WHAT EVERY EMPLOYEE NEEDS TO KNOW ABOUT ISO 9001:2000

A Pocket Guide to the Basics

Third Edition

New requirements and changes from the 1994 version of ISO 9001 are clearly identified through the use of blue text.

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THE ISO 9001:2000 STANDARD

WHAT EXACTLY IS ISO 9001?

ISO 9001 is an international standard containing requirements for establishing and maintaining a company's **quality management system**.

A quality management system is set up by a company to:

- establish a quality policy and quality objectives, and
- establish the means to achieve those objectives.

This standard can be applied to almost any company — from product manufacturers to service providers. It is not specific to any product or industry.

Rather than specify requirements for your final product — *what* you produce — ISO 9001 focuses further "upstream" on the processes — or *how* you produce. ISO 9001 requires systems for controlling the processes you use to develop and produce your products and/or deliver your services. This standard is based on the idea that there are certain elements every quality management system must have in place in order to ensure that quality products and services are consistently provided to the customer on time.

ISO 9001 was developed and is maintained by committees that include representatives from countries around the world. Over 90 countries have adopted ISO 9001 as the accepted standard of quality management system requirements.

WHAT IS THE "PROCESS APPROACH"?

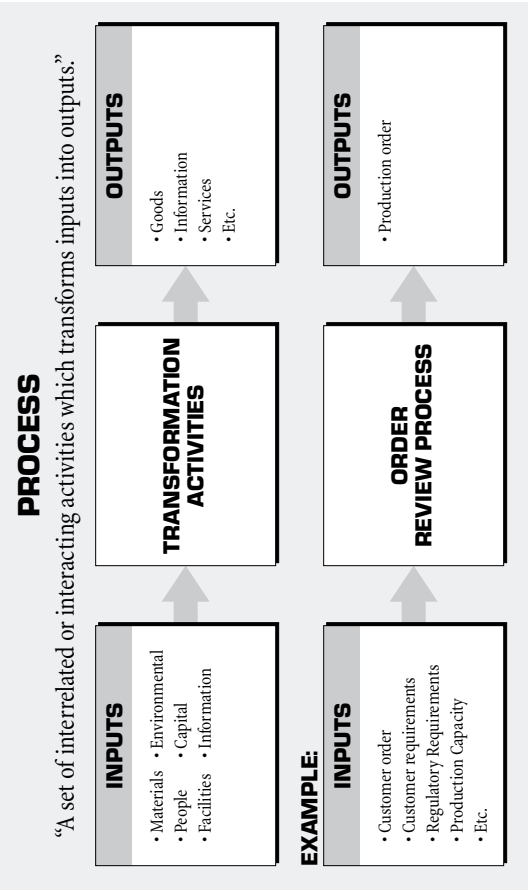
ISO 9000 Quality Management Systems — Fundamentals and Vocabulary defines a **process** as a *"set of interrelated or interacting activities which transforms inputs into outputs"*. (See figure on next page.)

In a company, the output of a process often becomes the input to another "downstream" process. For example, the output of the Sales process may be the generation of a production order by Sales or Production Control, which becomes one of the inputs to the Production process.

By identifying and managing the "processes" in your company (and the interactions and handoffs between these processes), your company is embracing the "Process Approach" to management.

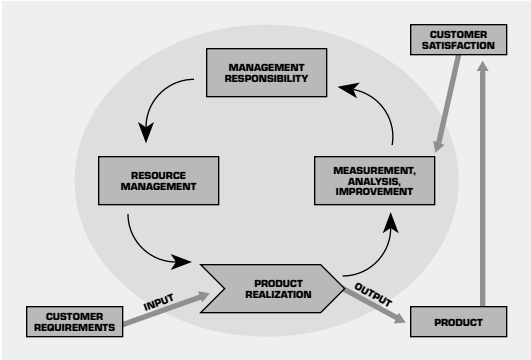
ISO 9001 is divided into four main sections that state requirements for the primary process "categories" in your company:

- **Management processes**, including planning and management review. These "Management Responsibility" requirements are found in Clause 5.
- **Resource management processes**, including human resources, infrastructure, and the work environment. These "Resource Management" requirements are found in Clause 6.
- **Product realization (production) processes**, including sales order review, product design, purchasing, calibration, and the actual "production" of your product or service. These "Product Realization" requirements are found in Clause 7.
- **Measurement, analysis and improvement processes**, including internal auditing, inspection, testing, and corrective/preventive action. These "Measurement, Analysis & Improvement" requirements are found in Clause 8.



In addition, general quality management system and documentation requirements are found in Clause 4.

You can see how these main sections relate to each other in the following diagram.



In this diagram:

- Management defines requirements and objectives for both the organization and the quality management system and identifies the resources needed to achieve them.
- Once we understand what the customer wants, we produce it.
- We measure customer satisfaction and other factors affecting the performance of the system.
- Finally, Management reviews the results of the measurements and takes action to improve.

The goal is to focus on the needs of the customer and continually improve.

- Understand how processes relate to each other in the system;
- Establish measures to drive continual improvement.

Principle 6 — Continual Improvement: *Continual improvement of the organization's overall performance should be a permanent objective of the organization.*

Continual improvement includes actions to improve:

- Product features and characteristics (making a better product);
- Process effectiveness and efficiency (to do it with fewer resources, quicker, and "make it right the first time").

Principle 7 — Factual Approach to Decision Making: *Effective decisions are based on the analysis of data and information.*

Decisions should not be made based on guesses, hearsay, or personal opinion, but on hard data. As it is often said, "In God we trust, all others bring data".

Principle 8 — Mutually Beneficial Supplier Relationships: *An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.*

Your company is dependent upon its suppliers to provide a quality product or service to your customers. Developing "win-win" relationships with key suppliers helps to ensure and improve supplier quality, reliability, and timeliness.

WHAT DOES BEING "REGISTERED" MEAN?

Companies may be "registered" (or "receive certification") to ISO 9001 by applying to a registrar and paying a registration fee. A registrar is a company that will audit your company's quality management system to see if it is meeting all the necessary requirements.

Unlike the 1994 revision of the standard, all companies will now be registered to ISO 9001 — not ISO 9002 or ISO 9003. If certain aspects of ISO 9001 do not apply to your company (for example, if your company doesn't develop its own product designs), your company would exclude those requirements from the scope of its registration.

WHY WOULD MY COMPANY WANT TO BE REGISTERED?

A major reason that most companies want to become registered is that their customers are demanding it. Registration to ISO 9001 assures your customers that you have a quality management system with the ability to provide quality products and/or services on time. Some of the other benefits a company might expect to see include:

- Competitive advantages in marketing an improved "quality" image
- Better performance of internal operations (less scrap / rework)
- Better quality
- Fewer customer audits
- A stronger focus on customer satisfaction and continual improvement
- Better company-wide communication
- Reduced costs
- Better documentation (see "What's the value of all this documentation?")

And all of the above changes can lead to higher levels of financial security for the company and its employees.

CLAUSE 6 RESOURCE MANAGEMENT

CLAUSE 6.1 PROVISION OF RESOURCES

Essence of the clause: Resources must be determined and provided to successfully implement and continually improve the quality management system and to enhance customer satisfaction.

Who's most involved: Management (of almost every department)

This clause requires your company to determine and provide the resources required by your quality management system, including human resources, infrastructure, and work environment.

Specific requirements related to these resources are detailed in clauses 6.2, 6.3, and 6.4.

CLAUSE 6 RESOURCE MANAGEMENT

CLAUSE 6.2 HUMAN RESOURCES

Essence of the clause: All personnel at your company must get the training they need, and you must have the records to prove it.

Who's most involved: All departments and especially Human Resources

People performing work affecting product quality must be qualified to perform that work based on appropriate education, training, skills, and/or experience.

This clause also requires your company to:

- Identify competency needs for its personnel
- Provide required training
- Evaluate training effectiveness
- Ensure personnel are aware of the effects of their actions on quality and how they contribute to the quality objectives
- Maintain education, experience, training, and qualification records for all personnel

THE AUDIT PROCESS

WHAT'S THE PURPOSE OF QUALITY MANAGEMENT SYSTEM AUDITS?

Registration to ISO 9001 requires that your company periodically go through two types of audits:

- Third-party audits (audits by your registrar), and
- Internal audits (self-audits by your company).

The general purpose of both types of audits is to determine whether your company has developed and implemented a quality management system that:

- Meets the requirements of ISO 9001, and
- Is effective in providing quality products and services.

There are some key differences between the two types of audits:

- The **third-party audit** has a pass/fail result — the registrar's auditors are there to determine whether your company should become (or stay) registered to ISO 9001. These auditors will tell you what's wrong with the system, but they are not there as consultants. They will not really tell you "how" to fix the problems.

- The **internal audit** looks for ways to make the quality management system work better for everyone, and tries to catch problems before your customer or registrar does. In the internal audit situation, employees should feel free to ask the auditors for help and to point out areas that may have problems.

It's important to understand that internal audits are trying to find problems with the **quality management system**, not with the people who are carrying it out. They are not intended to place blame on anyone. If someone is not carrying out a procedure correctly, it should be viewed as a system problem (such as lack of proper training, incomplete documentation, incorrect documentation, etc.).

WHAT ARE AUDITORS LOOKING FOR?

On each audit, auditors will only be looking at a **sample** of the quality management system. They obviously will not have time to look at everything in the company that affects quality, so the auditors will try to pick out what they feel are the more important activities.

They will also check up on areas that have had problems in the past to see how they are improving.

In general, auditors are looking for:

- Evidence that the system (as **documented**) meets the requirements stated in ISO 9001.
- Evidence that all employees understand the documentation that affects them.
- Evidence that the system (as **implemented**) works according to planned arrangements (such as the instructions stated in your quality management system documentation or in agreements with customers).
- Evidence that the system is effective in providing quality products and services.

In order to find such evidence, auditors will be looking at a lot of documents and talking to people about how they use the documentation and carry out their work. The type of evidence an auditor finds might be in the form of:

- Something the auditor sees. For example:
  - out-of-date documentation

Third-party Audits

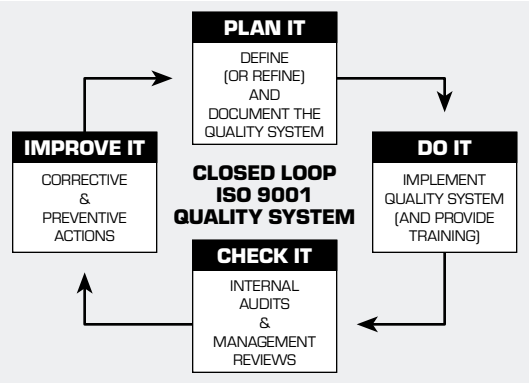
Frequency: Third-party audits (by the registrar) are typically conducted every six to twelve months, once your company has passed the registration audit.

*Many companies have their registrar first come in to do a **pre**-registration audit — a "check-up" to see if the company will be ready for the actual registration audit in a few months. This practice also allows the company to get to know the auditors and how they conduct business prior to the more formal registration audit.*

Length: Between one and five days, depending on the size of your company, number of auditors used, and the status of your quality management system.

The audits performed by the registrar after registration are known as "surveillance" audits. While the registration audit usually lasts several days and covers all the clauses of ISO 9001, the surveillance audits are shorter, covering only certain key elements of your quality management system per audit. Typically, every three years, the registrar will perform a full audit of the system in order to determine whether the registration should be renewed. These audits are very much like the original registration audit and have similar outcomes to those listed in the "What if we don't pass the registration audit?" section.

You'll find that auditing continues to be an important way of life for the company, essentially "closing the loop" of the quality management system and providing a means for continual improvement.



WORK INSTRUCTIONS THAT APPLY TO MY JOB

RECORDS AND FORMS THAT APPLY TO MY JOB