

Current Audit Practice Accreditation Body's Perspective

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Outline

- The value of audits
- Accreditation body audit requirements
- Observed audit practices
- Challenges & Possible Solutions
- Lessons learnt
- Conclusion

The value of audits

- Audits are a key aspect of any QMS
 - Introspection of the system
- Internal audits
 - First party audit, are we as laboratory
Doing what we committed to do?
- External audit
 - An external independent body
interrogates the system
 - Determine whether or not the laboratory is implementing its own documented
system



Audits from an accreditation body's perspective



- Determine whether or not the laboratory is meeting the requirements of the standard
 - As it related to audits
- Determine the effectiveness of a QMS
- Determine whether or not user needs are met
- Determine whether or not accreditation body requirements are met



Accreditation Body Audit Requirements:

1. Requirements of the Standard

The laboratory MUST meet the requirements of the standard with regards to Internal Audits

- ISO 15189:2012 Clause 14.14 Evaluations & audits
 - 4.14.5 Internal audits
- Documented procedure for audits
- Documented audit plan
 - The audit plan must be adequate for the QMS being audited



Accreditation Body Audit Requirements:

1. Requirements of the Standard

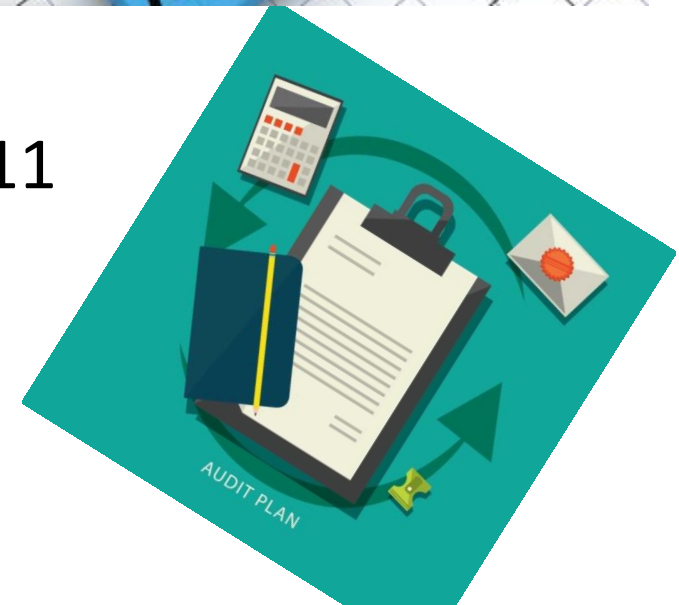
- The audit plan **MUST** be effectively implemented
- Qualified and competent auditors
- Root Cause Analysis and Corrective Action to address audit findings
 - Is there a documented system
 - Is the system being effectively implemented



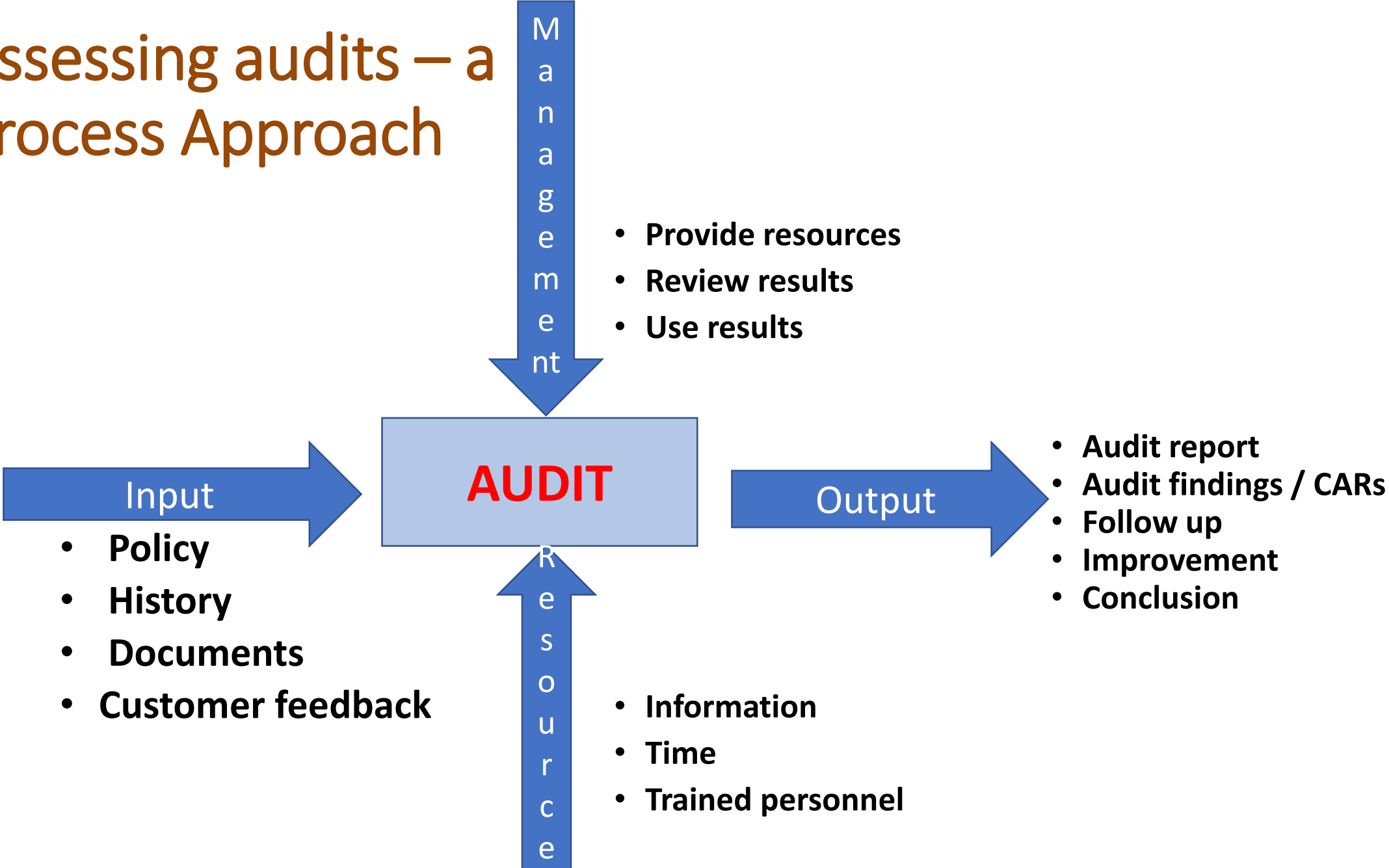
Accreditation Body Audit Requirements:

2. The Audit Plan

- Documented audit plan
- Cover the full scope of testing services
- Audit Plan to include
 - The audit dates
 - Auditors to conduct the audit
 - The scope of audit the audit
- Audit plan based of the requirements of the ISO 19011



Assessing audits – a Process Approach



Observed Current audit practices

Auditor

- Laboratories are aware of the audit requirements of the standard
- Audits are planned and conducted
- Laboratories use standardized tools to conduct audits
 - Generally use accreditation body checklists
 - However, these do not always meet the audit objectives
- Limited auditing skills and competences among laboratory professionals



Observed Current audit practices

- Ineffective implementation of the audit plan
 - Audits not conducted as per plan
 - Incorrect focus of the audit
 - Inappropriate audit culture
 - Audits aimed at auditors, accreditation bodies....
- Ineffective conclusion of the audit process

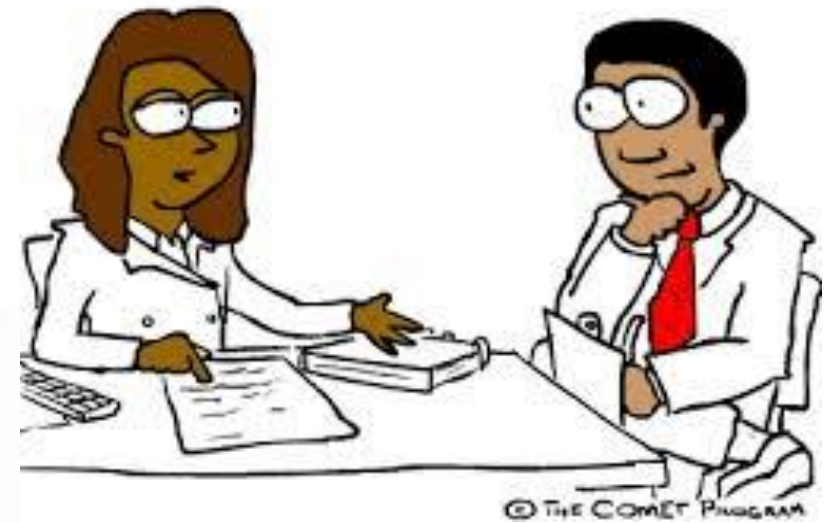
Auditor



Challenges and Possible Solutions

Training & competence
assessment

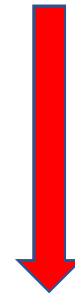
Limited Auditor
competence



Challenges and Possible Solutions

Audit culture

- Fault finding
- Performing audits for auditors, accreditation bodies.....
- Plans not implemented



Challenges and Possible Solutions

Tools & Checklists

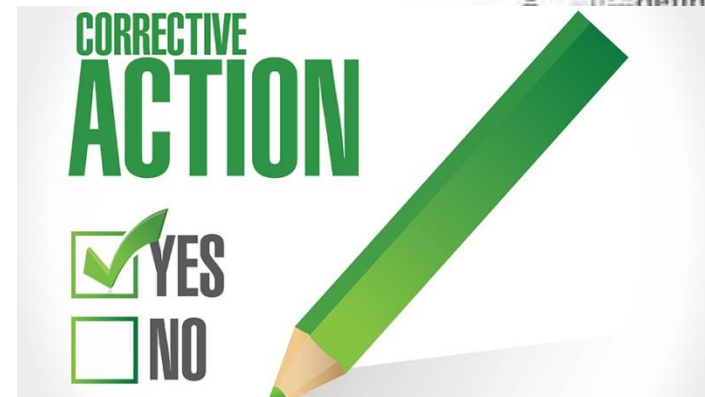
- Develop appropriate tools to meet audit objectives



Challenges and Possible Solutions

Conclusion of audits

- Documentation of findings
- Root cause analysis
- Corrective action
- The Report
- Action on audit findings



THE WAY FORWARD

STRONGER TOGETHER

Strengthen audit practice, for improved, sustainable implementation of the QMS, laboratory service delivery, patient care & health outcomes



Questions & Comments

