

ISO 9001:2000 Strives For a New Direction in Quality Requirements

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ISO 9001:2000 is the third edition of the international quality management standard originally issued in 1987. It replaces the 1994 versions of ISO 9001, 2, and 3, and is renamed Quality Management Systems. As its new name and the changes to the standard suggest, the standard has a new orientation, built around a process approach, customer satisfaction, and continual improvement.

At the time of its first revision in 1994, some 75,000 organizations worldwide had registered to the standard, including about 7,500 in the U.S. Those figures have swelled to over 200,000 and 30,000, respectively. Moreover, in the United States, the automotive, aerospace, and telecommunications industries have made ISO 9000:1994 the cornerstone of industry-specific quality management requirements, and the FDA has incorporated it into its Quality System Requirement for medical devices. This standard has clearly gained acceptance.

The original rationale for ISO 9000 registration centered around European Union requirements. Companies wanting to serve a global market were told that ISO 9000 compliance would make it easier to do business in Europe, while organizations doing business exclusively in the U.S. saw little incentive to get certified. As the year 2000 approaches, however, there are many more motives for ISO 9000 registration or compliance, including industry requirements, customer mandates, keeping up with the competition, public relations value, and even the simple realization that it can improve the way an organization does business.

Between the 1987 and 1994 versions, few changes were made—mostly clarification of wording and linkages between management review, internal quality auditing, and corrective/preventive action. The year 2000 standard looks altogether new, but it may not BE as different as it LOOKS.

Scope of the Changes

The standard requires review every five years, and as of this writing, the standard has reached its second Committee Draft (CD2) on its way to becoming a Draft International Standard (DIS), a Final DIS, and the ratified standard, ISO 9000:2000. As you read this, transformation from CD2 to DIS take place in late September, 1999:

The member bodies of TC-176, looking at customer needs as the force behind the revision, identified four main thrusts for changes.

- (1) The desire for a common structure based on a process model, similar to the Malcolm Baldrige National Quality Award criteria.
- (2) The need to demonstrate continuous improvement and prevention of nonconformity—a clear push toward performance measurement.
- (3) A request for ease of use and clarity of terminology (an attempt to harmonize the requirements of service-based and manufacturing industries).
- (4) The desire for compatibility with ISO 14000, the environmental management standard.

Paging through the standard, the most obvious difference is the numbering scheme. Gone are the twenty elements of 1994—from 4.1 to 4.20. In their place are four major sections:

- Management Responsibility
- Resource Management
- Product and/or Service Realization
- Measurement, Analysis and Improvement

What might not be apparent at first is that all 20 of the old elements are alive and well, residing in new sections.

A second difference is the "process model" —a schematic view of an organization that uses customer input to guide internal processes, and customer satisfaction, confidence, and feedback to recharge the business processes in a continual improvement loop— the plan-do-check-act of total quality management.

A third difference is the language. The strong orientation toward manufacturing in the previous versions is replaced by a sensitivity toward service industries, both in the requirements and descriptions. Unfortunately, some of the new language is clumsy; for example, "product and/or service" appears over sixty times.

How will the new standard affect your operations?

First, the new version emphasizes strengthening the supply chain through organization-to-customer communication, written and unwritten specifications, contract and design/development review, process management, and supplier and customer feedback.

Second, the onus is on the organization to determine measurement opportunities in all aspects of the business —order specification, training, process management, monitoring, nonconformity, customer satisfaction— not only to measure but to analyze the data for fact-based decision making and as a basis for continual improvement.

Third, meeting customer requirements is represented in every part of the business transaction. Organizations must go beyond "meeting specs" by being aware of and responding proactively to "fitness for purpose," unspecified requirements, process efficiencies, mid-stream changes, postproduction activities, and customer satisfaction, or what the standard refers to as achieving "customer confidence."

Some companies have suggested that the new standard will force them to rewrite most of their documentation, staff new functions (statisticians, for example), and add activities to their already-full agendas —all as required changes to an already ISO 9000-registered quality management system. However, that would be their decision based on their analysis of the standard, and may be as much a function of size and business complexity as of new requirements. More activities will be needed to support the new requirements. Some businesses will hire, and job descriptions might be for process engineers, customer advocates, and data managers. Regarding documentation, it is estimated that an ISO-registered organization is at least 80 percent of the way to year 2000 compliance, the main differences being a new quality manual and several new procedures.

These are problems that industry must face. In the final analysis, ISO 9001:2000 is attempting to take a major step forward from traditional quality control and quality assurance to becoming a model for a modern, information-based, customer-driven quality management system that will add value to an organization's processes. As a standard written by a committee of over 90 member bodies, it contains compromises and contradictions. If these are overcome, ISO 9001:2000 has the potential to become a worldwide model for the next generation of quality improvement.