



# SLOVENSKI STANDARD SIST EN ISO 9000-1:1997

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## Standardi za vodenje in zagotavljanje kakovosti - 1. del: Smernice za izbiro in uporabo (ISO 9000-1:1994)

Quality management and quality assurance standards - Part 1: Guidelines for selection and use (ISO 9000-1:1994)

Normen zum Qualitätsmanagement und zur Qualitätssicherung/QM-Darlegung - Teil 1: Leitfaden zur Auswahl und Anwendung (

Normes pour le management de la qualité et l'assurance de la qualité - Partie 1: Lignes directrices pour leur sélection

Ta slovenski standard je istoveten z: EN ISO 9000-1:1994

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### ICS:

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
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Quality management and quality assurance  
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use (ISO 9000-1:1994)

Normes pour la gestion de la qualité et  
l'assurance de la qualité - Partie 1: Lignes  
directrices pour la sélection et l'utilisation  
(ISO 9000-1:1994)

Normen zur Qualitätsmanagement und zur  
Darlegung von Qualitätsmanagementsystemen -  
Teil 1: Leitfaden zur Auswahl und Anwendung  
(ISO 9000-1:1994)

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PREVZET PO METODI RAZGLASITVE

-12- 1997

This European Standard was approved by CEN on 1994-06-20. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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# CEN

European Committee for Standardization  
Comité Européen de Normalisation  
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

## Foreword

This European Standard has been prepared by ISO/TC 176 "Quality management and quality assurance" of the International Organization for Standardization (ISO) and was adopted by ISO and CEN following a parallel voting procedure.

This European Standard replaces EN 29000:1987.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 1995, and conflicting national standards shall be withdrawn at the latest by January 1995.

In accordance with the CEN/CENELEC Internal Regulations, following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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The text of the International Standard ISO 9000-1:1994 has been approved by CEN as a European Standard without any modification.

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INTERNATIONAL  
STANDARD

**ISO**  
**9000-1**

First edition  
1994-07-01

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**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*



Reference number  
ISO 9000-1:1994(E)

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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.

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, subsuppliers, 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.

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# 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.