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# ISO 9001 Made Easy

by **Syed Hasan Jaffrey**

ISO 9001 is a quality management system (QMS) standard that requires an organization to meet its own requirements and those of its customers and regulators. It is based on the plan-do-check-act methodology, which helps organizations establish, implement, monitor and measure their processes to deliver results that align with the organization's requirements and continually improve performance by taking appropriate action.

ISO 9001 is made up of eight sections: scope, normative reference, terms and definitions, quality management system, management responsibility, resource management, product realization and measurement, analysis and improvement.<sup>1</sup> The first three sections provide general information about the standard, and the last five focus on how to implement it.

**Section 1—scope:** specifies that the organization needs to meet customer and regulatory requirements and ensure its employees follow its policies and procedures while advancing quality through continual improvement.

**Section 2—normative reference:** provides normative references—those that conform to ISO 9000's related norms—to constitute the terms of ISO 9001.

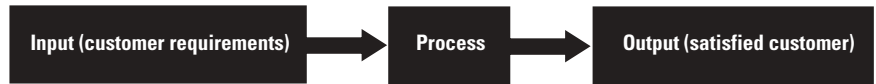
**Section 3—terms and definitions:** defines the terms used in the standard and highlights the differences between the 2000 version and the 1994 version.

**Section 4—quality management system:** describes the standard's general requirements, which encompass all activities from quality manual documentation and control of documents and records to determining the sequence and interaction of the processes to implementing actions to achieve planned results.

**Section 5—management responsibility:** requires management's commitment to the QMS and explains that management must be dedicated to the organization's products, customers and planning and review processes.

**Section 6—resource management:** provides the criteria needed to per-

**FIGURE 1** A Process Approach



form a job competently and in a safe environment. Human resources, infrastructure planning and work environment are discussed in this section.

## A straightforward look at one of the world's most popular standards.

**Section 7—product realization:** defines the steps in product development. These steps include everything from the initial design phase to the final delivery phase. For example: product realization planning, customer related processes, design and development, the product purchasing process, production and service provisions and the control of monitoring and measuring devices.

**Section 8—measurement, analysis and improvement:** focuses on measuring, analyzing and improving the QMS by having companies perform periodical internal audits, monitor customer satisfaction, control nonconforming product, analyze data and take corrective and preventive actions.

To ease implementation, ISO 9001 suggests companies adopt a process approach, which is a series of operations that transform inputs into value added output (see Figure 1). A process can be measured by accuracy, timeliness, cycle time, downtime, efficiency, effectiveness, turnaround and setup time.

### Benefits

Of the many benefits of ISO 9001:2000, these are the three most significant:

- It provides a framework for a

well-organized QMS.

- It creates satisfied customers, management and employees.
- It helps companies continually improve.

ISO 9001:2000 certification authenticates the high quality standards of an organization. Besides benefiting the employees, it also benefits the organization by organizing its processes. It not only gives flexible criteria, but also allows an organization to monitor and increase the efficiency of its processes.

To achieve certification, a company must:

- Follow the guidelines of the ISO 9001 standard.
- Fulfill its own requirements and those of its customers.
- Follow statutory and regulatory requirements.
- Create documents.
- Keep track of records.

And always remember to say what you do and do what you say. In other words, be honest.

### REFERENCE

1. ANSI/ISO/ASQ Q9001-2000: *Quality Management Systems: Requirements*, International Organization for Standardization, [www.iso.org](http://www.iso.org).

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