

## What is ISO 9000?

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ISO 9000 • Quality Management • Customer Satisfaction • Continued Improvement

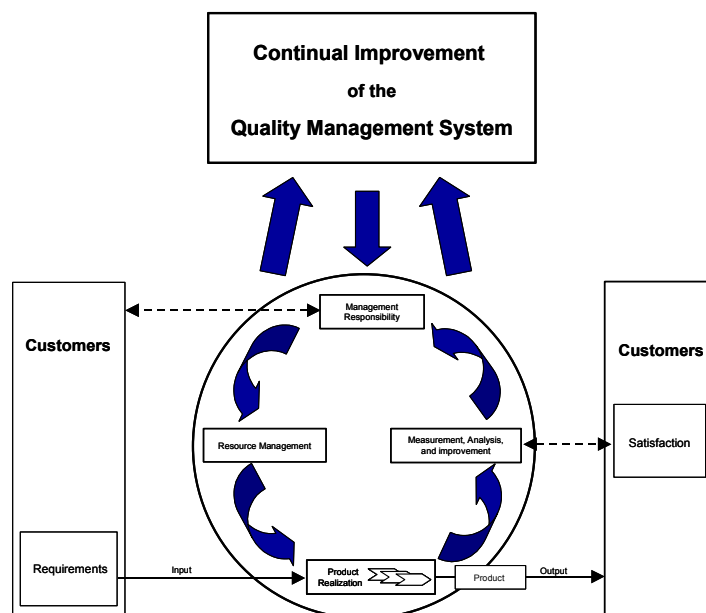
ISO 9000 is a component of quality management. ISO 9000 is a series of standards - that represent an international consensus on good management practices - that apply to any industry or organization - whether manufacturing or service-based. The primary aim of the ISO 9000 series of standards is to supply guidelines on what constitutes an effective quality management system that can serve as the framework for continuous improvement.

First published in 1987, the ISO 9000 standards have been adopted by more than 90 countries throughout the world. Today business and industry leaders realize that to be competitive in the global marketplace, their companies must be world class. To become world class, quality must be reflected in products, services, practices, and procedures.

Whether ISO 9000 compliance is driven by customer demand or marketplace trends, its ultimate goal is to build a quality management system that will support continuous improvement as well as integration with other business processes or regulatory requirements.

Since their initial publication, the ISO 9000 series of standards have been updated and reissued to reflect changing practices and customer/user requirements. The current standard to which organizations can attain third-party registration is called ISO 9001:2000. The standard was published in December 2000.

The recently published standard follows a process- based approach as illustrated by the diagram below. Take note as to the sequence and interaction of the processes that will ultimately result in improvements for the organization.



## Benefits of ISO 9001:2000

There are many benefits to the development of an ISO 9001:2000 quality management system (QMS). These benefits can be divided into both internal and external categories.

Internal	External
◆ Continuous improvement	◆ Competitive advantage
◆ Increased operational efficiency	◆ Increased customer satisfaction
◆ Reduced scrap/rework	◆ Consistent product quality
◆ Greater quality awareness	◆ Quicker time to market
◆ Enhanced inter-company relationships	◆ Increased market share

Savings \$\$\$\$\$ Savings

Most organizations new to ISO 9000 obtain measurable benefits early in the process of deploying the requirements in their operations. These initial benefits are generally due to process improvements in the organization and more efficient internal communication. Establishing a QMS provides immediate, measurable savings!

The benefits must be strengthened through effective internal auditing and management review of system performance. Like all systems, it either improves or becomes less effective. It does not remain static for long.

When you adopt ISO 9001:2000, you must strive for the satisfaction of your customers and the continual improvement of your quality management system. Continual improvement is a process of increasing the effectiveness of your organization to fulfill your quality policy and your quality objectives.

ISO 9001:2000 requires that you plan and manage the processes necessary for the continual improvement of your quality management system. ISO 9004:2000 provides information that will be helpful in going beyond ISO 9001:2000 to improving the efficiency of your operation. It is recommended that you obtain data from various sources, both internal and external, to assess the appropriateness of your quality system goals. This information can also be used to improve the performance of your processes.

Some organizations expand their management systems by extending the ISO 9001:2000 structure to include the requirements of ISO 14001:1996. ISO 14001:1996 is an international standard for environmental management systems. The structural and organizational requirements of these two management systems have been designed to be very compatible to encourage dual registration in both standards. You can almost think of this dual registration as “two for one.”

## The ISO 9000 Process

The process of developing and implementing an effective quality management system can be separated into the following three key areas:

### *Documentation*

Traditionally, ISO 9000 programs were very “document” oriented. The latest release of the ISO 9000 standards place less strict requirements on the amounts of documents that must be established.

Of course, there are still some documents that must be developed. These include a quality manual and written quality procedures. Other documents normally created are quality objectives, quality policy, process maps, organization charts, and quality plans.

### *Implementation*

There are many strategies organizations can use to successfully develop and implement ISO 9000. The experience of Synergest, Inc. has proven that a customized system based on the needs of the organization will enable the quality management system to be most effective for the organization.

#### **Minimize Documentation**

The documentation must be practical, usable, and understandable. Expanding upon and streamlining existing documentation encourages success.

#### **Management Involvement**

When management is committed and involves the entire organization in the process, the organization then commits to “owning” the system. The Synergest approach is to work with and train management and employees. When our job is finished, there is a smooth transition and the quality system will continuously improve.

#### **Integration**

Aligning the quality management system implementation project to what currently exists is the key to success. Ensuring that ISO 9000 is “tied into” and not separate from those strategies will ensure maximum benefits for your organization.

### *Registration*

Registration is the final step after documenting and implementing the system, and is the stamp of approval that is given after a successful ISO registration audit. A successful registration audit illustrates that you have successfully satisfied the requirements as stated in the ISO 9001:2000 standard.

The audit is conducted by an accredited ISO registrar, and will typically last 5-7 days for an organization that has 100 employees. The required semi-annual or annual surveillance audits conducted by the same registrar ensure that you continue to satisfy the stated requirements on a continual basis.

## Timeframes and Costs

The timeframes and fees associated to effectively develop, implement, and register a quality management system will vary for every organization. The variance in time is due to the amount of resources (internal and external) that have been committed to the project.

Synergest's experience has shown that for an organization of 100 employees, with committed internal resources to the project, and use of an experienced ISO consultant, will be able to effectively establish and successfully register the Quality Management System (QMS) in 1 year.

In contrast, an organization that attempts to establish a QMS - without the use of an ISO consultant - will take more than two years to attempt registration, and will have a less-than 30 percent chance of successful registration. This statistic alone can be one of the decisive reasons to engage the use of an ISO consultant.

The normal approximate costs to engage an ISO consultant to direct a 1-year implementation and development period range in the area of \$45,000 to \$65,000. For this amount of money, the consultant becomes deeply involved in developing the entire system, educates management on organizational best practices, and trains personnel so the transition period after registration is smooth. This ensures that no additional and unnecessary costs are incurred during the registration process.

Of course, the timing and fees associated with the ISO 9001:2000 program are affected by a number of factors. For instance, the series of questions below are some of the normal questions that are asked to help predict the timing and costs that will be associated leading a company to ISO 9001:2000 registration.

1. Is management committed to the development and implementation of the QMS?
2. Is there an appointed individual that will be responsible for the QMS?
3. How high a priority is quality in relation to your products and services?
4. Is there a documented quality manual? Are their standard, written procedures?
5. Are your organizations processes effectively mapped?
6. Are their annual organizational objectives to improve services and processes?
7. Is customer satisfaction quantified from project to project or product to product?
8. Is there an effective problem solving procedure in place?
9. Are the employees trained on the requirements of ISO 9000?
10. How are your suppliers and vendors monitored and controlled?

## Continuously Improve the System

Continuous improvement is important in maintaining compliance to the ISO 9001:2000 standards. When a registrar conducts a surveillance audit, continuous improvement is one of the key areas that must be verified. This ensures that the organization has processes in place to improve the Quality Management System (QMS).

A simple and proven method to ensure continuous improvement is to use the proven strategy of PDCA: Plan - Do - Check - Act

The PDCA methodology is described as follows.

### *Plan*

Repeatedly establish objectives and analyze the processes that are required to deliver results according to the customer requirements and organizational requirements.

### *Do*

Implement processes. Do what you planned to do.

### *Check*

All processes and products should be continuously monitored against policies, objectives and requirements - with recorded results. Look at what you are doing.

### *Act*

Actions should be taken to continually improve process performance. Fix the things that need fixing.

The ISO 9001 standard also has many built in requirements that if properly developed will also ensure improvements. For instance, establishing an effective corrective and preventive action process, and conducting thorough internal audits will also help ensure improvements.

## Next Steps

We hope this document helped explain ISO 9000 and the steps required in gaining registration. Consider contacting Synergest, Inc. for a free consultation about what it would take to get your organization registered in the most timely and cost-effective manner possible.

Synergest has experienced Lead Auditors, project managers, and management consultants who have been there and done that. We honestly care about what we do, and work for the benefit of our clients. In other words, we make your needs our own.