

Understanding the ISO 9001 Quality Manual

The ISO 9001 Quality Manual is a top-level document describing how an organization intends to manage, maintain and improve its quality management system (QMS). At the core of the ISO 9001 quality manual is the quality policy statement. This statement acts as a narrative describing an organization's approach to achieving customer satisfaction whilst also providing focus and direction to the procedures which must be implemented in order to meet the requirements of ISO 9001:2008.

Structuring the ISO 9001 Quality Manual

Often, it is common to align the structure of the ISO 9001 quality manual with that of the ISO 9001 standard itself, but this 'belt and braces' approach is not always necessary. Conversely, a four page quality manual may do little to inspire confidence that your quality management system has the necessary elements to be truly effective.

As long as the quality manual clearly shows how the quality management system processes interact, and at the highest level, what policies and methods are established to maintain and control those processes, an auditor is less worried about the structure of the manual.

Don't try to structure the ISO 9001 quality manual to suit an external auditor's expectations, this is the wrong approach. It is not for external auditors to 'agree' with the structure of the quality manual, instead, they must simply determine whether the manual's content complies with the requirements of the standard.

The ISO 9001 quality manual undertakes the essential role of formalising and communicating the relationship between the organization's processes. Everyone expects something different from their quality manual but as long as it meets the stated requirements of ISO 9001 as well as organizational needs, the question of structure becomes irrelevant.

Who uses the Quality Manual?

Customers want to understand how your organization and more importantly, how your quality management system will take care of their needs. They want to know that you know how to plan, implement, and control the processes that will deliver satisfaction.

Auditors want to know how the organization meets the requirements of the standard, and if the system is effective in achieving the objectives. If the requirements of the standard are addressed in the manual, along with some details of the method, then auditors can use the manual as a guide to help them find the evidence they need.

Management and other users should be able to see from the manual how the organization's quality management system is designed to work. It should show how the processes of the system interact.

Amending the Quality Manual

Amendment of the quality manual or procedures should be initiated by the departmental heads as and when the need for amendment becomes apparent. The amendment should be approved by an authorised signatory before the actual changes are implemented.

It is not a requirement to wait for a formal management review prior to amending the documentation. If major changes must be made to key documents, such as the quality policy or quality objectives, it is prudent to include these for inclusion during the management review process.

Resource box

The Quality Management Representative is responsible for developing the [ISO 9001 quality manual](#) with a clear understanding of the organization's vision, mission, goals, key objectives, policies and procedures needed to achieve certification.

1so 9001 Policy Manual

Lingsheng Yao



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