




MODULE 7

Effective Audits



ROLE OF INTERNAL AUDIT

-  **Internal Audit play the critical role in maintaining and improving the quality system.**
-  **The '*health*' of a company's quality system depends on how well these audits are executed.**
-  **Internal auditors should clearly identify their role and not to duplicate of 3rd Party auditors.**

ROLE OF INTERNAL AUDIT



Internal audit should be an important part in the company's internal improvement mechanism and focus towards:

- **Conformance** with all related requirements of MS ISO/IEC 17025:2005.
- **Effectiveness**, expand beyond identifying problems but finding out what is done to resolve it & to encourage the operators to be involved in providing inputs based on his/her experience.

ROLE OF INTERNAL AUDIT

	3rd Party Auditors	Internal Auditors
<i>Focus</i>	Conformance with Standards	Conformance & Effectiveness of Execution
<i>Policy</i>	Identify if policies are defined & documented	Policies are understood, effective & shared by employees
<i>Cost</i>	Does not investigate what cost one involved	Can cost be reduced by changing features of process or by use of other alternative methods? Identify costs-due to product or process failure
<i>Auditee</i>	Formal relation with auditee but sufficient to obtain information	Close rapport with auditee. Find out if auditee can contribute to improvement. Listen to auditee's problems.

ROLE OF INTERNAL AUDIT

	3rd Party Auditors	Internal Auditors
<i>Checklist</i>	Standard checklist based on ISO 17025 elements	To be developed according to scope of investigation, past audit & current problems related to the activity
<i>Knowledge</i>	Need only a general knowledge on the activity or lab process	Need to have good understanding of activity or lab process
<i>Process</i>	Investigate the control points of the process & to ensure that they are adequate	Investigates every part of the process. Identify & measure process efficiency
<i>Value</i>	Does not necessarily add immediate value	Must add immediate value

ROLE OF INTERNAL AUDIT

	3rd Party Auditors	Internal Auditors
<i>Procedure</i>	Audit to investigate whether the procedures comply to ISO 17025 clauses & whether these procedures are followed	Investigate compliance to procedures but also investigate the details of the procedure itself to ensure that they are efficient & not bureaucratic. Asks 'why' should it be done this way? How can we do this better?'
<i>Improvements</i>	Not allowed to provide consultancy or advisory to auditee	Provide suggestion & advisory for improvement

ROLE OF INTERNAL AUDIT

Evaluating Internal Audit Results

- ❑ Do not stop at management review.
- ❑ Compare internal audit results with the findings of 2nd or 3rd party audits results.
- ❑ Areas where deficiencies are uncovered by external auditors but missed by internal auditors should be thoroughly investigated.
- ❑ Audit checklists should be updated to reflect these items checked by external auditors.

ROLE OF INTERNAL AUDIT

Internal Audits – Common Pitfalls

- ❑ Inappropriate assignment of auditors.
- ❑ Audits were carried out by personnel who have direct responsibility for the activity being audited.
- ❑ No audit notes, checklists to lend evidence that functions, activities & procedures had been comprehensively covered.
- ❑ Audits were not scheduled on the basis of the status & importance of the activity to be audited.
- ❑ There was no cause analysis carried out on non conformance detected.
- ❑ Follow-up audit statement did not reflect effectiveness of the corrective action verified.

Internal Audit Tips

Tip 1

Ensure auditors are adequately trained.
“The blind can only lead the blind”.

Tip 2

Ensure auditors know the area they are entering. Do some research prior to the audit. Read procedures, previous audits reports & other records. Investigate if there are problems like customers complaints, sample lost, absenteeism, etc. Take time to prepare your **CHECKLIST**.

Internal Audit Tips

Tip 3

Ensure support from Department Head, Supervisor & other personnel. They should be clear of the purpose of audit & the benefit gain from the audit exercise.

Tip 4

Record incidence as they occur. Usually it will be more difficult to record them later.

Internal Audit Tips

Tip 5

Compare the manner of operating between one operator and the other over the same activity. This is a short cut to identify discrepancy.

Tip 6

Record also potential non conformities and report it to the management. This is to help them rectify potential problem later.

Being Audited

- A positive and constructive attitude toward auditing can make the exercise enjoyable for both auditor and auditee. (Most people enjoy telling you what they know and how good they are at their job).
- An auditor is a person. Really! Their job is to validate documentation and implementation. They are just people who ask questions about how you do your job.

Who will be audited

- Absolutely everyone whose job affects quality is subject to the audit. Which is to say everyone.
- Be prepared:
 - Know documentation affects YOU...
 - Know your responsibilities and authorities.
 - Know the requirements/policies related to your activities.
 - Know what measurements related to your process/product.
 - Know what training you have had.
 - Know what records related to YOU...

Things to do!!!

- Be patient. Wait for the auditor to ask question.
- Listen closely before answering any questions. Tell the auditor if you do not understand the question. Never answer a question you do not understand!
- Always tell the truth. Don't ever hide to something. One lie can destroy confidence.
- Do not try to answer a question for another person/job. Tell the auditor who they should ask if you know.
- Tell auditor if you have to look something up in your documentation. Auditor are NOT trying to test your memory.

Thank you



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