



BS 5750: Part 0: Section 0.2: 1987

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British Standard

# Quality systems

Part 0. Principal concepts and applications

## Section 0.2 Guide to quality management and quality system elements

[ISO title : Quality management and quality system elements — Guidelines]

Systèmes qualité

Partie 0. Principaux concepts et applications

Section 0.2 Gestion de la qualité et éléments du système qualité — Lignes directrices

Qualitätssicherungssysteme

Teil 0. Grundbegriffe und Anwendungen

Abschnitt 0.2 Leitfaden zu Qualitätsmanagement und Elementen eines Qualitätssicherungssystems

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## National foreword

This Section of BS 5750 : Part 0 is identical with ISO 9004-1987 'Quality management and quality system elements — Guidelines' published by the International Organization for Standardization (ISO). It has been adopted nationally under the direction of the Quality, Management and Statistics Standards Committee.

Following publication of BS 5750 : Parts 1, 2 and 3 in 1979 and BS 5750 : Parts 4, 5 and 6 in 1981, the BS 5750 series has rapidly been adopted in a wide variety of industrial sectors. As such this series now forms a corner-stone of the National Quality Campaign and the reference basis for the Department of Trade and Industry 'Register of Quality Assessed United Kingdom Companies' (published by HMSO). Subsequently, BS 5750 : Parts 1, 2 and 3 were used as the basis for part of the new series of ISO standards (ISO 9001, 9002 and 9003) within ISO/TC 176, Quality Assurance, during the period 1983 to 1986.

After a review of the complete (1987) series of documents prepared by ISO/TC 176 (i.e. ISO 9000 to ISO 9004) and further consideration of the operation of the existing standards, it was decided to introduce additional fundamental guidance by the allocation of a new designation, BS 5750 : Part 0 'Principal concepts and applications' comprising the following separately published Sections:

Section 0.1 'Guide to selection and use' (Identical with ISO 9000)

Section 0.2 'Guide to quality management and quality system elements' (Identical with ISO 9004)

In 1987 the European Committee for Standardization (CEN) accepted ISO 9004-1987:  
as European Standard EN 29004-1987.

**Terminology and conventions.** The text of the international standard has been approved as suitable for publication as a British Standard without deviation. Some terminology and certain conventions are not identical with those used in British Standards; attention is drawn especially to the following.

Wherever the words 'International Standard' appear, referring to this standard, they should be read as 'Section of BS 5750'.

## Cross-references

| International standard | Corresponding British Standard                                                                            |
|------------------------|-----------------------------------------------------------------------------------------------------------|
| ISO 8402-1986          | BS 4778 Quality vocabulary<br>Part 1 : 1987 International terms<br>(Identical)                            |
|                        | BS 5750 Quality systems<br>Part 0 Principal concepts and applications                                     |
| ISO 9000-1987          | Section 0.1 : 1987 Guide to selection and use<br>(Identical)                                              |
| ISO 9001-1987          | Part 1 : 1987 Specification for design/development, production, installation and servicing<br>(Identical) |
| ISO 9002-1987          | Part 2 : 1987 Specification for production and installation<br>(Identical)                                |
| ISO 9003-1987          | Part 3 : 1987 Specification for final inspection and test<br>(Identical)                                  |

Compliance with a British Standard does not of itself confer immunity from legal obligations.



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English version

## Quality management and quality system elements Guidelines

Gestion de la qualité et éléments de système  
qualité — Lignes directrices

Qualitätsmanagement und Elemente eines  
Qualitätssicherungssystems; Leitfaden

This European Standard was accepted by CEN on 10 December 1987. CEN members are bound to comply with the requirements of the CEN/CENELEC Rules 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 CEN Central Secretariat or to any CEN member.

This European Standard exists in the 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 CEN Central Secretariat has the same status as the official versions.

CEN members are the national standards organizations of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, 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 Bréderode 2, B-1000 Brussels

**Brief history**

The Technical Board decided to submit the International Standard ISO 9004-1987 Quality management and quality system elements – Guidelines to the Formal Vote.

In accordance with the CEN/CENELEC Common Rules, all CEN members are bound to implement this European Standard:

Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

**Statement**

The text of the International Standard ISO 9004, 1st edition, 15 March 1987 was approved by CEN as a European Standard without any modification.

All references within this document to ISO 9000, ISO 9001, ISO 9002, ISO 9003 and ISO 9004 should be read as EN 29000, EN 29001, EN 29002, EN 29003 and EN 29004 respectively.

British Standard

## Quality systems

Part 0. Principal concepts and applications

Section 0.2 Guide to quality management and quality system elements

### 0 Introduction

#### 0.1 General

A primary concern of any company or organization must be the quality of its products and services.

In order to be successful, a company must offer products or services that

- a) meet a well defined need, use or purpose;
- b) satisfy customers' expectations;
- c) comply with applicable standards and specifications;
- d) comply with statutory (and other) requirements of society (see 3.3);
- e) are made available — at competitive prices;
- f) are provided at a cost which will yield a profit.

#### 0.2 Organizational goals

In order to meet its objectives, the company should organize itself in such a way that the technical, administrative and human factors affecting the quality of its products and services will be under control. All such control should be oriented towards the reduction, elimination and, most importantly, prevention of quality deficiencies.

A quality management system should be developed and implemented for the purpose of accomplishing the objectives set out in a company's quality policies.

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

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

#### 0.3 Meeting company/customer needs

A quality management system has two inter-related aspects :

##### a) The company's needs and interests

- For the company, there is a business need to attain and to maintain the desired quality at an optimum cost;

the fulfilment of this quality aspect is related to the planned and efficient utilization of the technological, human and material resources available to the company.

##### b) The customer's needs and expectations

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

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

### 0.4 Risks, costs and benefits

#### 0.4.1 General

Risk, cost and benefit considerations have great importance for both company and customer. These considerations are inherent aspects of most products and services. The possible effects and ramifications of these considerations are given in 0.4.2 to 0.4.4.

#### 0.4.2 Risk considerations

##### 0.4.2.1 For the company

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

##### 0.4.2.2 For the customer

Consideration has to be given to risks such as those pertaining to the health and safety of people, dissatisfaction with goods and services, availability, marketing claims and loss of confidence.

#### 0.4.3 Cost considerations

##### 0.4.3.1 For the company

Consideration has to be given to costs due to marketing and design deficiencies, including unsatisfactory materials, re-work, repair, replacement, re-processing, loss of production, warranties and field repair.

**0.4.3.2 For the customer**

Consideration has to be given to safety, acquisition cost, operating, maintenance, downtime and repair costs, and possible disposal costs.

**0.4.4 Benefit considerations****0.4.4.1 For the company**

Consideration has to be given to increased profitability and market share.

**0.4.4.2 For the customer**

Consideration has to be given to reduced costs, improved fitness for use, increased satisfaction and growth in confidence.

**0.4.5 Conclusion**

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

**1 Scope and field of application**

This International Standard describes a basic set of elements by which quality management systems can be developed and implemented.

The selection of appropriate elements contained in this International Standard and the extent to which these elements are adopted and applied by a company depends upon factors such as market being served, nature of product, production processes, and consumer needs.

**NOTES**

- 1 This International Standard is not intended to be used as a checklist for compliance with a set of requirements.
- 2 ISO/TC 176, *Quality assurance*, is considering preparing a separate International Standard on the subject of service.

**2 References**

ISO 8402, *Quality — Vocabulary*.

ISO 9000, *Quality management and quality assurance standards — Guidelines for selection and use*.

ISO 9001, *Quality systems — Model for quality assurance in design/development, production, installation and servicing*.

ISO 9002, *Quality systems — Model for quality assurance in production and installation*.

ISO 9003, *Quality systems — Model for quality assurance in final inspection and test*.

**3 Definitions**

For the purposes of this International Standard, the definitions given in ISO 8402 and the following definitions apply.

**3.1 organization** : A company, corporation, firm or enterprise, whether incorporated or not, public or private.

**3.2 company** : Term used primarily to refer to a business first party, the purpose of which is to supply a product or service.

**3.3 requirements of society** : Requirements including laws, statutes, rules and regulations, codes, environmental considerations, health and safety factors, and conservation of energy and materials.

**3.4 customer** : Ultimate consumer, user, client, beneficiary or second party.

**4 Management responsibility****4.1 General**

The responsibility for and commitment to a quality policy belongs to the highest level of management. Quality management is that aspect of the overall management function which determines and implements quality policy.

**4.2 Quality policy**

The management of a company should develop and state its corporate quality policy. This policy should be consistent with other company policies. Management should take all necessary measures to ensure that its corporate quality policy is understood, implemented and maintained.

**4.3 Quality objectives**

**4.3.1** For the corporate quality policy, management should define objectives pertaining to key elements of quality, such as fitness for use, performance, safety and reliability.

**4.3.2** The calculation and evaluation of costs associated with all quality elements and objectives should always be an important consideration, with the objective of minimizing quality losses.

**4.3.3** Appropriate levels of management, where necessary, should define specialized quality objectives consistent with corporate quality policy as well as other corporate objectives.

**4.4 Quality system**

**4.4.1** A quality system is the organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

**4.4.2** Management should develop, establish and implement a quality system as the means by which stated policies and objectives might be accomplished.

**4.4.3** The quality system should be structured and adapted to the company's particular type of business and should take into account the appropriate elements outlined in this International Standard.

**4.4.4** The quality system should function in such a manner as to provide proper confidence that

- a) the system is well understood and effective;
- b) the products or services actually do satisfy customer expectations;
- c) emphasis is placed on problem prevention rather than dependence on detection after occurrence.

## 5 Quality system principles

### 5.1 Quality loop

**5.1.1** The quality system typically applies to, and interacts with, all activities pertinent to the quality of a product or service. It involves all phases from initial identification to final

satisfaction of requirements and customer expectations. These phases and activities may include the following :

- a) marketing and market research;
- b) design/specification engineering and product development;
- c) procurement;
- d) process planning and development;
- e) production;
- f) inspection, testing and examination;
- g) packaging and storage;
- h) sales and distribution;
- i) installation and operation;
- j) technical assistance and maintenance;
- k) disposal after use.

See the figure for a schematic representation of the quality loop, which is similar in concept to the quality spiral.

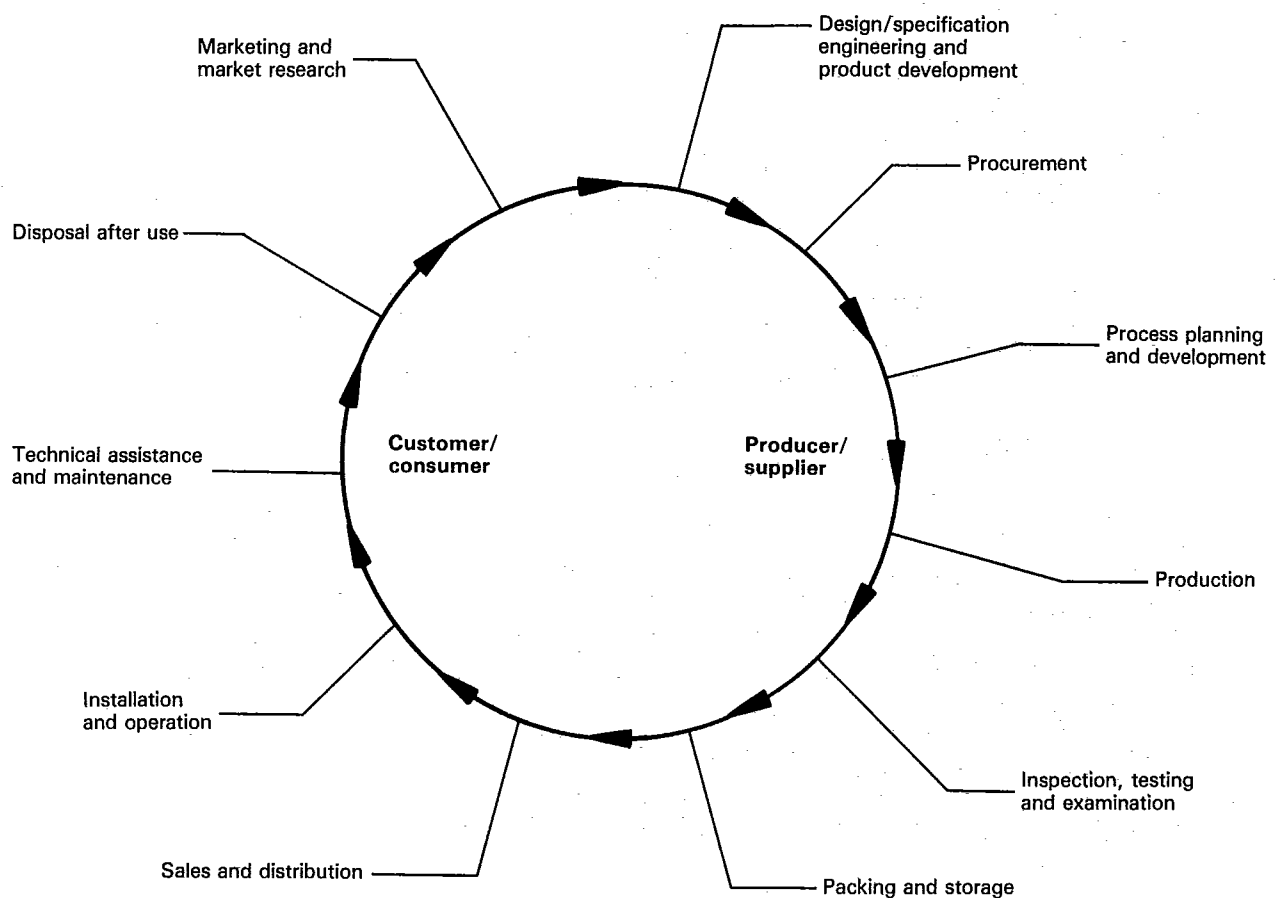


Figure — Quality loop

**5.1.2** In the context of interacting activities within a company, marketing and design should be emphasized as especially important for

- a) determining and defining customer needs, expectations and the product requirements;
- b) providing the concepts (including back-up data) for producing a product or service to defined specifications at optimum cost.

## 5.2 Structure of the quality system

### 5.2.1 General

Management is ultimately responsible for establishing the quality policy and for decisions concerning the initiation, development, implementation and maintenance of the quality system.

### 5.2.2 Quality responsibility and authority

Activities contributing to quality, whether directly or indirectly, should be identified and documented, and the following actions taken :

- a) General and specific quality responsibilities should be explicitly defined.
- b) Responsibility and authority delegated to each activity contributing to quality should be clearly established; authority and responsibility should be sufficient to attain the assigned quality objectives with the desired efficiency.
- c) Interface control and coordination measures between different activities should be defined.
- d) Management may choose to delegate the responsibility for internal quality assurance and for external quality assurance where necessary; the persons so delegated should be independent of the activities reported on.
- e) In organizing a well structured and effective quality system, emphasis should be placed on the identification of actual or potential quality problems and the initiation of remedial or preventive measures.

### 5.2.3 Organizational structure

The organizational structure pertaining to the quality management system should be clearly established within the overall management of a company. The lines of authority and communication should be defined.

### 5.2.4 Resources and personnel

Management should provide sufficient and appropriate resources essential to the implementation of quality policies and the achievement of quality objectives. These resources may include

- a) human resources and specialized skills;
- b) design and development equipment;

- c) manufacturing equipment;
- d) inspection, test and examination equipment;
- e) instrumentation and computer software.

Management should determine the level of competence, experience and training necessary to ensure the capability of personnel. (See clause 18.)

Management should identify quality factors affecting market position and objectives relative to new products, processes or services (including new technologies) in order to allocate company resources on a planned and timely basis.

Programmes and schedules covering these resources and skills should be consistent with the company's overall objectives.

### 5.2.5 Operational procedures

The quality system should be organized in such a way that adequate and continuous control is exercised over all activities affecting quality.

The management system should emphasize preventive actions that avoid occurrence of problems, while not sacrificing the ability to respond to and correct failures should they occur.

Operational procedures coordinating different activities with respect to an effective quality system should be developed, issued and maintained to implement corporate quality policies and objectives. These procedures should lay down the objectives and performance of the various activities having an impact on quality, e.g. design, development, procurement, production and sales.

All written procedures should be stated simply, unambiguously and understandably, and should indicate methods to be used and criteria to be satisfied.

## 5.3 Documentation of the system

### 5.3.1 Quality policies and procedures

All the elements, requirements and provisions adopted by a company for its quality management system should be documented in a systematic and orderly manner in the form of written policies and procedures. Such documentation should ensure a common understanding of quality policies and procedures (i.e. quality programmes/plans/manuals/records).

The quality management system should include adequate provision for the proper identification, distribution, collection and maintenance of all quality documents and records. However, care should be taken to limit documentation to the extent pertinent to the application. (See clause 17.)

### 5.3.2 Quality manual

**5.3.2.1** The typical form of the main document used in drawing up and implementing a quality system is a "Quality Manual".