

ISO 9001:2015 Clause Primer

4 Context of the Organization

In order to design an effective Quality Management System, the organization must understand the issues and the stakeholders that influence how the system is designed and operates. This understanding stems from seeing your operation as a sequence of interconnected processes. How these processes are linked and support each other determines how the organization delivers consistently on the customers' requirements.

5 Leadership

Leadership takes responsibility for assuring the organization understands the aims of the Quality Management System and establishes a policy that includes a commitment to continuous improvement as well as delivering on customer requirements. The leadership assures the organization is supported in fulfilling the expectations of the Quality Management System.

6 Planning

The impact of risks and opportunities on the ability of the QMS to deliver on expectations are actively managed by the organization. This includes setting Quality Objectives for the organization and having a system in place that will manage changes to the QMS.

7 Support

Support systems for the QMS include human and non-human resources, awareness of and communication about the QMS to the organization, and necessary documentation to assure consistency in practices.

8 Operation

Clause 8 covers the core operating mechanisms within the organization. These include planning operations, understanding requirements, and production or service delivery controls, including assuring nothing is released to the customer unless it meets their requirements. In addition, any internal design and development work supports the QMS and the supplier community is considered as an extension of the organization's QMS. Finally, a system for managing non-conforming outputs and assuring root cause analysis and corrective measures is a requirement.

9 Performance evaluation

Clause 9 requires that the organization reflects on its performance as a Quality Management System. Formal reflection opportunities exist in Management Reviews and Internal Audits. However, there is a significant expectation that process effectiveness measures are in place that allow the business to understand, monitor, and act upon performance in a real-time way.

10 Improvement



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Improvement is expected to be driven by findings during normal operation, as a result of internal audits, and as a matter of periodic reviews. Improvements made should connect back to flaws identified in the way the system operates and should go beyond fixing a bad part to correcting a weak system so the bad part no longer can occur.

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