EQAsia

Document control and SOP Development

By Tobin Guarnacci

October 16 (15- 16:30 KST)

House keeping rules

Please turn off your microphones – this will help with bandwidth and maximize audibility.

Do frequently use the chat function to share your views, comments and challenges. Keep the chat constructive, respectful and on topic!

If you would like to ask questions, please type them in the chat box

Please note that we will record the session to maintain a record of the questions asked and to distribute it to the laboratory team for future reference.

Agenda

S/N	**Topic**	**Time**	**Expected Duration**
1	Welcome and Pre-test	3:00 - 3:10 pm	10 min
2	Presentation on Document control and SOP development	3:10 – 4:10pm	60 min
3	Post-test quiz questions and case studies	4:10 - 4:20 pm	10 min
4	Q/A session	4:20 - 4:30 pm	10 min

Pre-test Quiz (30 seconds)

1. What is a primary goal of establishing a document control system in a laboratory?

   a) To keep all documents stored digitally

   b) To ensure only authorized personnel can create documents

   c) To maintain up-to-date, accurate, and accessible documents

   d) To reduce the number of documents in use

Pre-test Quiz (30 seconds)

2. What is the first step in developing a new SOP?

a) Defining the objective

b) Identifying the process that requires an SOP

c) Choosing the format

d) Identifying the audience

Pre-test Quiz (30 seconds)

3. Document review is required when?

a) Following investigations of a nonconforming event (NCE).

b) In response to findings from internal or external laboratory audits or assessments.

c) Whenever a problem arises

d) At regular intervals, such as annually, or when there are process changes

e) All

Pre-test Quiz (30 seconds)

4. How can a laboratory ensure that all staff members are aware of changes to SOPs?

   a) By posting updates on the laboratory bulletin board

   b) By emailing the changes to staff

   c) By conducting regular training sessions and requiring acknowledgment of the updates

   d) By waiting for staff to notice the changes themselves

Pre-test Quiz (30 seconds)

5. Why is version control important in document management?

a) To increase the number of documents in circulation

b) To ensure all users are working with the most current and accurate information

c) To keep documents confidential

d) To allow multiple versions to be used simultaneously

Document control

Overview

- Document Control
- Document Lifecyle
- SOP Development
- SOP Deviation
- Periodic Review
- SOP Training

Definitions

- **Controlled Document**: Policies, Processes, and Procedures that describe the work to be done
- **Document control** : The mechanism that ensures only the latest version of an approved document is available for use as a resource.
- **The Master File** : Serves as an historic record of a single controlled document from its inception to the current date.
- **The Master File Index** : Serves as a table of contents for all controlled documents and their distributions
- **Superseded document**: Document status that is updated and replaced with a new version of a document (a master copy of a superseded document must be retained to ensure historical traceability and compliance with ALCOAC (Attributable, Legible, Contemporaneous, Original record, Accurate and Complete, Consistent, Enduring, and Available))
- **Obsolete document**: Documents that are outdated and no longer in use

Document control definition

ISO 9001:2015,4.5.3.1 Quality Management Systems- Requirements

- ISO 9001:2015,4.5.3.1 is an international industry standard that defines implementation and management of document control system

ISO 9001:2015,4.5.3.1 states that “ documented information required by the quality management system shall be controlled to ensure:

- The information is available and suitable for use where and when needed
- The information is adequately protected (e.g., from loss of confidentiality, improper use or loss of integrity)

- Document control ensures staff members have the current, correct and consistent information to perform their work

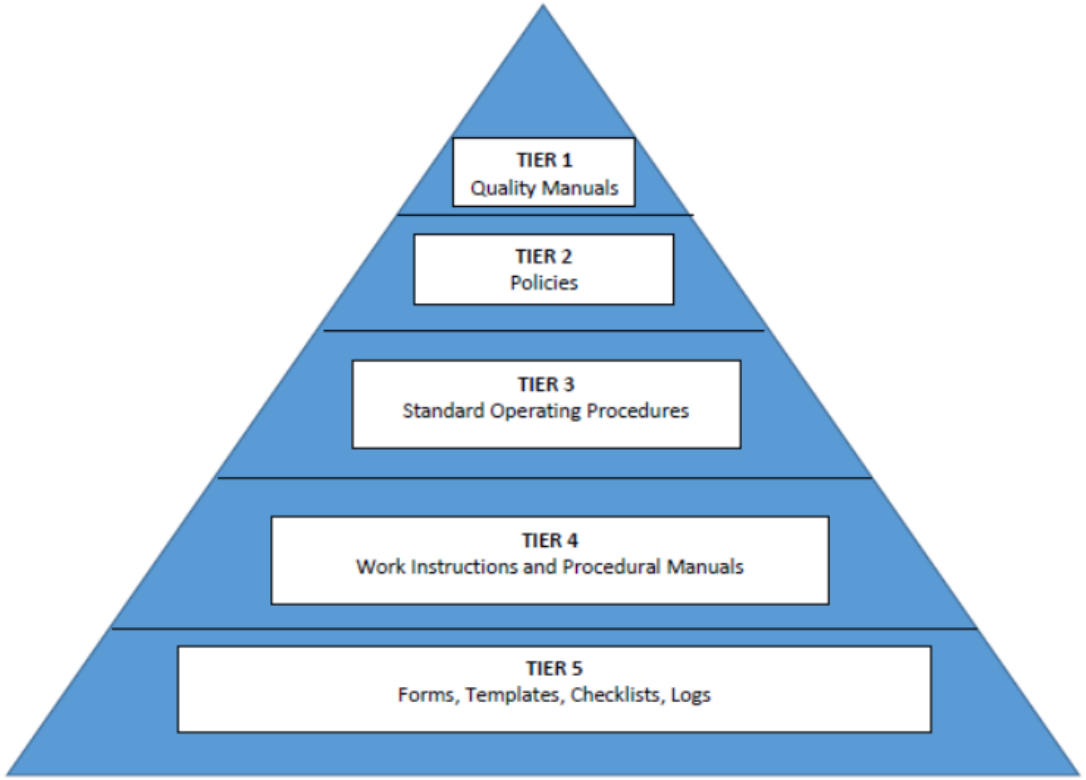
Document control

- The document control system is typically managed by a laboratory's Quality Assurance (QA) Unit/Department to ensure objective oversight of the document management system.

- In the absence of a dedicated QA Unit/Department, laboratories should assign appropriate personnel for ensuring that document control systems are developed, implemented and maintained in a manner that ensures objective oversight and effectiveness of the system.

Document Control

Hierarchy of controlled documents- a description of the structure and relationships of the documentation used in the Quality Management System (QMS)



Document control

Requirement for document control

1. Document identification and control

- Required elements for document identification includes:
  - Title that designates it is a policy, process or procedure
  - Laboratory name
  - Laboratory logo
  - Unique document number
  - Version Number
  - Number of pages
  - Approval date and signature
  - Effective date
  - Controlled copy number, for paper copies
  - Authority for use

Document control

2. A document control process must be defined to describe the controlled document life cycle which includes :

- Identification of need for a controlled document
- Creation/draft, review, approval for use, and distribution of a new document
- Revisions (changes) to an approved document and its distribution
- Periodic review of current documents (annual review is recommended,CLSI QMS 02 ED 7-2024).
- Archiving and retention of obsolete documents

3. Accessibility and control over external documents (e.g., legislators, regulators, standardization bodies, or business partners)

4. Clear labelling (e.g., version control) of ***document lifecycles (***e.g., draft, issued, superseded, obsolete, etc.)

Document control

- **What is a document lifecycle?**
- A series of stages that represent the life cycle of a document from creation to obsolescence.
- Controlled documents within this lifecycle include those that control activities that are *frequently* performed or referenced (i.e., those procedures that are performed multiple times) such as, Quality manuals, polices, SOPs, work instructions, Templates (e.g., forms, checklists and templates)

Example of document Lifecyle stages

- **Draft to effective** lifecycle

Document control

Example of document lifecycle stage

- **Draft** – Initial version of a controlled document which will be subject to review by assigned Subject Matter Experts (SME)
- **In-review** – draft controlled document submitted to SMEs for review and comment
- **Approved** – Final version of a controlled document to be submitted for approval (either within electronic system or Hard-copy system) for which signatures are required (either electronic or wet signatures).
- **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

- 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 (e.g., GMP, GCP, GLP, as applicable) or accreditation standards requirements and be documented 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, Reviewer, Approver and Quality Assurance (QA) Approver) and document should be approved as per the procedure required according to the document lifecycle.

Document control

Document creation

- Written information should be presented in a manner that makes it easily understood by readers. When creating documents, it is essential to consider the ***format*** as well as ***content***.
- A standard format helps staff members to become familiar with the same format and be able to locate and refer to the desired information more quickly
- Consistent document formats can be achieved using document templates, which also improve readability and comprehension of the content
- **A template** is a standardized document used as the basis for creating multiple documents with the same kind of information. It provides the following advantages:
  - Standardization
  - Completeness
  - Ease of document management

Document control

Elements that can be standardized

- **Format elements**:
  - The placement of information in document headers and footers
  - Font type and size, line spacing and attributes such as bold, italics, and underline
  - Placement and size of any organization logo(s)
  - Height and width of margins
  - Numbering of instruction steps

- **Content elements :**
  - Headings within the body of the document
  - Some wording, such as purpose/scope statements
  - Acronyms, abbreviations, and units of measure

Document control

Reviewing documents

- A document review ensures correct format and content (defined in an organizations SOP on SOPs), verifying the process or procedure's successful completion. Using a checklist is recommended for this purpose:
- Format section should :
  - Complies with designated format and layout requirements, including correct template selection and completion.
  - Adheres to laboratory- or organization-specific good documentation practices.
  - Includes assigned document and version numbers.
  - Corrects any spelling, punctuation, or grammatical errors.

- Content section should:
  - Complies with the manufacturer’s instructions for use.
  - Meets regulations, standards, and/or accreditation requirements.
  - Accurately reflects actual day-to-day practice.
  - Follows the correct sequential order of activities or steps.
  - Includes all critical activities.
  - Is easy to read and understand.

Document control

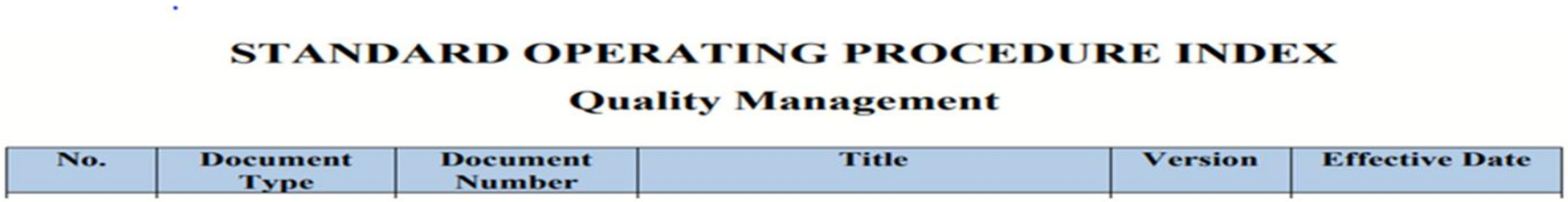
Document approval

- Laboratories need a defined process for approving new and modified documents, specifying:
  - Which individuals (by position or function) are involved
  - The order in which the approvals are done (e.g., SMEs should review prior to QA approval as QA should be the final approver)
  - The individual who ultimately approves and authorizes the document (i.e., QA)
- The laboratory director or designate must always review, approve, and sign these documents (CLSI QMS 02 ED 7-2024).
- Approval signatures, either written or password-protected electronic records, must be recorded before the document's release and use.
- Approval dates must precede the document's issue date, and *necessary training should occur after approval and before the document becomes effective*

Document control

Document distribution and implementation

- The document control coordinator/QA must maintain a controlled document master list (SOP index), including title, versions, effective dates, and locations of all documents.)
- Ensure the SOP index is current and accessible to users with a list of approved controlled documents.



STANDARD OPERATING PROCEDURE INDEX

Quality Management

No.	Document Type	Document Number	Title	Version	Effective Date

- Additionally master file will be created to contain the original approved and signed version of a document (if this is a hard-copy system, if an electronic system this will be traceable within the systems audit trail)
- When distributing revised documents, request recipients to remove older versions from circulation for a hard-copy system; if a validated electronic system this function will be performed by the system with traceability to predicate controlled documents.

Document control

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

- Access to documents should be restricted to only the personnel responsible for using them
- Electronic system: Access can be controlled by security setting (e.g., an individual with ready only access, an individual with viewer access (i.e., visibility of 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.
- To reduce the likelihood of unauthorized changes, the documents should be accessible electronically in PDF or a “read only” format or controlled by electronic system access configuration
- 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

Making Changes to Documents

- When changes are necessary following a review of an existing document, the following steps should be taken to maintain effective document control :
  - **Version control**:
    - Establish a system for tracking all changes made to a currently approved document and maintain the integrity of previous versions using date or revision number which identifies the current version of a document.
  - **Editing and tracking changes**:
    - Track all changes and comments, including who made them, when and why
    - Document the history of changes to provide evidence of actions taken.
  - **Impact on other documents or validated systems**:
    - Assess whether changes affect other documents or processes.
    - Record this assessment**.**
  - **Approval:**
    - Changed documents should be approved in the same manner as for a new document

Document control

Accessibility and control over reference documents.

- Reference documents used in the Quality Management System (QMS) should be managed like internal documents. They should be recorded on the laboratory's master document list and included in the routine document review schedule.

Examples of Reference Documents:

- Testing/examination package inserts
- Operator's manuals
- Manufacturer's instructions
- Standards and accreditation requirements
- National and regional regulations
- Guidance from referral and reference laboratories
- Supplier contracts
- Textbooks and articles related to testing or reagent preparation methods

SOP development

Why should SOP be developed?

Written SOPs ensure the following.

- Consistency and Quality Control (Delivery of consistent results and 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 guidelines
- Responsibilities
- Procedures
- Reference
- 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: to satisfy GxP or accreditation standards, international and local regulatory requirements and other internal or external procedures, guidelines and /or standards

✓ **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 listed in this section

✓ **Applicable Regulations and/or Guidelines**

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

SOP Development Guideline

✓**Responsibilities**

- A summary of the roles listed in the procedure and responsibilities of each role holder for the procedure detailed in the CDoc
- The summery 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 of 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 details, 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. Note: version history will be automatically captured by a validated electronic system

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 a 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)

- Incase of deviation, deviation owner (e.g., individual identifying deviation) should report to QA 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
  - ✓ Attached 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 QA
- 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

➢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(s) 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 – Investigation

Corrective and/ or Preventive Action Determination

Based on the investigation finding, indicate if the CAPA is needed:

- If CAPA is needed, follow CAPA SOP which should be created within respective organizations

- Once a CAPA is initiated all corrective actions/preventive action plans associated with the deviation will need to be approved prior to closing the deviation.

- If a CAPA is not required, QA should provide justification for this decision.

SOP Deviation – Closure

Closure:

The QA will ensure:

- That sufficient information is provided to describe the event, the root cause(s) has been identified and the outcome impact is appropriate
- The Deviation form is complete, the final Investigation Report is attached, if applicable, sign the deviation and forward the closed Deviation to QA
- That the closed deviation is archived in the paper or electronic system as appropriate and ensures deviation status, owner, root cause(s), impacted project, date initiated, date closed, date occurred.

Periodic Review

Document periodic review

- Document periodic review (recommended annually, CLSI QMS 02 ED 7-2024) is part of regulatory requirement to ensure organizational controlled document contents are current and aligned with regulatory requirements
- In addition to periodic reviews, unscheduled reviews may be necessary due to:
  - Investigations following a nonconforming event (NCE)/deviations
  - Findings from internal or external laboratory regulatory inspections, audits or assessments
  - Outcomes of continual improvement projects
  - Modifications to related processes that require compatibility checks
- All document reviews should be documented to provide evidence that the reviews have been conducted.
- Authorized and qualified personnel should conduct the reviews.

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
- All training activities must be documented (e.g., hard copy training records or validated electronic system)

IVI Controlled Documents Training Matrix

NOTES:

Document Number	Title	Job Function			
		PM Head	PM Lead	PM	Grant Development PM
CARE SOPs					
CARE-00001	Management of Data Safety Monitoring Board	M	M	M	M
CARE-00007	Investigational Product Management		M	M	
CARE 00023	Study Handover Process and Documentation	R	R	R	
CARE 00043	Clinical Trial Site Selection	M	M	M	M
CARE-00024	Posting Clinical Trial Information and Results on Clinical Trial Registries		M	M	
CARE-00081	Trial Master File Management	M	M	M	
CARE-00032	Vendor Selection	M	M	M	M
CARE-00035	Safety Data Oversight	M	M	M	
CARE-00038	Clinical Study Report Development		M	M	M
CARE-00047	Clinical Trial Site Quality Control Visit		M	M	
CARE-00051	Clinical Vendor Oversight	M	M	M	M
CARE-00056	Informed Consent Preparation, Process, and Documentation		M	M	M
CARE-00065	Safety Coding and Validation		R	R	
CARE-00067	Clinical Trial Protocol Development and Amendment		M	M	M

Quizzes and Case studies

Quiz (30 seconds)

1. What is a primary goal of establishing a document control system in a laboratory?
   a) To keep all documents stored digitally
   b) To ensure only authorized personnel can create documents
   c) To maintain up-to-date, accurate, and accessible documents
   d) To reduce the number of documents in use

Quiz (30 seconds)

2. What is the first step in developing a new SOP?

a) Defining the objective

b) Identifying the process that requires an SOP

c) Choosing the format

d) Identifying the audience

Quiz (30 seconds)

3. Document review is required when?

a) Following investigations of a nonconforming event (NCE).

b) In response to findings from internal or external laboratory audits or assessments.

c) Whenever a problem arises

d) At regular intervals, such as annually, or when there are process changes

e) All

Quiz (30 seconds)

4. How can a laboratory ensure that all staff members are aware of changes to SOPs?

a) By posting updates on the laboratory bulletin board

b) By emailing the changes to staff

c) By conducting regular training sessions and requiring acknowledgment of the updates

d) By waiting for staff to notice the changes themselves

Quiz (30 seconds)

5. Why is version control important in document management?

a) To increase the number of documents in circulation

b) To ensure all users are working with the most current and accurate information

c) To keep documents confidential

d) To allow multiple versions to be used simultaneously

Case study 1(1 minute)

1. Your laboratory has a range of documents, including safety manuals, testing procedures, and scientific articles, that span from a few months to twenty years old. These documents include various sample collection procedures, some testing procedures, and many reference materials. You have been tasked with creating a system to evaluate these old documents adding a new document as needed and ensure that all existing documents, both within and outside the laboratory (such as those for specimen collection and result reporting), comply with current laboratory requirements and are complete.

What are the steps your laboratory should take?

a) Establish a document control system.

b) Collect, review, and update all existing documents and records.

c) Determine if there is a need to develop new procedures.

d) All of the above.

Case study 2 (1 minute)

2. In 2019, a clinical laboratory technologist attended a specialized workshop on new techniques for pathogen identification and antimicrobial susceptibility testing (AST). Upon returning to the laboratory, the technologist discussed the new techniques with the team. However, this information was not formally documented or incorporated into the laboratory's standard procedures. The current SOPs, last updated in 2017, do not include these advanced methods. As a result, newly hired staff continue to follow the outdated protocols, unaware of the more efficient and accurate methods available.

1. What are the steps the laboratory staff should take?

a) Review and Update the SOPs to reflect the inclusion of the new methods

b) Update the master file index including the change

c) Maintain the original approved SOP in the master file

d) Conducting training sessions for all relevant staff to familiarize them with the updated procedures

e) All

Case study 2 cont.,(30 seconds)

2. When updating existing SOPs, what is essential to ensure proper document control?

a) Assign a new version number and mark the old version as obsolete.

b) Delete the old SOP and replace it with the new one.

c) Keep both the old and new versions available for use.

d) Combine the old SOP with the new one.

QUESTIONS ???

Thank you