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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.