Chapter – 13:

QUALITY AUDIT

Dr. Shyamal Gomes

Introduction:

The term ‘audit’ was defined in the 16th Century as “the official examination of the accounts with verification by reference to witness and vouchers”. Gradually, it came to be associated with ‘any systematic investigation or appraisal or procedures or operation for the purpose of determining conformity with prescribed procedures’. Today audit can be defined as “Checking – Inspection – Examination - Reporting”. According to ISO 8402: “An audit is a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and suitable to achieve objectives” (ISO – 8402)

What is Quality Audit?

A quality audit entails a systematic evaluation of a representative sample of the activities and drawing inference on the quality system as a whole. Quality audit is always performed against a documented system. The process of the quality system determines whether:

1. The documentation meets the defined quality objective of the organization.
2. The activities performed are in conformity with the documented system.
3. The quality system is effective with respect to documentation and its implementation, in meeting the defined quality objectives, and
4. Statutory and safety requirements are being fulfilled.

Now question come what is quality auditing? Quality auditing is the process of examining the effectiveness of management control programs, the purposes of which is to prevent problems. Quality audit, which forms an important part of a quality management system, is an independent review conducted to compare the given aspects of quality performance with a standard for that performance. It is one of the key management tools for achieving the objectives set out by the organization. It is an activity of gathering information for the improvement or corrective actions for standard.

Audit should be carried out to:

1. Determine conformity or non-conformity of quality system elements with specified requirements.
2. Determine the effectiveness of the implemented quality system in meeting the specified quality objective.
3. Afford an opportunity to improve the quality system

Types of Quality Audit:

There are three types of quality audits, namely, first party (internal), second party (external) and third party (extrinsic) audits. Let us understand each of these in details:

1) First party quality audit (Internal audit): when an organization conducts an audit on its own quality system using its own staff / external consultants, the audit is known as first part quality audit or internal quality audit. Important points are: auditing staff must be trained for conducting this exercise and should not bias against the functional department being audited.

2) Second party quality audit (external quality audit): The second party quality audit is performed by the purchasing organization upon the supplier organization. The idea here is to have an assessment of the supplier’s processes in order to have confidence that the supplier would be able to supply goods or services of an agreed quality level on a sustained basis. Important point is these audits can be performed by the trained personnel of the purchasing organization or an outside agency hired by them.

3) Third party quality audit (extrinsic audit): this audit is performed by the certification bodies (ISO registered bodies) on the applicant organization seeking such certification. If these, auditors, after conducting the quality audit on the organization with respect to a standard, find the organization to be worthy enough, the certification is granted to the organization. Third party audits normally results in the disruption of day-to-day activities of the organization being audited during the duration of the audit. Apart from the registered certification bodies, the third part audit may also be conducted by some government departments dealing with environment and pollution, health and safety, atomic energy etc.

Quality Audit Categories:

1. **System Audits** are looking at a particular system which includes multiple processes and can spread across several employees and departments. The audit of your calibration system can be consider a system audit. Your interaction chart lists your systems.

2. **Conformance Audits** are audits to define system requirements. These are global in nature. For example a 3rd party audit of your ISO 9001 SYSTEM is a conformance audit.

3. **Compliance Audit** is an audit to regulatory requirements. This includes government agency audits.
4. **Process Audit** is a focused audit on a set of processes within your organization. It examines adherence to procedures and specifications during production or service activities.

5. **Product Audit** is a focus audit on the product itself. This may be an inspection activity or an out of the box audit.

6. **Department Audit** is a focus audit on one department that looks at the processes, specifications, and systems in one department only. It will look at the different operations within that department. It will also examine department organization and training.

**Audit Stages:**
1. Determine the audit focus
2. Prepare for the audit
3. Perform the audit
4. Report the findings in the initial findings report
5. Determine the corrective action
6. Update the findings report with the corrective action
7. Conduct the corrective action
8. Update the findings report when actions are completed
9. Follow Up
10. Closure

**Quality Audit Benefits:**

1. It drives continuous improvement
2. Lets management know problems or potential problems
3. Provides input into management decisions
4. Accesses training and effectiveness
5. Shows management support of the quality program
6. Verifies compliance

Therefore quality audit is an important tool for continuous improvement and the auditee and auditing organization must follow the above stages. During auditing the auditor must follow some important guidelines to fulfill the objectives:

1. Do not be biased
2. Keep an open mind
3. Do not be argumentative
4. Be patient
5. Remind the participant that the audit is for continuous improvement
6. Always state the facts
7. Do not correct the person on the spot.
8. Report accurately and clearly
9. Be familiar with the procedure

Finally an ISO 9001:2000 certificate proves that the Quality Management System has been certified against a best practice standard and found compliant. Issued by a third party certification body/registrar after auditing, the certificate lets customers know they can trust that the company have implemented the necessary internal processes to meet obligations.

### Auditor’s Worksheet

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<th>Clause of the ISO Standard/ Area Covered</th>
<th>Details of person(S) Met, Activity Observed, Location of activity, Records/Documents Audited</th>
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Signature of the Auditor:

Name:

Name of the Company