

QUALITY SYSTEMS AUDITING**AUDIT OBJECTIVES:**

Audits are designed for one, or more, of the following purposes:

- a) To determine the conformance or non-conformance of the quality systems elements with specified requirements.
- b) To determine the effectiveness of the quality system in meeting specified quality objectives.
- c) To provide the auditee with an opportunity to improve the quality system, or particular sections.

Audits are generally initiated to evaluate the quality system against a known quality Standard. Audits can also be initiated by significant changes in the quality system, process or product line, or by a need to follow up on previous corrective actions. Audits conducted by different auditors should arrive at similar conclusions when the same operation is audited under the same conditions.

AUDITOR'S ACTIVITIES:

An auditor should:

- a) Exercise objectivity
- b) Collect and analyse evidence that is relevant and sufficient to permit the drawing of conclusions regarding the area being audited.
- c) Remain alert to any indications of evidence that can influence the audit result and possibly require more extensive auditing.
- d) Be able to answer such questions as:
 - i) Are the procedures, documents and other information describing or supporting the required elements of the audited area known, available, understood and used by the relevant personnel?
 - ii) Are all the documents and other information used to describe the audited area adequate to achieve the required objectives?

AUDITOR'S PERSONAL ATTRIBUTES:

An auditor should be open minded and mature; possess sound judgement, analytical skills and tenacity; have the ability to perceive situations in a realistic way, to understand complex operations from a broad perspective, and understand the role of the individual within the overall organisation. The above attributes are then applied in order to:

- Obtain and assess objective evidence fairly;
- Remain true to the purpose of the audit without fear or favour;
- Evaluate constantly the effects of audit observations and personal interactions during an audit;
- Treat concerned personnel in a way that will best achieve the audit purpose;
- Perform the audit process without deviating due to distractions;
- Commit full attention to the audit process;
- React effectively in stressful situations;
- Arrive at generally acceptable conclusions based on audit observations;
- Remain true to a conclusion despite pressure to change that is not based on evidence.
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COLLECTING EVIDENCE:

Evidence should be collected through interviews, examination of documents, and observation of activities and conditions in the areas of concern. Clues suggesting non-conformities should be noted if they seem significant, even though not covered by checklists, and should be investigated (the audit trail).

Information gathered, through interviews, should be tested by acquiring the same information from other independent sources, such as physical observation, measurements and records.

AUDIT OBSERVATIONS:

All observations should be documented. After all activities have been audited, the auditor should review the observations to determine which are to be reported as non-conformities. The auditor should then ensure that these are documented in a clear, concise manner and are supported by evidence.

Non-conformities should be identified in terms of the specific requirements of the standard or other related documents against which the audit has been conducted.

CORRECTIVE ACTION FOLLOW-UP:

The auditee is responsible for determining and initiating corrective action needed to correct a non-conformity or to correct the cause of a non-conformity. The auditor is only responsible for identifying the non-conformity.

Corrective action and subsequent follow-up audits should be completed within an agreed time period.

Should this time agreed time period overdue then an immediate superior must be made aware of the situation and one only further extension allowed to complete the corrective action(s).