5.3 INTERNAL AUDITS AND REGISTRATION

ISO 9001 is an internationally recognized framework that outlines the criteria for a robust QMS to enhance customer satisfaction and continual improvement. The ISO 9001 has set forth requirements for the Quality Management System of organizations (QMS). A systematic examination of the QMS to ensure its compliance with the requirements is called Internal Quality Audit ISO 9001.

Internal audits are a fundamental component of ISO 9001, serving as a proactive tool to assess whether the organization's processes, procedures, and practices align with the standard's stipulations and the company's own objectives. These audits are conducted by qualified personnel independent of the audited area, ensuring impartiality and objectivity in their evaluations.

The primary objectives of internal quality audit ISO 9001 include verifying the effectiveness and efficiency of the QMS, identifying areas for improvement, ensuring compliance with ISO 9001 requirements, and determining whether implemented processes align with planned arrangements. Auditors examine documentation, records, procedures, and practices to evaluate conformity and effectiveness.

The audit process typically involves planning, conducting the audit, reporting findings, and implementing corrective actions where necessary. Through this systematic review, companies can detect non-conformities, inefficiencies, or gaps in their processes, allowing them to take corrective and preventive actions to enhance overall performance.

Internal quality audit ISO 9001 ensure compliance with ISO standards and facilitate a culture of continual improvement within the organization. By addressing shortcomings and optimizing processes, companies can enhance product or service quality, increase <u>customer satisfaction</u>, reduce risks, and ultimately improve their competitiveness in the market. Regular and thorough internal audits are crucial in maintaining the effectiveness of the QMS and achieving sustained success in today's competitive business landscape.

Steps in Internal Audit of Quality Management System

Conducting an internal audit of a <u>Quality Management System</u> (QMS) involves a systematic and structured approach to assess compliance with established procedures, standards, and regulations

by its own personnel. Internal audit of a quality management system aims to assess compliance, identify areas for improvement, and ensure effectiveness in achieving the objectives while adhering to established standards, policies, and procedures. Here are the critical steps involved in performing an internal audit of a quality management system:



Planning:

Define the audit scope, objectives, and criteria based on the requirements of the ISO 9001 standard and the organization's goals.

Select qualified auditors and assemble an audit team.

Develop an audit plan detailing the schedule, areas to be audited, resources needed, and evaluation methods.

Documentation Review:

Examine documented processes, procedures, quality manuals, and records related to the QMS.

Verify that documented procedures align with actual practices and meet the requirements of ISO 9001.

On-Site Assessment:

Conduct interviews and discussions with personnel involved in various processes to understand their roles and responsibilities.

Observe processes and activities to ensure they comply with documented procedures and standards.

Evaluate Compliance:

Use checklists or audit tools to systematically assess each area of the QMS against ISO 9001 requirements.

Collect evidence and data to support findings, including records of non-conformities and areas for improvement.

Reporting and Analysis:

Prepare an audit report summarizing audit findings, observations, identified non-conformities, and opportunities for improvement.

Differentiate between minor <u>non-conformities</u> and critical issues requiring immediate attention.

Corrective Actions and Follow-Up:

Collaborate with relevant stakeholders to develop corrective action plans to address identified nonconformities.

Monitor and verify the implementation and effectiveness of corrective actions taken.

Closure and Continuous Improvement:

Close the audit process by verifying the resolution of identified issues.

Use audit findings to initiate improvements in the QMS, fostering a culture of continuous improvement.

Types of Internal audits:

Types of Internal audits include

- Compliance audits
- Operational audits
- Financial audits
- Information technology audits.

A compliance audit is an examination of conformity and adherence of a particular area, process, or system to policies, plans, procedures, laws, regulations, contracts, or other requirements that govern the conduct of the area, process, or system subject to audit.

An operational audit is a review mainly focused on the internal controls of key processes, procedures, or systems. The main objective is to improve productivity, as well as efficiency and effectiveness of the operation.

A financial audit is an objective examination and evaluation of the internal controls and systems surrounding financial reporting processes and preparation of financial statements for the benefit of management and the board of directors.

An information technology audit is an examination of the management controls within IT applications, operating systems, databases, or the infrastructure. Reviews may be focused exclusively on IT or performed in conjunction with a compliance, operational, or financial audit.

The Four Pillars of High-Performing Internal Audit Functions:

Internal audit departments play a critical role in safeguarding an organization's health. But what separates a good internal audit function from a truly high-performing one? Research suggests four key characteristics distinguish the best internal audit teams. Let's explore these pillars and how they contribute to overall success.

Alignment with Organizational Value

High-performing internal audits don't operate in a vacuum. They ensure their activities align strategically with the organization's goals and objectives. This means understanding the company's value proposition and tailoring audits to identify and address risks that could hinder its success.

Stakeholder Relationship Management

Internal audits don't exist solely for internal audit departments. Effective teams cultivate strong relationships with a wide range of stakeholders, including management, the board of directors, and even external auditors. Clear communication and a #collaborative approach foster trust and ensure everyone benefits from the audit process.

Empowering Leadership

Micromanagement stifles innovation and engagement. High-performing internal audit functions embrace empowering leadership styles. These leaders provide clear direction and support but also give their teams the autonomy and freedom needed to deliver high-quality audits.

Accountability and Efficiency

Transparency is key. High-performing internal audit teams are accountable for their work and strive for continuous improvement. This means being open about their performance metrics and

actively seeking feedback from stakeholders. They also operate efficiently, maximizing their impact without unnecessary bureaucracy.

The Synergy Effect

These four characteristics are not independent; they work together to create a powerful synergy. By aligning with organizational goals, fostering strong relationships, empowering their teams, and remaining accountable, internal audit functions can deliver significant value to their organizations. This, ultimately, positions them as true business partners, driving positive change and contributing to the organization's overall success.

