

INTERNATIONAL
STANDARD

ISO
9000-1

First edition
1994-07-01

**Quality management and quality assurance
standards —**

Part 1:
Guidelines for selection and use
(standards.iteh.ai)

Normes pour le management de la qualité et l'assurance de la qualité —

Partie 1: Lignes directrices pour leur sélection et utilisation

INTERNATIONAL

ISO



Reference number
ISO 9000-1:1994(E)

Contents

	Page
1 Scope	1
2 Normative reference	1
3 Definitions	1
4 Principal concepts	2
4.1 Key objectives and responsibilities for quality	2
4.2 Stakeholders and their expectations	3
4.3 Distinguishing between quality system requirements and product requirements	3
4.4 Generic product categories	3
4.5 Facets of quality	3
4.6 Concept of a process	4
4.7 Network of processes in an organization	5
4.8 Quality system in relation to the network of processes	6
4.9 Evaluating quality systems	6
5 Roles of documentation	6
5.1 Value of documentation	6
5.2 Documentation and evaluation of quality systems	7
5.3 Documentation as a support for quality improvement	7
5.4 Documentation and training	7
6 Quality system situations	7
7 Selection and use of International Standards on quality	8
7.1 General	8
7.2 Selection and use	8
7.3 Application guidelines	8
7.4 Software	9

ITC STANDARD PREVIEW
(standards.iteh.ai)

<https://standards.iteh.ai/catalog/standards/sist/e965aad6-e168-444d-8e5d-d815fbaa480e/iso-9000-1-1994>

© ISO 1994

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

7.5 Dependability 9

7.6 Quality assurance: design, development, production, installation and servicing 9

7.7 Quality assurance: production, installation and servicing 9

7.8 Quality assurance: final inspection and test 9

7.9 Quality management 9

7.10 Services 10

7.11 Processed materials 10

7.12 Quality improvement 10

7.13 Audits 10

7.14 Auditors 10

7.15 Managing audits 10

7.16 Quality assurance for measurement 11

8 Selection and use of International Standards for external quality assurance 11

8.1 General guidance 11

8.2 Selection of model 11

8.3 Demonstration of conformance to the selected model 11

8.4 Additional considerations in contractual situations 12

iTeh STANDARD PREVIEW
(standards.iteh.ai)

<https://standards.iteh.ai/catalog/standards/sist/905a2d11-0700-4940-b030-d815fbaa480e/iso-9000-1-1994>

Annexes

A Terms and definitions taken from ISO 8402:1994 13

B Product and process factors 15

B.1 Purpose 15

B.2 Factors 15

C Proliferation of standards 16

D Cross-reference list of clause numbers for corresponding topics 17

E Bibliography 18

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.

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.

International Standard ISO 9000-1 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

The first edition of ISO 9000-1 cancels and replaces ISO 9000:1987. ISO/TC 176 adopted in 1990 a strategy for revision of the ISO 9000 series originally published in 1987. This is the first revision. This part of ISO 9000, which has the role of road map for the series, has been expanded substantially.

ISO 9000 consists of the following parts, under the general title *Quality management and quality assurance standards*:

- *Part 1: Guidelines for selection and use*
- *Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003*
- *Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software*
- *Part 4: Guide to dependability programme management*

Annex A forms an integral part of this part of ISO 9000. Annexes B, C, D and E are for information only.

Introduction

Organizations — industrial, commercial or governmental — supply products intended to satisfy customers' needs and/or requirements. Increased global competition has led to increasingly more stringent customer expectations with regard to quality. To be competitive and to maintain good economic performance, organizations/suppliers need to employ increasingly effective and efficient systems. Such systems should result in continual improvements in quality and increased satisfaction of the organization's customers and other stakeholders (employees, owners, sub-suppliers, society).

Customer requirements often are incorporated in "specifications". However, specifications may not in themselves guarantee that a customer's requirements will be met consistently, if there are any deficiencies in the organizational system to supply and support the product. Consequently, these concerns have led to the development of quality system standards and guidelines that complement relevant product requirements given in the technical specifications. The International Standards in the ISO 9000 family are intended to provide a generic core of quality system standards applicable to a broad range of industry and economic sectors (clause 7).

The management system of an organization is influenced by the objectives of the organization, by its products and by the practices specific to the organization and, therefore, quality systems also vary from one organization to another. A major purpose of quality management is to improve the systems and processes so that continual improvement of quality can be achieved.

This part of ISO 9000, which has the role of road map for the ISO 9000 family, has been expanded substantially. In particular, it contains guidance concepts not included in the 1987 version. These additional concepts

- are needed for effective understanding and current application of the ISO 9000 family, and
- are planned for complete integration into the architecture and content of future revisions of the ISO 9000 family.

In revision of the ISO 9000 family, there are no major changes in the architectures of ISO 9001, ISO 9002, ISO 9003 and ISO 9004. (However, ISO 9003 does contain additional clauses compared to the 1987 version.) Each of these International Standards has had small-scale changes. These changes move toward future revisions to meet better the needs of users.

This part of ISO 9000 and all other International Standards in the ISO 9000 family are independent of any specific industry or economic sector. Collectively they provide guidance for quality management and general requirements for quality assurance.

The International Standards in the ISO 9000 family describe what elements quality systems should encompass but not how a specific

organization implements these elements. It is not the purpose of these International Standards to enforce uniformity of quality systems. Needs of organizations vary. The design and implementation of a quality system must necessarily be influenced by the particular objectives, products and processes, and specific practices of the organization.

This part of ISO 9000 clarifies the principal quality-related concepts contained within the quality management and quality assurance International Standards generated by ISO/TC 176 and provides guidance on their selection and use.

iTeh STANDARD PREVIEW **(standards.iteh.ai)**

ISO 9000-1:1994

<https://standards.iteh.ai/catalog/standards/sist/e965aad2-e168-444d-8e5d-d815fbaa480e/iso-9000-1-1994>

Quality management and quality assurance standards —

Part 1: Guidelines for selection and use

1 Scope

This part of ISO 9000

- a) clarifies principal quality-related concepts and the distinctions and interrelationships among them;
- b) provides guidance for the selection and use of the ISO 9000 family of International Standards on quality management and quality assurance.

The usage of all of these terms conforms with their formal definitions in ISO 8402. The remaining differences in terminology in table 1 reflect, in part, a desire to maintain historical continuity with usage in the 1987 edition of these International Standards.

NOTES

1 In all these International Standards, the grammatical format of the guidance or requirements text is addressed to the organization in its role as a supplier of products (the third column of table 1).

2 In the ISO 9000 row of table 1, the use of "subsupplier" emphasizes the supply chain relationship of the three organizational units, using the self-defining term in relation to "supplier". Where appropriate, especially in discussing quality management situations, the term "organization" is used rather than "supplier".

3 In the ISO 9001, ISO 9002 and ISO 9003 rows of table 1, the use of "subcontractor" reflects the fact that, in an external quality assurance context, the relevant relationship often is (explicitly or implicitly) contractual.

4 In the ISO 9004 row of table 1, the use of "organization" reflects the fact that quality management guidance is applicable to any organizational unit, irrespective of the categories of products it may supply, or whether it is a free-standing unit or part of a larger organization.

For the purposes of this part of ISO 9000, the definitions given in ISO 8402, together with the following definitions, apply.

NOTE 5 For the convenience of users of this part of ISO 9000, some relevant definitions from ISO 8402 are contained in annex A.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 9000. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 9000 are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1994, *Quality management and quality assurance — Vocabulary*.

3 Definitions

This revision of ISO 9000, ISO 9001, ISO 9002, ISO 9003 and ISO 9004 has improved the harmonization of terminology for organizations in the supply chain. Table 1 shows the supply chain terminology used in these International Standards.

Table 1 — Relationships of organizations in the supply chain

ISO 9000-1	Subsupplier	→	supplier or organization	→	customer
ISO 9001, ISO 9002, ISO 9003	Subcontractor	→	supplier	→	customer
ISO 9004-1	Subcontractor	→	organization	→	customer

3.1 hardware: Tangible, discrete product with distinctive form.

NOTE 6 Hardware normally consists of manufactured, constructed or fabricated pieces, parts and/or assemblies.

3.2 software: An intellectual creation consisting of information expressed through supporting medium.

NOTES

7 Software can be in the form of concepts, transactions or procedures.

8 A computer program is a specific example of software.

3.3 processed material: Tangible product generated by transforming raw material into a desired state.

NOTES

9 The state of processed material can be liquid, gas, particulate material, ingot, filament or sheet.

10 Processed material is typically delivered in drums, bags, tanks, cylinders, cans, pipelines or rolls.

3.4 industry/economic sector: A grouping of suppliers whose offerings meet similar customer needs and/or whose customers are closely interrelated in the marketplace.

NOTES

11 Dual use of "industry sector" and "economic sector" recognizes that each term is used for the intended meaning in specific countries or languages.

12 Industry/economic sectors include administration, aerospace, banking, chemicals, construction, education, food, health care, leisure, insurance, mining, retailing, telecommunications, textiles, tourism, and so forth.

13 Industry/economic sectors apply to the global economy or a national economy.

3.5 stakeholder: An individual or group of individuals with a common interest in the performance of

the supplier organization and the environment in which it operates.

3.6 ISO 9000 family: All those International Standards produced by the technical committee ISO/TC 176.

NOTE 14 At present, the family comprises

- a) all the International Standards numbered ISO 9000 through to ISO 9004, including all parts of ISO 9000 and ISO 9004;
- b) all the International Standards numbered ISO 10001 through to 10020, including all parts; and
- c) ISO 8402.

iTech STANDARD PREVIEW
(standards.itech.ai)
ISO 9000-1:1994
<https://standards.itech.ai/catalog/standards/sist/e965aad2-e168-444d-8e5d-d815fbaa480e/iso-9000-1-1994>

4 Principal concepts

4.1 Key objectives and responsibilities for quality

An organization should:

- a) achieve, maintain and seek to improve continuously the quality of its products in relationship to the requirements for quality;
- b) improve the quality of its own operations, so as to meet continually all customers' and other stakeholders' stated and implied needs;
- c) provide confidence to its internal management and other employees that the requirements for quality are being fulfilled and maintained, and that quality improvement is taking place;
- d) provide confidence to the customers and other stakeholders that the requirements for quality are being, or will be, achieved in the delivered product;
- e) provide confidence that quality system requirements are fulfilled.

4.2 Stakeholders and their expectations

Every organization as a supplier has five principal groups of stakeholders: its customers, its employees, its owners, its sub-suppliers and society.

The supplier should address the expectations and needs of all its stakeholders.

Supplier's stakeholders	Typical expectations or needs
Customers	Product quality
Employees	Career/work satisfaction
Owners	Investment performance
Sub-suppliers	Continuing business opportunity
Society	Responsible stewardship

The International Standards in the ISO 9000 family focus their guidance and requirements on satisfying the customer.

The requirements of society, as one of the five stakeholders, are becoming more stringent worldwide. In addition, expectations and needs are becoming more explicit for considerations such as: workplace health and safety; protection of the environment (including conservation of energy and natural resources); and security. Recognizing that the ISO 9000 family of International Standards provides a widely used approach for management systems that can meet requirements for quality, these management principles can be useful for other concerns of society. Compatibility of the management system approach in these several areas can enhance the effectiveness of an organization. In the same manner that product and process technical specifications are separate from management systems requirements, the technical specifications in these other areas should be separately developed.

4.3 Distinguishing between quality system requirements and product requirements

The ISO 9000 family of International Standards makes a distinction between quality system requirements and product requirements. By means of this distinction, the ISO 9000 family applies to organizations providing products of all generic product categories, and to all product quality characteristics. The quality system requirements are complementary to the technical requirements of the product. The applicable technical specifications of the product (e.g. as set out in product standards) and technical specifications of the process are separate and distinct from the applicable ISO 9000 family requirements or guidance.

International Standards in the ISO 9000 family, both guidance and requirements, are written in terms of the quality system objectives to be satisfied. These International Standards do not prescribe how to achieve the objectives but leave that choice to the management of the organization.

4.4 Generic product categories

It is useful to identify four generic product categories (see clause 3 and annex A), as follows:

- a) hardware;
- b) software;
- c) processed materials;
- d) services.

These four generic product categories encompass all the kinds of product supplied by organizations. International Standards in the ISO 9000 family are applicable to all four generic product categories. The quality system requirements are essentially the same for all generic product categories, but the terminology and management system details and emphases may differ.

Two or more of the generic product categories usually are present in the marketplace offerings of any organization, whatever the industry/economic sector (see clause 3) in which the organization operates. For example, most organizations that supply hardware, software or processed materials have a service component to their offering. Customers (and other stakeholders) will look for value in each generic product category that is present in the offering.

Analytical instruments are examples where hardware (i.e. the instrument), software (for computing tasks within the instrument), processed materials (such as titrating solutions or reference materials) and services (such as training or maintenance servicing) might all be important features of the offering. A service organization such as a restaurant will have hardware, software and processed materials as well as service components.

4.5 Facets of quality

Four facets that are key contributions to product quality may be identified as follows.

a) **Quality due to definition of needs for the product**

The first facet is quality due to defining and updating the product, to meet marketplace requirements and opportunities.

b) **Quality due to product design**

The second facet is quality due to designing into the product the characteristics that enable it to meet marketplace requirements and opportunities, and to provide value to customers and other stakeholders. More precisely, quality due to product design is the product design features that influence the intended performance within a given grade, plus product design features that influence the robustness of product performance under variable conditions of production and use.

c) **Quality due to conformance to product design**

The third facet is quality due to maintaining day-to-day consistency in conforming to product design and in providing the designed characteristics and values for customers and other stakeholders.

d) **Quality due to product support**

The fourth facet is quality due to furnishing support throughout the product life cycle, as needed, to provide the designed characteristics and values for customers and other stakeholders.

For some products, the important quality characteristics include dependability characteristics. Dependability (i.e. reliability, maintainability and availability) may be influenced by all four facets of product quality.

A goal of the guidance and requirements of the International Standards in the ISO 9000 family is to meet the needs for all four facets of product quality. Some facets of quality may be specifically important, for example, in contractual situations, but, in general, all facets contribute to the quality of the product. The ISO 9000 family explicitly provides generic quality management guidance and external quality assurance requirements on facets a), b), c) and d).

When considering the complete product offering, the customer will bear in mind additional factors. These include the following.

- The supplier's market status and strategy: if the supplier has an established and reputable marketplace status and/or a strategy that is achieving a

satisfactory market share, the customer is likely to place higher value on the supplier's offering.

- The supplier's financial status and strategy: if the supplier has an established and reputable financial status and/or a strategy that is improving financial performance, the customer is likely to place higher value on the supplier's offering.
- The supplier's human resources status and strategy: if the supplier has an established and reputable human resources status and/or a strategy that is developing improved skills, diversity and commitment in its human resources, the customer is likely to place higher value on the supplier's offering.

These additional factors are of vital importance in managing a supplier organization as a total enterprise.

NOTE 15 Product value involves both quality and price and, as such, price is not a facet of quality.

STANDARD PREVIEW
(standards.iteh.ai)

4.6 Concept of a process

The International Standards in the ISO 9000 family are founded upon the understanding that all work is accomplished by a process (see figure 1). Every process has inputs. The outputs are the results of the process. The outputs are products, tangible or intangible. The process itself is (or should be) a transformation that adds value. Every process involves people and/or other resources in some way. An output may be, for example, an invoice, computing software, liquid fuel, a clinical device, a banking service, or a final or intermediate product of any generic category. There are opportunities to make measurements on the inputs, at various places in the process, as well as on the outputs. As shown in figure 2, inputs and outputs are of several types.

Type	Examples
Product-related (solid lines in figure 2)	Raw materials Intermediate product Final product Sampled product
Information-related (dashed lines in figure 2)	Product requirements Product characteristics and status information Support-function communications Feedback on product performance and needs Measurement data from sampled product

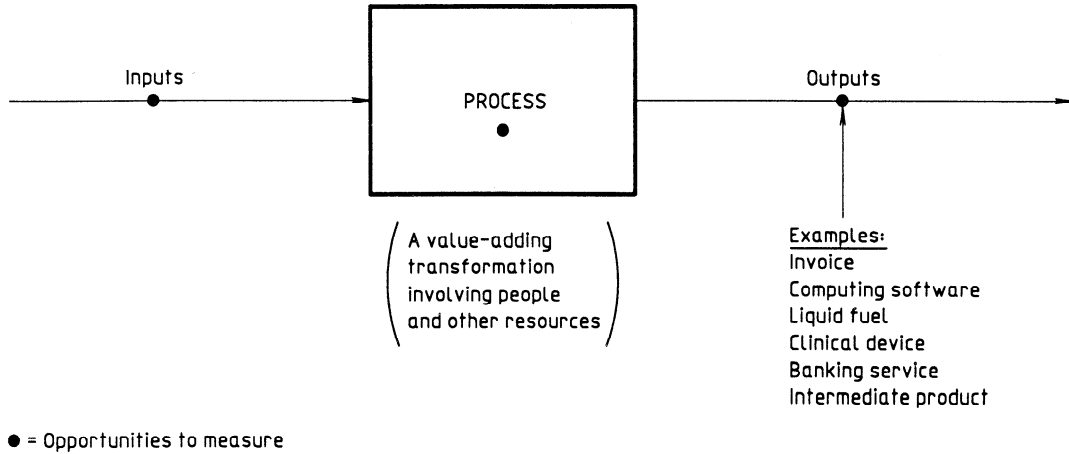


Figure 1 — All work is accomplished by a process

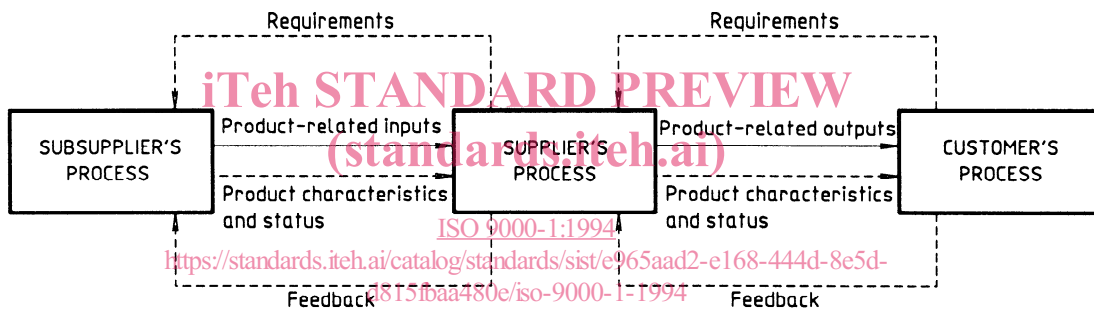


Figure 2 — Supply chain relationship of processes, with product-related and information-related flow

Figure 2 shows the supplier in a supply chain relationship to a subsupplier and a customer. In this supply chain structure, the various inputs and outputs need to flow in different directions, as illustrated in figure 2. It is emphasized that in this context "product" includes all four generic product categories.

Quality management is accomplished by managing the processes in the organization. It is necessary to manage a process in two senses:

- the structure and operation of the process itself within which the product or information flows; and
- the quality of the product or information flowing within the structure.

4.7 Network of processes in an organization

Every organization exists to accomplish value-adding work. The work is accomplished through a network

of processes. The structure of the network is not usually a simple sequential structure, but typically is quite complex.

In an organization there are many functions to be performed. They include production, product design, technology management, marketing, training, human resources management, strategic planning, delivery, invoicing and maintenance. Given the complexity of most organizations, it is important to highlight the main processes and to simplify and prioritize processes for quality management purposes.

An organization needs to identify, organize and manage its network of processes and interfaces. The organization creates, improves and provides consistent quality in its offerings through the network of processes. This is a fundamental conceptual basis for the ISO 9000 family. Processes and their interfaces should be subject to analysis and continuous improvement.