



US Standards Group On QEDS

INFORMATION SHEET

Web Site Address: <http://standardsgroup.asq.org>

TC 176 — ISO 9000:2000 FAMILY FAQs

This list of Frequently Asked Questions (FAQs) was extracted from the FAQs prepared by the ISO Technical Committee (TC) 176. Input was obtained from experts and users of the ISO 9000 standards, expressed during seminars and presentations 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. The latest version of the complete list is available on the ISO/TC 176 web site: <http://www.tc176.org>.

Why were the standards revised?

The main reason for the year 2000 revision to the ISO 9000 standards is to give users the opportunity to add value to their activities and to improve their performance continually by focussing on the major processes within the organization.

Extensive surveys were performed on a worldwide basis to understand the needs of all users of the quality management system standards. The new revisions took into account previous experience with quality management system standards (1987 and 1994 editions) and emerging insights into generic management systems. They resulted in a closer alignment of quality management systems with the needs of organizations and better reflect the way organizations run their business activities.

ISO directives also specify that standards be periodically revised to ensure that those standards are current and satisfy the needs of the global community.

The major reasons for the year 2000 revisions of the standards include emphasizing the need to monitor customer satisfaction, meeting the need for more user-friendly documents, assuring consistency between quality management system requirements and guidelines, promoting the use of generic quality management principles by organizations, and enhancement of their compatibility with ISO 14001.

Who is responsible for revising the standards?

The revision process is the responsibility of ISO/TC 176 and is conducted on the basis of consensus among

quality and industry experts nominated by ISO Member bodies, and representing all interested parties

Do the year 2000 revision affect my organization's current quality system registration?

Yes. The strategy adopted by your organization to meet the requirements of ISO 9001:2000 should include an appropriate timing for upgrading your organization's registration.

It is expected that the process of upgrading registration/certification will be a smooth transition that is incorporated into the applicable Registrar's regular audit routine.

The International Accreditation Forum (IAF) has established a set of guidelines for Registrars to follow, and this includes a transition period of up to three years from the standards publication date. You are advised to contact your registrar to negotiate a suitable transition time frame for your own organization.

How much does the transition to the new standards cost?

One of the goals of ISO/TC 176 was to produce standards that minimize any potential costs during a smooth transition. Any additional costs may be considered as a value-added investment.

The cost of implementing any necessary changes in order to meet the new requirements of ISO 9001:2000 will vary from one organization to another, depending on various factors such as the actual state of implementation of the quality management system, the size and complexity of the organization, the attitude and commitment of the top management, etc. It is expected that the benefits to all organizations will outweigh eventual costs associated with the transition.

Regarding the costs of upgrading the certification, IAF guidelines provide for the incorporation of audits to the new standard into surveillance visits for existing (1994) certifications, wherever possible.

Where can I obtain information on ISO 9000:2000?

There are a number of sources of information on ISO 9000:2000 quality management system standards, including, of course, the Standards Group web site at <http://standardsgroup.asq.org>, which carries detailed information on the revision program and is updated on a regular basis. The ISO Central Secretariat in Switzerland also maintains a web site at <http://www.iso.ch> that carries general information on the revision program. There are also a number of publications available that focus on the ISO 9000 quality management system standards, such as *THE INFORMED OUTLOOK* newsletter (for information, call 703-680-1436 or visit www.informintl.com).

Does my organization have to change its quality system and, if so, when?

It is not the intention that you should have to change the whole structure of your system or re-write all your procedures; however, the revised standards do include some new requirements and you should consider addressing them in your system at an appropriate opportunity.

Transition planning guidelines are available to assist you in identifying the new requirements and the timing of those changes.

Does my organization have to re-write all its documentation?

No. If your current quality management system is successfully implemented, satisfies the needs and objectives of your organization, reflects the way your organization works, and already addresses all of the new requirements, no changes are required. However, if your current documented system does not address all of the new requirements, additional documentation may be necessary.

ISO 9001:2000 has clarified the need for required documentation. Only 6 documented procedures are required by the standard for administration of the system; however, other documented procedures may be required by your organization in order to manage the processes which are necessary for the effective operation of the quality management system. This will clearly vary depending on the size of the organization, the kind of activities in which it is involved, and their complexity.

Are the revised standards more compatible with national quality award criteria?

The quality management principles are now the basis for the revised standards, making them better 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.

Further information on the quality management principles can be obtained from the Standards Group web site at <http://standardsgroup.asq.org> or at the TC 176/SC 2 web site at <http://www.bsi.org.uk/iso-tc176-sc2>.

Do the revised standards address financial issues?

Financial issues are not addressed in the ISO 9001:2000 standard, which is a requirements standard.

The ISO 9004:2000 guidance standard emphasizes the financial resources needed for the implementation and improvement of a quality management system.

What are the benefits of the revised standards?

There are a number of major benefits with the revised quality management systems standards. The benefits are:

- Applicability to all product categories, in all sectors and to all sizes of organizations
- Simple to use, clear in language, readily translatable, and easily understandable
- Significant reduction in the amount of required documentation
- Connection of quality management systems to organizational processes
- Provision of a natural move towards improved organizational performance
- Greater orientation toward continual improvement and customer satisfaction
- Compatibility with other management systems such as ISO 14000

- Provision of a consistent basis to address the needs and interests of organizations in specific sectors (e.g. medical devices, telecommunications, automotive, etc.)
- The concept of the consistent pair — ISO 9001 covering the requirements and ISO 9004 for going beyond the requirements in order to further improve the performance of the organization
- Consideration of the needs of and benefits to all interested parties.
- Continual improvement
- Increased emphasis on the role of top management
- Consideration of legal and regulatory requirements
- Establishment of measurable objectives at relevant functions and levels
- Monitoring of information of customer satisfaction as a measure of system performance
- Increased attention to resource availability
- Determination of training effectiveness
- Measurements extended to system, processes and product
- Analysis of collected data on the performance of the quality management system.

What are the main changes to the standards?

The main changes that have been introduced in the consistent pair of quality management system standards are:

- A new process-oriented structure and a more logical sequence of the contents.
- A continual improvement process as an important step to enhance the quality management system.
- Increased emphasis on the role of top management, which includes its commitment to the development and improvement of the quality management system, consideration of legal and regulatory requirements, and establishment of measurable objectives at relevant functions and levels.
- The concept of “Application” of the standard has been introduced (in clause 1.2) as a way to cope with the wide spectrum of organizations and activities.
- A requirement for the organization to monitor information on customer satisfaction as a measure of system performance.
- Significant reduction in the amount of required documentation.
- Terminology changes/improvements for easier interpretation.
- Increased compatibility with the environmental management system standard.
- Specific reference to quality management principles.
- Consideration of the benefits and needs of all interested parties.
- Addition of the concept of organizational self-assessment as a driver for improvement (ISO 9004).

What new requirements have been introduced into the revised ISO 9001 standard?

The new/more clearly defined requirements include:

Why has the requirement for monitoring of customer satisfaction been included in ISO 9001?

“Customer satisfaction” is recognized as one of the driving criteria for any organization. In order to evaluate if the product meets customer needs and expectations, it is necessary to monitor the extent of customer satisfaction. Improvements can be made by taking action to address any identified issues and concerns.

Do the revised standards improve customer satisfaction?

The quality management system described in the revised standard is 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 the product meets their needs and increases their satisfaction.

What is a process?

Any activity or operation, which receives inputs and converts them to outputs, can be considered as a process. Almost all activities and operations involved in making a product or providing a service are processes.

For organizations to function, they have to define and manage numerous inter-linked processes. Often the output from one process will directly form the input into the next process. The systematic identification and management of the various processes employed within an organization, and particularly the interactions between such processes, may be referred to as the ‘process approach’ to management.

The revised quality management system standards are

based on just such a process approach, in line with the guiding quality management principles.

What is meant by “continual improvement”?

Continual improvement is the process focused on continually increasing the effectiveness and/or efficiency of the organization to fulfill its policies and objectives. Continual improvement (where “continual” highlights that an improvement process requires progressive consolidation steps) responds to the growing needs and expectations of the customers and ensures a dynamic evolution of the quality management system.

How does the implementation of the new standards help my organization to improve its efficiency?

ISO 9001:2000 aims at guaranteeing the effectiveness (but not necessarily the efficiency) of the organization. For improved organizational efficiency, however, the best results can be obtained by using the new ISO 9004:2000 in addition to ISO 9001:2000. The guiding quality management principles are intended to assist an organization in continual improvement, which should lead to efficiencies throughout the organization.

Which standard will my organization be registered to?

Existing ISO 9001, ISO 9002, and ISO 9003 standards will be replaced by the revised ISO 9001 standard. The scope of registration needs to reflect clearly the activities covered by the organization’s Quality Management System, and any exclusions to non-applicable requirements of the standard (through clause 1.2 “Application”) documented and justified in the quality manual.

How do the revised standards improve the perception of ISO 9001 registration?

By demonstrating to organizations that the process of certification based on the new ISO 9000 standards adds value to their own business goals, a market-wide improvement in the perception of ISO 9001 certification should be developed. The rationale behind the revision process places great emphasis on making quality management systems closer to the processes of the organization and on continual improvement. As a result, the revised standards (ISO 9001:2000 and ISO 9004:2000) are directed to the achievement of business results, including satisfaction of customers and others.

There is confidence that management of the organization will be able to adopt the quality management system

standards not only for certification purposes, but also as a profitable investment.

What happens to my organization if it is currently registered to ISO 9002:1994?

The organization is not obliged to include within the scope of its certification all the products that it provides. (Note that the ISO 9000:2000 definition of “Product” includes services!). HOWEVER, for those products that ARE included in the certification scope, all applicable requirements of ISO 9001:2000 will need to be addressed. The standard allows for the exclusion of some 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 Section 7 (“Product Realization”), and requirements may only be excluded if it can be shown that they do not affect the organization’s ability to provide product which meets customer and applicable statutory/regulatory requirements. If design activities are required to demonstrate your organization’s capability to meet customer or statutory/regulatory requirements for products covered by the quality management system certification, then these design activities must be included in the scope of your registration/certification to the ISO 9001:2000 standard.

If design activities are not required to demonstrate your organization’s capability to meet customer and applicable statutory/regulatory requirements, or if your product is provided on the basis of established design, you will still be registered to ISO 9001:2000. In this case, you will need to justify the exclusion of the design and development requirements in your quality manual.

Can organizations remain registered to the 1994 version of ISO 9001, 9002 and 9003?

Although organizations are encouraged to make the transition to ISO 9001:2000 certification as soon as possible, according to the IAF/ISO-CASCO/ISO-TC 176 Communiqué on transition policy, organizations may choose to continue or even seek new certification/registration to the 1994 versions of ISO 9001, ISO 9002, and ISO 9003. Any certificates issued or renewed will, however, only remain valid for a maximum of three years from the publication of ISO 9001:2000.

What does my organization need to do if it is currently registered to ISO 9002:1994 or ISO 9003:1994?

Now that ISO 9001:2000 is published, ISO 9002 and

ISO 9003 have become obsolete. You need to evaluate which specific requirements of ISO 9001:2000 are applicable to the nature of your business and the extent to which your present QMS meets those requirements. Provisions have been made to exclude non-applicable requirements within Section 7 of the standard through clause 1.2 “Application”.

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 will need to discuss and justify the exclusion of these requirements with your certification/registration body.

Am I able to register my organization to ISO 9004:2000?

Since ISO 9004:2000 is a guidance document, it is not intended to be used for third party certification purposes. A key element in the new ISO 9004 is the ability to perform self-evaluation, but third party QMS certifications/registrations are to ISO 9001:2000, which consolidate the old ISO 9001, 9002, and 9003 standards.

How do certificates to the revised ISO 9001:2000 identify the scope of the quality management system?

It has always been necessary to define clearly the scope of registration/certification. The merging of ISO 9001, 9002, and 9003 into a single requirements standard (ISO 9001:2000) requires more emphasis for the scope to define the products, services and processes covered by registration.

How do interested parties benefit by the organization adopting the new ISO 9004?

If the system is appropriately implemented, utilizing the eight Quality Management Principles, all the interested parties will benefit from ISO 9004.

Customers and users 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 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.

How do the consistent pair of standards affect a registered organization?

The idea of a “consistent pair” of standards is the very core of the revised standards. The aligned structure of ISO 9001:2000 and ISO 9004:2000 encourages organizations not only to look at their activities from a process standpoint, but also to look beyond certification to a system which is truly beneficial in improving operational performance.

What’s the relationship between the revised ISO 9001 and ISO 14001?

The revised ISO 9001 was developed to have enhanced compatibility with ISO 14001, particularly with regard to terminology and content. There is close collaboration between the technical experts of ISO/TC 176 and ISO/TC 207 (the Technical Committee responsible for the ISO 14000 series of standards).

ISO 14001 and ISO 14004 are currently being revised by ISO/TC 207/SC 1. This will provide the opportunity for further enhancement of the compatibility between the ISO 9000 and ISO 14000 standards.

How does a small organization adapt to the requirements of the standard? What flexibility is allowed?

The requirements of the revised ISO 9001 are applicable to small, medium, and large organizations alike. Provisions have been made to exclude non-applicable requirements through clause 1.2 "Application". It is, however, up to the individual organization to determine the complexity of the system needed to demonstrate its capability to meet customer and applicable statutory/regulatory requirements for its products.

Are there any guidelines covering joint implementation of ISO 9001 and ISO 14001?

It is expected that the revisions of the two standards will be compatible in terminology and content. It is not expected that an ISO guideline will be prepared on this subject at the present time. If the need for such a document arises, ISO will consider the request as a new project.

For the quality and environmental auditing guidance standards (ISO 10011 and ISO 14010/14011/14012) the two responsible ISO technical committees (TC 176 and TC 207) are preparing a single common auditing standard (ISO 19011), scheduled for publication in the third quarter of 2002.

My organization provides services. How are the new standards applicable to us?

The standards are applicable to all types of organizations. The language in the revised standards is simpler, more user-friendly, and with less manufacturing bias. The new standards are equally appropriate to all sectors, including service providers.

Is there a common guideline standard for auditing QMS and EMS according to ISO 9001 and 14001?

Yes. A specific agreement between TC 176 and TC 207 has set up a joint working group which is preparing a single standard on auditing activities, both for quality management and environmental management systems. This new standard (ISO 19011) will replace the existing ISO 10011 and ISO 14010/14011/14012 documents. The planned publication date for this new standard is the third quarter of 2002.

I am a qualified quality management practitioner (consultant, auditor, or trainer). What do I need to do?

As a minimum, you should familiarize yourself not only with the requirements of the new ISO 9001:2000, but also with the content and philosophies of ISO 9000:2000, ISO 9004:2000 and the quality management principles. You must clearly understand your client's activities and processes and appropriately interpret the requirements of the standards to add value to their operations.

My organization is a regulatory body. What do we need to do?

You should review the regulations currently in effect and ensure that any references to the quality management system standards are appropriate. You should then examine the revised standards and determine if the changes are relevant to the regulations that you have issued and make recommendations to the legislative body.

What needs to be done to ensure that auditors will be ready to work to the revised standards?

Auditors, whether external or internal, need to demonstrate their competence not only on the structure, content and terminology of the revised standards, but also on the underlying quality management principles. The revised standards require that auditors be able to understand the organization's activities and processes and appropriately audit against the requirements of the standard in relation to the organization's objectives. According to the IAF/ISO-CASCO/ISO TC 176 Transition Policy, auditors must demonstrate competency in:

- The requirements of ISO 9001:2000.
- The concepts and terminology of ISO 9000:2000.
- The eight Quality Management Principles.
- A general understanding of the performance improvement guidelines of ISO 9004:2000.
- Familiarity with the latest draft of the auditing guidance standard (ISO 19011).

Contacts:

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For more information, visit the Standards Group web site: <http://standardsgroup.asq.org>.