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Cracking the Case of ISO 9001:2008 for Manufacturing

A Simple Guide to Implementing
Quality Management in
Manufacturing

Second Edition

**Charles A. Cianfrani
and John E. (Jack) West**

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www.asq.org
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<http://standardsgroup.asq.org>
E-mail: authors@asq.org



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Chapter 1

Why Do ISO 9001:2008?

ISO 9001:2008 provides a model for quality management. While no such model is perfect, this one has proven to be applicable to virtually all sizes of organizations, in every marketplace, and for every product category throughout the world for over 20 years.

Why has ISO 9001 become the world's most used standard? Why has it achieved such widespread acceptance and use? Certainly not because of the elegance of the text in the standard, for this writing is among the dullest, most boring prose the human mind and hand have ever crafted. The ISO 9001 standard has survived and flourished because it adds value to how organizations are managed, from the viewpoint of both managers and workers.

Workers like ISO 9001 because it makes life simpler. In an ISO 9001 system, workers have:

- A better understanding of what to do and how to do it
- The ability to ensure that their work meets requirements



- The ability to adjust processes when results are not meeting requirements
- A means to get help in solving problems
- Increased opportunities to communicate problems in a nonthreatening manner by focusing on process issues
- An environment where they are not blamed for issues that can be resolved only by managers

Middle managers have embraced ISO 9001 because it has contributed to better control of processes and has resulted in a higher level of consistency throughout the organization. Middle managers find that ISO 9001 has:

- Made it easier to manage using facts and data rather than opinions
- Enhanced communication throughout the organization (between management and workers, between departments, and with executive management)
- Encouraged clarity of responsibility and accountability

- Standardized the way things are done, reducing variability and making it easier to solve problems
- Fostered continual improvement as an institutionalized core value, and provided a platform for moving to performance excellence



Top managers find that adopting a formal ISO 9001 quality management system (QMS) helps the organization focus on meeting objectives. Top managers find that ISO 9001 has:

- Improved their organization's ability to fully understand and meet customer requirements in a consistent manner
- Brought greater clarity to the goals and objectives of the organization
- Helped align all employees and processes to meet objectives
- Improved bottom-line performance by enhancing revenue and reducing costs, created a competitive advantage in some markets, and enabled their organizations to compete in markets where most other potential suppliers are registered

Perhaps the most important reason for doing ISO 9001 is survival. In these times of uncertainty, people are concerned about protecting their jobs.

All of these reasons for embracing ISO 9001:2008 can be reduced to a single effect: It facilitates quality improvement. And quality improvement has two positive impacts on an organization:

- Better processes and reduced variation in production can yield dramatic reductions in cost
- Better customer satisfaction can yield more sales

If an organization does not have a foundation of uncompromising integrity, adventures into the world of performance excellence or attempts to sustain improvement programs are futile exercises. The requirements of ISO 9001 can be used to create a foundation upon which a successful organization can be built. They may not be sexy or exciting, but unless they are performed consistently and well, an organization will not prosper and may not survive in the contemporary marketplace.

This guide is intended to help everyone in an organization participate in creating and sustaining a foundation of integrity, and meeting requirements and customer expectations to the advantage of everyone in the organization and to each of its customers.

Charlie Cianfrani
cianfranic@aol.com

Jack West
jwest92144@aol.com



Chapter 2

Principles and Key Concepts

This chapter describes the eight quality management principles that were used as the basis for the development of ISO 9001:2008. It also discusses several key concepts that are important to fully understand.

QUALITY MANAGEMENT PRINCIPLES

The eight quality management principles were a key input in the development of ISO 9001:2008. The principles may be found in clause 0.2 of ISO 9000:2005, which is quoted as follows:

To lead and operate an organization successfully, it is necessary to direct and control it in a systematic and transparent manner. Success can result from implementing and maintaining a management system that is designed to continually improve performance while addressing the needs of all interested parties. Managing an organization encompasses quality management amongst other management disciplines.

Eight quality management principles have been identified that can be used by top management in order to lead the organization towards improved performance.

- a. Customer focus. Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.*
- b. Leadership. Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.*
- c. Involvement of people. People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.*
- d. Process approach. A desired result is achieved more efficiently when activities and related resources are managed as a process.*
- e. System approach to management. Identifying, understanding and managing inter-related processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.*
- f. Continual improvement. Continual improvement of the organization's overall perfor-*

mance should be a permanent objective of the organization.

- g. Factual approach to decision making. Effective decisions are based on the analysis of data and information.*
- h. Mutually beneficial supplier relationships. An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.*

These eight quality management principles form the basis for the quality management system standards within the ISO 9000 family. (Source: ANSI/ISO/ASQ Q9000-2005)

More details on using the principles and the benefits of using each can be found on the ISO Web site at <http://www.iso.ch/iso/en/iso900014000/iso9000/qmp.html>.



CUSTOMERS—CUSTOMER FOCUS AND MEASURING SATISFACTION

The purpose of ISO 9001 is to achieve customer satisfaction by meeting customer requirements. While meeting requirements

and preventing nonconformities have been fundamental to ISO 9001 since its initial issue in 1987, ISO 9001:2008 continues the enhanced emphasis on customers. There are key things an organization needs to understand and implement that are related to customer focus:

- Top management is required (clause 5.1) to communicate to all in the organization the importance of meeting customer requirements.
- Top management is required (clause 5.2) to ensure that processes are in place to determine and meet customer requirements, with an aim to enhance customer satisfaction.
- The quality policy is required (clause 5.3) to contain a commitment to meet requirements. This includes meeting customer requirements.
- Appointment of a management representative is required. The management representative's duties include (clause 5.5.2) ensuring promotion of awareness of customer requirements.
- Customer feedback is required (clause 5.6.2) as an input to the management review process, and improvement of product related to customer requirements is a required management review output (clause 5.6.3).
- Resources are required (clause 6.1) to “. . . enhance customer satisfaction by meeting customer requirements.”
- Customer requirements are the key input to product realization. Processes are required to determine

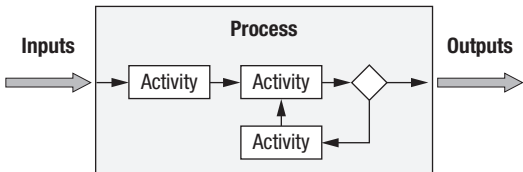
(clause 7.2.1) and review (clause 7.2.2) those customer requirements.

- Processes are required (clause 7.2.3) for communications with customers.
- Monitoring of information related to customer perception is required (clause 8.2.1).

Understanding this focus on the customer is critical to implementation of an effective ISO 9001 quality management system. The organization needs to carefully think about the interrelated processes that are needed to meet the ISO 9001 requirements in a way that will enhance customer satisfaction.

PROCESS APPROACH—ACTIVITIES, PROCESS MANAGEMENT, AND THE SYSTEM APPROACH TO MANAGEMENT

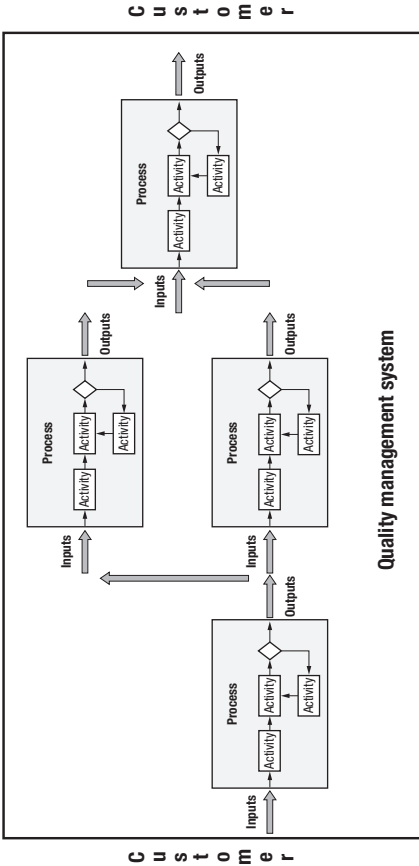
Of particular importance among the eight quality management principles are “system approach to management” and “process approach.” People in any organization perform activities. These activities are interrelated. The process approach involves managing the interrelated activities and associated resources together to achieve a particular output.



The system approach to management is basic to ISO 9001:2008. It encourages organizations to link interrelated value-adding processes. This linked system of processes results in the outputs that go to customers. Thus, the quality management system needs to be composed of interrelated processes. Clause 0.2 of ISO 9001:2008 describes this concept of a system of processes within an organization.

This approach is easy to implement and has many advantages:

- It maintains focus on the creation of value by managing across the functional departments of the organization, thereby reducing the number and severity of quality problems that occur at department boundaries
- It helps the organization focus on what is important to both itself and its customers through measurement of product characteristics and performance of processes
- It encourages open communications—based on facts supported with data—between internal customers, between internal suppliers, and between levels in the organization
- It encourages continual improvement, since any gaps between customer requirements and process performance are highlighted—quantitatively—and can be targeted for improvement efforts
- It directly supports the principles of “leadership” and “involvement of people” with improvements involving everyone and every level of the organization
- It provides a framework for managing innovation and changes.



C u s t o m e r

C u s t o m e r

Quality management system

In summary, the process approach is very generic and applicable to all sectors and sizes of organizations. It helps create value by managing horizontally across functional departments, thereby reducing quality problems that typically occur between departments. And by tying key indicators of process performance to customer needs and supplier performance, it focuses on what is important to customers. It also strongly encourages continual improvement since it helps identify gaps between customer requirements and process performance. Finally, it involves everyone and every level of the organization in meeting requirements, customer satisfaction, and continual improvement.

The ISO committee responsible for the ISO 9000 family of standards has developed additional guidance on the process approach. As of July 2009, N 544R3—*ISO 9000 Introduction and Support Package: Guidance on the Concept and Use of the Process Approach for management systems* was available as a free download at <http://www.bsi.org.uk/iso-tc176-sc2>.

ALIGNMENT—QUALITY OBJECTIVES, PROCESS MEASUREMENT, AND COMMUNICATIONS

ISO 9001:2008 requires that quality objectives be measurable and aligned with the quality policy. It also requires that the measurable objectives be deployed.

The intent of this requirement is to ensure that responsibility and authority for key dimensions of the quality management system are understood and deployed throughout the organization with the involvement of top management. Ensuring that objectives are measurable is intended to enhance improvement.