

Quality systems

**Part 4. Guide to the use of
BS EN ISO 9001 ‘Model for quality
assurance in design, development,
production, installation and servicing
(Formerly BS 5750 : Part 1)’,
BS EN ISO 9002 ‘Model for quality
assurance in production, installation and
servicing (Formerly BS 5750 : Part 2)’
and BS EN ISO 9003 ‘Model for quality
assurance in final inspection and test
(Formerly BS 5750 : Part 3)’**

Committees responsible for this British Standard

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Associated Offices Technical Committee	Department of Trade and Industry (Standards Policy Unit)
Association for Services Management International	Electricity Association
Association of British Certification Bodies	Energy Industries Council
Association of British Health-Care Industries	Engineering Equipment and Materials Users' Association
Association of Consulting Engineers	Federation of Small Businesses
Association of Consulting Scientists	Federation of the Electronics Industry
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British Quality Foundation	Mercury Communications Limited
British Railways Board	Ministry of Defence
British Retail Consortium	National Accreditation Council of Certification Bodies
British Standards Society	National House-building Council
British Steel Industry	National Quality Development Support Network
British Surgical Trades Association	PERATEC Limited
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Consumers' Association	Water Services Association of England and Wales
Cranfield University	West Midlands Enterprise Board
Defence Manufacturers' Association	
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Foreword

This Part of BS 5750 has been prepared by Technical Committee QMS/22, Quality Management and Quality Assurance Procedures. It supersedes BS 5750 : Part 4 : 1990, which is withdrawn.

This Part of BS 5750 does not add any requirements to those in BS EN ISO 9001, BS EN ISO 9002 and BS EN ISO 9003. Care should be taken that the guidance given, which may suggest various methods of providing assurance, is not used in place of, or as additional requirements to, those given in BS EN ISO 9001, BS EN ISO 9002 and BS EN ISO 9003.

This new edition of BS 5750 : Part 4 has been prepared as a quick response to the demand for guidance on the 1994 editions of BS EN ISO 9001, BS EN ISO 9002 and BS EN ISO 9003. It seeks to align the guidance given with the revised requirements in BS EN ISO 9001, BS EN ISO 9002 and BS EN ISO 9003 compared to those in the 1987 editions of BS 5750 : Parts 1, 2 and 3. It is intended that a more comprehensive revision of BS 5750 : Part 4 will be undertaken at a later date.

Technical Committee ISO/TC 176 of the International Organization for Standardization (ISO) is in the process of revising ISO 9000-2 *Quality management and quality assurance standards — Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003*, to bring it into alignment with the 1994 editions of ISO 9001, ISO 9002 and ISO 9003. When a revised edition of ISO 9000-2 is published, it will be considered for a revision to this Part of BS 5750.

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

Guide

Introduction

This Part of BS 5750 has been prepared to give guidance to organizations providing product (i.e. hardware, software, service, processed materials) and that wish to ensure those organizations comply with the requirements of BS EN ISO 9001, BS EN ISO 9002 or BS EN ISO 9003. This Part of BS 5750 is not a substitute for, or a supplement to, BS EN ISO 9000-1 or BS EN ISO 9004-1, which have their own distinct relationship to BS EN ISO 9001, BS EN ISO 9002 and BS EN ISO 9003.

A major change to the 1994 editions of the ISO 9001, ISO 9002 and ISO 9003 standards (to which the BS EN ISO 9001, BS EN ISO 9002 and BS EN ISO 9003 standards are respectively identical) compared to the earlier 1987 editions, is the replacement of references to two party contractual situations by the need for suppliers to demonstrate their capability during assessment by external parties.

NOTE. Although the references to two party contractual situations have been deleted, the implication has been retained by reference in the last paragraph of the Introduction clauses to 'tailoring', i.e. the adding or deleting (of) certain quality system requirements for specific contractual situations.

This Part of BS 5750 gives amended guidance for the application of the 1994 editions of BS EN ISO 9001, BS EN ISO 9002 and BS EN ISO 9003. These standards incorporate revisions that do not alter the basic approach and structure of the 1987 editions of BS 5750 : Parts 1, 2 and 3 but, instead, enhance their clarity and usability.

Wherever possible, the 1994 editions of BS EN ISO 9001, BS EN ISO 9002 and BS EN ISO 9003 have aligned clause and subclause numbers and identical text (see annex A). Some of the clauses of BS EN ISO 9001 are not applicable to BS EN ISO 9002, or BS EN ISO 9003. Additionally, some of the clauses in BS EN ISO 9003 have less stringent requirements than those of similar clauses in BS EN ISO 9001 or BS EN ISO 9002.

Arrangement of this guide

The guidance given in this Part of BS 5750 has been arranged so that the numbers of the subclauses are the same as the numbers of the subclauses of BS EN ISO 9001 on which the guidance given always applies. Where the guidance does not also apply to BS EN ISO 9002 and BS EN ISO 9003, this is highlighted in parentheses after the titles of the subclauses in clause 4. For example, after the title of 4.4 is '(not applicable to BS EN ISO 9002 or BS EN ISO 9003)'.

There is no relation between the sub-subclause numbers of this Part of BS 5750 and the sub-subclause numbers of BS EN ISO 9001, BS EN ISO 9002 and BS EN ISO 9003. To assist in the location of guidance, an alphabetical index of the subject titles of the sub-subclauses of those standards with the appropriate page number in this Part of BS 5750 is given in annex B.

A cross-reference of quality system elements in this Part of BS 5750 and BS EN ISO 9001, BS EN ISO 9002 and BS EN ISO 9003 is given in annex A.

1 Scope

This Part of BS 5750 provides guidance on the implementation of BS EN ISO 9001, BS EN ISO 9002 and BS EN ISO 9003. It is intended to provide a better understanding of those requirements and to assist in their use, either in implementing or in evaluating a quality system. The guidance given is not intended to be exhaustive but to highlight important aspects to which attention should be given.

NOTE. Annex C gives a list of standards that are relevant to quality systems and statistical methods.

2 References

2.1 Normative references

This Part of BS 5750 incorporates, by dated or undated reference, provisions from other publications. These normative references are made at the appropriate places in the text and the cited publications are listed on the inside back cover. For dated references, only the edition cited applies; any subsequent amendments to or revisions of the cited publication apply to this Part of BS 5750 only when incorporated in the reference by amendment or revision. For undated references, the latest edition of the cited publication applies, together with any amendments.

2.2 Informative references

This Part of BS 5750 refers to other publications that provide information or guidance. Editions of these publications current at the time of issue of this standard are listed on the inside back cover, but reference should be made to the latest editions.

3 Definitions

For the purposes of this Part of BS 5750 the definitions given in BS 4778 apply together with the following.

3.1 specified requirements

Either of the following applies.

- a) Requirements prescribed by the customer and agreed by the supplier for product.
- b) Requirements prescribed by the supplier which are perceived as satisfying a market need.

3.2 product

Result of activities or processes.

NOTE 1. A product may include service, hardware, processed materials, software or a combination thereof.

NOTE 2. A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts) or a combination thereof.

For illustration, a book contains information which may be considered to be software. An author supplies the text (software) to a printer, who produces the book (hardware) from paper (a processed material), thus allowing the publisher to use shops or a mail order system (services) to supply to the customer a product which is a combination of all four product categories.

4 Guidance on quality system elements

4.1 Management responsibility

4.1.1 Quality policy

The supplier of the product is required to develop and define its policy, business objectives and commitment in a recorded statement, which is required to be relevant to its organizational goals and the expectations and needs of its customers. This statement should be formulated by the supplier's management with executive responsibility, published throughout the organization and be seen to be fully supported by the management.

All employees should be trained so that they understand the objectives of the management and the commitment required to achieve these objectives. Management should also take the necessary steps to ensure that all new employees are trained and that customers for their product are made aware, as required, of this policy.

4.1.2 Organization

4.1.2.1 Responsibility and authority

Management with executive responsibility is that person or group of persons with the necessary level of authority for making policy and setting objectives, planning their implementation and reviewing achievement.

NOTE. The term 'management with executive responsibility' provides a clear link to the highest levels of management within the supplier's organization, i.e. to those responsible for establishing its quality policy. The supplier will need to clearly identify those persons having such executive responsibility.

To achieve the policy objectives there needs to be a structured organization with established levels of responsibility, authority and inter-relationships.

In particular the personnel having the responsibility and authority to control the key elements of the quality system and processes should be identified and the job requirements defined and documented. Of these key elements the following should be included:

- a) the control and maintenance of the quality system aimed at the prevention of quality deficiencies as defined by the documentation of the organization;
- b) the control of a corrective action system that prevents the recurrence of any quality deficiencies found in the products, processes, or quality systems (of the organization);
- c) a control to ensure that corrective and preventive actions taken are effective;
- d) an assurance that management reviews the defined quality system to ensure that it remains appropriate to the business objectives.

4.1.2.2 Resources

Consideration needs to be given by the appropriate level of management, to the resources needed to carry out its policies and achieve its goals. This will involve the identification and provision of adequate resources to meet general policy requirements and to satisfy customer needs and expectations. The resources will include the provision of trained personnel to manage, perform work and carry out control and verification activities.

4.1.2.3 Management representative

Within the supplier's own organization, a management representative with delegated authority is required to be appointed for arranging and overseeing the working of the quality system. This management representative is required to be appointed by management with executive responsibility. The functions of the management representative may be totally related to quality system activities or be in conjunction with other functions and responsibilities within the organization. If the management representative has other functions to perform, there should be no conflict of interest.

The management representative should have the authority to ensure that the requirements of BS EN ISO 9001, BS EN ISO 9002 or BS EN ISO 9003 are satisfied and that compliance is maintained, together with the responsibility to ensure that they are operated throughout the organization.

The defined role should include liaison with customers on quality matters and reporting on the adequacy and effectiveness of the quality system as a basis for improvement and management review.

4.1.3 Management review

The concept of a management review of the quality system under consideration includes the following activities.

- a) The regular review of the documented policies and procedures that define the system. These are required to be reviewed at specified intervals and updated as necessary to ensure that they reflect the working methods and the organization's stated quality policy and objectives. This review should be performed in accordance with a documented procedure. Records are required to be kept of the reviews.
- b) A review of internal audit results to ensure that the defined quality system is implemented and followed as required.
- c) A review of all relevant information relating to product, process and quality system, including the authorization to commit resources where required.

The purpose of these activities is to ensure that the system is up to date, controlled and effective in both its aim and implementation.

4.2 Quality system

4.2.1 System organization

The quality system of an organization is inextricably interwoven with most of the organization's management systems. The quality system is part of the overall business management system. It is designed to ensure that the output of each part or function meets the agreed customer requirements. A customer in this context is the person, internal or external to the organization, who receives the output in question.

The organization is required to define and record its quality system by having it fully documented and recorded in a quality manual. This should be in any medium that can be retrieved for either reading or the production of hard copies.

A quality system has the following two inter-related aspects:

- a) the supplier's needs and interests;
- b) the customer's needs and expectations (see BS EN ISO 9004-1).

An organization providing a product should meet the customer's needs and expectations fully but in the most economical way. It fulfills this requirement by the planned and efficient utilization of the technological, human and material resources available to the organization.

The customer needs assurance and confidence that the supplier has the ability to provide the product consistently to the defined quality. Therefore the following are required:

- 1) a well planned and well managed quality system;
- 2) documentary evidence that this system exists and is operating as intended.

An important aspect to be recognized is that the structure of the quality system that has been developed to meet the organizational needs of individual suppliers will vary widely among and within the different sectors of industry.

The complexity of the documented procedures for process operations should be dependent on the skill levels required for performing individual work activities. Due account should be taken of this, when determining the degree of documentary evidence needed for the quality system.

4.2.2 Quality planning

The supplier needs to demonstrate that quality planning activities have been performed, and that they establish the means by which the quality policy objectives will be realized. Planning should include the application of the quality system elements, and how the requirements for product quality will be met.

This may require the following.

- a) For objectives: ensuring consistency of the objectives with the supplier's organizational goals.
- b) For managerial and operational planning: preparing the application of the quality system.
- c) For product planning: setting out in a quality plan the specific quality practices, resources and sequence of activities relevant to a particular product, project or contract.

4.2.3 Quality plan

A quality plan identifies those key elements in the product necessary to provide fitness for purpose and the means by which they are to be measured and provided.

It is emphasized that the documentation required for this purpose only needs to be as complex and extensive as the product, project or contract demands. It could be as simple as a document containing one paragraph or a drawing suitably dimensioned and inscribed or a flow chart (showing the functions from contract review of customer requirements through to product delivery).

4.2.4 Quality manual

Any planned system should be recorded and documented and should form the basis for a quality manual which becomes a description of the way the organization conducts its business.

Each quality manual format is unique to an organization, just as the quality system developed with the product or service in mind is unique. The manual contains the detailed procedures and interfaces of the operating unit which may provide a multiplicity of products or services. The manual needs to be sufficiently detailed to be used by the supplier or the customer to audit the systems in use to check that:

- a) the systems exist;
- b) they are operating;
- c) they are fit for their purpose.

The manual should contain the key elements given in BS EN ISO 9004-1 and BS EN ISO 9001, BS EN ISO 9002 or BS EN ISO 9003, as appropriate.

4.3 Contract review

In the situation where a tender, contract or order is to be established between a supplier and a customer, the key to achieving satisfaction lies in the contract review process.

Contract review is one of a supplier's primary interfaces with its customers. The documented procedures should address the review of customer requirements (whether expressed in a tender, contract, or written or verbal orders) and how the review of customer requirements is coordinated and communicated within the organization.

The importance of a complete understanding of the customer's needs cannot be overstated. This applies from initial contact, whether through tendering or receiving verbal orders, to the formulation of a contract, or processing of an order and in all subsequent stages. Where no written statement of requirement is received from the customer, it is up to the supplier to ensure that an order (statement of requirements) is understood, adequately documented, and agreed with the customer.

During contract negotiation there is a need to review the contract requirements in a systematic and defined manner to ensure clarity, comprehension, feasibility and reliability prior to the contract being finalized. This review should be conducted against prescribed stages, or steps.

The key steps to be taken should include the following:

- a) ensuring that the requirements are clearly understood and agreed by both parties and that they are then properly recorded and kept;
- b) discussions by both parties of any difference or nonconformity to the specified requirements and the recording as part of the contract documentation of the conclusions reached, together with how the differences are to be

resolved;

- c) both parties going through a defined process to ensure that they have the necessary resources, organization and facilities to conform to all the requirements in the contract.

Not only should all these steps be defined in a procedure, but as they are performed records of them should be made and kept. This process should be carried out by both parties to any contract made or proposed and should be continued until contract completion.

Amendments made to contracts or accepted orders should be reviewed and agreed. Procedures should be established to ensure that such amendments are made known to those in the supplier and customer organizations best able to put them into effect.

4.4 Design control (not applicable to BS EN ISO 9002 or BS EN ISO 9003)

The supplier's design function should be capable of taking the customer's needs and translating these, in a systematic and controlled way, into a specification which defines a product. This specification should be such that the product is producible, verifiable and controllable under the proposed production, installation, commissioning, operational conditions or servicing (see BS EN ISO 9004-1).

Where products or services are designed, this activity should be covered by the quality system. The requirements for such cover are fully documented in BS EN ISO 9004-1 and also summarized as follows for ease of reference.

- a) Organizational structure, responsibility and authority during the management of design should be clearly defined.
- b) Design project plans should include the following:
 - 1) identification of responsibility for each design and development activity;
 - 2) assignment to qualified personnel equipped with adequate resources;
 - 3) an effective communication system;
 - 4) a procedure for monitoring and control of activities assigned;
 - 5) timing of project plans;
 - 6) review of design activities;
 - 7) verification that each design stage conforms to the specified requirements;
 - 8) validation that the product design meets its intended use.
- c) During the design process the following related quality activities should be observed.
 - 1) The design specification should comply with the agreed customer requirement and should contain all the necessary information from which a design can be created.