.5 (c) have policies and procedures
- 4.7.1 service to customer:
- 5.4.7.2 (b) control of data :

The 2017 Standard now has its own section on confidentiality. The requirements have not changed however there is much more detail.

4.2 Confidentiality

Highlights

- Responsible, through legally enforceable commitment and specifics about information placed in the public domain;
- Specifics when the laboratory is required by law or authorized by contractual arrangements to release confidential information;
- Information about the customer obtained from sources other than the customer (e.g. complainant, regulators)
- Individuals acting on the laboratory's behalf, shall keep confidential all information

5.0 Structural Requirements

- Legal Entity
- Identify management that has overall responsibility for the laboratory

- *Gives responsibility to the level it is needed. The term quality and technical manager is not specified in ISO/IEC 17025:2017*

- Define and document the range of laboratory activities
- Laboratory Activities covered in both fixed and temporary facilities (onsite)
- Define organizational structure
- The functions of quality manager are there however does not define titles, These functions can be a team and not an individual

5 Structural Requirements

Laboratory management shall ensure that:

- Communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;
- The integrity of the management system is maintained when changes to the management system are planned and implemented.

6 Resource requirements

6.1 General

- Introduction

6.2 Personnel

- Shall act impartially, be competent
- Shall document the competence requirements
- Competence to perform laboratory activities
- Management of the laboratory shall **communicate** to personnel their duties, responsibilities and authorities

- *There is no longer a requirement for a formal job description*

6.2 Personnel

Shall have procedure(s) and **retain records** for:

a) determining the competence requirements;

b) selection of personnel;

c) training of personnel;

d) supervision of personnel;

e) authorization of personnel;

f) **monitoring** of competence of personnel (*NEW*)

6.2 Personnel

The laboratory shall authorize personnel to **perform specific laboratory activities**, including but not limited to, the following:

a) development, modification, verification and validation of methods;

b) analysis of results, including statements of conformity or opinions and interpretations;

c) report, review and authorization of results

Laboratory activities will include those involved directly in the testing, calibration or sampling activities, however will also incorporate other functions such as internal auditing .

6.3 Facilities and environmental conditions

Basically everything intact from ISO/IEC 17025:2005

- Measures to control facilities shall be implemented, monitored and **periodically reviewed**
- Activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions are met.

If environmental criteria is out of limits specified by the method, then further requirements are specified in

7.4 Handling of test or calibration items

7.8 Reporting of results

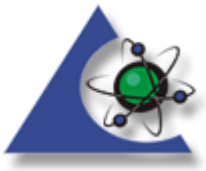
6.4 Equipment

Differentiates between verifying equipment and calibrating equipment

17025:2005 states Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements

ISO/IEC 17025:2017

Calibration if traceability is needed or effects accuracy or uncertainty



6.5 Metrological Traceability

Overall this section is in tact however has been slimed down with a lot of the notes and repeatability gone.

Added Annex A "Metrological Traceability"

Informative

This closely correlates to the requirements already specified in PL-2 which recognizes the use of 17025 accredited sources or producing objective evidence in regards to 6 elements of traceability;

To SI through NIST

Commercial Lab

6.6 Externally Provided Products and Services

- Procurement and subcontracting are considered as externally provided services; combines Section 4.5 and 4.6 from ISO/IEC 17025:2005;
- No explicit reference to "subcontracting" anymore
- External testing and calibration services are basically treated like external services
- -summarized in *one* section

6.6 Externally Provided Products and Services

- Shall ensure that only **suitable** externally provided products and services are used,
- Shall have a **procedure** and retain **records for**

new

defining the criteria for evaluation, selection, **monitoring** of performance, and **re-evaluation**

- - Got rid of the list as 2017 is more electronic driven - Added monitoring & re-evaluation

The laboratory shall **communicate** its requirements to external providers

-- *There is no requirement for a record or document*

Section 7 Review of Requests, Tenders and Contracts

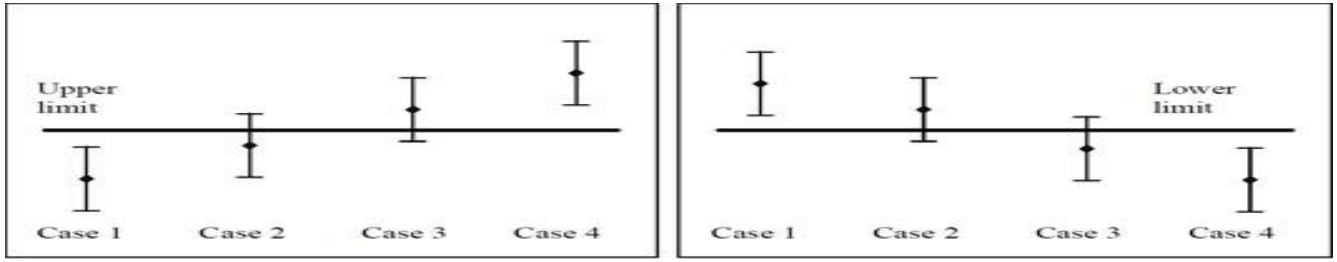
- Procedure is still required;
- When externally provided services are used (subcontractors) the customer must be notified. This is no longer qualified “when appropriate”; which was stated in the 2005 Standard
- Notes added to specify when external provider's could be used and also simplified manner of reviewing work for routine customers;

new

- ***7.1.3*** *When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance) the specification or standard, and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with the customer.*

NOTE: For further guidance on statements of conformity, see ISO/IEC Guide 98-4.

New Definition **3.7 decision rule**- a rule that describes how measurement uncertainty will be accounted for when stating conformity with a specified requirement.



7.2 Selection, Verification and Validation of Methods

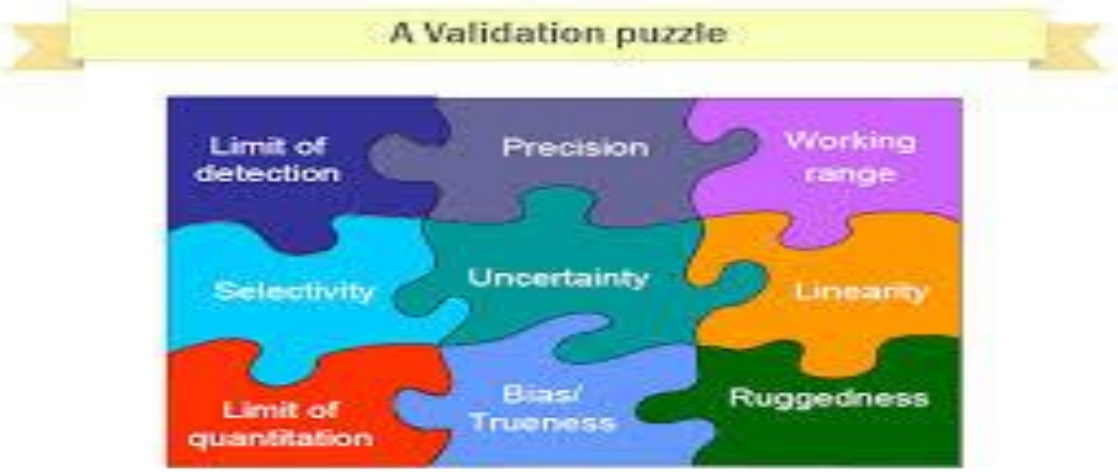
- In general, not many changes in the requirements themselves
- The section has been re-organized, mainly to differentiate between when the lab has to "verify" (7.2.1), that it can properly perform methods vs when the lab has to "validate (7.2.2) methods.
- *Definitions added and examples (section 3 terms and definitions).*
- **Verification** provision of objective evidence that a given item fulfils specified requirements;
- **Validation** where the specified requirements are adequate for an intended use;

7.2 Selection, Verification and Validation of Methods

- ***7.2.2.4*** *The laboratory shall retain the following* ***records*** *of validation:*

Added to the 2017 Standard

- *determination of the performance characteristics of the method;*
- *a statement on the validity of the method, detailing its fitness for the intended use.*



7.3 Sampling

Change - These requirements were notes in the 2005 Standard

7.3.2 The sampling method shall describe:

a) the selection of samples or sites;

b) the sampling plan;

c) preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration.

Note added to the 2017 Standard;

NOTE: When received in the laboratory, further handling can be required as specified in 7.4 “Handling of Test or Calibration Items”

The note added implies sampling is different from “sub-sampling”

7.3 Sampling

- ***7.3.3*** *The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant*

Added

- Date and time of sampling
- Data to identify and describe the sample (eg., number, amount, name)
- Identification of the equipment used
- Transport conditions
- Deviations, additions to the exclusions from the sampling method and sampling plan

Sampling Clover Seed

7.4 Handling of Test or Calibration Items

- Shall have a procedure
- The laboratory shall have a system for the unambiguous identification of test or calibration items

-Added the word "unambiguous"

7.4 Handling of Test or Calibration Items

New

Deviations From Specified Conditions 7.4.3

- *Deviations from specified conditions shall be recorded, asking the customer for further instructions and record the results of the consultation, and inclusion of a disclaimer*
- *Added the requirement that if the customer wants the items tested or calibrated anyway, the lab needs to include a statement with the results*

7.5 Technical records

REMOVED! *Any wording that implies paper records – e.g., "crossed out", "not erased", "signed", etc..*

No substantive changes to technical requirments requirements these requirements are separated from quality records which are found in Section 8.4 "Control of Records"

- Technical records shall contain information to enable the repletion of the test or calibration activity undertaken.
- Amendments to technical records can be tracked to previous versions

Not specific to paper copies (cross out initial and date) however specifies tracked to previous versions or to original observations. Both the original and amended data and files shall be kept, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations

7.6 Evaluation of measurement uncertainty

ISO/IEC 17025:2005 - Section 5.4.6

Estimation vs. Evaluation

Where the test method precludes rigorous evaluation of measurement uncertainty, an **estimation** shall be made

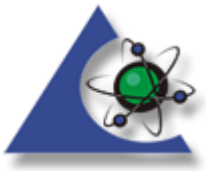
A laboratory performing calibrations, including of its own equipment, shall **evaluate** the measurement uncertainty

7.6 Evaluation of measurement uncertainty

- Laboratories shall identify the contributions to measurement uncertainty
- A laboratory performing calibrations, including of its own equipment, shall **evaluate** the measurement uncertainty

ISO/IEC 17025:2005 specified “shall have and shall apply a procedure to estimate the uncertainty of measurement”

- Requirements for testing labs which states where the test method precludes rigorous **evaluation** of measurement uncertainty, an **estimation** shall be made;



7.7 Ensuring the Validity of Results

Replaces 5.9 Assuring the Quality of Test and Calibration Results in the 2005 Standard

Separated internal (7.7.1) from external (7.7.2) activities

This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:

<u>Additional quality control tools</u>:

- Use of alternative instrumentation that has been calibrated
- Functional check(s) of measuring and testing equipment
- Review of reported results
- Intra-laboratory comparisons
- Testing of blind samples

7.7 Ensuring the validity of results

7.7.2 The laboratory shall monitor its performance by comparison with results of other laboratories, **where available and appropriate**. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:

a) participation in proficiency testing;.

b) participation in interlaboratory comparisons other than proficiency testing

CHANGE!

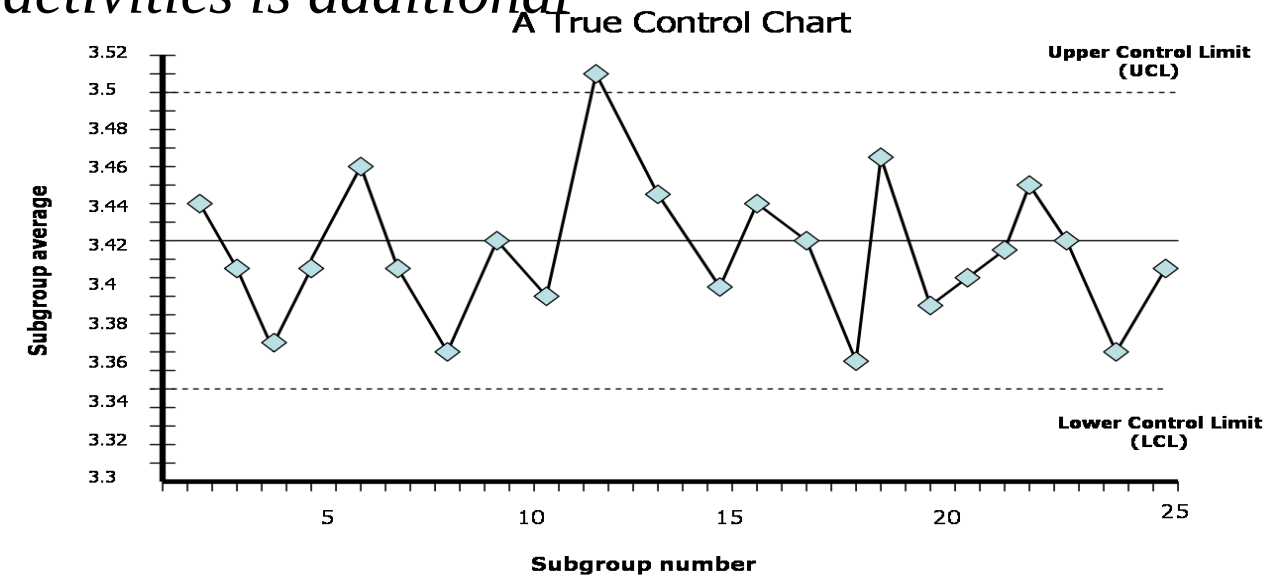
*7.7.2 – Requirement for participation in **either or both** Proficiency Testing (3.5) (PT) or Interlaboratory comparisons (3.3)*

PROFICIENCY TESTING

7.7 Ensuring the Validity of Results

- Data from monitoring activities shall be analyzed, used to **control and, if applicable, improve the laboratory's activities**

– concept of analyzing QC data to "control" and "improve" laboratory activities is additional



7.8 Reporting of Results

The results shall be **reviewed and authorized prior to release**

Agreed with the customer, the results may be reported in a simplified way

--*no longer specifies internal customers or written agreement with external customers*

Testing, Calibration, Sampling Additions.

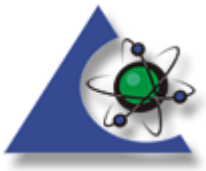
Each report shall include at least the following information unless the laboratory has valid reasons for not doing so,

- the date of issue of the report
- clear identification when results are from external providers
- the name and **contact information** of the customer

7.8 Reporting of Results

7.8.2.2 – NEW

- Lab shall be responsible for all information in the report, except when information is provided by the customer
- Data provided by the customer shall be clearly identified
- Disclaimer put on the report when the information is supplied by the customer and can affect the validity of the results
- When the sample is provided by the customer, it shall state in the report that the results apply to the sample "**as received "**



7.8 Reporting of Results

Calibration Reports shall include:

- The measurement uncertainty of the measurement result

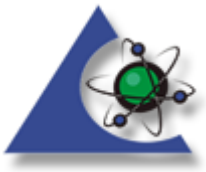
The 2005 Standard specifies “the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof”

Reporting sampling – specific requirements

Where the laboratory is responsible for the sampling activity, in reports shall include where necessary for the interpretation of results

- information required to evaluate measurement uncertainty for subsequent testing or calibration

This is new



7.8 Reporting of Results

Reporting Statements of Conformity

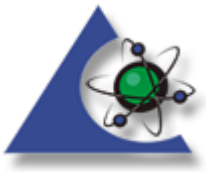
The laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the **decision rule**.

NOTE Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

7.8.6.2 The laboratory shall report on the statement of conformity, such that the statement clearly identifies:

new

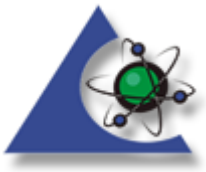
the **decision rule** applied



7.9 Complaints

ISO heightened awareness

- **No** procedure or policy – a process
- The laboratory shall have a **documented process – three elements need to be included**
- A description of the handling process for complaints shall be available to any interested party on request
- the laboratory shall confirm whether the complaint relates to laboratory
- The process for handling complaints shall include a description of the process for receiving, validating, investigating the complaint, tracking and recording complaints, and ensuring that any appropriate action is taken



7.9 Complaints

- The laboratory shall acknowledge receipt of the complaint;
- 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;**
- Shall give formal notice of the end of the complaint handling to the complainant;

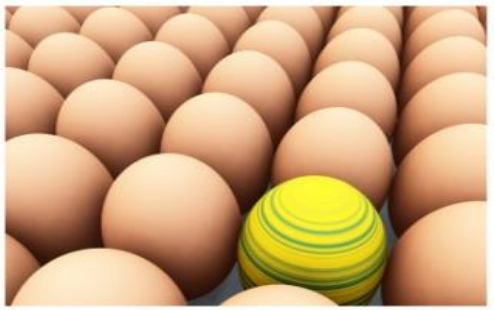
7.10 Nonconforming Work

The laboratory shall have a **procedure**

Additionally will need to assure the following**:**

- actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the **risk levels** established by the laboratory;
- an evaluation is made of the significance of the nonconforming work, including an **impact analysis** on previous results;

All requirements are intact from the 2005 Standard

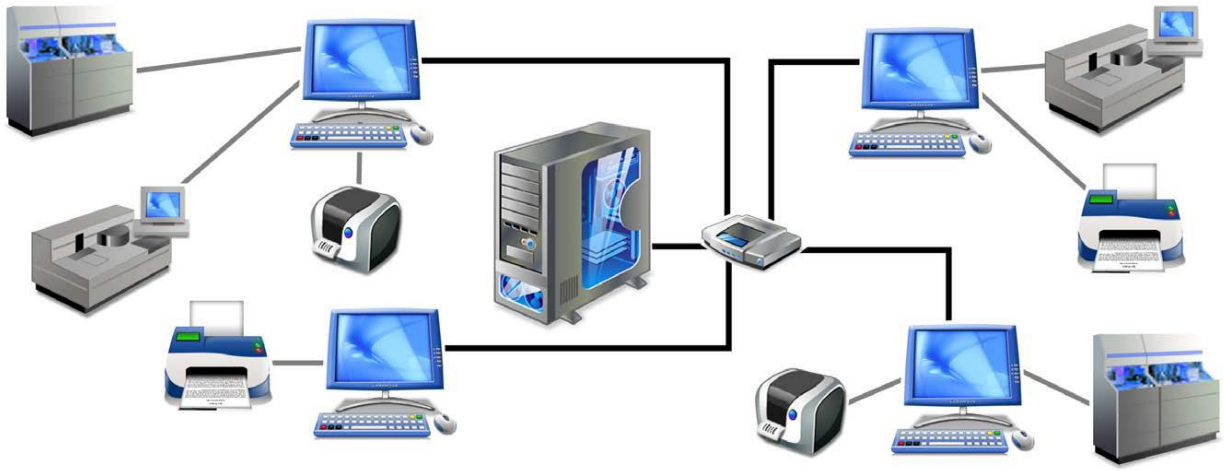


7.11 Control of Data and Information Management

7.11 Control of Data and Info. Mgmt.

	17025:2005	**17025:2017**
Control of Records	Section 4.13	Section 7.11
calculations & transfers	5.4.7.1	7.11.6
computer systems	5.4.7.2	7.11.2

Transition from "paper" to LIMS



7.11 Control of Data and Information Management

The laboratory information management system(s) shall

- include recording system failures and the appropriate immediate and corrective actions.

- *this new and would address system crashes*

- When a laboratory information management system is managed and **maintained off-site** or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.

8.1 Options

8.1.1 General

8.1.2 Option A

8.1.3 Option B

Consensus among AB's is that we still need to assess, however as to the extent would be up to the AB's. PJLA has developed a guidance document that samples the areas of Section 8

8.2 Management system documentation (Option A)

- Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

- verbatim of 4.2.3 in 2005 version except for the removal of the term "Top Management

- All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system;

-no longer requires quality manual. Still can use quality manual. There is no requirement specifying it needs to be rewritten or realigned with the new Standard

8.2 Management system documentation (Option A)

The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory.

The prescriptive quality policy statement requirement from 2005 has been removed

Removed from the 2005 Standard

- have technical management which has overall responsibility for the technical operations
- appoint a member of staff as quality manager (however named)
- The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, shall be defined in the quality manual

8.3 Control of Management System Documents

Changes to this section are centered around the following:

- *LIMS focus from 7.11 Information Management*
- *No longer refer to hand-written amendments*
- *No "Master List"*
- *Less prescriptive*
- The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document;

There is more fexiblitly for the laboratory to ensure how this is accomplished. The basic requirements are the same. A master list can still be used to ensure that the requirements are being met, however it is not required.

8.4 Control of records (Option A)

- The laboratory shall **implement the controls needed** for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records.

There is no requirement for a formal procedure however a formal procedure can be used to implement the controls needed, but it is not a requirement;

8.5 Actions to address risks and opportunities (Option A)

- A new chapter on risk-based thinking has been added. The employment of this information has enabled some reduction of the standard's prescriptive guidelines and resulted in their replacement by performance-based guidelines.
- 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.
- The laboratory is responsible for deciding which risks and opportunities need to be addressed. The accreditation body, however, assesses whether the laboratory has established appropriate actions for dealing with risks and opportunities in accredited laboratories

8.5 Actions to address risks and opportunities (Option A)

The laboratory shall consider the risks and opportunities associated with the laboratory activities in order 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;

d) achieve improvement

8.5 Actions to address risks and opportunities (Option A)

The laboratory shall plan:

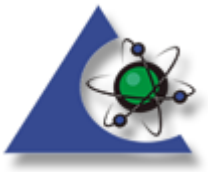
a) actions to address these risks and opportunities;

b) how to:

— integrate and implement the actions into its management system;

— evaluate the effectiveness of these actions.

NOTE Although this document specifies that the organization plans actions to address risks, **there is no requirement for formal methods for risk management** or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards



8.6 Improvement (Option A)

- The laboratory shall identify and select opportunities for improvement and implement any necessary actions
- The laboratory shall seek feedback, both positive and negative, from its customers;

- *There is no longer a separate category for preventive action*

8.7 Corrective Action (Option A)

Requirements are still in place from the 2005 Standard however there is no requirement for a formal procedure.

Root cause - determining the causes of the nonconformity;

Also now need to incorporate:

- updating risks and opportunities determined during planning, if necessary;
- make changes to the management system, if necessary.

8.8 Internal Audits (Option A)

- The laboratory shall conduct internal audits at planned intervals

2005 Standard specified in accordance with a predetermined schedule

In previous sections of the Standard, the requirements for competence and impartiality would apply to the internal auditor. These requirements are specific for all laboratory activities.

8.9 Management Reviews (Option A)

8.9.1 – Planned intervals

Re-organized the requirements into: 8.9.1 – Planned intervals objectives

8.9.2 – Inputs

8.9.3 – Outputs

8.9 Management Reviews (Option A)

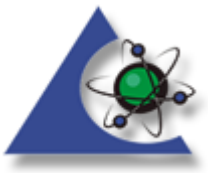
Additions include

- changes in internal and external issues that are relevant to the laboratory; (a)
- status of actions from previous management reviews; (d)
- personnel feedback; (i)
- results of risk identification

8.9 Management Reviews (Option A

The outputs from the management review shall record all decisions and actions related to at least:

- the effectiveness of the management system and its processes;
- improvement of the laboratory activities related to the fulfilment of the requirements of this document;
- provision of required resources;
- any need for change



Annex

Annex A(informative)**Metrological traceability**

Annex B(informative)**Management system options**

ISO/IEC 17025:2017

This time is allocated for answering questions. You should have a space provided for submitting questions.

Please keep questions related to the topic covered in this webinar;

ISO/IEC 17025:2017

Save the date

Next scheduled webinar is set for

Friday January 24, 2020

A look at the requirements within PL-1 "PJLA Policy on Proficiency Testing" and also those specified in Section 7.7 of ISO/IEC 17025:2017 "Ensuring the validity of results"

Happy Holidays

On behalf of Perry Johnson Laboratory Accreditation I would like to wish everyone a great holiday season. We are looking forward to having you all log in with us in 2020