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Guidelines for auditing quality systems —

Part 1:
Auditing

Lignes directrices pour l'audit des systèmes qualité —
Partie 1: Audit

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Contents

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 10011-1 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*.

ISO 10011 consists of the following parts, under the general title *Guidelines for auditing quality systems*:

— *Part 1: Auditing*

— *Part 2: Qualification criteria for quality systems auditors*

— *Part 3: Management of audit programmes*

Annex A of this part of ISO 10011 is for information only.

Introduction

The ISO 9000 series emphasizes the importance of quality audit as a key management tool for achieving the objectives set out in an organization's policy.

Audits should be carried out in order to determine that the various elements within a quality system are effective and suitable for achieving the stated quality objectives.

This part of ISO 10011 provides guidelines for performing an audit of a quality system of an organization. It allows users to adjust the guidelines described to suit their needs.

The quality system audit also provides objective evidence concerning the need for the reduction, elimination and, especially, prevention of nonconformities.

The results of these audits can be used by management to improve the performance of the organization.

Guidelines for auditing quality systems —

Part 1:
Auditing

1 Scope

This part of ISO 10011 establishes basic audit principles, criteria and practices, and provides guidelines for establishing, planning, carrying out and documenting audits of quality systems.

It provides guidelines for verifying the existence and implementation of elements of a quality system and for verifying the system's ability to achieve defined quality objectives. It is sufficiently general in nature to permit it to be applicable or adaptable to different kinds of industries and organizations. Each organization should develop its own specific procedures for implementing these guidelines.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 10011. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10011 are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1986, *Quality — Vocabulary*.

3 Definitions

For the purposes of this part of ISO 10011, the definitions given in ISO 8402, together with the following definitions, apply.

NOTE 1 Some terms in ISO 8402 are repeated here and the source is indicated in brackets.

3.1 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.

[ISO 8402]

NOTES

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

3 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.

4 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.

5 Quality audits can be conducted for internal or external purposes.

3.2 quality system: The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

[ISO 8402]

NOTES

6 The quality system should only be as comprehensive as is needed to meet the quality objectives.

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

3.3 auditor (quality): A person who has the qualification to perform quality audits.

NOTES

8 To perform a quality audit, the auditor must be authorized for that particular audit.

9 An auditor designated to manage a quality audit is called a "lead auditor".

3.4 client: A person or organization requesting the audit.

NOTE 10 The client may be:

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

b) a customer wishing to audit the quality system of a supplier using his own auditors or a third party;

c) an independent agency authorized to determine whether the quality system provides adequate control of the products or services being provided (such as food, drug, nuclear, or other regulatory bodies);

d) an independent agency assigned to carry out an audit in order to list the audited organization's quality system in a register.

3.5 auditee: An organization to be audited.

3.6 observation: A statement of fact made during an audit and substantiated by objective evidence.

3.7 objective evidence: 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, which is based on observation, measurement or test and which can be verified.

3.8 nonconformity: The nonfulfilment of specified requirements.

[ISO 8402]

NOTE 11 The definition covers the departure or absence of one or more quality characteristics or quality system elements from specified requirements.

4 Audit objectives and responsibilities

4.1 Audit objectives

Audits are normally designed for one or more of the following purposes:

— to determine the conformity or nonconformity of the quality system elements with specified requirements;

— to determine the effectiveness of the implemented quality system in meeting specified quality objectives;

— to provide the auditee with an opportunity to improve the quality system;

— to meet regulatory requirements;

— to permit the listing of the audited organization's quality system in a register.

Audits are generally initiated for one or more of the following reasons:

— to initially evaluate a supplier where there is a desire to establish a contractual relationship;

— to verify that an organization's own quality system continues to meet specified requirements and is being implemented;

— within the framework of a contractual relationship, to verify that the supplier's quality system continues to meet specified requirements and is being implemented;

— to evaluate an organization's own quality system against a quality system standard.

These audits may be routine, or may be prompted by significant changes in the organization's quality system, process, product or service quality, or by a need to follow up on corrective action.

NOTES

12 Quality audits should not result in a transfer of the responsibility to achieve quality from operating staff to the auditing organization.

13 Quality audits should not lead to an increase in the scope of quality functions over and above those necessary to meet quality objectives.

4.2 Roles and responsibilities

4.2.1 Auditors

4.2.1.1 Audit team

Whether an audit is carried out by a team or an individual, a lead auditor should be placed in overall charge.

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

4.2.1.2 Auditor's responsibilities

Auditors are responsible for

— complying with the applicable audit requirements;

— communicating and clarifying audit requirements;

— planning and carrying out assigned responsibilities effectively and efficiently;

— documenting the observations;

— reporting the audit results;

— verifying the effectiveness of corrective actions taken as a result of the audit (if requested by the client);

— retaining and safeguarding documents pertaining to the audit:

  • submitting such documents as required,

  • ensuring such documents remain confidential,

  • treating privileged information with discretion;

— cooperating with and supporting the lead auditor.

4.2.1.3 Lead auditor's responsibilities

The lead auditor is ultimately responsible for 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 observations.

The lead auditor's responsibilities also cover:

— assisting with the selection of other audit team members;

— preparation of the audit plan;

— representing the audit team with the auditee's management;

— submitting the audit report.

4.2.1.4 Independence of the auditor

Auditors should be free from bias and influences which could affect objectivity.

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

4.2.1.5 Auditor's activities

The lead auditor should

— define the requirements of each audit assignment, including the required auditor qualifications;

— comply with applicable auditing requirements and other appropriate directives;

— plan the audit, prepare working documents and brief the audit team;

— review documentation on existing quality system activities to determine their adequacy;

— report critical nonconformities to the auditee immediately;

— report any major obstacles encountered in performing the audit;

— report on the audit results clearly, conclusively and without undue delay.

Auditors should

— remain within the audit scope;

— exercise objectivity;

— collect and analyse evidence that is relevant and sufficient to permit the drawing of conclusions regarding the audited quality system;

— remain alert to any indications of evidence that can influence the audit results and possibly require more extensive auditing;

— be able to answer such questions as

  • "are the procedures, documents and other information describing or supporting the required elements of the quality system known, available, understood and used by the auditee's personnel?"

  • "are all the documents and other information used to describe the quality system adequate to achieve the required quality objectives?"

— act in an ethical manner at all times.

4.2.2 Client

The client

— determines the need for and the purpose of the audit and initiates the process;

— determines the auditing organization;

— determines the general scope of the audit, such as what quality system standard or document it is to be conducted against;

— receives the audit report;

— determines what follow-up action, if any, is to be taken, and informs the auditee of it.

4.2.3 Auditee

The auditee's management should

— inform relevant employees about the objectives and scope of the audit;

— appoint responsible members of staff to accompany members of the audit team;

— provide all resources needed for the audit team in order to ensure an effective and efficient audit process;

— provide access to the facilities and evidential material as requested by the auditors;

— cooperate with the auditors to permit the audit objectives to be achieved;

— determine and initiate corrective actions based on the audit report.

5 Auditing

5.1 Initiating the audit

5.1.1 Audit scope

The client makes the final decisions on which quality system elements, physical locations and organizational activities are to be audited within a specified time frame. This should be done with the assistance of the lead auditor. If appropriate, the auditee should be contacted when determining the scope of the audit.

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

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 and effectiveness of the auditee's quality system.

The resources committed to the audit should be sufficient to meet its intended scope and depth.

5.1.2 Audit frequency

The need to perform an audit is 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 to be considered when deciding audit frequency. Within an organization, internal audits may be organized on a regular basis for management or business purposes.

5.1.3 Preliminary review of auditee's quality system description

As a basis for planning the audit, the auditor should review for adequacy the auditee's recorded description of the methods for meeting the quality system requirements (such as the quality manual or equivalent).

If this review reveals that the system described by the auditee is not adequate to meet the requirements, further resources should not be expended on the audit until such concerns are resolved to the satisfaction of the client, the auditor and, where applicable, the auditee.

5.2 Preparing the audit

5.2.1 Audit plan

The audit plan should be approved by the client and communicated to the auditors and auditee.

The audit plan should be designed to be flexible in order to permit changes in emphasis based on information gathered during the audit, and to permit effective use of resources. The plan should include:

— the audit objectives and scope;

— identification of the individuals having significant direct responsibilities regarding the objectives and scope;

— identification of reference documents (such as the applicable quality system standard and the auditee's quality manual);

— identification of audit team members;

— the language of the audit;

— the date and place where the audit is to be conducted;

— identification of the organizational units to be audited;

— the expected time and duration for each major audit activity;

— the schedule of meetings to be held with auditee management;

— confidentiality requirements;

— audit report distribution and the expected date of issue.

If the auditee objects to any provisions in the audit plan, such objections should immediately be made known to the lead auditor. They should be resolved between the lead auditor and the auditee and, if necessary, the client before executing the audit.

Specific details of the audit plan should only be communicated to the auditee throughout the audit if their premature disclosure does not compromise the collecting of objective evidence.

5.2.2 Audit team assignments

Each auditor should be assigned specific quality system elements or functional departments to audit. Such assignments should be made by the lead auditor in consultation with the auditors concerned.

5.2.3 Working documents

The documents required to facilitate the auditor's investigations, and to document and report results, may include:

— check-lists used for evaluating quality system elements (normally prepared by the auditor assigned to audit that specific element);

— forms for reporting audit observations;

— forms for documenting supporting evidence for conclusions reached by the auditors.

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

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

5.3 Executing the audit

5.3.1 Opening meeting

The purpose of an opening meeting is to

— introduce the members of the audit team to the auditee's senior management;

— review the scope and the objectives of the audit;

— provide a short summary of the methods and procedures to be used to conduct the audit;

— establish the official communication links between the audit team and the auditee;

— confirm that the resources and facilities needed by the audit team are available;

— confirm the time and date for the closing meeting and any interim meetings of the audit team and the auditee's senior management;

— clarify any unclear details of the audit plan.

5.3.2 Examination

5.3.2.1 Collecting evidence

Evidence should be collected through interviews, examination of documents, and observation of activities and conditions in the areas of concern. Clues suggesting nonconformities should be noted if they seem significant, even though not covered by check-lists, and should be investigated. Information gathered through interviews should be tested by acquiring the same information from other independent sources, such as physical observation, measurements and records.

During the audit, the lead auditor may make changes to the auditors' work assignments, and to the audit plan with the client's approval and the auditee's agreement, if this is necessary to ensure the optimal achievement of the audit objectives.

If the audit objectives appear to become unattainable, the lead auditor should report the reasons to the client and the auditee.

5.3.2.2 Audit observations

All audit observations should be documented. After all activities have been audited, 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 requirements of the standard or other related documents against which the audit has been con-

ducted. Observations should be reviewed by the lead auditor with the responsible auditee manager. All observations of nonconformities should be acknowledged by the auditee management.

5.3.3 Closing meeting with auditee

At the end of the audit, prior to preparing the audit report, the audit team should hold a meeting with the auditee's senior management and those responsible for the functions concerned. The main purpose of this meeting is to present audit observations to the senior management in such a manner so as to ensure that they clearly understand the results of the audit.

The lead auditor should present observations, taking into account their perceived significance.

The lead auditor should present the audit team's conclusions regarding the quality system's effectiveness in ensuring that quality objectives will be met.

Records of the closing meeting should be kept.

NOTE 14 If requested, the auditor may also make recommendations to the auditee for improvements to the quality system. Recommendations are not binding on the auditee. It is up to the auditee to determine the extent, the way and means of actions to improve the quality system.

5.4 Audit documents

5.4.1 Audit report preparation

The audit report is prepared under the direction of the lead auditor, who is responsible for its accuracy and completeness.

5.4.2 Report content

The audit report should faithfully reflect both the tone and content of the audit. It should be dated and signed by the lead auditor. It should contain the following items, as applicable:

— the scope and objectives of the audit;

— details of the audit plan, the identification of audit team members and auditee's representative, audit dates, and identification of the specific organization audited;

— identification of the reference documents against which the audit was conducted (quality system standard, auditee's quality manual, etc.);

— observations of nonconformities;

— audit team's judgement of the extent of the auditee's compliance with the applicable quality system standard and related documentation;

— the system's ability to achieve defined quality objectives;

— the audit report distribution list.

Any communication made between the time of the closing meeting and the issue of the report should be by the lead auditor.

5.4.3 Report distribution

The audit report should be sent to the client by the lead auditor. It is the client's responsibility to provide the auditee's senior management with a copy of the audit report. Any additional distribution should be determined in consultation with the auditee. Audit reports containing confidential or proprietary information shall be suitably safeguarded by the auditing organization and the client.

The audit report should be issued as soon as possible. If it cannot be issued within an agreed time period, the reasons for the delay should be given to both the client and the auditee and a revised issue date established.

5.4.4 Record retention

Audit documents should be retained by agreement between the client, the auditing organization and the auditee, and in accordance with any regulatory requirements.

6 Audit completion

The audit is completed upon submission of the audit report to the client.

7 Corrective action follow-up

The auditee is responsible for determining and initiating corrective action needed to correct a nonconformity or to correct the cause of a nonconformity. The auditor is only responsible for identifying the nonconformity.

Corrective action and subsequent follow-up audits should be completed within a time period agreed to by the client and the auditee in consultation with the auditing organization.

NOTE 15 The auditing organization should keep the client informed of the status of corrective action activities and follow-up audits. After verification of corrective action implementation, the auditing organization may prepare a follow-up report and distribute it in a manner similar to the original audit report.

Annex A
(informative)

Bibliography

[1] ISO 9000:1987, *Quality management and quality assurance standards — Guidelines for selection and use*.

[2] ISO 9001:1987, *Quality systems — Model for quality assurance in design/development, production, installation and servicing*.

[3] ISO 9002:1987, *Quality systems — Model for quality assurance in production and installation*.

[4] ISO 9003:1987, *Quality systems — Model for quality assurance in final inspection and test*.

[5] ISO 9004:1987, *Quality management and quality system elements — Guidelines*.

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