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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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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 the **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.

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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)

3.6 audit client

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

NOTE The audit 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

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.

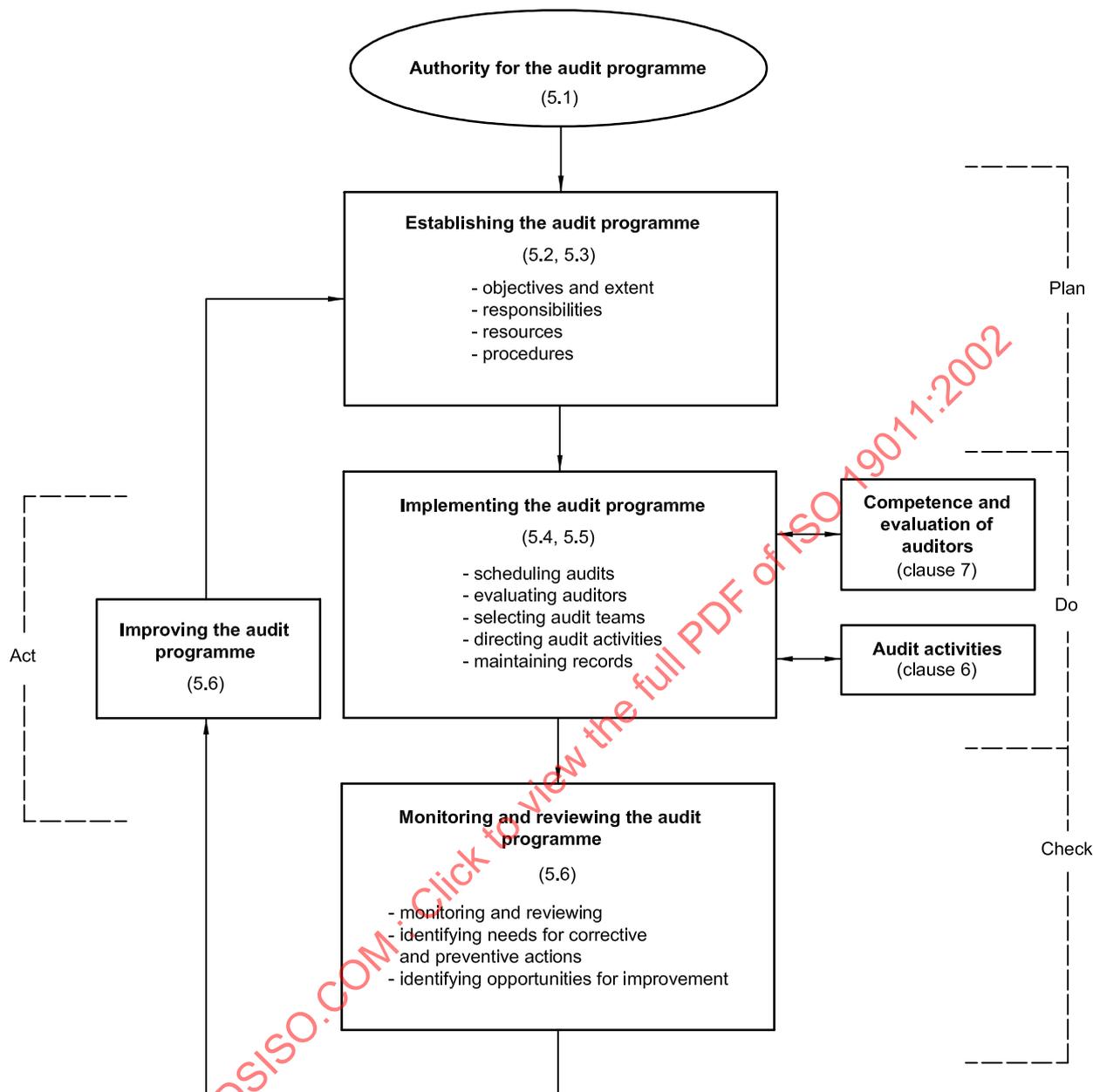


Figure 1 — Illustration of the process flow for the management of an audit programme

NOTE 1 Figure 1 also illustrates the application of the Plan-Do-Check-Act methodology 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.

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.

5.2.2 Extent of an audit programme

The extent of an audit programme can vary and will be influenced by the size, nature and complexity of the organization to be audited, as well as by the following:

- a) the scope, objective and duration of each audit to be conducted;
- b) the frequency of audits to be conducted;
- c) the number, importance, complexity, similarity and locations of the activities to be audited;
- d) standards, statutory, regulatory and contractual requirements and other audit criteria;
- e) the need for accreditation or registration/certification;
- f) conclusions of previous audits or results of a previous audit programme review;
- g) any language, cultural and social issues;
- h) the concerns of interested parties;
- i) significant changes to an organization or its operations.

5.3 Audit programme responsibilities, resources and procedures

5.3.1 Audit programme responsibilities

The responsibility for managing an audit programme should be assigned to one or more individuals with a general understanding of audit principles, of the competence of auditors and the application of audit techniques. They should have management skills as well as technical and business understanding relevant to the activities to be audited.

Those assigned the responsibility for managing the audit programme should

- a) establish the objectives and extent of the audit programme,
- b) establish the responsibilities and procedures, and ensure resources are provided,
- c) ensure the implementation of the audit programme,
- d) ensure that appropriate audit programme records are maintained, and
- e) monitor, review and improve the audit programme.

5.3.2 Audit programme resources

When identifying resources for the audit programme, consideration should be given to

- a) financial resources necessary to develop, implement, manage and improve audit activities,
- b) audit techniques,
- c) processes to achieve and maintain the competence of auditors, and to improve auditor performance,
- d) the availability of auditors and technical experts having competence appropriate to the particular audit programme objectives,
- e) the extent of the audit programme, and
- f) travelling time, accommodation and other auditing needs.

5.3.3 Audit programme procedures

Audit programme procedures should address the following:

- a) planning and scheduling audits;
- b) assuring the competence of auditors and audit team leaders;
- c) selecting appropriate audit teams and assigning their roles and responsibilities;
- d) conducting audits;
- e) conducting audit follow-up, if applicable;
- f) maintaining audit programme records;
- g) monitoring the performance and effectiveness of the audit programme;
- h) reporting to top management on the overall achievements of the audit programme.

For smaller organizations, the activities above can be addressed in a single procedure.

5.4 Audit programme implementation

The implementation of an audit programme should address the following:

- a) communicating the audit programme to relevant parties;
- b) coordinating and scheduling audits and other activities relevant to the audit programme;
- c) establishing and maintaining a process for the evaluation of the auditors and their continual professional development, in accordance with respectively 7.6 and 7.5;
- d) ensuring the selection of audit teams;
- e) providing necessary resources to the audit teams;
- f) ensuring the conduct of audits according to the audit programme;
- g) ensuring the control of records of the audit activities;
- h) ensuring review and approval of audit reports, and ensuring their distribution to the audit client and other specified parties;
- i) ensuring audit follow-up, if applicable.

5.5 Audit programme records

Records should be maintained to demonstrate the implementation of the audit programme and should include the following:

- a) records related to individual audits, such as
 - audit plans,
 - audit reports,
 - nonconformity reports,

- corrective and preventive action reports, and
 - audit follow-up reports, if applicable;
- b) results of audit programme review;
- c) records related to audit personnel covering subjects such as
- auditor competence and performance evaluation,
 - audit team selection, and
 - maintenance and improvement of competence.

Records should be retained and suitably safeguarded.

5.6 Audit programme monitoring and reviewing

The implementation of the audit programme should be monitored and, at appropriate intervals, reviewed to assess whether its objectives have been met and to identify opportunities for improvement. The results should be reported to top management.

Performance indicators should be used to monitor characteristics such as

- the ability of the audit teams to implement the audit plan,
- conformity with audit programmes and schedules, and
- feedback from audit clients, auditees and auditors.

The audit programme review should consider, for example,

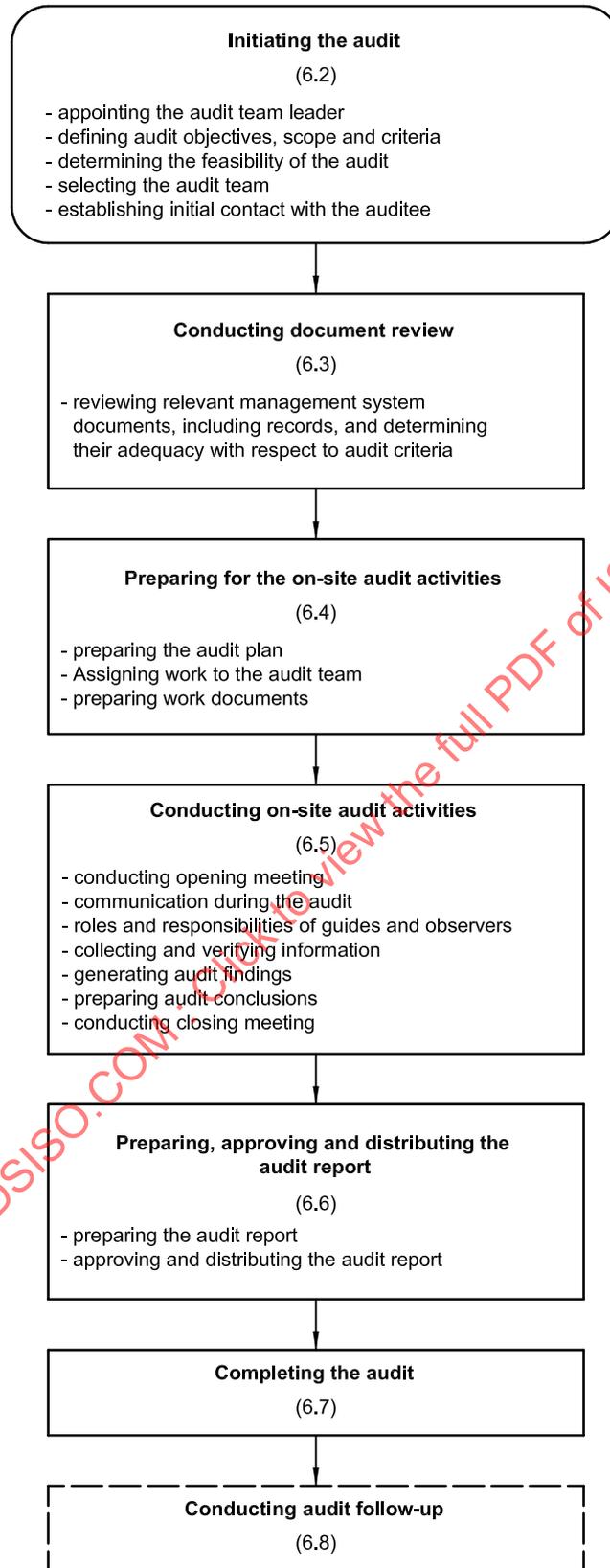
- a) results and trends from monitoring,
- b) conformity with procedures,
- c) evolving needs and expectations of interested parties,
- d) audit programme records,
- e) alternative or new auditing practices, and
- f) consistency in performance between audit teams in similar situations.

Results of audit programme reviews can lead to corrective and preventive actions and the improvement of the audit programme.

6 Audit activities

6.1 General

This clause contains guidance on planning and conducting audit activities as part of an audit programme. Figure 2 provides an overview of typical audit activities. The extent to which the provisions of this clause are applicable depends on the scope and complexity of the specific audit and the intended use of the audit conclusions.



NOTE The dotted lines indicate that any audit follow-up actions are usually not considered to be part of the audit.

Figure 2 — Overview of typical audit activities

6.2 Initiating the audit

6.2.1 Appointing the audit team leader

Those assigned the responsibility for managing the audit programme should appoint the audit team leader for the specific audit.

Where a joint audit is conducted, it is important to reach agreement among the auditing organizations before the audit commences on the specific responsibilities of each organization, particularly with regard to the authority of the team leader appointed for the audit.

6.2.2 Defining audit objectives, scope and criteria

Within the overall objectives of an audit programme, an individual audit should be based on documented objectives, scope and criteria.

The audit objectives define what is to be accomplished by the audit and may include the following:

- a) determination of the extent of conformity of the auditee's management system, or parts of it, with audit criteria;
- b) evaluation of the capability of the management system to ensure compliance with statutory, regulatory and contractual requirements;
- c) evaluation of the effectiveness of the management system in meeting its specified objectives;
- d) identification of areas for potential improvement of the management system.

The audit scope describes the extent and boundaries of the audit, such as physical locations, organizational units, activities and processes to be audited, as well as the time period covered by the audit.

The audit criteria are used as a reference against which conformity is determined and may include applicable policies, procedures, standards, laws and regulations, management system requirements, contractual requirements or industry/business sector codes of conduct.

The audit objectives should be defined by the audit client. The audit scope and criteria should be defined between the audit client and the audit team leader in accordance with audit programme procedures. Any changes to the audit objectives, scope or criteria should be agreed to by the same parties.

Where a combined audit is to be conducted, it is important that the audit team leader ensures that the audit objectives, scope and criteria are appropriate to the nature of the combined audit.

6.2.3 Determining the feasibility of the audit

The feasibility of the audit should be determined, taking into consideration such factors as the availability of

- sufficient and appropriate information for planning the audit,
- adequate cooperation from the auditee, and
- adequate time and resources.

Where the audit is not feasible, an alternative should be proposed to the audit client, in consultation with the auditee.

6.2.4 Selecting the audit team

When the audit has been declared feasible, an audit team should be selected, taking into account the competence needed to achieve the objectives of the audit. If there is only one auditor, the auditor should perform all applicable

duties of an audit team leader. Clause 7 contains guidance on determining the competence needed and describes processes for evaluating auditors.

In deciding the size and composition of the audit team, consideration should be given to the following:

- a) audit objectives, scope, criteria and estimated duration of the audit;
- b) whether the audit is a combined or joint audit;
- c) the overall competence of the audit team needed to achieve the objectives of the audit;
- d) statutory, regulatory, contractual and accreditation/certification requirements, as applicable;
- e) the need to ensure the independence of the audit team from the activities to be audited and to avoid conflict of interest;
- f) the ability of the audit team members to interact effectively with the auditee and to work together;
- g) the language of the audit, and an understanding of the auditee's particular social and cultural characteristics; these issues may be addressed either by the auditor's own skills or through the support of a technical expert.

The process of assuring the overall competence of the audit team should include the following steps:

- identification of the knowledge and skills needed to achieve the objectives of the audit;
- selection of the audit team members such that all of the necessary knowledge and skills are present in the audit team.

If not fully covered by the auditors in the audit team, the necessary knowledge and skills may be satisfied by including technical experts. Technical experts should operate under the direction of an auditor.

Auditors-in-training may be included in the audit team, but should not audit without direction or guidance.

Both the audit client and the auditee can request the replacement of particular audit team members on reasonable grounds based on the principles of auditing described in clause 4. Examples of reasonable grounds include conflict of interest situations (such as an audit team member having been a former employee of the auditee or having provided consultancy services to the auditee) and previous unethical behaviour. Such grounds should be communicated to the audit team leader and to those assigned responsibility for managing the audit programme, who should resolve the issue with the audit client and auditee before making any decisions on replacing audit team members.

6.2.5 Establishing initial contact with the auditee

The initial contact for the audit with the auditee may be informal or formal, but should be made by those assigned responsibility for managing the audit programme or the audit team leader. The purpose of the initial contact is

- a) to establish communication channels with the auditee's representative,
- b) to confirm the authority to conduct the audit,
- c) to provide information on the proposed timing and audit team composition,
- d) to request access to relevant documents, including records,
- e) to determine applicable site safety rules,
- f) to make arrangements for the audit, and
- g) to agree on the attendance of observers and the need for guides for the audit team.

6.3 Conducting document review

Prior to the on-site audit activities the auditee's documentation should be reviewed to determine the conformity of the system, as documented, with audit criteria. The documentation may include relevant management system documents and records, and previous audit reports. The review should take into account the size, nature and complexity of the organization, and the objectives and scope of the audit. In some situations, this review may be deferred until the on-site activities commence, if this is not detrimental to the effectiveness of the conduct of the audit. In other situations, a preliminary site visit may be conducted to obtain a suitable overview of available information.

If the documentation is found to be inadequate, the audit team leader should inform the audit client, those assigned responsibility for managing the audit programme, and the auditee. A decision should be made as to whether the audit should be continued or suspended until documentation concerns are resolved.

6.4 Preparing for the on-site audit activities

6.4.1 Preparing the audit plan

The audit team leader should prepare an audit plan to provide the basis for the agreement among the audit client, audit team and the auditee regarding the conduct of the audit. The plan should facilitate scheduling and coordination of the audit activities.

The amount of detail provided in the audit plan should reflect the scope and complexity of the audit. The details may differ, for example, between initial and subsequent audits and also between internal and external audits. The audit plan should be sufficiently flexible to permit changes, such as changes in the audit scope, which can become necessary as the on-site audit activities progress.

The audit plan should cover the following:

- a) the audit objectives;
- b) the audit criteria and any reference documents;
- c) the audit scope, including identification of the organizational and functional units and processes to be audited;
- d) the dates and places where the on-site audit activities are to be conducted;
- e) the expected time and duration of on-site audit activities, including meetings with the auditee's management and audit team meetings;
- f) the roles and responsibilities of the audit team members and accompanying persons;
- g) the allocation of appropriate resources to critical areas of the audit.

The audit plan should also cover the following, as appropriate:

- h) identification of the auditee's representative for the audit;
- i) the working and reporting language of the audit where this is different from the language of the auditor and/or the auditee;
- j) the audit report topics;
- k) logistic arrangements (travel, on-site facilities, etc.);
- l) matters related to confidentiality;
- m) any audit follow-up actions.

The plan should be reviewed and accepted by the audit client, and presented to the auditee, before the on-site audit activities begin.

Any objections by the auditee should be resolved between the audit team leader, the auditee and the audit client. Any revised audit plan should be agreed among the parties concerned before continuing the audit.

6.4.2 Assigning work to the audit team

The audit team leader, in consultation with the audit team, should assign to each team member responsibility for auditing specific processes, functions, sites, areas or activities. Such assignments should take into account the need for the independence and competence of auditors and the effective use of resources, as well as different roles and responsibilities of auditors, auditors-in-training and technical experts. Changes to the work assignments may be made as the audit progresses to ensure the achievement of the audit objectives.

6.4.3 Preparing work documents

The audit team members should review the information relevant to their audit assignments and prepare work documents as necessary for reference and for recording audit proceedings. Such work documents may include

- checklists and audit sampling plans, and
- forms for recording information, such as supporting evidence, audit findings and records of meetings.

The use of checklists and forms should not restrict the extent of audit activities, which can change as a result of information collected during the audit.

Work documents, including records resulting from their use, should be retained at least until audit completion. Retention of documents after audit completion is described in 6.7. Those documents involving confidential or proprietary information should be suitably safeguarded at all times by the audit team members.

6.5 Conducting on-site audit activities

6.5.1 Conducting the opening meeting

An opening meeting should be held with the auditee's management or, where appropriate, those responsible for the functions or processes to be audited. The purpose of an opening meeting is

- a) to confirm the audit plan,
- b) to provide a short summary of how the audit activities will be undertaken,
- c) to confirm communication channels, and
- d) to provide an opportunity for the auditee to ask questions.

Practical help — Opening the meeting

In many instances, for example internal audits in a small organization, the opening meeting may simply consist of communicating that an audit is being conducted and explaining the nature of the audit.

For other audit situations, the meeting should be formal and records of the attendance should be kept. The meeting should be chaired by the audit team leader, and the following items should be considered, as appropriate:

- a) introduction of the participants, including an outline of their roles;
- b) confirmation of the audit objectives, scope and criteria;
- c) confirmation of the audit timetable and other relevant arrangements with the auditee, such as the date and time for the closing meeting, any interim meetings between the audit team and the auditee's management, and any late changes;
- d) methods and procedures to be used to conduct the audit, including advising the auditee that the audit evidence will only be based on a sample of the information available and that therefore there is an element of uncertainty in auditing;
- e) confirmation of formal communication channels between the audit team and the auditee;
- f) confirmation of the language to be used during the audit;
- g) confirmation that, during the audit, the auditee will be kept informed of audit progress;
- h) confirmation that the resources and facilities needed by the audit team are available;
- i) confirmation of matters relating to confidentiality;
- j) confirmation of relevant work safety, emergency and security procedures for the audit team;
- k) confirmation of the availability, roles and identities of any guides;
- l) the method of reporting, including any grading of nonconformities;
- m) information about conditions under which the audit may be terminated;
- n) information about any appeal system on the conduct or conclusions of the audit.

6.5.2 Communication during the audit

Depending upon the scope and complexity of the audit, it can be necessary to make formal arrangements for communication within the audit team and with the auditee during the audit.

The audit team should confer periodically to exchange information, assess audit progress, and to reassign work between the audit team members as needed.

During the audit, the audit team leader should periodically communicate the progress of the audit and any concerns to the auditee and audit client, as appropriate. Evidence collected during the audit that suggests an immediate and significant risk (e.g. safety, environmental or quality) should be reported without delay to the auditee and, as appropriate, to the audit client. Any concern about an issue outside the audit scope should be noted and reported to the audit team leader, for possible communication to the audit client and auditee.

Where the available audit evidence indicates that the audit objectives are unattainable, the audit team leader should report the reasons to the audit client and the auditee to determine appropriate action. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit.

Any need for changes to the audit scope which can become apparent as on-site auditing activities progress should be reviewed with and approved by the audit client and, as appropriate, the auditee.

6.5.3 Roles and responsibilities of guides and observers

Guides and observers may accompany the audit team but are not a part of it. They should not influence or interfere with the conduct of the audit.

When guides are appointed by the auditee, they should assist the audit team and act on the request of the audit team leader. Their responsibilities may include the following:

- a) establishing contacts and timing for interviews;
- b) arranging visits to specific parts of the site or organization;
- c) ensuring that rules concerning site safety and security procedures are known and respected by the audit team members;
- d) witnessing the audit on behalf of the auditee;
- e) providing clarification or assisting in collecting information.

6.5.4 Collecting and verifying information

During the audit, information relevant to the audit objectives, scope and criteria, including information relating to interfaces between functions, activities and processes, should be collected by appropriate sampling and should be verified. Only information that is verifiable may be audit evidence. Audit evidence should be recorded.

The audit evidence is based on samples of the available information. Therefore there is an element of uncertainty in auditing, and those acting upon the audit conclusions should be aware of this uncertainty.

Figure 3 provides an overview of the process, from collecting information to reaching audit conclusions.

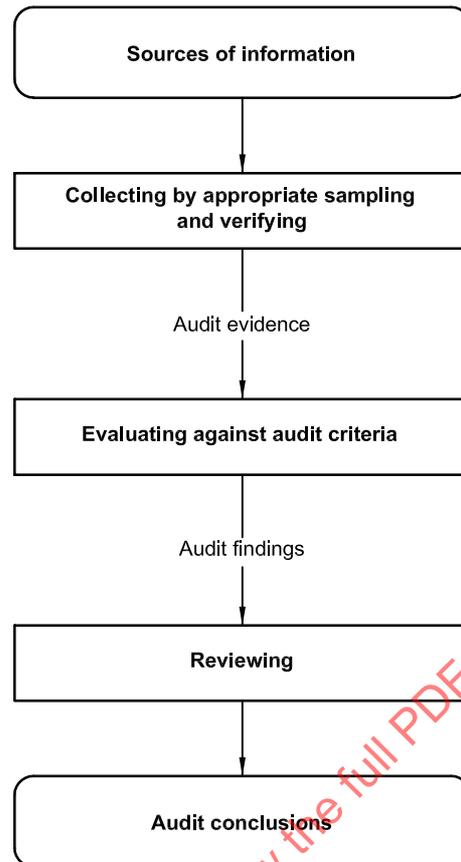


Figure 3 — Overview of the process from collecting information to reaching audit conclusions

Methods to collect information include

- interviews,
- observation of activities, and
- review of documents.

Practical help — Sources of information

The sources of information chosen may vary according to the scope and complexity of the audit and may include the following:

- a) interviews with employees and other persons;
- b) observations of activities and the surrounding work environment and conditions;
- c) documents, such as policy, objectives, plans, procedures, standards, instructions, licences and permits, specifications, drawings, contracts and orders;
- d) records, such as inspection records, minutes of meetings, audit reports, records of monitoring programmes and the results of measurements;
- e) data summaries, analyses and performance indicators;
- f) information on the auditee's sampling programmes and on procedures for the control of sampling and measurement processes;
- g) reports from other sources, for example, customer feedback, other relevant information from external parties and supplier ratings;
- h) computerized databases and web sites.

Practical help — Conducting interviews

Interviews are one of the important means of collecting information and should be carried out in a manner adapted to the situation and the person interviewed. However, the auditor should consider the following:

- a) interviews should be held with persons from appropriate levels and functions performing activities or tasks within the scope of the audit;
- b) interviews should be conducted during the normal working hours and, where practical, at the normal workplace of the person being interviewed;
- c) every attempt should be made to put the person being interviewed at ease prior to and during the interview;
- d) the reason for the interview and any note taking should be explained;
- e) interviews can be initiated by asking the persons to describe their work;
- f) questions that bias the answers (i.e. leading questions) should be avoided;
- g) the results from the interview should be summarized and reviewed with the interviewed person;
- h) the interviewed persons should be thanked for their participation and cooperation.

6.5.5 Generating audit findings

Audit evidence should be evaluated against the audit criteria to generate the audit findings. Audit findings can indicate either conformity or nonconformity with audit criteria. When specified by the audit objectives, audit findings can identify an opportunity for improvement.

The audit team should meet as needed to review the audit findings at appropriate stages during the audit.

Conformity with audit criteria should be summarized to indicate locations, functions or processes that were audited. If included in the audit plan, individual audit findings of conformity and their supporting evidence should also be recorded.

Nonconformities and their supporting audit evidence should be recorded. Nonconformities may be graded. They should be reviewed with the auditee to obtain acknowledgement that the audit evidence is accurate, and that the nonconformities are understood. Every attempt should be made to resolve any diverging opinions concerning the audit evidence and/or findings, and unresolved points should be recorded.

6.5.6 Preparing audit conclusions

The audit team should confer prior to the closing meeting

- a) to review the audit findings, and any other appropriate information collected during the audit, against the audit objectives,
- b) to agree on the audit conclusions, taking into account the uncertainty inherent in the audit process,
- c) to prepare recommendations, if specified by the audit objectives, and
- d) to discuss audit follow-up, if included in the audit plan.

Practical help — Audit conclusions

Audit conclusions can address issues such as

- a) the extent of conformity of the management system with the audit criteria,
- b) the effective implementation, maintenance and improvement of the management system, and
- c) the capability of the management review process to ensure the continuing suitability, adequacy, effectiveness and improvement of the management system.

If specified by the audit objectives, audit conclusions can lead to recommendations regarding improvements, business relationships, certification/registration or future auditing activities.

6.5.7 Conducting the closing meeting

A closing meeting, chaired by the audit team leader, should be held to present the audit findings and conclusions in such a manner that they are understood and acknowledged by the auditee, and to agree, if appropriate, on the timeframe for the auditee to present a corrective and preventive action plan. Participants in the closing meeting should include the auditee, and may also include the audit client and other parties. If necessary, the audit team leader should advise the auditee of situations encountered during the audit that may decrease the reliance that can be placed on the audit conclusions.

In many instances, for example internal audits in a small organization, the closing meeting may consist of just communicating the audit findings and conclusions.

For other audit situations, the meeting should be formal and minutes, including records of attendance, should be kept.

Any diverging opinions regarding the audit findings and/or conclusions between the audit team and the auditee should be discussed and if possible resolved. If not resolved, all opinions should be recorded.

If specified by the audit objectives, recommendations for improvements should be presented. It should be emphasized that recommendations are not binding.

6.6 Preparing, approving and distributing the audit report

6.6.1 Preparing the audit report

The audit team leader should be responsible for the preparation and contents of the audit report.

The audit report should provide a complete, accurate, concise and clear record of the audit, and should include or refer to the following:

- a) the audit objectives;
- b) the audit scope, particularly identification of the organizational and functional units or processes audited and the time period covered;
- c) identification of the audit client;
- d) identification of audit team leader and members;
- e) the dates and places where the on-site audit activities were conducted;
- f) the audit criteria;
- g) the audit findings;
- h) the audit conclusions.

The audit report may also include or refer to the following, as appropriate:

- i) the audit plan;
- j) a list of auditee representatives;
- k) a summary of the audit process, including the uncertainty and/or any obstacles encountered that could decrease the reliability of the audit conclusions;
- l) confirmation that the audit objectives have been accomplished within the audit scope in accordance with the audit plan;
- m) any areas not covered, although within the audit scope;
- n) any unresolved diverging opinions between the audit team and the auditee;
- o) recommendations for improvement, if specified in the audit objectives;
- p) agreed follow-up action plans, if any;
- q) a statement of the confidential nature of the contents;
- r) the distribution list for the audit report.

6.6.2 Approving and distributing the audit report

The audit report should be issued within the agreed time period. If this is not possible, the reasons for the delay should be communicated to the audit client and a new issue date should be agreed.

The audit report should be dated, reviewed and approved in accordance with audit programme procedures.

The approved audit report should then be distributed to recipients designated by the audit client.

The audit report is the property of the audit client. The audit team members and all report recipients should respect and maintain the confidentiality of the report.

6.7 Completing the audit

The audit is completed when all activities described in the audit plan have been carried out and the approved audit report has been distributed.

Documents pertaining to the audit should be retained or destroyed by agreement between the participating parties and in accordance with audit programme procedures and applicable statutory, regulatory and contractual requirements.

Unless required by law, the audit team and those responsible for managing the audit programme should not disclose the contents of documents, any other information obtained during the audit, or the audit report, to any other party without the explicit approval of the audit client and, where appropriate, the approval of the auditee. If disclosure of the contents of an audit document is required, the audit client and auditee should be informed as soon as possible.

6.8 Conducting audit follow-up

The conclusions of the audit may indicate the need for corrective, preventive or improvement actions, as applicable. Such actions are usually decided and undertaken by the auditee within an agreed timeframe and are not considered to be part of the audit. The auditee should keep the audit client informed of the status of these actions.

The completion and effectiveness of corrective action should be verified. This verification may be part of a subsequent audit.

The audit programme may specify follow-up by members of the audit team, which adds value by using their expertise. In such cases, care should be taken to maintain independence in subsequent audit activities.

7 Competence and evaluation of auditors

7.1 General

Confidence and reliance in the audit process depends on the competence of those conducting the audit. This competence is based on the demonstration of

- the personal attributes described in 7.2, and
- the ability to apply the knowledge and skills described in 7.3 gained through the education, work experience, auditor training and audit experience described in 7.4.

This concept of competence of auditors is illustrated in Figure 4. Some of the knowledge and skills described in 7.3 are common to auditors of quality and environmental management systems, and some are specific to auditors of the individual disciplines.

Auditors develop, maintain and improve their competence through continual professional development and regular participation in audits (see 7.5).

A process for evaluating auditors and audit team leaders is described in 7.6.

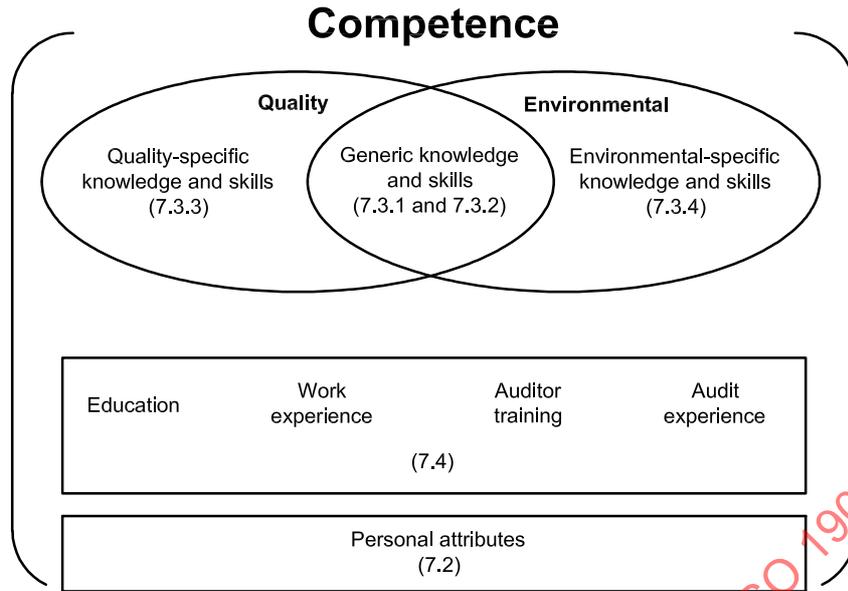


Figure 4 — Concept of competence

7.2 Personal attributes

Auditors should possess personal attributes to enable them to act in accordance with the principles of auditing described in clause 4.

An auditor should be:

- a) ethical, i.e. fair, truthful, sincere, honest and discreet;
- b) open-minded, i.e. willing to consider alternative ideas or points of view;
- c) diplomatic, i.e. tactful in dealing with people;
- d) observant, i.e. actively aware of physical surroundings and activities;
- e) perceptive, i.e. instinctively aware of and able to understand situations;
- f) versatile, i.e. adjusts readily to different situations;
- g) tenacious, i.e. persistent, focused on achieving objectives;
- h) decisive, i.e. reaches timely conclusions based on logical reasoning and analysis; and
- i) self-reliant, i.e. acts and functions independently while interacting effectively with others.

7.3 Knowledge and skills

7.3.1 Generic knowledge and skills of quality management system and environmental management system auditors

Auditors should have knowledge and skills in the following areas.

- a) Audit principles, procedures and techniques: to enable the auditor to apply those appropriate to different audits and ensure that audits are conducted in a consistent and systematic manner. An auditor should be able
- to apply audit principles, procedures and techniques,
 - to plan and organize the work effectively,
 - to conduct the audit within the agreed time schedule,
 - to prioritize and focus on matters of significance,
 - to collect information through effective interviewing, listening, observing and reviewing documents, records and data,
 - to understand the appropriateness and consequences of using sampling techniques for auditing,
 - to verify the accuracy of collected information,
 - to confirm the sufficiency and appropriateness of audit evidence to support audit findings and conclusions,
 - to assess those factors that can affect the reliability of the audit findings and conclusions,
 - to use work documents to record audit activities,
 - to prepare audit reports,
 - to maintain the confidentiality and security of information, and
 - to communicate effectively, either through personal linguistic skills or through an interpreter.
- b) Management system and reference documents: to enable the auditor to comprehend the scope of the audit and apply audit criteria. Knowledge and skills in this area should cover
- the application of management systems to different organizations,
 - interaction between the components of the management system,
 - quality or environmental management system standards, applicable procedures or other management system documents used as audit criteria,
 - recognizing differences between and priority of the reference documents,
 - application of the reference documents to different audit situations, and
 - information systems and technology for, authorization, security, distribution and control of documents, data and records.
- c) Organizational situations: to enable the auditor to comprehend the organization's operational context. Knowledge and skills in this area should cover
- organizational size, structure, functions and relationships,
 - general business processes and related terminology, and
 - cultural and social customs of the auditee.

- d) Applicable laws, regulations and other requirements relevant to the discipline: to enable the auditor to work within, and be aware of, the requirements that apply to the organization being audited. Knowledge and skills in this area should cover
- local, regional and national codes, laws and regulations,
 - contracts and agreements,
 - international treaties and conventions, and
 - other requirements to which the organization subscribes.

7.3.2 Generic knowledge and skills of audit team leaders

Audit team leaders should have additional knowledge and skills in audit leadership to facilitate the efficient and effective conduct of the audit. An audit team leader should be able

- to plan the audit and make effective use of resources during the audit,
- to represent the audit team in communications with the audit client and auditee,
- to organize and direct audit team members,
- to provide direction and guidance to auditors-in-training,
- to lead the audit team to reach the audit conclusions,
- to prevent and resolve conflicts, and
- to prepare and complete the audit report.

7.3.3 Specific knowledge and skills of quality management system auditors

Quality management system auditors should have knowledge and skills in the following areas.

- a) Quality-related methods and techniques: to enable the auditor to examine quality management systems and to generate appropriate audit findings and conclusions. Knowledge and skills in this area should cover
- quality terminology,
 - quality management principles and their application, and
 - quality management tools and their application (for example statistical process control, failure mode and effect analysis, etc.).
- b) Processes and products, including services: to enable the auditor to comprehend the technological context in which the audit is being conducted. Knowledge and skills in this area should cover
- sector-specific terminology,
 - technical characteristics of processes and products, including services, and
 - sector-specific processes and practices.

7.3.4 Specific knowledge and skills of environmental management system auditors

Environmental management system auditors should have knowledge and skills in the following areas.