

# International Standards on Quality Management (ISO) 9000

## Description

International Standards on Quality Management (ISO) 9000 is defined as a set of international standards on quality management and quality assurance developed to help companies effectively document the quality system elements needed to maintain an efficient quality system. They are not specific to any one industry and can be applied to organizations of any size.

ISO 9000 can help a company satisfy its customers, meet regulatory requirements, and achieve continual improvement. It should be a first step or the base level of a quality system. Its aim is to increase an organization's awareness of its commitment to meeting the needs and expectations of customers and satisfaction with products and services.

## Background

The **International Organization for Standardization (ISO.org)** is an international standard setting body composed of representatives from various national standard setting organizations. ISO gives this explanation of the name: "Because 'International Organization for Standardization' would have different acronyms for each language."

The organization began in the 1920s as the International Federation of the National Standardizing Associations (ISA). It was suspended in 1942 during World War II, but after the war, ISA was approached by the recently formed United Nations Standards Coordinating Committee (UNSCC) with a proposal to form a new global standards body. In October 1946, ISA and UNSCC delegates from 25 countries met in London and agreed to join forces to create the new International Organization for Standardization. The new organization was founded and officially began operations in February 1947. The organization promotes worldwide proprietary, industrial, and commercial standards. It is headquartered in Geneva, Switzerland, and works in 165 countries.

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). It was one of the first organizations granted general consultative status with the United Nations Economic and Social Council. The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

The International Organization for Standards organizes a committee comprising of technical experts from its members. Standards are then developed and refined until there is agreement.

This process can take up to three years. The ISO 9000-3 was established in 2005 and updated in 2015 with additional definitions.

## Purpose

ISO 9000 serves as a starting point for any organization intending to establish a quality management system utilizing seven basic principles for quality management and assurance.

## Core Values, Principles, and Concepts

There are seven quality management principles for ISO 9000. The definition of a "principle" is that it is a basic belief, theory or rule that has a major influence on the way in which something is done. Quality management principles (QMP) are a set of fundamental beliefs, norms, rules, and values that are accepted as true and can be used as a basis for quality management.

The QMPs can be used as a foundation to guide an organization's performance improvement. They were developed and updated by international experts of ISO/TC 176, which is responsible for developing and maintaining ISO's quality management standards.

### Principle 1 – Customer focus

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

### Principle 2 – 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.

### Principle 3 – Engagement 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. People are an essential resource and the organization's performance is dependent on how the people in the organization behave. People become engaged through developing a common understanding of the organizations quality policies and desired results.

### Principle 4 – Process approach

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

### Principle 5 – Improvement

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

## Principle 6 – Evidence-based decision-making

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

## Principle 7 – Relationship management

An organization and its external providers (suppliers, contractors, service providers) are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

## Framework

For each of the seven principles, a rationale explaining why the organization would address the principle is given, as well as the Key Benefits and Actions that can be taken to implement the principle.

### Customer Focus

The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

**Rationale:** Sustained success is achieved when an organization attracts and retains the confidence of customers and other interested parties.

Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to sustained success of the organization.

#### Key benefits:

- Increased customer value
- Increased customer satisfaction
- Improved customer loyalty
- Enhanced repeat business
- Enhanced reputation of the organization
- Expanded customer base
- Increased revenue and market share

#### Actions that can be taken:

- Recognize direct and indirect customers as those who receive value from the organization.
- Understand customers' current and future needs and expectations.
- Link the organization's objectives to customer needs and expectations.
- Communicate customer needs and expectations throughout the organization.
- Plan, design, develop, produce, deliver, and support goods and services to meet customer needs and expectations.

- Measure and monitor customer satisfaction and take appropriate actions.
- Determine and take actions on interested parties' needs and expectations that can affect customer satisfaction.
- Actively manage relationships with customers to achieve sustained success.

## Leadership

Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives.

**Rationale:** Creation of unity of purpose and direction and engagement of people enable an organization to align its strategies, policies, processes, and resources to achieve its objectives.

### Key benefits:

- Increased effectiveness and efficiency in meeting the organization's quality objectives
- Better coordination of the organization's processes
- Improved communication between levels and functions of the organization
- Development and improvement of the capability of the organization and its people to deliver desired results

### Actions you can take:

- Communicate the organization's mission, vision, strategy, policies, and processes throughout the organization.
- Create and sustain shared values, fairness, and ethical models for behavior at all levels of the organization.
- Establish a culture of trust and integrity.
- Encourage an organization-wide commitment to quality.
- Ensure that leaders at all levels are positive examples to people in the organization.
- Provide people with the required resources, training, and authority to act with accountability.
- Inspire, encourage, and recognize people's contribution.

## Engagement of people

Competent, empowered and engaged people at all levels throughout the organization are essential to enhance its capability to create and deliver value.

**Rationale:** To manage an organization effectively and efficiently, it is important to involve all people at all levels and to respect them as individuals. Recognition, empowerment, and enhancement of competence facilitate the engagement of people in achieving the organization's quality objectives.

**Benefits:**

- Improved understanding of the organization's quality objectives by people in the organization and increased motivation to achieve them
- Enhanced involvement of people in improvement activities
- Enhanced personal development, initiatives, and creativity
- Enhanced people satisfaction
- Enhanced trust and collaboration throughout the organization
- Increased attention to shared values and culture throughout the organization

**Actions you can take:**

- Communicate with people to promote understanding of the importance of their individual contribution.
- Promote collaboration throughout the organization.
- Facilitate open discussion and sharing of knowledge and experience.
- Empower people to determine constraints to performance and to take initiatives without fear.
- Recognize and acknowledge people's contribution, learning and improvement.
- Enable self-evaluation of performance against personal objectives.
- Conduct surveys to assess people's satisfaction, communicate the results, and take appropriate actions.

## Process Approach

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

**Rationale:** The quality management system consists of interrelated processes. Understanding how results are produced by this system enables an organization to optimize the system and its performance.

**Key benefits:**

- Enhanced ability to focus effort on key processes and opportunities for improvement
- Consistent and predictable outcomes through a system of aligned processes
- Optimized performance through effective process management, efficient use of resources, and reduced cross-functional barriers
- Enabling the organization to provide confidence to interested parties as to its consistency, effectiveness, and efficiency

**Actions you can take:**

- Define objectives of the system and processes necessary to achieve them.
- Establish authority, responsibility, and accountability for managing processes.

- Understand the organization's capabilities and determine resource constraints prior to action.
- Determine process interdependencies and analyze the effect of modifications to individual processes on the system.
- Manage processes and their interrelations as a system to achieve the organization's quality objectives effectively and efficiently.
- Ensure the necessary information is available to operate and improve the processes and to monitor, analyze and evaluate the performance of the overall system.
- Manage risks that can affect outputs of the processes and overall outcomes of the quality management system.

## Improvement

Successful organizations have an ongoing focus on improvement.

**Rationale:** Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities.

### Key benefits:

- Improved process performance, organizational capabilities, customer satisfaction
- Enhanced focus on root-cause investigation and determination, followed by prevention and corrective actions
- Enhanced ability to anticipate and react to internal and external risks and opportunities
- Enhanced consideration of both incremental and breakthrough improvement
- Improved use of learning for improvement
- Enhanced drive for innovation

### Actions you can take:

- Promote establishment of improvement objectives at all levels of the organization.
- Educate and train people at all levels on how to apply basic tools and methodologies to achieve improvement objectives.
- Ensure people are competent to successfully
- promote and complete improvement projects.
- Develop and deploy processes to implement improvement projects throughout the organization.
- Track, review, and audit the planning, implementation, completion, and results of improvement projects.
- Integrate improvement considerations into the development of new or modified goods, services, and processes.
- Recognize and acknowledge improvement.

## Evidence-based decision-making

Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

**Rationale:** Decision-making can be a complex process, and it always involves some uncertainty. It often involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand cause-and-effect relationships and potential unintended consequences. Facts, evidence, and data analysis lead to greater objectivity and confidence in decision making.

### Key benefits:

- Improved decision-making processes
- Improved assessment of process performance and ability to achieve objectives
- Improved operational effectiveness and efficiency
- Increased ability to review, challenge and change opinions and decisions
- Increased ability to demonstrate the effectiveness of past decisions

### Actions you can take:

- Determine, measure, and monitor key indicators to demonstrate the organization's performance.
- Make all data needed available to the relevant people.
- Ensure that data and information are sufficiently accurate, reliable, and secure.
- Analyze and evaluate data and information using suitable methods.
- Ensure people are competent to analyze and evaluate data as needed.
- Make decisions and take actions based on evidence, balanced with experience and intuition.

## Relationship management

For sustained success, an organization manages its relationships with interested parties, such as suppliers.

**Rationale:** Interested parties influence the performance of an organization. Sustained success is more likely to be achieved when the organization manages relationships with all of its interested parties to optimize their impact on its performance. Relationship management with its supplier and partner networks is of particular importance.

### Key Benefits:

- Enhanced performance of the organization and its interested parties through responding to the opportunities and constraints related to each interested party
- Common understanding of goals and values among interested parties
- Increased capability to create value for interested parties by sharing resources and competence and managing quality-related risks

- A well-managed supply chain that provides a stable flow of goods and services

#### **Actions you can take:**

- Determine relevant interested parties (such as suppliers, partners, customers, investors, employees, and society as a whole) and their relationship with the organization.
- Determine and prioritize interested party relationships that need to be managed.
- Establish relationships that balance short-term gains with long-term considerations.
- Pool and share information, expertise, and resources with relevant interested parties.
- Measure performance and provide performance feedback to interested parties, as appropriate, to enhance improvement initiatives.
- Establish collaborative development and improvement activities with suppliers, partners, and other interested parties.
- Encourage and recognize improvements and achievements by suppliers and partners.

## **Application**

Administration, fiscal, data collection, program services. ISO 9000 is meant to provide a total comprehensive review of an organization's total quality management processes.

ISO 9000 has application throughout the agency. As the seven principles would indicate, evaluation of and the implementation of QMPS can impact on all aspects.

## **Vocational Rehabilitation**

Examples of a VR agency utilizing or becoming ISO 9000 certified could not be found. In a broad sense, the application of the seven principles would serve as a guideline for any VR agency wanting to develop a comprehensive quality management system. If a full certification is not desired or possible, ISO 9000 can be utilized in conjunction with other QM systems, such as Total Quality Management.

## **Other Organizations**

ISO 9000 has been used by Human Service Organizations and Public Service or other related organizations, such as The Department of Defense Procurement Office, the General Accounting Office, and Federal Building Management. Each of these public organizations utilized ISO 9000 to improve their procurement systems.



## Criticisms or Concerns

ISO 9000 would appear to be too complex of a system for most VR agencies. It relies upon an audit heavily based on data and system processes. For any in-depth evaluation, an agency must have dedicated staff to participate in the audit. In addition, some agencies may share administrative units within a DSA such as fiscal, IT, and Personnel. The DSA may not allow a review or a change of procedures as required by the ISO 9000. Since the standards are copyrighted, standards can only be utilized by the purchasing agency.

## Recommendation for Use In VR

ISO 9000 has limited applicability to VR. Based upon the Federal organizations utilizing ISO 9000, a VR agency could utilize the standards to improve its procurement processes. ISO 9000 principles could be utilized as a broad guideline in areas involving agency operations, especially if it is combined with other QM processes, but certification does not seem beneficial.

## Certification

ISO 9000 is a set of standards utilizing the principles listed above. An organization can choose to become certified after a preparation process followed by an audit. To become certified, an organization would have to contract with a certified consultant(s). The certified consultant conducts an in-depth evaluation of all aspects of an organization utilizing the seven principles as an outline. Utilizing a certified consultant, preparation phase occurs (approximately 4-6 months) followed by an audit.

## Cost

There are two portions for the certification. First, an agency must undergo a preparation phase and then an audit phase. Cost for preparation phase can range from \$5,700 to \$15,000, and the audit phase costs approximately \$5,000.

Training time is 4-5 months for certification. Certification is available through various ISO 9000 consulting companies. A list and description of the standards can be purchased separately for approximately \$230.00.

## Resources

### Websites

- ISO 9000 website: <https://www.iso.org/home.html>
- ISO 9000 Series of Standards - What is ISO 9000? <https://asq.org/quality-resources/iso-9000>
- History of ISO: [www.sis.pitt.edu/mbsclass/standards/martincic/isohistr.htm](http://www.sis.pitt.edu/mbsclass/standards/martincic/isohistr.htm)