Document Control, Development of Standard Operating Procedures & Good Documentation Practices

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OVERVIEW

Overview

- Quality Management System
- Document Control
- SOP Development
- SOP Deviation
- Periodic Review
- SOP Training
- Good Documentation Practices

Quality Management System

Quality Management System (QMS)

- A set of systems supported by processes and practices that contribute to a quality outcome (e.g., product, lab results, clinical study results).
- Establishing QMS is a regulatory requirement/guidance that US FDA, EMA, MFDS and other regulatory agencies consider critical and cite in GxP regulatory requirements and guidance documents.
- GxP (i.e., GCP, GMP, GLP) systems require implementation of Document Control

Quality Management System

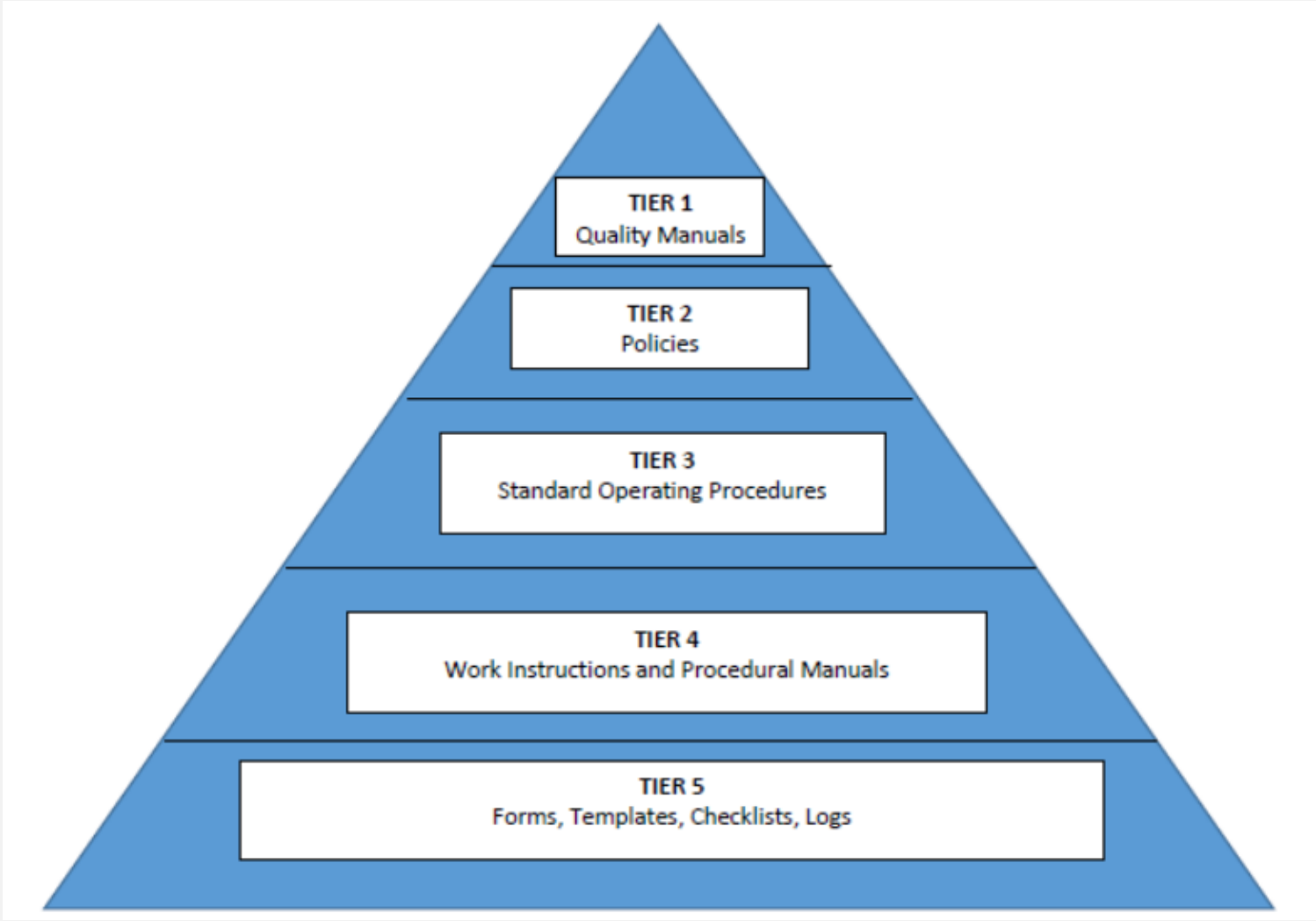
Document Control is one of the key elements of a QMS consistently conserved across GxP's (inclusive of labs):

- **Document Control**
- Quality Assurance/Quality Control
  - Risk Management/Corrective and Preventive Action Management
  - Audit / inspection Management
  - Vendor/supplier management
- Training Control
- Equipment and inventory management

Document Control

Document Control Requirements Overview

Hierarchy of controlled documents



Document Control Definition

GxP (GLP, GMP, GCP, ISO standards, WHO guidance) Requirements

- Regulatory requirements, industry standards/guidance and best practices (in a GxP environment) all define the necessity for development and implementation of document control systems.
  - GLP – as defined in US 21CFR58 and OECD requirements, ICH M series
  - GMP – as defined in US 21CFR210/211/820, EMA, ICH Q Series requirements
  - GCP – as defined in ICH E Series (e.g., ICH E6 (R2))
  - ISO Standards – ISO 9001:2015, ISO17025:2017, ISO15189:2012
  - Regulatory Guidance documents – US FDA, EMA, MHRA

Document Control Definition

ISO 9001:2015, 4.5.3.1 Quality management systems— Requirements

- ISO 9001:2015 is an international industry standard that defines implementation and management of document control system

ISO 9001:2015, states, "…documented information required by the quality management system shall be controlled to ensure:

- Information is available and suitable for use, where and when it is needed;
- Information is adequately protected (e.g., from loss of confidentiality, improper use, from indiscriminate changes or loss of integrity)

Document Control Requirements Overview

ISO 9001:2015 Requirements for Document Control

- Procedure for approving documents and ensuring they are appropriate to use (e.g., document lifecycle)
- Identifiable changes and revision status (i.e., audit trail)
- Procedures for accessibility
- Clear presentation, labelling and easily searchable
- Accessibility and control over external documents (e.g., legislators, regulators, standardization bodies, or business partners)
- Clear labelling (e.g., version control) of ***document lifecycles*** (e.g., draft, issued, superseded, obsolete, etc.)

Document Control Requirements

What is a Document Lifecycle?

- A series of stages that represent the life (cycle) of a document from creation to obsolescence
- Controlled documents within a document lifecycle are represented by documents that control activities that are *frequently* performed (i.e., those procedures that are performed multiple time), such as Quality Manuals (QM and Lab), Policies, SOPs/SSPs, Work Instructions, Templates (e.g., forms, checklists and templates)

Examples of Document Lifecycle Stages

- **Draft to Effective** Lifecycle

Document Control Requirements

Examples of Document Lifecycle Stages

- **Draft** – initial rendering of a controlled document which will be subject to review by assigned Subject Matter Experts (SME)
- **In-review** – draft controlled document submitted to SME's for review and comment
- **Approved** – Final version of controlled document to be submitted for approval (either within eSystem or Hard-copy system) for which signatures are required.
- **Issued** – Final authorized/signed version of controlled document for which personnel training will be required
- **Effective** – Upon complete of training, controlled document becomes effective for use

Document Control Requirements

A process must be defined to describe the controlled document life cycle to ensure controlled documents are reviewed, approved and appropriate for use

- This process should be defined to meet GxP requirements in an organization's SOP on SOPs (whether ISO9001 is utilized as a reference or not, as this is an industry best practice and a regulatory expectation)

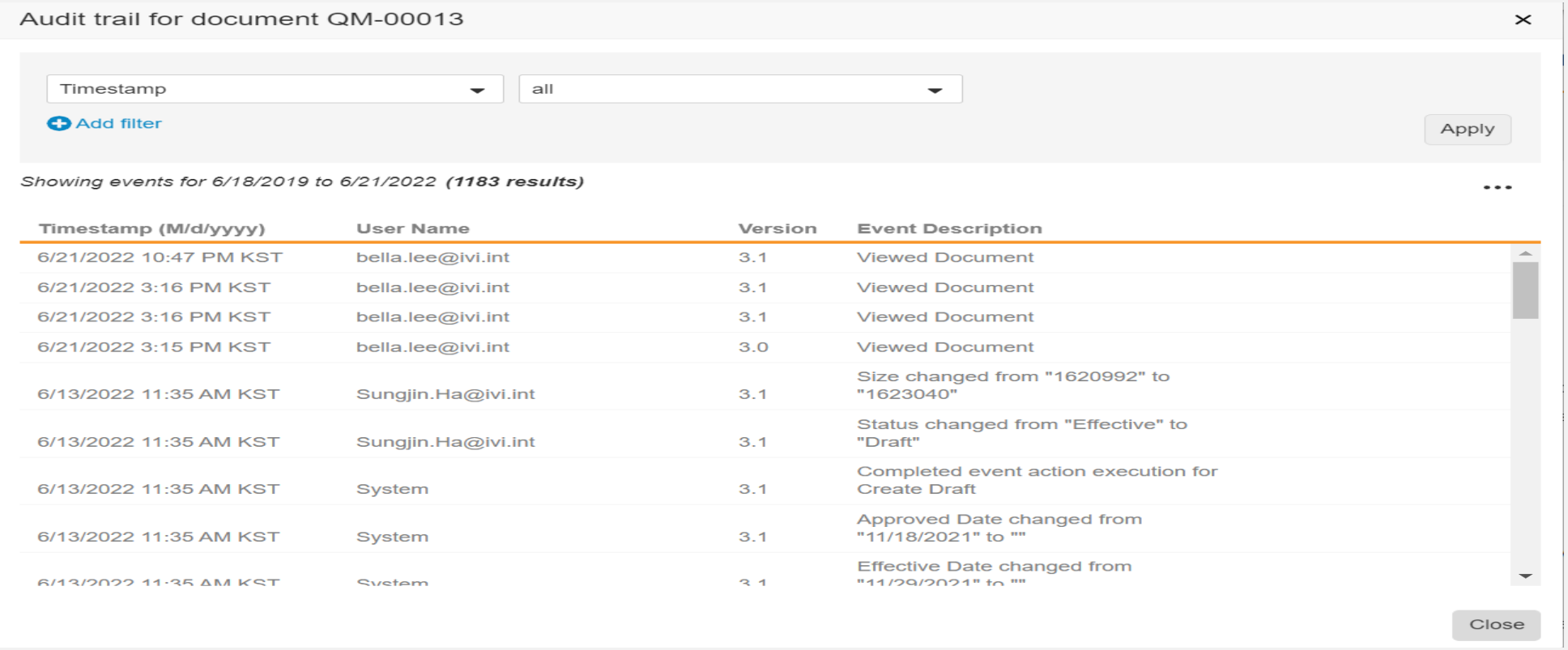
- According to each document lifecycle, key stakeholders should be assigned to the appropriate roles (i.e., Author, Editor, Reviewer, Approver and Quality Assurance (QA) Approver) and document should be approved as per the procedure required according to the document lifecycle.

Document Control Requirements

Audit Trail - Identifiable changes and revision status (i.e., audit trail)

- A set of records/history should be available to provide documented evidence of **what action** was made by **whom** and **when as it relates to any controlled document.**

Example Below:



Document Control Requirements

Procedures for accessibility must be defined for either hard-copy or electronic system

- Electronic system: Access can be controlled by security setting (e.g., an individual with read only access, an individual with viewer access (i.e., visibility for documents at all lifecycle), an individual with reviewer access (i.e., review and comment))
- Electronic system: As per required roles and responsibilities for each employee, access level should be determined and assigned.
- Hardcopy system: Dedicated locked files in QA dept requiring QA requests for distribution of copies
- Control and management of controlled documents is the responsibility of QA

Document Control Requirements

Controlled document must be clearly presented, labeled (e.g., titled, versioned) and easily searchable

- Recommend to use searchable system (e.g., search function for electronic system, excel spreadsheet for hardcopy system) as this will be easier to ensure clearer presentation, labeling and search functions

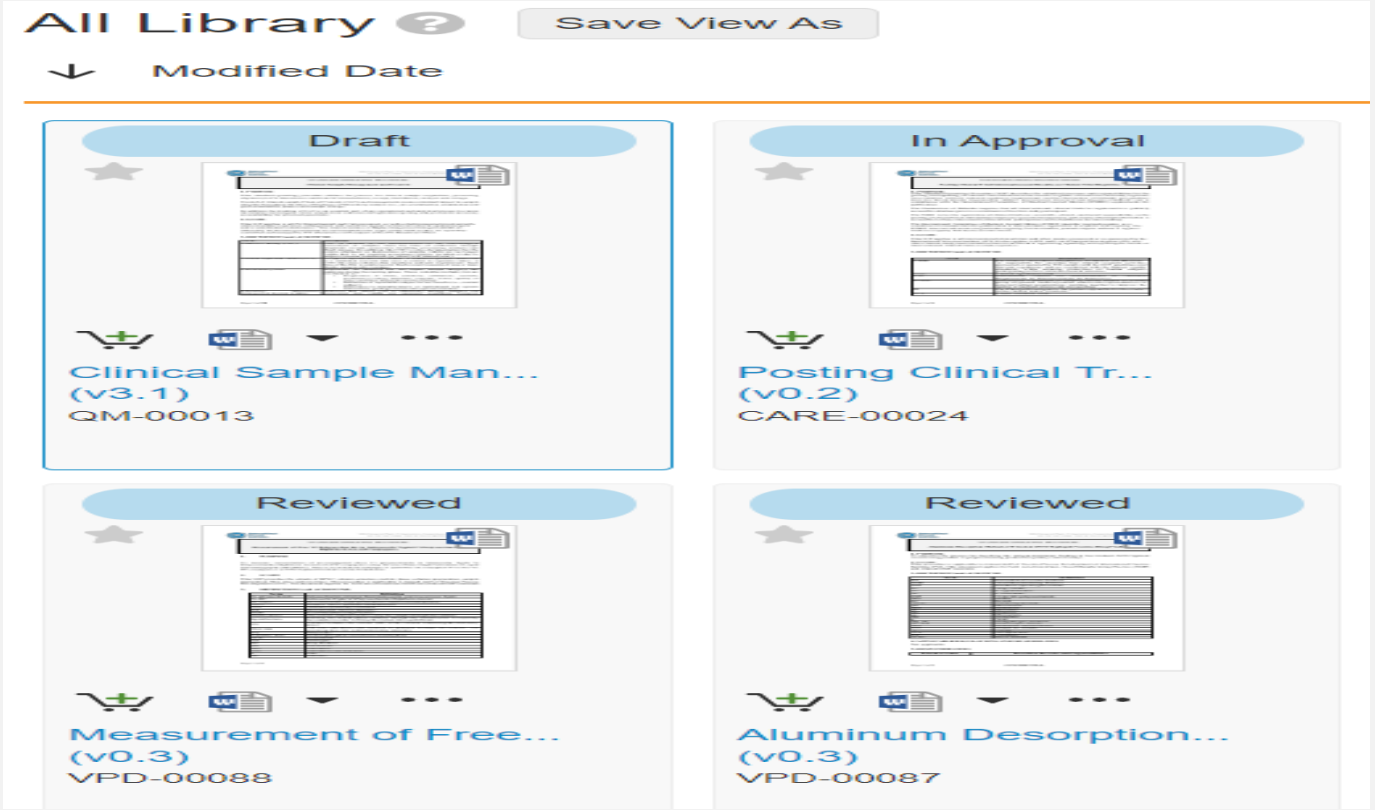
Accessibility and control over external documents

- External documents that are used as part of QMS should be handled the same way as the internal documents (e.g., regulations, standards, manufacturer requirements) and must be kept current.

Document Control Requirements

Clear labelling of document status (e.g., draft, issued, superseded, obsolete, etc.)

- Document status should be clearly labelled to prevent unintended use
- Consider use of ink stamps to ensure traceability within a hardcopy system; however, this function is configured in a validated electronic system.



Document Control Requirements

SOP Index

- SOP index should be managed to ensure users have a list of approved controlled documents and the SOP index should remain current

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STANDARD OPERATING PROCEDURE INDEX

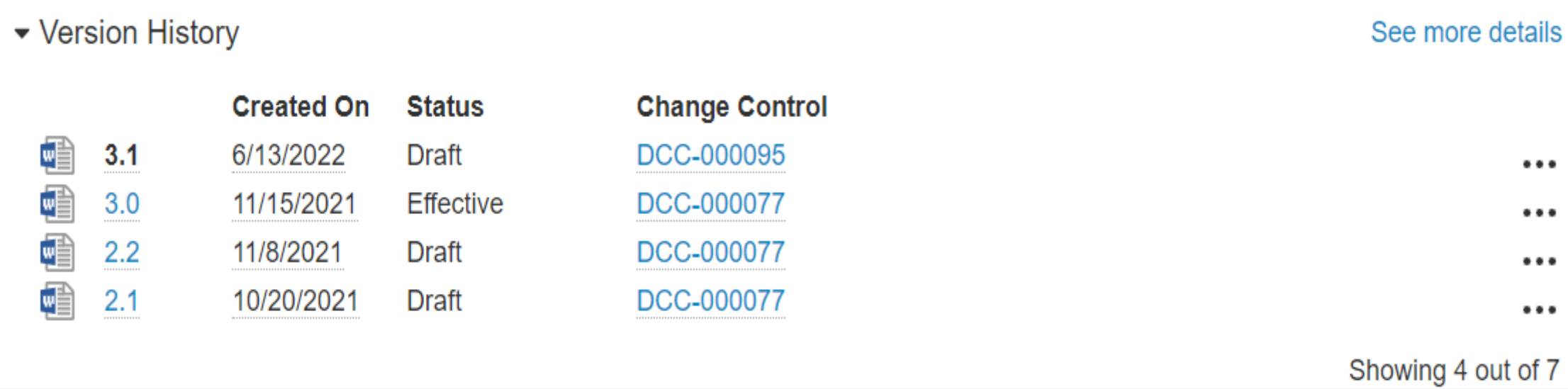
Quality Management

No.	Document Type	Document Number	Title	Version	Effective Date

Document Control Requirements

Clear version control and suitable identification for documents that are no longer in use

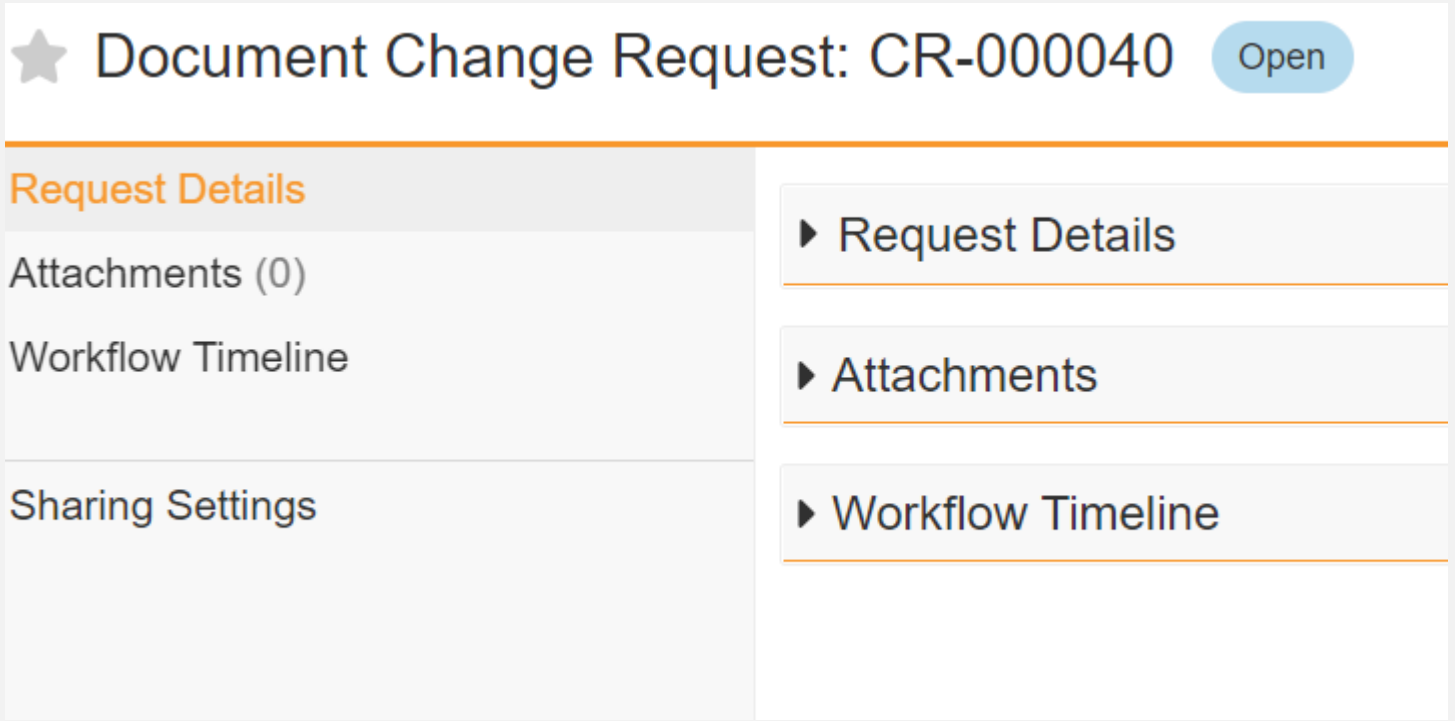
- Version histories/traceability should be maintained to ensure status of Controlled Documents is clearly understood (e.g., SOP status of unapproved, approved, retired)



Document Control Requirements

Controlled Document Change Control is required

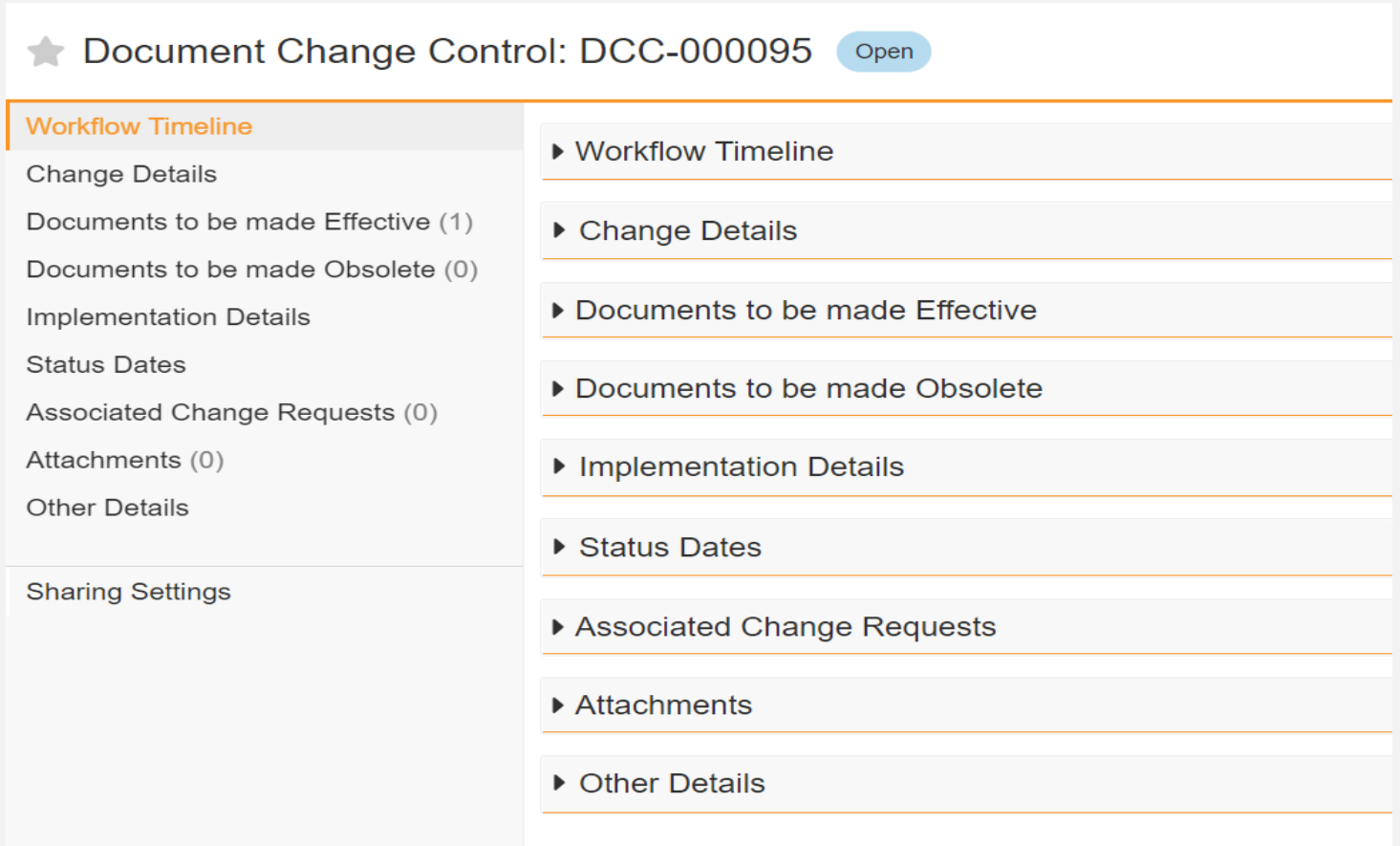
- When changes to a controlled document are required, request details to include - name, urgency, description, reason, target document, requested implementation date, document status and potential impact to interrelated controlled documents.



Document Control Requirements

Controlled Document Change Control

- Once change to a document has been approved, the change can be linked to the target document (Veeva systems define document change control as a “DCC”)



SOP Development

Why SOP should be developed?

- Consistency and Quality Control(Delivery of consistent results & Prevention of errors)
- Productivity and Performance (provides clear path from A to B)

- Safety and compliance
- Knowledge Transfer
- Training and onboarding

SOP Development Guideline

SOP Development Guideline

List of contents example

- Purpose
- Scope
- Definitions and Acronyms
- Applicable Regulations and/or Guidelines
- Responsibilities
- Procedures
- References
- Appendices
- Version History

Good Practice

Development of a controlled SOP **template** to be used at institutional level for enhanced control and unification of contents to be covered

Signature page example stakeholders

- ✓ Author
- ✓ Reviewer
- ✓ Approver
- ✓ QA Approver

SOP Development Guideline

✓ Purpose

- A brief description of the purpose of the SOP
- The reason why the SOP is required (e.g., compliance with Good Clinical Practice, Good Manufacturing Practice and/or Good Laboratory Practice (GxP), international and local regulatory requirements, and other internal or external procedures, guidelines and/or standards)

SOP Development Guideline

✓ Scope

- A statement that outlines the areas and context covered by the Controlled Document (Cdoc)
- If there are any areas in which this CDoc specifically does NOT apply, these should also be mentioned

SOP Development Guideline

✓ Definitions and Acronyms

- A list of definitions to be included for terms used in the CDoc
- Acronyms and abbreviations should be explained at the point of use within the CDoc and not listed in this section

SOP Development Guideline

✓ Applicable Regulations and/or Guidelines

- A list of all applicable regulatory requirements, guidance documents, industry standards (e.g., ISO, ICH guidelines)
- Relevant references to applicable organization-controlled documents (e.g., SOPs, forms, templates)

SOP Development Guideline

✓ Responsibilities

- A summary of the roles listed in the procedure and the responsibilities of each role holder for the procedures detailed in the CDoc.
- The details of the responsibilities should be a brief list of the key tasks performed. This section should not be a complete summary of the CDoc.

SOP Development Guideline

✓ Procedures

- This section is the main text of the CDoc. It details the procedure for the task to be performed. Sub-sections should be introduced as deemed beneficial to provide a logical structure of the procedure to be described
- There should be sufficient detail, clearly expressed, to enable a trained person to perform the procedure without supervision
- There should also be sufficient detail to enable a trained person to use the document to train others to perform the task
- The use of flow diagrams may be useful, especially in complex procedures

SOP Development Guideline

✓ References

- Include external documents that support the content of the SOPs (e.g., regulatory requirements, industry guidance, publications, etc.)

✓ Appendices

- Include internal (to SOP) documents that are utilized to further define process (e.g., flow diagram, forms, other associated documents, etc.)

SOP Development Guideline

✓ Version History

- State in sufficient detail, what changes were made, what parts of the SOPs were affected and when the changes become effective

Example:

Version	Revised section/Paragraph
1.0	Initial release
2.0	Migration to SOP template V1.3 and revision of contents to include: General • Revision of dates for issuing and responding to audit and non-audit related CAPAs (30 business days for auditor vs 30 calendar days for auditee) • Correction of document numbers • Correction of typos Section 4. Applicable Regulations and/or Guidelines • Addition of applicable guidelines (ICH Q9 and Q10) Section 6. Procedures • Addition of QM review timeline of CAPA response (10 business days) • Addition of three CAPA rounds or 90 days of CAPA comments to determine CAPA responses being unacceptable • To issue audit certificate to the auditee regardless of the acceptance CAPA responses • Specification of audit documentation archive location (i.e., SharePoint) • Revision of Figure 1. for auditee to define CAPA timeline prior to QM CAPA acceptance Section 8. Appendices • Addition of Appendix 5 – CAPA Overview

SOP Deviation

SOP Deviation

All non-conforming events should be marked as deviation (e.g., any deviation from the approved content of an SOP)

- A Deviation SOP must be developed and approved to define a process for oversight and compliance to approved Controlled Documents
- Identification and documentation of Cdoc deviations ensures accountability of functional areas and personnel within a given organization and improves/ ensures Cdoc compliance
- Deviation reports may be used to identify ambiguity/inconsistency of an approved process

SOP Deviation

All non-conforming events should be marked as deviation (e.g,. any deviation from the approved content of an SOP)

In case of deviation, deviation owner (e.g., individual identifying deviation) should report to Quality with the following:

- Follow established SOP Deviation procedure and complete deviation form
- Describe what happen, when, who was involved, where in the process/procedure, how, and an assessment of impact.
- Attach any copies of any associated documentation (e.g., data, charts, graphs, logbook pages, training records).

SOP Deviation – Deviation Form

Deviation Form

- Date Identified
- Date Reported to QM
- Deviation Number
- Deviation Title
- SOP Number
- Reason
- Impact Assessment
- Criticality (e.g., critical, major, minor)
- Responsible functional area (department/Unit(s))
- Remediation/CAPA
- Planned completion Date
- Actual Completion Date

SOP Deviation – Investigation

Investigation

- The investigator assigned by QA investigates the deviation

Investigation should include the following:

1. **Description of investigation including interviews and data review**
2. **Root Cause Analysis**
   - Determine the root cause based on investigative findings
   - The root cause must be an explanation of the direct cause of the deviation, not just a reiteration of the direct cause
   - Focus on programmatic and system deficiencies; select the most probable direct root cause for the corrective action and/or the preventive action which will prevent recurrence and has the greatest impact
   - Detail root cause analysis in a concise manner

SOP Deviation – Corrective Action Determination

Corrective and/or Preventive Action Determination

Based on the investigation findings, **indicate if a CAPA is needed**:

- If a CAPA is needed, follow CAPA SOP
- Once a CAPA is initiated all corrective actions plans associated with the deviation will need to be approved prior to closing the deviation
- If a CAPA is not required, justification is required

SOP Deviation – Closure

Closure

- Ensure that sufficient information is provided to describe the event, the root cause has been sufficiently identified, and the product impact statement is appropriate
- Ensure the Deviation form is complete, the final Investigation Report is attached, if applicable, sign the deviation, and forward the closed Deviation to QM
- QM ensures that the closed deviation is archived in the paper or electronic system as appropriate and ensures deviation status, owner, root cause, impacted project, date initiated, date closed, date occurred

Periodic Review

Document Periodic Review

Document Periodic Review is part of regulatory requirements to insure organizational controlled document contents are current and aligned with regulatory expectations

- [FDA] 21 CFR Part 211. 100, 211.180 (e), 211.192, 211., Process Validation: General Principles and Practices (2011)

- [ICH] Q10 2.6 (b) – [EU] EudraLex > Volume 4 Good Manufacturing Practice Medicinal Products for Human and Veterinary Use > Chapter 4 Process Validation: General Principles and Practices – 4.5 **Documents within the Quality Management System should be regularly reviewed and kept up-to-date**

- [WHO] TRS No. 986 Annex 2 – 15.5 **Documents should be regularly reviewed and kept up to date**. When a document has been revised, a system should exist to prevent inadvertent use of the superseded version. Superseded documents should be retained for a specific period

- Recommended cycle or upon update?
  -> **2-3 years**

SOP Training

SOP Training

Sample Procedure

- All impacted personnel must be trained prior to the document being made effective
- Upon revision and creation, departmental training coordinator updates the Controlled Documents Training Matrix
- SOP training task to the appliable personnel as per the predefined Training Matrix are assigned
- To ensure comprehension of training, limitations for number of training that can be completed in one day, minimum time to be spent for each SOP and providing quizzes can be applied
- All training activities must be documented (e.g., training records)

IVI Controlled Documents Training Matrix

NOTES:
Controlled Documents noted **M** in the matrix are mandatory for the selected job function. Training Record needs to be filled as an evidence for completion of mandatory training.

Document Number	Title	Job Function											
		Head of QM											
Example QM-00002	*Controlled Document Management and Control*	*M*											

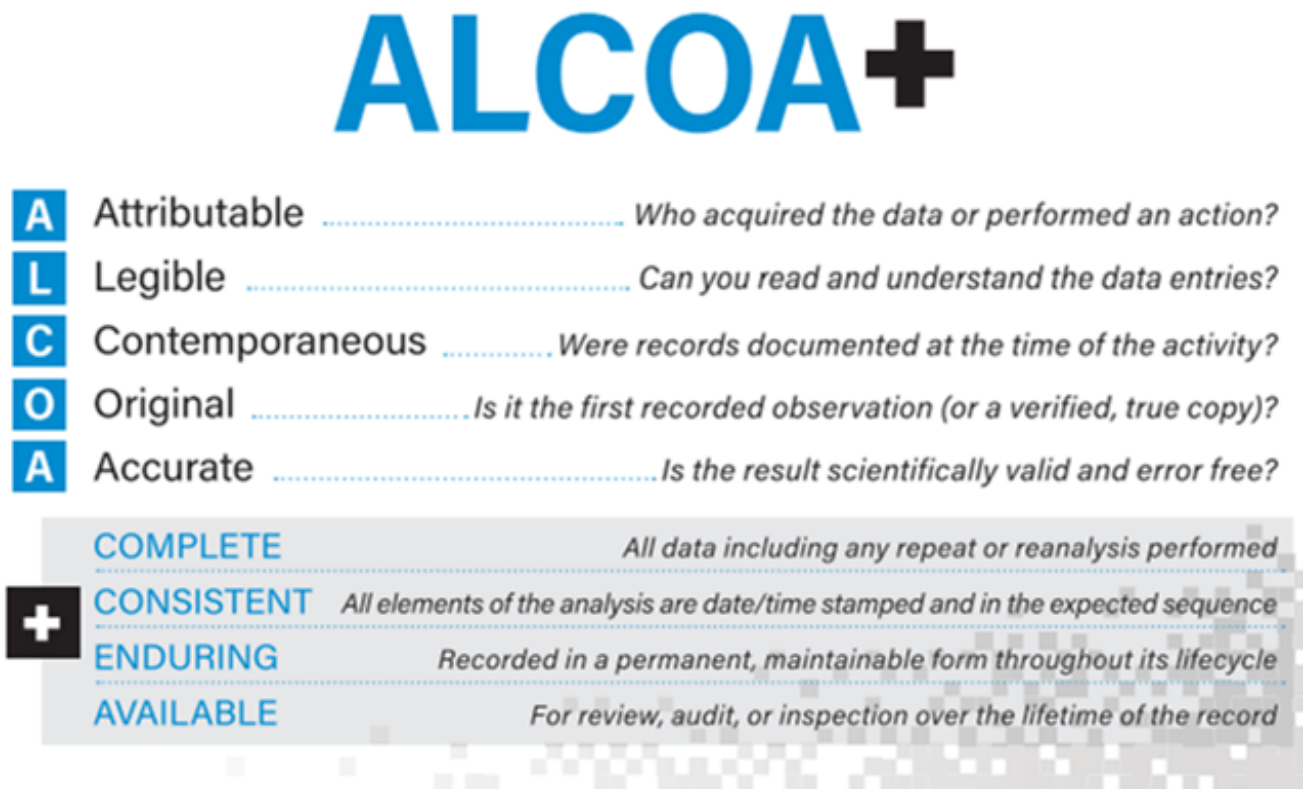
Good Documentation Practice

- Definitions supporting GDP
- Describe industry recognized criteria for GDP, ALCOAC+ and documentation
- Provide considerations and advice in support of GDP and process development

- **ALCOA+:** The data integrity acronym that stands for Attributable, Legible, Contemporaneous, Original record, Accurate and Complete, Consistent, Enduring, and Available
- **Correction:** A change made to any entry within a document.
- **Data Integrity:** The act of generating, transforming and maintaining the accuracy completeness and consistency of data over its life cycle in compliance with applicable regulations.
- **Document:** A document is a controlled or uncontrolled hardcopy or electronic transcript that provides information or data. To document, is to record information or data.
- **Documentation:** Documentation may include, but is not limited to procedures, instructions, contracts, records, and data in paper or electronic form.
- **Good Documentation Practices:** A set of requirements implemented to ensure attributable, legible, contemporaneous, original, permanent, and accurate, documentation of work.
- **GxP:** Refers to the applicable federal regulations for Good Practices such as Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Pharmacovigilance Practices (GVP) and Good Distribution Practices (GDP).
- **Traceability:** the ability to reconstruct the development history of documentation supporting GxP activities (either hard copy or electronic).

Use ALCOA+ Criteria for Data Integrity

ALCOA (+C)


ALCOA+
A Attributable ..... Who acquired the data or performed an action?
L Legible ..... Can you read and understand the data entries?
C Contemporaneous ..... Were records documented at the time of the activity?
O Original ..... Is it the first recorded observation (or a verified, true copy)?
A Accurate ..... Is the result scientifically valid and error free?
+
COMPLETE All data including any repeat or reanalysis performed
CONSISTENT All elements of the analysis are date/time stamped and in the expected sequence
ENDURING Recorded in a permanent, maintainable form throughout its lifecycle
AVAILABLE For review, audit, or inspection over the lifetime of the record

Good Documentation Practice

A set of requirements implemented to ensure documentation is attributable, legible, contemporaneous, original, permanent, and accurate, documentation of work.

Traceability –

- The ability to reconstruct the development history of documentation supporting GxP activities((either hard copy or electronic).
- The ability to trace the history, application, or location of an item or activity and like items or activities by means of recorded identification.

Common Documentation Errors which impact traceability

- Missing signature and dates at the time of activity performed.
- The write-over
- Non-uniform date and signature entry
- Writing a note that activity was performed on one day and signed for on other day.
- Blank spaces
- Illegible writing
- Too many corrections

Corrections or alterations of data

If a record or document requires additional information/amendment, this information must be entered in blue or black *ink* and signed/initialed and dated by the individual entering the information.

No changes should be made to documentation with any technique that *obliterates* the original entry.

NEVER:

- Use of correction fluid or correction tape
- Write over an entry
- Mark out an original entry with multiple lines
- Ink out an entry
- Erase an entry

If an item or result requires correction, it must be

- Crossed through with a single line
- Signed and dated by the corrector in close proximity to *EACH* corrected item.

NEVER USE STICKY NOTES / STICKERS

- Laboratory information necessary to ensuring traceability ***SHOULD NOT*** be captured on sticky notes
- Sticky notes that contain essential information can be easily dislodged and lost.

DOCUMENTATION

If you didn’t document it, you didn’t do it!!

Documentation-

The collection or compilation of all tangible materials, records, and forms used as evidence to support and/or define processes and procedures. Documentation includes but is not limited to the following: standard operating procedures (SOP), laboratory results, CRFs, batch records, etc.

Document all activities performed.

Do not perform an activity if it is not documented

DEFINING GDP PROCESS

Recording Results

1. Record data in real time as the process or task is performed (Contemporaneous).
2. Data are recorded by the individual performing or verifying the work (Attributable).
3. Results must be recorded in the same units as required by the reference document.
4. Record raw data consistent with the significant figures of the reference document or as it appears on the instrument read out. If the number of digits is not specified in the document, record digits displayed on the measuring instrument.

Recording Results (cont…)

5. Data for multiple repeated entries must be entered in their entirety. Do not use ditto marks (") or arrows (↓) to indicate repetitive information.
6. Do not destroy original documentation. If the original document is illegible due to the presence of ink blotch, solvent, grease, etc., transcribe the information to a new document then attach the original document to the transcribed document.
7. Do not record results on scratch paper, Post-it® Notes, etc. If original data is recorded on a sticky note/note pad etc., it is still considered original documentation and cannot be destroyed or discarded. Transcribe the information to a new document and staple or tape the paper to the transcribed document.
8. If data are transcribed from one document to another, a second employee must check the transcription for accuracy and initial/sign the transcribed document as a reviewer.

Signatures

1. Employees are responsible for their own signature/initials and must be prohibited from using another employee's signature/initials. For electronic signatures do not share passwords
2. Signatures and names should be consistent and match the signatures on a signature log or equivalent (to ensure traceability)
3. Never sign or initial for work completed by another individual unless authorized (and authorization is documented).
4. Signatures include the date signed and the printed name of the signer.
5. Electronic signatures, consisting of a login (user) name and a password, are the full legal equivalent of handwritten signatures.

Blank Spaces or Field

- Do not leave any blank spaces on forms unless it is intended for the information to be completed later
- If blank spaces or fields are present and not needed:
  - For a single space of Field, write N/A in the field, initials and date
  - For a block or area of spaces or fields, draw a diagonal line through affected blank spaces or fields, then write N/A and initial and date near the line
- Comments sections may be left blank without dating and initialing

Numbers and Unit

- Record a leading zero before the decimal point for numbers less than one (1). Example: 0.15 or -0.0009
- Include units of measurement unless already clearly identified on the document.
- Rounding Numbers
  - When appropriate and unless indicated otherwise round numbers as follows:
    - If the rounding digit under consideration is less than 5, it is eliminated, and the preceding number remains unchanged.
      Examples: 1.043 would round to 1.04.
      1.0831 would round to 1.08
    - If the rounding digit under consideration is greater than or equal to 5, it is eliminated, and the preceding number is increased by 1.
      Examples: 1.045 would round to 1.05.
      1.048 would round to 1.05
      1.099 would round to 1.10

Time and Dating Conventions

- Time Format

  Best practice is to record time shall follow the 24-hour time system (e.g., 1200, 1300, 1400, etc.)

- Date Formats

  Best practice format for recording dates shall follow standard conventions.

  - Use DDMMMYYYY format to record dates where DD is the number day of the month, MMM is the first three letters of the month (the month must be spelled out, should not be numeric to avoid misinterpretation), and YYYY are the four digits of the year all digits of the year.
  - Place a zero before day numbers less than 10.
  - Use of spaces, hyphens (dashes) or slashes are acceptable.
  - Examples:
    - 04Feb2020
    - 04/Feb/2020
    - 04-FEB-2020
    - 04 February 2020

SUMMARY Doc Control

- Document Control is one of the key elements for quality management system
- Document control should follow ISO 9001:2015 Requirements Quality Management System
- All non-conforming events should be identified as a deviation and remediated
- Document Periodic Review is part of regulatory requirement and recommended cycle is 2-3 years
- Upon revision and creation of SOPs, target audience must be trained, and all training activities must be documented

SUMMARY GDP

General Documentation Guidelines

- All documentation must follow ALCOAC+ practices and as outlined in this procedure.
- Prior to entering information on any forms or documentations, ensure necessary training on the process is completed and documented.
- Use only current, approved forms or documents to record activities.
- Write legibly, print if necessary.
- Use only blue or black permanent ink.
- Never use pencil, water soluble ink, felt markers or ink that may easily smear prior to drying.
- For records with multiple pages, ensure pages are numbered (e.g., page 1 of 2, page 2 of 2).
- If a record has attachments, ensure the attachments are labeled and the main document is referenced as required (e.g., Attachment 1 of Report # XYZ, Attachment 2 of Deviation # XYZ, etc.).
- Employees *are prohibited from reviewing or approving their own work/documentation* where a secondary review or approval is required unless deemed appropriate by Quality Assurance (QM) or Regulatory Compliance.
- Deliberate backdating or forward dating is prohibited and is considered FRAUD.
- Anyone discovered to have intentionally and/or negligently falsified data, destroyed or discarded original data may be subject to disciplinary action, up to and including termination.

Case Study

Evaluation of existing laboratory procedures in support of implementation of formal document control system

- **Your laboratory has several documents (e.g., safety manual, testing procedures, etc.) ranging in age from a few months to twenty years. These include several different sample collection procedures, some testing procedures, and many scientific articles used as references. You are asked to develop a system for evaluating the old documents (as they relate to current document control system implementation); evaluate the need to add new documents and assure all documents currently in use (both within and outside the laboratory, e.g., process for specimen collection, result reporting) meet current laboratory requirements and are complete.**
- **How would you implement and manage the documents? Please describe the procedures**

Answer

1. Establish a document control program that indicates:

- System for standardizing the format and/or numbering — It is necessary to have a numbering or coding system (e.g., version control) that applies to all documents created within the organization. All documents should be identified with the following information in a standard format:
  - Logo of the laboratory
  - Name of laboratory
  - Document Title
  - Document No:
  - Version No
  - Effective Date
  - Approval signatures
  - Page number to the total number of pages

Answer

- Document numbering system: Documents are numbered sequentially using an alphanumeric system with abbreviated form in the following order, e.g.
  - XYZ for the name of the Laboratory
  - XXX for the name of the laboratory section in which the document is applicable
  - YYY for the type of document
  - 000 for three-digit serial number, Example: XYZ/XXX/YYY-000, HUCSHL/MBL/SOP-001
- A process for formal approval of each new document, a distribution plan or list, and a procedure for updating and revising laboratory documents
- A master log or inventory of all documents of the laboratory; e.g.

STANDARD OPERATING PROCEDURE INDEX

Quality Management

No.	Document Type	Document Number	Title	Version	Effective Date

Answer

- A process to ensure that the documents are available to all who need them, including

users outside the laboratory;

- A method for archiving documents that become outdated but need to be kept for future reference

2. Once a process for document control has been established then collect, review, and update all existing documents and records

- since there is no document control system in place, they might be an outdated document that will need to be revised

3. Determine additional needs—Once all documents have been collected, it should be possible to determine needs for a new process or procedure descriptions.

Answer

4. If the quality manual has not yet been developed, this should be done at that time as it serves as the framework for all the efforts and develops forms and worksheets if needed.

5. Involve stakeholders—It is useful when creating documents to be used in the laboratory to involve all staff who will be using them

References

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Q&A

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