

1

1 Introduction to ISO 9001:2000

By the end of this chapter you should be able to:

- Describe the origins of quality management systems.
- Describe the potential benefits of ISO 9000 certification.
- Explain how ISO 9000 can have an impact on world trade.

CHAPTER 1

Introduction to ISO 9001:2000

To lead and operate an organization successfully requires that it be managed in a systematic and transparent manner. Success can result from implementing and maintaining a management system that is designed to continually improve performance by addressing the needs of all interested parties, from customers to employees. Managing an organization encompasses quality management as one of the management disciplines.

In ISO 9001 for 1994, quality management was defined as a system, with twenty elements of requirements that comprised that system. Each element referred to and intertwined with other elements or sections of the standard. The quality management standards of 1994 were based on the initial ISO 9000 series of standards issued in 1987, which were the first management system standards developed by an international committee under the authority of the International Organization for Standardization in Geneva, Switzerland. Prior to the ISO 9000 Series of Standards, quality management systems were based on Deming's Fourteen Points, which are emphasized in the ISO 9001: 2000 standard.

Structure of the New Standard

In the ISO 9001:2000 standard, the twenty elements of the 1994 standard were reorganized and streamlined to reflect a process-oriented structure more in line with the brief, high-level ISO 14001 environmental management system standard signed off in 1996. The International Organization for Standardization views a process as any activity that receives inputs and converts them to outputs, and views an organization as a group of numerous linked processes. Among these processes, the output of one is often the input of another. Identifying and managing these processes and their interactions in an organization is a process approach that is necessary for effective operations.

The element of human resources in the 1994 standard has been expanded and emphasized in ISO 9001:2000, along with work environment and the involvement of interested parties. A greater emphasis is placed on the role of top management, and a consideration of legal and regulatory requirements is now included.

The new standard also requires establishment of measurable objectives at relevant functions and levels, greater attention to resource availability, and determination of training effectiveness. Measurements have been extended to systems, products, and processes. Finally, it is necessary to analyze collected data on the performance of the quality management system.

What Remains

ISO 9002 and ISO 9003 have been eliminated, leaving the updated ISO 9001:2000 standard for quality management systems, and the ISO 9004:2000 standard to provide guidance on a wide range of objectives to improve overall performance. An organization that wants to become certified to ISO 9001:2000 must declare and document which elements of the standard its quality management system applies to and state why this is so. Exclusions to the standard are limited to section 7 requirements, and cannot affect the ability or responsibility of the organization to provide a conforming product.

Figure 1-1
ISO 9000 Standards: 1994 and 2000

1994	2000
	ISO 9000—Quality management systems: Fundamentals and vocabulary.
ISO 9001—Quality systems: Model for quality assurance in design/development.	ISO 9001—Quality management systems: Requirements. ISO 9001, 9002, and 9003 have merged into a single standard.
ISO 9002—Quality systems: Model for quality in production and installation.	
ISO 9003—Quality systems: Model for quality assurance in final inspection and test.	
ISO 9004—Quality management and quality system elements: Guidelines.	ISO 9004—Quality management systems: Guidelines for performance improvements.

ISO 9001:2000 is based upon eight quality management principles to enable the organization to meet its quality objectives. These principles can be applied by top management to direct the organization toward improved performance.

1. **Customer Focus:** Organizations depend on their customers, and need to understand current and future customer needs, meeting customer requirements, and striving to exceed customer expectations. The key benefits of customer focus include increased revenue and market share gained through flexible responses to opportunities.
2. **Leadership:** Purpose and direction of the organization are determined by its leaders who should cultivate an internal environment that allows people to become fully involved in meeting the organization’s objectives. With purpose and direction established and encouraged, people are able to understand and be motivated toward the organization’s goals and objectives. With a stronger sense of unity, activities are evaluated, aligned, and implemented in a focused way, and miscommunication between levels of the organization is minimized.

3. **Involvement of People:** The full involvement of people at all levels allows their abilities to be applied for the organization's benefit. Once involved, people become motivated and committed, contributing their creativity in furthering the organization's objectives. People who are accountable for their own performance are eager to participate in continual improvement.
4. **Process Approach:** When activities and related resources are managed as a process, the desired result can be achieved more efficiently. Having a process approach in place results in lower costs and shorter cycle times through the effective use of resources. With consistently better and more predictable results, it is then possible to have more focused and prioritized improvement opportunities.
5. **System Approach to Management:** The organization can be more efficient and effective in meeting its objectives when interrelated processes are identified, understood, and managed as a system. Processes can be integrated and aligned to achieve the best results, and allow an opportunity to focus effort on the key processes. The organization then provides confidence to interested parties regarding its consistency and efficiency.
6. **Continual Improvement:** Continual improvement should be integral to the organization's overall performance as a permanent objective. Improved performance increases the organization's capabilities and allows the flexibility to react quickly to opportunities. Continual improvement also has strategic implications, allowing the organization to align improvement activities at all levels with its intent.
7. **Factual Approach to Decision Making:** Focused and effective decisions are based on the analysis and evaluation of data and information, which allows informed decisions. The organization can more easily refer to factual records that document previous effective decisions, which results in an increased ability to review, challenge, and change opinions and decisions.
8. **Mutually Beneficial Supplier Relationships:** Cultivating a mutually beneficial relationship between the organization and its suppliers enables both to create value. Good organization and supplier relationships optimize costs and resources, and result in flexibility and speed of joint responses to changing market or customer needs and expectations.

Key Enhancements in ISO 9001:2000

For a complete list of summarized key enhancements to the standard—about seven pages in all—go to <http://www.iso.ch>, the website for the International Organization for Standardization. Under ISO 9000 and ISO 14000, then ISO 9000: Year 2000 Revisions, there is the file *Transition Planning Guidance for ISO 9001:2000*. Section 5.4 of this document is *Summarised Analysis to Key Enhancements Between ISO 9001:1994/ISO 9001:2000*.

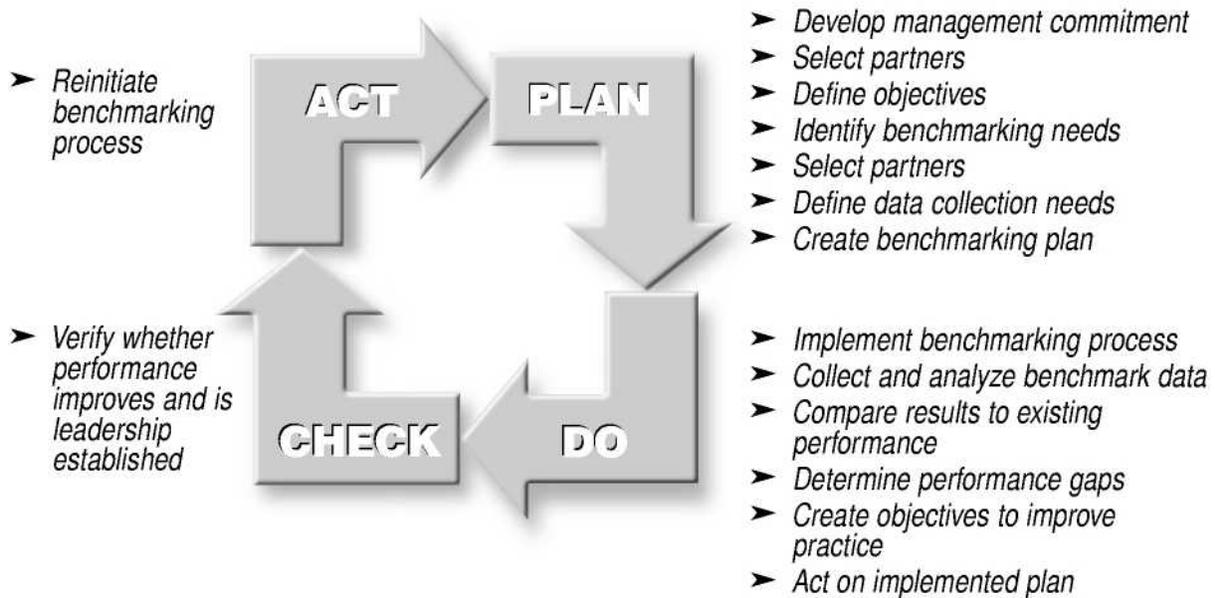
Deming's Fourteen Points for the Transformation of Management

1. Create constancy of purpose toward improvement of product and service, with the aim to become competitive and to stay in business, and to provide jobs.
2. Adopt the new philosophy. We are in a new economic age. Western management must awaken to the challenge, learn their responsibilities, and take on leadership for change.
3. Cease reliance on mass inspection to achieve quality. Eliminate the need for inspection on a mass basis by building quality into the product in the first place.
4. End the practice of awarding business on the basis of price tag. Instead, minimize total cost. Move toward a single supplier for any one item, on a long-term relationship of loyalty and trust.
5. Improve constantly and forever the system of production and service, to improve quality and productivity, and thus constantly decrease costs.
6. Institute training on the job.
7. Institute leadership with the aim of supervision to help people, machines, and gadgets do a better job. Supervision of management is in need of overhaul, as well as supervision of production workers.
8. Drive out fear, so that everyone may work effectively for the company.
9. Break down barriers between departments. People in research, design, sales, and production must work as a team, to foresee problems of production and in use that may be encountered with the product or service.
10. Eliminate slogans, exhortations, and targets for the work force that ask for zero defects and new levels of productivity. Such exhortations only create adversarial relationships, as the bulk of the causes of low quality and low productivity belong to the system, and thus lie beyond the power of the work force.
Eliminate work standards (quotas) on the factory floor. Substitute leadership.
Eliminate management by objective and numerical goals for people in management. Substitute leadership.
11. Remove barriers that rob the hourly workers of their right to pride of workmanship. The responsibility of supervisors must be changed from sheer numbers to quality.
12. Remove barriers that rob people in management and engineering of their right to pride of workmanship. This means abolishment of the annual or merit rating and/or management by objective.
13. Institute a vigorous program of education and self-improvement.
14. Put everybody in the company to work to accomplish the transformation. This transformation is everybody's job.

Reprinted from W. Edwards Deming, *Out of the Crisis*, MIT Press. Copyright ©1986 The W. Edwards Deming Institute.

The system is continually striving to improve the quality of the products and services offered by the company. The logical way to execute a quality system is to develop an action plan with a clear mission statement, which Deming called the Plan-Do-Check-Act (PDCA) cycle, as seen in Figure 1-2. The system is developed, documented, implemented, checked, and improved upon through action taken through activities. In the long term, a quality system reduces costs and improves the consistency of the product or service.

Figure 1-2 Continual Improvement's Plan-Do-Check-Act Cycle
Plan-Do-Check-Act Cycle



When Deming presented his ideas in the 1950s, they were ignored in the United States at the time. However, in Japan, top management and engineers applauded and readily accepted his system for the management of quality, and applied his statistical process control to their manufacturing operations. This process enabled companies to determine where defects were being generated so resources could be focused on correcting them.

Deming's teaching dramatically altered the economy of Japan. By the 1980s, Japanese automobiles and consumer electronics were consistently superior to similar American and European products. In recognition of his contribution to the success of their industries, the Union of Japanese Science and Engineering instituted the annual Deming Prizes for achievements in the quality and dependability of products.

Because Deming's approach was so successful, many countries began developing their own versions of quality management systems. By the 80s, it had become apparent to the International Organization for Standardization that a uniform standard for quality systems

was needed, resulting in the issuance of the ISO 9000 quality management series of standards in 1987.

World Trade Implications of ISO Certification

Following the rapid adoption of ISO 9000 quality management system standards worldwide, certification (registration) to these standards has become a prerequisite for trade in many regions. By 1997, there were more than 300,000 companies certified to ISO 9001, 9002, or 9003.

There are three main reasons for this interest in ISO 9000 certification:

1. **Potential Trade Barriers**

Japan, like the United States, ignored the early adoption of ISO 9000 because companies there believed that their quality systems were superior to the ISO 9000 standards. This attitude changed when a lack of ISO certification excluded their products from the European market.

2. **Product Performance**

Historically, organizations adopting quality management practices have demonstrated more reliable product performance than companies who do not adopt quality principles and systems. ISO 9000 is seen as a way for corporations to improve their product performance and reliability.

3. **Customer Preference**

As export-driven economies, the Asians have recognized that consumers have a growing expectation of reliability of product. The ISO 9000 standard has become a recognized baseline of quality and companies that are certified to this standard must maintain quality practices, thus giving consumers a sense of comfort that the products produced at certified companies will be more reliable than products produced at non-certified companies.

About the Registrars in This Book

The ISO 9001:2000 standard has been evolving over many months, with major changes even as it became the Final Draft International Standard (FDIS). Because ISO 9001:2000 involves such extensive changes in its transition from ISO 9001:1994, we asked two executives from major certification firms to share their insights about this process for our readers. Both are involved in operations on sites in the United States. Look for their comments and suggestions in sidebars throughout the text.

Garnett Davis, U.S. Operations Manager for DNV Certification, Inc. DNV is part of Det Norske Veritas, a major international foundation with more than 5,500 employees in 300 offices in 100 countries. With more than 33,000 certifications issued, DNV is one of the world leaders in management system certification to requirements of ISO 9000, ISO 14000, and related industry-specific standards. Garnett Davis has over 20 years experience in the quality arena. As a qualified Lead Assessor, he has developed and presented many courses on the interpretation of the standard, and is responsible for training DNV auditors to the revised standard.

Bill Poliseo, Executive Vice President of BVQI North American Operations. Bureau Veritas Quality International (BVQI) is a wholly owned subsidiary of Bureau Veritas, a multinational organization founded in 1828. BVQI was founded in 1988 to respond to the worldwide need for third party management system certification. Headquartered in London, the registrar has offices in 45 countries that serve 31,000 clients. As the most widely recognized certification body, BVQI is accredited by 22 accreditation bodies, and has 1,000 trained auditors. Bill Poliseo is a Registered Lead Auditor, and has participated in numerous assessments against ISO 9000, QS 9000, AS 9000, and EN 46000.

Recap

The foundations of quality management systems can be traced back to W. Edwards Deming. His effective concept that included a plan-do-check-act cycle was followed by the development of the ISO 9000 quality management system standards through the International Organization for Standardization's international technical committee (TC 176) in 1987. In addition to efficiencies created by implementation of the standard, a company can involve all employees in the process, and can experience positive cultural change within the organization.

The ISO 9001:2000 standard reorganizes the twenty elements of the 1994 standard to reflect process approach. The element of human resources has been expanded and highlighted, along with work environment and the involvement of interested parties. Additionally, ISO 9002 and ISO 9003 have been eliminated, resulting in one standard for quality management systems, with the requirement for an organization to declare and document which elements of Section 7 of the standard its quality management system does not apply to, and to state why it has these exclusions.



Review Questions!

Instructions: Here is the first set of review questions in this course. Answering the questions following each chapter will give you a chance to check your comprehension of the concepts as they are presented and will reinforce your understanding of them.

1. What are the quality management systems based on?

- (a) Management business practices.
- (b) Dr. W. Edwards Deming's fourteen points.
- (c) Japanese teachings.
- (d) World trade issues.

2. Dr. Deming is well known for:

- (a) Developing the ISO 9000 quality standards.
- (b) Forming the International Organization for Standardization.
- (c) Introducing cost saving methods at Xerox Corporation.
- (d) The PDCA cycle.

3. ISO 9000 is the standard for:

- (a) Environmental management systems.
- (b) Management business practices.
- (c) Quality management systems.
- (d) The PDCA cycle.

4. Why are quality management systems important to an organization?

- (a) They give top management focus.
- (b) Customers like them.
- (c) They allow an organization to operate in a systematic and transparent manner.
- (d) They are required by most contracts.

5. What are the three main reasons for ISO 9000 certification?

- (a) Trade barriers, product performance, and customer preference.
- (b) Internal recognition, employee morale, and customer requirements.
- (c) Employee performance, product yield, and process output.
- (d) Company recognition, marketing tactics, and management tools.

Answers:

1.b 2.d 3.c 4.c 5.a

