ISO/IEC 17025:2017 Requirements Concerning Document Control and Control of Records

ISO/IEC 17025:2017 Requirements Concerning Document Control and Control of Records (8.3,8.4,&7.5)

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ISO/IEC 17025:2017 Requirements Concerning Document Control and Control of Records

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Duration of webinar is set for one hour. You should have available a space provided for questions. Please keep questions related to today's topic. We will

Review and answer at the conclusion of

todays webinar;

8.3 Control of management system documents

- Overall this section has been simplified however the requirements still remain the same
- No longer refer to hand-written amendments
- No “Master List”
- Less prescriptive

ISO/IEC 17025:2005

4.3.3.3 If the laboratory's document control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued as soon as practicable;

8.3 Control of management system documents

. “Same principles, described differently’

Document Control can be looked at as controlled processes and practices for the creation, review, modification, issuance, distribution and accessibility of documents.

A document is anything that tells a person in the laboratory what to do or how to do it”

internal or external

;


QUALITY SYSTEM PROCEDURE

QP3

INTERNAL AUDIT

[Your Company]

	Signature	Position	Date
Prepared By			
Reviewed By			
Approved By			

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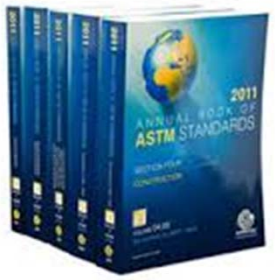


8.3 Control of management system documents

ISO/IEC 17025:2005

4.3.1 General The laboratory shall establish and **maintain procedures** to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals;

ISO/IEC 17025:2017

8.3.1 The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document

Procedure no longer required however can be used to assure documents are being controlled appropriately.

8.3 Control of management system documents

ISO/IEC 17025:2017

NOTE In this context, “documents” can be policy statements, procedures, specifications, manufacturer’s instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

2005 note: specified software.

7.11 Control of data and information management (new section)

8.3 Control of Management System Documents

ISO/IEC 17025:2017

.2017 Standard is more in tune with todays electronic age;

SharePoint

DocuWare

DOCUPHASE

DocStar

eFileCabinet

Document Locator

8.3 Control of Management System Documents

This can still me accomplished through the utilization of a master list (no longer required)

ISO/IEC 17025:2005

A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system **shall** be established and shall be readily available to preclude the use of invalid and/or obsolete documents;

8.3 Control of Management System Documents

However it can also be accomplished through a sophisticated electronic document control system which links the entire quality management system together electrically

How do you control your documents both internal and external?

Master Document List

Register Document

No.	Doc. No.	Doc. Title	Revision	Doc. Type	Department	Create Date	Owner Name	File
1	DocCon003	Testing Verification	1	QM	Marketing	07-Oct-2006	Dev Anand Balan	View
2	Doccon001	New procedures	1	QM	Marketing	07-Oct-2006	Dev Anand Balan	View
3	F-02	QUALITY RECORDS TABLE	1	Forms	Department 4	08-Aug-2005	Dev Anand Balan	View
4	FORM-03	TRAINING ACTION PLAN	1	Forms	Department 4	08-Aug-2005	Dev Anand Balan	View
5	QM-01	Quality System Manual	1	QM	Department 4	08-Aug-2005	Dev Anand Balan	View
6	QM-04	Management Responsibilty	1	QM	Marketing	22-Aug-2005	Dev Anand Balan	View
7	SOP-01	2. Document Control	1	SOP	Department 4	05-Aug-2005	Dev Anand Balan	View
8	SOP-03	DOCUMENT CONTROL	1	SOP	Department 4	08-Aug-2005	Dev Anand Balan	View
9	t-01	Design Plan	1	QM	Marketing	05-Aug-2005	Dev Anand Balan	View
10	qa011	title	1	QM	Marketing	05-Aug-2005	Sally Sally	View

8.3 Control of Management System Documents

8.3.2 The laboratory shall ensure that:

a) documents are approved for adequacy prior to issue by **authorized personnel;**

From section 6.2 “Personnel”

6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system

8.3 Control of Management System Documents

8.3.2 The laboratory shall ensure that:

b) documents are periodically reviewed, and updated as necessary;

- *Internal documents need to reflect what the laboratory is actually doing;*
- *External documents should be the latest;*

ISO/IEC 17025:2005

documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements

8.3 Control of Management System Documents

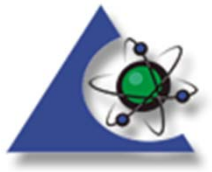
8.3.2 The laboratory shall ensure that:

c) changes and the current revision status of documents are identified;

ISO/IEC 17025:2005

Where practicable, the altered or new text shall be identified **in the document or the appropriate attachments.**

The 2017 Standard would allow use of a revision history within the document however it s not required that it is maintained within the document.



8.3 Control of Management System Documents

8.3.2 The laboratory shall ensure that:

d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled

ISO/IEC 17025:2005

authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;

8.3 Control of Management System Documents

8.3.2 The laboratory shall ensure that:

e) documents are uniquely identified;

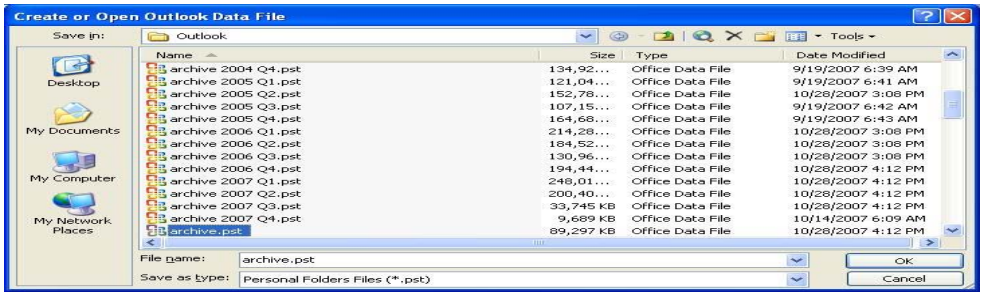
ISO/IEC 17025:2005

Management system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

8.3 Control of Management System Documents

8.3.2 The laboratory shall ensure that:

f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.



ISO/IEC 17025:2005

invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

obsolete documents retained for either legal or knowledge preservation purposes are suitably marked;

8.3 Control of Management System Documents

ISO/IEC 17025:2005

A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established

If the laboratory's document control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed and dated.

These are no longer required however can still be part of the lab's system

Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled

This would now be addressed in 7.11 Control of data and information management

8.4 Control of records

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

8.4 Control of records

Documents (8.3) vs Records (8.4)

- *Documents are created when something is to be done*
- *Records are created when something is done.*
- *Documents can change and records don't change*
- *Documents tell you haw to do something*
- *Records are created by plans*

8.4 Control of records

Example of Records

Meeting Minutes, Customer Reports, Purchase Orders, Completed Data Sheets, Intermediate Checks, Complaints, Audit Results, Corrective and Preventive Action Reports, Management Reviews, Completed Customer Surveys, Contracts, Control Graphs

7.4.3 Upon receipt of the test or calibration item, deviations from specified conditions shall **be recorded**

8.4 Control of records

Records are broken up in the 2017 Standard:

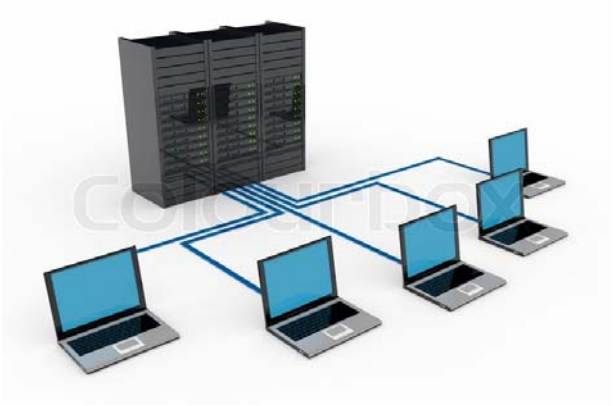
8.4 Control of records (Option A)

Correlates to Section 4 of the 2005 Standard

7.5 Technical records

8.4 Control of Records

8.4.1 The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.



ISO 17025:2005

The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.

8.4 Control of Records

8.4.2 The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.

Even though a procedure is no longer required, it can be utilized as a tool for fulfilling this requirement.

NOTE Additional requirements regarding technical records are given in 7.5.

7.5 Technical records

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

No substantive changes to technical requirements 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

8.4 Control of Records

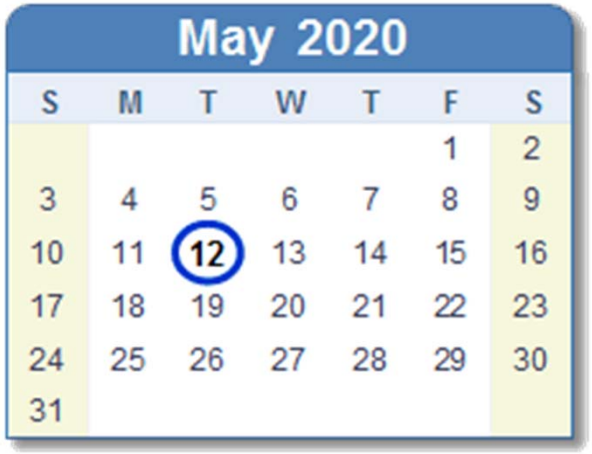
This time is allocated for questions. You should have a space provided for submitting questions;

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

Save the Dates

May 12, 2020 1:00 Eastern Time

Review of Section 8.5 "Actions to Address Risks and Opportunities"



Tuesday, May 12th 2020