



White Paper Requirements and Principles ISO 9001



ISO 9001 is the internationally recognized and most widely used standard for quality management (QM) in companies. It defines the minimum requirements for the introduction of a quality management system (QMS). The standard is aimed at companies of all types, sizes and industries. In this white paper the requirements, principles and prerequisites of the quality standard are described in more detail.

Requirements of ISO 9001 for the QMS

One of the most important requirements for a company's quality management system is to map its processes and activities. This central requirement has existed since the transition from ISO 9001:1994 to ISO 9001:2000 and has remained an important part of the standard ever since. In the new **ISO 9001:2015** this process-oriented approach was extended. Aspects that were dealt with in an informative way in older versions, such as expectations related to interested parties, are now requirements.

Section 4 of the ISO 9001 quality standard, „Context of the organization“, provides more details for understanding the business context:

Section 4.1: External and internal issues relevant to the strategic direction of the organization.

The factors that have an impact on the quality management system must be determined. A distinction is made between:

- **External topics**
aspects that arise, for example, from legal, technical, competitive, market, cultural and economic contexts.
- **Internal topics**
aspects arising from values, corporate culture or performance of the organization

Section 4.2: Understanding the needs and expectations of interested parties.

An interested party is a person or stakeholder with (potential) influence on the company. It is therefore one of the requirements of ISO 9001: 2015 to determine who the interested parties are and what their influence on the QMS is.

Section 4.3: Definition of the scope of the management system.

To determine the scope of application, the following aspects must be taken into account:

- internal and external topics,
- the requirements of interested parties,
- the products and services produced by the company

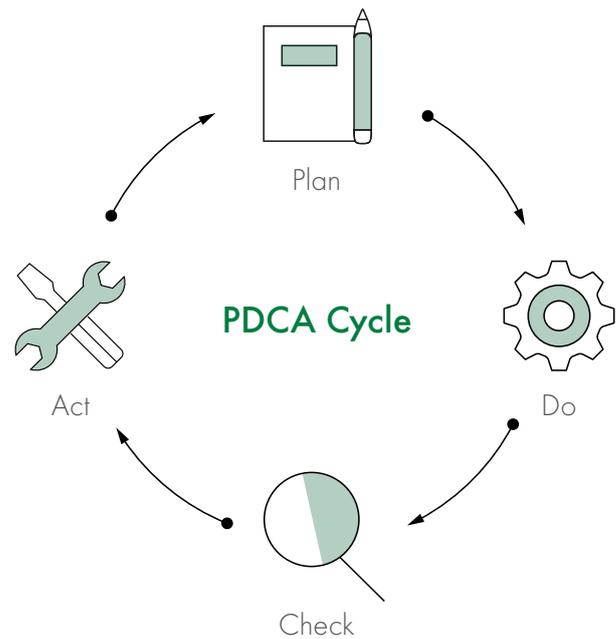
Section 4.4: Implementation of the quality management system and its processes.

The areas of application must be documented and accessible.

PDCA Cycle

The process-oriented approach is one of the new central features in the latest ISO 9001. The approach is intended to enable companies to continually optimize quality management and the processes it governs, to identify potential for improvement and to identify risks. In this way, quality management as a whole can fulfill goals more effectively. The systematic definition and control of processes and their interactions can be achieved with the help of the so-called PDCA cycle:

- **Plan**
In the first phase of the PDCA cycle, the current situation is analyzed and described. This includes identifying the causes of possible problems and formulating the desired target situation. To achieve this goal, optimization measures must be defined, taking into account possible



interactions and risks. The goals formulated should be in line with customer needs and corporate policy.

- **Do**
In the second phase of the cycle, the implementation phase, the measures to achieve the planned objectives are defined. The planning and its implementation is communicated to the company's employees so that the measures can be implemented accordingly.
- **Check**
The review phase reflects on the experience and results obtained in the previous phase. In order to be able to act effectively in the next phase, it is necessary to detect and evaluate deviations between the actual and target situations and the associated risks and improvements.
- **Act**
In the fourth and final phase of the PDCA cycle, the experience gained and results obtained are evaluated and, if deemed successful, standardized. This is done by comparing the actual and target situation. In the event of a divergence between the objective and the new actual situation, considerations for further action must be made and the phases repeated.

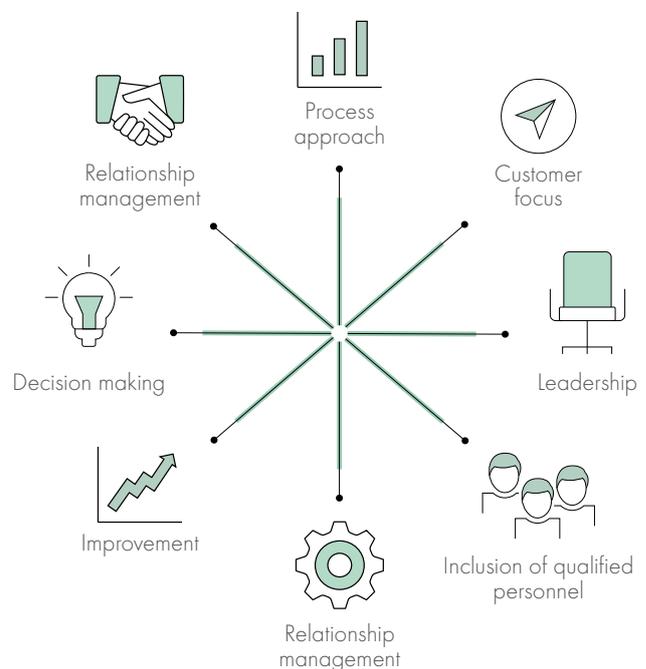
The process-oriented approach of ISO 9001:2015, risk-based thinking and the PDCA cycle complement each other. The combination of these three approaches makes it possible to secure and increase added value in a holistic and sustainable manner. The application of the cycle leads to an improvement in companies' process performance and a related increase in customer satisfaction. A more intense focus on the analysis of possible weak points and sources of error and the associated corrective measures lead to improved risk prevention.

ISO 9001 principles

When introducing a quality management system, various ISO 9001 principles should be observed. The internationally recognized quality standard is based on several principles which are described in more detail in ISO 9000 (Quality Management Systems - Basics and Terms):

- Customer focus**
 In order to establish an effective and sustainable quality management system, orientation towards the needs of customers is particularly important. A thorough assessment of customer needs is therefore essential.
- Leadership**
 The task of managing a company or organization is to ensure the long-term effectiveness of the QM system and its maintenance. It also ensures communication of the company's strategies and processes throughout the entire organization. Furthermore, company management supports the achievement of quality goals.
- Inclusion of qualified personnel**
 In order to optimize processes and structures effectively, the participation of competent, authorized and committed people is important. Motivated staff facilitates work and the achievement of set quality goals.

- Process approach**
 Another core component of the QMS according to ISO 9001 is alignment with company structures and processes. Understanding different activities as interrelated processes and as part of the system facilitates their optimization.
- Improvement**
 Since requirements are constantly multiplying and changing, the continuous improvement process is another important component of quality management in accordance with ISO 9001.
- Fact-based decision making**
 The decision-making process in companies is complex. An optimal procedure for it should be taken into account in the quality management system.
- Relationship management**
 The goal of relationship management is to benefit all interested parties, such as customers, suppliers or the company itself. Targeted management of a company's relationships has a lasting effect on its success.



Requirements for ISO 9001 certification

In order to obtain ISO 9001 certification, an effective and sustainable quality management system must be introduced in the company. This QM system must be communicated and accessible to all employees. It should contain all quality-relevant procedures and processes.

In addition to documented information, the practical implementation of the QMS is also necessary. All employees must

have been instructed in the use of the system and trained in such a way that they can fulfill the activities required in the process instructions.

For ISO 9001 certification, the effectiveness of the quality management system must also be tested and comprehensibly documented by means of internal audits in all areas of the quality standard.

Our experts will be happy to support you in introducing a quality management system in accordance with the requirements for ISO 9001 certification. Contact us today for more information!

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