

## MODULE 3

# Managing the Audit Process



# INTERNAL AUDIT PROCESS MANAGEMENT

*“ISO/IEC 17025 requires that the laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the management system and the standard.”*

Audits like any other processes need to be planned and managed so that they are carried out efficiently and effectively.

Management of the audit programme is the responsibility of the Quality Manager. The Quality Manager should therefore have an understanding of QMS requirements and audit techniques.

# Quality Manager's Responsibility

- **Establish & maintain internal audit system**
- **Develop schedule**
- **Coordinate audits**
- **Manage corrective action system**
- **Advise management of audit outcomes**

# Management's Responsibility

- Define [internal] auditing policy
- Assign responsibility of internal audit program
  - **Quality Manager**
- Must be advised of internal audit outcomes
  - discussed at management review

# OBJECTIVES OF AN AUDIT PROGRAMME

1. To perform and present audits meaningfully (in terms of appeal to management interests).
2. To ensure that all required audits are performed regularly, with audits of critical functions performed more frequently.
3. To ensure only trained, qualified and independent auditors are employed to perform audits.
4. To support the objectives/strategies/goals of the organization.



# INTERNAL AUDIT PROCESS MANAGEMENT

Auditing is often a function of an organisation's quality department. It can however reside in the operations. Regardless where it resides, it must be ...

1. Independent of the areas audited (if resource permits)
2. Supported by Management
3. Deployed in a positive manner

# INTERNAL AUDIT PROCESS MANAGEMENT

Management of the audit function includes the following activities:

1. Establishing a reporting relationship of audit function.
2. Establishing audit authority, operational freedom, constraints and boundaries.
3. Ensuring the availability of adequate resources for all audits.
4. Staffing and training of auditors.
5. Establishing procedures, processes, and criteria for an effective and efficient audit programme.

# INTERNAL AUDIT PROCESS MANAGEMENT

Management of the audit function includes the following activities (cont):

6. Establishing methods for evaluating an audit programme.
7. Establishing audit schedules.
8. Confirming audit dates and any requested changes of audit dates.
9. Setting priorities for audit subjects.
10. Providing periodic reports to management on the status of the audit programme.



REFERENCE DOCUMENTS	
Document Number	Document Title
ISO/IEC 17025:2005 Clause 4.14	General Requirements for the Competence of Calibration and Testing Laboratories
ISO/TR10013:2001	Guidelines for quality management system documentation

#### 4.14.1 Purpose

To verify laboratories' continued compliance with ISO/IEC 17025 and the competence of the laboratories to carry out specific tests.

#### 4.14.2 Scope

The section applies to all elements of the management system of the laboratories including the technical requirements.

#### 4.14.3 Audit programme

It shall be the responsibility of the QMR to plan, schedule, and ensure that internal audits are conducted.

The audit schedule should cover all aspects of the quality system and the applicable technical requirements as spelt out in ISO/IEC 17025. Random or unplanned audits may be carried out when there is sufficient reasons to warrant such audits, e.g. after customer complaints, or when new changes in the system are introduced. All internal audits shall be conducted as per procedure **TD/OP/.....**

#### 4.14.4 Selection of auditors

Selection of auditors shall be based on appropriate training and qualification. Where resources permit, they shall be independent of the activity being audited.

#### 4.14.5 Corrective actions

All corrective actions arising out of the internal quality audits shall be handled as per procedure **TD/OP/.....**

#### 4.14.6 Internal quality audit reports

Internal quality audits records shall be kept with the QMR who is also responsible for the monitoring of all corrective actions till they are closed out. These records shall include but not limited to audit reports, audit plans, completed checklists, auditors notes and non-conformity reports. Results of internal audits shall also be reported to the following management review meeting by the QMR.

Written by:	Reviewed by:	Approved by:	Approval date

# PLANNING AUDIT SCHEDULE

- Annual  
(The schedule typically spans a period of 6 to 12 months )
- Address all elements of the quality system
  - **HORIZONTAL AUDIT**
  - **VERTICAL AUDIT**

- Horizontal
  - all departments audited against one element of standard or procedure (eg training, document control)
- Vertical
  - one department audited against all elements of standard or procedure ( eg testing, test equipment, non-conformances etc)

# **FREQUENCY OF AUDITS**

**The following are among factors which influence the frequency of audit :**

- **calibrations, test/processes which exhibit known or potential problems**
- **processes which if not properly controlled, could create problems of a very serious nature.**
- **processes where training is a significant factor**
- **working environment which is subject to high turnover of personnel**
- **areas where new or significantly modified processes have been introduced**
- **following customer complaints**
- **safety of the process**
- **risk and consequences of things going wrong**

# Who Am I ?

## Auditor

*A person with the competence to conduct an audit.*

## Lead Auditor / Team Leader

*An Auditor qualified and appointed to lead and manage the audit team.*



# Role of Lead Auditor

To:

- **Manage the audit**
- **Prepare audit plan**
- **Represent audit team with auditee management**
- **Exercise decision on audit and findings**
- **Prepare and submit audit report**





# Role of Auditor

To:

- **Execute/conduct the audit**
- **Record audit observations and findings**
- **Prepare audit report**
- **Follow up and verify audit corrective actions**



# Basic Requirements of Internal Auditors

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Personal Attributes

Education

# Knowledge and Skills

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- **KNOWLEDGE**

Understands the requirements of ISO 17025 ,Company practices, legal requirements.

- **SKILLS**

Good audit techniques, good communication skills in writing and conversation and able to make fair judgements.

# Education and Experience

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**Education**

**Education level and background**

**Experience in related industry**

**Related training such as  
Understanding ISO 17025, Internal  
Auditors Training**

# Personal Attributes

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## Personal Attributes



- **Independence**

auditor should be independence of the activities that they audit.

- **Objective**

should be impartial and provide an honest, unbiased and complete summary of their findings.

- **Ethical Conduct**

The foundation of professionalism.



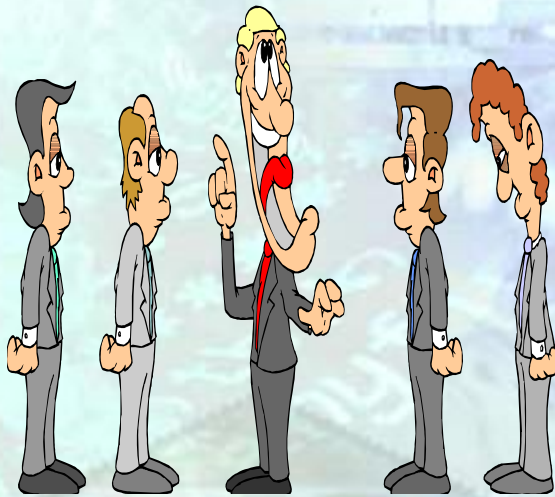
# Good Ethics of Auditor

- ✉ **Punctual**
- ✉ **Objective**
- ✉ **Opened minded**
- ✉ **Analytical**
- ✉ **Good judgement**
- ✉ **Good listener**
- ✉ **Polite**
- ✉ **Honest**
- ✉ **Hardworking**
- ✉ **Patient**



# Poor Ethics of Auditor

- **Poor At Preparation & Planning**
- **Too Rigid**
- **Fault Finding**
- **Jumps To Conclusions**
- **Argumentative**
- **Bad Communicator**
- **Easily Influenced**
- **Stays In Office**
- **Arrogant**
- **Poor Timekeeping**
- **Afraid Of Passing Unpopular Judgements**



# Am I A Qualified Auditor?



# END OF SESSION 3: MANAGING THE AUDIT PROCESS

## THANK YOU VERY MUCH