QMS Quick Learning Activity

Document and Records Control System

ISO/IEC 17025:2017

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Abbreviations, Terms, and Acronyms

- **Documents-**say what will be done
- **Policies-**rule of what will be done
- **Procedures-**how it will be done
- **e.g.-** for example (clarifying a statement)
- **i.e.-** in other words (in essence; a finite list)
- **QMS-**Quality Management System; the quality, administrative and technical systems that govern the operations of the laboratory
- **Records-**“proof” of what you are doing/have done
- **SOP-**Standard Operating Procedure

Documents

- Documents are controlled within the Quality Management System (QMS)
- ISO/IEC 17025:2017 5.5 c)

  "document its procedures to the extent necessary to ensure consistent application of laboratory activities and the validity of the results"
- What is the QMS?
  - Every part of the laboratory that management oversees
  - Essentially everything

- When 'define' and 'specify' are used in ISO/IEC 17025—it means the laboratory is expected to build a document that defines or specifies that "issue/item"
  - ISO/IEC 17025:2017 5.5.a) "define the organization and management structure of the laboratory, its place in any parent organization, etc…"
  - ISO/IEC 17025:2017 5.5 b) "specify the responsibility, authority and interrelationship of all personnel…"–

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Quality Management System Documents

- What are Policies?
  - Rule of “what” you are going to do
- What are Procedures?
  - “How” you are going to do it
- How do you know you are doing what you say you do?
  - Review
  - Monitor
  - Audit (evaluate)

What is Document Control and a Document Control System?

Document control includes:

- reviewing and approving documents prior to release
- Reviewing documents and updated
- ensuring changes and revisions are clearly identified
- ensuring that only the relevant versions of applicable documents are available at the point of use
- ensuring that documents are legible and identifiable; uniquely identified
- ensuring that external documents relevant to the work are identified and controlled
- preventing unintended use of obsolete documents and they are clearly identified
- A document control system is a system used to track, manage, and store documents. It can be:
  - manual-hands on with hard copies and perhaps an Access or Excel list
  - or electronic, e.g. a software solution that stores and archives documents; oftentimes, has tracking of documents through the review, approval, and even archival stages

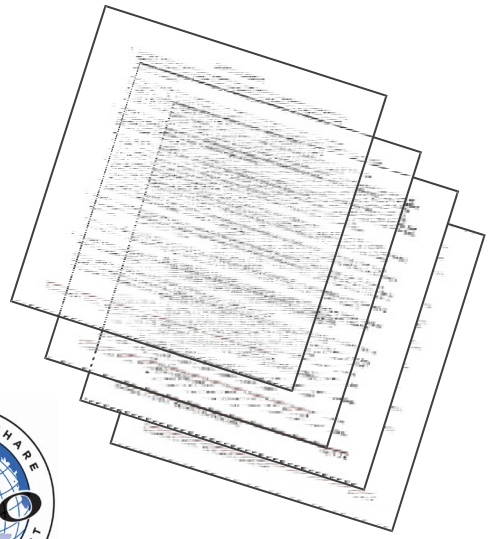
Which QMS Documents Need to be Covered by a Document Control System (hard copy or digital)?

- Policy Statements
- Regulations and standards (e.g., AIHA, ALACC, NELAP, ISO)
- References
- Procedures, SOPs (Internal and External); Instructions
- Job Descriptions
- Drawings, Plans, and Schedules
- Arrangements and Client Specifications (e.g., Memorandum of Understanding, Contracts, Grants)
- Notices, Memoranda
- Test Reports
- Textbooks, Posters
- Instrument Manuals, Software & Equipment Manuals
- Posters, Charts, Drawings, Tables, Forms
- Specifications, Calibration tables
- Flowcharts
- Checklists
- Excel spreadsheets with formulas
- Audits (internal/external)
- Software, etc.

ISO/IEC 17025 Standard

Documents vs. Records

- The ISO/IEC 17025 Standard distinguishes between documents-internal and external (section 8.3.1) and records (section 8.3.2)
- Each section has requirements that need to be met in order to comply with the standard



Documents (SOPs, Quality Manual, etc.)

- Establish and maintain procedure to control all documents that form QMS and fulfill the requirement of the ISO standard
- Documents need to be reviewed and approved for use before issue

Records
(Audit Reports, Test Reports, etc.)

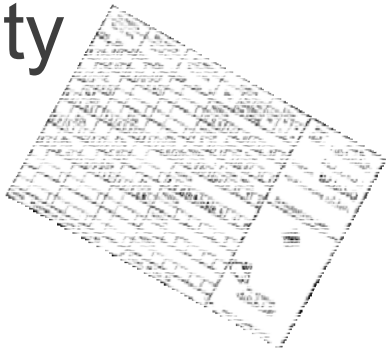
- Records need to be ***Legible!!***
- Establish Procedures for
  - Identification
  - Storage
  - Protection
  - Back-up
  - Archive
  - Retrieval
  - Retention time
  - Disposal

- Customer requirements drive record retention and the establishment of minimal levels of security
- Procedures to protect and back up electronic records and to prevent unauthorized access or amendment

Technical Records

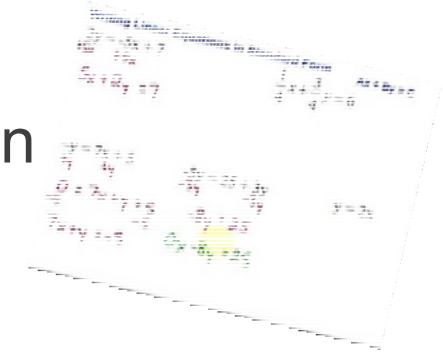
(Forms, Work Sheets, Control Charts, etc.)

- Retain records of original observations, data and calculations with sufficient information to establish an audit trail of calibration records, staff records, and a copy of each test report issued
- Define how long technical records kept
- Maintain sufficient information to facilitate identification of factors affecting the measurement result and its associated measurement uncertainty



Technical Records

- Records of each test/calibration contain sufficient information to enable laboratory activity to be repeated under conditions as close as possible to the original (*traceability*)
- The date and identity of personnel responsible for
  - Sampling
  - Performance of each test/calibration
  - Checking data and results

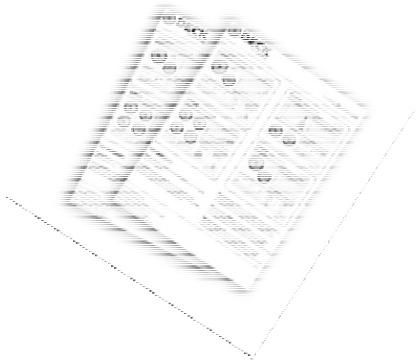


Technical Records

- Observations, data and calculations recorded at the time they are made and identifiable to a specific task
- Amendments to the record (i.e. mistakes) are crossed out (not erased or obliterated), with the correct information recorded alongside, along with the date & initials of the individual making the correction
- Electronic records have the ability to track who is making any correction and be able to retain original information just as non-electronic records

Why is Document Control needed?

- To ensure that:
  - Management is aware of, and has approved, all documents used by staff to guide them in their work (*authority*)
  - All documents specifying procedures have been checked by those with appropriate knowledge (*accuracy*)
  - There is a record of all copies of documents, so that they can be *Reviewed, Withdrawn, or Amended*
    - They can be recalled and updates issued
    - So all copies reflect the same procedure (consistency)



Why is Document Control needed?

- Most importantly:

To ensure that all staff are using the most current SOP, form, policy or related document

What does a Documentation System Do?

- It is a mechanism for defining the QMS so that it is:
  - A Consistent system
  - A Secure system
  - One that can be easily Monitored
- It is a means to communicate to staff:
  - Their responsibilities
  - What procedures and policies to follow

QMS Quick Learning Activity

Can you have Checklists, Templates, and Forms?

- Absolutely!
- They can be controlled in the same manner as Standard Operating Procedures (SOPs), policies, or other documents by making them attachments to the SOP
- OR by identifying them as an independent document in the document system

Why do we have to record so much information?

- Reproducibility provides confidence in results and assures that results are not erroneous or random in nature and is one of the main principles of the scientific method
- For results to be reproduced it is necessary to know (document) all the conditions (instruments used, environmental conditions, etc.) used to generate original results

Why do we have to record so much information?

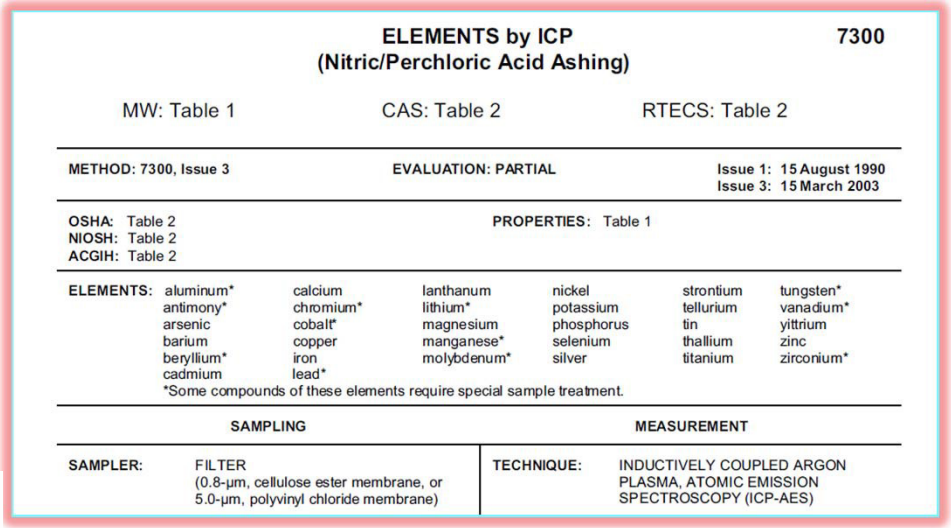
- Documenting, or being able to trace back, all the conditions that existed when the original analysis was done is how laboratories can assure their results can be reproduced
- This is why so much record keeping is necessary

Controlling Documents Means:

- Having a system that:
  - Identifies the current revision status
  - Determines the location(s) of the document
  - Is updated to ensure no invalid or obsolete documents are in use
    - Obsolete or archived documents must be retained per retention policies for either legal or knowledge purposes and must be suitably marked (electronic or hardcopies)
    - Obsolete or archived documents must be promptly removed from all points of use

QMS Documents:

- Must accurately reflect all phases of current laboratory activities, including:
  - Assessing data integrity
  - Corrective actions
  - Handling customer complaints
  - All methods (from laboratory SOPs to administration and support procedures)
- May be a copy of a published or referenced method
  - Modifications must be clearly described
  - Source must be given



ELEMENTS by ICP **7300**
(Nitric/Perchloric Acid Ashing)

MW: Table 1 CAS: Table 2 RTECS: Table 2

METHOD: 7300, Issue 3	**EVALUATION: PARTIAL**	**Issue 1: 15 August 1990** **Issue 3: 15 March 2003**

OSHA: Table 2
NIOSH: Table 2
ACGIH: Table 2

PROPERTIES: Table 1

ELEMENTS:	aluminum*	calcium	lanthanum	nickel	strontium	tungsten*
	antimony*	chromium*	lithium*	potassium	tellurium	vanadium*
	arsenic	cobalt*	magnesium	phosphorus	tin	yttrium
	barium	copper	manganese*	selenium	thallium	zinc
	beryllium*	iron	molybdenum*	silver	titanium	zirconium*
	cadmium	lead*				

*Some compounds of these elements require special sample treatment.

SAMPLING		**MEASUREMENT**	
SAMPLER:	FILTER (0.8-µm, cellulose ester membrane, or 5.0-µm, polyvinyl chloride membrane)	**TECHNIQUE:**	INDUCTIVELY COUPLED ARGON PLASMA, ATOMIC EMISSION SPECTROSCOPY (ICP-AES)

In Conclusion: The Purpose of Controlled Documents

- To establish a systematic process for documents to be:
  - Developed
  - Approved
  - Edited
- To assure they are:
  - Up-to-date, which is especially important to many regulatory agencies using standards (e.g., ALAC, NELAP, AIHA, ISO, etc.)
  - Reviewed, and where necessary, revised, in the proper timeframe (at an optimum minimum timeframe or as specified by the standard or client). As an example, one laboratory decided to review its::
    - Quality Manual-annually
    - Standard Operating Procedures-biennially (every 2 years)
    - Policies (e.g., Quality Assurance Section Plans, etc.) every 3 years
  - Uniquely identified (e.g., index # in a document control system such as iPassport™)
- Authorized documents must be available to staff who will use them

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References

- ISO/IEC 17025:2017
  - https://www.iso.org/standard/66912.html