

Quality management and quality assurance standards —

Part 1: Guidelines for selection and use —

Formerly BS 5750-0.1

The European Standard EN ISO 9000-1:1994 has the status of a
British Standard

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This British Standard, having been prepared under the direction of the Quality, Management and Statistics Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 1 July 1994

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National foreword

This Part of BS EN ISO 9000 has been prepared under the direction of the Quality, Management and Statistics Standards Policy Committee. It has been developed in the interests of international harmonization and international trade and is identical with ISO 9000-1:1994 *Quality management and quality assurance standards — Part 1: Guidelines for selection and use*, published by the International Organization for Standardization (ISO). It supersedes BS 5750-0.1:1987 which is withdrawn.

This standard has been revised in the light of user experiences with BS 5750-0.1:1987 in the UK and ISO 9000-1:1987 internationally. During the revision process, account was taken of the Vision 2000¹⁾ strategy for the longer term development of the ISO 9000 family of quality standards which was adopted by ISO Technical Committee ISO/TC 176, Quality management and quality assurance, in 1990.

In 1994 the European Committee for Standardization (CEN) accepted ISO 9000-1:1994 as European Standard EN ISO 9000-1.

Cross-references

International standard	Corresponding British Standard
Normative reference	
ISO 8402:1994	BS 4778 <i>Quality vocabulary</i> Part 1:1987 <i>International terms</i> (Identical) ²⁾
Informative references	
	BS 5750 <i>Quality systems</i>
ISO 9000-3:1991	Part 13:1991 <i>Guide to the application of BS 5750-1 to the development, supply and maintenance of software</i> (Identical)
ISO 9000-4:1993	Part 14:1993 <i>Guide to dependability programme management</i> (Identical)
ISO 9001:1994	BS EN ISO 9001:1994 <i>Quality systems — Specification for design, development, production, installation and servicing</i> (Identical)
ISO 9002:1994	BS EN ISO 9002:1994 <i>Quality systems — Specification for production, installation and servicing</i> (Identical)
ISO 9003:1994	BS EN ISO 9003:1994 <i>Quality systems — Specification for final inspection and test</i> (Identical)
ISO 9004-1:1994	BS EN ISO 9004-1 <i>Quality management and quality system elements</i> Part 1:1994 <i>Guidelines</i> (Identical)
ISO 9004-2:1991	BS 5750 <i>Quality systems</i> Part 8:1994 <i>Guide to quality management and quality systems elements for services</i> (Identical)

¹⁾ Available from BSI as PD 6538:1993 *Vision 2000. A strategy for international standards' implementation in the quality arena during the 1990s*.

²⁾ BS 4778-1:1987 is identical with ISO 8402:1986. ISO 8402:1994 is under consideration for implementation as a revisions to BS 4778-1.

ISO 9004-4:1993	BS 7850 <i>Total quality management</i> Part 2:1992 <i>Guidelines for quality improvement</i> (Identical)
ISO 10011-1:1991	BS 7229 <i>Quality systems auditing</i> Part 1:1991 <i>Auditing</i> (Identical)
ISO 10011-2:1991	Part 2:1991 <i>Qualification criteria for auditors</i> (Identical)
ISO 10011-3:1991	Part 3:1991 <i>Management of audit programmes</i> (Identical)
ISO 10012-1:1992	BS 5781 <i>Quality assurance requirements for measuring equipment</i> Part 1:1992 <i>Metrological confirmation system for measuring equipment</i> (Identical)

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Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, the EN title page, pages 2 to 20, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

English version

Quality management and quality assurance standards – Part 1: Guidelines for selection and 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)

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.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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, the 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.

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.

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.

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.