Laboratory Audit Conduct

March 22, 2024 (3:00- 4:30pm KST)

General assessment questions

1. What is your highest level of educational attainment?
   a. PhD
   b. Masters
   c. Bachelors/First Degree
   d. Technician

2. For how many years have you been working in the laboratory?
   a. < 5 years
   b. 5-10 years
   c. 10-15 years
   d. >20 years

General assessment questions

3. Which topic would you like to be included in the upcoming webinars?
    a. Corrective/Preventive Action
    b. Equipment Management
    c. Document Control and SOP Development
    d. Personnel Management
    e. Laboratory safety

4. In your opinion what is the best approach to deliver a training on QMS
    a. Needs to take curriculum-based courses.
    b. Self-learning
    c. On-site hands-on training
    d. Online modular on demand course
    e. Tailored interactive webinars.

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	3:00- 3:10 pm	10 min
2	Session 1: - Presentation on laboratory audit, types of audits, requirement of internal audit and area of assessment	3:10-3:40pm	30 min
3	Q/A session	3:40-3:45pm	5 min
4	Session 2: - Presentation on procedures for managing an audit by external organization and CAPA management	3:45:4:15pm	30 min
5	Q/A session	4:15-4:20pm	5 min
6	Case study	4:20-4:30pm	10 min

Session 1:

Introduction to a laboratory audit, types of audits, requirement of internal audit and audit scope/area of assessment

Objective

- To define what is a laboratory audit
- Types of audit
- Rationale & Process for Internal Audit
- Audit scope/area of assessment

Definition

- **Auditor**: Trained professional or group of professionals that conduct a systematic and objective examination of a process or system against a pre- defined standard or audit criteria
- **Auditee**: An organization being audited
- **Audit criteria/standard**: a set of polices, procedures or requirements used as a reference against which the audit evidence compared
- **Audit evidence:** Records, statements of fact or other information relevant to the audit criteria/ standard and verifiable
- **Conformity** : Fulfilment of the requirement
- **Non-conformity**: Non-fulfilment of a requirement.

Auditing a Laboratory

- **What is a laboratory audit**

- A systematic, independent and documented process to examine whether the laboratory activities, processes and management system comply with an established standard , audit criteria and such standards are implemented effectively

- A lab audit is an essential part of the quality assurance program of a laboratory which covers all aspects of the services provided.

- A lab audit allows the laboratory to understand performance criteria and how well the lab is meeting such criteria when compared to a **benchmark** or standard (e.g., standards such as ISO, CLSI, etc.).

Laboratory audit

- Audits are conducted for one or more of the following purposes:
  - To determine the conformity or non- conformity of the laboratory quality management system elements against specified requirements (e.g., WHO, ISO, local regulations, etc.)
  - To determine the effectiveness of an implemented quality management system
  - To verify the laboratory quality management systems are functioning as planned
  - To identify opportunities to improve the laboratory quality management system.

- Audit can be conducted by:
  1. laboratory's internal staff or external consultant (i.e., internal audit)
  2. National Regulatory Agency or Independent accreditation body for certification purposes (i.e., inspections or external audit)

Quiz(1 minutes)

1. An audit is conducted to determine **all except**
   a. Conformity of the laboratory quality management system with specified requirements/ standard
   b. Non-conformity of the laboratory quality management system against specified requirements/ standard
   c. To identify fault
   d. To identify opportunities for improvement
   e. To verify the laboratory management systems are functioning as planned.

Internal audit

- Internal audits are audits conducted by a laboratory's personnel (e.g., quality assurance) to determine whether all activities in the laboratory & quality management systems, including pre-examination, examination, and post-examination phases of analysis:
  - Conform to the requirements of regulations, International Standard and quality management system requirements established by the laboratory and
  - Are implemented, effective, and maintained

- Internal audit is a management system audit in which the laboratory plans ,establishes, implements and maintains an Audit program including its frequency, method, responsibilities, planning requirements and reporting.

Internal audit

- Internal audits are a requirement of ISO standards and provide an interim gap analysis prior to routine or upcoming regulatory and/or accreditation audits.
- Internal audits increase confidence in the laboratory service and demonstrate to its personnel that the organization is committed to the management system
- Internal audit should be conducted regularly (at least annually) and if observations are identified that require remediation (e.g., internal audits should be performed
  - After receiving an unacceptable proficiency testing (PT) result,
  - Based upon customer complaints
  - After an increased number of unexpected abnormal results for a particular tests

Values of internal audit

- **An internal audit is a valuable tool and can help the laboratory to:**
  - Prepare for an external audit;
  - Helps in pinpointing any shortcomings that could result in severe warnings or non-conformances.
  - Increase staff awareness of quality management system requirements;
  - Identify the opportunities for improvement;
  - Understand where preventive or corrective action is needed;
  - Identify areas where education or training needs to occur;
  - Determine weather the laboratory is meeting its own quality standards

Requirements of internal audit

Requirements of internal audit

- The laboratory should plan for audits of its management system at defined frequency
- The laboratory should nominate a person to be responsible for conducting the audit based upon subject matter expertise.
- The laboratory should have a documented procedure to define the responsibilities and requirements for planning and conducting audits, and for reporting results.
- The audit should be conducted in accordance with pre-planned program
- The results of the audit should be documented
- Corrective action should be initiated immediately by the laboratory to correct all non-conformities identified in the management system within a reasonable time frame
- The corrective action should be effective and completed promptly.

Internal audit

- **Criteria for selection of auditor :**

The auditor assigned to conduct the internal audit

- Should be independent of the section being audited
- Must have the technical skill needed to evaluate the area being audited and knowledge and understanding of the laboratory's quality management system.
- Must be detail oriented
- Must be able to communicate effectively and diplomatically
- Auditor qualifications and training should be documented

Quiz (1 minute)

1. Which of the following statements is **TRUE** concerning internal audits?
   a. They are not required for laboratories seeking ISO accreditation.
   b. They provide information for identifying training needs.
   c. Pre-planned program is not necessary for conducting internal audit
   d. They are conducted by groups or agencies from outside the laboratories.
   e. All

Quiz (1 minute)

2. Which of the following is **NOT** the criteria for selection of auditor for internal audit:
   a. The auditor must be selected from of the area being audited.
   b. The auditor should focus on the details.
   c. The auditor should have adequate skill for the area being audited.
   d. The auditor should be trained in the quality management system and audit procedure.
   e. The auditor must be able to communicate effectively and diplomatically.

Quiz (1 minute)

3. How often should internal audits be conducted in a laboratory?
   a. Only once during the lifetime of the laboratory
   b. At the discretion of laboratory staff
   c. At regular intervals, as defined by the laboratory's QMS.
   d. Continuously, without any breaks

Audit Scope/area of assessment

- Quality Management, quality assurance and quality control
- Facility, Environment, Safety and Security
- Organization and Management
- Personnel, Orientations, training and Assessment
- Document Control/Standard Operating Procedure
- Sample Shipping, Receipt, Processing
- Specimen Collection, Handling
- Equipment Calibration and Maintenance
- Inventory management (reagents and consumables)
- Electronic Systems
- PT/EQA

Areas of assessment

Quality Assurance/Quality Management

- ✓ Does the laboratory have a documented quality management (QM) program
- ✓ Does the laboratory summarize and review its records of errors and incident reports at defined intervals to identify trends and initiate corrective and preventive actions (CAPA) as appropriate (Complaints follow up and trending at defined intervals)?
- ✓ Are Preanalytical (e.g., order processing, specimen collection, transport), Analytical (e.g., sample receipt, processing, QC) and Post Analytic (e.g., turn-around-times and result reports) variables monitored?
- ✓ Is the QM program appraised at least annually for effectiveness?
- ✓ Is internal auditing performed to confirm that the laboratory's SOPs are being followed as documented?

Areas of assessment

- **Facility, Environment Safety and Security**
  - ✓The adequacy of the facilities relative to the scope of work.
  - ✓Environmental conditions (i.e., room temperature, humidity) monitored, controlled, and recorded?
  - ✓Access control and monitor?
  - ✓Good house keeping is practiced?

- **Organization and Management**
  - ✓Scope of operation
  - ✓Org chart: The relations between the laboratory, management, technical operations, support services and the quality management system

- **Personnel, Orientation, Training and Assessment**
  - ✓Staff qualifications, a training SOP, training plan, and training records.
  - ✓Employee competency records.
  - ✓An up-to-date job description for each employee.
  - ✓A personnel file for each staff member.

Areas of assessment

- **Doc Control/Standard Operating Procedures (SOP)**
  - ✓ Documented process for creation , review, updating , approval, and management of controlled documents?
  - ✓ Are all documents current and approved?
  - ✓ Periodically reviewed
  - ✓ Are obsolete documents removed?

- **Specimen Collection, Handling**
  - ✓ Sample collection manual: existence, reviews, approvals, training

- **Sample Shipping, Receipt/Processing and storage**
  - ✓ Specimen reception and handling procedure, acceptance/ rejection criteria
  - ✓ Adequacy of reception and storage area?
  - ✓ Training on sample reception?
  - ✓ Documented tracking system to prevent loss of sample and ensure integrity?

Areas of assessment

Equipment Calibration and Maintenance

- ✓SOP for the operation, maintenance and calibration?
- ✓SOP on remedial action in case of equipment failure?
- ✓Is equipment adequately inspected, cleaned, maintained, and calibrated?
- ✓ Equipment maintenance and calibration record?
- ✓ Current equipment data for all equipment

- **Quality Control (QC)**

✓Written QC program?

✓How is QC material prepared?

✓QC record and trending analysis?

Area of assessment

- **Inventory management (reagents and consumables)**
  - ✓Inventory system?
  - ✓Temperature and humidity of the storage room monitored?
  - ✓Is FIFO practiced?

- **Electronic Systems and IT**
  - ✓Is the computer system validated (e.g., LIMS)?
  - ✓Do SOPs exist for all uses, operation, and maintenance of the computer system?
  - ✓Is there a training manual for all computer applications?
  - ✓What is the backup procedure?

Assessment

Proficiency Testing (PT) /External Quality Assessment (EQA)
(CLIA 42 CFR 493.901, 903, 905 and ISO15189 ISO/IEC Guide 43-1 & ISO17043)

- PT is defined as determination of laboratory testing performance by means of interlaboratory comparisons, in which a PT/EQA program periodically sends multiple specimens to members of a group of laboratories for analysis and/or identification

- Does the laboratory have written procedures for the proper handling, analysis, review and reporting EQA materials?
- Are EQA materials handled and tested the same way as routine patient specimens?
- Is the EQA performance of the laboratory reviewed and discussed with relevant personnel?
- Is root cause analysis performed for unacceptable EQA performance?
- Is corrective action documented for unacceptable EQA performance?

Quiz (1 minute)

1. During the audit, what information regarding personnel is relevant to audit conduct?
   a. Employee holiday plan, and promotion record
   b. Age and vacation schedule.
   c. Job title, and salary.
   d. Qualifications, job description, training record, and competency assessment record
   e. Staff attendance

Quiz (1 minute)

2. What will the auditor verify related to **equipment**?
   a. Equipment color
   b. User job title
   c. Maintenance and calibration record
   d. None of the above

Quiz (1 minute)

3. What documents are to be verified (by the auditor) under the quality of the examination phase of analysis ?

a. Quality control (QC) procedure, QC records, trend analysis, corrective action record
b. Review of results, sample reception, storage record
c. Sample register record, sample acceptance/ rejection criteria
d. Approval signature

QUESTIONS ???

Session 2:
Procedures for managing an audit by external organization and CAPA Management

Objective

- To define procedures for managing an audit by external organization

- To explain corrective and preventive actions (CAPA) management and implementation

External audit

- **External audit is**:
  - An external audit serves the purpose of evaluation of laboratory management system compliance with regulatory requirements and accreditation standards
  - Assessments conducted by clients, accreditation or regulatory agencies from outside the laboratory
  - Different standards can be used for the assessment process ranging from international standards to a locally developed checklist
- **Stages of audit (auditee and auditor):**
  1. Audit planning stage
  2. Audit conduct stage
  3. Audit reporting and CAPA distribution
  4. Post audit activity

Audit Planning

- The first stage of the audit activity involves establishing the initial contact with auditee and determining the feasibility of the audit.
- The audit team leader should ensure that contact is made with the auditee to:
  - ✓ Confirm communication channels with the auditee’s representatives
  - ✓ Provide relevant information on the audit objectives, scope, standards, methods

- An Audit Plan will be created, based on content agreed upon during a planning meeting with the auditee (laboratory Quality) and the auditor.

Audit Planning

- **Audit planning should address the following**:

  - ✓ The audit objectives
  - ✓ The audit scope, including identification of the organization and its functions, as well as processes to be audited;
  - ✓ The audit standard
  - ✓ The locations (physical and virtual), dates, expected time and duration of audit activities to be conducted
  - ✓ The roles and responsibilities of the audit team members,

- The Auditor will develop new or utilize existing audit tools applicable to the audit scope
- Audit Notification Letter will be sent to confirm the agreed upon audit dates no later than 10 business days prior to audit conduct

Conducting the audit

- The second stage for the audit process is conducting the audit activities. During the audit, the auditor will conduct opening meeting

- The purpose of the opening meeting is to:

  - ✓ Confirm the agreement of all participants (e.g., auditee, audit team) to the audit plan
  - ✓ Introduce the audit team and their roles;
  - ✓ Sets the tone of the audit

- Information relevant to the audit objective, scope and standard will be collected through
  - ✓ Interview
  - ✓ Observation
  - ✓ Review of documentation

Conducting the audit

- The auditor will :
- Conduct a laboratory tour of applicable areas of the facility, Interview key individuals involved in support of activities supporting audit scope :

    - ✓ To ensure adherence to documented procedures and standards

- Interview the laboratory head or designee and Quality Assurance representative (if applicable):
    - ✓ To gather insights and clarification

- Performs document review (to include but not limited to):
    - ✓ Manuals, SOPs and training records
    - ✓ Review data supporting laboratory systems, (e.g., training and qualifications, equipment maintenance and calibration, software validation, etc.)

Conducting the audit

- The auditor will provide a daily debrief and a closing meeting will be arranged on the final day of audit conduct

During the closing meeting,

- The auditor will verbally present audit observations to the auditee and allow the auditee to verbally respond.
- Explain audit reporting and CAPA process to the auditee

- An Audit Thank You Letter will be sent to the auditee within 10 business days of the audit closing meeting.

Prepare Audit Report and CAPA table

- Upon audit completion the auditor or designee prepares an audit report and a CAPA table within 30 business days of audit closure (note: audit reporting requirements may vary contingent upon organization)
  - The auditor or designee ensures that the audit report and CAPA outline deficiencies noted and classifies observations as Critical, Major, Minor or Opportunity for Improvement.
  - The Auditor or designee ensures that the overall audit rating of Satisfactory, Caution or Unsatisfactory is assigned, based upon the criticality of audit observations and relative risk to patient safety, data integrity or project deliverables.

- Auditor or designee and management reviews the audit report and CAPA and signs the audit report.
- Auditees will only receive the CAPA table as the audit narrative report will be filed for internal (auditor) records.

Prepare Audit Report and CAPA table

- **Observations are assigned criticality as follows:**

- **Critical** -Observations that would be cited by a regulatory/accreditation agency, which would have major impact on data integrity and may result in loss of part or all data or impacts the rights or safety of patient
- **Major**-Observations that have the potential to be noted during a regulatory/accreditation inspection and/or could result in the loss of some data or integrity of data or impacts the rights or safety of patient
- **Minor**-Observations may be noted during a regulatory/accreditation inspection. These deviations are not serious enough to jeopardize the data integrity or impacts the rights or safety of patient
- **Opportunities for Improvement** -No deviations from regulatory/accreditation standards; however, generally accepted industry standards/best practices have not been followed

File Audit Report and Distribute CAPA Plan (table)

- The auditor or designee secures the final audit report within Quality files and distributes the CAPA table to the auditee once the audit report is executed (i.e., signed) by auditor management.

- The auditor or designee submits the CAPA table to the auditee within 30 business days from the date of the audit closure to allow the auditee to respond to objectionable conditions and observations post audit. (note: audit reporting requirements may vary contingent upon organization)

File Audit Report and Distribute CAPA Plan (table)

- The CAPA Response Table includes instructions to:
  - Respond to the CAPA observations within 30 calendar days from the date of the auditee's receipt of the completed CAPA Response Table. (note: audit response requirements may vary contingent upon organization)
  - Respond with a root cause analysis, corrective actions and/or preventive actions (as applicable), completion timelines and person responsible for addressing each corresponding CAPA item within the auditee's or stakeholder's/functional area's organization
- The auditor or designee may grant extensions to the auditee response time when deemed reasonable based on discussion with auditee by submitting a CAPA extension request
- The auditor or designee tracks distributed copies of the CAPA Table to ensure timing of CAPA responses and extensions are documented.

CAPA Responses and Close Audit

- The auditor or designee closes the audit when the documented responses to the CAPA table are assessed as satisfying regulatory, stakeholder and auditor requirements

- When auditee CAPA responses are deemed acceptable by auditor, an audit certificate will be issued to auditees.

- The auditee will receive written communication from the auditor (e.g., email) stating that the CAPA responses have been accepted.

- If CAPA responses from the auditee are deemed unacceptable, the auditor and auditee will discuss a means of resolution. Final resolution will be documented in the CAPA Table.

CAPA Responses: Effectiveness verification

- The auditor or designee may perform effectiveness verification (EV) of major or critical systemic observations identified to assess the effectiveness of the corrective and/or preventive action implemented per auditee defined completion times defined in the final approved CAPA table

- EV activities may include but not be limited to the following :

  - Relevant documentation review by submission of supporting documentation from auditee or stakeholder/functional area.
  - Discussion with auditee or stakeholder/functional area.
  - Follow up audit
  - EV will be documented within the CAPA Table

CAPA Responses and Close Audit

The auditor or designee closes the audit cycle when:

- Auditee provides responses are acceptable to demonstrate remediation and control over current and potential issues of noncompliance
- Auditee final responses to the CAPA Table are approved by the management and stakeholders.
- Auditee not responsive to the CAPA Table (i.e., ignores repeated requests to acknowledge or respond to audit observations through the CAPA process)

CAPA Responses and Close Audit

- The auditor or designee manages responses to CAPA observations to include collection of supporting documentation for corrective and/or preventive actions taken to address all observations (i.e., performs effectiveness verification).

- The auditor or designee will evaluate the responses and will either indicate: *Response Accepted* or indicate *Additional Information Requested* for each of the observations.

- Each auditee or stakeholder and auditor entry, within the CAPA table will be dated and initialed by individual writing responses.

CAPA Responses and Close Audit

- The auditor or designee discusses audit closure with the auditee and updates final CAPA tracking information
- CAPA Response Table is signed and dated by responsible party (e.g., auditee and lead auditor) or
- The auditor or designee completes and submits an audit certificate to the auditee once acceptable CAPA responses have been received (Prior to CAPA closure)

Archive Audit Documentation

The auditor or designee archives the original audit report, CAPA Table, responses to CAPA Plan, collected supporting evidence and final audit tracker in Quality files

CAPA activities must be tracked on a CAPA tracker.

Audit and CAPA Summary

Audit planning phase includes:

- Holding and audit planning meeting with the auditee
- Developing and sending and Audit Notification Letter to the auditee (describing information agreed upon at the audit planning meeting.

Audit Conduct phase includes:

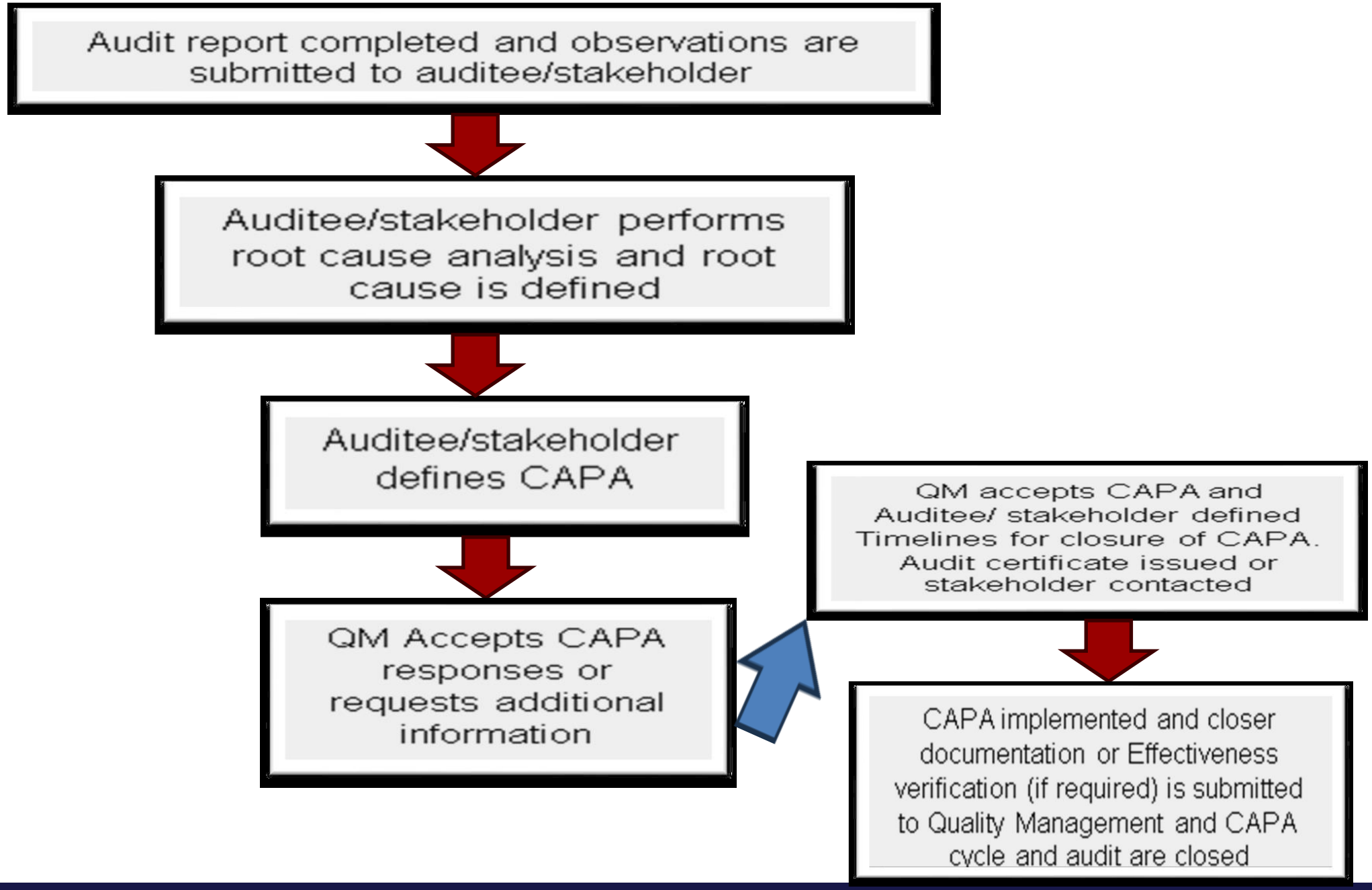
- Conducting and opening meeting
- Facility tour
- Key personnel interviews
- SOP and supporting document review
- Daily debriefs and final closeout meeting

Audit reporting and CAPA distribution includes:

- Audit reporting, finalization and filing
- CAPA distribution, auditee/auditor responses, and CAPA acceptance
- Possible CAPA extension request (by auditee)
- Issuance of Audit Certificate
- EV after all CAPA timelines have been met.

Post audit activity includes:

- Audit documentation management and filing (by auditor’s organization)
- CAPA tracking and management (by auditor’s organization)


Audit report completed and observations are submitted to auditee/stakeholder
Auditee/stakeholder performs root cause analysis and root cause is defined
Auditee/stakeholder defines CAPA
QM Accepts CAPA responses or requests additional information
QM accepts CAPA and Auditee/ stakeholder defined Timelines for closure of CAPA. Audit certificate issued or stakeholder contacted
CAPA implemented and closer documentation or Effectiveness verification (if required) is submitted to Quality Management and CAPA cycle and audit are closed

Quiz (1 minute)

1. When conducting an external audit, auditors will:
   a. Only assess the processes related to the examination phase of testing.
   b. Compare the laboratory's practices with established standards.
   c. Identify issue of non-compliance to regulatory/accreditation standards during opening meeting
   d. Prepare the audit plan prior to contacting the auditee to check the feasibility of the audit.
   e. All

Quiz (1 minute)

2. Which of the following is not included in the content of the audit plan?
   a. Scope
   b. objective
   c. Audit criteria.
   d. Audit evidence.

Quiz (1 minute)

3.During the audit, information relevant to the audit objective, scope, and standards would be collected through:

a. Observation
b. Interview
c. Document review.
d. All

Quiz (1 minute)

1. The CAPA (corrective/preventive action) table includes all except
   a. All observations
   b. Root cause and corrective/preventive action as applicable
   c. Responsible person for addressing the observation and timeline for completion.
   d. Audit thank you letter.

Quiz (1 minute)

1. The auditor closes the audit when:
   a. The auditee provides responses to the CAPA Table & supporting evidence that the observation has been remediated.
   b. The auditee is not responsive to the CAPA Table
   c. The auditee's final response to the CAPA Table is unacceptable.
   d. All except C

QUESTIONS ???

Case study

1. **You are a newly assigned internal auditor in a microbiology laboratory that specializes in clinical diagnostics laboratory. The laboratory aims to maintain the highest standards in microbiological testing for the diagnosis of infectious diseases. The management has identified the need for an internal audit to ensure the effectiveness of the laboratory's quality management system (QMS) and to enhance the overall microbiological testing processes.**

Which of the following steps are correct to follow the process for conducting the internal audit ?

a. Develop a checklist **b.** Conducting audit **c.** Audit report **d.** Audit planning **e** . Follow up

1. a b c d e
2. b c a d e
3. d a b c e
4. d b a c e

Answer

1. Develop an audit plan describing the department or functional area to be audited, its objectives and scope, names of the auditor and auditee, schedule (including start and end times), and duration. The audit plan should then be distributed to laboratory management for review.

E.g., of audit plan

Audit number		Audit objective		
Audit scope: Microbiology laboratory		1. To evaluate whether the quality management system of the laboratory comply with the audit criteria. 2. To determine the effectiveness of the implemented quality management system 3. To evaluate the ability of the lab to meet regulatory requirements. 4. To identify opportunities for improvement		
Audit criteria/standard: ISO 15189,				
Areas /processes to be audited	Date	Time	Auditee	Auditor

Answer

2. Prepare a checklist based on the scope of the audit.
3. Conduct the audit.
    - ➢ Opening meeting
    - Opening meeting will be conducted with laboratory management and, where appropriate, those responsible for the functions or processes to be audited to discuss the audit objectives, scope, duration and expectations.
    - Information relevant to the audit objective, scope and criteria/standards will be collected through:
        - ➢ Document review.
- Documents (i.e., quality manual, SOPs, work instructions, forms) will be reviewed to understand the laboratory operations and evaluate compliance with the audit criteria/standards. i.e.,
    - ✓ Are they available?
    - ✓ Current and Approved by authorized personnel?
    - ✓ Periodically reviewed?
    - ✓ Absolute documents are removed?

Answer

- Also, review records related to IQC, EQA, training and competency assessments, equipment calibration and maintenance, non-conformities, corrective actions, and internal audits.
    - ➢ Observation
- Conduct a laboratory tour covering the pre-examination, examination, and post-examination phases of the laboratory to:

    - ✓Evaluate microbiological testing processes, including sample handling, culturing, identification, and susceptibility testing adherence to the documented procedures.
    - ✓Evaluate the adequacy of the work area.
    - ✓Equipment calibration and maintenance status
    - ✓To examine the standard of Housekeeping
    - ✓To ensure that environmental conditions (room temperature, humidity), controlled, monitored and recorded daily

Answer

➢ Interview

- Interview will be conducted with key individuals involved in activities where the audit conducted to gather insights and clarification, to assess their understanding of SOPs and the training they have received.

➢ Closing meeting:

- Closing meeting will be conducted with laboratory management and staff from the area being audited to present audit findings and provide recommendations.

4. Audit Report;

- Audit report will be developed and submitted to the laboratory management .

5. Follow-Up:

- Monitor the effectiveness of the implemented corrective action.