BRITISH STANDARD

BS 5750 :
Part 4 : 1990

Quality systems

Part 4. Guide to the use of BS 5750 : Part 1 'Specification for design/development, production, installation and servicing', Part 2 'Specification for production and installation' and Part 3 'Specification for final inspection and test'

(Formerly BS 5750 : Parts 4, 5 and 6)

Systèmes qualité
Partie 4. Guide pour l'usage de BS 5750 : Partie 1 'Conception/développement, production, installation et soutien après vente - Spécifications', Partie 2 'Production et installation' et Partie 3 'Contrôle et essais finals - Spécifications'

Qualitätssicherungssysteme
Teil 4. Anleitung zur Verwendung von BS 5750 : Teil 1 'Qualitätssicherungs - Nachweisstufe für Entwicklung und Konstruktion, Produktion, Montage und Kundendienst', Teil 2 'Qualitätssicherungs - Nachweisstufe für Produktion und Montage' und Teil 3 'Qualitätssicherungs - Nachweisstufe für Endprüfungen'

BSI STANDARDS

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British Shipbuilders
British Telecommunications plc
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Continued on inside back cover

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Foreword

This combined Part of BS 5750 has been prepared under the direction of the Quality, Management and Statistics Standards Policy Committee.

This Part of BS 5750 does not add any requirements to those in BS 5750 : Parts 1, 2 and 3. 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 5750 : Parts 1, 2 and 3.

This Part of BS 5750 supersedes BS 5750 : Part 4 : 1981, Part 5 : 1981 and Part 6 : 1981 which were published separately and which are withdrawn.

The reproduction of each requirement of BS 5750 : Part 1, Part 2 or Part 3 before guidance is given has been omitted.

Technical Committee ISO/TC 176 of the International Organization for Standardization (ISO) is preparing a draft guide to ISO 9001, ISO 9002 and ISO 9003 (implemented as BS 5750 : Parts 1, 2 and 3 respectively) which, when published, will be considered as a revision of this Part of BS 5750.

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

Guide

0 Introduction

This combined Part of BS 5750 has been prepared to give guidance to organizations providing a product or service and wishing to ensure that they comply with BS 5750 : Parts 1, 2, or 3. The guide needs to be read in conjunction with the Part of BS 5750 with which compliance is sought. This Part of BS 5750 is not a substitute for, or supplement to, BS 5750 : Sections 0.1 and 0.2, which have their own distinct relationship to BS 5750 : Parts 1, 2 and 3.

It is recognized that the origins of BS 5750 : Parts 1, 2 and 3 lay in the procurement of materials and products and that to a large extent the 1987 editions still reflect this today. For this reason this Part of BS 5750 has dealt with products and services and attempts to redress some of the unintended residual ambiguity of BS 5750 : Parts 1, 2 and 3. The aim in preparing this Part of BS 5750 is primarily to assist those managing a business to achieve the requirements of BS 5750 : Parts 1, 2 and 3. It attempts to explain what has to be done and is not a guide for quality assessors only.

NOTE. See appendix A.

1 Scope

This combined Part of BS 5750 provides guidance on the implementation of BS 5750 : Parts 1, 2 and 3. It is intended to provide a better understanding of those specifications 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 1. Particular care should be taken when applying the guidance to some clauses in BS 5750 : Part 2 and to all clauses in BS 5750 : Part 3 where the requirements of the clauses are less stringent than in BS 5750 : Part 1 (see appendix B).

NOTE 2. The titles of the publications referred to in this standard are listed on the inside back cover. Appendix C gives a list of British Standards that are relevant to quality systems and statistical methods.

2 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 5750 : Part 1 on which the guidance given always applies. Some of the guidance also applies to the subclauses of BS 5750 : Parts 2 and 3 many of which do not bear the same subclause number as Part 1. The appropriate subclause number(s) of Parts 1, 2 and 3 are given in parentheses after the titles of the subclauses in clause 4. For example, after the title of **4.8** is '(covers **4.8** of Part 1, **4.7** of Part 2, and **4.4** of Part 3)'.

A cross-reference of quality system elements in this Part of BS 5750 and BS 5750 : Parts 1, 2 and 3 is given in appendix A.

There is no relation between the sub-subclause numbers of this Part of BS 5750 and sub-subclause the numbers of BS 5750 : Parts 1, 2 and 3. To assist in the location of guidance an alphabetical index of the subject titles of the subclauses and sub-subclauses of those Parts with the appropriate page number in this Part of BS 5750 is given in appendix B.

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 purchaser and agreed by the supplier in a contract for products or services.

(b) Requirements prescribed by the supplier which are perceived as satisfying a market need.

3.2 product (or service)

Output that an organization supplies to a user.

4 Guidance on quality system elements

4.1 Management responsibility (covers 4.1 of Parts 1, 2 and 3)

4.1.1 *Quality policy*

The supplier of the product or service should develop and define its total policy, business objectives and commitment in a recorded statement. This statement should be published throughout the organization and be seen to be supported by 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 or service are made aware, as required, of this policy.

4.1.2 *Responsibility and authority*

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. 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 services, products or quality systems (of the organization);

(c) a control to ensure that corrective actions taken are effective;

(d) an assurance that management reviews the defined quality system to ensure that it remains appropriate to the business objectives.

4.1.3 *Verification, resources and personnel*

Within the organization consideration should be given to the verification tasks required to deliver the product or service in accordance with the quality objectives.

In any type of organization these verification activities need to include inspection, testing of products, checking the outputs of services given by internal departments or functional groups and testing the satisfaction of all customers whether internal or external.

Design reviews and quality audits need to be performed by people independent of those producing the particular output under review.

4.1.4 *Management representative*

Within the organization there should be appointed a management representative whose function, either totally or in conjunction with other functions and responsibilities, is to maintain and have responsibility for the quality system. If the management representative has other functions to perform, there should be no conflict of interests.

The representative should have the authority to ensure that BS 5750 : Part 1, Part 2 or Part 3 are complied with and that compliance is maintained, together with the responsibility to ensure that they are implemented and operated throughout the organization.

4.1.5 *Management review*

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

(a) The regular review of the documented policies and procedures that define the system. These should be reviewed at a specified interval and updated as necessary to ensure that they reflect the working methods and the business objectives of the organization. This review should be performed in accordance with a documented procedure and records should be kept of the reviews and changes made.

(b) A review of internal audit results to ensure that the defined quality system is implemented and followed as required. The purpose of these two activities is to ensure that the system is up to date, controlled and effective in both its aim and implementation.

4.2 Quality system (covers 4.2 of Parts 1, 2 and 3)

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 total 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 should define and record its quality system by having it fully documented and recorded. This should be in any form of legible record 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 5750 : Section 0.2).

An organization providing a product or service needs to 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 or service consistently to the defined quality. Therefore the following things are required:

(1) a well planned and well managed quality system;

(2) documentary evidence that this system exists and is operating as intended.

4.2.2 *Quality plan*

In both product and service requirements the use of a quality plan is an important tool. This identifies those key elements in the product or service 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 project, product or service demands. It could be as simple as a document containing one paragraph or a drawing suitably dimensioned and inscribed.

4.2.3 *Quality manual*

The extent and detailed content of quality systems are recorded in other standards publications such as BS 4891 and BS 5750 : Section 0.2 and the minimum requirements are dealt with in BS 5750 : Parts 1, 2 and 3.

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 the company 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 5750 : Section 0.2 and Parts 1, 2 or 3, as appropriate.

4.3 Contract review (covers 4.3 of Parts 1 and 2)

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

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 though 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.

4.4 Design control (covers 4.4 of Part 1)

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 or service. This specification should be such that the product or service is producable, verifiable and controllable under the proposed production, installation, commissioning or operational conditions (see BS 5750 : Section 0.2).

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 5750 : Section 0.2 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 the design conforms to the agreed requirements.

(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. If during the design process the need to deviate from the specification arises, permission to do so should be sought from the originators of the specification and any changes permitted should be recorded.

NOTE. Very few design specifications (design briefs) are complete and unambiguous at the first writing. There is a need for development of the specifications and refinement of the detailed requirements which frequently can only take place during the design process.

(2) The design specification should take into account the problems identified in a full assessment of the hazards associated with the product and include statutory regulations relating to its use, i.e. safety, environmental, product liability, etc.

(3) During the process of design of the product or service, the acceptance criteria with respect to its required performance should be continually evaluated and means for verification should be provided.

NOTE. Verification can be carried out as measurement of specific dimensions such as strength, speed and heat which are required during the performance (use) of a product. The output of a service or process may well be capable of measurement, e.g. by customer reaction (feedback), pilot studies and in-process checks, in the same way as a product is measured. Thought should be given to measurement of, and checks to, the process and service as part of the design process.

(4) It is likely, particularly with complex product or service design, that changes will take place before the design is complete. It is important that a procedure to document and record any changes which are authorized is installed and maintained. Such a procedure should make provision for all aspects of any projected change to be considered.

Before permitting a change the following questions may be useful.

(i) Does the product or service still conform to the design specification?

(ii) Is the fitness for purpose affected?

(iii) Are changes to the specification possible in order to accommodate the change?

(iv) Are associated parts of the product or system affected by the change?

(v) Is there a need for further interface design (i.e. physical contact with other components in a product or the interaction of two or more finite procedures in a system or service)?

(vi) Does the change create problems in manufacture, installation or use which may affect the plan.

(vii) Does the product or service still remain verifiable?

(5) Design verification should be an ongoing activity punctuated by specific and formal design reviews. Design reviews should be planned to take place throughout the design process for the purpose of ensuring that the objectives set out in the design specification continue to be achieved. It is through this formal design review that changes to the specification can be sought and authorized when the requirements adversely affect the quality objectives of the customer and/or supplier.

4.5 Document control (covers 4.5 of Part 1, 4.4 of Part 2 and 4.3 of Part 3)

All quality documentation should be controlled through a formal and defined system that indicates the format of the documentation, how and by whom it is reviewed and approved prior to issue and the method of its review and updating.

Changes and updates to the documentation have to be controlled and changes have to be indicated to the users. A system for the control of documentation should be maintained to preclude the use of unauthorized documents e.g. out-of-date issues, drawings, standards or process instructions.

Some quality data need to be recorded and the methods of doing this should be built into a total quality documentation system.

The key to effective quality documentation is ensuring that it is brief while covering the essential points. While a small organization's system should cover the same elements as that of a multinational organization, its documentation is likely to be less owing to the fewer interfaces and shorter lines of communication.

It is essential that procedures reflect the actual working practices and business needs of the organization.

Examples of documentation types and amplification of the requirements are given in clause **17** of BS 5750 : Section 0.2 : 1987.

4.6 Purchasing (covers 4.6 of Part 1 and 4.5 of Part 2)

4.6.1 ***General***

In the procurement of material or external services, whether for inclusion in the product or service or in support of activities which form part of the supplier's quality system, e.g. calibration services or specialist inspection or test activities, the supplier should ensure that such material or service is of the quality specified and that conformity can be assured.

4.6.2 ***Assessment of subcontractors***

In developing a system to ensure the conformance of purchased materials or services the supplier should establish that all subcontractors have the capability of supplying materials or services of the required quality.

To achieve this knowledge it is necessary for the supplier to operate a formal system to assess the capability of his subcontractors. The extent of assessment varies according to the importance to the supplier of the material being procured.

An assessment may vary from a comprehensive audit of the subcontractor's quality system to the acceptance of an assessment and approval by

reference to historical data, e.g. records of past performance, or certified products and quality system registration schemes. In any event the supplier should be able to demonstrate that formal consideration was given to the extent of the assessment required and that documentary evidence regarding the selection of a subcontractor was based on a sufficiently structured appraisal appropriate to the product being procured.

The supplier should be able to demonstrate that he continually reassesses subcontractors on the basis of performance during subcontracts and takes due account of such information when placing future subcontracts.

4.6.3 *Purchasing data*

When placing orders for material or services it is necessary that the supplier follows a formal procedure to ensure that all the necessary information is communicated to the subcontractor. He should identify and include all information and specifications necessary to conform to the customer's requirements. Lines of communication should be established to ensure that changes in orders or specifications are dealt with correctly and that these are implemented.

It is important to identify at a contract review, or prior to an order being placed, whether the customer is entitled to verify the conformity of subcontract material at source or otherwise.

In determining the level of verification of the subcontractor's activities the supplier should not depend on his customer's involvement, where this occurs, unless otherwise and specifically agreed.

4.7 Purchaser supplied product (covers 4.7 of Part 1 and 4.6 of Part 2)

When materials, commonly described as 'free issue', are provided by the customer to the supplier the onus for their conformity to specified requirements is that of the customer. However, the supplier should not knowingly incorporate nonconforming parts into the production or service supplied to the customer.

The supplier's system should include the provision for verification, proper storage and maintenance of such materials supplied.

There should also be a formalized method for dealing with losses, damage or other problems discovered with such material.

4.8 Product identification and traceability (covers 4.8 of Part 1, 4.7 of Part 2 and 4.4 of Part 3)

A fundamental in the achievement of good product quality is to have traceability, where appropriate, throughout the procurement and production phases of materials, parts, products and services (see **4.9**).

Traceability may be necessary in order that a problem arising at any stage in the supply of a product or service can be analysed and the root cause established. Failure to trace the root cause results in preventive corrective action to eliminate the problem being speculative and ineffective.

Product identification can be useful in preventing errors. For example, on visually identical parts with functionally different characteristics, such as 50 Hz and 60 Hz motors where colour coding would be used to advantage.

In the service industries or in servicing there are cases where traceability transfers from the product or component parts to the personnel involved at each stage of the design and service delivery process. In practice there are cases where an intermixing of both types of traceability is necessary.

4.9 Process control (covers 4.9 of Part 1 and 4.8 of Part 2)

4.9.1 *General*

Whether the process is concerned with manufacturing a product or the procedures by which a service is performed, to exercise control necessitates careful planning of performance standards and process limits. Those features closely affecting the quality of the product or service can be identified from the quality plan where this exists.

Written procedures or work instructions at each stage of the process should be employed as useful tools necessary for the successful control of the enterprise. Inadequate or non-existent work instructions may be a frequent cause of poor quality performance. Such instructions should be within the document control procedures. (see **4.5**).

Material control and traceability at varying levels are necessary for product manufacturing processes. All materials and parts should conform to appropriate specifications and quality standards before being introduced into production. However, in determining the amount of test and/or inspection necessary, consideration should be given to the cost impact and the effect that substandard material quality has on the production process.

Materials should be appropriately stored, segregated, handled and protected during production to maintain their suitability. Special consideration should be given to shelf-life and deterioration control.

Where in-plant traceability of material is important to quality, appropriate identification should be maintained throughout the production process to ensure traceability to original material identification and quality status (see also **11.2** of BS 5750 : Section 0.2 : 1987.

Process control in the performance of a service should be maintained in a similar way. Identification of discrete stages should be observed so that operations are not omitted. Verification and check stages of the service delivery process should be planned. Materials used during the service delivery process should conform to the appropriate specifications and standards. Materials used should be properly stored taking into consideration the declared shelf-life and/or storage requirements.

4.9.2 ***Special processes***

Special consideration should be given to production processes in which control is particularly important to product quality. Such special consideration may be required for product characteristics that are not easily or economically measured, for special skills required in their operation or maintenance or for a product or process the results of which can not be fully verified by subsequent inspection and test. More frequent verification of special processes should be made to keep a check on the following:

(a) the accuracy and variability of equipment used to make or measure the product, including settings and adjustments;

(b) the skill, capability and knowledge of operators to conform to quality requirements;

(c) the special environments, time, temperature or other factors affecting quality;

(d) the certification records maintained for personnel, processes and equipment, as appropriate.

The performance of services may require planned controls during the execution. Consideration should also be given to the levels of skill required and to in-process checks to ensure that the delivered service conforms to the quality requirement.

NOTE. See **11.4** of BS 5750 : Section 0.2 : 1987.

4.10 Inspection and testing (covers 4.10 of Part 1, 4.9 of Part 2 and 4.5 of Part 3)

The quality plan or documented procedures should include the requirements for inspection and/or testing and release of product or service.

When considering the overall process of producing a product or service there are three phases where inspection/verification and/or testing may take place and these are as follows:

(a) on receipt of any purchased or subcontracted items or service i.e. as a customer;

(b) during the manufacturing or service delivery process;

(c) prior to final release to the customer.

Phase (a) might be interpreted as being 'receiving inspection or test'. In many cases, effective preventive techniques may be employed, and in these cases the need for a receiving inspection function is not necessarily a requirement.

During product manufacture or service delivery (phase (b)) the specified in-process checks and tests should be performed and recorded prior to the completion of the product or service. Criteria for the release of products or services to further production stages should be defined.

Similarly, before final delivery the required tests or inspections should be performed and the results recorded.

It is important that the last phase in the process includes a clear final release stage during which a properly authorized person checks the results against the release criteria and ensures that the results are correctly recorded as required.

Records of the results should be kept in order to maintain traceability into the field and customer usage.

4.11 Inspection, measuring and test equipment (covers 4.11 of Part 1, 4.10 of Part 2 and 4.6 of Part 3)

For any product or service, equipment used to check the conformity to specified and end-user requirements during or after the production phase, needs control and calibration.

The more practical needs for such systems are specified in clause **13** of BS 5750 : Section 0.2: 1987 and in greater detail in BS 5781 : Parts 1 and 2.

Appendix D relates the clauses in BS 5750 : Part 1: 1987 to those in BS 5781 : Part 1 : 1981.

The control of measurement consistency needs to be applied to less tangible measures such as auditing, measuring customer satisfaction by polling or test shopping, as well as to the physical tools and equipment used in any production process.

The key to complying with this requirement of the standard lies in understanding that a procedure is required throughout all design, construction manufacture and delivery processes.

4.12 Inspection and test status (covers 4.12 of Part 1, 4.11 of Part 2 and 4.7 of Part 3)

There should be a way of identifying the inspection and test status of products or services at all times during the design to delivery stages.

The way of achieving this may vary according to the form of the product or service. Whatever method is chosen, it should be possible to establish quickly and clearly the inspection status of products or services at any stage and, in particular, identify those which do not conform to specified requirements.

Inspection and test records should identify the inspection authority or individual responsible for

verifying the conformance to specification of products, at whatever point in the production process the inspection and testing take place. This allows traceability and analysis where problems are discovered in later stages of use.

The system should define who has the authority for the final release of the product or service to customer.

4.13 Control of nonconforming product (covers 4.13 of Part 1, 4.12 of Part 2 and 4.8 of Part 3)

As production or service delivery processes may yield suspect or defective items, methods for preventing further processing, delivery or installation of such items are necessary. The method of identifying a nonconforming item depends on the nature of the product or service. However, it should be such as to ensure that the identification of nonconformity should stay in place until a decision regarding further action is made. This action might be to scrap, to use under concession from the appropriate authority, to rework or to repair. Repaired or reworked items should be subjected to reinspection. (It may be necessary that this reinspection includes all prior inspection stages.)

The supplier should ensure that his procedures provide instructions for the segregation and identification of a nonconforming product, who is responsible for doing and authorizing this, and how it is to be done. The procedures should also provide instructions for the disposition of the nonconforming product and identify who has the authority for making these decisions. The supplier should record, when known, information on nonconforming items such as the cause and the corrective action taken. The records should include the following:

(a) the material or product identification;

(b) the stage in process;

(c) the quantity involved;

(d) the nature and extent of the nonconformance;

(e) the assessment and disposition decision;

(f) the action taken to resolve the root cause of the problem;

(g) the distribution of copies for corrective action and records;

(h) the controlling authority.

The system of control for a nonconforming product should ensure that in all cases information concerning such items is fed back to all appropriate personnel, so that action is taken to identify and correct the cause of the nonconformance and prevent recurrence. These records form a good measure of the effectiveness of the system and their analysis should be used as such.

Requests by suppliers for concessions or changes in specification should be processed in accordance with documented procedures and agreed with the purchaser. The supplier should ensure that his requests are clear and accurate. He should provide any additional information, comment or recommendation that might assist the purchaser to arrive at his decision. Concessions requested by subcontractors should be agreed by the supplier. The purchaser's agreement to these concessions may form part of the contract with the supplier.

The foregoing guidance is equally applicable to a product or service purchased from subcontractors that is found to depart from the specified requirements.

4.14 Corrective action (covers 4.14 of Part 1 and 4.13 of Part 2)

A quality system should contain a defined method to eliminate the causes of nonconforming product or service by initiating appropriate corrective action designed to remove the root cause of each problem. (Clause **15** of BS 5750 : Section 0.2 : 1987 deals comprehensively with this subject.) The following may be appropriate.

(a) *Immediate corrective action.* Direct actions taken to resolve the causes of nonconforming products or services that may be implemented during any stage of the system/operation. The corrective actions taken should be recorded and maintained to ensure effectiveness. Corrective action implemented following customer complaints should be fully recorded and documented. These actions should follow documented procedures which identify who is responsible for initiating corrective action.

(b) *Long-term corrective action.* Records relating to the performance of products or services in the field including customer complaints should be analysed regularly to detect any trends and then to identify problems and determine the causes and action necessary to eliminate them.

4.15 Handling, storage, packaging and delivery (covers 4.15 of Part 1, 4.14 of Part 2 and 4.9 of Part 3)

The handling of materials during the manufacture of a product or the performance of a service should be properly planned and controls should be set up to ensure that the plans can be monitored. There should be a documented procedure for the handling of incoming materials, materials in process and completed or supplied goods.

The method of handling and storage of materials should provide for the correct pallets, containers, conveyors and vehicles to prevent damage due to

vibration, shock, abrasion, corrosion, temperature or any other conditions occurring during handling and storage. Items in storage should be checked periodically to detect possible deterioration.

The marking and labelling of materials should be legible and durable and conform to the specified requirements. Identification should remain intact from the time of initial receipt to delivery to the final destination. Marking should be adequate to identify a particular product in the event that a recall or special inspection becomes necessary.

The methods of cleaning and preserving and instructions on packing; including moisture elimination, cushioning, blocking and crating, should be documented as appropriate.

Instructional documents should contribute to proper installations and should include provisions which preclude improper installation or factors degrading the quality, reliability, safety and performance of any product or material.

Items with limited shelf-life or requiring special protection during transport or storage should be identified and procedures should be maintained to ensure that deteriorated items are not put into use. Provision for protection of the quality of product is important during all phases of delivery. Shelf life commences during manufacture and may be influenced by the quality of storage.

For a service the recording, labelling and identification of its delivery or completion is an important factor in providing evidence that the service has been performed, together with a date of delivery or reminder of the likely period following which a further service may be required.

4.16 Quality records (covers 4.16 of Part 1, 4.15 of Part 2 and 4.10 of Part 3)

Records are the objective evidence of the operation of a quality system at all its stages. Therefore they are required to be kept to prove the effectiveness of the implemented system.

The records may be maintained in any system which allows them to be:

(a) clearly identified as to the product or service applicable;

(b) indexed and readily retrievable;

(c) stored in a manner to prevent deterioration, damage or loss;

(d) retained for periods agreed contractually, or as defined within the quality system.

The type and extent of records kept depends on the processes and products involved but they should be designed to demonstrate the achievement of required quality and they include pertinent subcontractor quality records. They almost certainly include such data as the following:

(1) the audit of the system;

(2) the calibration of test and measuring equipment;

(3) the analyses of process control data;

(4) any corrective actions;

(5) any concessions;

(6) the product test data.

4.17 Internal quality audits (covers 4.17 of Part 1 and 4.16 of Part 2)

In order to ensure that the defined quality system is being operated correctly and effectively it is necessary to carry out planned and documented checks on the implementation and operation of the system. These checks are designed to ensure the following:

(a) that the quality system documentation adequately defines the needs of the business;

(b) that the documented procedures are practical, understood and followed;

(c) that the training is adequate (see **4.18**).

The timing and frequency of audits varies depending on the importance of a particular part of the system but should be predetermined and recorded. The audits should be carried out by responsible persons independent of the activity being audited. It is useful to have an audit programme spanning a set period. This may change according to experience and circumstances of a particular operation. The results of audits should be documented and the records should indicate the following:

(1) the deficiencies found;

(2) the corrective action required;

(3) the time agreed for corrective action to be carried out;

(4) the person responsible for carrying out the corrective action.

The persons conducting audits should be properly trained to carry out the task objectively and effectively (see also BS 7229).

4.18 Training (covers 4.18 of Part 1, 4.17 of Part 2 and 4.11 of Part 3)

The training both by specific training to perform assigned tasks and general training to heighten quality awareness and to mould attitudes of all personnel in an organization is central to the achievement of quality. The comprehensiveness of such training varies with the complexity of the organization. The following steps should be taken:

(a) identification of the way in which tasks and operations influence quality in total;

(b) identification of the individuals training needs against those required for satisfactory performance of the task;

(c) planning and carrying out appropriate specific training;

(d) planning and organizing general quality awareness programmes;

(e) recording training and achievement in an easily retrievable form so that records can be updated and gaps in training can be readily identified.

4.19 Servicing (covers 4.19 of Part 1)

This requirement of the standard applies mainly to manufactured products that are designed so that their durability depends on regular maintenance in certain specific areas. Such maintenance is sometimes known as 'after sales service'. In this respect the following activities are relevant.

(a) Special-purpose tools or equipment for handling and servicing products during or after installation should have their design and function validated, as for any new product.

(b) Measuring and test equipment used in field installation and tests should be controlled.

(c) Instructions for use dealing with the assembly and installation, commissioning, operation, spares or parts lists and servicing of any product should be comprehensive and supplied in a timely manner. The suitability of instructions for the intended reader should be verified.

(d) Assurance should be provided for an adequate, logistic back-up, to include technical advice, spares or parts supply and competent servicing. Responsibility should be clearly assigned and agreed among suppliers, distributors and users.

(e) Servicing personnel should be properly trained to carry out the task required.

Servicing activities, whether carried out by the manufacturer of the product or by a separate agent, need to be properly designed, planned and implemented.

4.20 Statistical techniques (covers 4.20 of Part 1, 4.18 of Part 2 and 4.12 of Part 3)

Statistical methods are a very powerful tool when used correctly within the total quality process. They should be selected with care to suit the application required and to produce the necessary objective.

The use of statistical methods can be beneficial in most aspects of data collection, analysis and application. They assist in making best use of the available data, to gain a better understanding of customer requirements and expectations, in process control, in defect avoidance, in problem analysis, in finding root causes, process limits, forecasting, verification, measurement or assessment of quality.

As with all such tools, statistical methods have limitations and can only achieve their designed aims when used in the correct way and for the designed objectives.

Selection should be made wherever possible from recognized published techniques or, if not, it is essential that the validity of the tool in use has audit traceability to base statistical theory. Applications include the following:

(a) market analysis;

(b) product design;

(c) reliability specification and longevity/durability prediction;

(d) process control/process capability studies;

(e) determination of quality levels/inspection plans;

(f) data analysis/performance assessment/defect analysis.

Statistical techniques include the following:

(1) design of experiments/factorial analysis;

(2) analysis of variance/regression analysis;

(3) safety evaluation/risk analysis;

(4) tests of significance;

(5) quality control charts/cusum techniques;

(6) statistical sampling inspection.

NOTE. See BS 5750 : Sections 0.1 and 0.2 and Parts 1, 2 and 3.

Appendices

Appendix A. Cross-reference of quality system elements in this Part of BS 5750 and BS 5750 : Parts 1, 2 and 3

Table 1 provides a cross-reference of quality system elements in this Part of BS 5750 and BS 5750 : Parts 1, 2 and 3.

Table 1. Cross-reference of quality system elements in this Part of BS 5750 and BS 5750 : Parts 1, 2 and 3

Subclause numbers in this Part of BS 5750	Title	Corresponding subclause numbers		
		BS 5750 : Part 1 (ISO 9001/EN 29001[1])	BS 5750 : Part 2 (ISO 9002/EN 29002)	BS 5750 : Part 3 (ISO 9003/EN 29003)
4.1	Management responsibility	**4.1**[2]	**4.1**[3]	**4.1**[4]
4.2	Quality system	**4.2**[2]	**4.2**[2]	**4.2**[3]
4.3	Contract review	**4.3**[2]	**4.3**[2]	[5]
4.4	Design control	**4.4**[2]	[5]	[5]
4.5	Document control	**4.5**[2]	**4.4**[2]	**4.3**[3]
4.6	Purchasing	**4.6**[2]	**4.5**[2]	[5]
4.7	Purchaser supplied product	**4.7**[2]	**4.6**[2]	[5]
4.8	Product identification and traceability	**4.8**[2]	**4.7**[2]	**4.4**[3]
4.9	Process control	**4.9**[2]	**4.8**[2]	[5]
4.10	Inspection and testing	**4.10**[2]	**4.9**[2]	**4.5**[3]
4.11	Inspection, measuring and test equipment	**4.11**[2]	**4.10**[2]	**4.6**[3]
4.12	Inspection and test status	**4.12**[2]	**4.11**[2]	**4.7**[3]
4.13	Control of nonconforming product	**4.13**[2]	**4.12**[2]	**4.8**[3]
4.14	Corrective action	**4.14**[2]	**4.13**[2]	[5]
4.15	Handling, storage, packaging and delivery	**4.15**[2]	**4.14**[2]	**4.9**[3]
4.16	Quality records	**4.16**[2]	**4.15**[2]	**4.10**[3]
4.17	Internal quality audits	**4.17**	**4.16**[2]	[5]
4.18	Training	**4.18**[2]	4.17[3]	**4.11**[4]
4.19	Servicing	**4.19**[2]	[5]	[5]
4.20	Statistical techniques	**4.20**[2]	**4.18**[2]	**4.12**[3]

[1] EN = European Standard.

[2] Full requirement.

[3] Less stringent than BS 5750 : Part 1.

[4] Less stringent than BS 5750 : Part 2.

[5] Element not present.

Appendix B. Alphabetical index of the titles of the subclauses and sub-subclauses of BS 5750 : Parts 1, 2 and 3 and the page reference in this Part of BS 5750

Subject in BS 5750 : Parts 1, 2 and 3	Page in this Part of BS 5750
Activity assignment	5
Assessment of subcontractors	6
Contract review	5
Control of nonconforming product	9
Corrective action	9
Design changes	5
Design control	5
Design development and planning	5
Design input	5
Design verification	6
Document approval and issue	6
Document changes/modification	6
Document control	6
Final inspection and testing	8
Handling, storage, packaging and delivery	9
Inspection and test records	8
Inspection and test status	8
Inspection and testing	8
Inspection, measuring and test equipment	8
Internal quality audits	10
Management representative	4
Management responsibility	3
Management review	4
Nonconformity review and disposition	9
Organizational and technical interfaces	4
Process control	7
Product identification	7
Product identification and traceability	7
Purchaser supplied product	7
Purchasing	6
Purchasing data	7
Quality manual	5
Quality plan	4
Quality policy	3
Quality records	10
Quality system	4
Receiving inspection and testing	8
Responsibility and authority	3
Servicing	11
Special processes	3
Statistical techniques	11
Training	10
Verification of purchased product	8
Verification resources and personnel	4

Appendix C. British Standards relevant to quality systems and statistical methods

The following British Standards are relevant to quality systems and statistical methods.

BS 600 The application of statistical methods to industrial standardization and quality control

BS 2564 Control chart technique when manufacturing to a specifcation, with special reference to articles machined to dimensional tolerances

BS 2846 Guide to statistical interpretation of data

BS 4891 A guide to quality assurance

BS 5700 Guide to process control using quality control chart methods and cusum techniques

BS 5701 Guide to number-defective charts for quality control

BS 5703 Guide to data analysis and quality control using cusum techniques

Part 1. Introduction to cusum charting

Part 2. Decision rules and statistical tests for cusum charts and tabulations

Part 3. Cusum methods for process/quality control by measurement

Part 4. Cusums for counted/attributes data

BS 5760 Reliability of constructed or manufactured products, systems, equipments and components

Part 0. Introductory guide to reliability

Part 1. Guide to reliability and maintainability programme management

Part 2. Guide to the assessment of reliability

Part 3. Guide to reliability: examples

Part 4. Guide to specification clauses relating to the achievement and development of reliability in new and existing items

BS 5781 Measurement and calibration systems

Part 1. Specification for system requirements

Part 2. Guide to the use of BS 5781 : Part 1 'Specification of system requirements'

BS 6000 Guide to the use of BS 6001, sampling procedure and tables for inspection by attributes

BS 6001 Sampling procedures for inspection by attributes

Part 1. Specification for sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection

Part 2. Specification for sampling plans indexed by limiting quality (LQ) for isolated lot inspection

Part 3. Specification for skip-lot procedures

BS 6002 Specification for sampling procedures and charts for inspection by variables for percent defective

BS 7229 Guide to quality systems auditing

Appendix D. Cross-reference of clauses in BS 5750 : Part 1 : 1987 relating to calibration and clauses in BS 5781 : Part 2 : 1981 that give appropriate guidance

Table 2 cross-references those clauses in BS 5750 : Part 1 : 1987 relating to calibration with those clauses in BS 5781 : Part 2 : 1981 that give appropriate guidance.

Table 2. Cross-reference of clauses in BS 5750 : Part 1 : 1987 relating to calibration and clauses in BS 5781 : Part 2 : 1981 that give appropriate guidance

Clause in BS 5750 : Part 1 : 1987	Subject	Clause in BS 5781 : Part 2 : 1981 that gives appropriate guidance	Subject
4.1.3	Management review	**4.2.2**	Periodic review of the calibration system
4.6.2	Assessment of subcontractors	**4.11.2**	Subcontractors
4.6.4	Verification of purchased product	**4.16.2**	Evaluation of systems
4.11	Inspection, measuring and test equipment	**4.1.2**	Calibration system
		4.14.2	Cumulative effect of errors
		4.4.2	Measurement limits
4.11 (a)	Selection of equipment	**4.3.2**	Planning
4.11 (b)	Identification of equipment	**4.13.2**	Traceability
4.11 (c)	Establishment of procedures	**4.5.2**	Documented calibration procedures
		4.10.2	Invalidation of calibration
4.11 (d)	Accuracy and precision requirements	**4.3.2**	Planning
4.11 (e)	Indication of calibration status	**4.7.2**	Calibration labelling
4.11 (f)	Maintenance of records	**4.6.2**	Records
4.11 (g)	Equipment out of calibration	**4.10.2**	Invalidation of calibration
4.11 (h)	Environmental conditions	**4.15.2**	Environmental control
4.11 (i)	Care of equipment	**4.12.2**	Storage and handling
4.11 (j)	Safeguard of integrity	**4.8.2**	Sealing for integrity
4.11	General	**4.9.2**	Intervals of calibration
4.18	Training	**4.17.2**	Training

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Publications referred to

BS 4778	Quality vocabulary Part 1 International terms Part 2 National terms
BS 4891	A guide to quality assurance
BS 5750	Quality systems Part 0 Principal concepts and applications Section 0.1 Guide to selection and use Section 0.2 Guide to quality management and quality system elements Part 1[1] Specification for design/development, production, installation and servicing Part 2[2] Specification for production and installation Part 3[3] Specification for final inspection and test
ISO 9001[1]	Quality systems - Model for quality assurance in design/development, production, installation and servicing
ISO 9002[2]	Quality systems - Model for quality assurance in production and installation
ISO 9003[3]	Quality systems - Model for quality assurance in final inspection and test

Continued from inside front cover

The folowing bodies were also represented in the drafting of the standard, through subcommittees and panels:

Association of Consulting Engineers
Association of Consulting Scientists
British Cement Association
British Coal Corporation
British Gas plc
British Industrial Fasteners Federation
British Maritime Technology
British Non-ferrous Metals Federation
British Nuclear Forum
British Nuclear Fuels
British Steel Industry
British Welded Steel Tube Association
Business Equipment and Information Technology Association
Cable and Wireless plc
Chartered Institute of Management Accountants
Department of Trade and Industry (National Physical Laboratory)
Engineering Equipment and Materials Users Association
Guildford County College and Technology
Institute of Maintenance and Building Management
Institute of Purchasing and Supply
London Regional Transport
National Association of Plumbing, Heating and Mechanical Services Contractors
PIRA
Post Office
Power Generation Contractors Association (BEAMA) Ltd
Rotating Electrical Machines Association (BEAMA) Ltd
Society of Motor Manufacturers and Traders Ltd
Solvents Industry Association Ltd
Steel Casting Research and Trade Association
Transmission and Distribution Association (BEAMA) Ltd

[1] Identical to EN 29001
[2] Identical to EN 29002
[3] Identical to EN 29003

BS 5750 :
Part 4 : 1990

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