Guidelines for Internal Auditing to ISO 9001:2008

Internal Audit Process

- Departments identified for annual audit
- Initial audit performed
- Departments respond to audit
- Final audit report including recommendations
- Final report reviewed by Audit & Finance Committee
- Follow-up 9-12 months after final audit reviewed

With the introduction of ISO 9001:2008, internal audit has greater impact as a tool for organizations to evaluate their systems' effectiveness and to seek continual improvement.

- ## What is an Internal Audit?

  - An internal audit is an exercise where a team of competent auditors conduct an assessment of the organization's quality management system to determine whether it is able to effectively produce products and services that meet customer and all relevant requirements.

- ## What is not an Internal Audit?

  - An internal audit is not:
    - A fault finding mission
    - Looking at documentation only; and
    - Purely a check on compliance to procedures

- **What does the standard require?**
  - It requires the audit to determine whether the quality management system:
    - Conforms to the quality plan for product realization
    - Conforms to the requirements of ISO 9001:2008
    - Conforms to the system requirements established by the organization and;
    - Is effectively implemented and maintained
- **What are the auditor requirements?**
  - To achieve an effective audit, the auditors shall possess the following attributes and skills:
    - Complete a formal course on internal auditing(can include in-house training, if conducted by a competent trainer);
    - Be technically conversant with the organization's processes and
    - Have a good understanding of ISO 9001:2008 requirements
- **Can audit be outsourced?**
  - Yes, outsourcing in an acceptable practice. However, the organization shall establish procedures for the outsourcing process, including the criteria for selection of auditors, and the review and analysis of audit results

- **How can we achieve an effective audit?**
    - To achieve an effective audit, the following shall be observed:
        - Appoint competent auditors
        - Plan the audit, taking into consideration the status and importance of the processes and areas to be audited as well as the results of previous audits
        - Conducts the audit using the process model approach
        - Do not concentrate on documentation, but to focus on the effectiveness of the processes to determine whether they can achieve the desired results, and
        - Assist the organization to identify areas for further improvements

- **What are the audit strategies available?**
    - A process approach audit could adopt one of the following strategies:
        - Vertical Audit – audit by functions, departments or individual process
        - Horizontal audit – auditing either downstream or upstream of organization's business process, which cuts across functions.

- **What are auditors required to look for?**
  - Overall conformance to the requirements of the standard;
  - Demonstration of management commitment;
  - Ability of the processes to meet customer requirements
  - Effectiveness in achieving customer satisfaction; and
  - Demonstration of continual improvement

- **Are the audit results required to be analyzed?**
  Yes, the analysis would provide information relating to:
    - Customer satisfaction
    - Conformity to product requirements
    - Characteristics and trends of processes and products including opportunities for preventive action and
    - Suppliers

Quality audit Objectives

- **Quality audits are intended to achieve the following kinds of objectives:**
  - To determine to what extent your quality system:
    - Achieves its objectives.
    - Conforms to your requirements.
    - Complies with regulatory requirements.
    - Meets customers' contractual requirements.
    - Conforms to a recognized quality standard.
  - To improve the efficiency and effectiveness of your quality management system.
  - To list your quality system in registry of an independent agency.
  - To verify that your quality system continues to meet requirements.

Professional Conduct

- Auditors must behave in a professional manner. Auditors must:
  - Have integrity and be independent and objective.
  - Have the authority they need to do a proper job.
  - Avoid compromising the audit by discussing audit details with auditees during the audit.

Auditor's job

- **An auditor's job is to:**
  - Evaluate the quality system.
  - Carry out assigned audit tasks.
  - Comply with audit requirements.
  - Respect all confidentiality requirements.
  - Collect evidence about the quality system.
  - Document audit observations and conclusions.
  - Safeguard audit documents, records, and reports.
  - Determine whether quality policy is being applied.
  - Find out if the quality objectives are being achieved.
  - See whether quality procedures are being followed.
  - Detect evidence that might invalidate audit results.

Auditee's job

- **An auditee's job is to:**
  - Explain the nature, purpose, and scope of the audit to employees.
  - Appoint employees to accompany and assist the auditors.
  - Ensure that all personnel cooperate fully with the audit team.
  - Provide the resources the audit team needs to do the audit.
  - Allow auditors to examine all documents, records, and facilities.
  - Correct and prevent problems that were identified by the audit.
- NOTE: *An " auditee" is the organization being audited or a member of that organization.*

When to do an audit

- **A client may initiate an audit because:**
  - A regulatory agency requires an audit.
  - A previous audit indicated that a follow-up audit was necessary.
  - An auditee has made important changes in:
    - Policies or procedures.
    - Technologies or techniques.
    - Management or organization.
- An auditee may carry out audits on a regular basis to improve quality system performance or to achieve business objectives.