EQAsia

Corrective and Preventive action (CAPA)

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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- 3:05 pm	5 min
2	Presentation on CAPA process	3:05-3:35pm	30 min
3	Quiz questions and case studies	3:35-3:55pm	20 min
4	Q/A session	3:55-4:00pm	5 min

Content

- Definition
- Introduction to Corrective and Preventive Action (CAPA)
- CAPA Initiation
- Root Cause Analysis and CAPA Implementation
- Effectiveness Verification
- CAPA Management and Tracking
- CAPA Closure
- Quiz Questions and Case Studies

Definitions

Definitions:

- **Correction –** An immediate action taken to rectify the nonconformity or defect
- **Corrective Action** - Planned action taken to eliminate the cause(s) of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.
- **Preventive Action** – Planned action taken to eliminate the causes of a potential nonconformity, defect, or other undesirable situation in order to prevent occurrence.
- **Effectiveness Verification** - The means by which effectiveness of corrective and/or preventive action implementation is verified by a documented and systemic process.
- **Isolated Audit Finding** - An audit finding that can be attributed to an isolated error but does not reflect a systemic/system wide problem.
- **Root Cause** - Is the basic cause of any undesirable condition or problem, which when eliminated or mitigated will prevent or significantly reduce the effect of the condition or problem.
- **Root Cause Analysis (RCA)** - Is a structured approach utilized in the identification of the basic factor(s) that attribute to an issue(s) of non-compliance within a system (i.e., root cause(s)).
- **Systemic Audit Finding** - Observations that define a systemic and/or recurring trend or pattern that can be attributed to a root cause(s)
- **Non-conformity**: Non fulfilment of the requirement or standard.

CAPA process

- A CAPA process is an essential part of a quality management system ensuring ongoing improvement and adherence to quality standards.
- A CAPA process provides a structured method for the investigation, follow- up, and resolution of issues of non-compliance identified during the audit process or internal escalation by the laboratory functional area
- CAPA plays a crucial role in support of a Quality Management System by:
  - ✓ Identifying and addressing deviations, defects, or issue of non-compliance within the QMS.
  - ✓ Facilitating in-depth investigations to identify the underlying causes of quality problems.
  - ✓ Formulating corrective actions to eliminate the root cause of the defects, or issue of non-compliance and prevent recurrence .
  - ✓ Formulating preventive actions to proactively eliminate potential future problems by modifying processes, systems, or procedures.
  - ✓ Verifying that implementation of CAPA effectively prevents recurrence, ensuring that corrective and preventive actions are effective and sustainable.

CAPA process

Differences between correction, corrective action and preventive action

Correction
Put fire out
(at the time)

Corrective Action
What caused fire
and how to prevent
recurrence
(after event)

Preventive Action
Stop fire from
happening
(before event)

CAPA process

- In order to enhance a laboratory's understanding of quality issues, resolution, and the effectiveness of corrective and preventive measures, the laboratory must establish and maintain procedure for implementing corrective and preventive actions.
- Such procedure should include:
  - ✓ Review of nonconformities.
  - ✓ Identification of root cause by conducting root cause analysis.
  - ✓ Determining and implementing corrective/preventive actions.
  - ✓ Documenting the outcomes of corrective/preventive actions taken.
  - ✓ Assessing the effectiveness of implemented corrective/preventive actions.
  - ✓ Closure of the CAPA process.

CAPA process

Information for CAPA initiation can be gathered through (but not limited to):

Internal sources

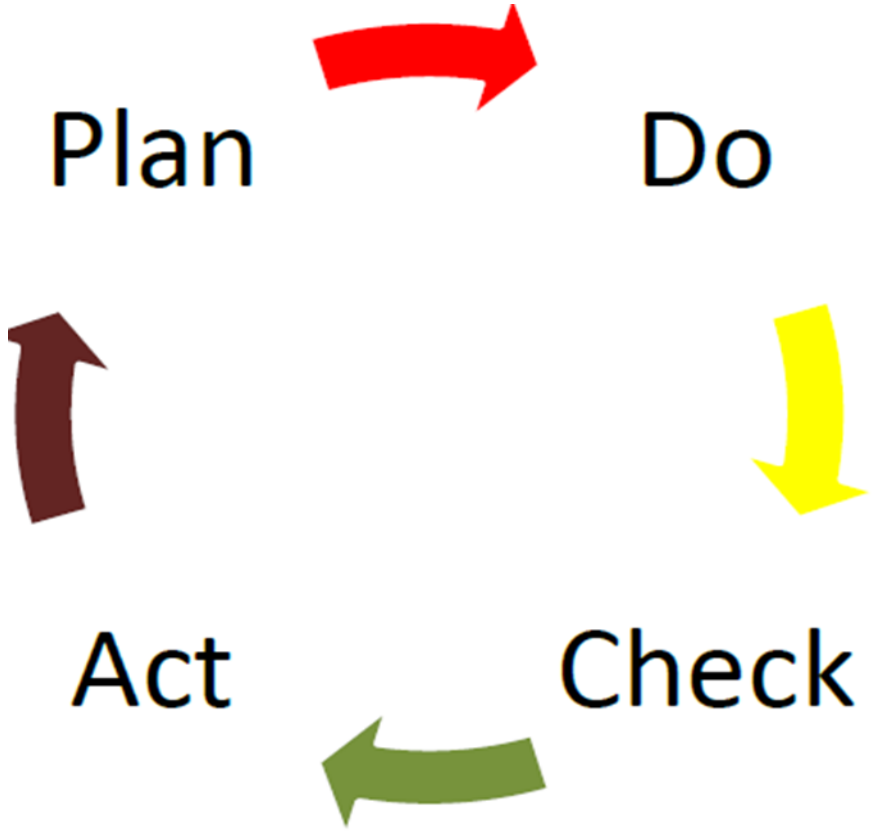
- Mistakes and issues encountered at any point in the laboratory's workflow (Pre-analytical, Analytical and Post analytical .
- Reviews of documentation.
- Observations made by staff.

External sources

- Customer complaints.
- Findings from inspection and external audits.
- Failures in proficiency testing (PT).

CAPA process

A CAPA process uses an efficient approach of the PDCA (Plan-Do-Check-Act) cycle to resolve issue of non-compliance, defects or problems



CAPA process

Escalation of Audit Observations or Non-audit Related observations

- Audit Reporting and CAPA are a means of identifying and escalating significant issues of noncompliance that represent a departure from regulations/standards/guidance and that may impact patient safety and/or data integrity.
- Non-audit observation identified by the laboratory department or functional area must be documented (e.g., by use of hard-copy or electronic CAPA management system) and reported to the Quality Assurance Unit of the laboratory to initiate the CAPA process
- The laboratory should designate a dedicated Quality Assurance Unit responsible for *objectively* overseeing the quality of the laboratory activities.
- The laboratory should align identification and management of audit/non-audit observations and escalation with a CAPA process as a means of ensuring that audit/non-audit observations are documented, tracked and effectively resolved.

CAPA process

Auditor / Auditee / Quality Assurance / Stakeholder Interactions

- The most effective CAPA process is fielded by interactions between an organization's Quality Assurance/Quality Management (QA/QM) and the Auditee/Laboratory.
- Interaction with Quality Management (QM) should consist of guidance and support through discussion with the auditee /Laboratory(especially for Auditee/Laboratory that are unfamiliar with a CAPA process).
- QM should refrain from providing recommendations (i.e., defining the auditees or Laboratory CAPA responses) as this introduces bias; however, QM should mentor and support stakeholders.

Note: the auditee/Laboratory is most familiar with systems and should better understand how to address issues of non-compliance. QM defining corrections/preventions may negatively impact both the auditee/stakeholder and QM.

CAPA process

CAPA Initiation

- The CAPA process is initiated upon receiving audit or non audit related observations from the auditor's organization or through internal escalation. The **Auditee/Laboratory** then begins the CAPA process by :
  - ✓ Identification the root cause by performing root cause analysis (RCA) for each finding
  - ✓ Developing action plan and defining corrective and/or preventive actions based upon root cause
  - ✓ Defining timing of anticipated CAPA closure(s)
  - ✓ Auditor/ QA unit and Auditee/Laboratory interactions supporting CAPA acceptance, effectiveness verification and CAPA closure.

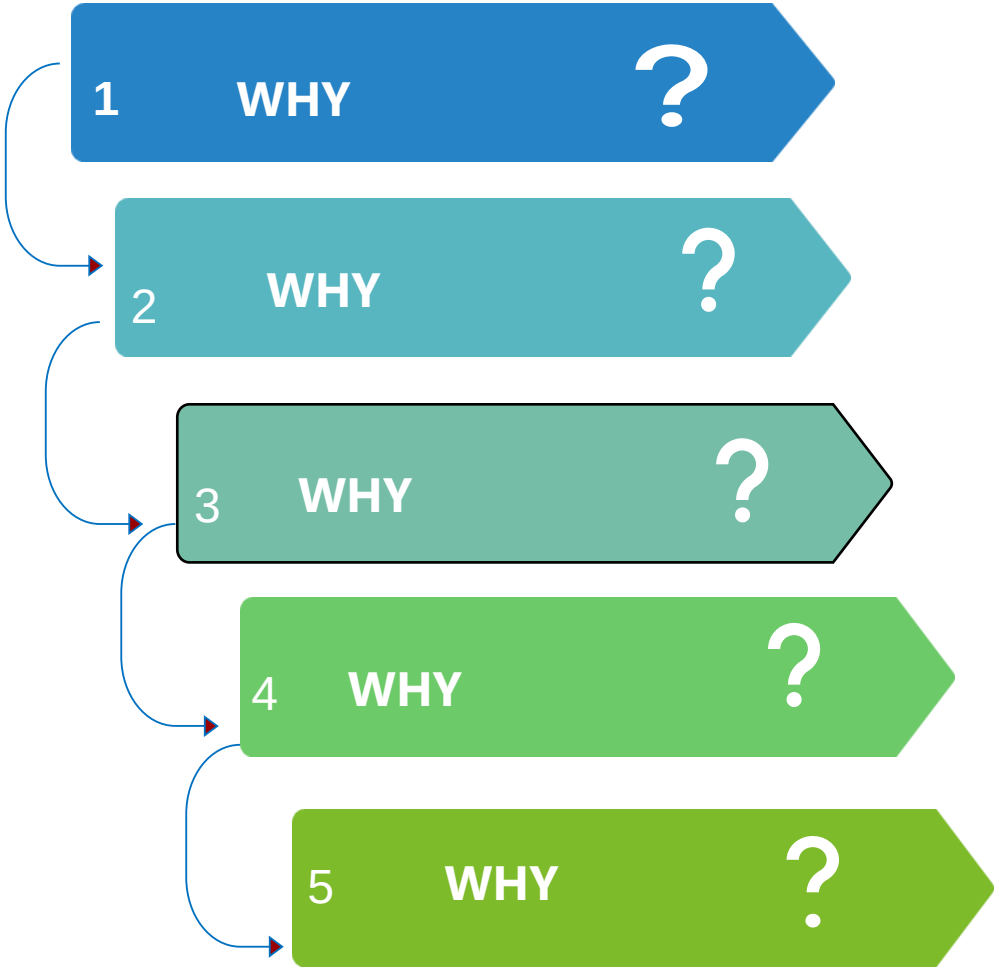
CAPA process

How to perform root cause analysis (RCA)

- **RCA is required to identify the basic cause(s) of any undesirable condition within a quality system. There are several techniques which may be utilized by the Auditee/Laboratory in identifying root cause; two common and effective methods are:**
- **Five (5) Whys Technique** –
  - ✓ A question-asking method used to explore the cause/effect relationships underlying a particular problem.
  - ✓ This method is simple but effective in evaluating root cause relating to a single or less complex issue. Ultimately, the goal of applying the 5 Whys method is to determine a root cause of a defect or problem

Example 5 Whys Technique

Problem statement : Why is the patient still in the hospital



Because the test results are not available

Because the laboratory has not completed testing.

Because the instrument is not working

Because the instrument periodic maintenance was not performed on schedule, which caused it to malfunction.

Because it was not included in the maintenance schedule.

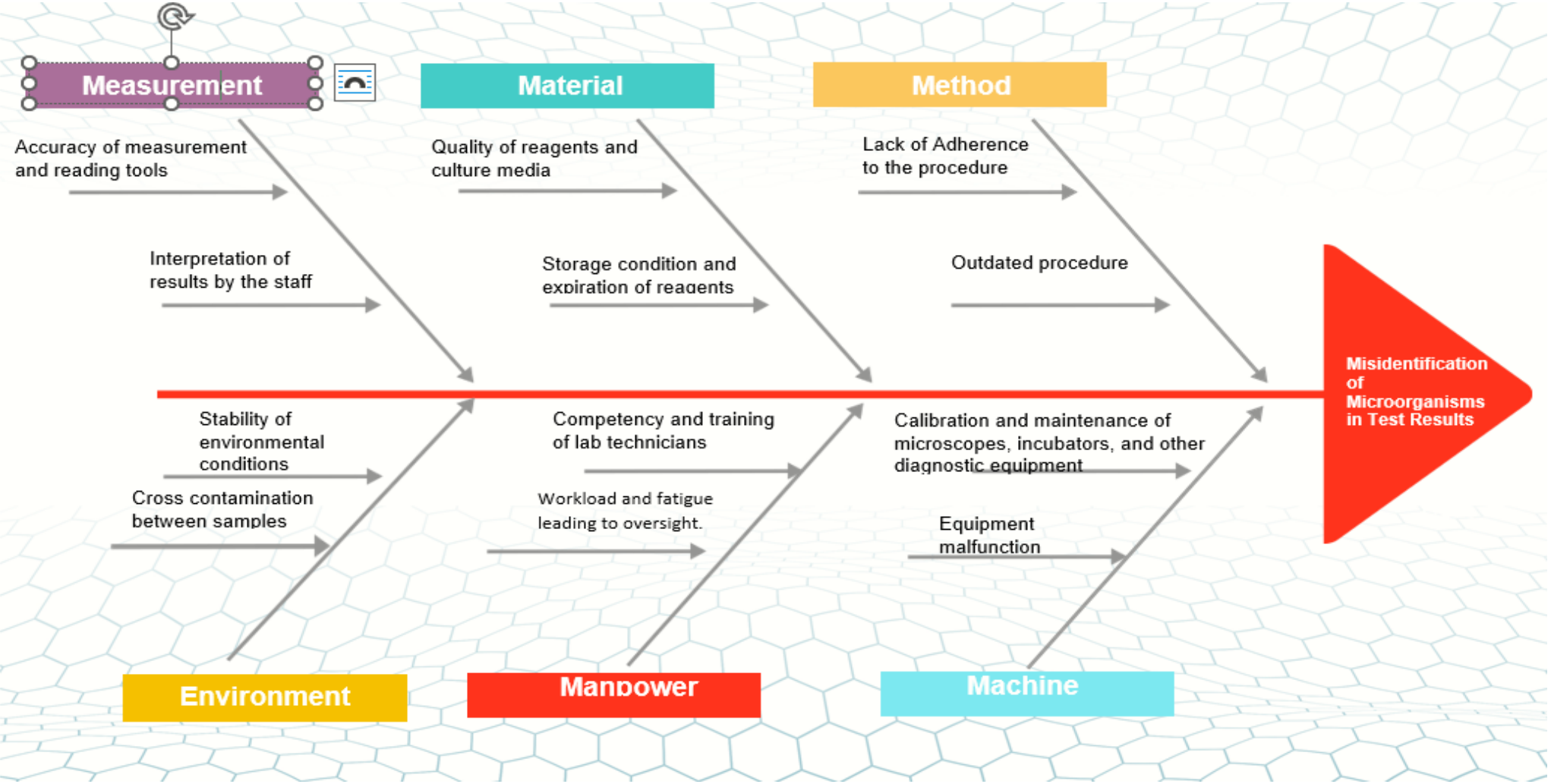
Root cause

CAPA process

2. **Fishbone diagram**

- ✓ Is a brainstorming tool used to identify potential cause of a problem and organizing ideas into meaningful categories
- ✓ This method of RCA is useful in evaluating more complex/multi-factorial issues which have led to issues of non-compliance.
- ✓ Procedure for fishbone diagram includes:
  - Assemble a team of members who have direct insight into the current issue.
  - Agree upon a problem statement (effect) with the team, which will be displayed at the head or mouth of the fish.
  - Brainstorm the major categories that may have contributed to the problem or non-compliance (e.g., Method, Material, Machine, Manpower, Environment, and Measurement).
  - Write these categories as branches from the main problem statement.
  - Brainstorm all possible causes of the issue using **5 Whys technique** until the final root cause has been identified.

Example fishbone diagram



CAPA process

Identification of Root Cause (RC) and CAPA Implementation

- Once RC is defined, the Auditee/Laboratory proceeds to develop an action plan and describe how corrective and/or preventive measures will be defined and applied to address the observation(s):
  - Observations may require both corrective and/or preventive action
  - Observations may only require preventive measures only (e.g., due to elapsed time of noncompliance it is too late to correct data)
  - Observations may only require corrective measures (e.g., isolated observations)

CAPA process

CAPA Responses and Timelines

- **Once CAPA response is complete, the *Auditee/Laboratory* must then define timelines for the completion and closure of the CAPA.**
  - The Auditee/Laboratory should ensure that realistic timelines for completion of the task at hand are described.
  - Often an inexperienced Auditee/Laboratory will describe a time for completion of a CAPA that falls short of the actual time required for implementation. In this case, a member of the audit team or the Quality assurance unit of the laboratory may be needed to mentor and guide the Auditee/Laboratory to an acceptable CAPA response related to timing.
  - Again, care should be taken to ensure that the auditor or the Quality assurance unit of the laboratory only advises and do not directly instruct the Auditee/Laboratory as this will introduce bias.

CAPA process

Effectiveness Verification (EV)

➢Once the auditor/ QA unit and the Auditee/Laboratory have agreed that the defined CAPA and timelines for completion are acceptable to address the issue(s) of non-compliance, then the CAPA moves towards the final completion phase of the CAPA cycle: effectiveness verification.

- EV is a means by which effectiveness of corrective and/or preventive action implementation is verified by a documented and systemic process.
- EV may include the Auditee/Laboratory providing documentation which describes evidence of action taken by the Auditee/Laboratory which has resolved the audit/non observation (i.e., Documentation is provided to the audit team/QA unit of the laboratory which reflects, to a reasonable degree, that actions taken by the Auditee/Laboratory have effectively resolved the audit/non audit finding and that the issue will not recur).

CAPA process

CAPA Closure

- When all phases of the CAPA process have been satisfied through documented interaction between the auditor/ Quality assurance unit(e.g., compliance unit's document control and management system) and the Auditee/Laboratory ; and the CAPA process and effectiveness of the CAPA have been confirmed, then the CAPA can be designated as closed.
- The auditor's organization/QA unit and the Auditee/Laboratory should both maintain records to support the CAPA effort in their official files.

Note: As CAPA documentation supports audit activity and defines audit observations, CAPA documentation should not be maintained in files with direct visibility to regulatory agencies.

CAPA process

CAPA Management and Tracking

- To ensure all CAPAs are tracked to closure,
  - Quality Assurance/Quality Management units should develop and implement a CAPA tracking system.
  - In many organizations this is linked to their audit management or compliance department systems and ensures that the CAPA and its status (e.g., open or closed) can be determined at any point to satisfy both organization management and/or regulatory agency queries.

CAPA Plan/Table Example

OBSERVATION 1 of 4 Classification: Audit Internal Escalation Criticality: Critical Major Minor Opportunity for Improvement 1. <Enter GXP Related Categories of Observation, e.g., Training and Qualification, IRB/IEC, etc.>	
Observation: <Enter general description of observation consistent with verbiage entered under "observations" in the audit report.>	
Evidence/Comments:	
<Enter supporting evidence and detailed comments and examples related to the audit observation> 1.X a. X	Response (please include date, initials and department of responder with each entry): Root-Cause: Corrective Action (as applicable): Preventive Action (as applicable): Date of Projected Completion: Date Action Completed: Effectiveness Verification (QA USE ONLY): Responsible Person:
References: •<Enter applicable regulatory requirements, SOPs, Industry Guidance, etc.>	

Observation criticality designation:

Critical	Observations that would be sited 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 right or safety of patient
Major	Observations that have a 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 right or safety of patients
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

Conclusion

- Audit Reporting and CAPA are a means of identifying and escalating significant issues of noncompliance that may impact compliance to regulations/standards/guidance requirements and may negatively impact patient safety and/or data integrity.

Quiz (1 minutes)

1. Which of the following is a key objective of the CAPA process?
    a. To assign blame to individuals responsible for the non-conformity.
    b. To Identify and address the root cause of non-conformities and preventing their recurrence
    c. Reducing the number of employees in the laboratory
    d. Limiting the scope of quality audits

Quiz(1 minutes)

2. The final phase of the CAPA process is:

   a. Defining corrective/preventive action

   b. Defining the non-conformities

   c. Performing root cause analysis

   d. Performing effectiveness verification

Quiz (1 minute)

3. Corrective actions differ from preventive actions in that corrective actions:

   a. Address potential issues before they occur

   b. Are implemented after a problem has been identified

   c. Focus solely on financial aspects

   d. Are not documented within the quality management system

Quiz(1minute)

4. Which of the following actions are examples of preventive measures to address recurrent equipment failures in a microbiology laboratory?

a. Reacting to failures as they occur
b. Providing ongoing training to laboratory personnel on proper equipment handling and maintenance.
c. Implementing regular equipment maintenance.
d. Increasing the workload of laboratory technicians to compensate for equipment downtime.

Case study 1(1 minute)

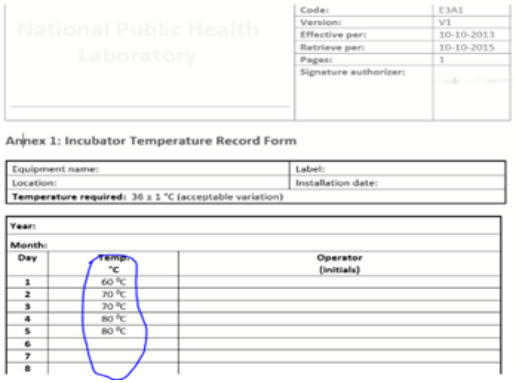
5. In a microbiology laboratory, a technologist observed that the automated incubator used for microbial culture is consistently running at a higher temperature than the setpoint, potentially affecting the accuracy of test result. What step should be taken to address this observation and ensure the integrity of laboratory processes?

a. Ignore the observation since slight temperature variations are common in laboratory equipment.

b. Immediately recalibrate the incubator to the correct temperature setting.

c. Conduct a root cause analysis to identify the reason for the temperature deviation.

d. Place a thermometer inside the incubator to manually monitor the temperature.



Case study 2 (1minute)

6. During routine quality control checks, a microbiology laboratory technologist discovers that several culture plates have been mislabeled, leading to potential errors in test results. What is the appropriate corrective action in this scenario?

a. Continue testing with the mislabeled plates and record the discrepancies in the final report.
b. Immediately discard the mislabeled plates and request new samples for testing.
c. Conduct a root cause analysis to determine why the mislabeling occurred and implement measures to prevent recurrence.
d. Ignore the mislabeling issue as it does not impact the validity of the test results.

Case study 3(1 minute)

7. Your laboratory recently participated in an External Quality Assessment (EQA) for bacterial identification and antimicrobial susceptibility testing. The laboratory received lower than expected results, indicating significant discrepancies in both identification and susceptibility testing compared to EQA standards (e.g., erroneous identification of pathogens, mis- interpretation of AST result).

7.1. What is the first step your laboratory should take to address the discrepancies identified in the EQA for bacterial identification and antimicrobial susceptibility testing?

a. Implement immediate corrective actions to rectify the errors identified in the EQA results.
b. Conduct a root cause analysis to determine the underlying reasons for the discrepancies observed in the EQA results.
c. Disregard the EQA results and continue laboratory operations as usual.
d. Blame individual laboratory technicians for the discrepancies and take disciplinary action.

Case study 3 Cont. (1 minute)

7.2. After conducting a root cause analysis, what is the next step your laboratory should take to address the discrepancies identified in the EQA for bacterial identification and antimicrobial susceptibility testing?

a. Assign blame to individual laboratory technicians responsible for the discrepancies.
b. Implement immediate corrective actions without further investigation.
c. Developing action plan and implementing corrective and/or preventive actions based upon root cause
d. Discontinue participation in EQA programs to avoid future discrepancies.

Case study 3 Cont. (1 minute)

7.3. What is the purpose of implementing preventive actions in response to discrepancies identified in an EQA for bacterial identification and antimicrobial susceptibility testing?

a. To assign blame for past discrepancies observed in the EQA results.
b. To address individual errors made by laboratory technicians during the EQA process.
c. To prevent the recurrence of future discrepancies by addressing systemic issues identified in the root cause analysis**.**
d. To disregard the EQA results and continue laboratory operations without any changes.

Case study 3 Cont. (1 minute)

7.4 Which of the following would be potential cause of the discrepancies in pathogen identification and AST

a. Lack of training or proficiency in pathogen identification and AST
b. Outdated procedure
c. Storage condition of the reagent (i.e., dehydrated media), antibiotic disc and quality control strain
d. Equipment malfunction
e. All

QUESTIONS ???