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

  - 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 on the requirements of the ISO 19011
Accreditation Body Audit Requirements:  
3. Effective Implementation

• Audits conducted as per plan
• Suitable auditors
  • Qualified and competent
  • Auditor independent of area being audited
• Comprehensive interrogation of the QMS
  • Confirm effective implementation of the system
  • Identify and gaps or ineffective implementation of the system
• Conclusion of the audit process
  • Root cause analysis and corrective action
  • The audit report
  • Feedback to all stakeholders
Assessing audits – a Process Approach

Management

- Provide resources
- Review results
- Use results

Input
- Policy
- History
- Documents
- Customer feedback

Resource
- Information
- Time
- Trained personnel

Output
- Audit report
- Audit findings / CARs
- Follow up
- Improvement
- Conclusion
Observed Current audit practices

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