A look at the ISO/IEC 17025:2017 Requirements Concerning Document Control and Control of Records.

Presenter: Michael Kramer
PJLA Calibration/Inspection Program Manager
29-April-2022

PJLA

A look at the ISO/IEC 17025:2017 Requirements Concerning Document Control and Control of Records

- This webinar is being recorded
- All PJLA webinar recordings and slides are available for download from the Past Webinars section of our website
  - https://www.pjlabs.com/training/pjla-webinars
- All attendees are muted. However, feel free to utilize the questions tab and they will be answered at the end of the session.

PJLA

8.3 Control of management system documents

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”

As noted in 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.

Software ?

7.11 Control of data and information management

PJLA

8.3 Control of management system documents

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

internal

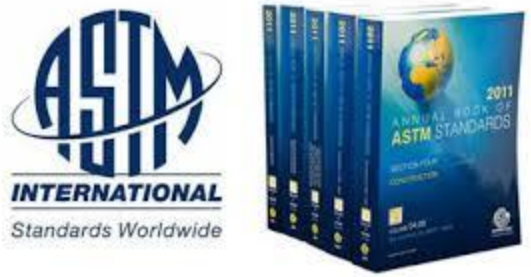

QUALITY SYSTEM PROCEDURE

QP3

INTERNAL AUDIT

[Your Company]

external



Procedure or a master documents list is not required however can be used to assure documents are being controlled appropriately.

PJLA

8.3 Control of Management System Documents

- ISO/IEC 17025:2017

ISO/IEC 17025:2017 Standard is in tune with todays electronic age. Flexibility is given in how compliance is maintained

SharePoint

DocuWare

DOCUPHASE

DocStar

eFileCabinet

Document Locator

PJLA

8.3 Control of Management System Documents

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	1-01	Design Plan	1	QM	Marketing	05-Aug-2005	Dev Anand Balan	View
10	qa011	title	1	QM	Marketing	05-Aug-2005	Sally Sally	View

It can be presented through a sophisticated electronic document control system which links the entire quality management system together electrically. It can also be presented through a simple but effective master documents list.

PJLA

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

PJLA

8.3 Control of Management System Documents

8.3.2 The laboratory shall ensure that:

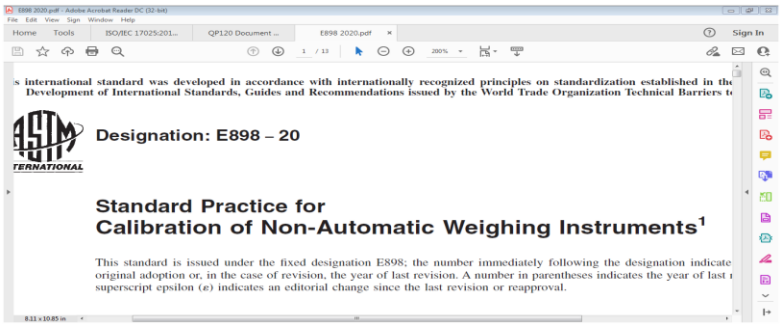
b) documents are periodically reviewed, and updated as necessary;

Internal documents need to reflect what the laboratory is actually doing;

Example: ABC organization shall back up electronic data daily using an external hard drive which is kept in a fireproof safe in the Quality Managers office.

Does it reflect what is being done to maintain compliance?

External documents should be the latest;



PJLA

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 17025:2017 would allow use of a revision history within the document however it s not required that it is maintained within the document.

What changed? Revision 1 archieved

Revision 2 current

PJLA

8.3 Control of Management System Documents

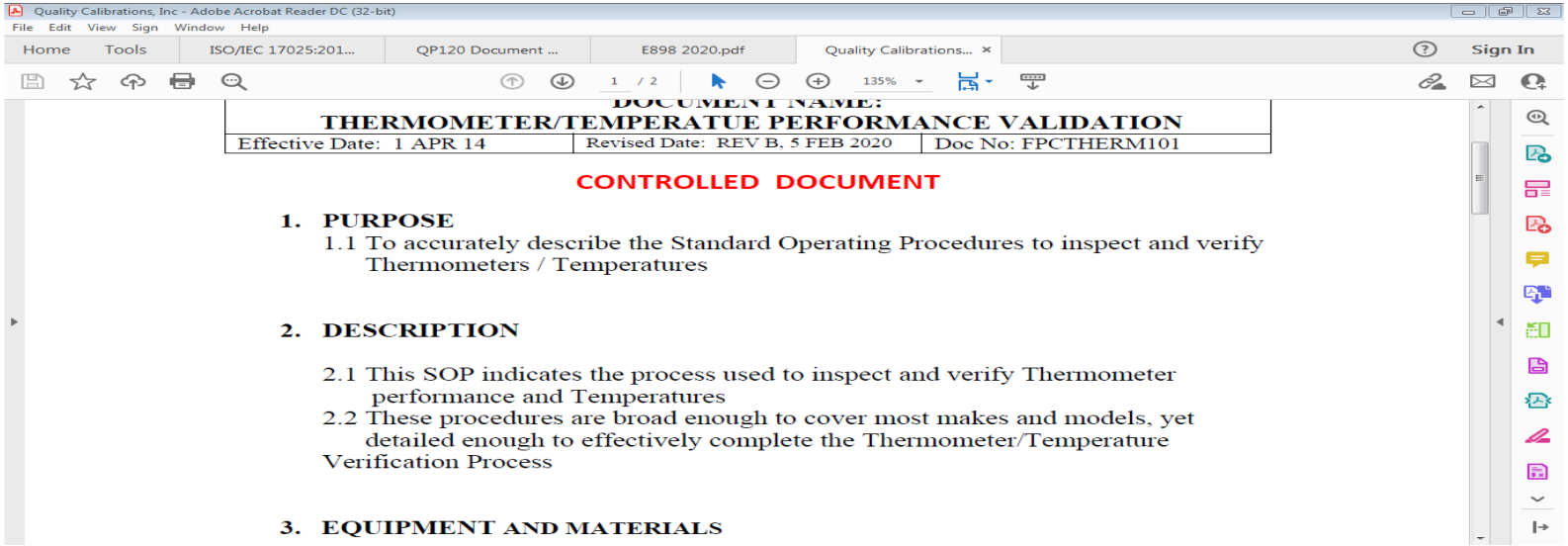
8.3.2 The laboratory shall ensure that:

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

PJLA

8.3 Control of Management System Documents

- **8.3.2** The laboratory shall ensure that:
- e) documents are uniquely identified;


Quality Calibrations, Inc - Adobe Acrobat Reader DC (32-bit)

File Edit View Sign Window Help

Home Tools ISO/IEC 17025:201... QP120 Document ... E898 2020.pdf Quality Calibrations... Sign In

DOCUMENT NAME:

THERMOMETER/TEMPERATUE PERFORMANCE VALIDATION

Effective Date: 1 APR 14	Revised Date: REV B, 5 FEB 2020	Doc No: FPCTHERM101

CONTROLLED DOCUMENT

1. PURPOSE

1.1 To accurately describe the Standard Operating Procedures to inspect and verify Thermometers / Temperatures

2. DESCRIPTION

2.1 This SOP indicates the process used to inspect and verify Thermometer performance and Temperatures

2.2 These procedures are broad enough to cover most makes and models, yet detailed enough to effectively complete the Thermometer/Temperature Verification Process

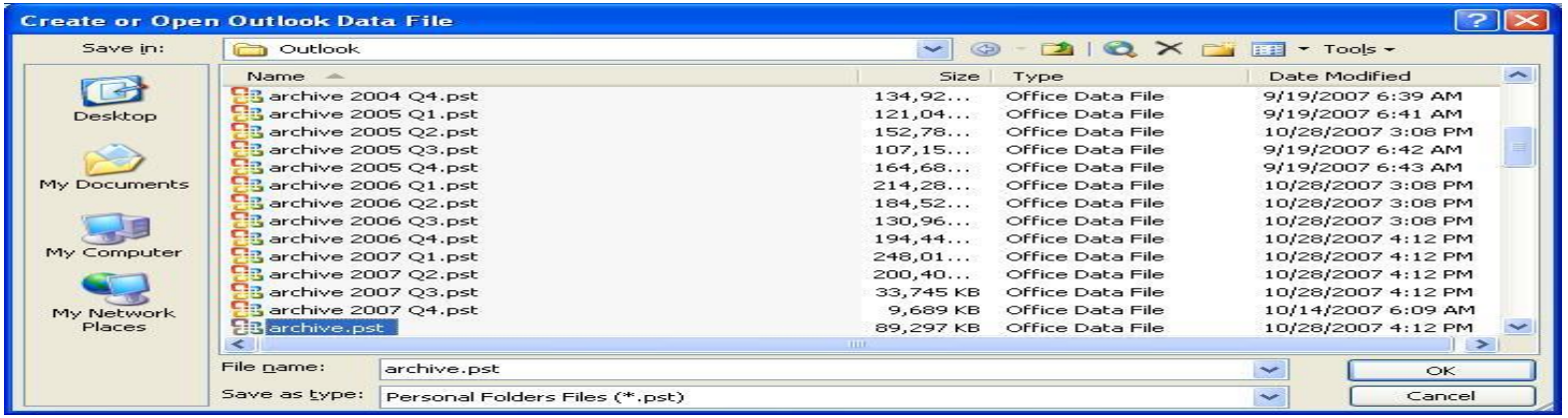
3. EQUIPMENT AND MATERIALS

PJLA

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.



PJLA

8.4 Control of records

When the pen hits the paper or the finger hits the keyboard, records can be both hard copy "paper" or electronic.

PJLA

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**

PJLA

8.4 Control of records

As noted in ISO/IEC 17025:2017: Additional requirements regarding technical records are given in 7.5.

8.4 Control of records (Option A)

7.5 Technical records

PJLA

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.

For example: Internal Audit 8.8.2e: retain records as evidence of the implementation of the audit program and the audit results

PJLA

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.

PJLA

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

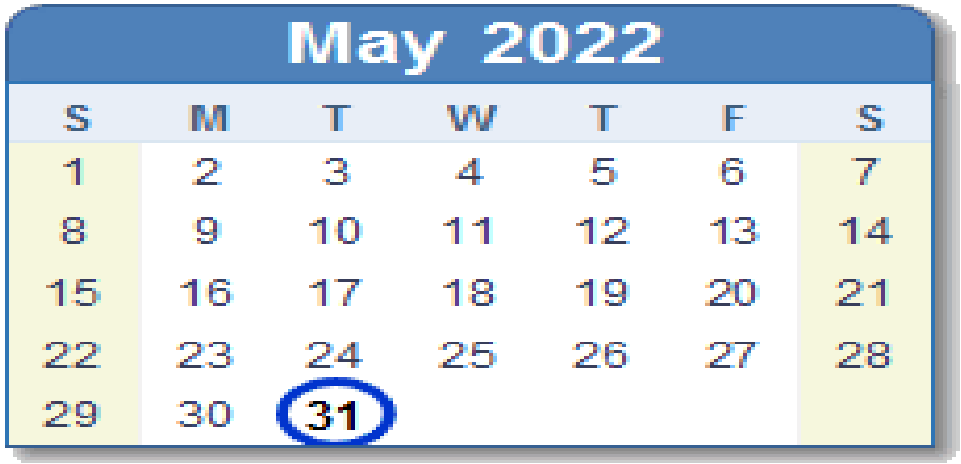
.

If a question is not answered, please submit directly to webinar@pjlabs.com

PJLA

Save the Date

A look at the Requirements Within ISO/IEC 17025:2017 Section 7.7 “Assuring the Validity of Results”, Along with Associated Requirements Within PL-1 “PJLA Policy on Proficiency Testing”



PJLA