

INTRODUCTION TO AUDITING

Outline

- Definition of a quality Audit
- Types of audit
- Qualifications of quality auditors
- The audit process

What is quality audit?

A quality audit is a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which agreed criteria are fulfilled

(ISO 9000:2005 clause 3.9.1)

Why Audit?

- To determine whether the quality system conforms to specified requirements
- To determine the effectiveness of the implemented system
- To initiate improvements in the system
- To compare practice with procedure
- To provide objective evidence that the system is in compliance with the standard (i.e for certification purpose) intake per set criteria

Types of Audits

- Process audits
- Product audits
- System audits

PROCESS AUDITS

Evaluation of the contents and effectiveness of specific processes & work activities:

- To confirm process parameters and improve capability of the process
- To ensure the realization the process quality characteristics.
- To ensure improvement of process control during service provision

Product Audits

Investigation of product conformance to specified characteristics:

- To obtain additional neutral assessment of product's level of quality
- To obtain additional assurance that specified quality requirements are met

Product audits

- To identify opportunities for improvement.
- To establish the quality level of units before final inspection and testing
- To establish the capability of the inspection function
- To determine the usefulness of inspections tests

System audits

Evaluation of all the elements of the quality system in order to:

- Verify usefulness, suitability and effectiveness
- Verify adequate documentation
- Verify compliance with requirements.
- Determine weak points

Distinction of system audits by parties

- 1st party audits (Internal Audits) – Organization audits its own QMS according to a quality standard
- 2nd party audits (Supplier Audits) – Customer audits the supplier's quality system
- 3rd party audits External certification audits by an independent institution in order to certify the QMS

Who is an auditor?

A person who has the qualification to perform quality audits

Criteria for quality auditors

- Education
- Training
- Experience
- Personal Attributes

Attributes of an auditor

A – Analytical

U – Unassuming/unbiased

D – Diplomatic

I – Inquisitive/independent

T – Thorough

O – Objective

R - Reliable

The Audit Process

- Plan and prepare the audit 50%
- Carry out the audit 30%
- Reporting and follow-up 20%

AUDIT PREPARATION

1. Establish audit type and scope
2. Establish audit basis – it is the standard, manual, procedures or combination thereof?
3. Establish audit personnel – size is dependent on the type, purpose and scope of audit.
Audit team may include specialists, trainee auditors, observers acceptable to auditee and audit team

AUDIT PREPARATION

1. Read basis documentation as well as previous audit reports and determine what records shall be pulled in advance
2. Prepare process model – identifying the expected results of the process to be audited
3. Prepare an audit plan

AUDIT PREPARATION

1. Notify the auditee in advance of: time, date, the scope, the basis, timetable of the audit
2. Prepare checklists – use open ended questions what? Why? Who? How? Which?

PERFORMING THE AUDIT

Before the start of audit:

- Auditee's management informs personnel in the involved departments about expected audit
- Lead auditor and rest of the team must be acceptable to auditee management

FOUR PHASES OF AN AUDIT

- Opening meeting
- Execution of audit
- Auditors' meeting
- Closing meeting

Typical opening meeting agenda

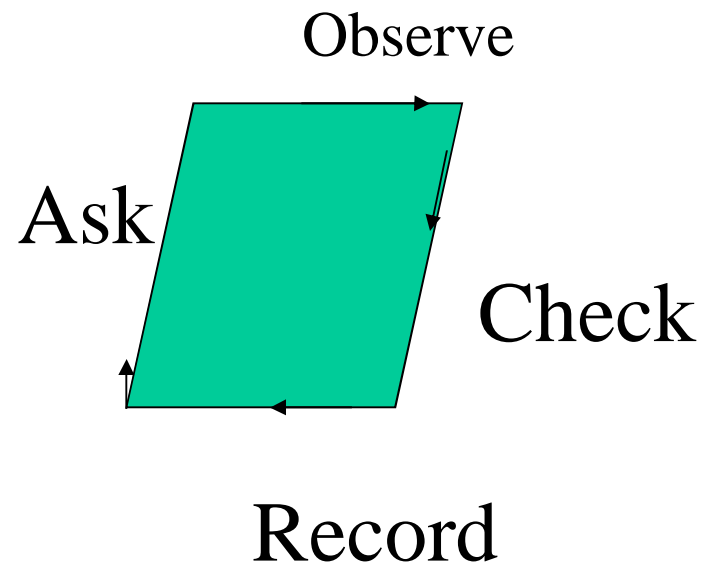
- Introduction of members and observers and recording of those present
- Confirm objectives, scope, basis, reasons and benefits of the audit
- Review of audit plan
- Explanation of the audit method and documentation to be used
- Explain the tasks of the accompanying auditee's representatives (i.e guide)

Typical opening meeting agenda

- Confirm method of communication
- Confirm availability of facilities
- Explain closing meeting/format
- Assure auditee of confidentiality
- Invite questions

Execution of audit

THE AUDIT LOZENGE



EXECUTION OF AUDIT

- Must be done according to timetable
- Only ask open, factual questions
- Verify answer through observation
- Follow an audit trail
- Do more listening than talking 2 ear 1 month; therefore listen 2/3 of the time

Some rules for auditors

- Keep calm and relaxed
- Look at the other person-eye contact
- Keep discussion factual
- Ask one question at a time
- Do not lecture
- Let the other person finish talking

Some rules for audit

- Keep the right distance from the person
- Be friendly without being too familiar
- If your question causes uneasiness or uncertainty, formulate it differently
- Involve all participants
- Use the right gestures/expressions
- Keep personal opinions to yourself

AUDITOR SINS

An auditor should never

- Compare the auditee with others
- Be sarcastic
- Swear
- Criticize
- Be side tracked
- Argue
- Discuss personalities
- Discuss religion or politics
- Discuss company policy
- Drink beer before an interview
- Be late

Objective evidence

- Remember ---- SHOW ME
- Check for documents, records, reports, data in computers etc
- Ensure auditees statements are cross checked by supporting evidence e.g. statements by other personnel with specified authority, records, documentary evidence e.t.c.

AUDITORS' MEETING

- Compilation of findings/observations
- Recording of non-conformities
- Preparation of summary report
- Formation of opinion to be presented at closing meeting

Typical closing meeting agenda

- Introductions and recording of attendance
- Thank the auditee
- Mention the principles of sampling followed during the audit
- Summarize audit observations
(positive, general observations and nonconformities)
- Give non – conformities in details

Typical Closing Meeting Agenda

- Present overall summary and conclusions
- Allow for discussion
- Request corrective actions and corrective action dates
- Agree on follow-up date
- Close meeting

Corrective Action Follow-up

It is important to ensure that the auditee implements: -

1. Effective correction
2. Effective corrective actions

REPORTING OF AUDITS

- A standard proforma for the reporting of audit should be used.
- Using the standard audit report sheets prepare a narrative summary of the audit
- Ensure the positive as well as the negative findings are summarized

REPORTING OF AUDITS

Report should cover the following headings: -

1. Title
2. Scope
3. Basis
4. Audit team
5. Introduction (opening meeting)
6. Findings
7. Debriefing (closing meeting)
8. Summary

The audit report including any non-conformity report,
Corrective action notices are issued to the auditee &
MR

REPORTING OF AUDITS

- ISO 19011:2002 includes recommendations for report contents
- Audit reports should be kept confidential lest
 - Auditors lose respect
 - Auditees are less willing to identify areas for improvement

ANALYSIS OF AUDITS

- Management Representative will analyze audit reports to identify areas of common deficiency within QMS
- This will initiate changes to the audit schedule
- A full analysis of audit reports is presented to management review meeting

Records & Administration of Audits

- The MR should enter the audits in the audit log.
- Following documents be retained in departmental QMS files as records: -
 - Original checklists
 - Audit reports
 - Related documents