Internal Audit Guidance

ISO 9001:2015

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Introduction to Internal Auditing

1.1 Purpose of Internal Auditing

Internal auditing aims 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 quality management system, processes, and documentation are implemented and maintained.

As an auditor, you'll need to gauge how well the quality management system and its processes function by gathering objective evidence of conformance and performance, or lack thereof. The auditee will often be a process owner; they are the experts of that process and can provide 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 with 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, health and safety, 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	.xlsx	Capturing compliance information from Suppliers as a basis for selection
Checking	Corrective Action Tracker	.xlsx	Tracking nonconformities that relate to corrective actions and monitoring timely close-out
Acting	Corrective Action Report	.docx	Documenting, problem-solving, and reporting nonconformities and their corrective actions
	Internal Audit Report	.docx	Summarising and reporting internal audit findings to Top management
			Capture opinions, opportunities for improvement, and lessons learned from auditees

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sections of the standards and the relevant management system documentation such as the manual, procedures, work instructions, SOPs, and forms.

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 Instructions; the audit criteria are the Work Instructions 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 audit. The *Gap Analysis Checklist.docx* highlights the new requirements contained in the standards, but it is not intended to cover all of the requirements comprehensively.

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

The gap analysis exercise results will help determine the differences, or gaps, between your existing management system and the requirements of ISO 9001. 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 and 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 of requirements that arise from standards like ISO 9001, 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 interactions, which 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 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 quality

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4. Does product information flow freely?
5. Is the procedure right, and does it meet the standard?
6. Is it helping the organization effectively?

1.7.5 Review the Findings

Mark findings and issues as you go. When you finish auditing, you should have a collection of various findings to review. Organize the notes you made; these findings need to be reported to management. As you moved through the audit, you should have noted the issues and improvements you saw.

When you have completed the audit, you will probably have findings. Some findings might be problems, and some might be opportunities for improvement. Review your notes and collect the findings into the audit report. Audit teams should review findings with the lead auditor and/or management representative as it is important to calibrate the findings, and this serves as a learning process. If there is disagreement over some findings, the Lead Auditor has the final vote.

1.7.6 Prepare the Report

Using the *Internal Audit Report.docx,* begin preparing the audit report. A good summary report is the output, which is the value of the audit. It deserves an appropriate amount of attention and effort. As you moved through the audit, you should have noted the issues and improvements you saw. These should have been marked clearly so you are now able to quickly review and capture them as you write the report.

The findings and conclusions should be formally documented as part of the summary report. Too often, the audit report only recites back facts and data the managers already know. The value is in identifying issues and opportunities they do not know! This summary should be reviewed first by the lead auditor and then by the Process Owner and Management Team. Make final revisions and file the audit report and all supporting audit materials and notes.

Gather the whole audit package together in an organized manner. The rest of the work instructions, flowcharts, notes, and relevant papers should be gathered into the audit package as supporting records. All adverse findings should also be documented on the *Corrective Action Report.docx* and tracked using the *Corrective Action Tracker.xlsx*.

The audit summary and the corrective action forms should be attached to the audit report, which now becomes the audit record. Only the summary report and corrective actions need to be given to the Process Owner, and a copy of the audit report should be given to Top management.

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