

INTERNAL AUDIT CLINICAL LABS

ISO 15189: 2012

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AUDIT

◉ Audit

“ systematic ,independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled”

TYPES OF AUDITS

- Internal Audit
 - First party audit
- External Audit
 - Second party
 - Third party audit

INTERNAL AUDITS

- ◉ A requirement of ISO 15189
- ◉ Management wants to discover any weakness in the laboratory's systems before these are detected by external assessors, e.g. from NABL
- ◉ Internal audits are a powerful management tool to aid quality improvement
- ◉ Internal audits verify the effectiveness of corrective actions

INTERNAL AUDITS

- Predetermined schedule
- Comply with requirements of quality management system and ISO 15189
- All elements of quality management system
- Trained and qualified personnel, where resources permit, are independent
- Maintained Records of audit findings and corrective actions

AUDIT CYCLE

The audit comprise the following four phases:

- Planning and preparation
- Conduct of audit
- Recording and reporting the audit findings
- Follow up and confirmation of corrective action

The audit is considered to be complete only when corrective actions have been taken & auditor has verified.

AUDIT PLANNING

- ◉ LIST THE ACTIVITY YOU PLAN TO AUDIT
- ◉ DETERMINE THE PERIOD YOU NEED TO COMPLETE THE AUDIT
- ◉ ENSURE THAT EACH ACTIVITY IS COVERED.
TAKE THE HELP OF CHECK LIST
- ◉ ARRIVE AT THE TOTAL DURATION NEEDED TO COMPLETE THE AUDIT
- ◉ IDENTIFYING THE PERSONS TO BE USED FOR AUDITING
- ◉ ENSURE THEIR AVAILABILITY AND PROPERLY COORDINATE WITH INDIVIDUAL(S) OF THE SECTION TO BE AUDITED
- ◉ DECIDE TO WHAT EXTENT SAMPLING IS TO BE DONE. DISCUSS IT WITH INDIVIDUALS OR LAB STAFF TO BE USED FOR AUDIT
- ◉ IF NEGATIVE FINDINGS ARE THERE, MORE SAMPLING TO BE DRAWN TO ESTABLISH THE FACT THAT THESE ARE ISOLATED CASES OR OTHERWISE

REQUIREMENTS FOR INTERNAL AUDITS

- a) The laboratory has planned for audits in its quality management system;
- b) The laboratory has nominated a person, or persons, to be responsible for conducting audits;
- c) The procedures for auditing are documented;
- d) The audits are actually carried out;
- e) The audits are conducted in accordance with a preplanned programme;
- f) The results of audits are recorded;
- g) Remedial action is initiated immediately by the laboratory to correct all non-compliances identified in its quality management system within a reasonable time scale;and;
- h) The remedial action is effective and completed promptly

IMPLEMENTING THE AUDIT PROGRAMME

Implementation of each audit programme should address:

- a) Documenting and communicating the audit programme;**
- b) Co-ordinating and scheduling activities**
- c) Assigning auditors and audit teams;**
- d) Providing required resources to the audit team;**
- e) Conducting audits according to the audit programme;**
- f) Collecting records of the audit activities;**
- g) Reviewing audit records;**
- h) Reviewing and distributing audit reports to the audit client and other specified parties;**
- i) Performing audit follow-up.**

AUDIT & ROLE OF QUALITY MANAGER

- ◉ **Quality Manager is the responsible person**
- ◉ **Planning of audit**
- ◉ **Records of audit**
- ◉ **Involvement of other experts to complete the audit**
- ◉ **CAN AUDIT Done by Customer be considered as Internal Audit**
- ◉ **CAN OUT - SIDE AGENCY INVOLVED FOR DOING INTERNAL AUDIT Acceptable to NABL**

AUDIT CONDUCT PROCESS

- ❖ Pre-audit briefing
- ❖ On Site audit
- ❖ Debriefing
- ❖ Closing Team meeting

AUDIT CHECKLIST

Checklist is a important tool for audit.

- ✓ Auditors need to be trained in usage of checklist by using good questioning technique.
- ✓ Checklist shall not be generic in nature. It shall be prepared using all applicable standards.
- ✓ There shall be no duplication and repetition, as it will slowdown the audit process

ADVANTAGE OF USAGE OF CHECKLIST

- ❖ It ensures that audit is conducted in a systematic and comprehensive manner .
- ❖ It provides structure and continuity to the audit.
- ❖ It ensure a consistent audit approach
- ❖ Act as a sampling plan and time manager
- ❖ Serve as a memory aid to ensure that the audit scope is followed and all the required standards are audited.
- ❖ It helps is gathering objective evidence and important information.

SAMPLING DURING AUDIT PROCESS

Data based on full populations gives the best indication of standard implementation but it is not possible due to constraint of resources and time .

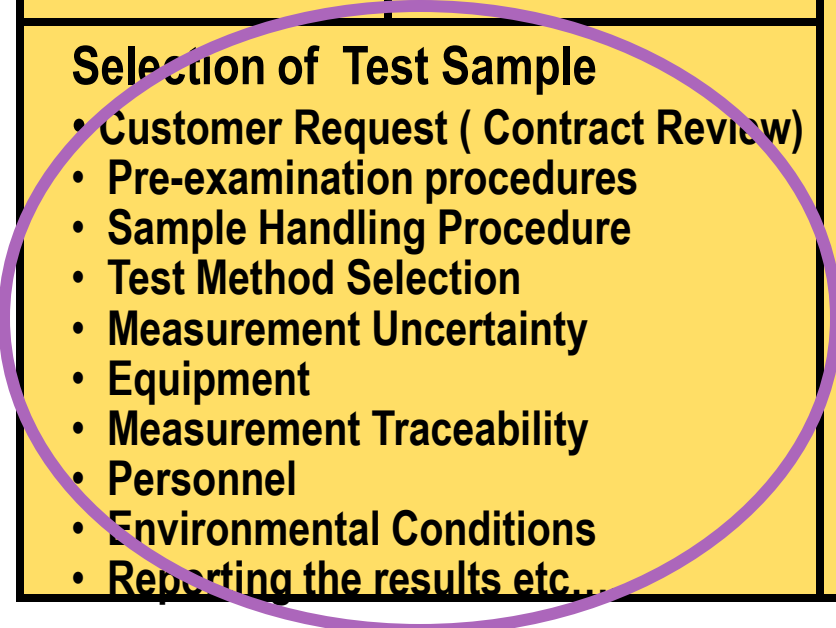
Sample audit can be a reasonable indicator, for full population. It is however important to control;

- ✓ Size of the sample
- ✓ Methodology to select the sample

AUDIT METHODOLOGY

- ❖ Tracer
 - ✓ Individual
 - ✓ System
- ❖ Document Review – Policies and procedures , Manuals etc.
- ❖ Closed Medical Record Review
- ❖ Human Resource Record Review
- ❖ Interview Process
 - ✓ Staff
 - ✓ Patient
 - ✓ Senior leaders and Management

VERTICAL AUDIT EXAMPLES

Area Procedure	Quality Manager Functions	Test Lab-1	Test Lab - 2
 - I.A. - Mgmt Rev - Complain - Doc. Contl. - EQA			
 Selection of Test Sample • Customer Request (Contract Review) • Pre-examination procedures • Sample Handling Procedure • Test Method Selection • Measurement Uncertainty • Equipment • Measurement Traceability • Personnel • Environmental Conditions • Reporting the results etc...			

HORIZONTAL AUDIT EXAMPLES

Area Procedure	Quality Manager Functions	Test Lab-1	Test Lab - 2
- I.A. - Mgmt Rev - Complain - Doc. Contl. - EQA			
Selection of Test Sample • Customer Request (Contract Review) • Pre-examination procedures • Sample Handling Procedure • Test Method Selection • Measurement Uncertainty • Equipment • Measurement Traceability • Personnel • Environmental Conditions • Reporting the results etc.....			

THE GENERAL PRINCIPLES OF AUDITING INCLUDE THE FOLLOWING:

- a) Audits are an effective management tool to examine activities and processes.
- b) Objectivity, independence and systematic approach are core principles, essential for effective audits;
- c) Audits are authorized, and authority may result from the decision of management,
- d) Audit programmes and audits are planned and managed to ensure that the audit conclusions are credible;
- e) Audit should ensure that all elements practiced and all the personnel are covered
- f) Audits are conducted so that audit evidence and audit findings are reliable and that audit teams working independently from one another will reach similar audit conclusions

GENERAL PRINCIPLES OF AUDITING

- g) The scope, objectives and audit criteria clearly defined.**
- h) Audit team members and audit programme managers are competent for the tasks they perform;**
- i) Audit team members act with due professional care and adhere to a prescribed auditor behavior. Audit team members are free from bias and conflict of interest;**
- j) The relationship between the audit team, auditee and the audit client is of discretion.**

ESSENTIALS FOR AN AUDITOR

- ◉ KNOWLEDGE OF QUALITY MANUAL, LABORATORY PROCEDURES AND OTHER DOCUMENTS
- ◉ KNOWLEDGE OF ACCREDITATION CRITERIA
- ◉ KNOWLEDGE OF SPECIFIC CRITERIA
- ◉ DON'T INVOLVE INDIVIDUALS TO AUDIT THEIR OWN WORK

AUDIT CONDUCT

AUDIT CONDUCT

- * PERSONAL RELATIONS
 - * TECHNICALITIES AND PROBING
- ◉ THE TECHNICALITIES OR THE TOPICS WHICH COULD BE TERMED AS THE BASICS OF AUDIT ARE :
- ◉ CLARIFY ON OBJECTIVES OF AUDIT
- ◉ AUDIT PLANNING
- ◉ HORIZONTAL AUDIT
- ◉ VERTICAL AUDIT
- ◉ UNDERSTANDING OF:
 - * THE CRITERIA REQUIREMENT(S)
- ◉ THE QUALITY MANUAL
 - * PROCEDURES
 - * INSTRUCTIONS
 - * RECORDS

PERSONAL RELATIONS / PERSONAL ATTRIBUTES

- ◉ OPEN MINDEDNESS
- ◉ MATURITY
- ◉ SOUND JUDGEMENT
- ◉ ANALYTICAL SKILL AND TENACITY
- ◉ ABILITY TO PERCEIVE SITUATION IN AREALISTIC WAY
- ◉ ABILITY TO UNDERSTAND THE ROLE OF INDIVIDUAL UNITS WITHIN OVERALL ORGANIZATION
- ◉ CONDUCTING INTERNAL AUDIT IS NOT :
 - *FAULTS FINDING
 - * TO EXHIBIT SUPREMACY OR KNOWLEDGE

CONTENTS OF AUDIT REPORT

- ❑ NAME OF AUDITOR
- ❑ DATE OF AUDIT
- ❑ AREAS AUDITED
- ❑ DETAILS OF ASPECTS EXAMINED INCLUDING SAMPLE NUMBER, EQUIPMENTS WITH IDENTIFICATION
- ❑ ANY NON COMPLIANCE OBSERVED
- ❑ CATEGORIZATION OF NONCOMPLIANCE e.g. MAJOR/MINOR
- ❑ CORRECTIVE ACTION AGREED, TIME PERIOD FOR CORRECTIVE ACTION
- ❑ DATE OF CONFIRMATION OF COMPLETION OF CORRECTIVE ACTION
- ❑ SIGNATURE OF QUALITY MANAGER CONFIRMING THAT CORRECTIVE ACTION HAS BEEN COMPLETED

IDENTIFICATION AND GRADING OF NON-CONFORMANCES

NC MAJOR/minor

IDENTIFYING NON-COMPLIANCES

Non-compliances can be :

- ⦿ Related to the quality management system
- ⦿ Related to technical activities
- ⦿ Failure to do some thing required
- ⦿ Difference between work practices and documented instructions

CLASSIFYING NON-COMPLIANCES

Major non-compliances

- ⊙ Absence of a procedure required by standard
- ⊙ Significant failure to implement a procedure
- ⊙ Direct effect on quality of results / Patient care

All other non-compliances are
minor

SEQUEL - MRM

- ⊙ Identification and control of Nonconformities
- ⊙ Follow up actions initiated
- ⊙ Changes in the system to monitor the effects.
- ⊙ Review the activities
- ⊙ Preparedness for the Assessment by external organisations

THANK YOU