

ISO 9000 in Brief

Frequently Asked Questions (FAQ's)

The ISO 9000 family of standards are among ISO's most widely known standards ever. ISO 9000 standards are implemented by all types of organization in industrial and service sectors around the globe in 162 countries. ISO 9000 has become an international reference for quality management requirements in business-to-business dealings in the world.

The **ISO 9000** family is primarily concerned with "**quality management**". This means what the organization does to fulfill:

- the customer's quality requirements, and
- applicable regulatory requirements, while aiming to
- enhance customer satisfaction, and
- achieve continual improvement of its performance in pursuit of these objectives.

In developing this list of Frequently Asked Questions (FAQ's), input has been obtained from experts and users of the ISO 9000 standards from around the world. The list will be reviewed and updated on a regular basis to maintain its accuracy, and to include new questions where appropriate. It is intended that this list will also provide a good source of information for new users of the standards.

What is ISO?

The International Organization for Standardization (ISO) was established in 1947 and is (currently) an association of approximately 149 National Standards Bodies, which each represent their own country. ISO employs a system of Technical Committees, Sub-committees and Working Groups to develop International Standards.

What are the ISO 9000 standards?

The ISO 9000 standards are a collection of formal International Standards, Technical Specifications, Technical Reports, Handbooks and web based documents on Quality Management and Quality Assurance. There are approximately 25 documents in the collection altogether, with new or revised documents being developed on an ongoing basis.

What happened to the 1994 editions of ISO 9001, ISO 9002 and ISO 9003?

Following extensive consultation with users and National Standards Bodies, it was agreed that the 1994 editions of ISO 9001, ISO 9002 and ISO 9003 should be consolidated into a single revised document, which is now represented by ISO 9001:2000.

What are the main benefits to be derived from implementing an ISO 9000 quality management system?

Adoption of the quality management system standards is an profitable business investment. The ISO 9000 standards give organizations an opportunity to increase value to their activities and to improve their performance continually, by focusing on their major processes. The standards place great emphasis on making quality management systems closer to the processes of organizations and on continual improvement. As a result, they direct users to the achievement of business results, including the satisfaction of customers and other interested parties. Among the perceived benefits of using the standards are:

- The connection of quality management systems to organizational processes
- The encouragement of a natural progression towards improved organizational performance, via:
 - the use of the Quality Management Principles
 - the adoption of a "process approach"

- emphasis of the role of top management
- requirements for the establishment of measurable objectives at relevant functions and levels
- being orientated toward "continual improvement" and "customer satisfaction", including the monitoring of information on "customer satisfaction" as a measure of system performance
- measurement of the quality management system, processes, and product
- consideration of statutory and regulatory requirements

What benefits are there to an organization implementing ISO 9004?

If a quality management system is appropriately implemented, utilizing the eight [Quality Management Principles](#), and in accordance with ISO 9004, all of an organization's interested parties should benefit. For example:

Customers and users will benefit by receiving the products (see ISO 9000:2000) that are:

- Conforming to the requirements
- Dependable and reliable
- Available when needed
- Maintainable

People in the organization will benefit by:

- Better working conditions
- Increased job satisfaction
- Improved health and safety
- Improved morale
- Improved stability of employment

Owners and investors will benefit by:

- Increased return on investment
- Improved operational results
- Increased market share
- Increased profits

Suppliers and partners will benefit by:

- Stability
- Growth
- Partnership and mutual understanding

Society will benefit by:

- Fulfillment of legal and regulatory requirements
- Improved health and safety
- Reduced environmental impact
- Increased security

Are the standards compatible with national quality award criteria?

The standards are based on 8 [Quality Management Principles](#), which are aligned with the philosophy and objectives of most quality award programs. These principles are:

- Customer focus
- Leadership

- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationships.

ISO 9004:2000 recommends that organizations perform self-assessments as part of their management of systems and processes, and includes an annex giving guidance on this approach. This is similar to many quality awards programmes.

Do the standards address financial issues?

Financial issues are not directly addressed in ISO 9001:2000, but may be inferred though the requirements for the provision of resources. ISO 9004:2000 gives guidance that emphasizes the financial resources needed for the implementation and improvement of a quality management system. ISO/TR 10014:1998 "*Guidelines for managing the economics of quality*" also gives further guidance.

How will implementation of the standards help an organization to improve its efficiency?

ISO 9001:2000 aims at guaranteeing the effectiveness (but not necessary the efficiency) of an organization. For improved organizational efficiency, however, the best results can be obtained by using the guidance given in ISO 9004:2000 in addition to ISO 9001:2000. Additionally, the guiding [Quality Management Principles](#) are intended to assist an organization in continual improvement, which should lead to efficiency throughout the organization.

Can the standards improve "customer satisfaction"?

The quality management system details that are described in the standards are based on Quality Management Principles that include the "process approach" and "customer focus". The adoption of these principles should provide customers with a higher level of confidence that products will meet their needs and increase their satisfaction.

What should an organization do to adopt the "process approach"?

To adopt the "process approach" an organization should apply the following steps:

- Identify the processes of the organization,
- Plan the processes,
- Implement and measure the processes,
- Analyze the processes,
- Improve the processes.

How can a process be measured?

There are various methods of measuring process controls and process performance, ranging from simple monitoring systems up to sophisticated statistically based systems (e.g. Statistical process control, or SPC, systems). The selection and use of any particular method will be dependent on the nature and complexity of an organization's processes and products. The effectiveness of an individual process may be measured by the conformity of its output or product to customer requirements. Its efficiency may be measured from its use of resources. In all cases the measurement of the process determines if its (measurable) objectives have been achieved. Sometimes it only requires monitoring to confirm process operations.

Typical factors that are useful to consider when identifying measures of process control and process performance include:

- Conformity with requirements,
- Customer satisfaction,

- Supplier performance,
- On time delivery,
- Lead times,
- Failure rates,
- Waste,
- Process costs.
- Incident frequency

What documentation is required by ISO 9001?

ISO 9001:2000 refers specifically to only 6 documented procedures; however, other documentation (including more documented procedures not specifically mentioned in ISO 9001:2000) may be required by an organization, in order to manage the processes that are necessary for the effective operation of the quality management system. This will vary depending on the size of the organization, the kind of activities in which it is involved and their complexity.

Which standard are organizations registered/certified to?

Organizations have their quality management system registered/certified to ISO 9001:2000. The scope of registration/certification will need to reflect precisely and clearly the activities covered by the organization's quality management system; any exclusion to non-applicable requirements of the standard (permitted through ISO 9001 clause 1.2 "Application") will need to be documented and justified in the quality manual.

What does an organization need to do to comply with ISO 9001?

When initially starting to use ISO 9001, an organization should familiarize its personnel with the Quality Management Principles, analyze the standards (especially ISO 9004), and consider how their guidance and requirements may affect your activities and related processes. If it then wishes to proceed to registration/certification, it should perform a gap analysis against the requirements of ISO 9001 to determine where its current quality management system does not address the applicable ISO 9001:2000 requirements, before developing and implementing additional processes to ensure that compliance will be achieved.

How does ISO 9001:2000 relate to the needs of specific business sectors?

The text of ISO 9001:2000 is applicable to organizations that provide different types of product and to organizations of different sizes. Due to this generic nature, some industrial or commercial sectors find that they need to identify additional requirements to attend to their specific requirements, so develop their own standards or related documents. A successful example of such a document is ISO Technical Specification ISO/TS 16949, which was developed in conjunction with representatives from the automotive industries.

Is an organization's ISO 9001 certificate applicable to all of its products?

When an organization seeks to have its quality management system registered/certified to ISO 9001:2000, it is required to agree a "scope of certification" with its registrar/certification body. This will define the products to which the organization's quality management system is applicable, and against which it will be assessed. An organization is not obliged to include within its "scope of certification" all the products that it provides (note that the ISO 9000:2000 definition of "Product" includes "services"), but may be selective about those that are included. All applicable requirements of ISO 9001:2000 will need to be addressed by the organization's quality management system that covers those products that are included in the "scope of certification".

Customers should ensure that a potential supplier's "scope of certification" covers the products that they wish to order.

What can an organization do if it is not able to comply with all of the requirements of ISO 9001?

ISO 9001 allows for the exclusion of some of its requirements (via clause 1.2 'Application'), but only if it can be shown that these requirements are not applicable to the organization.

Exclusions are limited to the requirements given in Section 7 ("Product Realization"), where individual requirements may only be excluded if it can be shown that they do not affect the organization's ability to provide product that meets customer and applicable statutory or regulatory requirements. Justification for such exclusions is also required to be detailed within the organization's quality manual.

For example, if design activities are not required by an organization to demonstrate its capability to meet customer and applicable statutory /regulatory requirements, or if its product is provided on the basis of established design, then it may be able to exclude some of the "design" requirements but still be able to be registered/certified to ISO 9001:2000.

How will a small organization be able to adapt the requirements of ISO 9001? What flexibility will be allowed?

The requirements of ISO 9001 are applicable to small, medium, and large organizations alike. ISO 9001:2000 provides some flexibility, through clause 1.2 "Application", on the exclusion of certain requirements for specific processes that may not be performed by the organization.

If, for example, the nature of your products does not require you to perform design activities, or if your product is provided on the basis of established design, you could discuss and justify the exclusion of these requirements with your certification/registration body. However, individual organizations will still need to be able demonstrate their capability to meet customer and applicable statutory or regulatory requirements for their products, and will need to consider this when determining the complexity of their quality management systems.

What is the relationship between ISO 9001 and ISO 14001?

ISO 9001 has been developed to be "compatible" with ISO 14001 *Environmental management systems – Requirements with guidance for use*, particularly with regard to terminology and content.

-- Adopted from ISO Website --