

ISO 9001 explained

It is essential that you and your team understand the elements of the standard. This is the foundation of your quality management system and continual improvement.



EVA
PAVLAKIS
CONSULTANT
PNP GROUP

It's all about the

"PLAN-DO-CHECK-
ACT" approach

leading to Continual Improvement and

business success.

CLAUSE 1: SCOPE

The first clause is an overview and scope of the standard.

CLAUSE 2: NORMATIVE REFERENCES

ISO 9000, Quality Management System - Fundamentals and vocabulary are referenced and provide valuable guidance.

CLAUSE 3: TERMS AND DEFINITIONS

This clause outlines all terms and definitions that are contained in ISO 9000:2015 and clarifies the meaning of such.

CLAUSE 4: CONTEXT OF THE ORGANISATION

This section outlines the requirement of understanding the framework of your business and the quality management system. This includes identifying requirements and obligations that govern and have an impact on your business and operations (such as contracts, relationships, regulators, etc.).

Then you need to identify all stakeholders "interested parties" that are relevant to your QMS (these could be employees, customers, etc.) and understand their requirements.

As next, the standard required a clear definition of your scope of your QMS. This may be the whole of your organisation or specific, identified functions.

Finally, you'll need to demonstrate a high-level process and approach how the business processes integrate to maintain, and continually improve the QMS in relation to the standard.

ISO 9001 explained

CLAUSE 5: LEADERSHIP

This clause is all about the role of the management of your organisation at the highest level. They need to be committed and ensure that the MS and its requirements are integrated into the organisation's processes. Their responsibilities and authorities need to be defined at all required levels people need to be aware of the role they play in the business, with the aim of delivering the high-quality outputs to ensure the effective operation of the QMS

A documented Quality Policy for the Management System must be established, which must be aligned with the strategic direction and goals of the business. Management needs to ensure that the policy is available, communicated and understood by relevant stakeholders and people.

Opposed to the ISO 9001:2008, the current 2015 standard makes not only the "Quality Representative" responsible for the compliance, instead the entire top management accountable.

CLAUSE 6: PLANNING

This clause focuses on strategic business planning. It requires management to address risks of the business and Management System while maximising opportunities, such as new product launches, new technology or expansion into new areas to achieve business goals.

Another key area of this clause is the need to establish measurable short- & long-term quality objectives. These shall be set at relevant functions/ departments and plans, and strategies must be in place how to achieve them. Team members must be aware of their function and how they contribute to achieving their objectives.

The last part of section six is the requirement of a systematic process to address needs for changes to the business's operation, how to deal with them when they occur including involvement of required parties and staff.

CLAUSE 7: SUPPORT

This section of the standard is about ensuring the right resources, the people, and infrastructure is in place to meet the strategic goals and objectives of the business, including continual improvement. This includes appropriate education, experience and competencies of people to perform a specific task that affects the Quality or performance of the QMS.

The organisation must ensure that people doing work under their control (incl contractors) are aware of and understand the quality policy, their contribution to quality and implications of not conforming.

The last component of this section of the standard is documented information - the organisation must determine and develop relevant documentation (incl. policies, procedures, and other means of documentation) necessary for the effective operation of the QMS including those that are required by the standard. There is no longer a need for quality manual and every process to be documented; however, a good level of documentation is required to support your practices. This also allows your staff to refer to a document when following a process. Always remember, it's good practice to back-up what you say you do and how you do it by a policy or procedure or other documented means.

ISO 9001 explained

CLAUSE 8: OPERATION

This clause is about the execution of the plans and controlled processes for the provision of products and services from start to end.

It requires the organisation to have processes in place for reviewing and communicating with customers in relation to products and service requirements, including the organisation's capability to supply the product/ service.

If you outsource any processes, products or services that may have an effect on the quality of your end products/ services you need to ensure that such outsourced processes, products, and services are under your control and conform to specified requirements.

If you design and develop products or services, you must have a process in place to ensure designs are reviewed and / or validated to ensure compliance with requirements.

You must also ensure that your operations/ service provisions are carried out in controlled conditions which including having documentation in place on product/ service requirements, intended results and required stages of inspection and product release.

The standard requires you to ensure there is a process in place for managing nonconforming outputs. If a product or service does not conform to the requirements, you must ensure that you are able to manage and correct the issue.

CLAUSE 9: PERFORMANCE EVALUATION

This is all about measuring and evaluating your QMS to ensure that it is effective, and it helps you to continually improve. You will need to determine what needs to be monitored, the methods of monitoring and analysis and at what stages such analysis will be performed.

The standard required to also have methods in place, such as surveys, for proactively monitoring customer satisfaction, including their perceptions of the degree to which their needs and expectations have been fulfilled.

The next part is about internal auditing and the requirements of documenting and retained information related to audit planning and audit results. Internal audits will need to be carried out, and there are certain "audit criteria" defined to ensure that the results of these audits are reported to relevant management.

The last requirement of this section of the standard is on management reviews of the quality management system to ensure suitability and effectiveness.

CLAUSE 10: IMPROVEMENT

This clause of the standard focuses on the continual improvement of the organisation's QMS. It requires the business to demonstrate that their quality management system effectively evolves with the business as it grows and changes. This includes continually improving the quality management system to match the strategic direction of the business.

In addition, the organisation is required to have appropriate processes in place to react and manage nonconformities and the related corrective actions, including determining the cause of non-conformities. The organisation must review the effectiveness of corrective actions and revise or implement changes to processes to prevent form recurrence.

"Regardless of the Risks, together we will Progress
and Succeed."

PNP Group of Companies



Speak to our consultants for your free proposal!

- P:** 1300 PNP GOC (1300 767 462)
- E:** Info@pnpgroup.co
- M:** PNP Australasia Pty Ltd,
PO BOX 174, Macarthur Square,
Campbelltown, NSW 2560
- W:** www.pnpgroup.co