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Guidelines for quality and/or environmental management systems auditing

*Lignes directrices pour l'audit des systèmes de management de la qualité
et/ou de management environnemental*

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ISO/CEN PARALLEL PROCESSING

The CEN Secretary-General has advised the ISO Secretary-General that this final draft International Standard covers a subject of interest to European standardization. Consultation on the ISO/DIS had the same effect for CEN members as a CEN enquiry on a draft European Standard. In accordance with subclause 5.1 of the Vienna Agreement, this final draft, established on the basis of comments received, is hereby submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

Positive votes shall not be accompanied by comments.

Negative votes shall be accompanied by the relevant technical reasons.

Member bodies are reminded to consult relevant national interests in each of the technical fields concerned [*Quality management and quality assurance* (ISO/TC 176), and *Environmental management* (ISO/TC 207)], before returning their ballot (one ballot for each technical committee) to the ISO Central Secretariat.

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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.

International standards are drafted in accordance with the rules given in the ISO/IEC Directives, part 3.

The main task of technical committees is to prepare International Standards. Draft International Standards accepted 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 members casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 19011 was prepared jointly by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*, and Technical Committee ISO/TC 207, *Environmental management*, Subcommittee SC 2, *Environmental auditing and related environmental investigations*.

This first edition of ISO 19011 cancels and replaces ISO 10011-1:1990, ISO 10011-2:1991, ISO 10011-3:1991, ISO 14010:1996, ISO 14011:1996 and ISO 14012:1996.

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Introduction

The ISO 9000 and ISO 14000 series of International Standards emphasize the importance of audits as a management tool for monitoring and verifying the effective implementation of an organization's quality and/or environmental policy. Audits are also an essential part of conformity assessment activities such as external certification/registration and of supply chain evaluation and surveillance.

This International Standard provides guidance on the management of audit programmes, the conduct of internal or external audits of quality and/or environmental management systems, as well as on the competence and evaluation of auditors. It is intended to apply to a broad range of potential users, including auditors, organizations implementing quality and/or environmental management systems, organizations needing to conduct audits of quality and/or environmental management systems for contractual reasons, and organizations involved in auditor certification or training, in certification/registration of management systems, in accreditation or in standardization in the area of conformity assessment.

The guidance in this International Standard is intended to be flexible. As indicated at various points in the text, the use of these guidelines can differ according to the size, nature and complexity of the organizations to be audited, as well as the objectives and scopes of the audits to be conducted. Throughout this International Standard, supplementary guidance or examples on specific topics are provided in the form of practical help in boxed text. In some instances, this is intended to support the use of this International Standard in small organizations.

Clause 4 describes the principles of auditing. These principles help the user to appreciate the essential nature of auditing and they are a necessary prelude to clauses 5, 6 and 7.

Clause 5 provides guidance on managing audit programmes and covers such issues as assigning responsibility for managing audit programmes, establishing the audit programme objectives, coordinating auditing activities and providing sufficient audit team resources.

Clause 6 provides guidance on conducting audits of quality and/or environmental management systems, including the selection of audit teams.

Clause 7 provides guidance on the competence needed by an auditor and describes a process for evaluating auditors.

Where quality and environmental management systems are implemented together, it is at the discretion of the user of this International Standard as to whether the quality management system and environmental management system audits are conducted separately or together.

Although this International Standard is applicable to the auditing of quality and/or environmental management systems, the user can consider adapting or extending the guidance provided herein to apply to other types of audits, including other management system audits.

This International Standard provides only guidance, however, users can apply this to develop their own audit-related requirements.

In addition, any other individual or organization with an interest in monitoring conformance to requirements, such as product specifications or laws and regulations, may find the guidance in this International Standard useful.

Guidelines for quality and/or environmental management systems auditing

1 Scope

This International Standard provides guidance on the principles of auditing, managing audit programmes, conducting quality management system audits and environmental management system audits, as well as guidance on the competence of quality and environmental management system auditors.

It is applicable to all organizations needing to conduct internal or external audits of quality and/or environmental management systems or to manage an audit programme.

The application of this International Standard to other types of audit is possible in principle, provided that special consideration is paid to identifying the competence needed by the audit team members in such cases.

2 Normative references

The following normative documents contain provisions which, through references in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative documents indicated below. For undated references, the latest edition of the normative document referred to apply. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

ISO 14050:2002, *Environmental management — Vocabulary*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 and ISO 14050 apply, unless superseded by the terms and definitions given below.

A term in a definition or note which is defined elsewhere in this clause is indicated by boldface followed by its entry number in parentheses. Such a boldface term may be replaced in the definition by its complete definition.

3.1

audit

systematic, independent and documented process for obtaining **audit evidence** (3.3) and evaluating it objectively to determine the extent to which **audit criteria** (3.2) are fulfilled

NOTE 1 Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the organization itself for management review and other internal purposes, and may form the basis for an organization's self-declaration of conformity. In many cases, particularly in smaller organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited.

NOTE 2 External audits include those generally termed second- and third-party audits. Second-party audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations, such as those providing registration or certification of conformity to the requirements of ISO 9001 or ISO 14001.

NOTE 3 When a quality management system and an environmental management system are audited together, this is termed a combined audit.

NOTE 4 When two or more auditing organizations cooperate to audit a single **auditee** (3.7), this is termed a joint audit.

3.2 audit criteria

set of policies, procedures or requirements

NOTE Audit criteria are used as a reference against which **audit evidence** (3.3) is compared.

3.3 audit evidence

records, statements of fact or other information, which are relevant to the **audit criteria** (3.2) and verifiable

NOTE Audit evidence may be qualitative or quantitative.

3.4 audit findings

results of the evaluation of the collected **audit evidence** (3.3) against **audit criteria** (3.2)

NOTE Audit findings can indicate either conformity or nonconformity with audit criteria or opportunities for improvement.

3.5 audit conclusion

outcome of an **audit** (3.1), provided by the **audit team** (3.9) after consideration of the audit objectives and all **audit findings** (3.4)

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3.6 audit client

organization or person requesting an **audit** (3.1)

NOTE The client may be the **auditee** (3.7) or any other organization which has the regulatory or contractual right to request an audit.

3.7 auditee

organization being audited

3.8 auditor

person with the **competence** (3.14) to conduct an **audit** (3.1)

3.9 audit team

one or more **auditors** (3.8) conducting an **audit** (3.1), supported if needed by **technical experts** (3.10)

NOTE 1 One auditor of the audit team is appointed as the audit team leader.

NOTE 2 The audit team may include auditors-in-training.

3.10**technical expert**

person who provides specific knowledge or expertise to the **audit team** (3.9)

NOTE 1 Specific knowledge or expertise is that which relates to the organization, the process or activity to be audited, or language or culture.

NOTE 2 A technical expert does not act as an **auditor** (3.8) in the audit team.

3.11**audit programme**

set of one or more **audits** (3.1) planned for a specific time frame and directed towards a specific purpose

NOTE An audit programme includes all activities necessary for planning, organizing and conducting the audits.

3.12**audit plan**

description of the activities and arrangements for an **audit** (3.1)

3.13**audit scope**

extent and boundaries of an **audit** (3.1)

NOTE The audit scope generally includes a description of the physical locations, organizational units, activities and processes, as well as the time period covered.

3.14**competence**

demonstrated personal attributes and demonstrated ability to apply knowledge and skills

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4 Principles of auditing

Auditing is characterized by reliance on a number of principles. These make the audit an effective and reliable tool in support of management policies and controls, providing information on which an organization can act to improve its performance. Adherence to these principles is a prerequisite for providing audit conclusions that are relevant and sufficient and for enabling auditors working independently from one another to reach similar conclusions in similar circumstances.

The following principles relate to auditors.

a) **Ethical conduct:** *the foundation of professionalism*

Trust, integrity, confidentiality and discretion are essential to auditing.

b) **Fair presentation:** *the obligation to report truthfully and accurately*

Audit findings, audit conclusions and audit reports reflect truthfully and accurately the audit activities. Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and the auditee are reported.

c) **Due professional care:** *the application of diligence and judgement in auditing*

Auditors exercise care in accordance with the importance of the task they perform and the confidence placed in them by audit clients and other interested parties. Having the necessary competence is an important factor.

Further principles relate to the audit, which is by definition independent and systematic.

d) **Independence:** *the basis for the impartiality of the audit and objectivity of the audit conclusions*

Auditors are independent of the activity being audited and are free from bias and conflict of interest. Auditors maintain an objective state of mind throughout the audit process to ensure that the audit findings and conclusions will be based only on the audit evidence.

e) **Evidence-based approach:** *the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process*

Audit evidence is verifiable. It is based on samples of the information available, since an audit is conducted during a finite period of time and with finite resources. The appropriate use of sampling is closely related to the confidence that can be placed in the audit conclusions.

The guidance given in the remaining clauses of this International Standard is based on the principles set out above.

5 Managing an audit programme

5.1 General

An audit programme may include one or more audits, depending upon the size, nature and complexity of the organization to be audited. These audits may have a variety of objectives and may also include joint or combined audits (see Notes 3 and 4 to the definition of audit in 3.1).

An audit programme also includes all activities necessary for planning and organizing the types and number of audits, and for providing resources to conduct them effectively and efficiently within the specified time frames.

An organization may establish more than one audit programme.

The organization's top management should grant the authority for managing the audit programme.

Those assigned the responsibility for managing the audit programme should

- a) establish, implement, monitor, review and improve the audit programme, and
- b) identify the necessary resources and ensure they are provided.

Figure 1 illustrates the process flow for the management of an audit programme.

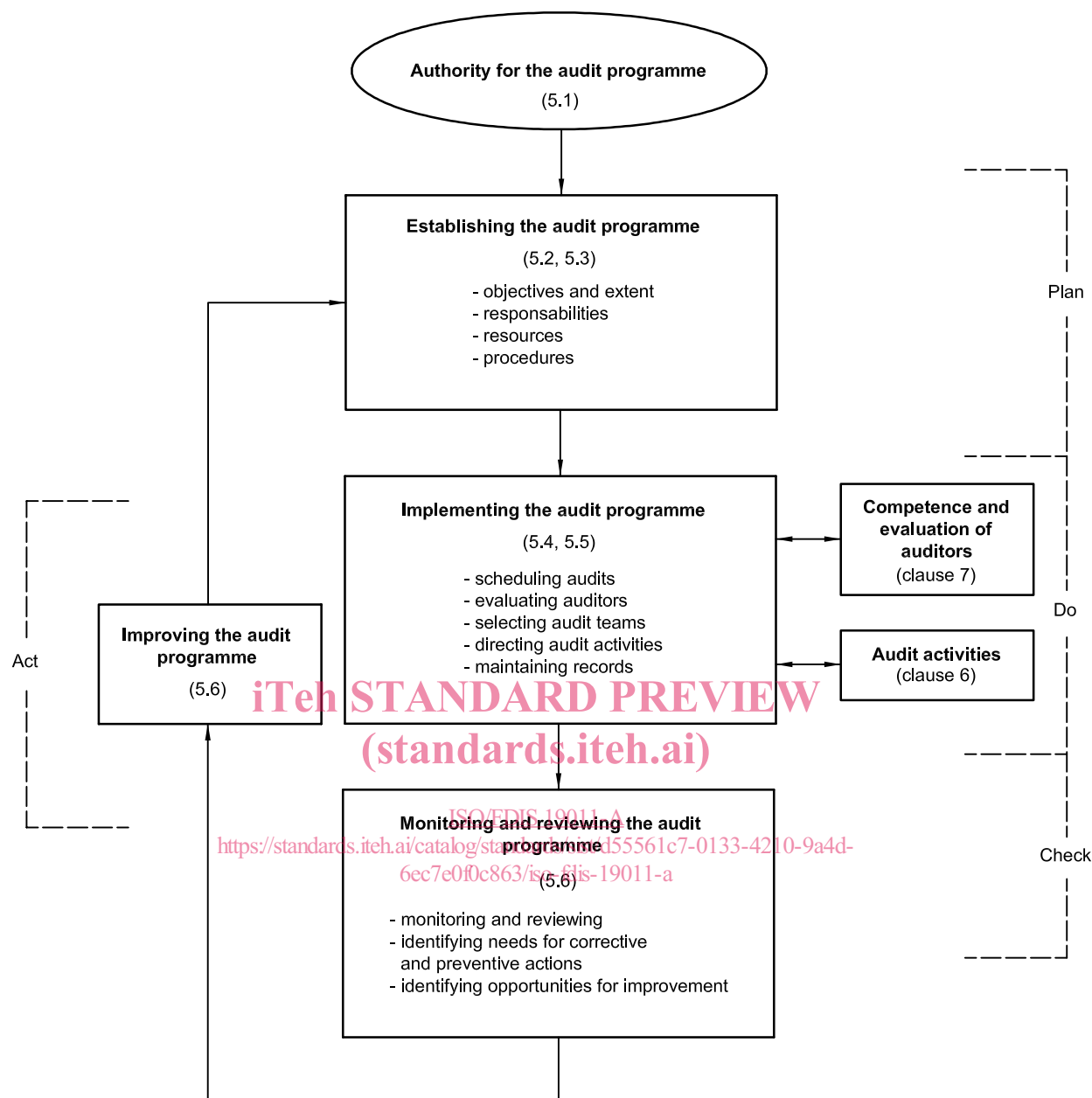


Figure 1 — Illustration of the process flow for the management of an audit programme

NOTE 1 Figure 1 also illustrates the application of the Plan-Do-Check-Act process in this International Standard.

NOTE 2 The numbers in this and all subsequent figures refer to the relevant clauses of this International Standard.

If an organization to be audited operates both quality management and environmental management systems, combined audits may be included in the audit programme. In such a case, special attention should be paid to the competence of the audit team.

Two or more auditing organizations may cooperate, as part of their audit programmes, to conduct a joint audit. In such a case, special attention should be paid to the division of responsibilities, the provision of any additional resources, the competence of the audit team and the appropriate procedures. Agreement on these should be reached before the audit commences.

Practical help — Examples of audit programmes

Examples of audit programmes include the following:

- a) a series of internal audits covering an organization-wide quality management system for the current year;
- b) second-party management system audits of potential suppliers of critical products to be conducted within 6 months;
- c) certification/registration and surveillance audits conducted by a third-party certification/registration body on an environmental management system within a time period agreed contractually between the certification body and the client.

An audit programme also includes appropriate planning, the provision of resources and the establishment of procedures to conduct audits within the programme.

5.2 Audit programme objectives and extent

5.2.1 Objectives of an audit programme

Objectives should be established for an audit programme, to direct the planning and conduct of audits.

These objectives can be based on consideration of

- a) management priorities,
- b) commercial intentions,
- c) management system requirements,
- d) statutory, regulatory and contractual requirements,
- e) need for supplier evaluation,
- f) customer requirements,
- g) needs of other interested parties, and
- h) risks to the organization.

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Practical help — Examples of audit programme objectives

Examples of audit programme objectives include the following:

- a) to meet requirements for certification to a management system standard;
- b) to verify conformance with contractual requirements;
- c) to obtain and maintain confidence in the capability of a supplier;
- d) to contribute to the improvement of the management system.