



THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH



Timely Accurate Diagnostics for a TB-Free Africa

Laboratory Quality Management System

Module 13: Assessment

Venue:

Presenter:

Date:

Learning Objectives

At the end of this module, participants will be able to:

- develop a process to prepare your laboratory staff for an external audit;
- plan and manage an internal audit;
- discuss how to use results from a laboratory audit;
- Advocate for the importance of taking corrective actions.



Module Outline

External Audit

Internal Audit

Internal Audit Program



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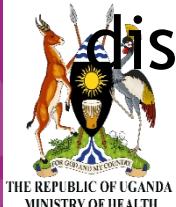
Activity 13-1: Scenario—Organizing an Internal Audit

Purpose:

The purpose of this activity is to discuss the main elements of organizing an audit based on the experience of the participants.

Suggested time: 10 minutes

Instructional method: Problem solving: use as an individual or group activity, or as a class discussion



Problem Scenario

You are the quality manager in your laboratory and you want to organize an internal audit.

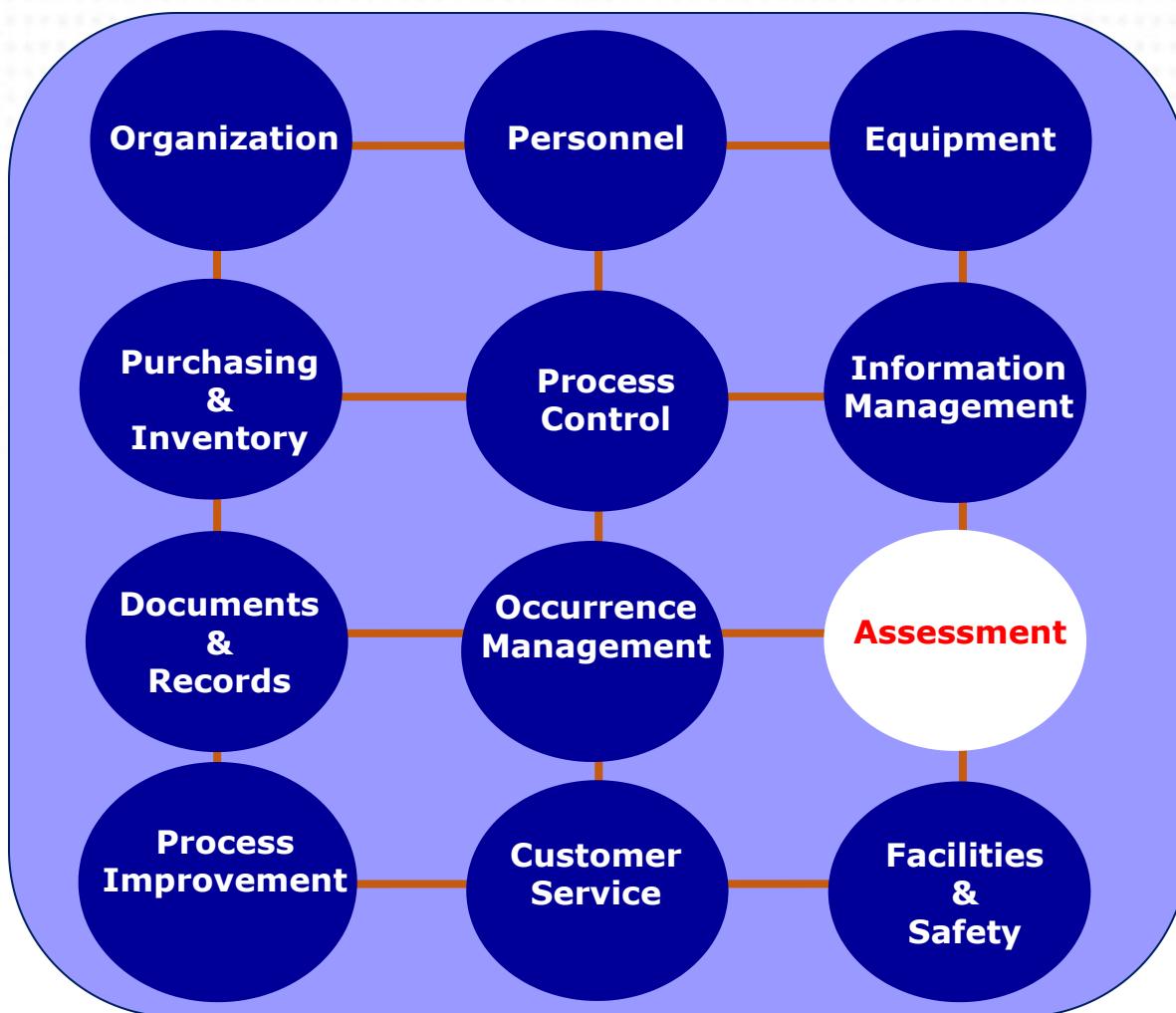
What steps will you take?



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The Quality Management System



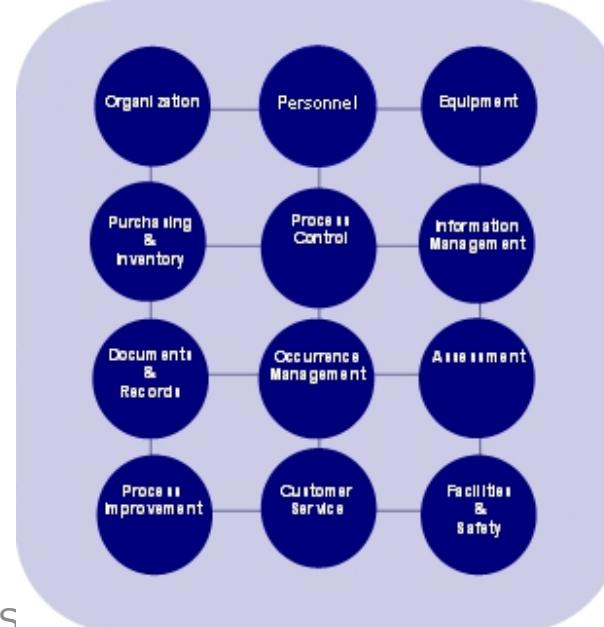
Introduction

Is a means for determining the effectiveness of Laboratory's QMS through internal and external audits



Assessment—Audit

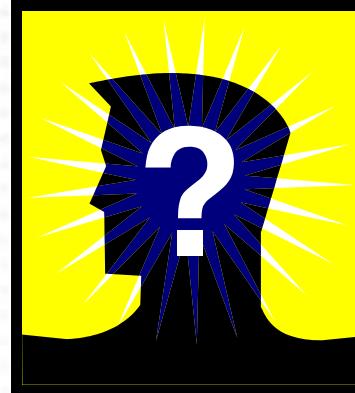
- systematic examination of some part (or all) of the quality management system
- conformance with requirements



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What is an assessment?

Someone is asking:



What is being done?

How does this comply with
written policies and procedures?

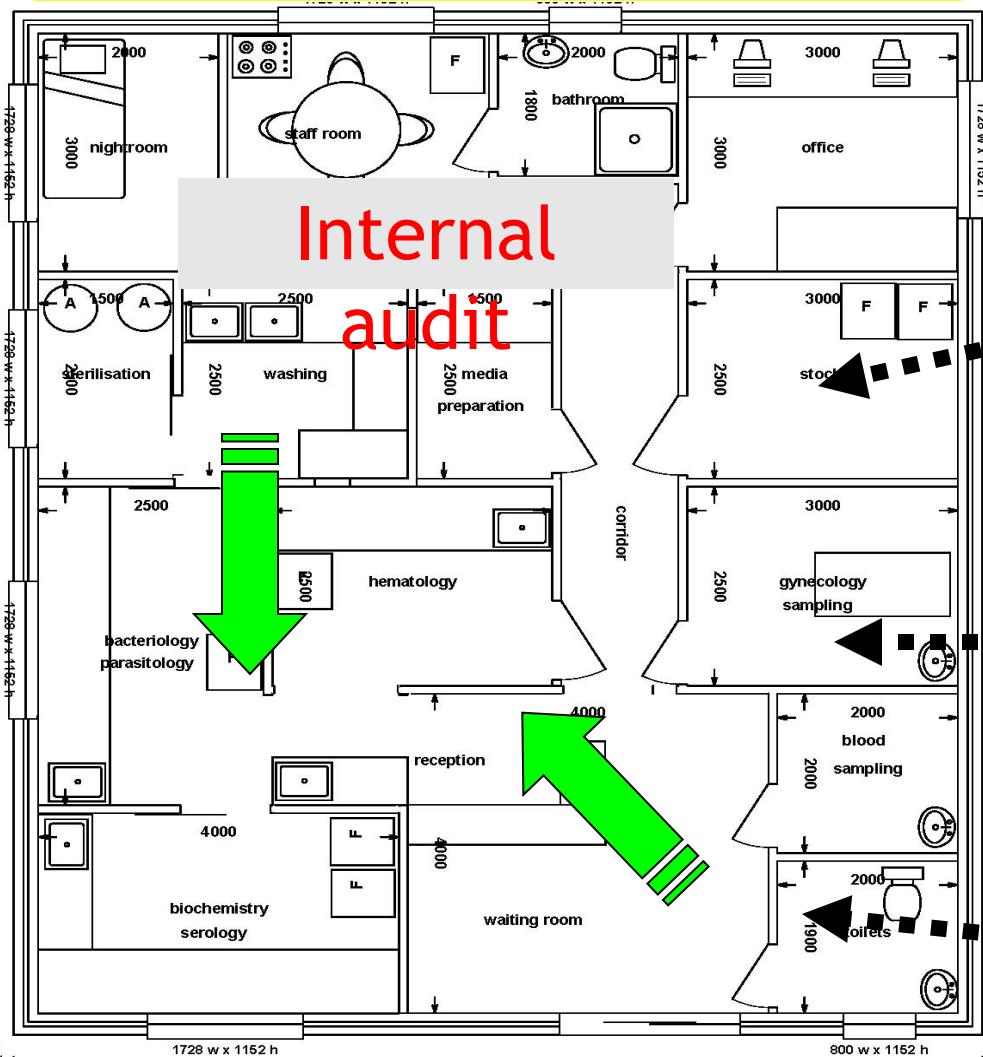


Why perform an assessment?

- learn “where we are” in terms of quality management
- measure gaps
- need information for:
 - planning and implementation
 - monitoring
 - continuous improvement



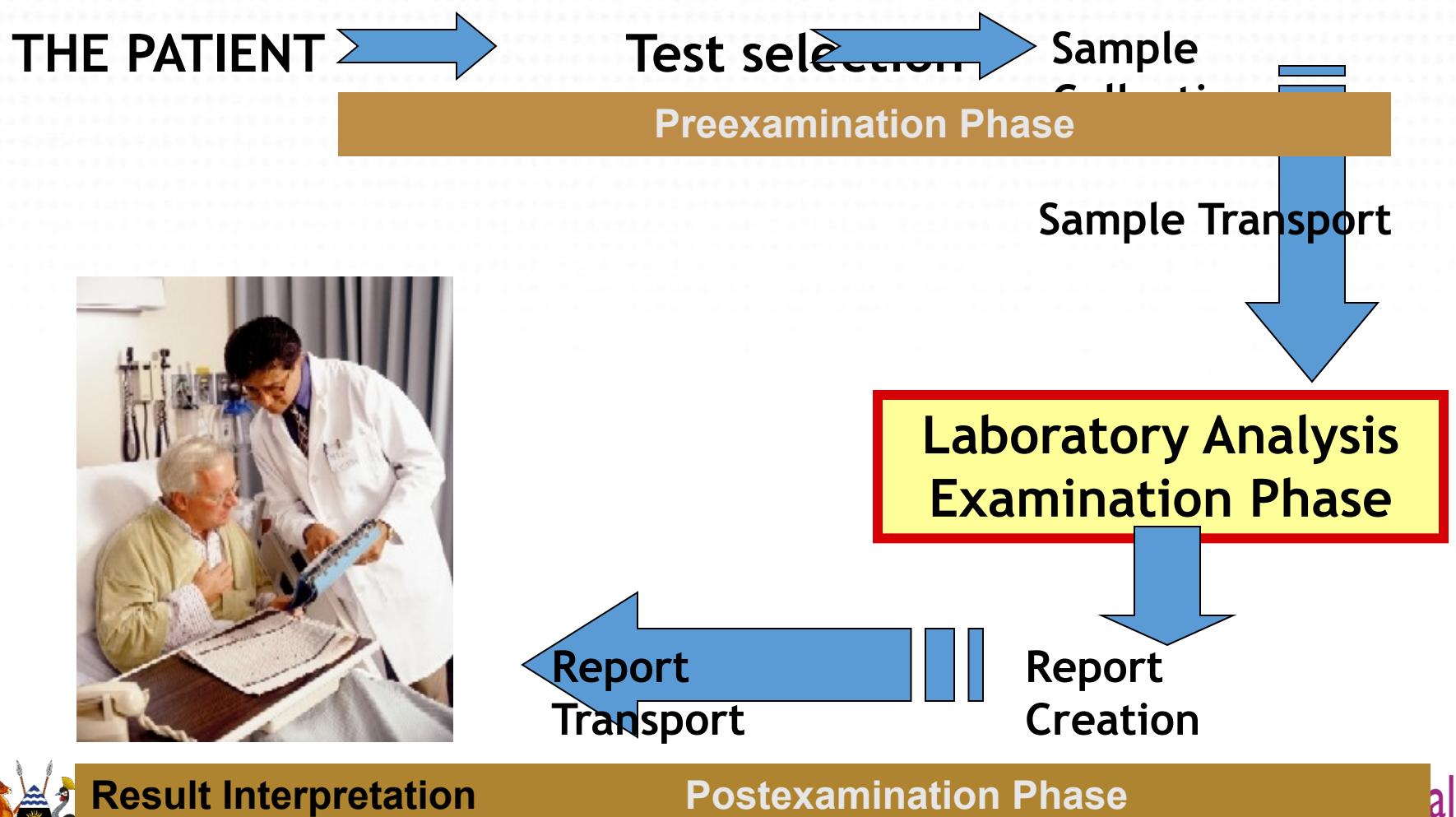
Quality Laboratory



External audit

Outside
group or
agency

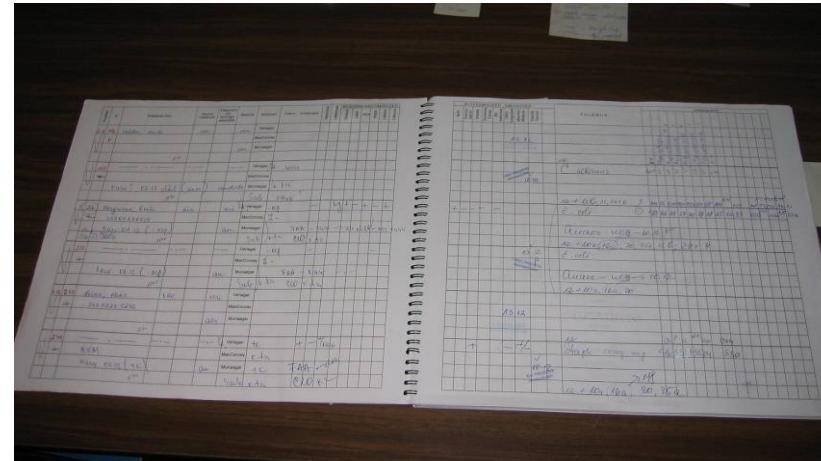
Path of Workflow



Auditing

1. Gather information about:

- process, operating procedures
- staff, equipment, test methods
- environment, handling of samples
- quality control verification activities
- recording and reporting practices



Auditing

2. compare findings with documented quality management system
3. identify breakdown in system or departure from procedures
4. do something with audit results



2. External Audits

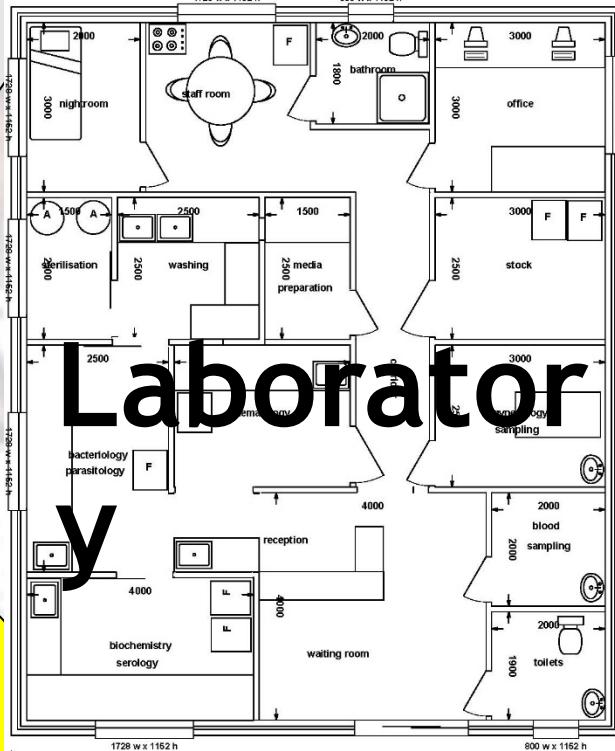
External auditors

Health authorities

Accreditation body

Funding program

Public health program



Standards

- Laboratory policies, processes, and procedures are documented and comply with designated standards.
- Different standards can be used i.e. international standards or locally developed checklist.
- Requirements as laid down in the standard are being followed.



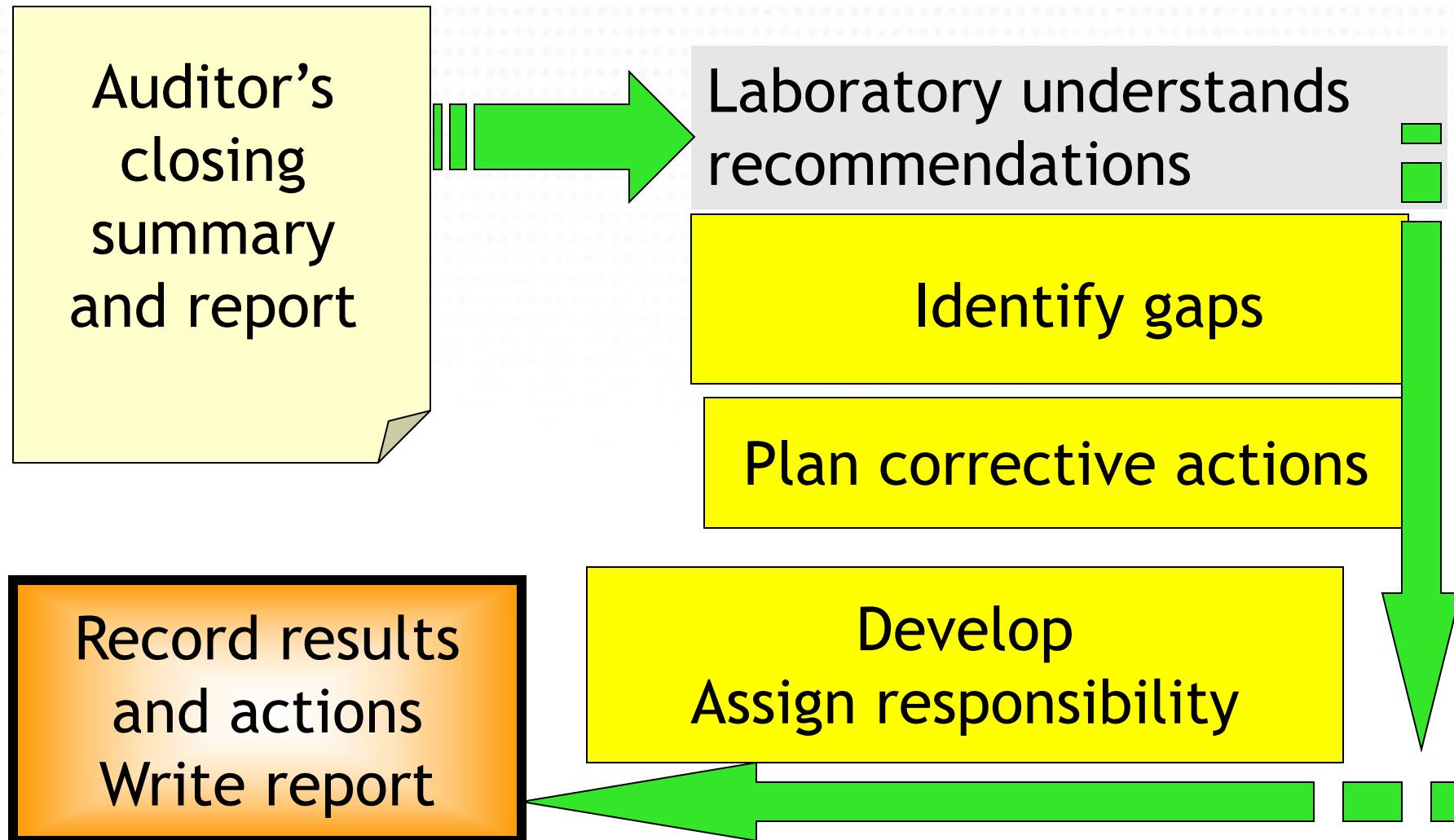
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External Audit Preparation



External Audit Report and Plan of Action



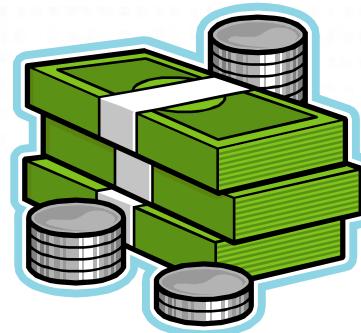
3. Internal Audit



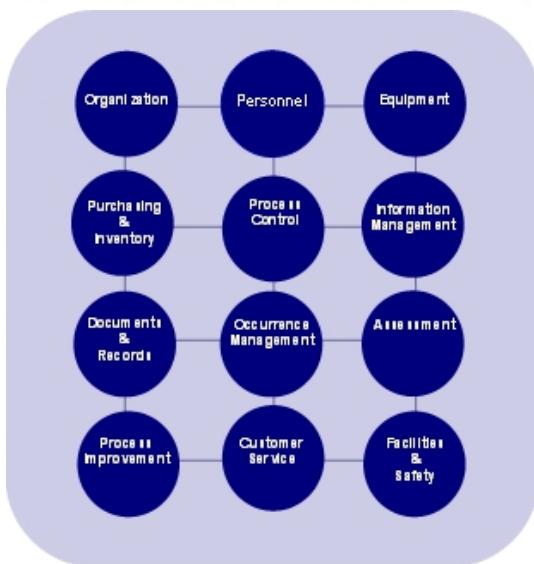
Look at your
own processes



Flexible



Costs less



required by ISO standards
conducted on a regular basis
conducted when problems
identified

Value of Internal Audits

- prepare for external audit
- increase awareness
- opportunity for improvements
- preventive and corrective actions
- opportunity for continuing education
- meeting quality standards



Internal Audits: ISO Requirements

- must have an audit program
- must document procedures
- auditors independent of activity
- results documented and reported to management for review
- prompt follow-up action



Internal Audits

Do not audit your own work

Consultant,
another
Laboratory

Quality Laboratory

Bacteriology

Uries

O&P

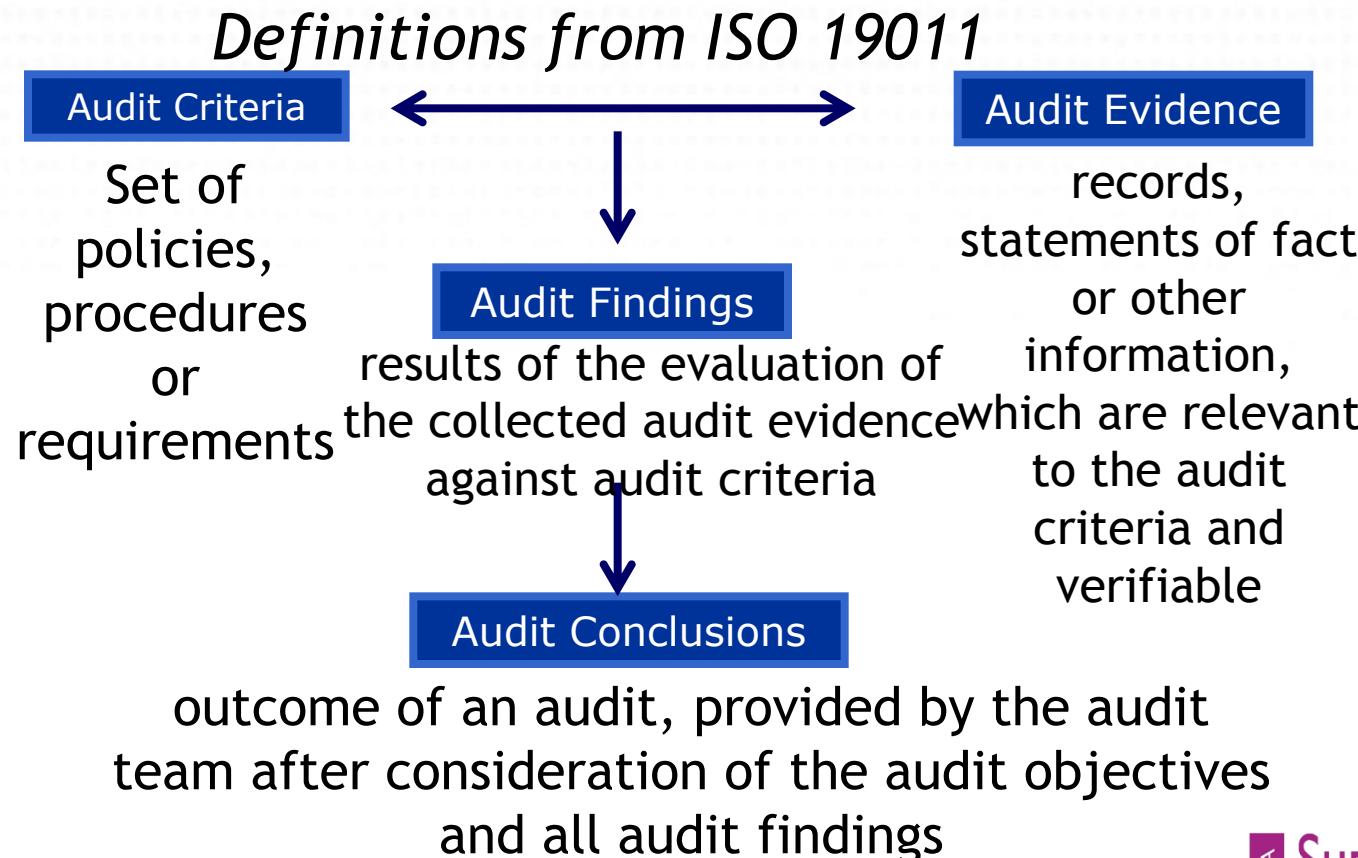
Int. Audit

Int. Audit

Virology



Other Key Definitions - Auditing

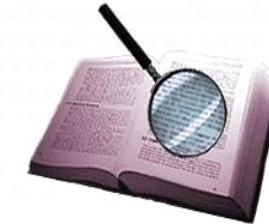


Other Key Definitions -Auditing



Audit Evidence
Objective Evidence

Data supporting the existence or verity of something. Objective evidence may be obtained through observation, measurement, test, or



Observation

Statement of fact made during an audit and substantiated by objective evidence

Non conformity

Non-fulfilment of a requirement

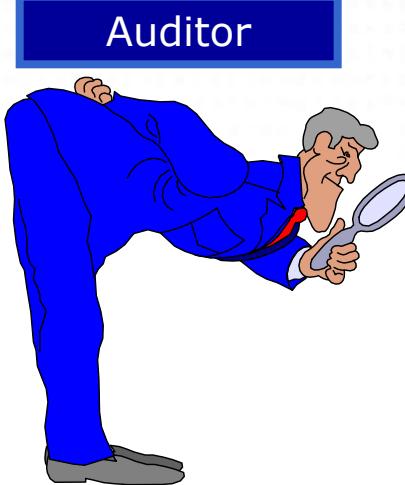
Corrective Action

Action taken to eliminate the cause of a detected nonconformity or other undesirable situation

Other Key Definitions -Auditing

Audit Client

organization or person requesting an audit

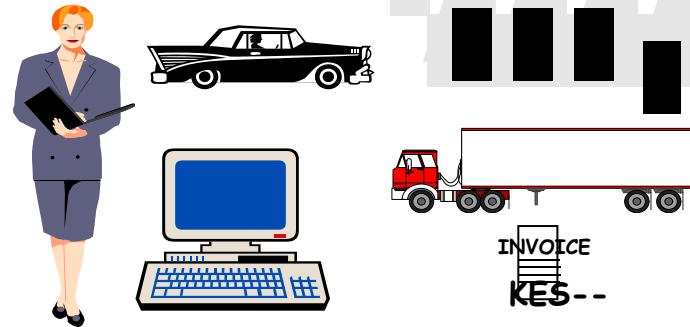


Auditor

person with the competence to conduct an audit

Auditee

organization being audited



Other Key Definitions -Auditing

Auditor



person with the competence to conduct an audit

Audit Team

one or more auditors conducting an audit, supported if needed by technical experts



Other Key Definitions -Auditing

Technical



Audit Team

one or more auditors conducting an audit, supported if needed by technical experts



person who provides specific knowledge or expertise to the audit team

Other Key Definitions- Auditing

Audit program	Set of one or more audits planned for a specific time frame and directed towards a specific purpose (<i>ISO 19011</i>)
Audit plan	Description of the activities and arrangements for an audit (<i>ISO 19011</i>)
Audit scope	Extent and boundaries of an audit (<i>ISO 19011</i>)
Competence	Demonstrated personal attributes and demonstrated ability to apply knowledge and skills (<i>ISO 19011</i>)

Qualifications of Auditors

Qualification as an auditor is based on;-

- Education: minimum qualification as set by the organization
- Training: As an auditor
- Experience: General and specific to the field
- Personal Attributes



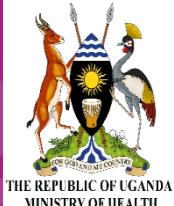
PRINCIPLES OF AUDITING

- INTEGRITY
- FAIR PRESENTATION
- DUE PROFESSIONAL CARE - the application of diligence and judgments in auditing
- CONFIDENTIALITY - security of information
- INDEPENDENCE - the basis for the impartiality of the audit and objectivity of the audit conclusions
- EVIDENCE BASED APPROACH - the rationale behind reliable and reproducible audit conclusions
- RISK BASED APPROACH

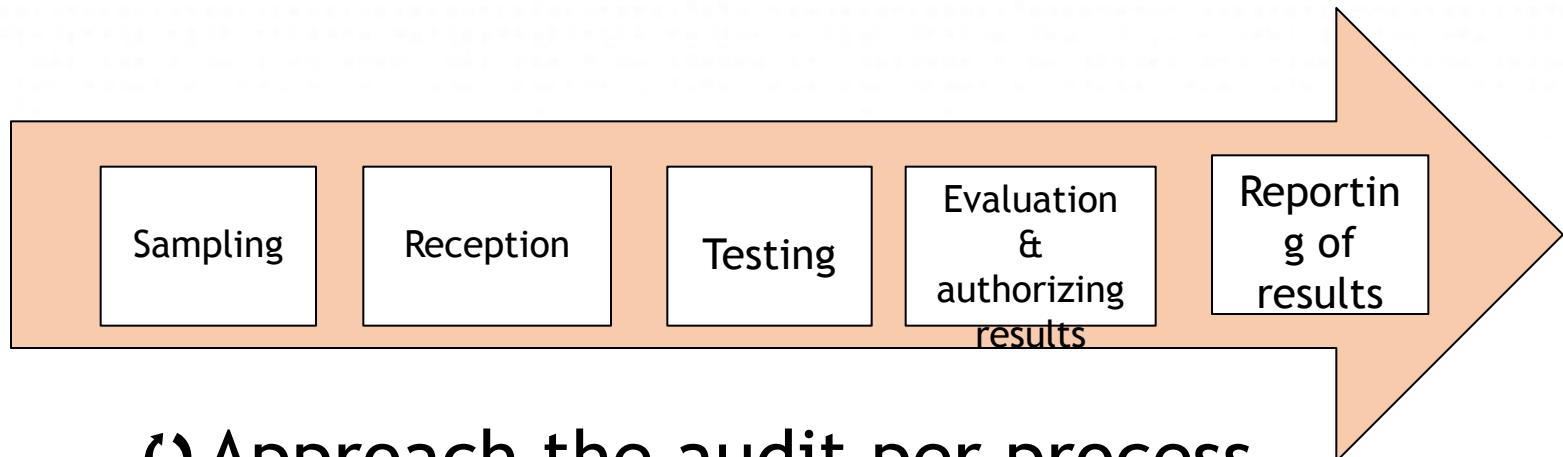


Types of Audits

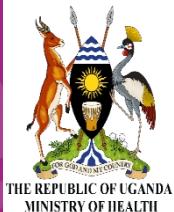
- Internal audit also first party audit - Organization audits its own Quality Management System according to a quality standard
- External audit also third party audit - These are audits by an external independent institution in order to Certify / register the quality management system
- Unscheduled audit either internal or external



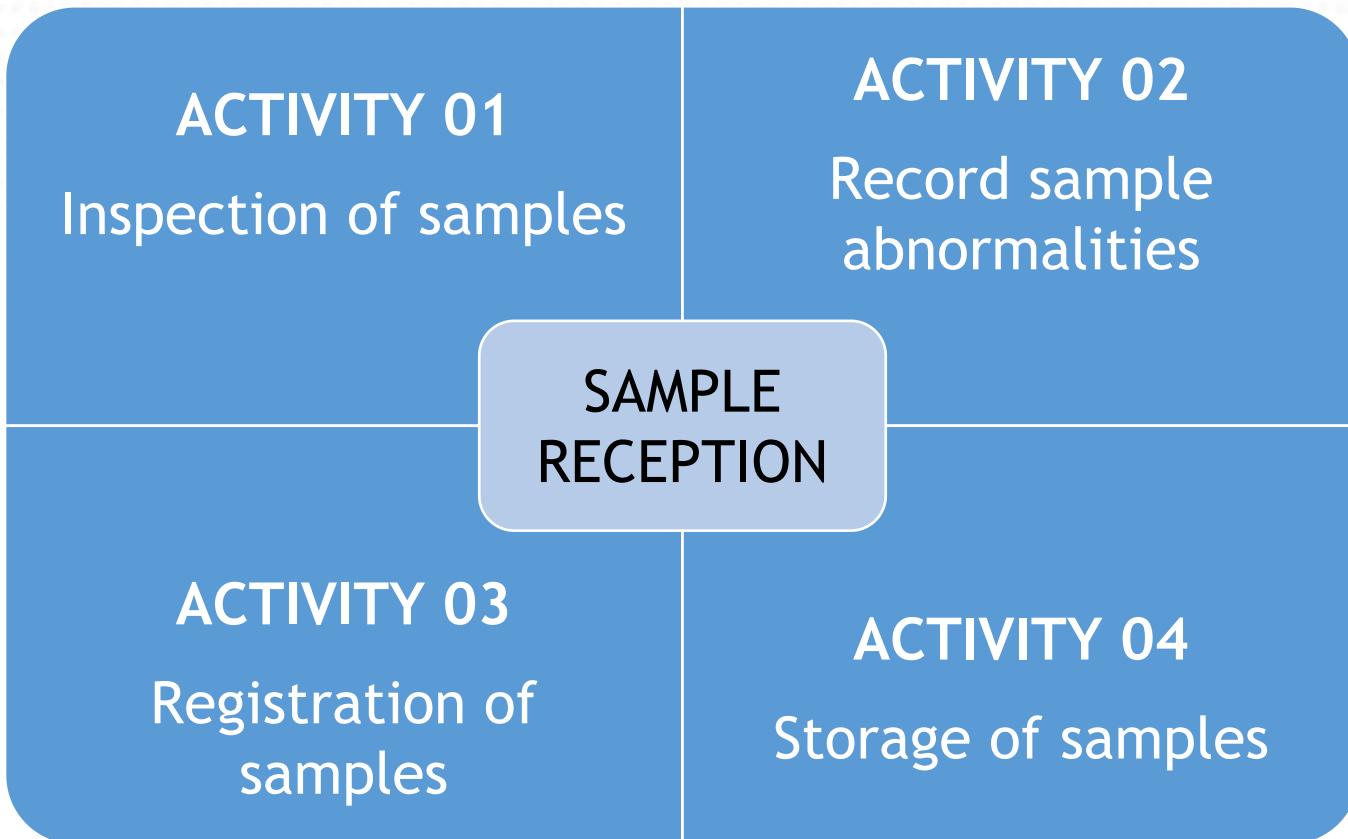
ACTIVITIES, PROCESS & SYSTEMS*



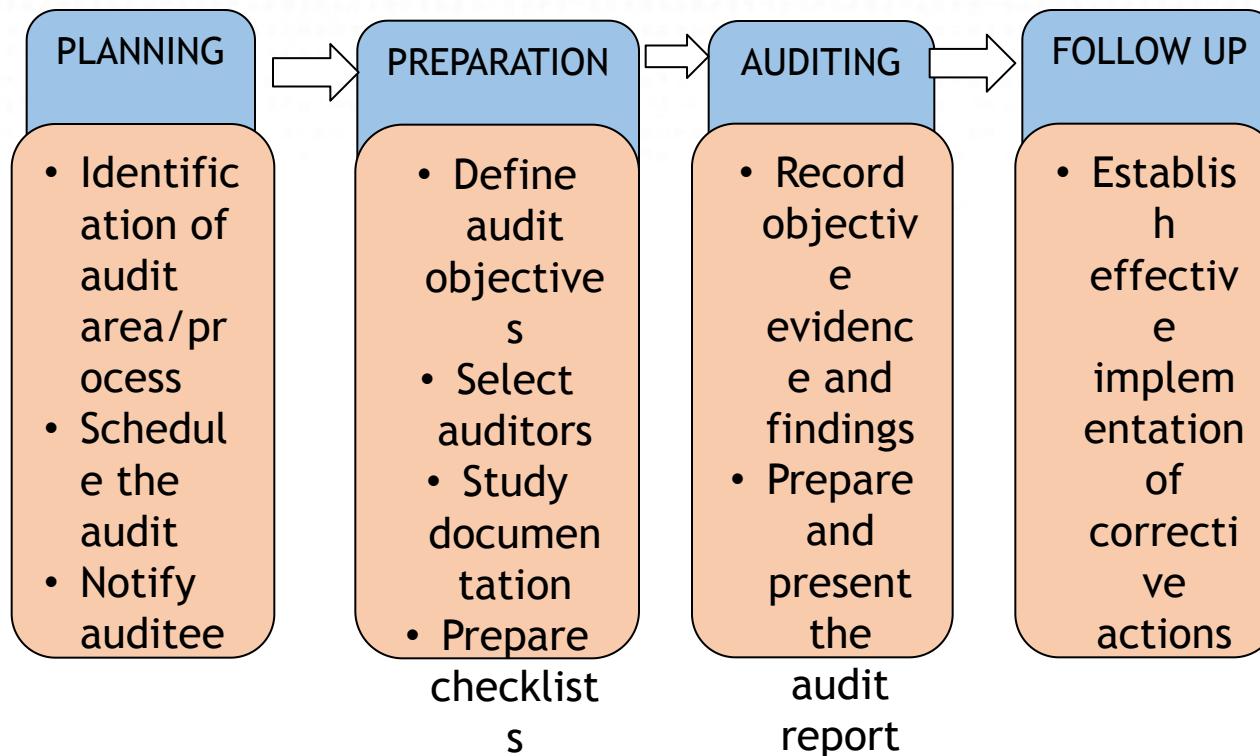
- Approach the audit per process
- Audit the activities within a process



AUDITING ACTIVITIES WITHIN THE PROCESS



Internal Auditing process*



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NC – CA Communication Process*

Internal Auditor

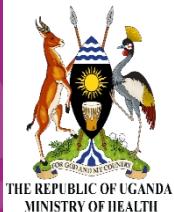
Auditees

- Identify discrepancy
- Record NC
- Leave the NC with Auditee

- Review the NC
- Determine root cause analysis
- Determine solution/CA

- Evaluate if the CA taken addresses the NC

- Evaluate effectiveness of the CA



4. Internal Audit Program



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Internal Audit Program

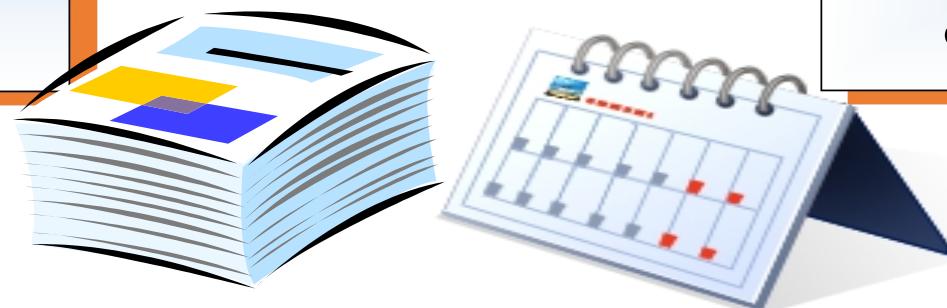


Prepare documents
checklists
forms

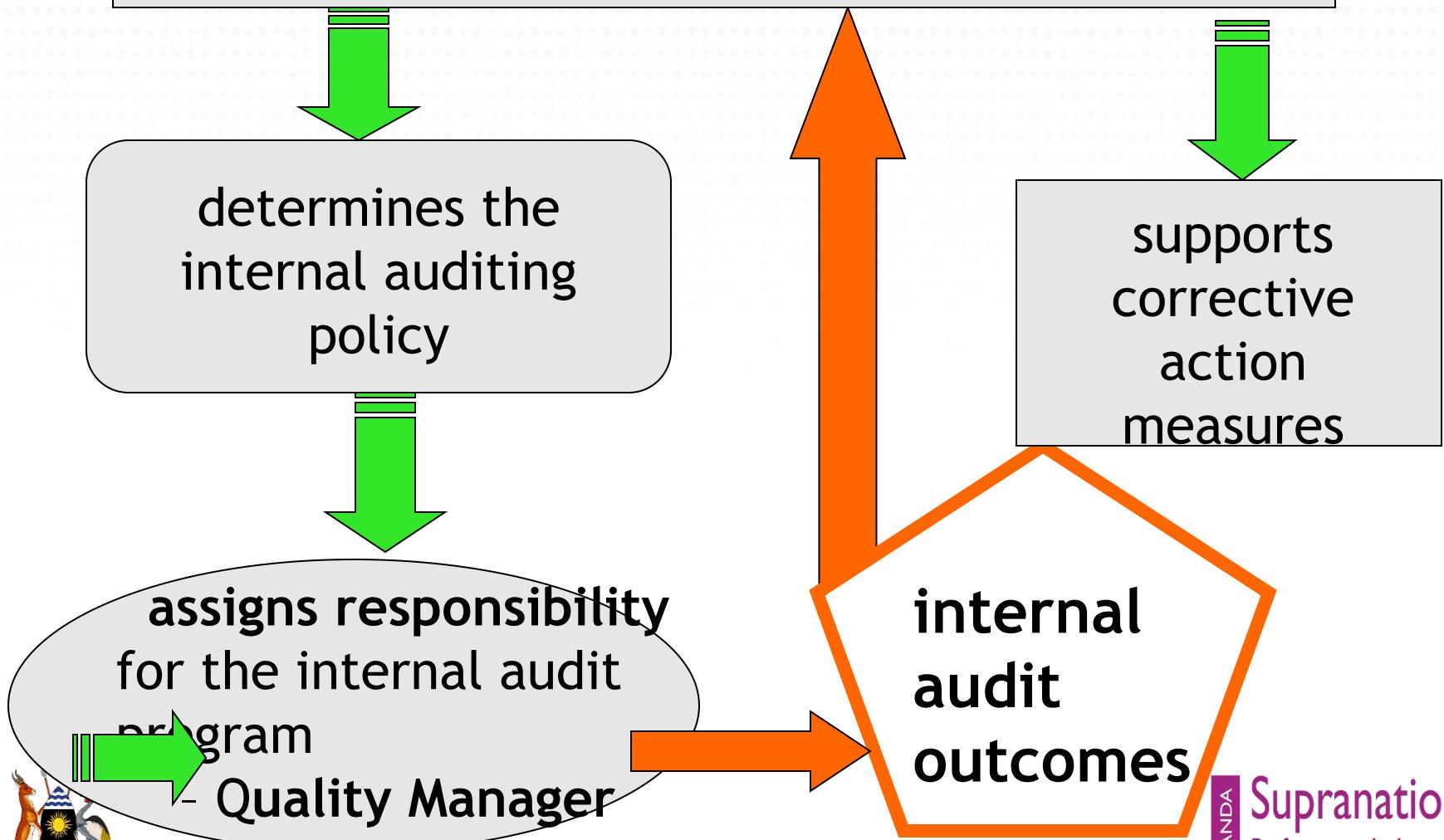
Assign responsibility



Schedule regular audits

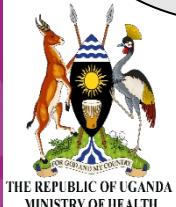
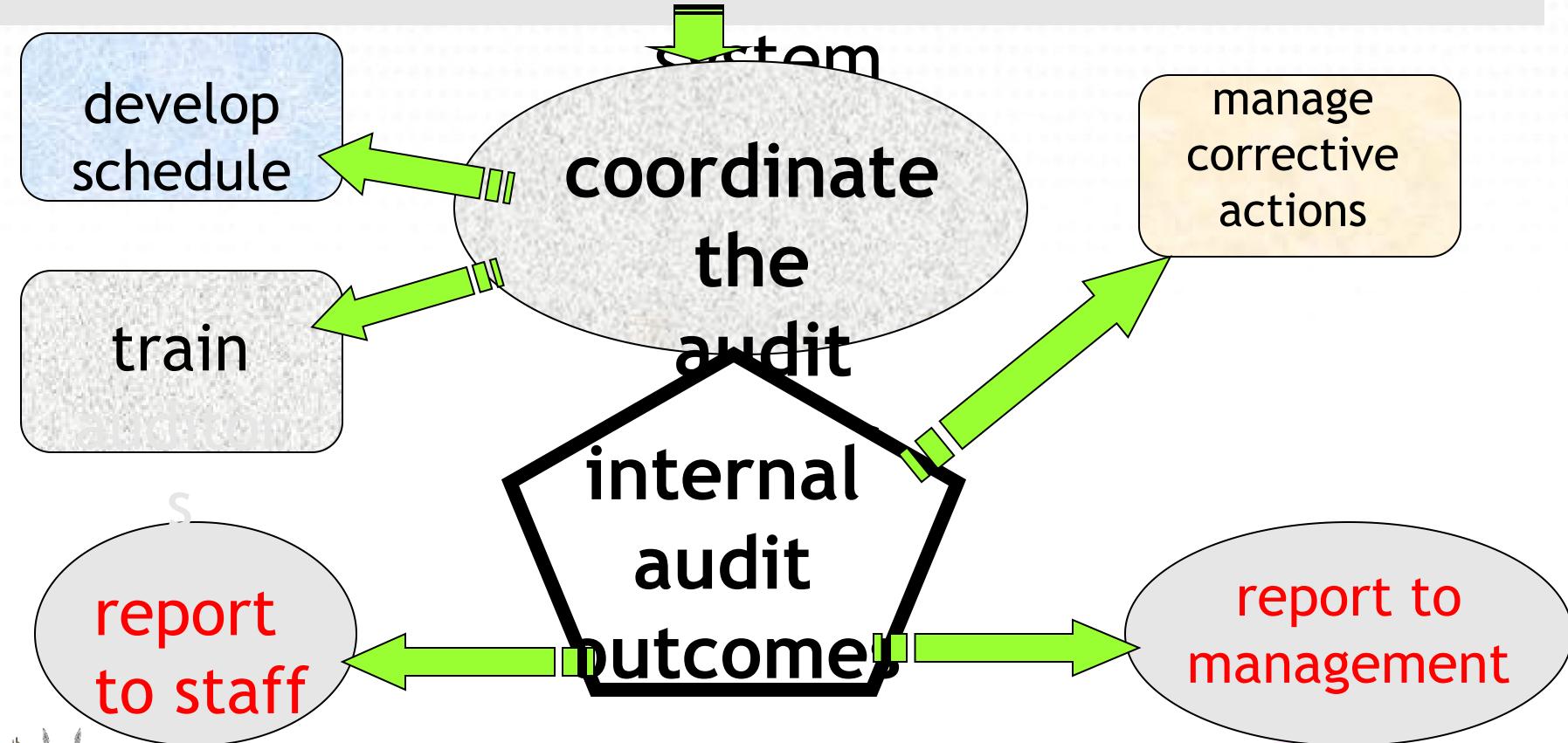


Responsibilities; Laboratory Director



Quality Manager Responsibility

establish and maintain an internal audit



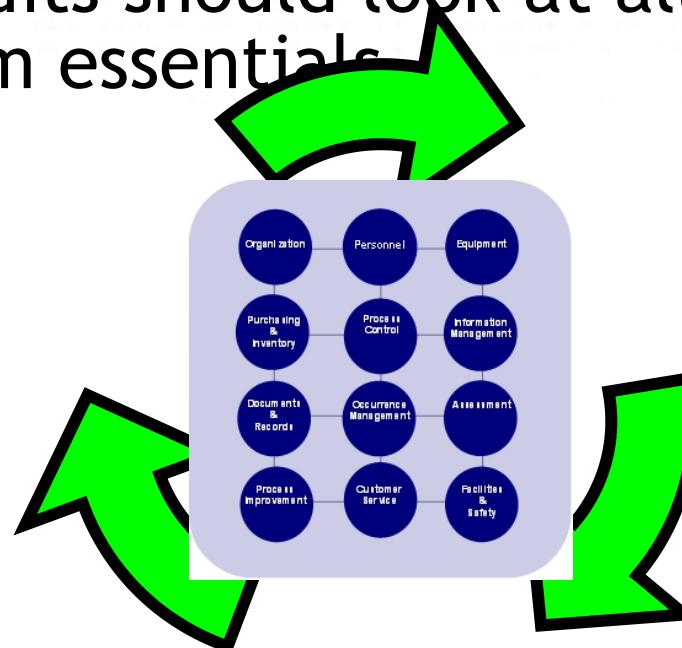
Conducting an Internal Audit

- ─ develop plan
- ─ write checklists
- ─ opening meeting
- ─ collect and analyze information
- ─ record results
- ─ conduct closing meeting
- ─ report



Establishing an Audit Schedule

- conduct regularly
- more frequent audits for problems or areas needing improvement
- over time audits should look at all of the quality system essentials



Documents

- checklists
- develop forms for documenting corrective actions and reports



CORRECTIVE ACTION FORM

This Corrective Action is a result of:

Occurrence Date _____ Time: _____
 Internal Assessment Date _____ Time: _____
 External Assessment: Date _____ Time: _____

Description of Problem or Finding: (What happened and Why)

Reported by: (Staff Name) _____

Corrective Action Taken: (What was done to prevent re-occurrence?)

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**Communicate
effectively**



**Technical/
Quality
management
expertise**



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**Attention
to detail**



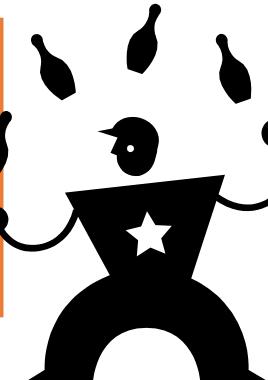
**Important
Skills
for Auditors**



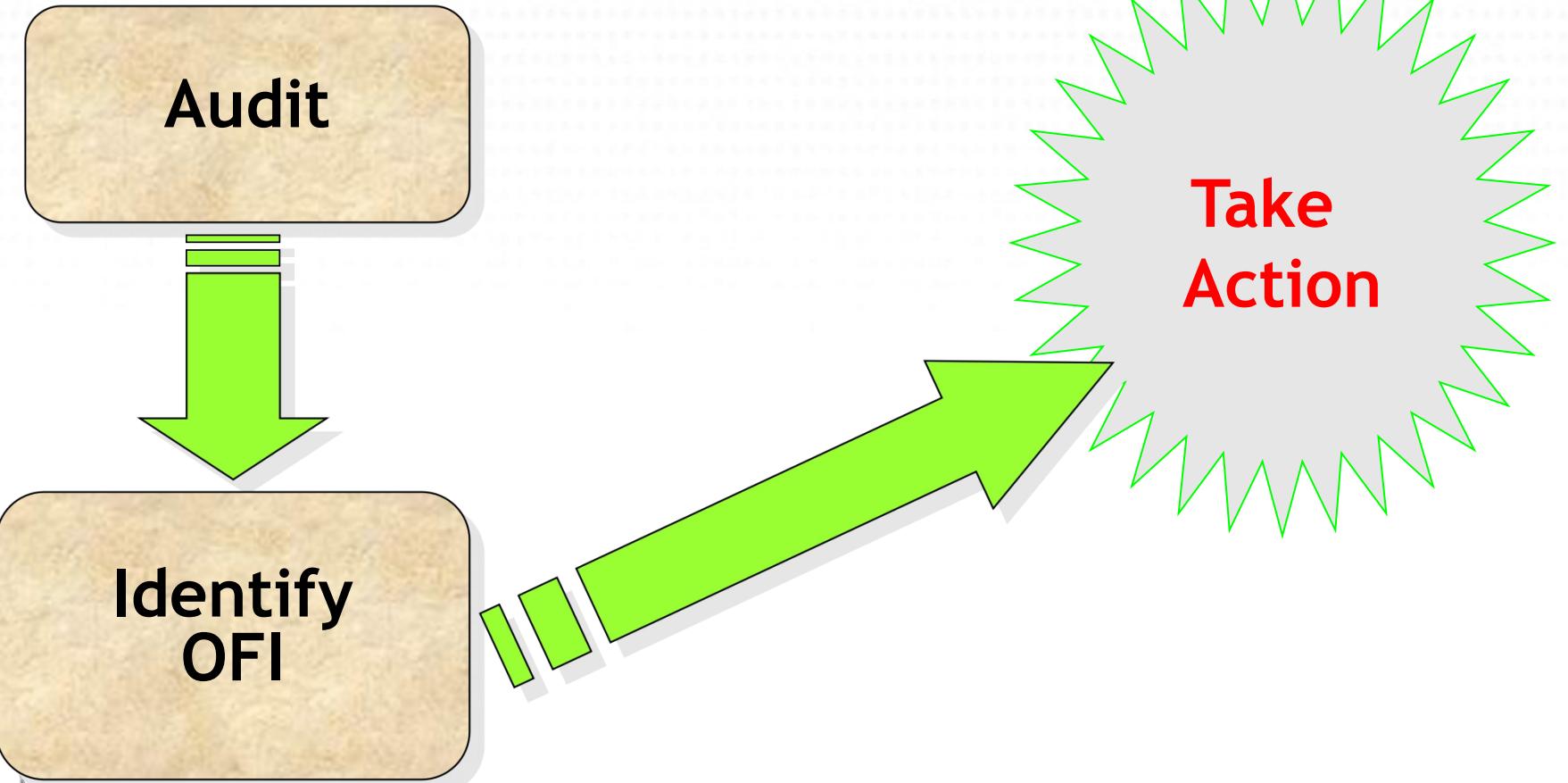
Trained



Diplomatic



Audits Should Lead to Actions



Corrective and Remedial Actions

These actions are the steps taken to improve a process or to correct a problem

Who is responsible?
Quality Manager



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Taking corrective action

- using problem-solving team:
 - investigate root causes
 - develop appropriate corrective action
- implement corrective action
- examine effectiveness
- record all actions and findings

Opportunity for Improvement Form

CORRECTIVE ACTION FORM

This Corrective Action is a result of:

Occurrence Date _____ Time: _____
 Internal Assessment Date _____ Time: _____
 External Assessment: Date _____ Time: _____

Description of Problem or Finding: (*What happened and Why*)

Reported by: (Staff Name) _____

Corrective Action Taken: (*What was done to prevent re-occurrence?*)

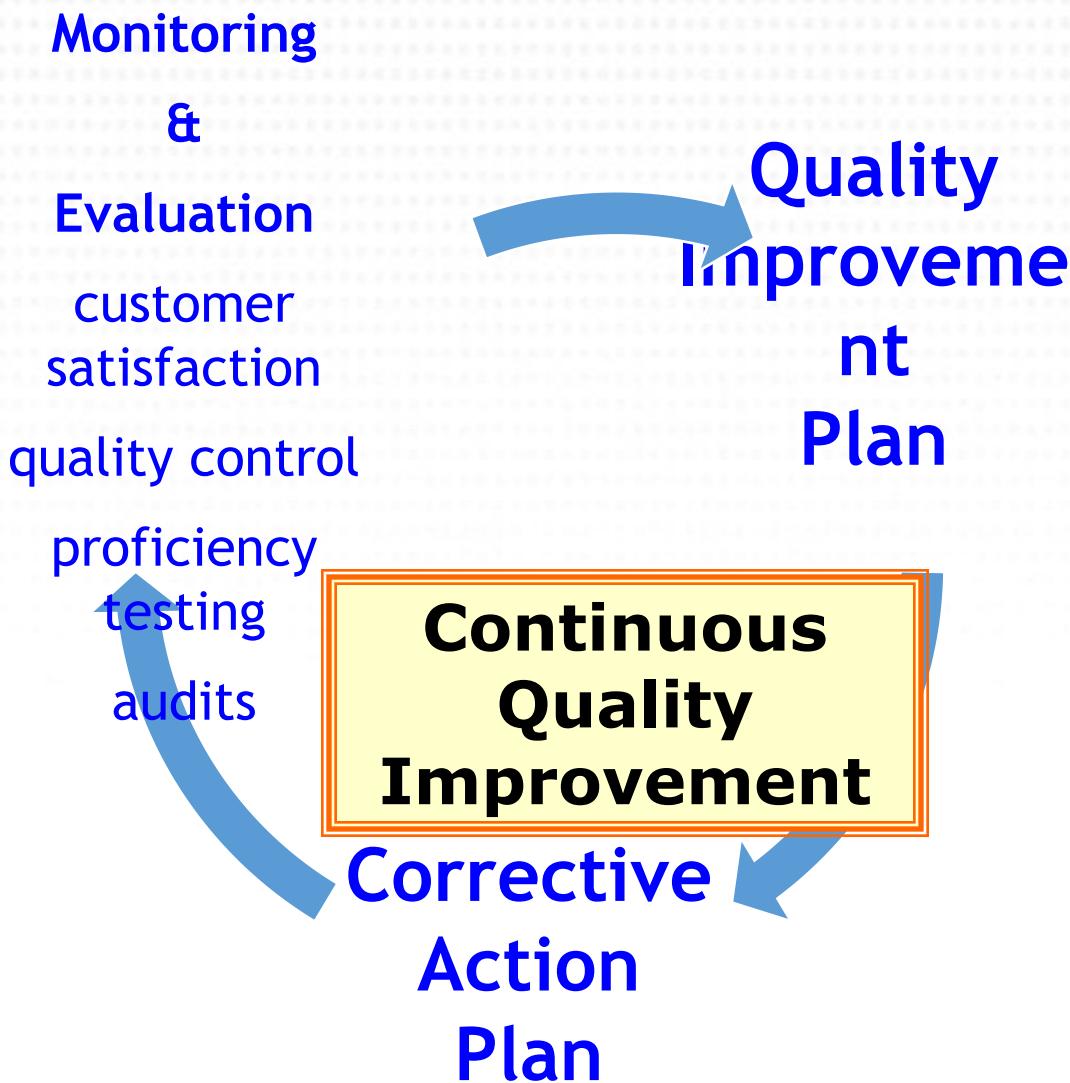




**Continuous monitoring is
the key element to
success in the Quality
System**



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**“It isn’t what you find...
it’s what you do
about what you find.”**

Philip Crosby



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Assessment

- Outline the process to prepare your laboratory staff for an external audit.
- Describe how to use results from a laboratory audit.
- What is the importance of taking corrective actions after the assessment.



Summary

- Assessment is important in monitoring the effectiveness of the laboratory quality management system.
- Both external and internal audits yield useful information.
- An outcome of assessment is finding root causes of problems and taking corrective actions.



Key Messages

- All laboratories should establish an internal audit program. Conducted on a regular basis, it will provide information for continual improvement.
- Problems become opportunities for improvement.

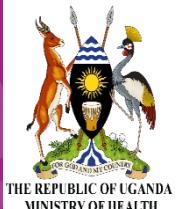


Reference

- ISO 15189:2012 Medical Laboratories - Requirements for Quality and Competence
« Clause 4.14»

CLSI

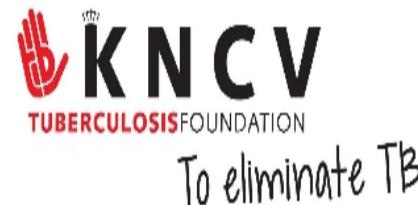
ASLM



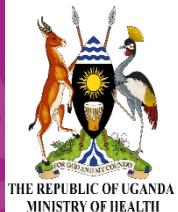
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