

New ISO 9000 Standards Raise the Bar

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The countdown has begun for all ISO-certified organizations to meet a December 15, 2003, deadline for compliance with the upgraded ISO 9000 standards. The Switzerland-based International Organization for Standardization (ISO) introduced its ISO 9001:2000 upgrade in December 2000. The goal was to produce standards that are more customer-centric, require greater management involvement and, most important, enforce the long-term ISO goal of continuous improvement. The upgrade replaced the previous ISO 9001:1994 standards. In addition, ISO 9002:1994 and ISO 9003:1994 were officially discontinued.

As always, ISO standards are voluntary, but certifying organizations are directed to no longer certify adherence to the ISO9000:1994 standards. Furthermore, companies with ISO9000:1994 certification are encouraged by ISO to re-certify to the new ISO9000:2000 standards by the December deadline. Re-certification demonstrates ongoing acceptance and practice of ISO ideals.

According to ISO, all companies can now use ISO 9001:2000 and can reduce the scope of the standard to exclude requirements that don't apply. The role of ISO 9004 in the series is unchanged. As in previous editions, ISO 9004:2000 is a guide for developing quality-management systems (QMS). It has now been streamlined into ISO 9001:2000.

The new ISO standards demand a comprehensive and improved QMS. They are customer-focused and require companies seeking ISO certification to achieve, measure, and monitor customer satisfaction, as well as improve communication with customers. The goals of the 9001:2000 standards are to identify and implement system improvements and to evaluate the effectiveness and suitability of QMS.

ISO 9001:2000 specifics

The new requirements focus predominantly on customer-related processes and continual improvement. With regard to customer processes, they require top management to:

Ensure that customer needs and expectations are identified and converted into specific requirements

Demonstrate commitment to creating awareness of the importance of fulfilling customer requirements, needs and expectations

Make employees aware of the importance of meeting customer requirements

Establish procedures for customer communication

Implement a system for obtaining and using information on customer satisfaction.

Together, these requirements demand that organizations expand their QMSs to all departments and functions dealing with and representing customers. Typically, these include marketing, sales, customer service and billing. In the area of continual improvement, many of the elements supporting the continual-improvement cycle were already required in previous editions of the standard. Now there is a new, stronger link between these elements. There are also several new requirements, designed to:

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Establish quality objectives, and plan activities and resources needed to achieve quality objectives

Provide a framework for the development and periodic review of quality objectives

Ensure management's commitment to meeting requirements and reviewing the QMS on an ongoing basis

Collect and analyze data to determine effectiveness of the QMS

Establish a procedure for the use of quality policy, objectives and quality-related data and information to facilitate continual improvement.

Rather than being grouped in specific, additional clauses, the new ISO 9001:2000 requirements are spread throughout the standard. They are often restated and expanded upon under multiple sections. For example, requirements pertaining to process control are introduced in Section 5, developed in two separate clauses of Section 7, then restated in Section 8. This approach follows the logic of the standard's new organization, but identification and interpretation of the requirements is difficult. Often the intent of the standard is not clear until after related requirements are culled from different sections and analyzed together. The effort necessary to implement the new requirements will depend on the complexity of marketing, sales and customer-service operations, and how widespread a company's documentation and QMS are. The good news is that the standards' documentation requirements are easier to implement. With the new standards, for example, only six documented procedures are necessary for administration of the system. The 1994 standard required 15. Most existing documentation will fold into the new QMS. It is likely, however, that adjustments will be needed to address new specific requirements. In this case, an organization may *choose* to document additional procedures beyond the ISO requirements to best manage the QMS.

Upgrade tools

There are a variety of Web-based upgrade tools on the market to ease your transition to the new standards. Prism eSolutions offers the equationASP2000 Upgrade, for example. It includes updated ISO templates, samples, online training, and proven ISO methodologies that decrease the time spent in developing additional documentation a primary cause of upgrade delay and certification failures. In addition, the product's project-management system outlines the complete project and sets deadlines for every step, assuring timely project completion and compliance.

Another tool is the Powerway Suite 2000 from Powerway, Inc., Indianapolis, IN. This is a client-server software solution that provides tools for the creation, control and sharing of documents, data, and knowledge. This product automates paper-intensive engineering, quality, and manufacturing processes, which helps to reduce costs, improve quality and speed time to market. This tool primarily handles document management. It is not designed to be the sole support of a complete QMS.

Upgrade tips

With the proper solution, ISO 9000 re-certification can be a fast, cost-efficient process. But before you start, here are a few tips to keep in mind:

Understand the new requirements. The American Society for Quality (www.asq.org) and ISO (www.iso.org) are good places to start. These sites also provide background

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information about ISO, its mission and standards.

Determine the project scope and permissible exclusions. ISO 9001:2000 is intended to be generic and applicable to all organizations, regardless of type, size and product category. However, not all requirements in the new standard will be relevant to all organizations; an organization may exclude some requirements.

Adopt the process approach. A process is a system of activities that uses resources to transform inputs into outputs. The process approach promoted by ISO 9001:2000 systematically identifies and manages these processes and their interaction within a QMS.

Revise your quality manual and procedures. The documentation for a compliant QMS must include the quality policy, quality objectives, quality manual, required procedures, and other documents deemed necessary for its effective planning, operation and control.

Focus on the top-management role. ISO 9001:2000 defines top management as the person or group of people who directs and controls an organization at the highest level. Top-management leadership, commitment and active involvement are essential for an effective QMS.

Establish measurable quality objectives. Your organization needs to identify the key quality measures for evaluating the performance of your QMS. Use your quality policy statement as the framework for establishing your process and product goals. Then set specific, measurable targets on the path to attaining these goals.

Prepare a transition plan. To form a transition plan, assess your current system against the requirements of the new standard. This gap analysis will identify any missing documentation and practices. By knowing needed deliverables, you can better determine the appropriate activities and assignments to enhance your current system for compliance with ISO 9001:2000. Develop the transition schedule in consultation with your registrar.

Inform your organization. It is important to inform everyone involved in your QMS of plans and progress. This will enable everyone to help improve performance and meet the established objectives for their areas.

Update your audit program. Your internal audit schedule should focus on the areas of new and changed practices. Prism eSolutions, LLC, is an international consulting and training company specializing in ISO 9000/QMS, ISO 14000/EMS, and other areas of business improvement. The company provides Web-based applications for companies seeking ISO certification in the manufacturing, telecommunications, healthcare and business services sectors.

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