

We're committed to helping you and your organization understand the updated requirements. This guidance document identifies the steps you should take to achieve compliance to ISO 9001:2015, and more importantly; what you don't need to do!

Internal Auditing Guidance

Assessing ISO 9001:2015

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Your organization may already have in place an ISO 9001:2008 compliant quality management system or you might be running an uncertified system. If this is the case, you will want to determine how closely your system conforms to the requirements ISO 9001:2015.

The results of a gap analysis exercise will help to determine the differences, or gaps, between your existing management system and the new requirements. 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.

System Audits

The system audits are best undertaken using the internal audit checklist. This type of audit focuses on the organization's 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.

Process Audits

The process audit is an in-depth analysis which verifies that the processes comprising the management system are performing and producing in accordance with desired 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.

Product Audits

The product audit may be a series of audits, at appropriate stages of design, production and delivery to verify conformity to any specified product requirements, such as dimensions, functionality, packaging and labelling, at a defined frequency.

Internal Audit Programme

Implementing the Audit Programme

During the early stages of implementing ISO 9001:2015, or any other management system standard, the internal audit programme often focuses on ensuring that any compliance issues or non-conformities are discovered and rectified prior to the Certification Body assessment.

However, once your organization becomes certified, the audit programme must evolve. The focus of the internal audit programme should be re-directed, away from 'elemental' compliance with ISO 9001:2015, to an audit strategy that considers the 'status and importance' of each process comprising the quality management system. This is one of the most disregarded aspects of ISO 9001:2015.

Has your internal audit programme been developed on an annual calendar that forecasts which aspects of your QMS are going to be audited? If so, you should begin programming your internal audits by basing the audit frequency upon current process performance data, feedback from customers, etc., to ensure that you are focusing on the risks and issues that are on Top management's radar.

Focus on Risk-based Auditing

Internal audit programmes that are based on risk and customer feedback will help your organization to embark upon new methods of compliance in which risk based thinking and continual improvement are the drivers, rather than something done simply for compliance. Improving the internal audit programme in this manner will help to ensure corrective actions are regarded as important to process results and that management reviews of the QMS become an integral way of managing risk.

How to Programme your Audits

How do you plan your internal audits, whilst taking into account the status, practices and importance of your processes? If you purchased the Audit Tracker Pro™ workbook, you can use the status and importance worksheet to help determine which of your processes are critical and therefore which should be audited more frequently. You can also create your own status and importance tracker using the criteria described in this section.

The ranking criteria are based on processes' ability to adversely affect your customers and how well the process is performing. This is a great way to mathematically substantiate your audit programme and to introduce elements of risk based auditing to your internal audits. You should then schedule processes with high, red scores for additional audits, perhaps or three or even more times per year.

Step 1 – Determine Process Status

You should consider your processes status in terms of maturity and stability; a more established, proven process will need to be audited less frequently than a newly implemented or recently modified (changed or improved) process and should receive a lower status score. Conversely;

processes which are not performing to the planned arrangements, should be assigned a higher status score.

Score/Rank	Description
1 = Low	All indicators show stability and consistently achieve targets
2 = Medium	Minor problems exist, process or product changes planned
3 = High	Poor performance/adverse trends, results not achieved
4 = Critical	Any process with major audit finding in past 12 months

Step 2 – Determine Process Practices

You should consider how process practices can affect product conformity, are process participants applying best practice to create conforming process outputs? Consider whether the practices are documented and whether they are applied consistently between other, similar processes?

Score/Rank	Description
1 = Low	Consistently applying documented practice
2 = Medium	Current practices conform but are not documented
3 = High	Practices are applied inconsistently
4 = Critical	Practices are non-conforming

Step 3 – Determine Process Importance

You should consider process importance as the degree of direct impact that process performance has on customer satisfaction and perception; i.e. could the process provide the customer with a non-conforming product?

Support processes should be given a lower ranking than the manufacturing or service provision processes. In addition, the results of previous audits should be considered too. Processes that have been

audited recently and which show continued effectiveness should be audited less frequently.

Score/Rank	Description
1 = Low	Low risk of adversely affecting customer satisfaction
2 = Medium	Adverse effect on customer satisfaction & product quality
3 = High	Likely have a significant adverse effect on customer satisfaction
4 = Critical	Likely cause safety or regulatory compliance issues

Step 4 – Determine Quality Ranking

Consider how a failure in quality attributes could affect your customers in terms of providing non-conforming product. In fact, why not ask your customers which attributes could affect them the most, as this method provides a great way to engage with them and to objectively justify the audit programme to top management.

Step 5 – Determine the Number of Customer Complaints

Simply put, enter the actual number of complaints in the relevant cell that is related to the process. Customer complaints are ranked very highly in terms of seriousness and will elicit a red warning to highlight that process as requiring greater audit scrutiny.




Step 6 – Determine the Number of Corrective Actions

Include the number of open corrective actions in the relevant cell that are related to the process. The corrective actions should be included and must cover all those that were raised internally or externally.

External corrective actions rank higher in terms of importance than internal corrective actions. External corrective actions might arise from customer audits, registrar audits or from other stakeholders.

Step 7 – Use the Indicators to Determine Audit Frequency

After you have entered the scores necessary to rank each process by its current performance attributes, the assessment tool will generate resulting simple, 'traffic light' indicators that are highlighted in the worksheet to indicate whether the process requires more frequent auditing. The process indicators will also copy in to the audit programme in order to provide a cross reference to the indicator that influenced the audit frequency.

Indicator	Description
	An audit should be scheduled at least once per year unless otherwise required
	An audit should be scheduled within 12 weeks with an additional audit within 6 months
	An audit should be scheduled within 4 weeks with an additional audit after 12 weeks and then reoccurring quarterly

Step 8 – Enter Planned Audit Dates

Now that you have determined which processes require more frequent internal auditing, based on their status and importance, you schedule a series of internal audits for each process based on the priority scores shown. Simply enter the start date and the finish date of each audit. The internal audit programme will automatically highlight the relevant cells in the programme. The programme has space to track one planned audit and three additional audits for each process.

Audit Methodology

Introduction

The adoption of the 'process approach' is mandated by ISO 9001:2015 and is one of the most important concepts relating to quality management