

INTRODUCTION TO ISO 9001:2000

In the 1990's, everyone is demanding quality - whether they're looking to acquire a multi-million dollar communications satellite or just shopping for a decent sweet potato for dinner. The message for companies hoping to succeed in these competitive times is clear:

QUALITY MUST BE A PRIORITY!

Prior to 1979 there were numerous and various national and multinational quality system standards for commercial, industrial, military or nuclear industries.

The Technical Committee ISO/TC 176 of the International Organization for Standards, based in Geneva, Switzerland, was formed to develop and maintain the ISO 9000 International Standards.

The ISO 9000 series were first published in 1987 to provide harmonization on an international scale and has supported the growing impact of quality as a factor in international trade. The 1994 editions of the ISO 9000 series represented the first major set of revisions that the series had undergone since 1987. The revisions incorporated changes that did not alter the basic approach or structure of the existing ISO 9000 series, but significantly enhance its clarity and usability.

As of December 15, 2000, there are three new ISO standards:

ISO 9000:2000, Quality Management Systems - Fundamentals and Vocabulary

ISO 9001:2000, Quality Management Systems - Requirements

ISO 9004:2000, Quality Management Systems 0 Guidelines for Performance Improvements

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Companies who wish to register a new or existing Quality Management System have until December 2003 to comply with the ISO 9001:2000 requirements.

Significant improvements have resulted with the publication of ISO 9001:2000.

KEY IMPROVEMENTS:

- 1. The three standards previously incorporated into the ISO 9000 family have been replaced by one standard: ISO 9001:2000, Quality Management Systems - Requirements.*
- 2. ISO 9004:2000, Quality Management Systems - Guidelines for Performance Improvements has also been extensively revised.*
- 3. The revised ISO 9001:2000 provides guidance on which activities can be excluded from the scope of a Quality Management System. The new standard has been written in such a way that service industries can more easily comply with the requirements.*
- 4. Continual improvement is now a requirement of ISO 9001:2000.*
- 5. ISO 9001:2000 is structured as a process-orientated standards. Requirements and guidelines appear in a more logical sequence. The standard is intended to be more business oriented and "user-friendly".*
- 6. Monitoring and reacting to customer satisfaction is now a requirement of ISO 9001:2000.*
- 7. The role of upper management is given greater emphasis.*

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Businesses need to change their understanding of quality; it is no longer a department, a discipline or a measure of compliance of conformance.

Quality has numerous meanings today, but if there's one element common to every definition of quality, it is ongoing customer satisfaction. A quality product consistently meets or exceeds a level of performance that has been spelled out by the customer or promised by a company.

In today's global economy, businesses must ensure they do things right the first time, on time, every time and to the customer's satisfaction.

Consistency in the product or services provided is a key factor to survival for these companies.

A quality system is a mechanism for maintaining consistent quality - for producing products the consistently meet or exceed the customer's requirements.

Any organization must have a plan to attain this goal. A company should implement and maintain a quality system that will strengthen its own competitiveness and achieve the needed product quality in a cost-effective way.

Technical specifications may not in themselves guarantee that a customer's requirements will be consistently met.

This has led to the development of quality system standards and guidelines that complement relevant product requirements i.e. technical specifications.

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The ISO 9001:2000 and ISO 9004:2000 standards are based on eight quality management principles that can be used by top management as a framework to guide their organization towards improved performance.

THE EIGHT QUALITY MANAGEMENT PRINCIPLES:

1. CUSTOMER FOCUS:

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and should strive to exceed customer expectations.

2. LEADERSHIP:

Leaders establish unity of purpose and the direction of the organization. They should create and maintain an internal environment in which people can become fully involved in achieving the organization's objectives.

3. 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.

4. PROCESS APPROACH:

A desired result is achieved more efficiently when activities and related resources are managed as a process.

5. SYSTEMS APPROACH TO MANAGEMENT:

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

6. CONTINUAL IMPROVEMENT:

Continual improvement of the organization's overall performance should be a permanent objective of the organization.

7. FACTUAL APPROACH TO DECISION-MAKING:

Effective decisions are based on the analysis of data and information.

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8. MUTUALLY BENEFICIAL SUPPLIER RELATIONSHIP:

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

*The ISO 9000 series provide guidelines describing **WHAT** elements a quality system should encompass, but not necessarily **HOW** the elements should be implemented.*

The implementation of these elements should be consistent with the way the company runs. The quality system should meet the company's objectives, standards, specifications and customer's expectations.

The ISO 9000 series describe quality system requirements, which are complementary to, but not a replacement for, the technical specifications for a product.

Thus, an ISO 9000 quality system may apply to any organization within any industry and to all product or service quality characteristics.

A quality system should be developed and implemented for the purpose of accomplishing the objectives set out in the organization's quality policy and manual.

Each element in a quality system varies in importance from one type of activity to another and from one product (or service) to another.

Companies with registered ISO 9001 quality systems discover that they provide an excellent baseline for measuring quality improvements, implementing continuous improvement and determining quality costs. It also supports the company's aim of providing consistent product to their customers.

Implementing a quality system can cut down on scrap, rework and down-time by having processes which are run under controlled conditions.

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THE ISO 9001:2000 IMPLEMENTATION PROCESS

(FOR COMPANIES WITH NO QMS EXPERIENCE)

STEP 1:	GAIN MANAGEMENT COMMITMENT; DOCUMENT THE QUALITY POLICY AND QUALITY OBJECTIVES DEVELOPED BY UPPER MANAGEMENT
STEP 2:	REVIEW THE ISO 9001:2000 AND ISO 9004:2000 DOCUMENTS
STEP 3:	CHOOSE A LEADER - INTERNAL OR EXTERNAL; ENSURE YOUR LEADER HAS A ADEPT UNDERSTANDING OF THE REQUIREMENTS
STEP 4:	TRAIN ALL EMPLOYEES ON WHAT THE IMPLEMENTATION PROCESS IS AND HOW IT WILL AFFECT THEIR JOBS
STEP 5:	PROCESS MAP THE CURRENT PROCESSES
STEP 6:	COMPARE THE CURRENT PROCESSES TO THE STANDARD
STEP 7:	FILL THE GAPS AND REVISE THE PROCESS MAPS
STEP 8:	DOCUMENT THE SYSTEM - QUALITY MANUAL, QUALITY PROCEDURES / FLOW CHARTS, WORK INSTRUCTIONS, FORMS, RECORDS, ETC.
STEP 9:	TRAIN ALL EMPLOYEES ON THE DOCUMENTATION RELATED TO THEIR RESPONSIBILITIES AND FUNCTIONS
STEP 10:	PERFORM INTERNAL QUALITY AUDITS
STEP 11:	IMPLEMENT CORRECTIVE ACTION
STEP 12:	PERFORM FOLLOW-UP AUDITS

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STEP 13:	REGISTRATION AUDIT
STEP 14:	CONTINUAL IMPROVEMENT TO THE ISO 9001:2000 REGISTERED QUALITY MANAGEMENT SYSTEM