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Quality management systems — Fundamentals and vocabulary

*Systèmes de management de la qualité — Principes essentiels et
vocabulaire*

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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 2.

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.

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

ISO 9000 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 1, *Concepts and terminology*.

This third edition cancels and replaces the second edition (ISO 9000:2000). It includes the changes accepted in the Draft Amendment ISO/DAM 9000:2004.

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

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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.

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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.

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Quality management systems — Fundamentals and vocabulary

1 Scope

This International Standard describes fundamentals of quality management systems, which form the subject of the ISO 9000 family, and defines related terms.

This International Standard is applicable to the following:

- a) organizations seeking advantage through the implementation of a quality management system;
- b) organizations seeking confidence from their suppliers that their product requirements will be satisfied;
- c) users of the products;
- d) those concerned with a mutual understanding of the terminology 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 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;
- g) developers of related standards.

2 Fundamentals of quality management systems

2.1 Rationale for quality management systems

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 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.

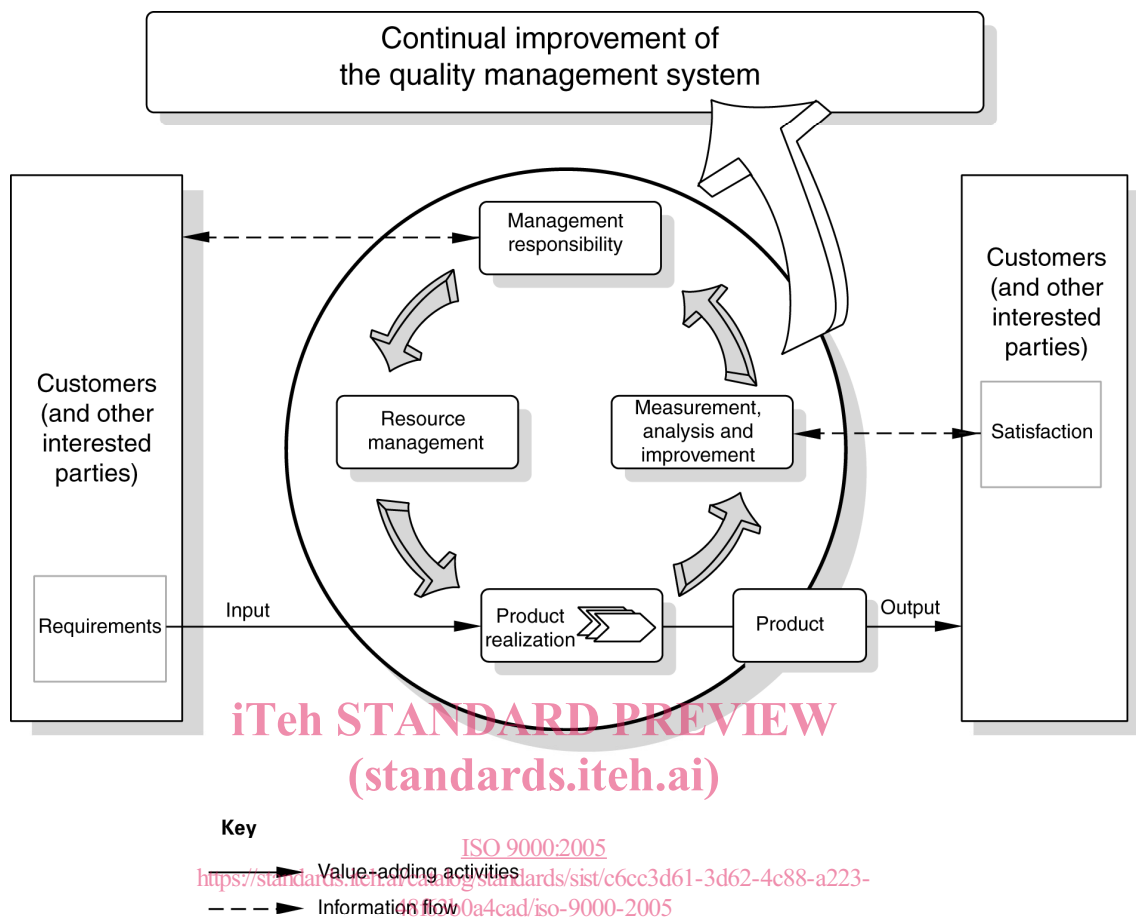
For organizations to function effectively, they have to identify and manage numerous interrelated and interacting processes. Often, the output from one process will directly form the input into the next process. The systematic identification and management of the processes employed within an organization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



NOTE Statements in parentheses do not apply to ISO 9001.

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

2.6 Role of top management within the quality management system

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:

- to establish and maintain the quality policy and quality objectives of the organization;
- to promote the quality policy and quality objectives throughout the organization to increase awareness, motivation and involvement;
- to ensure focus on customer requirements throughout the organization;
- 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;
- to ensure that an effective and efficient quality management system is established, implemented and maintained to achieve these quality objectives;
- to ensure the availability of necessary resources;
- to review the quality management system periodically;
- to decide on actions regarding the quality policy and quality objectives;
- to decide on actions for improvement of the quality management system.

2.7 Documentation

2.7.1 Value of documentation

Documentation enables communication of intent and consistency of action. Its use contributes to

- a) achievement of conformity to customer requirements and quality improvement,
- b) provision of appropriate training,
- c) repeatability and traceability,
- d) provision of objective evidence, and
- e) evaluation of the effectiveness and continuing suitability of the quality management system.

Generation of documentation should not be an end in itself but should be a value-adding activity.

2.7.2 Types of document used in quality management systems

The following types of document are used in quality management systems:

- a) documents that provide consistent information, both internally and externally, about the organization's quality management system; such documents are referred to as quality manuals;
- b) documents that describe how the quality management system is applied to a specific product, project or contract; such documents are referred to as quality plans;
- c) documents stating requirements; such documents are referred to as specifications;
- d) documents stating recommendations or suggestions; such documents are referred to as guidelines;
- e) documents that provide information about how to perform activities and processes consistently; such documents can include documented procedures, work instructions and drawings;
- f) documents that provide objective evidence of activities performed or results achieved; such documents are referred to as records.

Each organization determines the extent of documentation required and the media to be used. This depends on factors such as the type and size of the organization, the complexity and interaction of processes, the complexity of products, customer requirements, the applicable regulatory requirements, the demonstrated ability of personnel, and the extent to which it is necessary to demonstrate fulfilment of quality management system requirements.

2.8 Evaluating quality management systems

2.8.1 Evaluating processes within the quality management system

When evaluating quality management systems, there are four basic questions that should be asked in relation to every process being evaluated.

- a) Is the process identified and appropriately defined?
- b) Are responsibilities assigned?
- c) Are the procedures implemented and maintained?
- d) Is the process effective in achieving the required results?

The collective answers to the above questions can determine the result of the evaluation. Evaluation of a quality management system can vary in scope and encompass a range of activities, such as auditing and reviewing the quality management system, and self-assessments.

2.8.2 Auditing the quality management system

Audits are used to determine the extent to which the quality management system requirements are fulfilled. Audit findings are used to assess the effectiveness of the quality management system and to identify opportunities for improvement.

First-party audits are conducted by, or on behalf of, the organization itself for internal purposes and can form the basis for an organization's self-declaration of conformity.

Second-party audits are conducted by customers of the organization or by other persons on behalf of the customer.

Third-party audits are conducted by external independent organizations. Such organizations, usually accredited, provide certification or registration of conformity with requirements such as those of ISO 9001.

ISO 19011 provides guidance on auditing.

2.8.3 Reviewing the quality management system

One role of top management is to carry out regular systematic evaluations of the suitability, adequacy, effectiveness and efficiency of the quality management system with respect to the quality policy and quality objectives. This review can include consideration of the need to adapt the quality policy and objectives in response to changing needs and expectations of interested parties. The review includes determination of the need for actions.

Amongst other sources of information, audit reports are used for review of the quality management system.

2.8.4 Self-assessment

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An organization's self-assessment is a comprehensive and systematic review of the organization's activities and results referenced against the quality management system or a model of excellence.

Self-assessment can provide an overall view of the performance of the organization and the degree of maturity of the quality management system. It can also help to identify areas requiring improvement in the organization and to determine priorities.

2.9 Continual improvement

The aim of continual improvement of a quality management system is to increase the probability of enhancing the satisfaction of customers and other interested parties. Actions for improvement include the following:

- a) analysing and evaluating the existing situation to identify areas for improvement;
- b) establishing the objectives for improvement;
- c) searching for possible solutions to achieve the objectives;
- d) evaluating these solutions and making a selection;
- e) implementing the selected solution;
- f) measuring, verifying, analysing and evaluating results of the implementation to determine that the objectives have been met;
- g) formalizing changes.

Results are reviewed, as necessary, to determine further opportunities for improvement. In this way, improvement is a continual activity. Feedback from customers and other interested parties, audits and review of the quality management system can also be used to identify opportunities for improvement.

2.10 Role of statistical techniques

The use of statistical techniques can help in understanding variability, and thereby can help organizations to solve problems and improve effectiveness and efficiency. These techniques also facilitate better use of available data to assist in decision making.

Variability can be observed in the behaviour and outcome of many activities, even under conditions of apparent stability. Such variability can be observed in measurable characteristics of products and processes, and may be seen to exist at various stages over the life cycle of products from market research to customer service and final disposal.

Statistical techniques can help to measure, describe, analyse, interpret and model such variability, even with a relatively limited amount of data. Statistical analysis of such data can help to provide a better understanding of the nature, extent and causes of variability, thus helping to solve and even prevent problems that may result from such variability, and to promote continual improvement.

Guidance on statistical techniques in a quality management system is given in ISO/TR 10017.

2.11 Quality management systems and other management system focuses

The quality management system is that part of the organization's management system that focuses on the achievement of results, in relation to the quality objectives, to satisfy the needs, expectations and requirements of interested parties, as appropriate. The quality objectives complement other objectives of the organization such as those related to growth, funding, profitability, the environment and occupational health and safety. The various parts of an organization's management system might be integrated, together with the quality management system, into a single management system using common elements. This can facilitate planning, allocation of resources, definition of complementary objectives and evaluation of the overall effectiveness of the organization. The organization's management system can be assessed against the organization's management system requirements. The management system can also be audited against the requirements of International Standards such as ISO 9001 and ISO 14001. These management system audits can be carried out separately or in combination.

2.12 Relationship between quality management systems and excellence models

The approaches of quality management systems given in the ISO 9000 family of standards and in organizational excellence models are based on common principles. Both approaches

- a) enable an organization to identify its strengths and weaknesses,
- b) contain provision for evaluation against generic models,
- c) provide a basis for continual improvement, and
- d) contain provision for external recognition.

The difference between the approaches of the quality management systems in the ISO 9000 family and the excellence models lies in their scope of application. The ISO 9000 family of standards provides requirements for quality management systems and guidance for performance improvement; evaluation of quality management systems determines fulfilment of those requirements. The excellence models contain criteria that enable comparative evaluation of organizational performance and this is applicable to all activities and all interested parties of an organization. Assessment criteria in excellence models provide a basis for an organization to compare its performance with the performance of other organizations.

3 Terms and definitions

A term in a definition or note which is defined elsewhere in this clause is indicated by boldface followed by its entry number in parentheses. Such a boldface term may be replaced in the definition by its complete definition. For example: