



ISO 9000

Selection and use
of the ISO 9000
family of standards

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The ISO 9000 family of international quality management standards and guidelines has earned a global reputation as a basis for establishing effective and efficient quality management systems.

The need for International Standards is very important as more organizations operate in the global economy by selling or buying products and services from sources outside their domestic market.

This brochure has been developed by ISO technical committee ISO/TC 176, *Quality management and quality assurance*, which is responsible for developing and maintaining the ISO 9000 family. Supporting guideline standards and other documents are developed and updated on a continual basis to meet the needs and expectations of users and the market itself.

The brochure provides a general perspective on the ISO 9000 family and explains how you can use it to improve your quality management system. It gives an overview of the standards and demonstrates how, collectively, they form a basis for continual improvement and business excellence.

This brochure provides you with :

- An **overview** of the **ISO 9000 family** of core standards
- A **step-by-step process** to implement a quality management system
- **Examples** of typical **applications of the standards**, and
- A **bibliography** listing the ISO 9000 family of standards

This publication was developed by ISO/TC 176, the ISO technical committee specialized in quality management. For further information on ISO 9001 and related standards, visit <https://committee.iso.org/tc176sc2>.

ISO 9001 specifies the basic requirements for a quality management system that an organization must fulfil to demonstrate its ability to consistently provide products and services that enhance customer satisfaction and meet applicable statutory and regulatory requirements. The standard can be used for certification/registration and contractual purposes by organizations seeking recognition of their quality management system. ISO 9001 has been organized in a user-friendly format with terms that are easily recognized by all business sectors. You will obtain the greatest value by using the entire family of standards in an integrated manner. It is highly recommended that you use ISO 9000 to become familiar with the fundamental concepts, principles and normative vocabulary of a quality management system before you adopt ISO 9001 to achieve an effective level of performance. The practices described in ISO 9004 may then be implemented to make your quality management system more efficient in achieving your business goals and objectives.

ISO 9001 and ISO 9004 have been written to enable you to relate them to other management systems (e.g. environmental), or to sector-specific requirements (such as ISO/TS 16949 in the automotive industry, AS9100/EN 9100 in aviation, space and defence, TL 9000 in telecommunications) and to assist you in gaining recognition through national or regional award programmes.

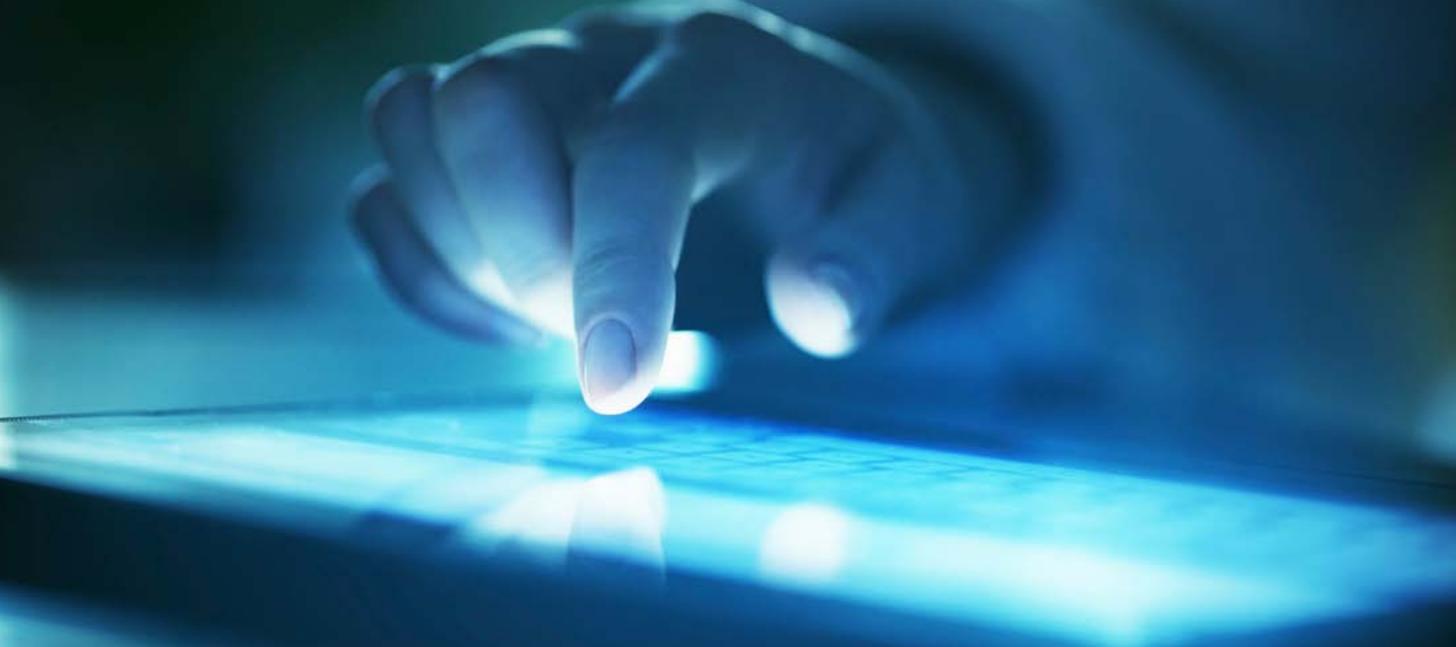


The ISO 9000 family Core standards

ISO 9000, Quality management systems – Fundamentals and vocabulary, provides the fundamental concepts, principles and vocabulary used in the entire ISO 9000 family of standards. It sets the stage for understanding the basic elements of quality management as described in the ISO standards. ISO 9000 introduces users to the seven quality management principles as well as the use of the process approach to achieve continual improvement.

ISO 9001, Quality management systems – Requirements, is used when you are seeking to establish a quality management system that provides confidence in your organization's ability to provide products that fulfil customer needs and expectations.

ISO 9001 specifies the requirements against which your quality management system can be certified by an external body. The standard recognizes that the term “products and services” applies to services, processed material, hardware and software intended for your customer.



There are seven clauses in the standard specifying activities that need to be considered when you implement your system :

- ▶ Context of the organization
- ▶ Leadership
- ▶ Planning
- ▶ Support
- ▶ Operation
- ▶ Performance evaluation
- ▶ Improvement

The requirements in all sections of ISO 9001 are applicable. An organization will need to provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system. A manual, or other documented information, will demonstrate how you meet the ISO 9001 requirements in your organization.

ISO 9001 defines what you should do to consistently provide product that meets customer expectations and applicable statutory and regulatory requirements. In addition, you will seek to enhance customer satisfaction by continual improvement of your quality management system.

ISO standards apply a process approach. Processes are recognized as consisting of one or more linked activities that require resources and must be managed to achieve predetermined output. The output of one process may directly form the input to the next process and the final product is often the result of a network or system of processes.

Further guidance can also be found in the ISO 9001:2015 introduction and support package prepared by subcommittee SC 2, *Quality systems*, of ISO/TC 176, which provides further guidance on :

- ▶ Summary of changes
- ▶ Implementation
- ▶ Documentation requirements
- ▶ Process approach
- ▶ Risk-based thinking
- ▶ Frequently asked questions (FAQs)
- ▶ Management of change
- ▶ Correlation between ISO 9001:2008 and ISO 9001:2015

ISO/TC 176 maintains a database of approved interpretations of the ISO 9001 standard.

ISO 9004, Managing for the sustained success of an organization – A quality management approach, is used to extend the benefits obtained from ISO 9001 to all parties that are interested in, or affected by, your operations.

Interested parties include your employees, owners, suppliers, partners and society in general.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than ISO 9001, particularly in managing for the long-term success of an organization. ISO 9004 is recommended as a guide for organizations whose top management wishes to extend the benefits of ISO 9001 in pursuit of systematic and continual improvement of the organization's overall performance. However, it is not intended for certification or contractual purposes.

ISO 19011, *Guidelines for auditing management systems*, covers the area of auditing of quality management systems and environmental management systems. It provides guidance on audit programmes, the conduct of internal or external audits, and information on auditor competence.

ISO 19011 provides an overview of how an audit programme should operate and how management system audits should take place. Effective audits ensure that an implemented QMS meets the requirements specified in ISO 9001.

The nature of your organization and your specific needs will determine how you apply these standards to achieve your goals and objectives. Useful hints and tips for conducting audits have been developed by the ISO 9001 Auditing Practices Group. Information on third-party auditing has also been compiled by the joint ISO-IAF (International Accreditation Forum) Accreditation Auditing Practices Group.

Implementing and maintaining a quality management system based on ISO 9001



The implementation process is important in achieving the full benefits of the quality management system (QMS). Most new users will obtain measurable payback early in the process.

- ▶ A QMS is a dynamic system that evolves over time through periods of improvement.
- ▶ It is necessary to determine activities that already exist and their suitability within the context of the organization.
- ▶ A formal QMS provides a framework for planning, executing, monitoring and improving the performance of quality management activities.
- ▶ In developing the QMS, the fundamental concepts and principles given in ISO 9000 can provide valuable guidance.
- ▶ A successful QMS must fit your organization. The following seven steps may be helpful as guidance:

1

Engage top management to

- ▶ Agree on why to implement a QMS
- ▶ Determine the context of the organization, strategic objectives and business processes
- ▶ Determine customer and interested parties' needs and expectations
- ▶ Understand the quality management principles described in ISO 9000
- ▶ Review the implication of risk-based thinking
- ▶ Define the objectives of the organization
- ▶ Describe the scope of the QMS
- ▶ Define the policy
- ▶ Determine quality objectives

2

Identify key processes

- ▶ Identify the processes needed to deliver products and services
- ▶ Understand ISO 9001 requirements
- ▶ Determine the risks and opportunities applicable to the processes

3

Plan your QMS

- ▶ Identify the gaps in the existing system compared to QMS requirements
- ▶ Identify the process controls needed
- ▶ Define the working environment needed
- ▶ Define the skills and facilities needed

4

Document your QMS

- ▶ Document the processes, activities and controls needed
- ▶ Prepare the documented information (procedures and records) required by the standard and according to your needs
- ▶ Ensure the QMS conforms to ISO 9001 requirements

5

Implement your QMS

- ▶ Manage the processes
- ▶ Control monitoring and measuring equipment
- ▶ Train employees
- ▶ Verify effective operation of processes

6

Manage your QMS

- ▶ Monitor and measure performance
- ▶ Audit process effectiveness
- ▶ Focus on customer satisfaction
- ▶ Manage system and operational change
- ▶ Perform management review

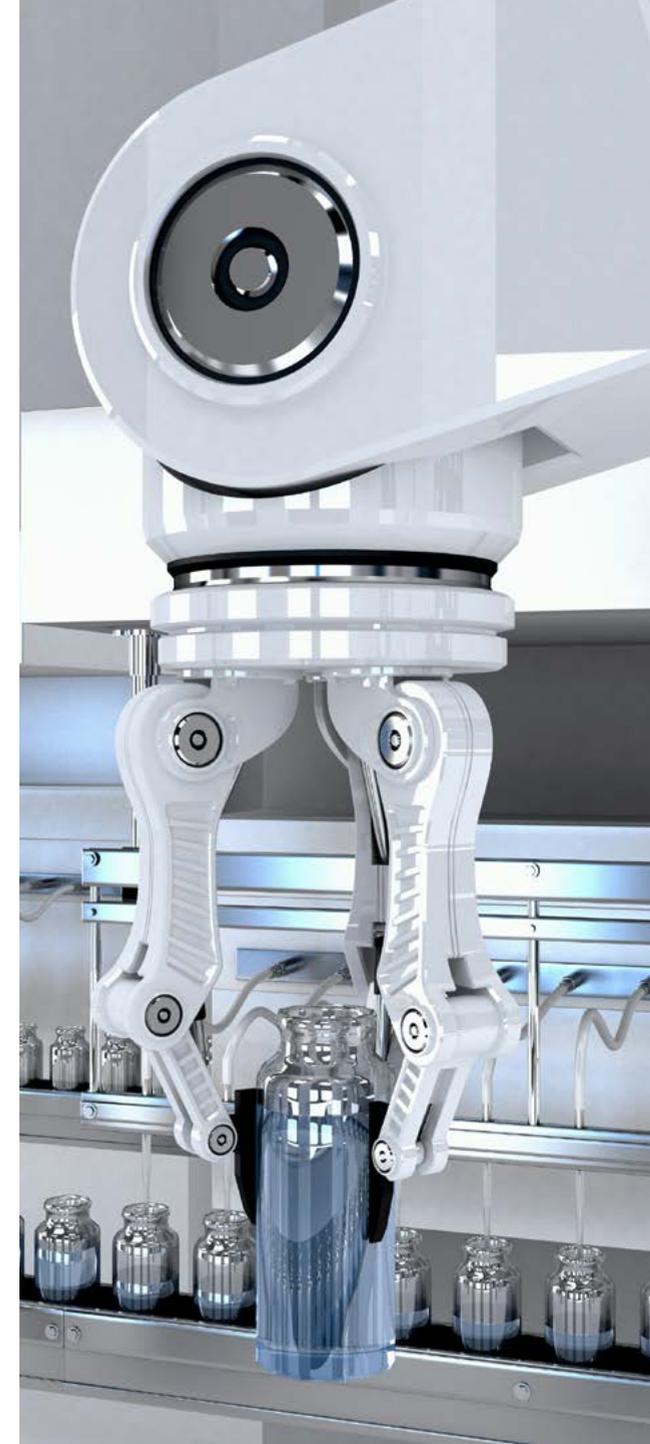
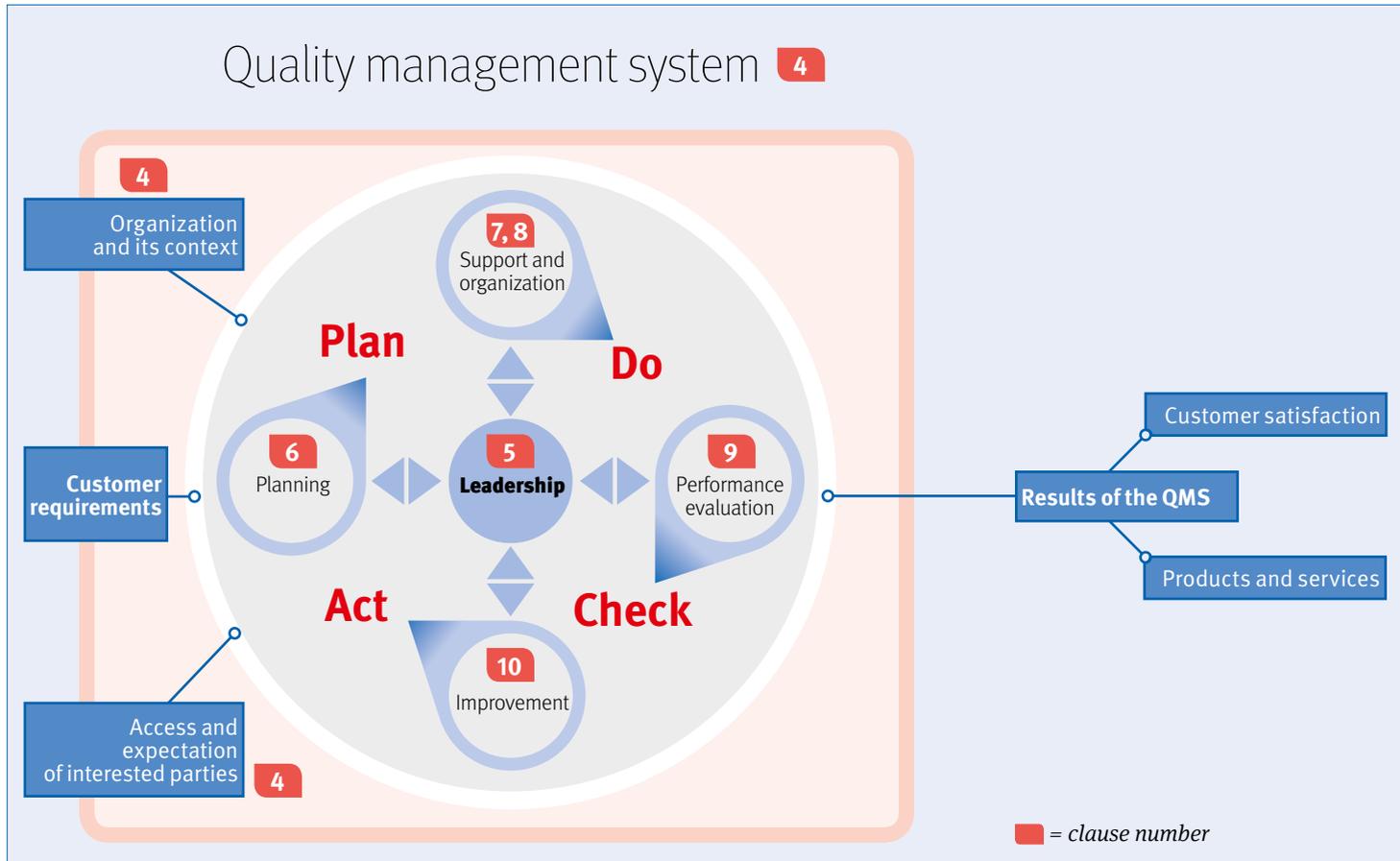
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Improve your QMS

- ▶ Seek third-party certification/registration of the QMS
- ▶ Strive for improvement with reference to ISO 9004
- ▶ Consider implementing business excellence models in company operations

Process model of ISO 9001

The **Plan-Do-Check-Act (PDCA)** cycle can be applied to all processes and to the quality management system as a whole. The figure below illustrates how **Clauses 4 to 10** can be grouped in relation to the PDCA cycle.



Representation of the structure of this International Standard in the PDCA cycle.

Examples

Using the ISO 9000 family of standards



Example 1

A metal parts manufacturer, recognizing the need to demonstrate its capability to produce consistent quality product, had implemented a QMS based on ISO 9001:2008 and was now required to become registered to ISO 9001:2015. It reviewed the matrix showing the correlation between ISO 9001:2008 and ISO 9001:2015 (see www.iso.org/tc176/sc02/public) and saw that the basic requirements of its existing QMS could be retained. Annexes A and B of ISO 9001:2015 provided additional information when performing a gap analysis of its existing QMS. The manufacturer decided to retain the documented information in its quality manual and the structure of the QMS after addressing the implication of risk-based thinking. Later, in order to bid on the supply of parts to a major automotive company, it upgraded its quality system to meet the automotive sector-specific requirements of ISO/TS 16949.

Example 2

A local government in a developing country wanted to improve its services and enhance community confidence. It turned to ISO 9000 and ISO 18091 to establish a quality management system. The guidance given in ISO 9004 helped develop training modules in process management, explaining how each person contributes to achieving reliable services. Similarly, the engineering department used the guidelines contained in ISO 10006 for managing its public works programmes. ISO 10005 served as a basis to create training courses in the use of quality plans, enabling a wide variety of organizations to engage in construction and maintenance contracts, whether or not they maintained a formal QMS.



Example 3

An electrical appliance manufacturer had a well-established company culture of continual improvement and effective production control. The management decided to improve the company's development processes and implement ISO 9001 to obtain certification for commercial purposes. The company used ISO 9004 to guide its improvement processes and ISO 10006 to develop a project management plan for the development project. Regulatory agencies demanded that products be designed and packaged recognizing the end-of-life disposition of products and packaging. The company adopted risk-based thinking and used ISO 10005 to develop a quality plan identifying the sequence of processes from concept to disposal of the product.



Example 4

A large chemical processing company was required by its major customers to gain certification to ISO 9001 and to be environmentally friendly. To address these issues, the company leadership planned a comprehensive management strategy linking its QMS and an ISO 14001 environmental management system (EMS). A thorough review of the business processes indicated that all elements of ISO 9001 were applicable to its QMS. The company used ISO/TR 10013 to guide the development of any required documented information for its QMS and EMS in its various production divisions, ISO 10015 for guidance in the preparation of training plans for realizing the required competence of its employees, and ISO 19011 for auditing both the QMS and EMS. Management achieved additional benefits and continual improvements using ISO 9000 and ISO 9004.

Example 5

A firm of international lawyers wanted to improve its client management processes using the systematic approach found in ISO 9001, but did not intend to gain certification. Its QMS provides for the design and development of new services such as international tax planning and modifying traditional services to meet the requirements of new or amended legislation. Purchasing control was included to cover the selection of computer hardware and software, as well as purchasing the services of specialist lawyers as needed. After successfully implementing ISO 9001, the company also used the self-assessment guidelines of ISO 9004 to monitor progress as it improved its QMS to achieve greater satisfaction of customers and other relevant stakeholders.



Example 6

A bank decided to implement a quality management system limited to the scope of its online banking services. It used ISO 10019 to help select a quality management consultant to guide it in its QMS implementation, taking account of the need to meet statutory and regulatory requirements. The bank obtained guidance from ISO 9000 on quality management principles together with quality management concepts and terminology. It then applied all the requirements relating to operational planning and control, recognizing that design and development are an important part of creating new service processes. The bank used ISO 10005 to develop a service quality plan for the provision of online services. The plan was indispensable to personnel for identifying which activities required participation of other functions and approvals of changes prior to implementation. The bank used the guidelines set out in ISO/TR 10013 to prepare the required documented information, which it posted on its internal computer network to ensure current procedures are available to staff.



Example 7

A franchise organization had difficulty maintaining consistent operation by franchisees and determined that an enhanced management system was required. It learned that ISO 9001 included the tools it needed and, with the help of ISO/TR 10013, it developed the documented information for its quality system to be used throughout the franchise network. To ensure a consistent approach in managing customer satisfaction, the organization used guidelines for customer satisfaction found in ISO 10001, ISO 10002 and ISO 10003. It also opened up an entirely new revenue stream by adding a business-to-consumer e-commerce dimension to its operation, using ISO 10008 as a guide to maintain a consistent customer-friendly approach throughout its operations. When the system was implemented, the franchise organization used ISO 19011 to establish an audit programme that confirmed the ISO 9001-based QMS continued to function as required and was improved on a continual basis.

Example 8

A corporation managing government infrastructure services implemented a QMS based on ISO 9001 and used ISO 10006 to manage the programme of projects in planned time periods. It needed to hire large, medium-sized and small organizations, including large construction companies, consulting engineers and small specialist companies such as geologists and small maintenance contractors. Only some of these organizations had implemented ISO 9001. The corporation specified minimum quality management requirements for each project referring to the guidance on quality plans available in ISO 10005. Under each contract, the corporation approved quality plans to establish jointly agreed commitments. Corporation assessors monitored the various providers to ensure the quality management requirements were being met.

Maintaining the benefits and continual improvement

Most new users of the ISO 9000 family of standards obtain measurable benefits soon after implementing the requirements in their operations. These initial benefits are generally due to improvements in their organization and internal communication, and must be strengthened through effective internal auditing and management review of system performance. Like all systems, it can either improve or become less effective. It does not remain static for long.

ISO 10014 provides guidelines for making financial and economic gains from the application of the ISO 9000 quality management principles. It is aimed at the top management of organizations and complements ISO 9004 for performance improvements.

When you adopt ISO 9001, you must strive to satisfy your customers and to achieve continual improvement of your operations through the QMS.

Continual improvement is a process of increasing the effectiveness of your organization in order to fulfil established policy and quality objectives, which are updated



periodically. ISO 9001 requires that you plan and manage the processes necessary to continually improve your QMS.

ISO 10004 provides guidance for defining and implementing processes to monitor and measure customer satisfaction. Information obtained from monitoring and measuring customer satisfaction can help an organization identify opportunities to improve the strategies, products, processes and characteristics that are valued by its customers and reach its objectives. Such improvements can strengthen customer confidence and bring commercial and other benefits.

ISO 9004 can be used to go beyond ISO 9001 to strengthen your organization's competitive position and provide improvements to operational efficiency. It is recommended that you obtain data from various sources, both internal and external, to assess how appropriate your quality system objectives are to changing circumstances. This information can also be used to improve the performance of all your business processes.

Many organizations expand their management systems by extending the ISO 9001 structure to include the requirements of other management system standards, including ISO 14001 on environmental management systems. The structural and organizational requirements of ISO management system standards are designed to be compatible.

Bibliography

- ISO 9000** *Quality management systems – Fundamentals and vocabulary*
- ISO 9001** *Quality management systems – Requirements*
- ISO 9004** *Managing for the sustained success of an organization – A quality management approach*
- ISO 10001** *Quality management – Customer satisfaction – Guidelines for codes of conduct for organizations*
- ISO 10002** *Quality management – Customer satisfaction – Guidelines for complaints handling in organizations*
- ISO 10003** *Quality management – Customer satisfaction – Guidelines for dispute resolution external to organizations*
- ISO 10004** *Quality management – Customer satisfaction – Guidelines for monitoring and measuring*
- ISO 10005** *Quality management systems – Guidelines for quality plans*
- ISO 10006** *Quality management systems – Guidelines for quality management in projects*
- ISO 10007** *Quality management systems – Guidelines for configuration management*
- ISO 10008** *Quality management – Customer satisfaction – Guidelines for business-to-consumer electronic commerce transactions*
- ISO 10012** *Measurement management systems – Requirements for measurement processes and measuring equipment*
- ISO/TR 10013** *Guidelines for quality management system documentation*
- ISO 10014** *Quality management – Guidelines for realizing financial and economic benefits*
- ISO 10015** *Quality management – Guidelines for training*
- ISO/TR 10017** *Guidance on statistical techniques for ISO 9001:2000*
- ISO 10018** *Quality management – Guidelines on people involvement and competence*
- ISO 10019** *Guidelines for the selection of quality management system consultants and use of their services*
- ISO 14001** *Environmental management systems – Requirements with guidance for use*
- ISO 18091** *Quality management systems – Guidelines for the application of ISO 9001:2008 in local government*
- ISO 19011** *Guidelines for auditing management systems*
- ISO 31000** *Risk management – Principles and guidelines*
- ISO 37500** *Guidance on outsourcing*
- ISO/IEC 90003** *Software engineering – Guidelines for the application of ISO 9001:2008 to computer software*
- IEC 60300-1** *Dependability management – Part 1: Guidance for management and application*
- IEC 61160** *Design review*
- Quality management principles, ISO¹*

1 Available from www.iso.org.

The future of the ISO 9000 family

More information

- ISO's Website
www.iso.org
- ISO's Website section on the ISO 9000 family
www.iso.org/iso/iso_9000.htm
- *isofocus* magazine
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- ISO videos
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In order for the ISO 9000 family to maintain its effectiveness, the standards are periodically reviewed to benefit from new developments in the quality management field and also from user feedback. ISO/TC 176, comprising experts from businesses and other organizations around the world, monitors the use of the standards to determine how they can be improved to meet user needs and expectations when the next revisions are due. All ISO standards are reviewed regularly for relevancy; changes are made when there is a demonstrated need to improve the standard.

Based on input from the user community, ISO/TC 176 will continue to evaluate and adopt new concepts in the field of quality management for incorporation into ISO standards. This can include sector-specific initiatives and supporting documents within the ISO 9000 family. Most ISO technical committees recognize the structure of ISO 9001 when new management systems standards are developed for other or specific purposes.

ISO's commitment to sustaining the ISO 9000 momentum through reviews, improvement and streamlining of the standards guarantees that your investment in ISO 9000 today will continue to provide effective management solutions well into the future.

About ISO

ISO (International Organization for Standardization) is an independent, non-governmental international organization with a membership of 161* national standards bodies. Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market-relevant International Standards that support innovation and provide solutions to global challenges.

ISO has published more than 21 000* International Standards and related documents covering almost every industry, from technology to food safety, to agriculture and healthcare.

For more information, please visit www.iso.org.

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