

Quality Management System Guidance

Internal Auditing - Planning, Conducting & Reporting

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1 Introduction to Internal Auditing

1.1 Purpose of Internal Auditing

The purpose of internal auditing is to assess the effectiveness of your organization's quality management system and your organization's overall performance. Internal audits demonstrate compliance with your 'planned arrangements', e.g. the management system, its processes and documentation are implemented and maintained.

As an auditor, you'll need to gauge how well the management system and its processes are functioning by gathering objective evidence of conformance and performance, or lack thereof. The auditee will often be a processes owner; they are the experts of that process and as such will provide an invaluable insight into the mechanics of the process. Begin allocating more time for internal audits:

1. Allocate more time to prepare for the audit;
2. After initial implementation, shift to more process-based assessments;
3. Follow new audit trails and linkages through the processes;
4. Interview Top management in more depth.

Your organization will likely conduct internal audits for one or more of the following reasons:

1. Ensuring compliance to the requirements of internal, international and industry standards and regulations, and customer requirements;
2. To determine the effectiveness of the implemented system in meeting specified objectives (quality, environmental, safety, financial, etc.);
3. To explore opportunities for improvement;
4. To meet statutory and regulatory requirements;
5. To provide feedback to Top management.

In addition to this guidance document, the package contains the following documents, which include essential reports, checklists, trackers, and programmes:

Phase	Document Title	Format	How/when to Use
Planning	Internal Audit Programme	.xlsx	Planning and communicating short and long-range internal audit activities
	Gap Analysis Checklist	.docx	Conducting an initial gap analysis in preparation for full implementation
Doing	Internal Audit Checklist	.xlsx	Conducting compliance to requirements (system) audits to ensure comprehensive coverage
	Process Audit Template	.xlsx	Conducting, noting and reporting in-depth analysis of individual processes and their linkages
	Supplier Audit Checklist	.docx	Capturing QMS compliance information from Suppliers as a basis for selection
Checking	Corrective Action Log	.xlsx	Tracking non-conformities that relate to corrective actions and monitoring timely close-out
Acting	Corrective Action Report	.docx	Documenting, problem solving and reporting non-conformities and their corrective actions
	Internal Audit Report	.docx	Summarising and reporting internal audit findings to Top management
	Internal Audit Feedback	.docx	Capture opinions, opportunities for improvement and lessons learnt from auditees

ISO 9001:2015, the audit criteria become ISO 9001 + relevant quality management system documentation such as the quality manual, procedures, work instructions, SOPs, and forms, etc.

If you are going to conduct a product audit against a production control plan, the audit criteria will be the control plan itself, or relevant parts of it. The same applies when auditing an operator to see whether they follow the Work Instruction, the audit criteria is the Work Instruction for that process and any applicable criteria.

1.5 Types of Internal Audit

1.5.1 Gap Analysis

Within the sphere of internal auditing there are a number of methods for undertaking internal audits. The gap analysis will likely be your first ISO 9001:2015 audit. The [Gap Analysis Checklist.docx](#) highlights the new requirements contained in ISO 9001:2015 but it not intended to cover all of the requirements from ISO 9001:2015 comprehensively.

The unique knowledge obtained about the status your existing quality management system will be a key driver of the subsequent implementation approach. Armed with this knowledge, it allows you to establish accurate budgets, timelines and expectations which are proportional to the state of your current management system when directly compared to the requirements of the standards.

The results of a gap analysis exercise will help to determine the differences, or gaps, between your existing management system and the requirements of ISO 9001:2015. Not only will the analysis template help you to identify the gaps, it will also allow you to recommend how those gaps should be filled.

The gap analysis output also provides a valuable baseline for the implementation process as a whole and for measuring progress. Try to understand each business process in the context of each of the requirements by comparing different activities and processes with what the standard requires. At the end of this activity you will have a list of activities and processes that comply and ones that do not comply. The latter list now becomes the target of your implementation plan.

1.5.2 System Audits

System audits are commonly referred to as a 'first-party audit' and are conducted by an organization to determine compliance to a set of audit criteria in the form requirements that arise from standards like ISO 9001:2015, as well as customer, or regulatory requirements.

The system audits are best undertaken using the [Internal Audit Checklist.xlsx](#). This type of audit focuses on the quality management system as a whole, and compares the planning activities and broad system requirements to ensure that each clause or requirement has been implemented.

1.5.3 Process Audits

The adoption of the 'process approach' is mandated by ISO 9001:2015 and is one of the most important concepts relating to quality management systems. Process auditing is about auditing your organization's processes and their interactions, which together comprise the quality management system. The process audit provides assurance that the processes have been implemented as planned and provides information on the ability of the process to produce a quality output.

Using the [Internal Audit Checklist.xlsx](#) to undertake a clause-by-clause audit works very effectively for the initial audits in preparation for implementation, gap analysis or certification. However, once your management

system is implemented, your organization is expected to develop a process approach to its auditing programme.

Use the *Process Audit Template.xlsx* for conducting an in-depth analysis to verify that the individual processes comprising the management system are performing and producing outputs in accordance with the planned outcomes. The process audit also identifies any opportunities for improvement and possible corrective actions. Process audits are used to concentrate on any special, vulnerable, new or high-risk processes.

The process approach is one of the core quality management principles, which is defined as a 'consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system'.

A process is a set of interrelated activities that transform inputs, such as materials, customer requirements and labor, via a series of activities into outputs, such as a finished product or service. Various stages of the process must meet various applicable clauses of the standard. There are six characteristics to look out for when auditing a process:

1. Does the process have an owner?
2. Is the process defined?
3. Is the process documented?
4. Are links between other processes established?
5. Are processes and their links monitored?
6. Are records maintained?

As part of the process approach, the process audits must be scheduled according to the processes defined by your management system. The audit schedule should not be based on the clauses of the standard, but it should instead be based upon the importance and criticality of the process itself. The process approach to auditing should cover three vital stages:

1. Preparing for the audit; (desk review)
2. Auditing the process and its linkages;
3. Preparing the summary and audit report.

An audit each process should be conducted at planned intervals in order to determine whether the processes conform to planned arrangements in order to determine whether the process is properly implemented and maintained and to provide process performance information to top management.

Effective process auditing requires the auditor to identify and record audit trails that will make a difference to the organization. The audit should begin with the process owner in order to understand how the process interacts with the other process inputs, outputs, suppliers and/or customers.

1.6 Using the Internal Audit Checklist

1.6.1 Internal Audit Checklist

The internal audit checklist is just one of the many tools which are available from the auditor's toolbox that help ensure your audits address the necessary requirements. The checklist stands as a reference point before, during and after the audit, and will provide the following benefits:

1. Ensures the audit is conducted systematically;