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British Standard Guide to

Quality systems auditing

Guide pour l'audit des systèmes de qualité

Leitfaden für Qualitätsaudits

Foreword

This British Standard has been prepared under the direction of the Quality, Management and Statistics Standards Policy Committee.

It was developed in conjunction with an international draft on quality auditing planned to be titled 'Generic Guideline for Auditing Quality Systems' in the work programme of Technical Committee ISO/TC 176, Quality management and quality assurance. It was considered, by the BSI Committee responsible, that early publication as a British Standard guide was desirable in view of the increasing certification related activity in the United Kingdom.

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

Contents

Guide

0 Introduction

This British Standard provides guidance on auditing quality systems. Audits are needed in order to verify whether the individual elements making up the quality systems are effective in achieving stated quality objectives.

The growing use of British Standards and now international standards giving minimum requirements for quality assurance (e.g. BS 5750 : Parts 1, 2 and 3†) emphasizes the importance of quality auditing as a management tool for achieving the objectives set out in a company's quality policy.

The guidance given in this British Standard can be equally applied to any one of the following three specific and different auditing activities.

(a) A quality systems audit carried out by a company on its own systems for the purpose of giving assurance to the management that its quality systems are effectively achieving the planned quality objectives. These audits known as first party, or internal, audits, can be carried out by the organization's own staff, provided that they are independent of the systems being audited, or by an outside agency.

(b) An audit can be carried out by one organization on another, with whom they either have a contract to purchase goods or services or intend to do so. The purpose of this audit is to provide assurance to the purchasing organization that the quality systems of the supplier are capable of sustaining the delivery of products or services, if already under contract, or providing those goods or services to an agreed quality level. These second party audits can be carried out by the purchasing organization, or by an outside agency.

(c) Third party audits can be carried out by independent agencies that may be accredited, using a national or international standard such as BS 5750 : Parts 1, 2 and 3† to provide assurance on the effectiveness of the quality systems.

In the case of a third party audit the purpose of the audit would be to obtain confirmation of compliance with the standard which could be used to provide assurance to existing and prospective customers for the product or service.

This standard establishes basic auditing principles, criteria and practices, and provides guidelines for establishing, planning, carrying out and documenting quality systems audits.

1 Scope

This British Standard provides guidance on the auditing of quality systems. It provides audit principles, criteria and requirements for audit practice, and assists in the establishment, planning and execution of audits of quality systems. It is prepared in a general way so as to be applicable to different industries and organizations.

The principles and practices described in this standard can be adjusted for product quality audits, process quality audits, delivery conformance audits, and quality of service audits. The field of application of this standard covers all those activities conducted by internal or external personnel or organizations.

NOTE. The titles of the publications referred to in this standard are listed on the inside back cover.

2 Definitions

For the purposes of this British Standard the following definitions apply.

NOTE. Over the course of time there has come into use a variety of names and conventions in the area of audits and auditing. Principal amongst these is the term 'assessment' which in this standard is accepted as being the same as and interchangeable with the term 'audit'.

2.1 quality audit*. A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

NOTE 1. The quality audit typically applies, but is not limited, to a quality system or elements thereof, to processes, to products, or to services. Such audits are often called 'quality systems audit', 'process quality audit', 'product quality audit', 'service quality audit'.

NOTE 2. Quality audits are carried out by staff not having direct responsibility in the areas being audited but, preferably, working in cooperation with the relevant personnel.

NOTE 3. One purpose of the quality audit is to evaluate the need for improvement or corrective action. An audit should not be confused with 'surveillance' or 'inspection' activities performed for the sole purpose of process control or product acceptance.

NOTE 4. Quality audits can be conducted for internal or external purposes.

2.2 quality system*. The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

NOTE 1. The quality system should only be as comprehensive as needed to meet the quality objectives.

NOTE 2. For contractual, mandatory and assessment purposes, demonstration of the implementation of identified elements in the system may be required.

2.3 auditor. A person who has the qualification and is authorized to perform all or any portion of a quality system audit.

2.4 lead auditor. An auditor who has the qualification and is authorized to manage a quality system audit.

2.5 client. The person or organization requesting the audit. Depending upon the circumstances, the client may be the auditing organization, the auditees or a third party.

NOTE. More specifically, the client may be:

(a) the auditee wishing to have its own quality system audited against some quality system standard;

†These British Standards are identical to international standards ISO 9001, ISO 9002, ISO 9003 and european standards EN 29001, EN 29002, EN 29003 respectively.

* As defined in BS 4778 : Part 1. Identical with ISO 8402.

(b) a customer wishing to evaluate the quality system of a supplier using their own auditors, a third party, or an independent auditor or agency;

(c) an independent agency wishing to determine whether the quality system provides adequate control of the products being provided, e.g. food and drug, nuclear and other regulatory bodies.

2.6 auditee. The organization to be audited.

2.7 observation. A statement of fact made as part of the audit process and substantiated by objective evidence.

NOTE. Statements not substantiated by objective evidence may be made as comment if the auditor thinks this will be useful or constructive.

2.8 objective evidence. The qualitative or quantitative information, records, or statements of fact, pertaining to the quality of an item or service or to the existence and implementation of a quality system element or documented requirement, that is based on observation, measurement or test and which can be verified.

2.9 nonconformity*. The nonfulfilment of specified requirements.

3 Audit objectives and responsibilities

3.1 Audit objectives

3.1.1 *General objectives.* Audits should be carried out to:

(a) determine conformity or nonconformity of the quality system elements with specified requirements;

(b) determine the effectiveness of the implemented quality system in meeting specified quality objectives;

(c) afford an opportunity to improve the quality system.

3.1.2 *Specific objectives.* Audits should be initiated:

(a) within a contractual framework:

(1) to evaluate a supplier where there is a desire to establish a contractual relationship;

(2) to verify that the supplier's quality system continues to meet requirements, and is being implemented effectively;

(3) to follow up corrective action from a previous audit;

(b) for the purpose of an internal organization audit:

(1) as a routine examination of the organization quality system to verify that it continues to meet requirements;

(2) as a consequence of particular circumstances such as variation in the product quality, organizational modifications or to follow up corrective actions from a previous audit;

(3) for evaluation of the organization's quality system against quality systems standards.

Audits may also be needed for meeting regulatory requirements.

3.1.3 *Incorrect objectives.* Quality audits should not be directed in a way:

(a) that results in a transfer of the responsibility to achieve quality from operating staff to the auditing organization;

(b) that leads to an increase in the scope of quality functions over and above those necessary to meet quality objectives.

3.2 Responsibilities and roles

3.2.1 *Responsibilities of the auditor.* The auditor should be responsible for:

(a) complying with applicable audit requirements and standards;

(b) planning and implementing the assigned responsibilities effectively and efficiently;

(c) reporting the audit results;

(d) the maintenance and security of documentation and information pertaining to the audit:

(1) submitting such documents as are required;

(2) ensuring the confidentiality of such documents;

(3) treating privileged information with discretion;

(e) cooperating with and supporting the lead auditor;

(f) maintenance of independence from auditee.

3.2.2 *Responsibilities of the lead auditor.* The lead auditor should be responsible for managing all phases of the audit. The lead auditor should have management capabilities and experience and should be given authority to make final decisions regarding the conduct of the audit and any audit observation. In addition to those in 3.2.1 the lead auditor's responsibilities need to cover the following:

(a) assisting with the selection of other team members;

(b) planning the audit;

(c) representing the audit team;

(d) preparing and submitting the audit report.

3.2.3 *Independence of the auditor.* Auditors should be selected to be free from bias, independent of the operation being audited, and free of influences which could affect objectivity.

All persons involved with an audit should respect and support the independence of the auditors.

3.2.4 *Role of the auditors.* The auditor as a minimum should:

(a) assess the requirements for each audit assignment and his/her own competence to undertake the task;

(b) observe applicable auditing requirements and other directives;

(c) prepare working documents;

(d) verify that the defined system elements exist and are implemented;

(e) record all observations and, if possible, the cause of any nonconformity;

(f) remain within the audit scope and exercise objectivity;

*As defined in BS 4778 : Part 1.

(g) compile and analyse evidence that is material, relevant, necessary and sufficient for the audit and the resulting conclusions and inform the auditee;

(h) remain alert for any indications of evidence that may impact on the audit results and possibly warrant more intensive or extensive auditing, and report critical nonconformities immediately;

(i) maintain ethical conduct;

(j) report any major hinderance in performing the audit;

(k) report the audit results clearly, conclusively and without delay.

3.2.5 *Audit team.* When the audit is performed by more than one auditor, the lead auditor needs to be responsible for the joint audit performance in all phases of an audit assignment and should participate in the selection of team members.

If appropriate, the audit team may include experts with specialized background, auditor trainees or observers who are acceptable to the client, auditee and lead auditor.

3.2.6 *Role of the client.* The client should:

(a) initiate the audit, define the audit scope and receive the audit reports;

(b) decide on any necessary follow-up action and so inform the auditee.

3.2.7 *Responsibilities of the auditee.* The auditee should be responsible for:

(a) providing access to relevant facilities and evidential material as requested by the auditor;

(b) appointing a responsible person to accompany the auditor(s);

(c) cooperating with the auditor so as to achieve audit objectives;

(d) reviewing audit findings and to implement any agreed corrective action;

(e) informing relevant employees about audit objectives and scope;

(f) providing all resources needed for the audit team to ensure an effective and efficient audit.

4 Auditing

4.1 Audit initiation

4.1.1 *Scope of audit.* The client should determine the scope of audit based on his needs and make the final decisions on which quality system elements, physical locations, and organizational activities are to be audited within a specified time frame. This is generally done with the assistance of the lead auditor.

The scope and depth of the audit should be designed to meet the specific needs of the client.

The standards or documents with which the auditee's quality system is required to comply should be specified by the client.

Sufficient objective evidence should be available to demonstrate the operation of the auditee's quality system.

The resources committed to the audit should be sufficient to provide an evaluation, meeting the intended scope and depth.

4.1.2 *Frequency of audit.* The need to conduct an audit should be determined by the client, taking account of specified or regulatory requirements and any other pertinent factors.

Significant changes in management, organization, policy, techniques or technologies that could affect the quality system, or changes to the system itself and the results of recent previous audits, are typical of the circumstances that should be considered in deciding audit frequency. Within an organization, internal audits may be organized on a regular basis for management or business purposes. In the interests of efficiency and effectiveness of the audit, and in the optimum use of available resources, all of these audits should be integrated into an audit schedule.

4.2 Preparation for audit

4.2.1 *Review of auditee quality systems documentation.* As a basis for planning the audit, the auditor should review for adequacy the auditee's recorded description of his method for meeting the required quality systems standard.

Where such reviews disclose that the auditee's recorded description is inadequate to meet the requirements of the appropriate quality systems standard, such concerns should be resolved to the satisfaction of the client, the auditor and when applicable, the auditee.

4.2.2 *Audit programme.* The audit programme should be approved by the client and communicated to the auditors and auditees. A pre-audit visit may be helpful in establishing this programme. The programme should include:

(a) the scope of the audit with definitions and objectives;

(b) the persons having direct responsibilities in this scope;

(c) the reference documents;

(d) the selection of auditors including experts and auditor trainees;

(e) the method of implementation;

(f) the time and place where the audit is to be conducted;

(g) the audit report distribution;

(h) the schedule of events including meetings;

(i) the identification of auditee and auditors;

(j) the language of the audit.

Audit programmes should be kept flexible in order to ensure effective use of resources in meeting the audit objectives.

It is at this stage that the auditees should register any objections to the programme that they might have. Any such objections are matters needing to be resolved between the lead auditor, the client and the auditee.

Specific details of the audit programme may be withheld from the auditee until the audit begins, if this appears necessary in order to prevent the audit from being com-

promised by premature disclosure of the activities targeted for evaluation.

4.2.3 *Audit working documents.* These are the documents required to facilitate the auditor's investigations, and to document and report results. They may include:

(a) checklists used for evaluating quality system elements (normally prepared by the auditor assigned to audit that specific element);

(b) forms for reporting audit observations;

(c) forms for documenting supporting evidence for conclusions reached by the auditors.

Working documents should be designed so they do not restrict additional audit activities or investigations that may become necessary as a result of information gained during the audit.

Working documents involving confidential or proprietary information should be suitably safeguarded by the auditing organization.

4.3 Audit execution

4.3.1 *General.* A structured audit should be implemented by:

(a) an opening meeting;

(b) the examination and evaluation;

(c) a closing meeting;

(d) the audit report.

4.3.2 *Opening meeting.* The purposes of this meeting should be for:

(a) putting the different representatives in contact with each other;

(b) receiving a short summary of the methods and procedures to be used in conducting the audit from the lead auditor;

(c) agreeing the methods of official communications between the audit team and the auditee;

(d) confirming the arrangements for the closing meeting between the audit team and auditee's senior management;

(e) confirming the audit programme and clarifying unclear details.

4.3.3 *Examination and evaluation.* The auditor should obtain sufficient, relevant information and evidence to permit a valid and reliable verification and evaluation including the following.

(a) *Collecting evidence.* Evidence should be collected through interviews, examination of documents, and observation of activities and conditions in the areas of concern. Indications suggesting possible nonconformities should be noted, even though not covered by checklists, and should be investigated. Information gained through interviews should be tested by acquiring the same information through other independent sources, such as physical observation, measurements and records.

NOTE. The lead auditor can make changes in the audit programme and work assignments in order to ensure the optimal achievement of audit objectives. If the audit objectives appear to become unattainable, the reasons should be reported to the client and the auditee.

(b) *Audit observations.* All audit observations should be documented. The audit team should review all of their observations to determine which are to be reported as nonconformities. The audit team should then ensure that these are documented in a clear concise manner and are supported by evidence. Nonconformities should be identified in terms of the specific requirement of the standard or other related documents against which the audit has been conducted. Observations should be reviewed by the lead auditor with the responsible auditee manager. All observations of nonconformity should be acknowledged by auditee management in writing.

The audit team should meet prior to the closing meeting to prepare the material to be presented.

4.3.4 *Closing meeting with auditee.* At the end of the audit and prior to preparing the audit report a meeting should be held by the auditors with the auditee's senior management and/or those responsible for the functions concerned.

The main purpose of the meeting should be to present and clarify audit observations and supporting evidence to the auditee in order to clear up any misunderstanding and errors and so that the auditee clearly understands the result of the audit.

The lead auditor should present observations taking into account their critical significance, the drawn conclusions about compliance and the system effectiveness in achieving the quality objectives.

During the meeting, the auditee should be informed that the absence of recorded nonconformities does not indicate that none exist. The auditee should be advised of the date of issue of the audit report.

Records of this meeting should be kept.

4.4 Audit report

4.4.1 *Preparation of the audit report.* The lead auditor has the responsibility for the preparation of the audit report. Interim reports should not be precluded.

4.4.2 *Content of the audit report.* Normally the audit report should contain only those findings declared at the closing meeting. If, subsequently, during the preparation of the report, an unreported nonconformity is discovered it should be communicated to the auditee before the submission of the report. The report should summarize the results of the audit, further details being recorded in the working documents.

The audit report may include the following items as applicable:

(a) report identification;

(b) purpose, objective and scope of the audit;

(c) details of the audit programme, auditors, dates and organization in which the audit was conducted;

(d) identification of the reference documents against which the audit was conducted (quality systems standard, auditee quality manual, etc.);

(e) audit observations, nonconformities and supporting evidence;

(f) any recommendations for follow up of corrective action and for subsequent audits;

(g) confidentiality clause;

(h) reference to supporting documents, attached as required;

(i) conclusion by the audit team, judgement of the extent of the auditee's compliance with the applicable quality systems standard and related documentation and the system's ability to achieve defined quality objectives;

(j) distribution list.

The audit report should be dated and signed by the lead auditor.

NOTE. The auditor has the responsibility for identifying the nonconformity. The auditee has the responsibility for initiating corrective action.

4.4.3 *Distribution of the audit report.* The audit report should be sent to the client by the lead auditor.

The client decides on additional distribution of copies of the report. The managers of the organization in which the audit was conducted should receive a copy.

It is essential that audit reports containing confidential or proprietary information should be suitably safeguarded by the auditor and the client.

The report should be issued within the period agreed at the closing meeting.

5 Audit completion

5.1 General

An audit assignment should be complete upon submission of the audit report to the client, except when verification of corrective action is explicitly included in the audit assignment and plan.

5.2 Record retention

Audit documents should be retained according to agreement between the client, the auditing organization and the auditee.

6 Corrective action and follow-up

6.1 Corrective action

While the audit process itself stops at the report publication, it should be stressed that the improvement process continues.

The final responsibility for corrective action lies with the auditee. In any case where corrective action becomes necessary there should be a clearly defined requirement for the corrective action to be taken, stating by whom it is to be done and in what time period. Normally this should be agreed by the client and the auditee and recorded.

6.2 Follow-up

Within an agreed time the auditee should notify the client of the status and/or completion of any corrective actions specified when so required.

The client may then call for verification of implementation by means of physical verification or by initiating a verification audit covering the actions completed. Such an audit should be controlled and planned totally separate from the original audit. The result of verification should be reported.

Publications referred to

BS 4778 Quality vocabulary
Part 1 International terms
BS 5750 Quality systems
Part 1 Specification for design/development, production, installation and servicing
Part 2 Specification for production and installation
Part 3 Specification for final inspection and test

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Quality, Management and Statistics Standards Policy Committee (QMS/-) to Technical Committee QMS/2, upon which the following bodies were represented:

Association for Consumer Research (ACRE)
BEAMA Ltd.
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British Railways Board
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Association of Consulting Engineers
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British Cement Association
British Coal Corporation
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British Maritime Technology
British Nuclear Forum
British Nuclear Fuels Limited
Business Equipment and Information Technology Association
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