

Quality management and quality system elements —

Part 1: Guidelines —

Formerly BS 5750-0.2

The European Standard EN ISO 9004-1:1994 has the status of a British Standard

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Contents

	Page
Committees responsible	Inside front cover
National foreword	ii
Foreword	2
Introduction	3
1 Scope	4
2 Normative references	4
3 Definitions	4
4 Management responsibility	5
5 Quality-system elements	6
6 Financial considerations of quality systems	9
7 Quality in marketing	10
8 Quality in specification and design	11
9 Quality in purchasing	14
10 Quality in processes	15
11 Control of processes	16
12 Product verification	17
13 Control of inspection, measuring and test equipment	18
14 Control of nonconforming product	18
15 Corrective action	19
16 Post-production activities	20
17 Quality records	21
18 Personnel	21
19 Product safety	22
20 Use of statistical methods	22
Annex A (informative) Bibliography	24
Figure 1 — Main activities having an impact on quality	6
Table 1 — Relationships of organizations in the supply chain	5
List of references	Inside back cover

National foreword

This Part of BS EN ISO 9004 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 9004-1:1994 *Quality management and quality system elements — Part 1: Guidelines*, published by the International Organization for Standardization (ISO). It supersedes BS 5750-0.2:1987 which is withdrawn.

This standard has been revised in the light of user experiences with BS 5750-0.2:1987 in the UK and ISO 9004-1:1987 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 9004-1:1994 as European Standard EN ISO 9004-1.

Cross-references

International standard	Corresponding British Standard
Normative references	
ISO 8402:1994	BS 4778 <i>Quality Vocabulary</i> Part 1:1987 <i>International terms</i> (Identical) ²⁾
ISO 9000-1:1994	BS EN ISO 9000-1 <i>Quality management and quality assurance standards</i> Part 1:1994 <i>Guidelines for selection and use</i> (Identical)
Informative references	
ISO 9000-3:1991	BS 5750 <i>Quality systems</i> 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)

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 revision to BS 4778-1.

ISO 9004-2:1991	BS 5750 <i>Quality systems</i> Part 8: <i>Guide to quality management and quality systems elements for services</i> (Identical)
ISO 9004-4:1993	BS 7850 <i>Total quality management</i> Part 2:1992 <i>Guidelines for quality improvement</i> (Identical) BS 7229 <i>Quality systems auditing</i>
ISO 10011-1:1991	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 24, 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 system elements — Part 1: Guidelines

(ISO 9004-1:1994)

Gestion de la qualité et éléments de système
qualité —
Partie 1: Lignes directrices
(ISO 9004-1:1994)

Qualitätsmanagement und Elemente eines
Qualitätsmanagement —
Teil 1: Leitfaden
(ISO 9004-1:1994)

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 29004:1987.

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

0.1 General

This Part of ISO 9004 and all other International Standards in the ISO 9000 family are generic and independent of any specific industry or economic sector. Collectively they provide guidance for quality management and models for quality assurance.

The International Standards in the ISO 9000 family describe what elements quality systems should encompass, but not how a specific organization should implement these elements. Because the needs of organizations vary, it is not the purpose of these International Standards to enforce uniformity of quality systems. The design and implementation of a quality system will be influenced by the particular objectives, products, processes and individual practices of the organization.

A primary concern of any organization should be the quality of its products. (See 3.5 for the definition of “product” which includes service).

In order to be successful, an organization should offer products that:

- a) meet a well-defined need, use or purpose;
- b) satisfy customer's expectations;
- c) comply with applicable standards and specifications;
- d) comply with requirements of society (see 3.3);
- e) reflect environmental needs;
- f) are made available at competitive prices;
- g) are provided economically.

0.2 Organizational goals

In order to meet its objectives, an organization should ensure that the technical, administrative and human factors affecting the quality of its products will be under control, whether hardware, software, processed materials or services. All such control should be oriented towards the reduction, elimination and, most importantly, prevention of quality nonconformities.

A quality system should be developed and implemented for the purpose of accomplishing the objectives set out in the organization's quality policy.

Each element (or requirement) in a quality system varies in importance from one type of activity to another and from one product to another.

In order to achieve maximum effectiveness and to satisfy customer expectations, it is essential that the quality system be appropriate to the type of activity and to the product being offered.

0.3 Meeting customer/organization needs and expectations

A quality system has two interrelated aspects, as follows.

a) *The customer's needs and expectations*

For the customer, there is a need for confidence in the ability of the organization to deliver the desired quality as well as the consistent maintenance of that quality.

b) *The organization's needs and interests*

For the organization, there is a business need to attain and to maintain the desired quality at an optimum cost; the fulfilment of this aspect is related to the planned and efficient utilization of the technological, human and material resources available to the organization.

Each of the above aspects of a quality system requires objective evidence in the form of information and data concerning the quality of the system and the quality of the organization's products.

0.4 Benefits, costs and risks

Benefit, cost and risk considerations have great importance for both the organization and customer. These considerations are inherent aspects of most products. The possible effects and ramifications of these considerations are given in a) to c).

a) *Benefit considerations*

For the customer, consideration has to be given to reduced costs, improved fitness for use, increased satisfaction and growth in confidence.

For the organization, consideration has to be given to increased profitability and market share.

b) *Cost considerations*

For the customer, consideration has to be given to safety, acquisition cost, operating, maintenance, downtime and repair costs, and possible disposal costs.

For the organization, consideration has to be given to costs due to marketing and design deficiencies, including unsatisfactory product, rework, repair, replacement, reprocessing, loss of production, warranties and field repair.

c) *Risk considerations*

For the customer, consideration has to be given to risks such as those pertaining to the health and safety of people, dissatisfaction with product, availability, marketing claims and loss of confidence.

For the organization, consideration has to be given to risks related to deficient products which lead to loss of image or reputation, loss of market, complaints, claims, liability and waste of human and financial resources.

0.5 Conclusions

An effective quality system should be designed to satisfy customer needs and expectations while serving to protect the organization's interests. A well-structured quality system is a valuable management resource in the optimization and control of quality in relation to benefit, cost and risk considerations.

1 Scope

This Part of ISO 9004 provides guidance on quality management and quality system elements.

The quality system elements are suitable for use in the development and implementation of a comprehensive and effective in-house quality system, with a view to ensuring customer satisfaction.

This Part of ISO 9004 is not intended for contractual, regulatory or certification use. Consequently, it is not a guideline for the implementing of ISO 9001, ISO 9002 and ISO 9003. ISO 9000-2 should be used for that purpose.

The selection of appropriate elements contained in this Part of ISO 9004 and the extent to which these elements are adopted and applied by an organization depends upon factors such as the market being served, nature of the product, production processes, and customer and consumer needs.

References in this Part of ISO 9004 to a "product" should be interpreted as applicable to the generic product categories of hardware, software, processed materials or service (in accordance with the definition of "product" in ISO 8402).

NOTE 1 For further guidance, see ISO 9004-2 and ISO 9004-3.

NOTE 2 For informative references, see annex A.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Part of ISO 9004. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this Part of ISO 9004 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

Members of IEC and ISO maintain registers of currently valid International Standards.

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

ISO 9000-1:1994, *Quality management and quality assurance standards — Part 1: Guidelines for selection and use*.

3 Definitions

This revision of ISO 9004 has improved the harmonization of terminology with other International Standards in the ISO 9000 family. Table 1 shows the supply-chain terminology used in these International Standards. Thus, the term "subcontractor" is used rather than the term "supplier" in this Part of ISO 9004 to avoid confusion with the meaning of the term "supplier", in ISO 9000 and ISO 9001. See ISO 9000-1 for a fuller explanation of the basis for usage of these terms.

For the purposes of this Part of ISO 9004, the definitions given in ISO 8402 apply.

For the convenience of users of this Part of ISO 9004, the following definitions are quoted from ISO 8402.

3.1 organization

company, corporation, firm, enterprise or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration

3.2 customer

recipient of a product provided by the supplier

NOTE 3 In a contractual situation, the customer may be called the "purchaser".

NOTE 4 The customer may be, for example, the ultimate consumer, user, beneficiary or purchaser.

NOTE 5 The customer can be either external or internal to the organization.

3.3 requirements of society

obligations resulting from laws, regulations, rules, codes, statutes and other considerations

NOTE 6 Other "considerations" include notably protection of the environment, health, safety, security, conservation of energy and natural resources.

NOTE 7 All requirements of society should be taken into account when defining the requirements for quality.

NOTE 8 Requirements of society include notably jurisdictional and regulatory requirements. These may vary from one jurisdiction to another.