INTERNATIONAL STANDARD

ISO 9000

Redline version
compares Fourth edition to
Third edition

Quality management systems — Fundamentals and vocabulary

Systèmes de management de la qualité — Principes essentiels et vocabulaire

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IMPORTANT — PLEASE NOTE

This is a mark-up copy and uses the following colour coding:

Text example 1   — indicates added text (in green)

~~Text example 2~~   — indicates removed text (in red)

          — indicates added graphic figure

          — indicates removed graphic figure

1.x ...   — Heading numbers containg modifications are highlighted in yellow in the Table of Contents

All changes in this document have yet to reach concensus by vote and as such should only be used internally for review purposes.

DISCLAIMER

This Redline version provides you with a quick and easy way to compare the main changes between this edition of the standard and its previous edition. It doesn't capture all single changes such as punctuation but highlights the modifications providing customers with the most valuable information. Therefore it is important to note that this Redline version is not the official ISO standard and that the users must consult with the clean version of the standard, which is the official standard, for implementation purposes.

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Contents

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). 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. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

~~International Standards are~~ The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the ~~rules given in~~ editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

~~The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.~~

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

~~ISO 9000 was prepared by~~ The committee responsible for this document is Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 1, *Concepts and terminology*.

This ~~third~~ fourth edition cancels ~~and~~ replaces the ~~second~~ third edition (ISO 9000:~~2000~~ 2005). ~~It includes the changes accepted in the Draft Amendment ISO/DAM 9000:2004~~, which has been technically revised.

~~Annex A includes concept diagrams that provide a graphical representation of the relationships between terms in specific fields relative to quality management systems.~~

Introduction

0.1 General

The ISO 9000 family of standards listed below has been developed to assist organizations, of all types and sizes, to implement and operate effective quality management systems.

— ISO 9000 describes fundamentals of quality management systems and specifies the terminology for quality management systems.

— ISO 9001 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide products that fulfil customer and applicable regulatory requirements and aims to enhance customer satisfaction.

— ISO 9004 provides guidelines that consider both the effectiveness and efficiency of the quality management system. The aim of this standard is improvement of the performance of the organization and satisfaction of customers and other interested parties.

— ISO 19011 provides guidance on auditing quality and environmental management systems.

Together they form a coherent set of quality management system standards facilitating mutual understanding in national and international trade.

0.2 Quality management principles

To lead and operate an organization successfully, it is necessary to direct and control it in a systematic and transparent manner. Success can result from implementing and maintaining a management system that is designed to continually improve performance while addressing the needs of all interested parties. Managing an organization encompasses quality management amongst other management disciplines.

Eight quality management principles have been identified that can be used by top management in order to lead the organization towards improved performance.

a) Customer focus

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

b) 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.

c) 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.

d) Process approach

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

e) System approach to management

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

f) Continual improvement

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

~~g) Factual approach to decision making~~

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

~~h) Mutually beneficial supplier relationships~~

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

~~These eight quality management principles form the basis for the quality management system standards within the ISO 9000 family.~~

This International Standard provides the fundamental concepts, principles and vocabulary for quality management systems (QMS) and provides the foundation for other QMS standards. This International Standard is intended to help the user to understand the fundamental concepts, principles and vocabulary of quality management, in order to be able to effectively and efficiently implement a QMS and realize value from other QMS standards.

This International Standard proposes a well-defined QMS, based on a framework that integrates established fundamental concepts, principles, processes and resources related to quality, in order to help organizations realize their objectives. It is applicable to all organizations, regardless of size, complexity or business model. Its aim is to increase an organization's awareness of its duties and commitment in fulfilling the needs and expectations of its customers and interested parties, and in achieving satisfaction with its products and services.

This International Standard contains seven quality management principles supporting the fundamental concepts described in 2.2. In 2.3, for each quality management principle, there is a "statement" describing each principle, a "rationale" explaining why the organization would address the principle, "key benefits" that are attributed to the principles, and "possible actions" that an organization can take in applying the principle.

This International Standard contains the terms and definitions that apply to all quality management and QMS standards developed by ISO/TC 176, and other sector-specific QMS standards based on those standards, at the time of publication. The terms and definitions are arranged in conceptual order, with an alphabetical index provided at the end of the document. Annex A includes a set of diagrams of the concept systems that form the concept ordering.

NOTE   Guidance on some additional frequently-used words in the QMS standards developed by ISO/TC 176, and which have an identified dictionary meaning, is provided in a glossary available at: http://www.iso.org/iso/03_terminology_used_in_iso_9000_family.pdf

Quality management systems — Fundamentals and vocabulary

1 Scope

This International Standard describes ~~fundamentals~~the fundamental concepts and principles of quality management ~~systems, which form the subject of~~which are universally applicable to the ~~ISO 9000 family, and defines related terms.~~following:

~~This International Standard is applicable to the following.~~

~~a)~~— organizations seeking ~~advantage~~sustained success through the implementation of a quality management system;

— customers seeking confidence in an organization's ability to consistently provide products and services conforming to their requirements;

~~b)~~— organizations seeking confidence ~~from their suppliers that their product~~in their supply chain that product and service requirements will be ~~satisfied~~met;

~~c)   users of the products;~~

~~d)~~— ~~those concerned with a mutual~~organizations and interested parties seeking to improve communication through a common understanding of the ~~terminology~~vocabulary used in quality management ~~(e.g. suppliers, customers, regulators);~~

~~e)~~— ~~those internal or external to the organization who assess the quality management system or audit it for conformity with~~organizations performing conformity assessments against the requirements of ISO 9001 ~~(e.g. auditors, regulators, certification/registration bodies);~~

~~f)~~— ~~those internal or external to the organization who give advice or training on the quality management system appropriate to that organization~~providers of training, assessment or advice in quality management;

~~g)~~— developers of related standards.

This International Standard specifies the terms and definitions that apply to all quality management and quality management system standards developed by ISO/TC 176.

2 ~~Fundamentals of~~Fundamental concepts and quality management ~~systems~~principles

2.1 General

The quality management concepts and principles described in this International Standard give the organization the capacity to meet challenges presented by an environment that is profoundly different from recent decades. The context in which an organization works today is characterized by accelerated change, globalization of markets and the emergence of knowledge as a principal resource. The impact of quality extends beyond customer satisfaction: it can also have a direct impact on the organization's reputation.

Society has become better educated and more demanding, making interested parties increasingly more influential. By providing fundamental concepts and principles to be used in the development of a quality management system (QMS), this International Standard provides a way of thinking about the organization more broadly.

All concepts, principles and their interrelationships should be seen as a whole and not in isolation of each other. No individual concept or principle is more important than another. At any one time, finding the right balance in application is critical.

~~2.1~~2.2 ~~Rationale for quality management systems~~Fundamental concepts

~~Quality management systems can assist organizations in enhancing customer satisfaction.~~

~~Customers require products with characteristics that satisfy their needs and expectations. These needs and expectations are expressed in product specifications and collectively referred to as customer requirements. Customer requirements may be specified contractually by the customer or may be determined by the organization itself. In either case, the customer ultimately determines the acceptability of the product. Because customer needs and expectations are changing, and because of competitive pressures and technical advances, organizations are driven to improve continually their products and processes.~~

~~The quality management system approach encourages organizations to analyse customer requirements, define the processes that contribute to the achievement of a product which is acceptable to the customer, and keep these processes under control. A quality management system can provide the framework for continual improvement to increase the probability of enhancing customer satisfaction and the satisfaction of other interested parties. It provides confidence to the organization and its customers that it is able to provide products that consistently fulfil requirements.~~

2.2.1 Quality

An organization focused on quality promotes a culture that results in the behaviour, attitudes, activities and processes that deliver value through fulfilling the needs and expectations of customers and other relevant interested parties.

The quality of an organization's products and services is determined by the ability to satisfy customers and the intended and unintended impact on relevant interested parties.

The quality of products and services includes not only their intended function and performance, but also their perceived value and benefit to the customer.

2.2.2 Quality management system

A QMS comprises activities by which the organization identifies its objectives and determines the processes and resources required to achieve desired results.

The QMS manages the interacting processes and resources required to provide value and realize results for relevant interested parties.

The QMS enables top management to optimize the use of resources considering the long and short term consequences of their decision.

A QMS provides the means to identify actions to address intended and unintended consequences in providing products and services.

2.2.3 Context of an organization

Understanding the context of the organization is a process. This process determines factors which influence the organization's purpose, objectives and sustainability. It considers internal factors such as values, culture, knowledge and performance of the organization. It also considers external factors such as legal, technological, competitive, market, cultural, social and economic environments.

Examples of the ways in which an organization's purpose can be expressed include its vision, mission, policies and objectives.

2.2.4 Interested parties

The concept of interested parties extends beyond a focus solely on the customer. It is important to consider all relevant interested parties.

Part of the process for understanding the context of the organization is to identify its interested parties. The relevant interested parties are those that provide significant risk to organizational sustainability if their needs and expectations are not met. Organizations define what results are necessary to deliver to those relevant interested parties to reduce that risk.

Organizations attract, capture and retain the support of the relevant interested parties they depend upon for their success.

2.2.5 Support

2.2.5.1 General

Top management support of the QMS and engagement of people enables:

— provision of adequate human and other resources;

— monitoring processes and results;

— determining and evaluating of risks and opportunities;

— implementing appropriate actions.

Responsible acquisition, deployment, maintenance, enhancement and disposal of resources support the organization in achieving its objectives.

2.2.5.2 People

People are essential resources within the organization. The performance of the organization is dependent upon how people behave within the system in which they work.

Within an organization, people become engaged and aligned through a common understanding of the quality policy and the organization's desired results.

2.2.5.3 Competence

A QMS is most effective when all employees understand and apply the skills, training, education and experience needed to perform their roles and responsibilities. It is the responsibility of top management to provide opportunities for people to develop these necessary competencies.

2.2.5.4 Awareness

Awareness is attained when people understand their responsibilities and how their actions contribute to the achievement of the organization's objectives.

2.2.5.5 Communication

Planned and effective internal (i.e. throughout the organization) and external (i.e. with relevant interested parties) communication enhances people's engagement and increased understanding of:

— the context of the organization;

— the needs and expectations of customers and other relevant interested parties;

— the QMS.

2.2   Requirements for quality management systems and requirements for products

The ISO 9000 family distinguishes between requirements for quality management systems and requirements for products.

Requirements for quality management systems are specified in ISO 9001. Requirements for quality management systems are generic and applicable to organizations in any industry or economic sector regardless of the offered product category. ISO 9001 itself does not establish requirements for products.

Requirements for products can be specified by customers or by the organization in anticipation of customer requirements, or by regulation. The requirements for products and in some cases associated processes can be contained in, for example, technical specifications, product standards, process standards, contractual agreements and regulatory requirements.

2.3   Quality management systems approach

An approach to developing and implementing a quality management system consists of several steps including the following.

a)   determining the needs and expectations of customers and other interested parties,

b)   establishing the quality policy and quality objectives of the organization,

c)   determining the processes and responsibilities necessary to attain the quality objectives,

d)   determining and providing the resources necessary to attain the quality objectives,

e)   establishing methods to measure the effectiveness and efficiency of each process,

f)   applying these measures to determine the effectiveness and efficiency of each process,

g)   determining means of preventing nonconformities and eliminating their causes,

h)   establishing and applying a process for continual improvement of the quality management system.

Such an approach is also applicable to maintaining and improving an existing quality management system.

An organization that adopts the above approach creates confidence in the capability of its processes and the quality of its products, and provides a basis for continual improvement. This can lead to increased satisfaction of customers and other interested parties and to the success of the organization.

2.4   The process approach

Any activity, or set of activities, that uses resources to transform inputs to outputs can be considered as a process.

For organizations to function effectively, they have to identify and manage numerous interrelated and interacting processes. Often, the output from one process will directly form the input into the next process. The systematic identification and management of the processes employed within an organization and particularly the interactions between such processes is referred to as the "process approach".

The intent of this International Standard is to encourage the adoption of the process approach to manage an organization.

Figure 1 illustrates the process-based quality management system described in the ISO 9000 family of standards. This illustration shows that interested parties play a significant role in providing inputs to the organization. Monitoring the satisfaction of interested parties requires the evaluation of information relating to the perception of interested parties as to the extent to which their needs and expectations have been met. The model shown in Figure 1 does not show processes at a detailed level.

2.5 Quality policy and quality objectives

Quality policy and quality objectives are established to provide a focus to direct the organization. Both determine the desired results and assist the organization to apply its resources to achieve these results. The quality policy provides a framework for establishing and reviewing quality objectives. The quality objectives need to be consistent with the quality policy and the commitment to continual improvement, and their achievement needs to be measurable. The achievement of quality objectives can have a positive impact on product quality, operational effectiveness and financial performance and thus on the satisfaction and confidence of interested parties.
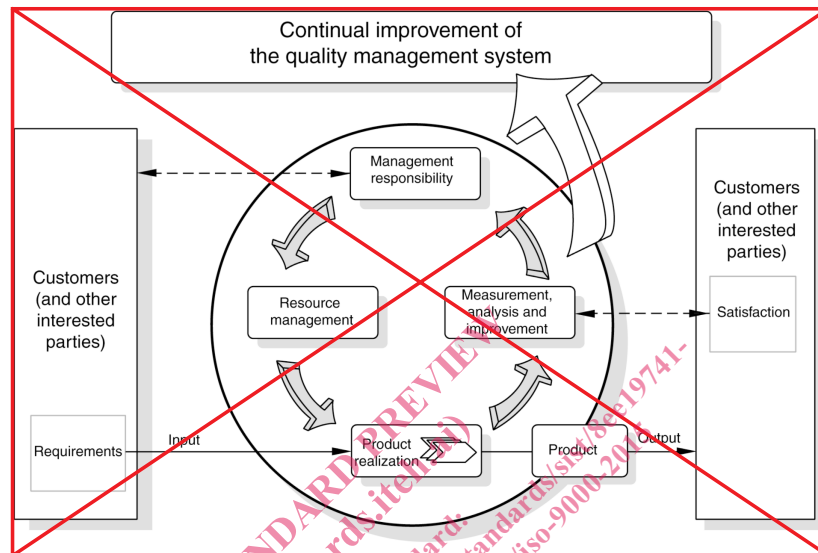
Key

⟩⟨ Value-adding activities

⟩⟨ information flow

NOTE   Statements in parentheses do not apply to ISO 9001.

Figure 1 — Model of a process-based quality management system

2.6 2.3 Role of top management within the quality management system Quality management principles

Through leadership and actions, top management can create an environment where people are fully involved and in which a quality management system can operate effectively. The quality management principles (see 0.2) can be used by top management as the basis of its role, which is as follows:

a)   to establish and maintain the quality policy and quality objectives of the organization;

b)   to promote the quality policy and quality objectives throughout the organization to increase awareness, motivation and involvement;

c)   to ensure focus on customer requirements throughout the organization;

d)   to ensure that appropriate processes are implemented to enable requirements of customers and other interested parties to be fulfilled and quality objectives to be achieved;

e)   to ensure that an effective and efficient quality management system is established, implemented and maintained to achieve these quality objectives;

f)   to ensure the availability of necessary resources;

g)   to review the quality management system periodically;