



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.

The requirements that ISO 9001 imposes on 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 OMS 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

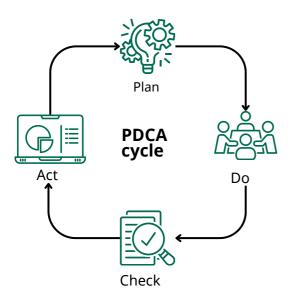
Section 4.4: Implementation of the quality management system and its processes.



PDCA Cycle

The process-oriented approach is one of the new core components of the new version of ISO 9001. The aim is to enable companies to continuously optimize quality management and managed processes and to identify risks and opportunities for improvement. This makes it possible to achieve the objectives in the field of quality management more effectively.

The systematic definition and management of processes and associated interactions is possible by going through what is called the PDCA cycle:



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 companys' 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.

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 are 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 principles of ISO 9001

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.



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.



The task of managing a company or organization is to ensure the long-term effectiveness of the QM system and its maintenance. Ιt also ensures communication of the company's strategies and processes throughout the organization. Furthermore, company management supports the achievement of quality goals.



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.



🍪 Improvement

Since requirements are constantly multiplying and changing, the continuous improvement process is another important component of quality management in accordance with ISO 9001.



ഫ്റ്റം Inclusion of qualified

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.

Obtain 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.



DEKRA Certification

Active. Diligent. Visionary. Whether you are focusing on efficient business processes, product and system reliability for your international market success or qualified experts: With more than 1,000 specialists worldwide, DEKRA Certification offers you a comprehensive service on all aspects of quality and performance, safety and health, sustainability and responsibility. Around 30,000 companies in more than 50 countries are already using our certifications, tests and inspections to turn their individual goals into reality, quickly and without complication.

Want know more?

Our experts are happy to help you introduce a quality management system that meets all the requirements of ISO 9001. Simply request a quote online or visit our website for more information about ISO 9001 certification.

Get in contact

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With our checklist, you can quickly and easily find out whether your business is properly prepared for certification according to ISO 9001:2015 for successful quality management.

ISO 9001:2015 - Evaluate your business correctly

The following questions are arranged according to the basic structure of management system standards. If you can answer a question with yes, mark it with a check.

That way you can see instantly which areas of your company already comply with ISO 9001 certification requirements, and which areas require more work.

Context of the organization	Planning	
Have you identified the relevant internal topics (such as targets, employees, strengths and weaknesses, compliance)?	Do you have defined measures for handling risks and opportunities?	
Have you identified the relevant external topics (such as markets, target audiences, competitors)?	Are you able to assess the effectiveness of your measures? Do you have documented quality targets for all relevant areas and processes?	
Have you defined measurable company targets? Have you determined how your most	Have you defined quality targets that are consistent with your quality policy?	
important business processes are managed and regularly checked?	Have you defined measures for achieving your targets?	
Do you know and understand the expectations and requirements of interested parties?	Support	
Do you have a procedure for checking your records and documents?	Are you able to define and provide the resources required for the quality management system?	
Are you able to check products/services from suppliers?	Are you able to provide the persons and infrastructure required for the implementation and control of your quality management system?	
Management	management system:	
Have you defined the active management and verifiable duties that your company managers must perform in relation to your	Are you able to provide a suitable environment (consisting of social, psychological and physical factors)?	
QM system? Have you included your customer focus in	Do you teach the necessary knowledge at your company?	
your business strategy?	Do you make sure that all persons at your company have the necessary knowledge	
Have you defined all relevant roles (e.g. management representative and their deputy) and assigned responsibilities and permissions to these persons?	Do you make sure that all relevant persons have the necessary awareness (e.g. in	
Have you defined how management will check the QM system, and at what intervals it will do so?	terms of quality policy, quality targets and possible effects)?	
Do you have specific training plans and documentation?		

Do you have defined communication strategies?	Do you have a method for checking, documenting and forwarding information about changes to products and services?	
Do you have a strategy for handling documented information?	Do you have a defined development process to assure subsequent production / service provision?	
Do you have a method for ensuring that your documentation is always up to date, and for checking and protecting that documentation?	Have you defined all design process steps and ensured verification by suitable employees?	
Operation	Have you made sure that outsourced processes and services meet your specific requirements?	
Do you have a strategy for communicating with your customers?	Do you document your process results during production and service provision?	
Do you have a method for obtaining customer feedback (to determine satisfaction and perception)?	Have you specified how to select suppliers and check their services?	
Have you determined how customer property should be handled?	Do you have comprehensible documentation for releasing products and services?	
Do you have a strategy for emergency measures (special requirements, unforeseeable events)?	Do you have a defined strategy for controlling non-compliant process results?	
Have you defined the requirements for your products and services in detail?		
Have you made sure that your products and services meet all legal and regulatory requirements?		

<u>We help you successfully certify your quality management system in accordance with ISO 9001:2015.</u>

<u>Contact our experts today!</u>



Do you want to create value in the continual improvement of your processes? DEKRA certificates are recognized around the world as a sign of quality. An ISO 9001 quality management system certification will help separate you from the competition and improve your market position, while also increasing customer satisfaction.

Definition and purpose of ISO 9001

This standard can apply to any organization, in any sector or industry. The purpose of ISO 9001 is to help you achieve your goals in an efficient way, while also increasing customer satisfaction.

A correctly implemented quality management system is an excellent way to help you advance your business and prepare for the future, with all the changes it may hold. DEKRA will verify the conformity of your quality management system to the requirements of ISO 9001 on the basis of documented procedures. Once certified, we will provide you with your certificate and access to the DEKRA Seal to demonstrate your compliance to others around the world.

What DEKRA offers you

With an ISO 9001-compliant system, you not only improve your quality management, you can also improve your competitive position and your efficiency.

- Defined responsibilities and procedures to motivate employees around a common goal
- Improved customer satisfaction
- Improved efficiency and results
- International recognition

Thanks to our industry expertise, we can work with you on a targeted, objective, impartial solution that fits the needs of your business.

The ISO 9001 certification in **7 steps** by DEKRA



1. Information meeting and internal audit (optional)

Information meeting (by telephone or in person), on-site project discussion and preparation for certification including document review.



2. On-site certification

Readiness analysis with assessment and review of the management system description, review of documented processes and optional post-audit (review of corrective actions)



3. Audit report and evaluation

Documentation of the audit and evaluation of the management system.



4. Certificate and seal

After successful completion, you will receive your certificate and the DEKRA test seal (with a maximum term of three years).



5. First surveillance audit

A surveillance audit of the practical implementation is conducted every twelve months.



6. Second surveillance audit

Repeated auditing of the practical implementation of the management system.



7. Recertification

Three years after initial certification, steps 2 to 6 are repeated for the recertification audit.



Are you interested in ISO 9001 certification?

Request your individual offer today!

We help successfully certify your quality management system in accordance with ISO 9001:2015.

Get in contact



Other services from which you can benefit

We offer our clients certification services to the following standards (among others):

- ISO 9001 quality management system certification
- ISO 14001 Environmental system certification
- ISO 45001 Occupational health and safety assessment system certification
- EN 1090-1 Steel and aluminium load-bearing structures
- EN 1090-2 Voluntary product certification: Execution of steel structures and aluminium structures
- EN 13084-7 Free-standing chimneys
- EN ISO 3834 Quality requirements for fusion welding of metallic materials

Our experts will be happy to support you in any certification and are ready to answer any questions.

Aquire the DEKRA SEAL

Signaling maximum quality and reliability – across different industries and internationally – the DEKRA seal is an excellent hallmark and marketing instrument which sets you apart from the competition. Use it to show your customers and business partners the value of what you offer. We are here to help you.

