

We've made it through Y2K ... now how about "Q" 2K?

By David O. Weibel

This article will help you if:

☛ You are currently registered to one of the ISO 900x Standards and want information about how the NEW Q2K (ISO 9001:2000) will impact your existing registration

☛ You are considering becoming registered to the ISO 9000 Quality Management System (QMS) and need some information about the New Standard

☛ You would like to know when you need to take action to convert your existing ISO

☛ You would like to know how the New Standard relates to the ISO 14000 Environmental Management System (EMS)

For those companies who already have completed, or are contemplating Registration to ISO 9000, the "Q" 2K or ISO 9000:2000 revision to the standard is an issue to be considered. The Quality Management System (QMS) is in the final stages of revision and is scheduled to be issued in its final "International Standard" (IS) form during the fourth quarter of 2000.

This article is intended to provide overview information. For more detailed information, please refer to the sources listed at the end of the article.

What are ISO Standards, and where do they come from?

ISO Standards come from Technical Committees formed by the International Organization of Standardization located in Geneva, Switzerland. There are over 130 Member Countries who contribute to the development and publication of the standards through various "Technical Committees" (TCs).

These TCs gather information on all types of subjects (Technical Fields except for Electrical and Electronic topics that are covered by another international body, the IEC), and develop a Standard. After numerous reviews, the Standard is

published and accepted by the Member Countries.

The Standards cover such areas as Film Speed, Telephone and BankCard Codes, Systems of Measurements, Paper Sizes, Quality and Environmental Management Systems, and many others. There are over 12,000 ISO Standards currently in existence.

What triggered the revision to the ISO 9000 Quality Management System (QMS) documents?

When the ISO 9000 Standard was first released in 1987, the ISO 9000 QMS documents had a planned revision cycle of 5 years. In fact, the second revision was published in 1994, and now the third revision is scheduled for late 2000. Thus, the revision has been planned and in process for several years. There are numerous "stakeholders" including industry, compliance bodies, registrars and others who have a strong interest in keeping them current.

What are the major changes to the "group" of Standards that make up the ISO 9000 Quality Management System?

During this revision to the QMS Standards, several significant changes have been implemented. One goal of this revision included making the documents easier to use when relating the Quality Management System to the various Processes and Activities of an organization or company. Other goals were to promote the concepts of Continual Improvement and the achievement of Customer Satisfaction.

The New Standard takes into account the increase in the number of organizations whose output is a "service" as opposed to a manufactured product.

Specific focus was placed on the following items:¹

- Applicability to all Products, Services, Sizes of Organizations
- Simple to use, clear language

- Improved connection between the Quality System and Business processes
- Allow natural progress toward Performance Improvement
- Focus on Continual Improvement and Customer Satisfaction
- Compatibility with other management systems including the ISO 14000 Environmental Management System
- Better address specific needs of Telecom, Aerospace, Medical, etc.

The QMS related Standards have been reduced from about 20 documents to only 3 (with some possible supplements to be added later). They are:

- ISO 9000:2000
QMS Foundations and Vocabulary
- ISO 9001:2000
QMS Requirements
- ISO 9004:2000
QMS Guidance for Performance Improvement

The last two have been revised together to form a "Consistent Pair" of documents which not only lay out the *Requirements*, but allow a *growth path for additional improvements* to the Quality Management System. The two documents are aligned to ease implementation of the fundamentals and to encourage progress beyond the initial phases.

What specific TOPICS are NEW to this revision?

This new version of the Standard introduces a list of eight Quality Management Principles. They are:¹

1. Customer focused organization
2. Leadership
3. Involvement of people
4. Process approach
5. System approach to management
6. Continual improvement
7. Factual approach to decision making

1. Taken from <http://www.bsi.org.uk/iso-tc176-sc2/Summary.html>

Message from GMP Labeling

We hope this newsletter includes information that you can use. Our goal is to periodically publish articles, written by quality professionals, that are timely and informative to the companies in our marketplace. Of course, along the way, we also hope to reinforce our image as a valuable resource to our customers.

Businesses regulated by the FDA and/or are ISO 9000 registered will find GMP Labeling products helpful in maintaining compliance. More than 5000 facilities in the U.S., Canada and Europe use the GMP Labeling System on a daily basis.

8. Mutually beneficial supplier relationship

Of these eight principles, several are significant in that they may require a slight change in thinking of the Management of the organization. The focus on a "Process Approach" (item 4), may require a shift in thinking for many members of the organization's Management Team. Simply stated, it implies that ALL WORK is a process and there are:

- a) inputs to the process
- b) work/actions accomplished
- c) outputs from the process.

In this manner, the total organization can be seen as a number of series and parallel paths or processes. Many Quality Problems today can be traced to the lack of adequate definition of what is required for a process to begin (INPUTS DEFINED), the specifics of the activity (PROCEDURES/PROCESS DEFINED), and what is really required/expected at the completion of the process (OUTPUTS DEFINED).

If the management team can use the new focus on "process" to better define the inputs and outputs required, and to rationalize the required *outputs* from one process to the required *inputs* of the next process, a significant improvement in operational performance can be achieved. The current focus of the standards is on the middle step, defining the processes and then documenting them in the form of procedures.

In addition to the "process" focus, some organizations may have to re-think their activities related to the issue of "Customer Focused Organization".

While no rational organization would have a deliberate policy to "abuse" customers, many organizations do not have a clear focus on satisfying the stated *and implied* characteristics² that lead to complete customer satisfaction. Other Quality Management Principles from the new standard that may not be fully addressed in current ISO Systems are:

- *Involvement of people*, to learn from them and solicit their ideas for improvement.
- *Continual improvement*, to establish ongoing activities including measurements to determine the actual amount of the improvements made and to assure an ongoing improvement process.
- *Factual approach to decision making*, including information gathering systems, and processing of objective information to allow consistent, information-based, decision making.

These additional Quality Management Principles incorporated in the new version of the standards provide considerable additional breadth and depth to an already solid foundation of Quality Management activities. Organizations that embrace and implement these principles will see substantial improvements in the effectiveness of their QMS.

What does the NEW Standard look like... I hear that it does not have the old familiar 20 elements?

The new standard (ISO 9001:2000) does look different, but all of the existing 20 elements from the 1994 version of the standard are included. The new standard has five sections that contain all of the prior 20 standards' 4.x elements. In addition, there are a few new requirements in the five new sections.

The NEW operational sections are:

- 4. Quality Management System
- 5. Management responsibility
- 6. Resource management
- 7. Product realization
- 8. Measurement, analysis and improvement

These five sections contain all of the requirements from the prior 20 elements plus the added items as mentioned above. There are cross-reference tables to show the relationships between the new standard and the ISO 14000 EMS standard, and ISO 9001:1994 QMS. Using these tables, you can find where an item from

the 1994 version of the standard is listed in the new "2K" version and vice versa.

How do I figure out if my current Quality System meets the new requirements?

If you are already conforming to ISO 9001:1994, a look at Table B2 in the ISO/DIS 9001:2000 will tell you where there are areas that are NOT covered in the older standard. For example, the table shows that there is no reference from the 1994 version for the new element 5.2 Customer Focus.

This indicates that you will need to add coverage of this requirement in your Quality System. A detailed review of the table will allow you to generate a list of topics that need work. You will need to develop your Policies, then document your Procedures and detailed Work Instructions (where required) to become compliant with the new Requirements.

Do I need to redo all my documentation?

If your Quality System is currently meeting the requirements, you will only have to ADD to the system documentation those requirements that are new to the 2000 version of the standard. One initial step to help you through the transition would be to develop a cross-reference of how your existing documents and systems meet the requirements of the new standard. Take the Table B2 in the ISO/DIS 9001:2000 and put your document names/numbers in the right hand column where they meet the requirements of the new standard.

How quickly do I have to bring my existing ISO 900x-1994 Quality System in line with the new ISO 9001:2000 requirements?

The guidance documentation for the transition planning (found on the Web at <http://www.bsi.org.uk/iso-tc176-sc2/>) indicates that the existing 1994 version of the standard will co-exist with the 2000 version for up to three years from the date of the issue of the New version. This means that both NEW REGISTRATIONS AND RENEWALS may be issued to the 1994 standards during this

2. Definition from ANSI/ISO/ASQ 8402 Vocabulary: Quality =Totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs. (Emphasis is mine.)

transition period in addition to registrations to the new standards. The registering organization (you) makes the choice.

Thus, if you wish to continue under the “old” standard, you will be able to do so for quite some time. Following this 3-year period, no new Registrations to the old standard will be granted and any existing Registrations to the old standard will no longer be valid.

For example, if you are currently Registered to the “old” version, and if you renew your Registration under the “old” standard one year after the effective issue date of the new standard, the Registration will be valid for a period of only two years. If your Registration Certificate expires during the year 2001, you should probably switch over to the new standard. Beyond 2001, your urgency to convert increases as time goes on, as the Registration will be valid for a shorter and shorter period of time.

If you are operating under one of the “Industry Sector Schemes” such as the Automotive, Telecommunications, Aerospace sectors, there will be further clarification coming in the future as to changes to those documents. The various Sector groups will have to update the requirements of those documents to be consistent with the revised QMS.

I am Registered to ISO 9002 or ISO 9003. The New Standard does not have a requirements document for ISO 9002 or 9003 ... what do I do about that?

The new standard has only one implementation, ISO 9001. There are provisions for “Permissible Exclusions” to the full requirements of the standard. These “exclusions” are permissible ONLY within Clause 7. Product Realization. Your organization will have to work with your Registrar to justify any exclusion based on:

- The nature of your product
- Your customer requirements
- Any regulatory requirements that are applicable

While it may be harder to exclude some activities (such as Design Control) from the Scope of Registration, it will be possible to exclude such activities where they DO NOT exist as a requirement in the fulfillment of product quality and customer satisfaction. It would be beneficial to open a dialog early with your Registrar if this a part of your situation.

Items related to management responsibility, resource management, and measurement, analysis, and improvement will NOT be candidates for exclusion.

New Requirements	1994 Version Requirements (Elements or Portions of the Element)
4. Quality Management System	Quality System
5. Management Responsibility	Management Responsibility Quality System Document and Data Control Quality Records
6. Resource Management	Management Responsibility Process Control Training
7. Product and/or service realization	Quality System Contract Review Design Control Purchasing Customer Supplied Product Product ID and Traceability Process Control Inspection and Testing Inspection, Measuring and Test Equipment Inspection and Test Status Handling, Storage, Packaging, Preservation, and Delivery Servicing
8. Measurement, analysis, and improvement	Management Responsibility Process Control Inspection and Test Nonconforming Material Corrective and Preventive Action Internal Audit Statistical Techniques

The 1994 version of the Standard did not have any requirements related to the financial activities of my company. Will the New Standard have any requirements in this area?

No, financial issues are not formally addressed in the ISO 9001:2000 Requirements document just as they were not addressed in the 1994 version. The ISO 9004:2000 Guideline for performance improvements does include reference to the use of financial resources and tools for “IMPROVEMENT” of the Quality System.

The use of Quality Cost models, while not required, are a very powerful tool to assist in measuring the benefits of your Quality System.

What benefits should I expect from implementing the requirements of the New Standard?

The benefits of ISO Registration are many and varied — but they should and CAN be related to increased efficiency and performance of the organization being Registered.

The requirement to think through and

establish policies related to the fulfillment of quality is a process that any organization can benefit from. All too often, organizations do not spend sufficient time in this activity to clearly establish and communicate these policies to their employees and customers.

Most organizations can benefit from having documented processes that define expectations and therefore the results coming from various parts of the organization. Consistency can be a result of such documentation. Consistency of output will also reduce “failure” costs. The focus on Customer Satisfaction will improve relationships with your customers and develop increased loyalty. Companies in a high growth situation will receive substantial benefit by using the documented procedures as part of the training to bring new employees quickly up to performance requirements.

A generally accepted feeling about ISO implementation is that it is good business sense, and it requires nothing more than would already be implemented in a successful and well-managed organization. Throughout this

article, I have used the term "organization" as opposed to "company" as I feel the concepts embodied in the Quality Management System work just as well in "not for profit" organizations as with profit making companies.

My observations in performing hundreds of audits is that companies who willingly and eagerly embrace the Quality Management System will see performance improvements that quickly repay the initial implementation costs. The benefits following the initial pay-back period are "bottom line" benefits in "for profit" organizations, and allow expanded capabilities in "not for profit" organizations.

How does the new Quality Management System Standard relate to the Environmental Management System Standard ISO 14001:1996?

This revision to the ISO 9000 series standards has no direct impact on the ISO 14000 series standards, but the revisions were written with an attempt to use the same terminology and content format as the ISO 14000 EMS. The ISO 14000 standards will be revised in the future under the Technical Committee established for that purpose and I am sure the

revisions will continue the rationalization of the two sets of documents.

There is a joint effort underway to prepare a revised standard on Auditing Activities. That standard will be identified as ISO 19011 and is scheduled for publication in late 2001.

Where do I go for more information relating to the New QMS Standard?

Copies of the DIS (Draft International Standard) versions of the three main documents are available from the International Organization of Standardization: (<http://www.iso.ch/>), and the American Society for Quality: (<http://www.asq.org/>).

The ASQ Web pages will no doubt carry information regarding the full release of the new standard. This is expected in late 2000. Copies of the revised Standards may be purchased from the above organizations.

The British Standards Institute website: (<http://www.bsi.org.uk/iso-tc176-sc2/>) has additional detailed information and, as the implementation dates come closer, I am sure that there will be substantial additional information in the quality press.

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Mr. Weibel provides training courses in the fundamentals of the ISO process, as well as specific topics including Corrective/Preventive Action, Root Cause Analysis, Internal Auditor Training, and Document Control. Mr. Weibel has performed over 500 Registration/Surveillance Audits for National Quality Assurance (NQA), Acton MA.

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