
**Quality management systems — Guidelines
for performance improvements**

*Systèmes de management de la qualité — Lignes directrices pour
l'amélioration des performances*

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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 drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9004 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This second edition of ISO 9004 cancels and replaces ISO 9004-1:1994, which has been technically revised. The title has been modified to reflect the comprehensiveness of the quality management system. Many of the existing International Standards within the ISO 9000 family will be reviewed for withdrawal, or for re-issue as Technical Reports, as many of their provisions are incorporated into this International Standard.

In comparison to previous editions, ISO 9001 and ISO 9004 now form a consistent pair of standards on quality management. ISO 9001 aims to give quality assurance of product and to enhance customer satisfaction, while ISO 9004 uses a broader perspective of quality management to give guidance for performance improvement.

Annexes A and B of this International Standard are for information only.

Introduction

0.1 General

The adoption of a quality management system should be a strategic decision by the top management of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. This International Standard is based on eight quality management principles. However, it is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The purpose of an organization is

- to identify and meet the needs and expectations of its customers and other interested parties (people in the organization, suppliers, owners, society), to achieve competitive advantage, and to do this in an effective and efficient manner, and
- to achieve, maintain, and improve overall organizational performance and capabilities.

The application of quality management principles not only provides direct benefits but also makes an important contribution to managing costs and risks. Benefit, cost and risk management considerations are important for the organization, its customers and other interested parties. These considerations on overall performance of the organization may impact

- customer loyalty,
- repeat business and referral,
- operational results such as revenue and market share,
- flexible and fast responses to market opportunities,
- costs and cycle times through effective and efficient use of resources,
- alignment of processes which will best achieve desired results,
- competitive advantage through improved organizational capabilities,
- understanding and motivation of people towards the organization's goals and objectives, as well as participation in continual improvement,
- confidence of interested parties in the effectiveness and efficiency of the organization, as demonstrated by the financial and social benefits from the organization's performance, product life cycle, and reputation,
- ability to create value for both the organization and its suppliers by optimization of costs and resources as well as flexibility and speed of joint responses to changing markets.

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness and efficiency of a quality management system to enhance interested party satisfaction by meeting interested party requirements.

For an organization to function effectively and efficiently, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, is considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions and managing of these processes can be referred to as the "process approach".

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

- a) understanding and fulfilling the requirements,
- b) the need to consider processes in terms of added value,
- c) obtaining results of process performance and effectiveness, and
- d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that interested parties play a significant role in defining requirements as inputs. Monitoring the satisfaction of interested parties requires the evaluation of information relating to the perception of interested parties as to whether the organization has met their requirements. The model shown in Figure 1 does not show processes at a detailed level.

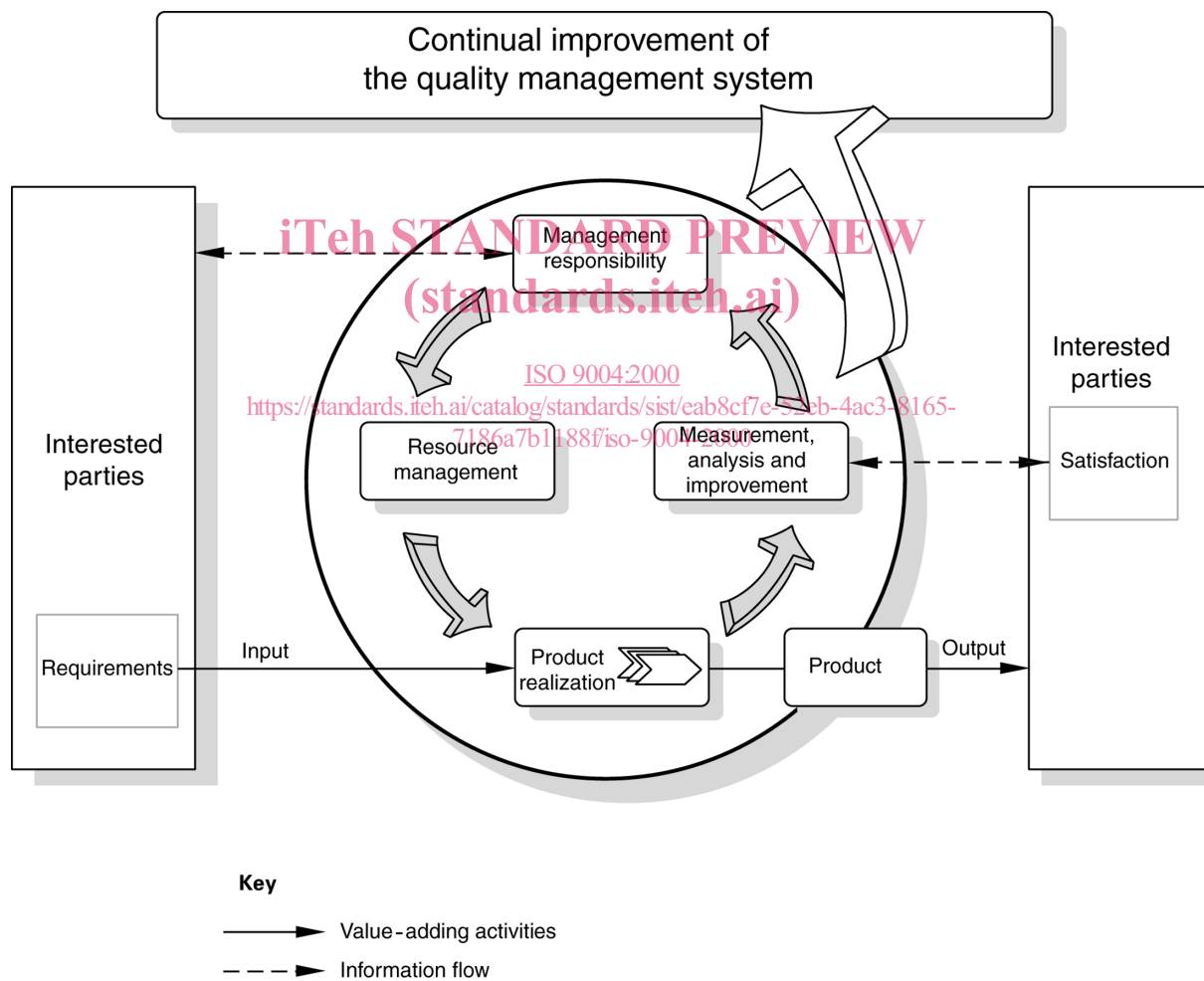


Figure 1 — Model of a process-based quality management system

0.3 Relationship with ISO 9001

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

For further benefit to the user, the basic content of the ISO 9001 requirements are included in boxed text following the comparable clause in this International Standard. Information marked "NOTE" is for guidance in understanding or clarification.

0.4 Compatibility with other management systems

This International Standard does not include guidance specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management, or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management systems. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that follows the guidelines of this International Standard.

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Quality management systems — Guidelines for performance improvements

1 Scope

This International Standard provides guidelines beyond the requirements given in ISO 9001 in order to consider both the effectiveness and efficiency of a quality management system, and consequently the potential for improvement of the performance of an organization. When compared to ISO 9001, the objectives of customer satisfaction and product quality are extended to include the satisfaction of interested parties and the performance of the organization.

This International Standard is applicable to the processes of the organization and consequently the quality management principles on which it is based can be deployed throughout the organization. The focus of this International Standard is the achievement of ongoing improvement, measured through the satisfaction of customers and other interested parties.

This International Standard consists of guidance and recommendations and is not intended for certification, regulatory or contractual use, nor as a guide to the implementation of ISO 9001.

2 Normative reference

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The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*.

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.

The following terms, used in this edition of ISO 9004 to describe the supply-chain, have been changed to reflect the vocabulary currently used:

supplier \longrightarrow **organization** \longrightarrow **customer (interested parties)**

Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

4 Quality management system

4.1 Managing systems and processes

Leading and operating an organization successfully requires managing it in a systematic and visible manner. Success should result from implementing and maintaining a management system that is designed to continually improve the effectiveness and efficiency of the organization's performance by considering the needs of interested parties. Managing an organization includes quality management, among other management disciplines.

Top management should establish a customer-oriented organization

- a) by defining systems and processes that can be clearly understood, managed and improved in effectiveness as well as efficiency, and
- b) by ensuring effective and efficient operation and control of processes and the measures and data used to determine satisfactory performance of the organization.

Examples of activities to establish a customer-oriented organization include

- defining and promoting processes that lead to improved organizational performance,
- acquiring and using process data and information on a continuing basis,
- directing progress towards continual improvement, and
- using suitable methods to evaluate process improvement, such as self-assessments and management review.

Examples of self-assessment and continual improvement processes are given in annexes A and B respectively.

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ISO 9001:2000, Quality management systems — Requirements

4 Quality management system ISO 9004:2000

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4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

- a) identify the processes needed for the quality management system and their application throughout the organization,
- b) determine the sequence and interaction of these processes,
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure and analyse these processes, and
- f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

4.2 Documentation

Management should define the documentation, including the relevant records, needed to establish, implement and maintain the quality management system and to support an effective and efficient operation of the organization's processes.

The nature and extent of the documentation should satisfy the contractual, statutory and regulatory requirements, and the needs and expectations of customers and other interested parties and should be appropriate to the organization. Documentation may be in any form or medium suitable for the needs of the organization.

In order to provide documentation to satisfy the needs and expectations of interested parties management should consider

- contractual requirements from the customer and other interested parties,
- acceptance of international, national, regional and industry sector standards,
- relevant statutory and regulatory requirements,
- decisions by the organization,
- sources of external information relevant for the development of the organization's competencies, and
- information about the needs and expectations of interested parties.

The generation, use and control of documentation should be evaluated with respect to the effectiveness and efficiency of the organization against criteria such as

- functionality (such as speed of processing),
- user friendliness,
- resources needed,
- policies and objectives,
- current and future requirements related to managing knowledge,
- benchmarking of documentation systems, and
- interfaces used by organization's customers, suppliers and other interested parties.

Access to documentation should be ensured for people in the organization and to other interested parties, based on the organization's communication policy.

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4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

- a) documented statements of a quality policy and quality objectives,
- b) a quality manual,
- c) documented procedures required by this International Standard,
- d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and
- e) records required by this International Standard.

NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

- a) the size of organization and type of activities,
- b) the complexity of processes and their interactions, and
- c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

- a) the scope of the quality management system, including details of and justification for any exclusions,
- b) the documented procedures established for the quality management system, or reference to them, and
- c) a description of the interaction between the processes of the quality management system.

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

4.3 Use of quality management principles

To lead and operate an organization successfully, it is necessary to manage it in a systematic and visible manner. The guidance to management offered in this International Standard is based on eight quality management principles.

These principles have been developed for use by top management in order to lead the organization toward improved performance. These quality management principles are integrated in the contents of this International Standard and are listed below

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.

Successful use of the eight management principles by an organization will result in benefits to interested parties, such as improved monetary returns, the creation of value and increased stability.

5 Management responsibility**5.1 General guidance****5.1.1 Introduction**

Leadership, commitment and the active involvement of the top management are essential for developing and maintaining an effective and efficient quality management system to achieve benefits for interested parties. To achieve these benefits, it is necessary to establish, sustain and increase customer satisfaction. Top management should consider actions such as

- establishing a vision, policies and strategic objectives consistent with the purpose of the organization,
- leading the organization by example, in order to develop trust within its people,
- communicating organizational direction and values regarding quality and the quality management system,
- participating in improvement projects, searching for new methods, solutions and products,
- obtaining feedback directly on the effectiveness and efficiency of the quality management system,
- identifying the product realization processes that provide added value to the organization,
- identifying the support processes that influence the effectiveness and efficiency of the realization processes,
- creating an environment that encourages the involvement and development of people, and
- provision of the structure and resources that are necessary to support the organization's strategic plans.

Top management should also define methods for measurement of the organization's performance in order to determine whether planned objectives have been achieved.

Methods include

- financial measurement,
- measurement of process performance throughout the organization,
- external measurement, such as benchmarking and third-party evaluation,
- assessment of the satisfaction of customers, people in the organization and other interested parties,
- assessment of the perceptions of customers and other interested parties of performance of products provided, and
- measurement of other success factors identified by management.

Information derived from such measurements and assessments should also be considered as input to management review in order to ensure that continual improvement of the quality management system is the driver for performance improvement of the organization.

5.1.2 Issues to be considered

When developing, implementing and managing the organization's quality management system, management should consider the quality management principles outlined in 4.3.

On the basis of these principles top management should demonstrate leadership in, and commitment to, the following activities:

- understanding current and future customer needs and expectations, in addition to requirements;
- promoting policies and objectives to increase awareness, motivation and involvement of people in the organization;
- establishing continual improvement as an objective for processes of the organization;
- planning for the future of the organization and managing change;
- setting and communicating a framework for achieving the satisfaction of interested parties.

In addition to small-step or ongoing continual improvement, top management should also consider breakthrough changes to processes as a way to improve the organization's performance. During such changes, management should take steps to ensure that the resources and communication needed to maintain the functions of the quality management system are provided.

Top management should identify the organization's product realization processes, as these are directly related to the success of the organization. Top management should also identify those support processes that affect either the effectiveness and efficiency of the realization processes or the needs and expectations of interested parties.

Management should ensure that processes operate as an effective and efficient network. Management should analyse and optimize the interaction of processes, including both realization processes and support processes.

Consideration should be given to

- ensuring that the sequence and interaction of processes are designed to achieve the desired results effectively and efficiently,
- ensuring process inputs, activities and outputs are clearly defined and controlled,
- monitoring inputs and outputs to verify that individual processes are linked and operate effectively and efficiently,
- identifying and managing risks, and exploiting performance improvement opportunities,
- conducting data analysis to facilitate continual improvement of processes,
- identifying process owners and giving them full responsibility and authority,

- managing each process to achieve the process objectives, and
- the needs and expectations of interested parties.

ISO 9001:2000, Quality management systems — Requirements

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

- a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- b) establishing the quality policy,
- c) ensuring that quality objectives are established,
- d) conducting management reviews, and
- e) ensuring the availability of resources.

5.2 Needs and expectations of interested parties

5.2.1 General

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Every organization has interested parties, each party having needs and expectations. Interested parties of organizations include

- customers and end-users, [ISO 9004:2000](https://standards.itih.ai/catalog/standards/sist/eab8cf7e-52eb-4ac3-8165-7186a7b1188f/iso-9004-2000)
- people in the organization, <https://standards.itih.ai/catalog/standards/sist/eab8cf7e-52eb-4ac3-8165-7186a7b1188f/iso-9004-2000>
- owners/investors (such as shareholders, individuals or groups, including the public sector, that have a specific interest in the organization),
- suppliers and partners, and
- society in terms of the community and the public affected by the organization or its products.

5.2.2 Needs and expectations

The success of the organization depends on understanding and satisfying the current and future needs and expectations of present and potential customers and end-users, as well as understanding and considering those of other interested parties.

In order to understand and meet the needs and expectations of interested parties, an organization should

- identify its interested parties and maintain a balanced response to their needs and expectations,
- translate identified needs and expectations into requirements,
- communicate the requirements throughout the organization, and
- focus on process improvement to ensure value for the identified interested parties.

To satisfy customer and end-user needs and expectations, the management of an organization should

- understand the needs and expectations of its customers, including those of potential customers,
- determine key product characteristics for its customers and end-users,