ISO/IEC 17025

A Glimpse at the Differences between ISO/IEC 17025:2017 & ISO/IEC 17025:2005

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ISO/IEC 17025:2017

This webinar is being recorded and will be available in it's entirely on the Perry Johnson Laboratory Accreditation Website.

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Duration of webinar is set for one hour. There will be time allocated at the end for questions.

ISO/IEC 17025:2017

The previous version of ISO/IEC 17025 was the second edition, published back in 2005. Since then, market conditions have changed. Furthermore, the shared aspects among ISO international standards has driven the need for further harmonization among other existing international documents.

In meeting these two progressions, the third edition of the standard, ISO/IEC 17025:2005, has undergone numerous changes.

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)

Terms and Definition

Section (3) Terms and Definition - 9 New Definitions

3.1 impartiality - presence of objectivity

3.2 complaint - 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.

3.3 interlaboratory comparison - organization, performance, and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

3.4 intralaboratory comparison - organization, performance and evaluation of measurements or tests on the same or similar items within the same laboratory (3.6) in accordance with predetermined conditions.

3.5 proficiency testing - evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (3.3).

Terms and Definition

*3.6 laboratory - body that performs one or more of the following activities:— **testing— calibration— sampling, associated with subsequent testing or calibration.***

3.7 decision rule -rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

3.8 verification -*provision of objective evidence that a given item fulfils specified*

3.9 validation- *where the specified requirements are adequate for an intended use.*

Option A & Option B

Option A is to comply with an explicit list of requirements, which broadly follow those in the 2005 Standard. 8.2 Management system documentation, 8.3 Control of management system documents, 8.4 Control of records, 8.5 Actions to address risks and opportunities, 8.6 Improvement, 8.7 Corrective action, 8.8 Internal audits,

8.9 Management reviews

Option B is important for laboratories already meeting ISO 9001 requirements for management systems. This makes it simpler for laboratories to manage implementation of the two standards; and is much clearer that a laboratory can cover many of the management system requirements using 9001-compliant processes and documentation, with no need for a separate set of documentation for 17025.

- Annex B Informative in regards to Option A and B
- Option B informs the lab that it's 9001 system complies with 17025, however as accreditation bodies we need to still assess these sections. As to the extent would be up to the individual Accreditation Bodies.

Section 5.0 General Requirments

4.1 Impartiality

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

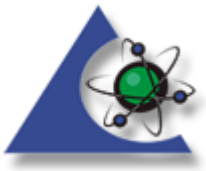
6.1 General

- 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;

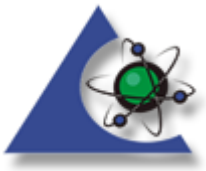
c) report, review and authorization of results

6.3 Facilities and environmental conditions

Basically everything intact from ISO/IEC 17025:2005

- Shall be suitable for the laboratory activities
- The requirements necessary for the performance shall be documented
- monitor, control and record environmental conditions
- 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 this needs to be communicated to the customer.



6.4 Equipment

- Shall have access
- If used outside permanent control, shall ensure requirements of this document are met.
- Procedure for handling, transport, storage, use and planned maintenance of equipment
- The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.

- *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*

6.4 Equipment

- Calibration if traceability is needed or effects accuracy or uncertainty
- Shall establish a calibration program
- Shall be labeled, coded or otherwise identified to allow the user of the equipment **to readily identify** the status of calibration or period of validity
- Equipment shown to be defective or outside specified requirements, shall be taken out of service
- Intermediate checks shall be carried out according to a procedure
- Reference materials addressed
- Unintended adjustments of equipment from invalidating results

Safeguarded removed

- Records

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

7 Process requirements

7.1 Review of Requests, Tenders and Contracts

- shall have a procedure

Requirements are intact from the 2005 however where external providers are used (subcontractor) the laboratory advises the customer and gains the customer's approval; *No longer qualified with "when appropriate"*

- inform the customer when the method requested by the customer is considered to be inappropriate or out of date
- When the customer requests a statement of conformity to a specification the specification 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.

Review of Requests, Tenders and Contracts

- Any differences shall be resolved before laboratory activities commence
- Customer shall be informed of any deviation from the contract
- If a contract is amended after work has commenced, the contract review shall be repeated
- Cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed
- **Records** of reviews, including any significant changes, shall be retained.

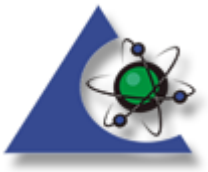
7.2 Selection, verification and validation of methods

In general, not many changes in the requirements themselves

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.

7.2 Selection, Verification and Validation of Methods

- The laboratory shall use appropriate methods
- Supporting documentation, such as instructions, relevant to the laboratory activities, shall be kept up to date
- Shall ensure that it uses the latest valid version of a method
- Shall select an appropriate method and inform the customer of the method chosen
- Shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance.
- When method development is required, this shall be a planned activity



7.2 Selection, Verification and Validation of Methods

- Deviations shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer;
- The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified When changes are made to a validated method a new method validation shall be performed.
- The laboratory shall retain the following **records** of validation:

a) the validation procedure used; b) specification of the requirements;

c) determination of the performance characteristics of the method;

d) results obtained; e) a statement on the validity of the method, detailing its fitness for the intended use.

2005 = record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

7.3 Sampling

- Shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration
- The sampling method shall describe: a) the selection of samples or sites; b) the sampling plan; c) preparation and treatment of sample(s)

NOTE When received into the laboratory, further handling can be required as specified in 7.4 "*Handling of Test or Calibration Items*"

Change - These requirements were notes in the 2005 version

NEW A 'Note" that states "When received into the laboratory further handling can be required as specified in 7.4

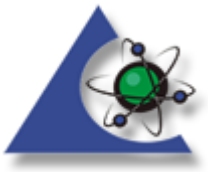
- This implies that "sampling is different from "sub-sampling

7.3 Sampling

- Shall retain records of sampling data that forms part of the testing or calibration that is undertaken;

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



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

7.4.3 Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation. 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;

- *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*

- *Removed terms such as "abnormalities" and "normal"*

- *Added the requirement that if the customer wants the items tested or calibrated anyway, the lab needs to include a statement with the results*

7.4 Handling of Test or Calibration Items

- When items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded

Redundancy has been removed – the requirement for the lab to have procedures and appropriate facilities for maintaining the integrity of the test or calibration item is captured in Section 6.3 – Facilities and Environmental Conditions

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

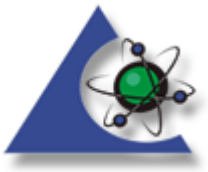
Estimation vs. Evaluation

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

Additional quality control tools:

- 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

7.8 Reporting of Results

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

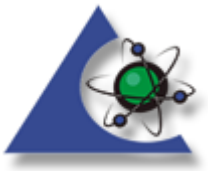
Agreed with the customer, the results may be reported in a simplified way

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

Testing and Calibration Additions.

Each report shall include at least the following information

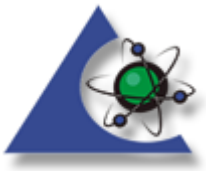
- the date of issue of the report
- clear identification when results are from external providers



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

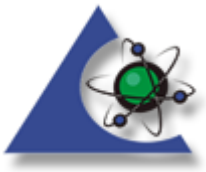
The 2005 Standard specifies “the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof”

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

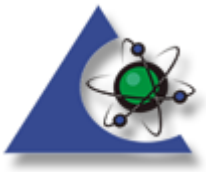
The laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the **decision rule**.

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

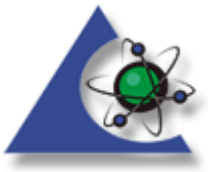
the **decision rule** applied



7.9 Complaints

ISO heightened awareness

- **No** procedure or policy – a process
- The laboratory shall have a **documented process**
- A description of the handling process for complaints shall be available to any interested party on reques
- 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**

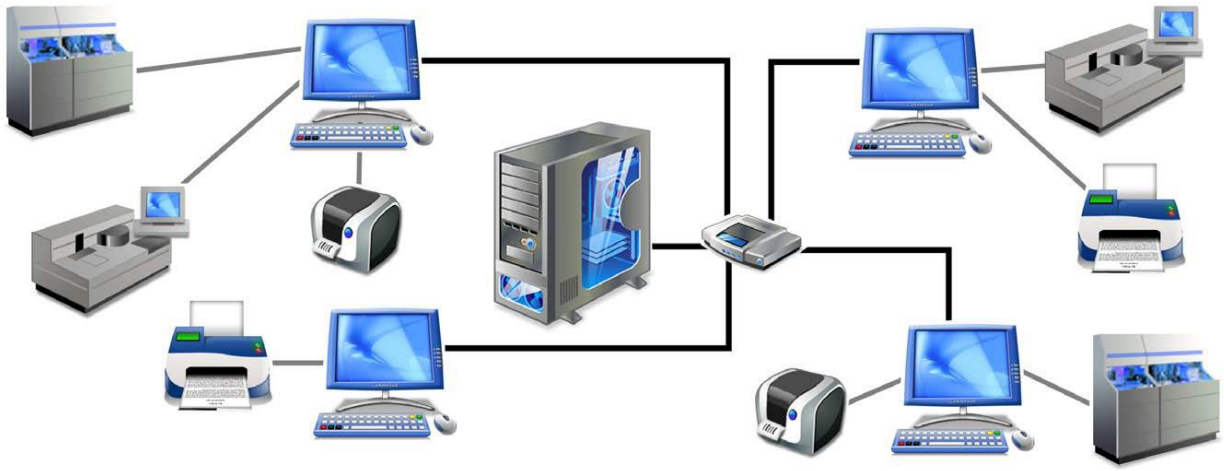
All requirements intact from the 2005 Standard.

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. Looking for possible APLAC guidance in this area;

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

8.3 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:

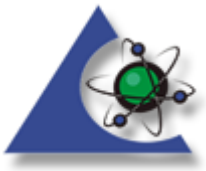
a) actions to address these risks and opportunities;

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;

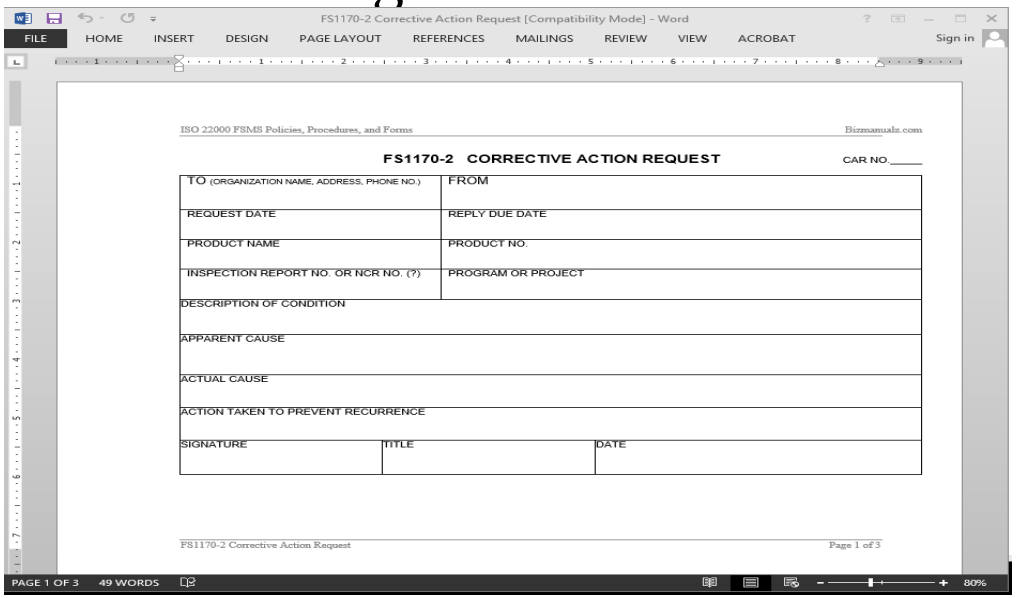
- *There is no longer a separate category for preventive action*

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;

Records must be maintained and a procedure can still be used to assure that the requirements are being met.



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TO (ORGANIZATION NAME, ADDRESS, PHONE NO.)	FROM
REQUEST DATE	REPLY DUE DATE
PRODUCT NAME	PRODUCT NO.
INSPECTION REPORT NO. OR NCR NO. (?)	PROGRAM OR PROJECT
DESCRIPTION OF CONDITION	
APPARENT CAUSE	
ACTUAL CAUSE	
ACTION TAKEN TO PREVENT RECURRENCE	
SIGNATURE / TITLE / DATE	

FS1170-2 Corrective Action Request — Page 1 of 3

PAGE 1 OF 3 49 WORDS 80%

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

New for inputs:

results of risk identification;

8.9 Management reviews (Option A

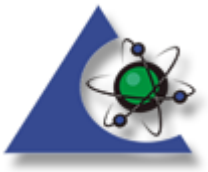
The outputs from the management review shall record all decisions and actions related to at least:

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



Annex

Annex A(informative)**Metrological traceability**

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

ISO 17025:2017

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

Will provide 5 minute time frame at this moment to submit questions.

At the end we will attempt to answer as many as possible.

If a question is unanswered please submit directly to webinar@pjlabs.com

ISO 17025:2017

Save the date

Next scheduled webinar is set for

Tuesday, April 24

7.7 Ensuring the Validity of Results Along with a Look at 7.6 Evaluation of Measurement Uncertainty