Selection and use of ISO 9000

ISO in brief

ISO is the International Organization for Standardization. It is made up of national standards institutes from countries large and small, industrialized and developing, in all regions of the world. ISO develops voluntary technical standards which add value to all types of business operations.They contribute to making the development, manufacturing and supply of products and services more efficient, safer and cleaner. They make trade between countries easier and fairer.
ISO standards also serve to safeguard consumers, and users in general,
of products and services – as well as to making their lives simpler.

ISO develops only those standards which are required by the market. This work is carried out by experts on loan from industrial, technical and business sectors which have asked for the standards, and which subsequently put them to use.
These experts may be joined by others with relevant knowledge, such as representatives of government agencies and testing laboratories.

Published under the designation of "International Standards", ISO standards represent an international consensus on the "state of the art" in the technology concerned.

ISO/TC 176, Quality management and quality assurance

ISO/TC 176 is the ISO technical committee responsible for developing and maintaining the ISO 9000 family of standards. Its scope is standardization in the field of generic quality management, including quality systems, quality assurance and generic supporting technologies, such as standards which provide guidance on the selection and use of these standards.

Selection and use of ISO 9000

The ISO 9000 family is a set of international quality standards and guidelines which has earned a global reputation as the basis for establishing quality management systems.

This brochure provides you with a general perspective on ISO 9000. It presents an overview of these standards and demonstrates how, collectively, they can form a basis for continuous improvement and business excellence. In particular, you will see how to distinguish between the various publications in the ISO 9000 family and how they may be utilized to your maximum benefit.

The frequent use of the three specific standards ISO 9001, ISO 9002 and ISO 9003 as a basis for quality system certification schemes has in the past focused attention on the external quality assurance aspects of the ISO 9000 family of standards. Furthermore, many people have seen the standards as applying only to the manufacturing sector. These somewhat limiting views have been answered in recent years by ISO with the release of new publications in the ISO 9000 family that address the needs of the service sector, software houses, small and medium enterprises etc.

From a management viewpoint, enterprises in all sectors stand to gain the greatest value from ISO 9000 when they use the entire set of standards in an integrated manner. Using the standards in this way will also enable you to relate them to other management systems (e.g. environmental), other quality management strategies (such as quality awards and Total Quality Management) and sector-specific requirements (such as QS-9000 in the automotive industry).

This brochure provides you with:

- a list of the ISO 9000 quality standards and guidelines, plus other ISO 9000 publications by ISO;
- examples of typical applications of the documents;
- a step-by-step outline of their selection and use;
- a brief view of the future evolution of the ISO 9000 family.

The ISO 9000 family

The ISO 9000 standards and guidelines listed below are available separately, or as collections. The *ISO 9000 Compendium* presents the ISO 9000 family in hard copy form. The documents are also available on CD ROM (with or without the ISO 14000 family of environmental management standards) for users who prefer the flexibility of an electronic format.

To purchase the latest edition of ISO 9000 standards, guidelines and other publications, contact your national standards body, or ISO Central Secretariat.

Visit the World Wide Web site, **ISO Online**, at **http://www.iso.ch/** which includes specific information on ISO 9000 and on ISO's standardization activities in general.

Standards and guidelines	Purpose
ISO 8402, *Quality management and quality assurance – Vocabulary*	Defines the fundamental terms used in the ISO 9000 family, which you need to know to be sure of avoiding misunderstandings both internally and externally.
ISO 9000-1, *Quality management and quality assurance standards* – Part 1: *Guidelines for selection and use*	Establishes a starting point for understanding and selecting the standards appropriate to your needs.
ISO 9000-2, *Quality management and quality assurance standards* – Part 2: *Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003*	Assists you in interpreting and applying ISO 9001, ISO 9002 and ISO 9003.
ISO 9000-3, *Quality management and quality assurance standards* – Part 3: *Guidelines for the application of ISO 9001:1994 to the development, supply, installation and maintenance of computer software*	Provides you with specific interpretation of the requirements of ISO 9001 for computer software development applications.
ISO 9000-4, *Quality management and quality assurance standards* – Part 4: *Guide to dependability programme management*	Gives you guidance on how to plan, organize and control resources to produce reliable and maintainable products.
ISO 9001, *Quality systems – Model for quality assurance in design, development, production, installation and servicing*	This is the requirement standard you use when you wish to demonstrate capability for design/development of your product or service, as well as for production, installation and servicing.

ISO 9002, *Quality systems – Model for quality assurance in production, installation and servicing*	This is the requirement standard you use when you are not responsible for the design/development of your product or service, but wish to demonstrate capability for production, installation and servicing (identical to ISO 9001 except for design control requirement).
ISO 9003, *Quality systems – Model for quality assurance in final inspection and test*	This is the requirement standard you use when you only need to demonstrate capability to control your product or service by final inspection and test.
ISO 9004-1, *Quality management and quality system elements* – Part 1: *Guidelines*	This is not a requirement standard, but provides you with guidelines to implement a quality system to satisfy your customers' and your own organization's needs.
ISO 9004-2, *Quality management and quality system elements* – Part 2: *Guidelines for services*	This standard is made up in a similar way as ISO 9004-1, but the guidelines are designed with special regard to the conditions pertinent to the service sector.
ISO 9004-3, *Quality management and quality system elements* – Part 3: *Guidelines for processed materials*	This standard provides you with quality management guidelines applicable if you are a producer of processed materials, which are typically provided in bulk.
ISO 9004-4, *Quality management and quality system elements* – Part 4: *Guidelines for quality improvement*	Provides you with guidelines for implementing continuous quality improvement within your organization using tools and techniques based on data collection and analysis.
ISO 10005, *Quality management – Guidelines for quality plans*	This standard gives you guidance on how to prepare quality plans for the control of specific products, projects or contracts.
ISO 10006, *Guidelines to quality in project management*	Guidelines to help you ensure the quality of both the project processes and the project product.
ISO 10007, *Quality management – Guidelines for configuration management*	Gives you guidelines to ensure that a complex product continues to function when components are changed individually.
ISO 10011-1, *Guidelines for auditing quality systems* – Part 1: *Auditing*	Provides you with guidelines for auditing a quality system, and for verifying the system's ability to achieve defined quality objectives. You can use this standard internally or for auditing your suppliers.
ISO 10011-2, *Guidelines for auditing quality systems* – Part 2: *Qualification criteria for quality systems auditors*	Provides guidance on the education, training, experience, personal attributes and management capabilities needed to carry out an audit.

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ISO 10011-3, *Guidelines for auditing quality systems* – Part 3: *Management of audit programmes*	Provides basic guidelines for managing quality system audit programmes.
ISO 10012-1, *Quality assurance requirements for measuring equipment* – Part 1: *Metrological confirmation system for measuring equipment*	Gives you guidelines on the main features of a calibration system to ensure that measurements are made with the intended accuracy.
ISO 10012-2, *Quality assurance for measuring equipment* – Part 2: *Guidelines for control of measurement processes*	Provides supplementary guidance on the application of statistical process control when this is appropriate for achieving the objectives of Part 1.
ISO 10013, *Guidelines for developing quality manuals*	Provides guidelines for the development, preparation and control of quality manuals tailored to your specific needs.

Other ISO 9000 publications

Publication	Purpose
ISO 9000 for Small Businesses	This handbook provides you with guidelines and practical examples of how to implement a simple and effective quality system in a small business environment. (Also includes full text of ISO 9001). It has been translated into other languages by ISO members.
ISO 9000 News	Published six times a year in separate English and French editions, this journal includes updates on the ISO 9000 family of quality management and quality assurance standards, and news on their implementation around the world, as well as related developments such as ISO 9000 certification. Coverage of ISO 14000 is being increased as these new standards are implemented.
Publicizing your ISO 9000 or ISO 14000 certification	This brochure (published in English and French editions) gives guidelines to help certificate holders avoid the pitfalls of false, misleading or confusing claims relating to ISO 9000 and ISO 14000 certification in advertisements and all forms of promotional material.
Table of worldwide equivalence of ISO 9000 series of standards	This table (bilingual, English and French) shows the state of worldwide adoption of ISO 9000 in ISO member countries.

Selection and use of the ISO 9000 family of standards

There are many different ways to apply and combine the standards of the ISO 9000 family. The nature of your business and the specific demands you have will determine the standards relevant to you.

Here are a few examples:

Example 1:

A small computer software development company used the handbook *ISO 9000 for Small Businesses* plus ISO 9000-3 as a basis for developing its quality system. When it undertook a contract for a more substantial software development project, it used ISO 10005 to guide the development of the contract quality plan and also consulted ISO 10007 for advice on configuration management.

Example 2:

A welfare agency decided to establish a quality improvement strategy. It adopted ISO 9004-2 and ISO 9004-4 as a basis for planning and implementing its system. The agency found that ISO 9002 and ISO 9000-2 provided very useful additional guidance, particularly since it expected that future certification to ISO 9002 would give it more credibility.

Example 3:

A washing machine manufacturer had a well-established company culture of continuous improvement and effective production control. It decided to improve its product development processes and to implement ISO 9001 as an internal improvement strategy. The company used ISO 9000-4 to guide its dependability management programme. Over a period of time, it developed a full quality management system in compliance with ISO 9001. It used ISO 10011 Parts 1, 2 and 3 to help its internal audit programme and as a basis for supplier audits.

Example 4:

A large chemical processing company was required by its major customers to gain certification to ISO 9002. In order to obtain additional benefits, it planned a comprehensive management strategy based on ISO 9004-1 and ISO 9002. The company used ISO 10013 to guide the development of quality documentation in its various production divisions and ISO 9004-3 for advice on quality assurance for processed materials. When it decided to commence a structured approach to quality improvement, it selected ISO 9004-4 as a guide.

To see which standards suit your business, look at the list of publications in the ISO 9000 family and follow the step-by-step approach *on the following pages.*

Implementing ISO 9000

Steps	Guidance
1 Identify what goals you want to achieve	Typical goals may be: ■ Be more efficient and profitable ■ Produce better products and services ■ Achieve customer satisfaction ■ Increase market share ■ Improve communication and morale in the organization ■ Reduce costs and liabilities
2 Identify what others expect of you	These are the expectations of interested parties (stakeholders) such as: ■ Customers and end users ■ Suppliers ■ Shareholders ■ Society ■ Employees
3 Establish your current status	You may use one or more of the following: ■ self assessment ■ assessment by an external organization ■ customer feedback
4 Obtain information about the ISO 9000 family	■ For general information, look to this brochure ■ For more detailed information, see ISO 9000-1 ■ For terminology, see ISO 8402 In some cases you may wish to use only one or two specific standards in the ISO 9000 family to meet your needs
5 Apply the ISO 9000 standards in your management system	■ Use ISO 9004-1 as a basis ■ For small and medium sized organizations refer to the handbook *ISO 9000 for Small Businesses* Where appropriate, consider the requirements in: ■ ISO 9001 if you are involved with any kind of product development, or ■ ISO 9002 if you are producing products or services (but not involved with any kind of product development), or ■ ISO 9003 if you are only relying on final inspection or testing

6 Use sector-specific and general guidance

For general guidance use:

- ISO 9000-2

For specific guidance use:

- ISO 9000-3 for computer software
- ISO 9004-2 for services
- ISO 9004-3 for process industry
- *ISO 9000 for Small Businesses*
- Relevant national standards and industry sector guidelines

For dependability guidance use:

- ISO 9000-4 for dependability programme management

7 Obtain guidance on specific topics within the quality management system

These topic-specific standards are:

- ISO 10005 for quality plans
- ISO 10007 for configuration management
- ISO 10011 for auditing
- ISO 10012 for measurement systems
- ISO 10013 for quality manuals

8 Do you need to demonstrate conformance?

YES

You may need to show conformance (certification/registration) for various purposes, for example:

- Contractual requirements
- Market reasons
- Regulatory requirements
- Risk management
- To set a clear goal for your internal quality development (motivation)

NO

9 Undergo independent audit

- Use all parts of ISO 10011 for guidance in auditing, auditor qualification and managing audit programmes
- Use ISO 9001, ISO 9002 or ISO 9003 as the specification for quality assurance

(*ISO 9000 for Small Businesses* may be used since it includes ISO 9001)

10 Continue to improve your business

Review the effectiveness and suitability of your management system.

ISO 9004-4 provides guidance for quality improvement

GO TO STEP 1

The future evolution of ISO 9000

In order for the ISO 9000 family to maintain its effectiveness, the standards are constantly being improved, so as to incorporate new initiatives in the quality management field. ISO's Technical Committee TC 176, which is made up of experts from businesses and other organizations around the world, is responsible for maintaining and developing the ISO 9000 standards. ISO/TC 176's current work aims to simplify and consolidate the ISO 9000 family of international quality standards and guidelines while maintaining continuity for existing users.

The new standards will be more specifically directed to the achievement of business results, including satisfaction of customers and other stakeholders. The incorporation of these standards into an integrated quality management philosophy will provide a basis to bring together quality assurance, quality management, sector-specific initiatives and various quality awards.

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

For more information on ISO 9000

➔ ***Contact***
your national standards institute or the ISO Central Secretariat.

➔ ***Subscribe to "ISO 9000 News Service", including:***
ISO 9000 News *(six issues a year), which includes updates on the ISO 9000 family of quality management and quality assurance standards, and news on their implementation around the world, as well as related developments, such as ISO 9000 certification; coverage of ISO 14000 is being increased as these new standards are implemented;*

ISO Bulletin *(monthly), which provides an overview of ISO's activities in international standardization over almost the entire range of technology, including articles on the ISO 14000 family of environmental management standards.*

Both publications are available through ISO's national members and the Central Secretariat.

➔ ***Connect***
with ***ISO Online****, the electronic information service on Internet, accessible via the World Wide Web by connecting with the following Uniform Resource Locator (URL):*

http://www.iso.ch/