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Environmental management systems — Requirements with guidance for use

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 207, *Environmental management*, Subcommittee SC 1, *Environmental management systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 14001:2015), which has been technically revised. It also replaces the Amendment ISO 14001:2015/Amd 1:2024.

The main changes are as follows:

— incorporation of latest ISO requirements for management system standards as appropriate;

— clarification of requirements associated with key topics.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 Background

Achieving a balance between the environment, society and the economy is considered essential to meet the needs of the present without compromising the ability of future generations to meet their needs. Sustainable development as a goal is achieved by balancing the three pillars of sustainability.

Societal expectations for sustainable development, transparency and accountability have evolved with increasingly stringent legislation and growing pressures on the environment from pollution, inefficient use of resources, improper waste management, climate change, degradation of ecosystems and loss of biodiversity. Undermining the environment can carry financial, social and business consequences, not just environmental implications.

These expectations have led organizations to adopt a systematic approach to environmental management by implementing environmental management systems with the aim of contributing to the environmental pillar of sustainability. As a result, organizations are better positioned to respond to the needs and expectations of interested parties and to meet the organization's compliance obligations.

0.2 Aim of an environmental management system

This document provides organizations with a framework to protect the environment and respond to changing environmental conditions in balance with socio-economic needs. It specifies requirements that enable an organization to achieve the intended outcomes it sets for its environmental management system.

A systematic approach to environmental management provides top management with information to build success over the long term and create options for contributing to sustainable development by:

— protecting the environment through preventing or mitigating adverse environmental impacts;

— mitigating the potential adverse effect of environmental conditions on the organization;

— assisting the organization to meet its compliance obligations;

— enhancing environmental performance;

— controlling or influencing the way the organization's products and services are designed, manufactured, distributed, consumed and disposed of by using a life cycle perspective that prevents adverse environmental impacts from being unintentionally shifted elsewhere within the life cycle;

— achieving financial and operational benefits that result from implementing environmentally sound alternatives that strengthen the organization's market position;

— communicating environmental information to relevant interested parties.

0.3 Success factors

The success of an environmental management system depends on commitment from all levels and functions of the organization, led by top management. Organizations can leverage opportunities to prevent or mitigate adverse environmental impacts and enhance beneficial environmental impacts, particularly those with strategic and competitive advantages. Top management can effectively address its risks and opportunities by integrating environmental management into the organization's business processes, strategic direction and decision-making, aligning them with other business priorities, and incorporating environmental governance into its overall management system. Demonstration of successful implementation of this document can be used to assure interested parties that an effective environmental management system is in place. Adoption of the requirements in this document, however, will not in itself guarantee optimal environmental outcomes.

Application of the requirements in this document can differ from one organization to another due to the context of the organization. Two organizations can carry out similar activities but can have different compliance obligations, commitments in their environmental policy, environmental technologies and environmental performance goals, yet both can conform to the requirements of this document.

The level of detail and complexity of the environmental management system will vary depending on the context of the organization, the scope of its environmental management system, its compliance obligations, and the nature of its activities, products and services, including its environmental aspects and associated environmental impacts.

0.4 Plan-Do-Check-Act model

The basis for the approach underlying an environmental management system is founded on the concept of Plan-Do-Check-Act (PDCA). The PDCA model provides an iterative process used by organizations to achieve continual improvement. It can be applied to an environmental management system and to each of its individual elements. It is briefly described as follows:

— Plan: Establish environmental objectives and processes necessary to deliver results in accordance with the organization's environmental policy.

— Do: Implement the processes as planned.

— Check: Monitor and measure processes against the environmental policy, including its commitments, environmental objectives and operating criteria, and report the results.

— Act: Take actions to continually improve.

Figure 1 shows how the framework used in this document can be integrated into a PDCA model, which can help new and existing users to understand the importance of a systems approach.

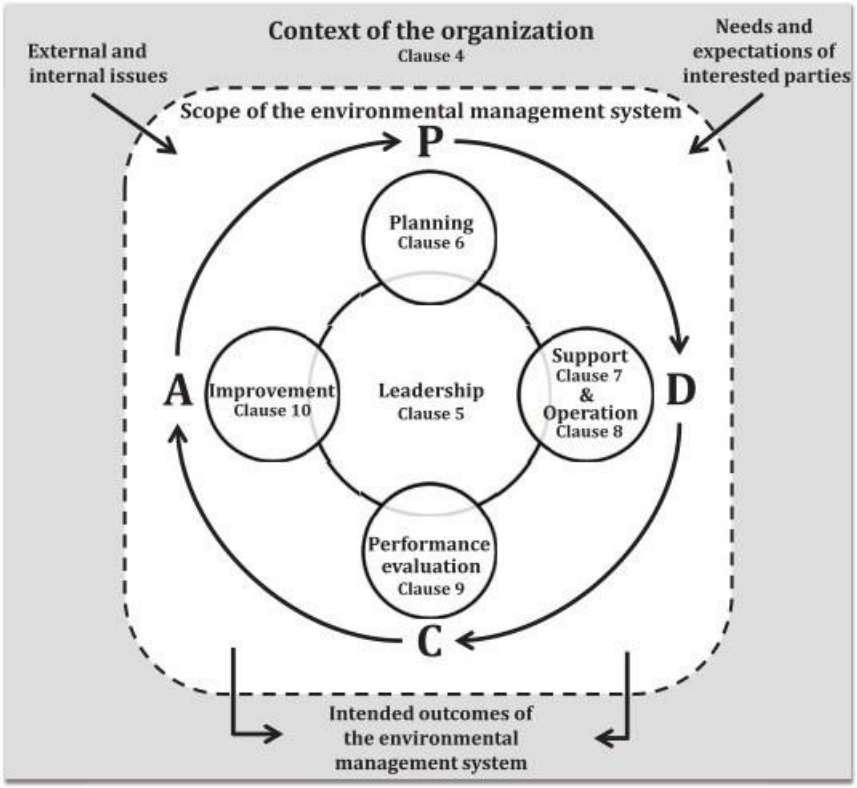

Figure 1 — Relationship between PDCA and the framework in this document

0.5 Contents of this document

This document conforms to ISO requirements for management system standards. These requirements include a harmonized structure, identical core text and common terms with core definitions, designed to benefit users implementing multiple ISO management system standards.

This document does not include requirements specific to other management systems, such as those for quality, occupational health and safety, energy or financial management. However, this document enables an organization to use a common approach and risk-based thinking to integrate its environmental management system with the requirements of other management systems.

This document contains the requirements used to assess conformity. An organization that wishes to demonstrate conformity with this document can do so by:

— making a self-determination and self-declaration; or

— seeking confirmation of its conformance by parties having an interest in the organization, such as customers; or

— seeking confirmation of its self-declaration by a party external to the organization; or

— seeking certification/registration of its environmental management system by an external organization.

Annex A provides explanatory information to prevent misinterpretation of the requirements of this document. Guidance on applying the ISO 14001 framework to specific environmental topic areas is addressed in the ISO 14002 series. Implementation guidance on environmental management systems is included in ISO 14004.

Clause A.3 provides further insights on specific words and phrases used in this document to enhance the understanding of concepts that are relevant to an environmental management system.

Environmental management systems — Requirements with guidance for use

1 Scope

This document specifies the requirements for an environmental management system that an organization can use to enhance its environmental performance. It is intended for use by an organization seeking to manage its environmental responsibilities in a systematic manner that contributes to the environmental pillar of sustainability.

This document helps an organization to achieve the intended outcomes of its environmental management system, which provide value for the environment, the organization itself and interested parties. The intended outcomes of an environmental management system include:

— enhancing environmental performance;

— meeting compliance obligations;

— achieving environmental objectives.

This document is applicable to any organization, regardless of size, type or nature, and applies to the environmental aspects of its activities, products and services that the organization determines it can either control or influence considering a life cycle perspective. This document does not state specific environmental performance criteria.

This document can be used in whole or in part to systematically improve environmental management. Claims of conformity to this document, however, are not acceptable unless all its requirements are incorporated into an organization's environmental management system and fulfilled without exclusion.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 Terms related to organization and leadership

3.1.1
management system
set of interrelated or interacting elements of an *organization* (3.1.5) to establish *policies* (3.1.3) and *objectives* (3.2.5) as well as *processes* (3.3.4) to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines.

EXAMPLE Quality, environment, occupational health and safety, energy or financial management.

Note 2 to entry: The management system elements include the organization's structure, roles and responsibilities, planning and operation.

Note 3 to entry: The scope of a management system can include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

3.1.2
environmental management system
part of the *management system* (3.1.1) used to manage *environmental aspects* (3.2.2), meet *compliance obligations* (3.2.9) and address *risks and opportunities* (3.2.10)

Note 1 to entry: The environmental management system elements include: context of the organization (Clause 4), leadership (Clause 5), planning (Clause 6), support (Clause 7), operation (Clause 8), performance evaluation (Clause 9) and improvement (Clause 10).

3.1.3
policy
intentions and direction of an *organization* (3.1.5) as formally expressed by its *top management* (3.1.6)

3.1.4
environmental policy
policy (3.1.3) related to *environmental performance* (3.4.11)

3.1.5
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.2.5)

Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

Note 2 to entry: If the organization is part of a larger entity, the term "organization" refers only to the part of the larger entity that is within the scope of the *environmental management system* (3.1.2).

3.1.6
top management
person or group of people who directs and controls an *organization* (3.1.5) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.

Note 2 to entry: If the scope of the *management system* (3.1.1) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

3.1.7
interested party (preferred term)
stakeholder (admitted term)
person or *organization* (3.1.5) that can affect, be affected by, or perceive itself to be affected by a decision or activity

EXAMPLE Customers, communities, suppliers, regulators, non-governmental organizations, investors and employees.

Note 1 to entry: To "perceive itself to be affected" means the perception has been made known to the organization.

3.2 Terms related to planning

3.2.1
environment
surroundings in which an *organization* (3.1.5) operates, including air, water, land, natural resources, flora, fauna, humans and their interrelationships

Note 1 to entry: Surroundings can extend from within an organization to the local, regional and global system.

Note 2 to entry: Surroundings can be described in terms of biodiversity, ecosystems, climate or other characteristics.

3.2.2
environmental aspect
element of an *organization's* (3.1.5) activities or products or services that interacts or can interact with the *environment* (3.2.1)

Note 1 to entry: An environmental aspect can cause (an) *environmental impact(s)* (3.2.4). A significant environmental aspect is one that has or can have one or more significant environmental impact(s).

Note 2 to entry: Significant environmental aspects are determined by the organization applying established criteria.

3.2.3
environmental condition
state or characteristic of the *environment* (3.2.1) as determined at a certain point in time

3.2.4
environmental impact
change to the *environment* (3.2.1), whether adverse or beneficial, wholly or partially resulting from an *organization's* (3.1.5) *environmental aspects* (3.2.2)

3.2.5
objective
result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as finance, health and safety, and *environment* (3.2.1)). They can be, for example, organization-wide or specific to a project, product, service or *process* (3.3.4).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended result, as a purpose, as an operational criterion, as an *environmental objective* (3.2.6) or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of *environmental management systems* (3.1.2), environmental objectives are set by the *organization* (3.1.5), consistent with the *environmental policy* (3.1.4), to achieve specific results.

3.2.6
environmental objective
objective (3.2.5) set by the *organization* (3.1.5) consistent with its *environmental policy* (3.1.4)

3.2.7
prevention of pollution
use of *processes* (3.3.4), practices, techniques, materials, products, services or energy to avoid, reduce or control (separately or in combination) the creation, emission or discharge of any type of pollutant or waste, in order to reduce adverse *environmental impacts* (3.2.4)

Note 1 to entry: Prevention of pollution can include source reduction or elimination; process, product or service changes; efficient use of resources; material and energy substitution; reuse; recovery; recycling; reclamation; or treatment.

3.2.8
requirement
need or expectation that is stated, generally implied or obligatory

Note 1 to entry: "Generally implied" means that it is custom or common practice for the *organization* (3.1.5) and *interested parties* (3.1.7) that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, e.g. in *documented information* (3.3.2).

3.2.9
compliance obligations (preferred term)
legal requirements and other requirements (admitted term)
legal *requirements* (3.2.8) that an *organization* (3.1.5) has to comply with and other requirements that an organization has to or chooses to comply with

Note 1 to entry: Compliance obligations are related to the *environmental management system* (3.1.2).

Note 2 to entry: Compliance obligations can arise from mandatory requirements, such as applicable laws and regulations, or voluntary commitments, such as organizational and industry standards, contractual relationships, codes of practice and agreements with community groups, non-governmental organizations, or other *interested parties* (3.1.7).

3.2.10
risks and opportunities
potential adverse effects (i.e. risks) and potential beneficial effects (i.e. opportunities)

3.3 Terms related to support and operation

3.3.1
competence
ability to apply knowledge and skills to achieve intended results

3.3.2
documented information
information required to be controlled and maintained by an *organization* (3.1.5) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

— the *management system* (3.1.1), including related *processes* (3.3.4);

— information created in order for the organization to operate (documentation);

— evidence of results achieved (records).

3.3.3
life cycle
consecutive and interlinked stages of a product (or service) system, from raw material acquisition or generation from natural resources to final disposal

Note 1 to entry: The life cycle stages include acquisition of raw materials, design, production, transportation/delivery, use, end-of-life treatment and final disposal.

[SOURCE: ISO 14044:2006, 3.1, modified — "(or service)" added to the definition. Note 1 to entry added.]

3.3.4
process
set of interrelated or interacting activities that uses or transforms inputs to deliver a result

Note 1 to entry: Whether the result of a process is called an output, a product or a service depends on the context of the reference.

Note 2 to entry: A process can be documented or not.

3.4 Terms related to performance evaluation and improvement

3.4.1
audit
systematic and independent *process* (3.3.4) for obtaining evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the *organization* (3.1.5) itself, or by an external party on its behalf.

Note 3 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.

Note 4 to entry: Independence can be demonstrated by freedom from responsibility for the activity being audited or freedom from bias and conflict of interest.

3.4.2
conformity
fulfilment of a *requirement* (3.2.8)

3.4.3
nonconformity
non-fulfilment of a *requirement* (3.2.8)

Note 1 to entry: Nonconformity relates to requirements in this document and additional *environmental management system* (3.1.2) requirements that an *organization* (3.1.5) establishes for itself.

3.4.4
corrective action
action to eliminate the cause(s) of a *nonconformity* (3.4.3) and to prevent recurrence

3.4.5
continual improvement
recurring activity to enhance *performance* (3.4.10)

Note 1 to entry: Enhancing performance relates to the use of the *environmental management system* (3.1.2) to enhance *environmental performance* (3.4.11) consistent with the *organization's* (3.1.5) *environmental policy* (3.1.4).

Note 2 to entry: The activity does not have to take place in all areas simultaneously or without interruption.

3.4.6
effectiveness
extent to which planned activities are realized and planned results are achieved

3.4.7
indicator
quantitative, qualitative or binary variable that can be measured or described, representing the status of operations, management, conditions or impacts

[SOURCE: ISO 14031:2021, 3.4.1]

3.4.8
monitoring
determining the status of a system, a *process* (3.3.4) or an activity

Note 1 to entry: To determine the status, there can be a need to check, supervise or critically observe.

3.4.9
measurement
process (3.3.4) to determine a value

3.4.10
performance
measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to managing activities, *processes* (3.3.4), products, services, systems or *organizations* (3.1.5).

3.4.11
environmental performance
performance (3.4.10) related to the management of *environmental aspects* (3.2.2)

Note 1 to entry: For an *environmental management system* (3.1.2), results can be measured against the *organization's* (3.1.5) *environmental policy* (3.1.4), *environmental objectives* (3.2.6) or other criteria, using *indicators* (3.4.7).

4 Context of the organization

4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended outcomes of its environmental management system.

These issues shall include environmental conditions being affected by the organization or capable of affecting the organization, such as pollution levels, availability of natural resources, climate change, biodiversity or ecosystem health (see A.4.1).

4.2 Understanding the needs and expectations of interested parties

The organization shall determine:

a) the interested parties that are relevant to the environmental management system;

b) the relevant needs and expectations (i.e. requirements) of these interested parties;

c) which of these needs and expectations become its compliance obligations (see 6.1.3) and will be addressed through the environmental management system.

NOTE 1 Relevant interested parties can have needs and expectations related to environmental conditions, such as pollution levels, availability of natural resources, climate change, biodiversity or ecosystem health.

NOTE 2 The relevant needs and expectations of interested parties, other than legal requirements, become a compliance obligation when the organization decides to comply with them.

4.3 Determining the scope of the environmental management system

The organization shall determine the boundaries and applicability of the environmental management system to establish its scope.

When determining this scope, the organization shall consider:

a) the external and internal issues referred to in 4.1;

b) the compliance obligations referred to in 4.2;

c) its organizational units, functions and physical boundaries;

d) its activities, products and services;

e) its authority and ability to exercise control and influence over the life cycle of its activities, products and services.

Once the scope is defined, all activities, products and services of the organization within that scope shall be included in the environmental management system.

The scope shall be available as documented information and shall be available to interested parties.

4.4 Environmental management system

To achieve the intended outcomes, including enhancing its environmental performance, the organization shall establish, implement, maintain and continually improve an environmental management system, including the processes needed and their interactions, in accordance with the requirements of this document.

The organization shall consider the knowledge gained in 4.1 and 4.2 when establishing and maintaining the environmental management system.

5 Leadership

5.1 Leadership and commitment

Top management shall demonstrate leadership and commitment with respect to the environmental management system by:

a) taking accountability for the effectiveness of the environmental management system;

b) ensuring that the environmental policy and environmental objectives are established and are compatible with the strategic direction and the context of the organization;

c) ensuring the integration of the environmental management system requirements into the organization's business processes;

NOTE Reference to "business" in this document can be interpreted broadly to mean those activities that are core to the purpose(s) of the organization's existence.

d) ensuring that the resources needed for the environmental management system are available;

e) communicating the importance of effective environmental management and of conforming to the environmental management system requirements;

f) ensuring that the environmental management system achieves its intended outcomes;

g) directing and supporting persons to contribute to the effectiveness of the environmental management system;

h) promoting continual improvement;

i) supporting other relevant roles to demonstrate their leadership as it applies to their areas of responsibility.

5.2 Environmental policy

Top management shall establish, implement and maintain an environmental policy within the defined scope of its environmental management system that:

a) is appropriate to the purpose and context of the organization, including the nature, scale and environmental impacts of its activities, products and services;

b) provides a framework for setting environmental objectives;

c) includes a commitment to the protection of the environment, including prevention of pollution and other specific commitment(s) relevant to the context of the organization;

NOTE Other specific commitment(s) to protect the environment can include: preservation or conservation of natural resources; sustainable resource use; climate change mitigation and adaptation; or protection of biodiversity and ecosystems.

d) includes a commitment to meet its compliance obligations;

e) includes a commitment to continual improvement of the environmental management system to enhance environmental performance.

The environmental policy shall:

— be available as documented information;

— be communicated within the organization;

— be available to interested parties.

5.3 Roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned and communicated within the organization.

Top management shall assign the responsibility and authority for:

a) ensuring that the environmental management system conforms to the requirements of this document;

b) reporting on the performance of the environmental management system, including environmental performance, to top management.

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 General

The organization shall establish, implement and maintain (a) process(es) needed to meet the requirements in 6.1.2 to 6.1.5.

The process(es) for 6.1.2 to 6.1.5 shall be available as documented information to the extent necessary to have confidence that they are carried out as planned.

6.1.2 Environmental aspects

Within the defined scope of the environmental management system, the organization shall determine the environmental aspects of its activities, products and services that it can control and those that it can influence, and their associated environmental impacts, considering a life cycle perspective.

NOTE 1 A life cycle perspective includes consideration of the environmental aspects and impacts at each life cycle stage. The life cycle stages include acquisition of raw materials, design, production, transportation/delivery, use, end-of-life treatment and final disposal.

The organization shall determine potential emergency situations (see 8.2), including those that can have an environmental impact.

When determining environmental aspects, the organization shall take into account:

a) normal and abnormal conditions;

b) change, including planned or new developments, and new or modified activities, products and services (see 6.3);

c) potential emergency situations.

The organization shall determine those aspects that have or can have a significant environmental impact (i.e. significant environmental aspects) by using established criteria.

NOTE 2 Significant environmental aspects can result in risks and opportunities associated with either adverse or beneficial environmental impacts.

The organization shall communicate its significant environmental aspects among the various levels and functions of the organization, as appropriate.

The following shall be available as documented information:

— environmental aspects and associated environmental impacts;

— criteria used to determine its significant environmental aspects;

— significant environmental aspects.

6.1.3 Compliance obligations

The organization shall:

a) determine and have access to the compliance obligations related to its environmental aspects;

b) determine how these compliance obligations apply to the organization;

c) take these compliance obligations into account when establishing, implementing, maintaining and continually improving its environmental management system.

NOTE Compliance obligations can result in risks and opportunities to the organization.

The compliance obligations shall be available as documented information.

6.1.4 Risks and opportunities

When planning for the environmental management system, the organization shall consider:

a) the external and internal issues referred to in 4.1;

b) the relevant needs and expectations (i.e. requirements) of interested parties referred to in 4.2;

c) the scope of its environmental management system referred to in 4.3;

and determine the risks and opportunities to the organization related to its environmental aspects (see 6.1.2), compliance obligations (see 6.1.3) and other issues and requirements, if any, identified in 4.1 and 4.2, that need to be addressed to:

— give assurance that the environmental management system can achieve its intended outcomes;

— prevent, or reduce, undesired effects, including the potential for external environmental conditions to affect the organization;

— achieve continual improvement.

The risks and opportunities that need to be addressed shall be available as documented information.

6.1.5 Planning action

The organization shall plan:

a) to take actions to address its:

1) significant environmental aspects determined in 6.1.2;

2) compliance obligations determined in 6.1.3;

3) risks and opportunities determined in 6.1.4;

b) how to:

1) implement the actions into its environmental management system processes (see 6.2, Clause 7, Clause 8 and 9.1) or integrate the actions into other business processes;

2) evaluate the effectiveness of these actions (see 9.1).

When planning these actions, the organization shall consider its technological options and its financial, operational and business requirements.

6.2 Environmental objectives and planning to achieve them

6.2.1 Environmental objectives

The organization shall establish environmental objectives at relevant functions and levels, taking into account the organization's significant environmental aspects and related compliance obligations, and considering its risks and opportunities.

The environmental objectives shall be:

a) consistent with the environmental policy;

b) measurable (if practicable);

c) monitored;

d) communicated;

e) updated as appropriate;

f) available as documented information.

6.2.2 Planning actions to achieve environmental objectives

When planning how to achieve its environmental objectives, the organization shall determine:

a) what will be done;

b) what resources will be required;

c) who will be responsible;

d) when it will be completed;

e) how the results will be evaluated, including indicators for monitoring progress toward achievement of its measurable environmental objectives (see 9.1.1).

The organization shall consider how actions to achieve its environmental objectives can be integrated into the organization's business processes.

6.3 Planning of changes

When the organization determines the need for changes that affect or can affect the environmental management system, the changes shall be carried out in a planned manner. The changes shall be managed to ensure that the organization can achieve the intended outcomes of its environmental management system.

NOTE 1 The need for change to the environmental management system can arise from internal or external sources. See A.6.3 for examples.

NOTE 2 Managing change is addressed in various requirements in this document. See A.6.3 for examples.

7 Support

7.1 Resources

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the environmental management system.

7.2 Competence

The organization shall:

a) determine the necessary competence of person(s) doing work under its control that affects its environmental performance and its ability to meet its compliance obligations;

b) ensure that these persons are competent on the basis of appropriate education, training, or experience;

c) determine training needs associated with its environmental aspects and its environmental management system;

d) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken.

NOTE Applicable actions can include, for example: the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

Appropriate documented information shall be available as evidence of competence.

7.3 Awareness

The organization shall ensure that persons doing work under the organization's control are aware of:

a) the environmental policy;

b) the significant environmental aspects and related actual or potential environmental impacts associated with their work;

c) their contribution to the effectiveness of the environmental management system, including the benefits of enhanced environmental performance;

d) the implications of not conforming with the environmental management system requirements, including not meeting the organization's compliance obligations.

7.4 Communication

7.4.1 General

The organization shall establish, implement and maintain the process(es) needed for internal and external communications relevant to the environmental management system including:

a) on what it will communicate;

b) when to communicate;

c) with whom to communicate;

d) how to communicate.

When establishing its communication process(es), the organization shall:

— take into account its compliance obligations;

— ensure that environmental information communicated is consistent with information generated within the environmental management system and is reliable.

The organization shall respond to relevant communications on its environmental management system.

Appropriate documented information shall be available as evidence of the organization's communications.

7.4.2 Internal communication

The organization shall:

a) internally communicate information relevant to the environmental management system among the various levels and functions of the organization, including changes to the environmental management system, as appropriate;

b) ensure that its communication process(es) enable(s) persons doing work under the organization's control to contribute to continual improvement.

7.4.3 External communication

The organization shall externally communicate information relevant to the environmental management system, as established by the organization's communication process(es) and as required by its compliance obligations.

7.5 Documented information

7.5.1 General

The organization's environmental management system shall include:

a) documented information required by this document;

b) documented information determined by the organization as being necessary for the effectiveness of the environmental management system.

NOTE The extent of documented information for an environmental management system can differ from one organization to another due to:

— the size of organization and its type of activities, processes, products and services;

— the need to demonstrate fulfilment of its compliance obligations;

— the complexity of processes and their interactions;

— the competence of persons doing work under the organization's control.

7.5.2 Creating and updating documented information

When creating and updating documented information, the organization shall ensure appropriate:

a) identification and description (e.g. a title, date, author, or reference number);

b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

c) review and approval for suitability and adequacy.

7.5.3 Control of documented information

Documented information required by the environmental management system and by this document shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

For the control of documented information, the organization shall address the following activities, as applicable:

— distribution, access, retrieval and use;

— storage and preservation, including preservation of legibility;

— control of changes (e.g. version control);

— retention and disposition.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the environmental management system shall be identified as appropriate, and controlled.

8 Operation

8.1 Operational planning and control

The organization shall establish, implement, control and maintain the process(es) needed to meet environmental management system requirements, and to implement the actions determined in Clause 6, by:

— establishing operating criteria for the process(es);

— implementing control of the process(es) in accordance with the operating criteria.

NOTE Controls can include engineering controls and procedures. Controls can be implemented following a hierarchy (e.g. elimination, substitution, administrative) and can be used individually or in combination.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that externally provided process(es), products or services that are relevant to the intended outcomes of the environmental management system are controlled or influenced. The type and extent of control or influence to be applied shall be defined within the environmental management system.

Consistent with a life cycle perspective, the organization shall:

a) establish controls, as appropriate, to ensure that its environmental requirement(s) is (are) addressed in the design and development process for the product or service, considering each life cycle stage;

b) determine its environmental requirement(s) for the procurement of products and services, as appropriate;

c) communicate its relevant environmental requirement(s) to external providers, including contractors;

d) consider the need to provide information about potential significant environmental impacts associated with the transportation or delivery, use, end-of-life treatment and final disposal of its products and services.

The process(es) for 8.1 shall be available as documented information to the extent necessary to have confidence that they are carried out as planned.

8.2 Emergency preparedness and response

The organization shall establish, implement and maintain the process(es) needed to prepare for and respond to the potential emergency situations determined in 6.1.2.

The organization shall:

a) prepare to respond by planning action(s) to prevent or mitigate adverse environmental impacts from emergency situations;

b) respond to actual emergency situations;

c) take action to prevent or mitigate the consequences of emergency situations, appropriate to the magnitude of the emergency and the potential environmental impact;

d) periodically test the planned response action(s), where practicable;

e) periodically review and revise the process(es) and planned response action(s), in particular after the occurrence of emergency situations or tests;

f) provide relevant information and training related to emergency preparedness and response, as appropriate, to relevant interested parties, including persons working under its control.

The process(es) for 8.2 shall be available as documented information to the extent necessary to have confidence that they are carried out as planned.

9 Performance evaluation

9.1 Monitoring, measurement, analysis, and evaluation

9.1.1 General

The organization shall evaluate its environmental performance and the effectiveness of the environmental management system.

The organization shall determine:

a) what needs to be monitored, measured and analysed;

b) the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results;

c) the criteria against which the organization will evaluate its environmental performance, and appropriate indicators;

d) when the monitoring and measuring shall be performed;

e) when the results from monitoring and measurement shall be analysed and evaluated.

The organization shall ensure that calibrated or verified monitoring and measurement equipment is used and maintained, as appropriate.

The organization shall communicate relevant environmental performance information both internally and externally, as identified in its communication process(es) and as required by its compliance obligations.

Appropriate documented information shall be available as evidence of the monitoring, measurement, analysis and evaluation results.

9.1.2 Evaluation of compliance

The organization shall establish, implement and maintain the process(es) needed to evaluate if it is meeting its compliance obligations.

The organization shall:

a) determine the frequency that compliance will be evaluated;

b) evaluate compliance and take action if needed;

c) maintain knowledge and understanding of its compliance status.

Appropriate documented information shall be available as evidence of the compliance evaluation result(s).

9.2 Internal audit

9.2.1 General

The organization shall conduct internal audits at planned intervals to provide information on whether the environmental management system:

a) conforms to:

1) the organization's own requirements for its environmental management system;

2) the requirements of this document;

b) is effectively implemented and maintained.

9.2.2 Internal audit programme

The organization shall establish, implement and maintain (an) internal audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting of its internal audits.

When establishing the internal audit programme(s), the organization shall consider the environmental importance of the processes concerned, changes affecting the organization and the results of previous audits.

The organization shall:

a) define the audit objective(s), audit criteria and scope for each audit;

b) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

c) ensure that the results of audits are reported to relevant management.

The following documented information shall be available:

— the audit programme(s);

— evidence of the implementation of the audit programme(s);

— evidence of the audit results.

9.3 Management review

9.3.1 General

Top management shall review the organization's environmental management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.

9.3.2 Management review inputs

The management review inputs shall include:

a) the status of actions from previous management reviews;

b) changes in:

1) external and internal issues that are relevant to the environmental management system;

2) the needs and expectations of interested parties that are relevant to the environmental management system, including compliance obligations;

3) its significant environmental aspects;

4) risks and opportunities;

c) the extent to which environmental objectives have been achieved;

d) information on the organization's environmental performance, including trends in:

1) nonconformities and corrective actions;

2) monitoring and measurement results;

3) meeting its compliance obligations;

4) audit results;

e) adequacy of resources;

f) relevant communication(s) from interested parties, including complaints;

g) opportunities for continual improvement.

9.3.3 Management review results

The results of the management review shall include:

a) conclusions on the continuing suitability, adequacy and effectiveness of the environmental management system;

b) decisions related to continual improvement opportunities;

c) decisions related to any need for changes to the environmental management system, including resources;

d) actions, if needed, when environmental objectives have not been achieved;

e) opportunities to improve integration of the environmental management system with other business processes, if needed;

f) any implications for the strategic direction of the organization.

Documented information shall be available as evidence of the results of management reviews.

10 Improvement

10.1 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the environmental management system to enhance environmental performance by determining opportunities for improvement (see Clause 9 and 10.2) and implementing necessary actions to achieve the intended outcomes of its environmental management system.

10.2 Nonconformity and corrective action

When a nonconformity occurs, the organization shall:

a) react to the nonconformity and, as applicable:

1) take action to control and correct it;

2) deal with the consequences, including mitigating adverse environmental impacts;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

1) reviewing the nonconformity;

2) determining the cause(s) of the nonconformity;

3) determining if similar nonconformities exist, or can potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) make changes to the environmental management system, if necessary.

Corrective actions shall be appropriate to the significance of the effects of the nonconformities encountered, including their environmental impact(s).

Documented information shall be available as evidence of:

— the nature of the nonconformities and any subsequent actions taken;

— the results of any corrective action.

Annex A
(informative)

Guidance on the use of this document

A.1 General

The explanatory information given in this annex is intended to prevent misinterpretation of the requirements contained in this document. While this information addresses and is consistent with these requirements, it is not intended to add to, subtract from, or in any way modify them. In addition, the ISO subcommittee that prepared this document (TC 207/SC 1) has a process for managing requests for interpretation to give users a better understanding of its requirements. These interpretations are found on the subcommittee's website: https://www.isotc207.org/subcomittees-iso/tc-207/sc-1.

The requirements in this document should be viewed from a systems or holistic perspective. The user should not read a particular sentence or clause of this document in isolation from other clauses. There is an interrelationship between the requirements in some clauses and the requirements in other clauses. For example, it is necessary for the organization to understand the relationship between the commitments in its environmental policy (see 5.2) and the requirements that are specified in planning action (see 6.1.5), evaluation of compliance (see 9.1.2) and continual improvement (see 10.1). Another example is the interrelationship between the issues (see 4.1) and needs and expectations of interested parties (see 4.2) that are part of its context, and its environmental aspects (see 6.1.2) and its compliance obligations (see 6.1.3), as sources of its risks and opportunities (see 6.1.4).

A.2 Clarification of structure and terminology

The clause structure and some of the terminology of this document is provided to enable organizations to understand its alignment with other management system standards. There is, however, no requirement in this document for its clause structure or terminology to be applied to an organization's environmental management system or its documentation. There is no requirement to replace the terms used by an organization with the terms used in this document. Organizations can choose to use terms that suit their business (e.g. "records", "documentation", "procedures") rather than "documented information".

A.3 Clarification of concepts

In addition to the terms and definitions given in Clause 3, clarification of selected concepts is provided below to prevent misunderstanding:

— In this document, the use of the word "any" implies selection or choice.

— The words "appropriate" and "applicable" are not interchangeable. "Appropriate" means suitable (for, to) and implies some degree of freedom, while "applicable" means relevant or possible to apply and implies that if it can be done, it has to be done.

— The word "consider" means it is necessary to think about the topic but it can be excluded, whereas "take into account" means it is necessary to think about the topic but it cannot be excluded.

— "Continual" indicates duration that occurs over a period of time, but with intervals of interruption (unlike "continuous" which indicates duration without interruption). "Continual" is therefore the appropriate word to use when referring to improvement.

— The word "outcome" refers to the anticipated and planned consequences of implementing an environmental management system. In contrast, "result" refers to a specific effect or output, often associated with measurement, qualitative or quantitative data, calculations, or indicators of performance. "Outcome"

emphasizes strategic intent and direction, whereas "result" refers to achievements that have already been attained.

— The phrase "intended outcome" is what the organization intends to achieve by implementing its environmental management system. The minimal intended outcomes include enhancing environmental performance, meeting compliance obligations and achieving environmental objectives. Organizations can set additional intended outcomes for their environmental management system. For example, consistent with their commitment to protection of the environment, an organization may establish an intended outcome to work towards sustainable development.

— In this document, the word "effect" is used to describe the result of a change to the organization. The phrase "environmental impact" refers specifically to the result of a change to the environment.

— The word "ensure" means the responsibility can be delegated, but not the accountability.

— The word "determine" implies a discovery process that results in knowledge.

— The concept of "target" is captured within the term "environmental objective".

— The phrase "person(s) doing work under its control" includes persons working for the organization and those working on its behalf for which the organization has responsibility (e.g. contractors).

This document uses some new terminology. A brief explanation is given below to aid both new users and those who have used previous editions of this document.

— The phrase "meet compliance obligations" replaces the phrase "fulfil compliance obligations" used in the previous edition of this document in order to adhere to ISO requirements for management system standards. The intent of this new phrase does not differ from that of the previous edition.

— To clarify the meaning of "documented information", two changes have been made. First, the phrase "shall be available as documented information" replaces "maintain documented information" which previously referred to documentation other than records. Second, "documented information shall be available as evidence of" replaces "retain documented information as evidence of" which previously referred to records. The phrase "as evidence of" is not a requirement to meet legal evidentiary requirements; its intent is only to indicate objective evidence is retained. In the context of documented information, the term "available" means the organization can obtain, use or provide the information to ensure an effective environmental management system. Where it is stated that the information "be available to interested parties", it means those parties may acquire the information from the organization (see 4.3 and 5.2).

— The term "outsource" has been deleted and the phrase "outsourced processes" has been replaced by "externally provided processes, products or services" in order to adhere to ISO requirements for management system standards. Externally provided processes, products or services are used by the organization but supplied by others outside the organization. The phrase "external provider" means an external supplier organization including a contractor that provides a product or a service.

— The definition of risk as stated in the previous edition of this document has been removed as the term "risk" is not used in isolation in the document requirements. The concept of the defined term "risks and opportunities" is used in the clauses of this document that contains requirements.

A.4 Context of the organization

A.4.1 Understanding the organization and its context

The intent of 4.1 is to provide a broad understanding of the issues that are relevant to the purpose of the organization and that can affect, either positively or negatively, the way the organization manages its environmental responsibilities. Issues are important topics for the organization, problems for debate and discussion or changing circumstances that affect the organization's ability to achieve the intended outcomes it sets for its environmental management system.

Examples of external and internal issues which can be relevant to the context of the organization include:

a) environmental conditions related to climate, air quality, water quality, land use, existing contamination, natural resource availability, ecosystem health and biodiversity that can either affect the organization's purpose or be affected by its environmental aspects;

b) the external natural, cultural, social, political, legal, regulatory, financial, technological, economic and competitive circumstances, whether local, regional, national or international;

c) the internal characteristics or conditions of the organization, such as its activities, products and services, environmental performance, strategic direction, culture and capabilities (i.e. people, knowledge, processes and systems).

Environmental conditions can be local, regional or global, and subject to sudden or gradual change. These conditions do not occur in isolation; they are interconnected. For example, climate interacts with many environmental conditions. Therefore, failure to consider the relevant environmental conditions and their potential interaction can contribute to worsening environmental impacts, which can increase risks and operational challenges for organizations. Understanding these interconnections is crucial for effective environmental management.

Ecosystem health refers to the overall condition or integrity of an ecosystem and its ability to maintain structure, function and resilience over time. An ecosystem consists of living organisms such as plants, animals and microbes, interacting with each other and with air, water and soil to form a functional unit, such as coral reefs, mangroves, forests, deserts, lakes, ponds, grasslands and tundra. Ecosystems are key components of natural capital, i.e. the world's stock of natural assets, that supply natural resources, regulate processes such as climate control and nutrient cycling, and offer nature-based recreational and educational benefits. Organizations depend on ecosystems, but their activities, products and services can preserve, enhance or degrade ecosystems.

An understanding of the context of an organization is used to establish, implement, maintain and continually improve its environmental management system to support the organization's purpose and strategic direction (see 4.4). The external and internal issues that are determined in 4.1, including environmental conditions, can result in risks and opportunities to the organization or to the environmental management system (see 6.1.4). The organization determines those that it will address (see 6.1.4) and manage (see 6.1.5, 6.2, Clause 7, Clause 8 and 9.1).

For information related to environmental conditions, refer to, for example, the ISO 14002 series, ISO 14055 series, ISO 14080, ISO 14090, ISO 14091, ISO 17298 and ISO 59014.

A.4.2 Understanding the needs and expectations of interested parties

An organization is expected to gain a general overview of the expressed needs and expectations of those external and internal interested parties that have been determined by the organization to be relevant. The organization considers the knowledge gained when determining which of these needs and expectations it has to or it chooses to comply with, i.e. its compliance obligations (see 4.2).

Interested party requirements are not necessarily requirements of the organization. Some interested party requirements reflect needs and expectations that are mandatory because they have been incorporated into laws, regulations, permits and licences by governmental or even court decision. The organization may decide to voluntarily agree to or adopt other requirements of interested parties (e.g. entering into a contractual relationship, subscribing to a voluntary initiative). Once the organization adopts them, they become organizational requirements (i.e. compliance obligations) and are taken into account when planning the environmental management system (see 4.4). A more detailed-level analysis of its compliance obligations is performed in 6.1.3.

In the case of an interested party perceiving itself to be affected by the organization's decisions or activities related to environmental performance, the organization considers the relevant needs and expectations that are made known or have been disclosed by the interested party to the organization.

Examples of interested parties' needs and expectations related to environmental conditions can include compliance with environmental pollutant regulations, or reporting information about natural resource

consumption and greenhouse gas emissions, or organizational practices to protect biodiversity and ecosystem health. While climate change is a focal point for many interested parties, it is not the only relevant issue that organizations should consider. The planet is experiencing other challenges to environmental conditions such as increased pollutant levels, natural resource depletion, biodiversity loss and ecosystem instability.

Understanding how the organization affects or is affected by these environmental conditions can be useful for determining which needs and expectations become part of its compliance obligations.

A.4.3 Determining the scope of the environmental management system

The scope of the environmental management system is intended to clarify the physical and organizational boundaries to which the environmental management system applies, especially if the organization is a part of a larger organization. An organization has the freedom and flexibility to define its boundaries. It may choose to implement the requirements in this document throughout the entire organization, or only in (a) specific part(s) of the organization, as long as top management for that (those) part(s) has authority to establish an environmental management system.

In setting the scope, the credibility of the environmental management system depends on the choice of organizational boundaries. The organization considers the extent of control or influence that it can exert over activities, products and services considering a life cycle perspective. Organizations that rely on other entities (e.g. corporate or regional offices) for key functions (e.g. resource allocation, decision-making, other types of support) should consider how this relationship affects the scope of their operations and their environmental management system.

Scoping should not be used to exclude activities, products, services or facilities that have or can have significant environmental aspects, or to evade compliance obligations. The scope is a factual and representative statement of the organization's operations included within its environmental management system. It should not be misleading nor exclude relevant information about the functions, operations or locations that conform to the environmental management system requirements.

Once the organization asserts it conforms to the requirements in this document, the requirement to make the scope statement available to interested parties applies.

A.4.4 Environmental management system

The organization retains authority and accountability to decide how it fulfils the requirements of this document, including the level of detail and extent to which it:

a) establishes one or more processes (including responsibilities for the process(es)) to have confidence that the organization can achieve the intended outcomes of its environmental management system;

b) integrates environmental management system requirements (see 5.1, 6.1.5, 6.2.2 and 9.3.3) into its various business processes (e.g. design and development, procurement, production, human resources, sales and marketing processes);

c) incorporates issues associated with the context of the organization (see 4.1) and interested party requirements (see 4.2) within its environmental management system.

The organization has the flexibility to establish how it structures the process(es) to meet the requirements of this document, which does not mandate separate processes or procedures for each requirement. For example, the organization may have a single planning process that addresses a number of requirements set out in Clauses 4 and 6. However, the organization ensures that each of the separate requirements have been addressed.

Processes and documented information developed by other business functions within the organization, or by a larger entity to which it belongs, can be used to meet the requirements of the environmental management system.

For information on maintaining the environmental management system as part of managing change, see A.6.3.

A.5 Leadership

A.5.1 Leadership and commitment

To demonstrate leadership and commitment, there are specific responsibilities related to the environmental management system in which top management is personally involved or directs. Top management can delegate certain responsibilities for actions to others as indicated by the word "ensuring" in 5.1; however, top management retains accountability.

Top management supports other roles to demonstrate their leadership by promoting a culture that engages persons working for the organization, or on its behalf, in activities that contribute to the intended outcomes of the environmental management system, including enhancing environmental performance, meeting compliance obligations and achieving environmental objectives.

Top management can demonstrate leadership and enhance trust with interested parties through their actions on environmental and sustainability issues.

A.5.2 Environmental policy

An environmental policy is a set of principles stated as commitments in which top management outlines the intentions of the organization to support and enhance its environmental performance. The environmental policy enables the organization to set its environmental objectives (see 6.2), take actions to achieve the intended outcomes of the environmental management system and achieve continual improvement (see Clause 10).

Consistent with the intended outcomes of an environmental management system, three basic commitments for the environmental policy are specified in this document to:

a) protect the environment;

b) meet the organization's compliance obligations;

c) continually improve the environmental management system to enhance environmental performance.

These commitments are then reflected in the processes an organization establishes to address specific requirements in this document, to ensure a robust, credible and reliable environmental management system.

The commitment to protect the environment is intended to not only prevent adverse environmental impacts through prevention of pollution, but also to protect the natural environment from harm and degradation arising from the organization's activities, products and services. The specific commitment(s) an organization pursues should be relevant to the context of the organization, including the local or regional environmental conditions. These commitments can address, for example, water quality, air quality or recycling, and can also include commitments related to natural resource preservation or conservation, climate change mitigation and adaptation, protection of biodiversity and ecosystems, and restoration.

While all the commitments are important, some interested parties are especially concerned with the organization's commitment to meet its compliance obligations, particularly applicable legal requirements. This document specifies a number of interconnected requirements related to this commitment. These include the need to:

— determine compliance obligations (see 6.1.3);

— ensure operations are carried out in accordance with these compliance obligations (see 8.1);

— periodically evaluate fulfilment of the compliance obligations (see 9.1.2);

— correct nonconformities related to compliance obligations (see 10.2).

A.5.3 Roles, responsibilities and authorities

Those involved in the organization's environmental management system should have a clear understanding of their role, responsibility(ies) and authority(ies) for conforming to the requirements of this document and

achieving the intended outcomes of the environmental management system. This enables employees to have confidence that what they do can contribute to environmental performance, meet compliance obligations and achieve environmental objectives.

Assigning responsibilities and authorities together with ensuring competence (see 7.2), awareness (see 7.3) and internal communication (see 7.4.2) can enhance employee engagement in the environmental management system.

The specific roles and responsibilities identified in 5.3 can be assigned to an individual, sometimes referred to as the "management representative", shared by several individuals or assigned to a member of top management.

A.6 Planning

A.6.1 Actions to address risks and opportunities

A.6.1.1 General

The overall intent of the process(es) established by the organization to meet the requirements in 6.1.2 to 6.1.5 is to ensure that the organization is able to achieve the intended outcomes of its environmental management system, to prevent or reduce undesired effects and to achieve continual improvement.

Planning for the environmental management system follows a risk-based approach to determine:

— significant environmental aspects based on their impacts (see 6.1.2);

— compliance obligations linked to environmental aspects (see 6.1.3);

— risks and opportunities that need to be addressed (see 6.1.4).

The organization chooses how to determine the risks and opportunities that need to be addressed. There is no specific method, number of steps or processes required. For example, the organization can use one process to look at environmental aspects and impacts, and a different process for risks and opportunities, or can use one process that covers both.

A.6.1.2 Environmental aspects

An organization determines its environmental aspects and associated environmental impacts within the scope of the environmental management system, and determines those that are significant and, therefore, will be addressed by its environmental management system.

Changes to the environment, either adverse or beneficial, that result wholly or partially from environmental aspects are called "environmental impacts". The environmental impact can occur at local, regional and global scales, and also can be direct, indirect or cumulative by nature. The relationship between environmental aspects and environmental impacts is one of cause and effect.

An organization does not have to consider each product, component or raw material individually to determine and evaluate their environmental aspects; it can group or categorize activities, products and services when they have common characteristics.

When determining its environmental aspects, the organization should consider, for example:

a) emissions to air;

b) releases to water;

c) releases to land;

d) use of raw materials and natural resources;

e) use of energy;

f) energy emitted (e.g. heat, radiation, vibration, sound, light);

g) generation of waste and/or by-products;

h) land use;

i) use of marine and coastal areas.

In addition to the environmental aspects that it controls directly, an organization determines whether there are environmental aspects that it can influence. These can be related to products and services used by the organization which are provided by others (i.e. externally provided process(es)), as well as products and services that it provides to others.

With respect to the products and services an organization provides to others, it can have limited influence on the use and end-of-life treatment of the products and services. In all circumstances, it is the organization that determines the extent of control it is able to exercise, the environmental aspects it can influence and the extent to which it chooses to exercise such influence.

When determining environmental aspects, the organization considers a life cycle perspective. The intent is to understand the environmental impacts of its activities, products or services at each stage of the life cycle. The life cycle stages that are applicable will vary depending on the activity, product or service.

Consideration should be given to environmental aspects related to the organization's activities, products and services, such as:

— design and development of its facilities, processes, products and services;

— acquisition of raw materials, including extraction;

— operational or manufacturing processes, including warehousing;

— operation, maintenance and decommissioning of facilities, organizational assets and infrastructure;

— environmental performance and practices of external providers;

— post-delivery activities, product transportation including packaging and service delivery;

— storage, use and end-of-life treatment of products;

— waste management, including reuse, refurbishing, recycling and disposal.

A life cycle perspective does not require a detailed life cycle assessment; thinking carefully about the environmental aspects that the organization can control or influence at each stage of the life cycle is sufficient. For example, by addressing environmental aspects where possible and practical during the design stage, an organization can prevent or reduce adverse environmental impacts at other stages in the life cycle.

Determining environmental aspects involves taking into account:

— the process inputs and outputs (both intended and unintended) associated with current and relevant past activities, products and services;

— planned or new developments;

— new or modified activities, products and services.

The method used considers normal and abnormal operating conditions, shut-down and start-up phases, and reasonably foreseeable emergency situations including past incidents.

Abnormal conditions include situations that are not typical, happen rarely or are unplanned. Such situations can introduce new environmental aspects or result in changes to environmental aspects. For example, adverse operating conditions or adverse environmental conditions can increase emissions or releases to the environment.

Emergency situations are unplanned or unexpected events that require urgent application of specific competencies, resources or processes to prevent or mitigate their actual or potential consequences. Emergency situations can result in adverse environmental impacts or other effects on the organization that do not normally occur during operations. When determining potential emergency situations (e.g. fire, chemical spill, flooding, severe weather), the organization should consider:

— the nature of onsite hazards (e.g. flammable liquids, storage tanks, compressed gasses);

— the most likely type and scale of an emergency situation;

— the potential for emergency situations at a nearby facility (e.g. plant, road, railway line).

By considering emergency situations when determining environmental aspects, an organization can uncover a new environmental aspect or, due to the potential severity or magnitude of the impact, a significant environmental aspect.

There is no single method for determining significant environmental aspects; however, the method and criteria used should provide consistent results. The organization sets the criteria for determining its significant environmental aspects. Environmental criteria are the primary and minimum criteria for assessing environmental aspects. Criteria can relate to the environmental aspect (e.g. type, size, frequency) or the environmental impact (e.g. scale, severity, duration, exposure) or environmental conditions. Other criteria may also be used. An environmental aspect that is not significant when only considering environmental criteria can, however, reach or exceed the threshold for determining significance when other criteria are considered. These other criteria can include organizational issues, such as legal requirements or interested party concerns. However, these other criteria are not intended to be used to downgrade an aspect that is significant based on its environmental impact.

"Significant" is intended to be a relative term. What is significant for one organization is not necessarily significant for another, and what an organization considers a significant environmental aspect can change over time.

A significant environmental aspect results in one or more significant environmental impacts, and can therefore result in risks and opportunities that need to be addressed to ensure the organization can achieve the intended outcomes of its environmental management system.

A.6.1.3 Compliance obligations

The organization determines, at a sufficiently detailed level, the compliance obligations it identified in 4.2 that are applicable to its environmental aspects and how they apply to the organization. Compliance obligations include legal requirements that an organization has to comply with and other requirements that the organization has to or chooses to comply with.

Mandatory legal requirements related to an organization's environmental aspects can include, if applicable:

a) requirements from governmental entities or other relevant authorities;

b) international, national and local laws and regulations;

c) requirements specified in permits, licences or other forms of authorization;

d) orders, rules or guidance from regulatory agencies;

e) judgments of courts or administrative tribunals.

Compliance obligations also include other interested party requirements related to its environmental management system which the organization has to or chooses to adopt. These can include, if applicable:

— agreements with community groups or non-governmental organizations;

— agreements with public authorities or customers;

— organizational requirements;

— voluntary principles or codes of practice;

— voluntary labelling or environmental commitments;

— obligations arising under contractual arrangements;

— relevant organizational or industry standards.

A.6.1.4 Risks and opportunities

During the planning stage of the environmental management system, the organization is expected to consider the broader context in which it operates, not only its environmental aspects and compliance obligations. This involves recognizing that external and internal issues within its context can also create risks and opportunities that can influence the organization's ability to achieve its intended outcomes, prevent or reduce undesired effects, and achieve continual improvement.

The organization establishes (a) process(es) to determine risks and opportunities that need to be addressed resulting from:

— external issues, such as environmental conditions affecting operations (see 4.1);

— internal issues, including changes to the business (see 4.1);

— interested party needs and expectations, such as customer expectations related to sustainability (see 4.2).

The organization retains the authority to determine which risks or opportunities to address based on its capacity and capability to mitigate risks and leverage opportunities effectively.

Examples of risks and opportunities with potential beneficial effects include:

— transitioning to a circular economy, including redesigning processes to minimize waste and maximize resource efficiency;

— implementing improved land management practices to enhance biodiversity or to address inequalities that have resulted in environmental harm to vulnerable populations;

— enhancing employee engagement and training that provides staff with the knowledge and tools to support environmental goals that lead to better adherence to sustainability practices, more innovative solutions and greater commitment across the organization;

— leveraging advanced analytics and real-time data collection (e.g. monitoring energy usage, water consumption) to help make more informed decisions, track progress and set more accurate sustainability targets;

— building partnerships with environmental organizations, local communities and suppliers to foster mutual support and increase resource sharing, leading to better overall improved environmental outcomes;

— adopting emerging environmental laws and regulations to increase competitiveness, prevent costly fines and help the organization maintain its social licence to operate, while protecting the environment;

— introducing new technology financed by governmental grants to reduce pollution levels.

Examples of risks and opportunities with potential adverse effects include:

— environmental spills due to literacy or language barriers among workers unable to understand local work procedures;

— climate change impacts (e.g. increased flooding, drought, extreme temperatures, wildfires) that affect the organization's assets;

— lack of available resources to maintain an effective environmental management system due to social or economic constraints;

— water scarcity during periods of drought that affects the organization's ability to operate its emission control equipment;

— resource constraints (e.g. supply chain disruptions, limited access to critical raw materials) that impact production and sustainability goals;

— changes in environmental conditions (e.g. biodiversity loss, water scarcity, limited availability of raw materials, rising temperatures) that have a long-term effect on the organization's operations;

— failure to meet compliance obligations that damages the organization's reputation or results in legal action.

The organization has the flexibility to select the method and degree of formality it will use to determine its risks and opportunities. The method can involve a simple qualitative process or a comprehensive quantitative assessment depending on the organization's needs. These needs can vary from one organization to another depending on:

— the size of the organization and its type of activities, processes, products and services;

— the need to demonstrate conformance with compliance obligations;

— the complexity of processes and their interactions;

— the competence of individuals applying the methodology selected.

The process of determining environmental conditions that affect the organization and other relevant issues that pose risks and opportunities can be integrated with other management system processes (e.g. with the determination of environmental aspects and impacts (see 6.1.2) or risks and opportunities (see 6.1.4)).

The risks and opportunities that need to be addressed are inputs for planning actions and for establishing the environmental objectives.

A.6.1.5 Planning action

The organization should develop a general understanding of the actions to be taken within the environmental management system to address its significant environmental aspects (see 6.1.2), compliance obligations (see 6.1.3) and the risks and opportunities (see 6.1.4) that are a priority for the organization to achieve the intended outcomes of its environmental management system. Based on this understanding, the organization plans action(s) accordingly. The organization does not have to take immediate action on all of its risks and opportunities at once; it can prioritize which action(s) to take and when based on its business needs and environmental goals.

The planned actions are incorporated into environmental management system processes, either individually or in combination, including:

— establishing environmental objectives (see 6.2);

— provision of resources (see 7.1);

— establishing competence (see 7.2);

— awareness (see 7.3);

— communication (see 7.4);

— documented information (see 7.5);

— operational planning and control (see 8.1);

— emergency preparedness and response (see 8.2);

— monitoring, measurement, analysis and evaluation (see 9.1).

Actions related to integrating environmental management system requirements into various business processes can include:

— specifying environmental requirements into the design and development process(es);

— specifying environmental requirements for externally provided products and services into the contracting or procurement process(es);

— incorporating competence requirements for education or experience into the human resources process(es);

— incorporating end-of-life or disposal requirements into the sales and marketing process(es).

Some actions can be addressed through other management systems, such as those related to energy, occupational health and safety, quality or business continuity, or other business processes related to risk, financial or human resource management (e.g. in an integrated management system).

When considering its technological options, an organization should consider the use of best-available techniques, where economically viable, cost-effective and judged appropriate. This is not intended to imply that organizations are obliged to use environmental cost-accounting methodologies.

A.6.2 Environmental objectives and planning to achieve them

Top management can establish environmental objectives at the strategic level, the tactical level or the operational level. The strategic level includes the highest levels of the organization and the environmental objectives can be applicable to the whole organization. The tactical and operational levels can include environmental objectives for specific units or functions within the organization and should be compatible with its strategic direction.

Environmental objectives are communicated to persons working under the organization's control who have the ability to influence the achievement of environmental objectives.

The requirement to take into account significant environmental aspects does not mean that an environmental objective has to be established for each significant environmental aspect; however, these have a high priority when establishing environmental objectives.

"Consistent with the environmental policy" means that the environmental objectives are broadly aligned and harmonized with the commitments made by top management in the environmental policy, including the commitment to continual improvement.

It is important that the organization is able to determine whether or not an environmental objective has been achieved. Indicators are selected to evaluate the achievement of measurable environmental objectives. "Measurable" means it is possible to use either quantitative or qualitative methods in relation to a specified scale to determine if the environmental objective has been achieved. By specifying "if practicable", it is acknowledged that there can be situations when it is not feasible to measure an environmental objective; however, this should be treated as an exception.

For additional information on environmental indicators, refer to ISO 14031.

A.6.3 Planning of changes

Managing change is an important part of maintaining the environmental management system that ensures the organization can achieve the intended outcomes of its environmental management system on an ongoing basis. The circumstances giving rise to the need for change(s) to the environmental management system can be planned or unplanned. As part of managing change, the organization evaluates changes that are anticipated and plans for the expected effects and environmental impacts of such changes. This ensures that the intended beneficial effects are achieved and changes with unintended consequences that have adverse effects or impacts are mitigated or minimized.

Changes affecting the environmental management system can arise from internal or external sources. The organization plans the implementation and control of temporary and permanent changes that can impact environmental performance, including:

a) new or changes to existing products, services, processes, operations, equipment or facilities;

b) changes to compliance obligations;

c) changes in knowledge or information about environmental aspects, environmental impacts or risks and opportunities;

d) developments in knowledge and technology;

e) changes to technical specifications of materials or process inputs;

f) changes in business assets due to mergers, acquisitions, joint ventures or divestitures;

g) changes in staff or external providers, including contractors;

h) business disruption due to, for example, supply chain issues, labour disputes, natural disasters, regime change, political unrest or war.

The organization should review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

NOTE Changes can result in risks and opportunities.

Requirements for managing change are included in various clauses in this document, such as:

— environmental aspects (see 6.1.2);

— internal communication (see 7.4.2);

— control of documented information (see 7.5.3);

— operational control (see 8.1);

— internal audit programme (see 9.2.2);

— nonconformity and corrective action (see 10.2).

A.7 Support

A.7.1 Resources

Resources are necessary for the effective functioning and improvement of the environmental management system and to enhance environmental performance. Top management ensures that those with environmental management system responsibilities are supported with the necessary resources.

Resources can include human resources, natural resources, infrastructure, technology and financial resources. Examples of human resources include specialized skills and knowledge. Examples of infrastructure resources include the organization's buildings, equipment, underground tanks and drainage system. Examples of technology resources include engineered pollution controls, information databases and software.

Internal resources may be supplemented by (an) external provider(s).

A.7.2 Competence

The competency requirements in this document apply to persons working under the organization's control who affect its environmental performance, including persons:

a) whose work has the potential to cause a significant environmental impact;

b) who are assigned responsibilities for the environmental management system, including those who:

   1) determine and evaluate environmental impacts or compliance obligations;

   2) contribute to the achievement of an environmental objective;

   3) respond to emergency situations;

   4) perform internal audits;

   5) perform evaluations of compliance.

A.7.3 Awareness

An organization can enhance awareness through a range of approaches, including employee engagement, communications, training and internal policies such as a code of conduct.

Awareness of the environmental policy should not be taken to mean that the commitments are memorized or that persons doing work under the organization's control have a copy of the documented environmental policy. Rather, these persons should be aware of its existence, its purpose and their role in achieving the commitments, including how their work can affect the organization's ability to meet its compliance obligations.

A.7.4 Communication

Communication allows the organization to provide and obtain information relevant to its environmental management system, including information related to its significant environmental aspects, environmental performance, compliance obligations, needs and expectations of interested parties, and recommendations for continual improvement.

Requirements for external communication to disclose environmental and sustainability information continue to grow. External communication can be mandatory or voluntary based on an organization's compliance obligations. Mandatory communications can relate to legal requirements, such as reporting to governmental entities or other authorities, for example, on performance related to environmental operating permits. External communication can also include communicating to the organization's other interested parties (e.g. investors, entities in its supply chain, customers, end consumers). An organization can decide to report voluntarily on environmental information related to its products or services (e.g. resource efficiency, water footprint). Organizations can benefit from engaging with suppliers and customers to obtain and share information on environmental aspects to support continual improvement across the product life cycle.

Communication is a two-way process, to and from the organization. When establishing its communication process(es), the internal organizational structure should be considered to ensure communication with the most appropriate levels and functions. A single approach can be adequate to meet the needs and expectations of many different interested parties, or in other cases, multiple approaches are necessary to address specific needs and expectations of individual interested parties.

Interested parties can request specific information related to the management of the organization's environmental aspects, or provide general impressions or views on environmental management. These impressions or views can be positive or negative. Particularly in the latter case (e.g. complaints), it is important that organization provides a prompt and clear answer. A subsequent analysis of these complaints can provide valuable information for detecting improvement opportunities for the environmental management system.

Communication should:

a) be transparent (i.e. the organization is open in the way it derives what it has reported on);

b) be timely;

c) be appropriate in terms of format, language and media, so that information meets the needs of relevant interested parties, enabling them to participate;

d) be truthful and not misleading to those who rely on the information reported;

e) be factual, accurate and able to be trusted;

f) not exclude relevant information;

g) be understandable to interested parties.

For information on communication as part of managing change, see A.6.3. For additional information on communication, refer to ISO 14063.

A.7.5 Documented information

An organization creates and maintains documented information in a manner sufficient to ensure a suitable, adequate and effective environmental management system. The primary focus is on the implementation of the environmental management system and on environmental performance, not on a complex documented information control system.

In addition to the documented information required in specific clauses of this document, an organization may choose to create additional documented information for purposes of transparency, accountability, continuity, consistency, training or ease in auditing. Retaining records enables an organization to demonstrate conformance to its compliance obligations and provides evidence of environmental performance and environmental management system effectiveness. The organization determines the time period for which records will be retained, consistent with the retention periods required by its compliance obligations.

Documented information originally created for purposes other than the environmental management system may be used. The documented information associated with the environmental management system can be integrated with other systems for managing information implemented by the organization. It does not have to be in the form of a manual.

If an organization decides that documented information of external origin is necessary for the planning and operation of its environmental management system, then the organization's process(es) ensures that the correct information is available to those who have a need for it. Examples of "documented information of external origin" can include environmental regulatory approvals, equipment manufacturer operation manuals, applicable standards or external environmental databases.

A.8 Operation

A.8.1 Operational planning and control

The type and extent of operational control(s) depend on the nature of the operations, significant environmental aspects, compliance obligations and risks and opportunities. An organization has the flexibility to select the type of operational control methods, individually or in combination, that are necessary to make sure the process(es) is (are) effective and achieve(s) the desired results. Such methods can include:

a) designing (a) process(es) in such a way as to prevent or minimize adverse environmental impacts and ensure consistent results;

b) using technology to control (a) process(es) and prevent adverse results (i.e. engineering controls);

c) using competent personnel to ensure the desired results;

d) performing (a) process(es) in a specified way;

e) monitoring or measuring (a) process(es) to check the results;

f) determining the use and amount of documented information necessary.

The organization decides the extent of control it has within its own business processes (e.g. procurement process) to control or influence (an) externally provided process(es) product(s) or service(s). Its decision can be based upon factors such as:

— knowledge, competence and resources, including:

  — the competence of the external provider to meet the organization's environmental management system requirements;

  — the technical competence of the organization to define appropriate controls or assess the adequacy of controls;

— the importance and potential effect the product and service will have on the organization's ability to achieve the intended outcomes of its environmental management system;

— the extent to which control of the process is shared;

— the capability of achieving the necessary control through the application of its general procurement process;

— improvement opportunities available.

When processes, products or services are supplied by (an) external provider(s), the organization's ability to exert control or influence can vary from direct control to limited or no influence. In some cases, products that are purchased, or processes and services performed by an external provider onsite, are under the direct control of an organization. In other cases, an organization can only have limited influence. Factors affecting the extent of influence can be related to the size of the organization as well as issues such as availability of alternatives.

When determining the type and extent of operational controls related to external providers, including contractors, the organization should consider one or more factors such as:

— environmental aspects and associated environmental impacts;

— risks and opportunities associated with the manufacturing of its products or the provision of its services;

— the organization's compliance obligations.

Examples of controls on externally provided processes, products and services can include:

— specifying requirements in purchasing documents;

— evaluating qualifications and performance history of an external provider;

— providing pre-job briefings or training;

— requiring submittal of documentation;

— conducting oversight or audits of an external provider.

Environmental requirements are the organization's environmental-related needs and expectations that it establishes and communicates to its interested parties (e.g. an internal function such as procurement, a customer, an external provider).

Some of the organization's significant environmental impacts can occur during the transportation, delivery, use, end-of-life treatment or final disposal of its product or service. By providing information, an organization can potentially prevent or mitigate adverse environmental impacts during these life cycle stages.

For information on operational control as part of managing change, see A.6.3. For information on life cycle perspective, see A.6.1.2.

A.8.2 Emergency preparedness and response

It is the responsibility of each organization to be prepared and to respond to emergency situations in a manner appropriate to the circumstances. The organization periodically reviews and revises the process(es) and planned response actions as necessary. For information on determining emergency situations, see A.6.1.2.

When establishing its emergency preparedness and response process(es), the organization should consider:

a) the most appropriate method(s) for responding to an emergency situation;

b) internal and external communication process(es);

c) the action(s) required to prevent or mitigate environmental impacts;

d) mitigation and response action(s) to be taken for different types of emergency situations;

e) the need for post-emergency evaluation to determine and implement corrective actions;

f) periodic testing of planned emergency response actions;

g) training of emergency response personnel;

h) a list of key personnel and aid agencies, including contact details (e.g. fire department, spillage clean-up services);

i) evacuation routes and assembly points;

j) the possibility of mutual assistance from neighbouring organizations.

A.9 Performance evaluation

A.9.1 Monitoring, measurement, analysis, and evaluation

A.9.1.1 General

When determining what is monitored and measured, in addition to progress on environmental objectives, the organization should take into account its significant environmental aspects, compliance obligations and operational controls.

The methods used by the organization to monitor and measure, analyse and evaluate are defined in the environmental management system in order to ensure that:

a) the timing of monitoring and measurement is coordinated with the need for analysis and evaluation results;

b) the results of monitoring and measurement are reliable, reproducible and traceable;

c) the analysis and evaluation are reliable, reproducible and enable the organization to report trends.

The environmental performance analysis and evaluation results should be reported to those with responsibility and authority to initiate appropriate action.

For additional information on environmental performance evaluation, refer to ISO 14031.

A.9.1.2 Evaluation of compliance

The organization determines how it will periodically evaluate compliance. The frequency and timing of compliance evaluations can vary depending on the importance of the requirement, variations in operating conditions, changes in compliance obligations and the organization's past performance. An organization can use a variety of methods to maintain its knowledge and understanding of its compliance status; however, all

compliance obligations have to be evaluated periodically. The organization can use the results of compliance evaluations conducted by external parties as part of its compliance evaluation process.

If compliance evaluation results indicate a failure to meet a compliance obligation, the organization determines and implements the actions necessary to achieve compliance. This can require communication with a regulatory agency and agreement on a course of action to meet its compliance obligations. Where such an agreement is in place, it becomes a compliance obligation.

A non-compliance is not necessarily elevated to a nonconformity if, for example, it is identified and corrected by the environmental management system processes. Compliance-related nonconformities have to be corrected, even if those nonconformities have not resulted in actual non-compliance with compliance obligations.

A.9.2 Internal audit

Audit evidence consists of records, statements of fact or other information which are relevant to the audit criteria and are verifiable. Audit criteria are the set of policies, procedures or requirements used as a reference against which audit evidence is compared.

Auditors should be independent of the activity being audited, wherever practicable, and should in all cases act in a manner that is free from bias and conflict of interest.

Nonconformities identified during internal audits are subject to appropriate corrective action.

When considering the results of previous audits, the organization should include previously identified nonconformities from internal and external audits and the effectiveness of the actions taken.

For information on internal audit programme as part of managing change, see A.6.3. For additional information on establishing an internal audit programme, performing environmental management system audits and evaluating the competence of audit personnel, refer to ISO 19011.

A.9.3 Management review

Top management, accountable for the environmental management system, carries out a comprehensive, top-level review of the system. This review does not have to cover every detailed piece of information but should provide a broad understanding to enable an assessment of the environmental management system.

“Suitability” refers to how the environmental management system fits the organization, its operations, culture and business systems. “Adequacy” refers to whether it meets the requirements of this document and is implemented appropriately. “Effectiveness” refers to whether it is achieving the desired results.

The management review topics do not have to be addressed all at once. The review can take place over a period of time and can be part of regularly scheduled management activities, such as board or management meetings, or other management system reviews. It does not have to be a separate activity. The organization should consider appropriate and adequate time intervals for management review so that actions to respond to decisions are effective and timely.

Relevant communication, including complaints received from interested parties, are reviewed by top management to determine opportunities for improvement.

When deciding on the need for changes to the environmental management system, top management should consider situations where the intended outcomes of the environmental management system have not been achieved.

For information on management review as part of managing change, see A.6.3.

A.10 Improvement

A.10.1 Continual improvement

The organization considers the results from analysis and evaluation of environmental performance, evaluation of compliance, internal and external audits, and management review when taking action(s) to improve. Continual improvement can come from any environmental management system process and other processes such as breakthrough change, innovation and re-organization.

The rate, extent and timescale of actions that support continual improvement are determined by the organization. Environmental performance can be enhanced by applying the environmental management system as a whole or improving one or more of its elements.

A.10.2 Nonconformity and corrective action

One of the key purposes of an environmental management system is to act as a preventive tool. The concept of preventive action is now captured in 4.1 (i.e. understanding the organization and its context) and 6.1.4 (i.e. actions to address risks and opportunities).

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Project Committee ISO/PC 302, Guidelines for auditing management systems, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/ JTC 1, Criteria for conformity assessment bodies, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 19011:2018), which has been technically revised.

The main changes are as follows:

— expansion of guidance on remote auditing methods through the introduction of guidance contained in ISO/IEC TS 17012;
— expansion of Annex A to provide guidance on remote auditing methods and virtual locations.

Any feedback or questions on this document should be directed to the user′s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Since the third edition of this document was published in 2018, several management system standards have been published in new fields. Most of them have a common structure, identical core requirements, and common terms and core definitions. As a result, there is a need to consider a broader approach to management system auditing, as well as to provide guidance that is more generic.

This document provides guidance which can be applied to audit against a range of audit criteria (separately or in combination) including, but not limited to:

— requirements specified in one or more management system standards;
— policies, processes and requirements specified by the organization or other relevant interested parties;
— statutory and regulatory requirements;
— one or more management system processes defined by the organization and/or other parties;
— management system plan(s) relating to the provision of specific results of a management system (e.g. quality plan, project plan).

This document provides guidance for all organizations regardless of their size and type, and audits of varying scopes. This includes those conducted by large audit teams, typically of larger organizations, and those by single auditors, whether in large or small organizations. This guidance should be adapted as appropriate to the scope and complexity of the audit programme.

This document concentrates on internal audits (first party) and audits conducted by organizations on their external providers and other external interested parties (second party). This document can also be useful for external audits conducted for purposes other than third-party management system certification. ISO/IEC 17021-1 provides requirements for auditing management systems for third-party certification; however, this document can provide useful additional guidance (see Table 1).

Table 1 — Different types of audits

First party	Second party	Third party
Internal audit	External provider audit	Certification audit or accreditation assessment
	Audit by the external interested party of an organization	Statutory, regulatory and similar audit

ISO/IEC TS 17012 addresses the growing need for remote auditing methods. Its aim is to provide guidance on implementing remote auditing methods effectively while supporting the general principles of auditing as outlined in this document.

To simplify the readability of this document, the singular form of "management system" is preferred, but the reader can adapt the implementation of the guidance to their own situation. This also applies to the use of "individual" and "individuals", "auditor" and "auditors".

This document is intended to apply to a broad range of potential users, including auditors, organizations implementing management systems and organizations needing to conduct management system audits for contractual or regulatory reasons. The guidance in this document can be applied to users in developing their own audit-related requirements.

The guidance in this document can also be used for the purpose of self-declaration and can be useful to organizations involved in the training, qualification and certification of persons participating in the audit programme.

The guidance in this document is intended to be flexible. As indicated at various points in the text, the use of this guidance can differ depending on the size and level of maturity of an organization′s management system. The nature and complexity of the organization to be audited, as well as the objectives and scope of the audits to be conducted, should also be considered.

This document adopts the combined audit approach when two or more management systems of different disciplines are audited together. Where these systems are integrated into a single management system, the principles and processes of auditing are the same as for a combined audit (sometimes known as an "integrated audit").

Guidelines for auditing management systems

1 Scope

This document gives guidance on auditing management systems, including the principles of auditing, managing an audit programme and conducting management system audits, as well as guidance on the evaluation of competence of individuals involved in the audit process. These individuals include those managing the audit programme, auditors and audit teams.

It is applicable to all organizations that need to plan and conduct audits of management systems or manage an audit programme.

The application of this document to other types of audits is possible, provided that special consideration is given to the specific

competence needed and the objectives to be achieved.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
audit
systematic, independent and documented process (3.25) for obtaining objective evidence (3.9) and evaluating it objectively to determine the extent to which the audit criteria (3.8) are fulfilled

Note 1 to entry: Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the organization itself.

Note 2 to entry: External audits include those generally called second and third-party audits. Second-party audits are conducted by parties having an interest in the organization, such as customers, or by other individuals on their behalf. Third-party audits are conducted by independent auditing organizations, such as those providing certification/ registration of conformity (3.21) or governmental agencies and regulatory authorities.

[SOURCE: ISO 9000:2026, 3.12.1, modified — "documented and "objective" added to the definition. Notes to entry replaced.]

3.2
combined audit
audit (3.1) carried out together at a single auditee (3.14) on two or more management systems (3.19) [SOURCE: ISO 9000:2026, 3.12.2, modified — Note 1 to entry deleted.]

joint audit
audit (3.1) carried out at a single auditee (3.14) by two or more auditing organizations [SOURCE: ISO 9000:2026, 3.12.3]

3.4
remote auditing method
method used for conducting audit activities from any place other than the location of the auditee (3.14)

Note 1 to entry: Remote auditing methods can be used in combination with on-site methods to achieve a full and effective audit (3.1).

Note 2 to entry: Remote auditing methods can be used for virtual locations, i.e. where an organization performs work or provides a service using an online environment, enabling individuals to execute processes (3.25) irrespective of physical locations.

Note 3 to entry: Remote auditing methods can be used by the auditor (3.16) at one site of the auditee to audit another site.

[SOURCE: ISO/IEC TS 17012:2024, 3.1]

3.5
audit programme
arrangements for a set of one or more audits (3.1) planned for a specific time frame and directed towards a specific purpose

3.6
audit scope
extent and boundaries of an audit (3.1)

Note 1 to entry: The audit scope generally includes a description of the physical and virtual locations (see 3.4, Note 2 to entry), functions, organizational units, activities and processes (3.25), as well as the time period covered.

3.7
audit plan
description of the activities and arrangements for an audit (3.1)

3.8
audit criteria
set of requirements (3.24) used as a reference against which objective evidence (3.9) is compared

Note 1 to entry: If the audit criteria are legal (including statutory or regulatory) requirements, the words "compliance" or "non-compliance" are often used in an audit finding (3.11).

Note 2 to entry: Requirements may include policies, procedures, work instructions, legal requirements, contractual obligations, industry standards, etc.

3.9
objective evidence
data supporting the existence or verity of something

Note 1 to entry: Objective evidence can be obtained through observation, measurement, test or by other means.

[SOURCE: ISO 9000:2026, 3.8.6, modified — Note 2 to entry deleted.]

3.10
audit evidence
records, statements of fact or other information, which are relevant to the audit criteria (3.8) and verifiable

3.11

audit finding
results of the evaluation of the collected audit evidence (3.10) against audit criteria (3.8)
Note 1 to entry: Audit findings indicate conformity (3.21) or nonconformity (3.22).
Note 2 to entry: Audit findings can lead to the identification of risks (3.20), opportunities for improvement or recording good practices.
Note 3 to entry: If the audit criteria are selected from statutory requirements or regulatory requirements, the audit finding is termed "compliance" or "non-compliance".
3.12
audit conclusion
result of an audit (3.1), after consideration of the audit objectives and all audit findings (3.11)
3.13
audit client
organization or person requesting an audit (3.1)
Note 1 to entry: In the case of internal audit, the audit client can also be the auditee (3.14) or the individual(s) managing the audit programme (3.5). Requests for external audit can come from sources such as regulatory authorities, contracting parties, or potential or existing customers.
[SOURCE: ISO 9000:2026, 3.12.4, modified — Note 1 to entry added.]
3.14
auditee
organization as a whole or parts thereof being audited
3.15
audit team
one or more persons conducting an audit (3.1), supported if needed by technical experts (3.17)
Note 1 to entry: One auditor (3.16) of the audit team is appointed as the audit team leader. Note 2 to entry: The audit team can include auditors-in-training.
3.16
auditor
person who conducts an audit (3.1)
3.17
technical expert
<audit> person who provides specific knowledge or expertise to the audit team (3.15)
Note 1 to entry: Specific knowledge or expertise relates to the organization, the activity, process (3.25), product, service, discipline to be audited, language or culture.
Note 2 to entry: A technical expert to the audit team does not act as an auditor (3.16).
3.18
observer
individual who accompanies the audit team (3.15) but does not act as an auditor (3.16) nor a technical expert (3.17)
3.19
management system
set of interrelated or interacting elements of an organization to establish policies and objectives, as well as processes (3.25) to achieve those objectives
Note 1 to entry: A management system can address a single discipline or several disciplines, e.g. quality management, financial management or environmental management.

Note 2 to entry: The management system elements establish the organization′s structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives and processes to achieve those objectives.
Note 3 to entry: The scope of a management system can include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.
[SOURCE: ISO 9000:2026, 3.4.2, modified — Examples added to Note 1 to entry. Note 2 to entry expanded. Notes 3 and 4 to entry deleted.]
3.20
risk
effect of uncertainty
Note 1 to entry: An effect is a deviation from the expected — positive or negative.
Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.
Note 3 to entry: Risk is often characterized by reference to potential events and consequences, or a combination of these.
Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood of occurrence.
[SOURCE: ISO 9000:2026, 3.7.2, modified — Note 5 to entry deleted.]
3.21
conformity
fulfilment of a requirement (3.24)
[SOURCE: ISO 9000:2026, 3.5.9, modified — Note 1 to entry deleted.]

3.22
nonconformity
non-fulfilment of a requirement (3.24) [SOURCE: ISO 9000:2026, 3.5.13]
3.23
competence
ability to apply knowledge and skills to achieve intended results [SOURCE: ISO 9000:2026, 3.10.6]
3.24
requirement
need or expectation that is stated, generally implied or obligatory
Note 1 to entry: "Generally implied" means that it is custom or common practice for the organization and interested parties that the need or expectation under consideration is implied.
Note 2 to entry: A specified requirement is one that is stated, e.g. in documented information.
[SOURCE: ISO 9000:2026, 3.5.1, modified ― Notes 3, 4 and 5 to entry deleted.]
3.25
process
set of interrelated or interacting activities that use inputs to deliver an intended result
[SOURCE: ISO 9000:2026, 3.3.1, modified ― "or transforms" deleted and "intended" added in the definition. Notes to entry deleted.]

3.26
performance
measurable result
Note 1 to entry: Performance can relate either to quantitative or qualitative findings.
Note 2 to entry: Performance can relate to managing activities, processes (3.25), products, services, systems or organizations.
[SOURCE: ISO 9000:2026, 3.7.3]
3.27
effectiveness
extent to which planned activities are realized and planned results are achieved [SOURCE: ISO 9000:2026, 3.7.17]

4 Principles of auditing

4.1 General

Auditing is characterized by reliance on a number of principles. These principles should help to make the audit an effective and reliable tool in support of management policies and controls, by providing information on which an organization can act in order to improve its performance. Adherence to these principles is fundamental to provide audit conclusions that are relevant and sufficient, and for enabling auditors, working independently from one another, to reach similar conclusions in similar circumstances.
The guidance given in Clauses 5 to 7 is based on the seven principles outlined in 4.2 to 4.8.

4.2 Integrity

Integrity is the foundation of professionalism.
Auditors and the individual(s) managing an audit programme should:
a) perform their work ethically, with honesty and responsibility;
b) only undertake auditing activities if they are competent to do so;
c) perform their work in an impartial manner, i.e. remain fair and unbiased in all their dealings;
d) be sensitive to any influences that can be exerted on their judgement while carrying out an audit.

4.3 Fair presentation

Fair presentation is the obligation to report truthfully and accurately.
Audit findings, audit conclusions and audit reports should reflect truthfully and accurately the auditing activities. Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and the auditee should be reported. The communication should be truthful, accurate, objective, timely, clear and complete.

4.4 Due professional care

Due professional care is the application of diligence and judgement in auditing.
Auditors should exercise due care irrespective of the importance of the task they perform, and the confidence placed in them by the audit client and other interested parties. An important factor in carrying out their work with due professional care is having the ability to make reasoned judgements in all audit situations.

4.5 Confidentiality

Confidentiality is security and privacy of information.
Auditors should exercise discretion in the use and protection of information acquired in the course of their auditing activities. Audit information should not be used inappropriately for personal gain by the auditor or the audit client, or in a manner detrimental to the legitimate interests of the auditee. This principle includes the proper handling of sensitive or confidential information.

4.6 Independence

Independence is the basis for the impartiality of the audit and objectivity of the audit conclusions.
Auditors should be independent of the activity being audited wherever practicable and should in all cases act in a manner that is free from bias and conflict of interest. Auditors should maintain objectivity throughout the audit process to ensure that the audit findings and conclusions are based only on the audit evidence.
When it is not possible for internal auditors to be independent of the activity being audited, every effort should be made to remove bias and encourage objectivity.

4.7 Evidence-based approach

Evidence-based approach is the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process.
Audit evidence should be verifiable. It should be based on samples of the information available, since an audit is conducted during a specified duration and with finite resources. An appropriate use of sampling should be applied, since this is closely related to the confidence that can be placed in the audit conclusions.

4.8 Risk-based approach

Risk-based approach is an audit approach that considers risks and opportunities.
The risk-based approach should substantively influence the planning and implementation of the audit programme, and the planning, conducting and reporting of audits in order to ensure that audits are focused on matters that are significant for the audit client, and for achieving the audit programme objectives.

5 Managing an audit programme

5.1 General

An audit programme should be established. It can include audits addressing one or more management system standards or other requirements, conducted either separately or in combination (combined audit).
The extent of an audit programme should be based on the size and nature of the auditee, as well as on the functionality, complexity, the type of risks and opportunities, the scope, and the level of maturity of the management system(s) to be audited.
The functionality of the management system can be even more complex in the case of multiple locations or when important functions are sourced externally.
Particular attention should be paid to where important decisions are made and to the design, planning and review of the audit programme.
The audit programme should be scaled in accordance with the size and complexity of the organization.
In order to understand the context of the auditee, the audit programme should take into account the organization's:

— organizational objectives;

— relevant external and internal issues;
— needs and expectations of relevant interested parties;
— application of technology such as digital tools;
— information security and confidentiality requirements.

When allocating resources and methods to the audit programme, priority should be given to matters in the management system with higher inherent risk and lower levels of performance.
Competent individuals should be assigned to manage the audit programme (see 5.4.2).
The audit programme should include information and identify resources to enable the audits to be conducted effectively within the specified time frames. The information should include:

a) objectives for the audit programme (see 5.2);
b) risks and opportunities associated with the audit programme (see 5.3) and the actions to address them;
c) scope (extent, boundaries, locations) of each audit within the audit programme;
d) schedule (number/duration/frequency) of the audits;
e) audit types, such as internal or external;
f) audit criteria;
g) auditing methods to be employed, including remote auditing methods (see Clause A.16);
h) criteria for selecting the audit team (audit team leader, auditors and, if needed, technical experts);
i) criteria for participation of observers, where relevant;
j) the organization's context based on external and internal issues;
k) relevant documented information.

Some of this information is not always available until more detailed audit planning is completed.
The implementation of the audit programme should be monitored and assessed on an ongoing basis (see 5.6) to ensure its audit programme objectives have been achieved. The audit programme should be reviewed in order to determine the need for changes and possible opportunities for improvements (see 5.7).
Figure 1 illustrates the process flow for the management of an audit programme.

NOTE 1 This figure illustrates the application of the Plan-Do-Check-Act cycle in this document. NOTE 2 Clause/subclause numbering refers to the relevant clauses/subclauses of this document.
NOTE 3 Conducting the audit follow-up (see 6.7) is not always applicable, as illustrated by the dashed lines.

Figure 1 — Process flows for managing an audit programme and conducting an audit

5.2 Establishing audit programme objectives

The audit client should ensure that the audit programme objectives are established to direct the planning and conducting of audits and should ensure the audit programme is implemented effectively. Audit programme objectives should be consistent with the audit client′s strategic direction, its context, and support its management system policies and objectives.

These objectives can be based on consideration of the following:

a) needs and expectations of relevant interested parties, both external and internal;
b) characteristics of and requirements for processes, products, services and projects, and any changes to them;
c) management system requirements, including differing specific requirements covered during a combined audit;
d) need for evaluation of organizations that are part of the supply chain;
e) auditee′s level of performance and level of maturity of the management system(s), as reflected in relevant performance indicators, the occurrence of nonconformities or incidents or complaints from interested parties;
f) identified risks and opportunities to the auditee;

g) results of previous audits.

Examples of audit programme objectives can include the following:

— identifying opportunities for the improvement of a management system and its performance;
— evaluating the capability of the auditee to determine its context;
— evaluating the capability of the auditee to determine risks and opportunities and to identify and implement effective actions to address them;
— determining the conformance to all relevant requirements (e.g. statutory and regulatory requirements, compliance commitments, requirements for certification to a management system standard);
— establishing the level of confidence in the capability of an organization in the supply chain;
— determining the continuing suitability, adequacy and effectiveness of the auditee′s management system;
— evaluating the compatibility and alignment of the management system objectives with the strategic direction of the organization.

5.3 Determining and evaluating audit programme risks and opportunities

There are risks and opportunities related to the context of the auditee that can be associated with an audit programme and can affect the achievement of its objectives. The individual(s) managing the audit programme should identify risks and opportunities and present them to the audit client when developing the audit programme and resource requirements, so that they can be addressed appropriately.

Risks can be associated with the following:

a) planning (e.g. failure to set relevant and appropriate audit objectives and determine the extent, number, duration, locations and schedule of the audits);
b) resources (e.g. allowing insufficient time, equipment and/or training for developing the audit programme or conducting an audit; lack of competent auditors; loss of auditors or availability of auditors);
c) selection of the audit team (e.g. insufficient overall competence to conduct audits effectively, lack of independence and impartiality of the auditors);

d) selection of the audit method (e.g. on-site, remote, taking into account the capability of the selected method to achieve the defined audit objective) (see Clause A.1, A.15 and A.16);
e) communication (e.g. ineffective communication processes/channels);
f) implementation (e.g. ineffective coordination of the audits within the audit programme, not conducting the audits in accordance with the audit programme or not considering information security and confidentiality);
g) control of documented information (e.g. ineffective determination of the necessary documented information required by auditors and relevant interested parties, failure to adequately protect audit records);
h) monitoring, reviewing and improving the audit programme (e.g. ineffective monitoring of audit programme outcomes);
i) sponsorship (e.g. failure to engage leadership to enable an effective audit programme implementation);
j) availability and cooperation of the auditee and availability of evidence to be sampled;
k) security of information communication technology methods (e.g. ineffective or unsecured platform selection).

Opportunities for improving the audit programme can include:

— allowing multiple audits to be conducted in a single visit;
— minimizing time and distances for the travel to locations;
— matching the audit team′s competence to the level required to achieve the audit objectives;
— selecting the audit method to be used to align with the capability and availability of information and communication technologies.

5.4 Establishing the audit programme

5.4.1 Roles and responsibilities of individual(s) managing the audit programme

The individual(s) managing the audit programme should:

a) ensure that the integrity of the audit programme is maintained and that there is no undue influence exerted over the audit programme;
b) establish the extent of the audit programme according to the relevant objectives (see 5.2) and any known constraints;
c) determine the external and internal issues, and risks and opportunities that can affect the audit programme, and implement actions to address them, integrating these actions in all relevant auditing activities, as appropriate;
d) ensure the selection of audit teams and the overall competence for the auditing activities by assigning roles, responsibilities and authorities, and supporting leadership, as appropriate;
e) establish all relevant processes including for:
1) the audit objectives, scope(s) and criteria of the audits, determination of auditing methods and selection of the audit team;
2) the coordination and scheduling of all audits within the audit programme;
3) the evaluation of auditor(s) competence (see 7.2);
4) the external and internal communications, as appropriate;

5) the resolution of disputes and handling of complaints;
6) the audit follow-up, if applicable;

7) reporting to the audit client and relevant interested parties, as appropriate;
f) determine and ensure provision of all necessary resources;
g) ensure that appropriate documented information is prepared and maintained, including audit programme records;
h) monitor, review and improve the audit programme;
i) communicate the audit programme to the audit client and, as appropriate, relevant interested parties. The individual(s) managing the audit programme should request its approval by the audit client.

5.4.2 Competence of individual(s) managing the audit programme

The individual(s) managing the audit programme should have the necessary competence to manage the programme, effectively and efficiently, including knowledge of:
a) audit principles (see Clause 4), methods and processes (see Clauses A.1 and A.2);
b) management system standards, other relevant standards and reference/guidance documents;
c) information regarding the auditee and its context (e.g. external/internal issues, relevant interested parties and their needs and expectations, business activities, products, services and processes of the auditee);
d) applicable statutory and regulatory requirements and other requirements relevant to the business activities of the auditee.
As appropriate, knowledge of risk management, project and process management, and information and communications technology can be considered.
The individual(s) managing the audit programme should be engaged in appropriate continual professional development activities to maintain the necessary competence to manage the audit programme.

5.4.3 Establishing the scope of the audit programme

The individual(s) managing the audit programme should determine the scope of the audit programme. This can vary depending on the information provided by the audit client or the auditee regarding its context (see 5.3).
NOTE In certain cases, depending on the auditee′s structure or its activities, the audit programme only consists of a single audit.
Other factors impacting the scope of an audit programme can include the following:
a) the objective, scope and duration of each audit and the number of audits to be conducted, reporting method and, if applicable, audit follow up;
b) the management system standards;
c) the number, importance, complexity, similarity and locations of the activities to be audited;
d) factors influencing the effectiveness of the management system;
e) applicable audit criteria, such as planned arrangements for the relevant management system standards, statutory and regulatory requirements and other requirements to which the organization is committed;
f) results of previous internal or external audits and management reviews, if appropriate;

g) results of a previous audit programme review;
h) language, cultural and social issues;
i) the concerns of interested parties, such as customer complaints, non-compliance with statutory and regulatory requirements and other requirements to which the organization is committed, or supply chain issues;
j) significant changes to the auditee′s context or its operations and related risks and opportunities;
k) availability of information and communication technologies (e.g. adequate network bandwidth, computer and network hardware and software) to support auditing activities, in particular the use of remote auditing methods (see Clause A.16);
l) the occurrence of external and internal events (e.g. nonconformities of products or services, or incidents impacting information security, health and safety or the environment);
m) business risks and opportunities, including actions to address them.

5.4.4 Determining audit programme resources

When determining resources for the audit programme, the individual(s) managing the audit programme should consider:
a) the financial and time resources necessary to develop, implement, manage and improve auditing activities;
b) auditing methods (see Clause A.1);
c) the individual and overall availability of auditors and technical experts having competence appropriate to the particular audit programme objectives (e.g. including interpreters);
d) the extent of the audit programme (see 5.4.3) and audit programme risks and opportunities (see 5.3);
e) travel time, travel cost, accommodation and other auditing needs;
f) the impact of different time zones and languages;
g) the availability of information and communication technologies (e.g. technical resources required to set up an audit using technologies that support remote collaboration);
h) the availability of any tools, technology and equipment required;
i) the availability of necessary documented information, as determined during the establishment of the audit programme (see Clause A.5);
j) requirements related to the facility, including any security clearances and equipment (e.g. background checks, personal protective equipment, ability to wear industry appropriate attire).

5.5 Implementing the audit programme

5.5.1 General

Once the audit programme has been established (see 5.4.3) and related resources have been determined (see 5.4.4), the operational planning and the coordination of all the activities within the programme should be implemented.
The individual(s) managing the audit programme should:
a) communicate the relevant parts of the audit programme, including the risks and opportunities involved, to relevant interested parties and inform them periodically of its progress, using established external and internal communication channels;

b) define objectives, scope and criteria for each individual audit;
c) select auditing methods (see Clause A.1);
d) coordinate and schedule audits and other activities relevant to the audit programme;
e) ensure the audit teams have the necessary competence (see 5.5.4);
f) provide necessary individual and overall resources to the audit teams (see 5.4.4);
g) ensure that audits are conducted in accordance with the audit programme, managing operational risks, opportunities and issues as they arise during the deployment of the programme;
h) ensure relevant documented information regarding the auditing activities is properly managed and maintained (see 5.5.7);
i) define and implement the operational controls (see 5.6) necessary for audit programme monitoring;
j) review the audit programme in order to identify opportunities for its improvement (see 5.7).

5.5.2 Defining the objectives, scope and criteria for an individual audit
Each individual audit should be based on defined audit objectives, scope and criteria. These should be consistent with the overall audit programme objectives.
The audit objectives define what is to be accomplished by the individual audit and can include the following:
a) determination of the extent of conformity of the management system to be audited, or parts of it, with audit criteria;
b) evaluation of the capability of the management system to assist the organization in meeting relevant statutory and regulatory requirements and other requirements to which the organization is committed;
c) evaluation of the effectiveness of the management system in meeting its intended results;
d) finding opportunities for improvement of the management system;
e) evaluation of the suitability and adequacy of the management system with respect to the context and strategic direction of the organization;
f) evaluation of the capability of the management system to establish and achieve objectives and effectively address risks and opportunities, in a changing context, including the implementation of the related actions;
g) consideration of any sector-specific management system auditing standards.
The audit scope should be consistent with the audit programme and audit objectives. It includes factors such as locations, functions, 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. These can include one or more of the following: applicable policies, processes, procedures, performance criteria including objectives, statutory and regulatory requirements, management system requirements, information regarding the context and the risks and opportunities as determined by the audit client (including relevant external/ internal interested parties requirements), sector codes of conduct or other planned arrangements.
In the event of any changes to the audit objectives, scope or criteria, the audit programme should be modified if necessary and communicated to interested parties for approval, if appropriate.
When more than one discipline is being audited at the same time, it is important that the audit objectives, scope and criteria are consistent with the relevant audit programmes for each discipline. Some disciplines can have a scope that covers the whole organization and others can have a scope that covers a subset of the whole organization.

5.5.3 Selecting and determining auditing methods
The individual(s) managing the audit programme should select and determine the methods for effectively and efficiently conducting an audit, depending on the defined audit objectives, scope and criteria.
Audits can be performed on-site, remotely or as a combination. The use of these methods should be suitably balanced, based on, among other things, consideration of associated risks and opportunities.
Where two or more auditing organizations conduct a joint audit of the same auditee, the individuals managing the different audit programmes should agree on the auditing methods and consider implications for resourcing and planning the audit, including the impact on the organization. If an auditee operates two or more management systems of different disciplines, combined audits can be included in the audit programme.
Annex A provides additional guidance on audit methods. The methods can include interviews, the use of checklists and questionnaires, document review, sampling, observing work, analysing data, and on-site review.

5.5.4 Selecting audit team members
The individual(s) managing the audit programme should appoint the members of the audit team, including the audit team leader and any technical experts needed for the specific audit.
An audit team should be selected, taking into account the competence needed to achieve the objectives of the individual audit within the defined scope. If there is only one auditor, the auditor should perform all applicable duties of an audit team leader.
NOTE Clause 7 contains guidance on determining the competence required for the audit team members and describes the processes for evaluating auditors.
To ensure the overall competence of the audit team, the following steps should be performed:

— identification of the competence needed to achieve the objectives of the audit;
— selection of the audit team members so that the necessary competence is present in the audit team.

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

a) Determination of the competence needed to achieve the objectives of the audit.
b) The complexity of the audit.
c) Whether the audit is combined or joint.
d) The selected auditing methods.
e) The audit process is carried out in an objective and impartial manner.
f) The ability of the audit team members to work and interact effectively with the representatives of the auditee and relevant interested parties.
g) The relevant external/internal issues, such as the language of the audit, and the auditee′s social and cultural characteristics. These issues can be addressed either by the auditor′s own skills or through the support of a technical expert. There can be a need for an interpreter.
h) The type and complexity of the audit (e.g. time zones, number of locations, processes to be audited).
i) Travel permissions (e.g. security clearances, health permits, visas, as applicable).

Where appropriate, the individual(s) managing the audit programme should consult the audit team leader on the composition of the audit team.

If the necessary competence is not covered by the auditors in the audit team, technical experts with complementary competence should be made available to support the team.

Auditors-in-training can be included in the audit team but should participate under the direction and guidance of an auditor.

Changes to the composition of the audit team can be necessary during the audit (e.g. if a conflict of interest or competence issue arises). If such a situation arises, it should be resolved with the appropriate parties (e.g. audit team leader, the individual(s) managing the audit programme, audit client or auditee) before any changes are made.

5.5.5 Assigning responsibility for an individual audit to the audit team leader

The individual(s) managing the audit programme should assign the responsibility for conducting the individual audit to an audit team leader.

The assignment should be made in sufficient time before the scheduled date of the audit, in order to ensure the effective planning of the audit.

To ensure effective conduct of the individual audit, the following information should be provided to the audit team leader:

a) audit objectives;
b) audit criteria and any relevant documented information;
c) audit scope, including identification of the organization and its functions and processes to be audited;
d) audit processes and associated methods;
e) composition of the audit team;
f) contact details of the auditee, and the locations, time frame and duration of the auditing activities to be conducted;
g) resources necessary to conduct the audit;
h) information needed for evaluating and addressing identified risks and opportunities to the achievement of the audit objectives;
i) information which supports the audit team leader in their interactions with the auditee for the effectiveness of the audit programme.

The assignment information should also cover the following, as appropriate:

— working and reporting language of the audit where this is different from the language of the auditor or the auditee, or both;
— audit conclusions required and to whom they are to be distributed;
— matters related to confidentiality and information security, as required by the audit programme;
— any health, safety and environmental arrangements for the auditors;
— requirements for travel or access to remote locations;
— any confidentiality, security, access and authorization requirements;
— any actions to be reviewed (e.g. follow-up activities from a previous audit);
— coordination with other auditing activities (e.g. when different teams are auditing similar or related processes at different locations or in the case of a joint audit).

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

5.5.6 Managing audit programme results

The individual(s) managing the audit programme should ensure that the following activities are performed:

a) evaluation of the achievement of the objectives for each audit within the audit programme;
b) review and approval of audit reports regarding the fulfilment of the audit scope and objectives;
c) review of the effectiveness of actions taken to address audit findings;
d) distribution of audit reports to the previously determined parties;
e) determination of the necessity for any follow-up audit.

The individual managing the audit programme should consider, where appropriate, communicating the audit conclusions and good practices to other areas of the organization.

5.5.7 Managing audit related records

The individual(s) managing the audit programme should ensure that audit records are generated, managed and retained to demonstrate the implementation of the audit programme. Processes should be established to ensure that any information security and confidentiality needs associated with the audit records are addressed.

Records can include the following:

a) Records related to the audit programme, such as:
1) schedule of audits;
2) audit programme objectives and extent;
3) those addressing audit programme risks and opportunities, and relevant external and internal issues;
4) reviews of the audit programme effectiveness.
b) Records related to each audit, such as:
1) audit plans and audit reports;
2) audit evidence and audit findings;
3) relevant feedback from the auditee, auditor(s) and interested parties;
4) nonconformity reports;
5) corrections and corrective action reports;
6) audit follow-up activities.
c) Records related to the audit team covering topics such as:
1) competence and performance evaluation of the audit team members;
2) criteria for the selection of audit teams and team members and formation of audit teams;
3) maintenance and improvement of competence.

The form and level of detail of the records should demonstrate that the objectives of the audit programme have been achieved.

5.6 Monitoring the audit programme

The individual(s) managing the audit programme should ensure the evaluation of:

a) whether audit schedules are being met and audit programme objectives are being achieved;
b) the performance of the audit team members including the audit team leader and the technical experts;
c) the ability of the audit teams to implement the audit plan;
d) feedback from audit clients, auditees, auditors, technical experts and other relevant parties;
e) sufficiency and adequacy of documented information in the audit process.

Some factors can indicate the need to modify the audit programme. These can include changes to:

— audit findings;
— demonstrated level of the auditee's management system effectiveness and maturity;
— effectiveness of the audit programme;
— audit scope or audit programme extent;
— the auditee's management system;
— standards and other requirements to which the organization is committed;
— organizations that are part of the supply chain;
— identified conflicts of interest;
— the audit client's requirements.

5.7 Reviewing and improving the audit programme

The individual(s) managing the audit programme and the audit client should review the audit programme to assess whether its objectives have been achieved. Lessons learned from the audit programme review should be used as inputs for the improvement of the programme.

The individual(s) managing the audit programme should ensure the following:

— review of the overall implementation of the audit programme;
— identification of areas with opportunities for improvement;
— implementation of changes to the audit programme if necessary;
— review of the continual professional development of auditors, in accordance with 7.6;
— reporting of the results of the audit programme and review of them with the audit client and relevant interested parties, as appropriate.

The audit programme review should consider the following:

a) results and trends from audit programme monitoring;
b) conformity to audit programme processes and relevant documented information;
c) evolving needs and expectations of relevant interested parties;
d) audit programme records;
e) alternative or new auditing methods;

f) alternative or new methods to evaluate auditors;

g) effectiveness of the actions to address the risks and opportunities, and external and internal issues associated with the audit programme;
h) confidentiality and information security issues relating to the audit programme.

6 Conducting an audit

6.1 General

This clause contains guidance on preparing and conducting a specific audit as part of an audit programme. Figure 1 provides an overview of the activities performed in a typical audit. The extent to which the provisions of this clause are applicable depends on the objectives and scope of the specific audit.

6.2 Initiating the audit

6.2.1 General

The responsibility for conducting the audit should remain with the assigned audit team leader (see 5.5.5) until the audit is completed (see 6.6).
To initiate an audit, the steps in Figure 1 should be considered; however, the sequence can differ depending on the auditee, processes and specific circumstances of the audit.

6.2.2 Establishing contact with the auditee

The audit team leader should ensure that contact is made with the auditee within an appropriate time frame to:
a) confirm communication channels with the auditee′s representatives;
b) confirm the authority to conduct the audit;
c) provide relevant information on the audit objectives, scope, criteria, methods and audit team composition, including any technical experts;
d) request access to relevant information for planning purposes, including information on the risks and opportunities the organization has identified and how they are addressed;
e) confirm applicable statutory and regulatory requirements and other requirements relevant to the activities, processes, products and services of the auditee;
f) confirm the agreement with the auditee regarding the extent of the disclosure and the treatment (e.g. storage, transfer and release) of confidential information;
g) make arrangements for the audit including the audit plan;
h) determine any location-specific arrangements for access, health and safety, security, confidentiality or other issues;
i) agree on the attendance of observers and the need for guides or interpreters for the audit team;
j) determine any areas of interest, concern or risks to the auditee in relation to the specific audit;
k) resolve issues regarding composition of the audit team with the auditee or audit client.

6.2.3 Determining the feasibility of the audit

The feasibility of the audit should be determined to provide reasonable confidence that the audit objectives can be achieved.
The determination of feasibility should take into consideration factors such as the following:
a) sufficient and appropriate information for planning and conducting the audit;
b) adequate cooperation from the auditee;
c) adequate time and other resources for conducting the audit;
d) local, regional, or world events or circumstances that would affect the scheduled audit.
NOTEResources include access to adequate and appropriate information and communication technology.
Where the audit is not feasible, an alternative should be proposed to the audit client, in agreement with the auditee.

6.3 Preparing auditing activities

6.3.1 Performing the review of documented information

The documented information for the relevant management system should be reviewed by audit team member(s) to:
— gather information to understand the auditee′s operations, inherent risks, and to prepare auditing activities and applicable audit working documents (see 6.3.4) (e.g. on processes or functions);
— establish an overview of the extent of the documented information to determine potential conformity to the audit criteria and detect possible areas of concern, such as deficiencies, omissions or conflicts.
The documented information should include, but is not limited to, management system documents and records, as well as previous audit reports. The review should take into account the context of the organization, including its size, nature and complexity, and its related risks and opportunities. It should also take into account the audit scope, criteria and objectives.
NOTEGuidance on how to verify information is provided in Clause A.5.

6.3.2 Audit planning

6.3.2.1 Risk-based approach to planning

The audit team leader should adopt a risk-based approach to plan the audit based on the information in the audit programme and the documented information provided by the auditee.

Planning should facilitate the efficient scheduling and coordination of the auditing activities in order to achieve the objectives effectively.
Practical application of the risk-based approach can include prioritizing audit focus based on factors such as product/process complexity, customer complaints, past audit findings, and changes in regulatory or operational environments.
The amount of detail provided in the audit plan should reflect the scope and complexity of the audit. In planning the audit, the audit team leader should consider the following:
a) the composition of the audit team and its overall competence;
b) the appropriate sampling techniques (see Clause A.6);
c) the risks to achieving the audit objectives created by ineffective audit planning;

d) opportunities to improve the effectiveness and efficiency of the auditing activities;
e) the risks to the auditee created by performing the audit.
Risks to the auditee can result from the presence of the audit team members adversely influencing the auditee's arrangements for health and safety, environment and quality, and its products, services, personnel or infrastructure (e.g. contamination in clean room facilities).
For combined audits, particular attention should be given to the interactions between operational processes and any competing objectives and priorities of the various management system requirements.
When identifying potential risks in joint audits, particular attention should be given to the coordination of different audit teams, including sampling and audit time arrangement, to ensure the achievement of the audit objectives.

6.3.2.2 Audit planning details
Audit planning should consider the risks of the auditing activities on the auditee's processes and provide the basis for the agreement among the audit client, the audit team and the auditee regarding the conduct of the audit. The scope and content of the audit planning can differ, for example, between initial and subsequent audits, as well as between external and internal audits. Audit planning should be sufficiently flexible to permit changes that can become necessary as the auditing activities progress.
Audit planning should address or reference the following:
a) the audit objectives;
b) the audit scope, including identification of the organization and its functions, as well as processes to be audited;
c) the audit criteria and any reference documented information;
d) the locations (physical and virtual), dates, expected time and duration of auditing activities to be conducted, including meetings with the auditee's management, breaks and audit team meetings;
e) the need for the audit team to familiarize themselves with the auditee's facilities and processes (e.g. by conducting a tour of physical location(s) or reviewing information and communication technology);
f) the auditing methods to be used, including the extent to which audit sampling is needed to obtain sufficient audit evidence;
g) the roles and responsibilities of the audit team members, as well as guides and observers or interpreters;
h) the allocation of appropriate resources based upon consideration of the risks and opportunities related to the activities that are to be audited.
Audit planning should take into account, as appropriate:
— identification of the auditee's representative(s) for the audit;
— the working and reporting language of the audit, where this is different from the language of the auditor or the auditee, or both;
— the expected contents of the audit report;
— logistics and communications arrangements, including specific arrangements for the locations to be audited;
— any specific actions to be taken to address risks to achieving the audit objectives;
— any specific actions to be taken to address opportunities arising;
— matters related to confidentiality and information security;

— any follow-up activities from a previous audit or other source(s) (e.g. lessons learned, project reviews);
— any follow-up activities to the planned audit, as required;
— coordination with other auditing activities, in the case of a joint audit.
Audit plans should be presented to the auditee and the audit client, as required. Any issues with the audit plans should be resolved between the audit team leader, the auditee and, if necessary, the individual(s) managing the audit programme.

6.3.3 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, activities, functions or locations and, as appropriate, authority for decision-making. Such assignments should take into account the impartiality and objectivity and competence of auditors and the effective use of resources, as well as the different roles and responsibilities of auditors, auditors-in-training and technical experts.
Audit team meetings should be held, as appropriate, by the audit team leader in order to allocate work assignments and decide possible changes. Changes to the work assignments can be made as the audit progresses in order to ensure the achievement of the audit objectives.

6.3.4 Preparing documented information for the audit

The audit team members should collect and review the information relevant to their audit assignments and prepare documented information for the audit, using any appropriate media. The documented information for the audit can include, but is not limited to:
a) checklists;
b) audit sampling details;
c) audiovisual information.
The use of these media should not restrict the extent of auditing activities, which can change as a result of information collected during the audit.
NOTEGuidance on preparing audit working documents is given in Clause A.13.
Documented information prepared for, and resulting from, the audit should be retained at least until audit completion, or as specified in the audit programme. Retention of documented information after audit completion is described in 6.6. Documented information created during the audit process involving confidential or proprietary information, including images and audiovisual recordings, should be suitably safeguarded at all times by the audit team members.

6.4 Conducting auditing activities

6.4.1 General

Auditing activities are normally conducted in a defined sequence as indicated in Figure 1. This sequence can be varied to suit the circumstances of specific audits.
Audit activities can be conducted concurrently and can be dependent on the result of previous audit activities.

6.4.2 Assigning the roles and responsibilities of guides and observers

Guides and observers can accompany the audit team with approvals from the audit team leader, audit client and/or auditee, if required. They should not influence or interfere with the conduct of the audit. If this cannot be ensured, the audit team leader should have the right to deny observers from being present during certain auditing activities.

For observers, any arrangements for access, health and safety, environmental, security and confidentiality should be managed between the audit client and the auditee.
Guides, appointed by the auditee, should assist the audit team and act on the request of the audit team leader or the auditor to whom they have been assigned. Their responsibilities should include the following:
a) assisting the auditors in identifying individuals to participate in interviews and confirming timings and locations;
b) arranging access to specific locations of the auditee;
c) ensuring that rules concerning location-specific arrangements for access, health and safety, environmental, security, confidentiality and other issues are known and respected by the audit team members and observers and any risks are addressed;
d) witnessing the audit on behalf of the auditee, when appropriate;
e) providing clarification or assisting in collecting information, when needed.

6.4.3 Conducting the opening meeting

The purpose of the opening meeting is to:
a) confirm the agreement of all participants (e.g. auditee, audit team) to the audit plan;
b) introduce the audit team and their roles;
c) ensure that all planned auditing activities can be performed.
An opening meeting should be held with the auditee′s management and, where appropriate, those responsible for the functions or processes to be audited. During the meeting, a contingency for asking questions should be provided.
The degree of detail should be consistent with the familiarity of the auditee with the audit process. In many instances (e.g. for internal audits in a small organization), the opening meeting can simply consist of communicating that an audit is being conducted and explaining the nature of the audit.
For other audit situations, the meeting can be formal and records of attendance should be retained.
The meeting should be chaired by the audit team leader. Other participants, including observers, guides, technical experts and interpreters should be introduced and their roles explained.
The following items should be confirmed or explained, as appropriate:
— the audit objectives, scope and criteria;
— the audit plan 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 change(s) needed;
— formal communication channels between the audit team and the auditee;
— the language to be used during the audit;
— the auditing methods to manage risks to the organization which can result from the presence of the audit team members;
— audit evidence to be collected through a sampling process;
— the auditee being kept informed of audit progress during the audit;
— the availability of the resources and facilities needed by the audit team;
— matters relating to confidentiality and information security;

— relevant access, health and safety, security, emergency and other arrangements for the audit team;
— activities on-site that can impact the conduct of the audit.

The presentation of information on the following items should be considered, as appropriate:
— the method of reporting audit findings including criteria for grading of nonconformities, if any;
— conditions under which the audit can be terminated;
— how to deal with possible audit findings during the audit;
— any plan for feedback from the auditee on the audit findings or conclusions of the audit, including complaints or appeals.

6.4.4 Communicating during the audit
During the audit, it can be necessary to make formal arrangements for communication within the audit team, as well as with the auditee, the audit client and potentially with external interested parties (e.g. regulatory authorities), especially where statutory and regulatory requirements require mandatory reporting of nonconformities.
The audit team should communicate periodically to exchange information, assess audit progress and reassign work between the audit team members, as needed.
During the audit, the audit team leader should periodically communicate the progress, any significant audit findings and any concerns to the organization and, as appropriate, the audit client. Evidence collected during the audit that suggests an immediate and significant risk should be reported without delay to the auditee and, as appropriate, to the audit client and the individual(s) managing the audit programme. 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, the auditee and the individual(s) managing the audit programme to determine appropriate actions. Such actions can include changes to the audit plan, the audit objectives or audit scope, or termination of the audit.
Any need for changes to the audit plan which become apparent as audit activities progress should be reviewed and accepted, as appropriate, by both the individual(s) managing the audit programme and the audit client, and presented to the auditee. These changes should be documented.

6.4.5 Providing access to audit information
The auditing methods chosen for an audit depend on the defined audit objectives, scope and criteria, as well as duration and location. The location is where the information needed for the specific audit activity is available to the audit team. This can include physical and virtual locations.
Where, when and how to access information is crucial to the audit. This is independent of where the information is created, used and/or stored. Based on these issues, the auditing methods need to be determined (see Clause A.1). The audit can use a mixture of methods. Also, audit circumstances can mean that the methods need to change during the audit.

6.4.6 Reviewing documented information while conducting the audit
The auditee′s relevant documented information should be reviewed to:
— determine the conformity of the management system, as far as documented, with audit criteria;
— gather information to support the auditing activities.
NOTEGuidance on how to verify information is provided in Clause A.5.

The review can be combined with the other auditing activities (e.g. interviewing relevant auditee′s personnel, observing auditee′s activities) and can continue throughout the audit, providing this is not detrimental to the effectiveness of the conduct of the audit.
If adequate documented information cannot be provided within the time frame given in the audit plan, the audit team leader should inform both the individual(s) managing the audit programme and the auditee. Depending on the audit objectives and scope, a decision should be made as to whether the audit should be continued or suspended until documented information concerns are resolved.

6.4.7 Collecting and verifying information
During the audit, information relevant to the audit objectives, scope and criteria, including information relating to interfaces among functions, activities and processes should be collected by means of appropriate sampling and should be verified, as far as practicable.
NOTE 1 For verifying information, see Clause A.5. NOTE 2 Guidance on sampling is given in Clause A.6.
Only information that can be subject to some degree of verification should be accepted as audit evidence. Where the degree of verification is low, the auditor should use their professional judgement to determine the degree of reliance that can be placed on it as evidence. Audit evidence leading to audit findings should be recorded. If, during the collection of objective evidence, the audit team becomes aware of any new or changed circumstances, or risks or opportunities, these should be addressed by the audit team accordingly.
Figure 2 provides an overview of a typical process, from collecting information to reaching audit conclusions.

Figure 2 — Overview of collecting and verifying information

Methods of collecting information include, but are not limited to, the following:
— interviews;
— observations;

— review of documented information (see Clauses A.5 and A.14).

NOTE 3 Guidance on selecting sources of information and observation is given in Clause A.14. NOTE 4 Guidance on visiting the auditee′s location is given in Clause A.15.

NOTE 5 Guidance on conducting interviews is given in Clause A.17.

6.4.8 Generating the audit findings

Audit evidence should be evaluated against the audit criteria in order to determine audit findings. Audit findings can indicate conformity or nonconformity to the audit criteria. When specified by the audit plan, individual audit findings should include conformity to audit criteria and good practices in the organization along with their supporting evidence, opportunities for improvement, and any recommendations to the auditee, and should be recorded.

Nonconformities and their supporting audit evidence should be recorded.

Nonconformities can be graded depending on the context of the organization and its risks. This grading can be quantitative (e.g. 1 to 5) or qualitative (e.g. minor, major). When nonconformities are graded, the criteria used by the auditing organization should be defined and communicated.

Nonconformities should be reviewed with the auditee in order 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 or audit findings. Unresolved issues should be recorded in the audit report.

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

NOTEAdditional guidance on the identification and evaluation of audit findings is given in Clause A.18.

6.4.9 Determining the audit conclusions

6.4.9.1 Preparing for the closing meeting

The audit team should confer prior to the closing meeting in order to:

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

6.4.9.2 Determining the content of the audit conclusions

Audit conclusions should address issues such as the following:

a) the extent of conformity to the audit criteria and robustness of the management system, including:
1) the effectiveness of the management system in meeting the intended results;
2) the identification of risks;
3) the effectiveness of actions taken by the auditee to address risks;
b) the effective implementation, maintenance and improvement of the management system;
c) achievement of audit objectives, coverage of audit scope and fulfilment of audit criteria;

d) similar audit findings made in different areas that were audited or from a joint or previous audit for the purpose of identifying trends.

If specified by the audit plan, audit conclusions can lead to recommendations for improvement or future audit activities.

Caution should be used when making recommendations to avoid negative impact on impartiality of audits.

6.4.10 Conducting the closing meeting

A closing meeting should be held to present the audit findings and conclusions.

The closing meeting should be chaired by the audit team leader and attended by the top management of the auditee and include, as applicable:

— those responsible for the functions or processes which have been audited;
— representatives from the audit client;
— other members of the audit team;
— other relevant interested parties as determined by the audit client and/or auditee.

If applicable, the audit team leader should advise the auditee of situations encountered during the audit that can decrease the confidence that can be placed in the audit conclusions. If defined in the management system or by agreement with the audit client, the participants should agree on the time frame for an action plan to address audit findings.

The degree of detail should take into account the effectiveness of the management system in achieving the auditee′s objectives, including consideration of its context and risks and opportunities.

The familiarity of the auditee with the audit process should also be taken into consideration during the closing meeting, to ensure the correct level of detail is provided to participants.

For some audit situations, the meeting can be formal and minutes, including records of attendance, should be kept. In other instances, the closing meeting can be less formal and consist solely of communicating the audit findings and audit conclusions.

As appropriate, the following should be explained to the auditee in the closing meeting:

a) advising that the audit evidence collected was based on a sample of the information available and is not necessarily fully representative of the overall effectiveness of the auditee′s processes;

b) the method of reporting;
c) how the audit findings should be addressed based on the agreed process;
d) possible consequences of not adequately addressing the audit findings;
e) presentation of the audit findings and conclusions in such a manner that they are understood and acknowledged by the auditee's management;
f) any related audit follow-up activities (e.g. implementation and review of corrective actions, addressing audit complaints, appeal process).

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

If specified by the audit objectives, opportunities for improvement can be presented as recommendations. It should be emphasized that recommendations are not binding.

6.5 Preparing and distributing the audit report

6.5.1 Preparing the audit report

The audit team leader should report the audit conclusions in accordance with the audit programme. The audit report should provide a complete, accurate, concise and clear record of the audit, using specific reporting formats when required, and should include or refer to the following:

a) audit objectives;
b) audit scope, particularly identification of the organization (the auditee) and the functions or processes audited;
c) identification of the audit client;
d) identification of the audit team and auditee's participants in the audit;
e) dates and locations where the auditing activities were conducted;
f) audit criteria;
g) audit findings and related audit evidence;
h) audit conclusions;
i) a statement on the degree to which the audit criteria have been fulfilled;
j) any unresolved diverging opinions between the audit team and the auditee;
k) a statement that audits by nature are a sampling exercise; as such there is a risk that the audit evidence examined is not representative.

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

— the audit plan, including the time schedule;
— a summary of the audit process, including any obstacles encountered that can decrease the reliability of the audit conclusions;
— confirmation that the audit objectives have been achieved within the audit scope in accordance with the audit plan;
— any areas within the audit scope that were not covered, including any issues of availability of audit evidence, resources or confidentiality, with related justifications;
— any identified auditee's good practices;
— follow-up activities related to agreed action plan, if any;
— a statement of the confidential nature of the contents;
— any implications for the audit programme or subsequent audits.

Nonconformities that have not been presented and discussed during the audit or the closing meeting should not be included in the audit report.

6.5.2 Distributing the audit report

The audit report should be issued within an agreed period of time. If it is delayed, the reasons should be communicated to the auditee and the individual(s) managing the audit programme.

The audit report should be dated, reviewed and, as appropriate, accepted, in accordance with the audit programme.

The audit report should then be distributed to the relevant interested parties defined in the audit programme or audit plan.

When distributing the audit report, appropriate measures to ensure confidentiality should be considered.

6.6 Completing the audit

The audit is completed when all planned auditing activities have been carried out, or as otherwise agreed with the audit client (e.g. there is a possibility that an unexpected situation prevents the audit from being completed according to the audit plan).

Documented information pertaining to the audit should be retained or disposed of as agreed between the participating parties and in accordance with the audit programme and applicable requirements.

The audit team and the individual(s) managing the audit programme should not disclose any 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 (e.g. by law), the audit client and auditee should be informed as soon as possible.

Lessons learned from the audit can identify risks and opportunities for the audit programme and the auditee.

6.7 Conducting the audit follow-up

The outcome of the audit can, depending on the audit objectives, indicate the need for corrections, or for corrective actions, or opportunities for improvement. Such actions are usually decided and undertaken by the auditee within an agreed time frame. As appropriate, the auditee should keep the individual(s) managing the audit programme and/or the audit team informed of the status of these actions.
The completion and effectiveness of these actions should be verified. This verification can be part of a subsequent audit. Outcomes should be reported to the individual managing the audit programme and reported to the audit client for management review.

7 Competence and evaluation of auditors

7.1 General

Confidence in the audit process and the ability to achieve its objectives depend on the competence of individuals involved, including auditors and audit team leaders. Competence should be evaluated regularly through a process that considers personal behaviour and the ability to apply the knowledge and skills gained through education, work experience, auditor training and audit experience. This process should take into consideration the needs of the audit programme and its objectives. Some of the knowledge and skills described in 7.2.3 are common to auditors of any management system discipline; others are specific to individual management system disciplines. It is not necessary for each auditor in the audit team to have the same competence. However, the overall competence of the audit team should be sufficient to achieve the audit objectives.
The evaluation of auditor competence should be planned, implemented and documented to provide an outcome that is objective, consistent, fair and reliable. The evaluation process should include four main steps, as follows:
a) determine the required competence to fulfil the needs of the audit programme;
b) establish the evaluation criteria;
c) select the appropriate evaluation method;
d) conduct the evaluation.

The outcome of the evaluation process should provide a basis for the following:
— selecting audit team members (as described in 5.5.4);
— determining the need for improved competence (e.g. additional training);
— conducting ongoing performance evaluations of auditors.
Auditors should develop, maintain and improve their competence through continual professional development and regular participation in audits (see 7.6).
A process for evaluating auditors and audit team leaders is described in 7.3, 7.4 and 7.5.
Auditors and audit team leaders should be evaluated against the criteria established in 7.2.1, 7.2.2 and 7.2.3. The competence required of the individual(s) managing the audit programme is described in 5.4.2.

7.2 Determining auditor competence

7.2.1 General

In determining the necessary competence to perform or participate in an audit, an auditor's knowledge and skills related to the following should be considered:
a) the size, nature and complexity of the organization and its products, services and processes;
b) methods for auditing including the application of emerging technology to facilitate the conducting of the audit, or to audit emerging technology-based processes;
c) the management system disciplines to be audited;
d) the complexity of the management system(s) to be audited;
e) methods for evaluating risks and opportunities;
f) the objectives and extent of the audit programme;
g) the uncertainty in achieving audit objectives;
h) other requirements, such as those imposed by the audit client or other relevant interested parties, where appropriate.
This information should be matched against that listed in 7.2.3.

7.2.2 Personal behaviour

Auditors should possess the necessary attributes to enable them to act in accordance with the principles of auditing as described in Clause 4. Auditors should exhibit professional behaviour during the performance of auditing activities. Desired professional behaviours include being:
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 individuals;
d) observant, i.e. actively observing physical surroundings and activities;
e) perceptive, i.e. aware of and able to understand situations;
f) versatile, i.e. able to readily adapt to different situations;
g) determined, i.e. persistent and focused on achieving objectives;

h) decisive, i.e. able to reach timely conclusions based on logical reasoning and analysis;
i) self-reliant, i.e. able to act and function independently while interacting effectively with others;
j) open to improvement, i.e. willing to learn from situations;

k) culturally sensitive, i.e. observant and respectful to the culture of the auditee;
l) collaborative, i.e. effectively interacting with others, including audit team members and the auditee's personnel.

7.2.3 Knowledge and skills

7.2.3.1 General

Auditors should possess:

a) the knowledge and skills necessary to achieve the intended results of the audits they are expected to perform;
b) generic competence and a level of discipline-specific and sector-specific knowledge and skills.

Audit team leaders should have the additional knowledge and skills necessary to provide leadership to the audit team (refer to 7.2.3.4).

7.2.3.2 Generic knowledge and skills of management system auditors

Auditors should have knowledge and skills in the areas outlined as follows:

a) Audit principles, processes and methods: knowledge and skills in this area enable the auditor to ensure audits are performed in a consistent and systematic manner. An auditor should be able to:
1) understand the types of risks and opportunities associated with auditing and the principles of the risk-based approach to auditing;
2) plan and organize the work effectively;
3) conduct the audit within the agreed time schedule;
4) prioritize and focus on matters of significance;
5) communicate effectively, both orally and in writing (either personally, or through the use of interpreters);
6) collect information through effective interviewing, listening, observing and reviewing documented information, including records and data;
7) understand the appropriateness and consequences of using sampling techniques for auditing;
8) understand and consider technical experts' opinions;
9) audit a process from start to finish, including the interrelations with other processes and different functions, where applicable;
10) understand the appropriateness and consequences of using information and communications technology tools, and emerging technology to conduct audits (e.g. artificial-intelligence-based evaluation tools);
11) verify the relevance and accuracy of collected information;
12) confirm the sufficiency and appropriateness of audit evidence to support audit findings and conclusions;
13) assess those factors that can affect the reliability of the audit findings and conclusions;
14) document auditing activities and audit findings, and prepare audit reports;
15) maintain the confidentiality and security of information;
16) achieve the intended results of the audit.

b) Management system standards and other references: knowledge and skills in this area enable the auditor to understand the audit scope and apply audit criteria. Knowledge and skills should include the following:
1) management system standards or other normative or guidance/supporting documents used to establish audit criteria or methods;
2) the application of management system standards by the auditee and other organizations;
3) relationships and interactions between the management system(s) processes;
4) understanding the importance and priority of multiple standards or references;
5) the application of standards or references to different audit situations.

c) The organization and its context: knowledge and skills in this area enable the auditor to understand the auditee's structure, purpose and management practices. Knowledge and skills should include the following:
1) the needs and expectations of relevant interested parties that impact the management system;
2) the type of organization, and its governance, size, structure, functions and relationships;
3) general business and management concepts, processes and related terminology, including planning, budgeting and management of individuals;
4) the cultural and social aspects of the auditee.

d) Applicable statutory and regulatory requirements and other requirements: knowledge and skills in this area enable the auditor to be aware of, and work within, the organization's requirements. Knowledge and skills specific to the jurisdiction or to the auditee's activities, processes, products and services should include the following:
1) statutory and regulatory requirements and their governmental agencies and regulatory authorities;
2) basic legal terminology;
3) contracting and liability;
4) data protection and information security.

NOTE Awareness of statutory and regulatory requirements does not imply legal expertise and a management system audit cannot be treated as a legal compliance audit.

7.2.3.3 Discipline-specific and sector-specific competence of auditors

Audit teams should have the collective discipline-specific and sector-specific competence appropriate for auditing the particular types of management systems and sectors.

The discipline-specific and sector-specific competence of auditors should include the following:
a) management system requirements and principles, and their application;
b) fundamentals of the discipline(s) and sector(s) related to the management system standards as applied by the auditee;

c) application of discipline-specific and sector-specific methods, techniques, processes and practices to enable the audit team to assess conformity within the defined audit scope and generate appropriate audit findings and conclusions;
d) principles, methods and techniques relevant to the discipline and sector, such that the auditor can determine and evaluate the risks and opportunities associated with the audit objectives.

7.2.3.4 Generic competence of the audit team leader
In order to facilitate the efficient and effective conduct of the audit, an audit team leader should have the competence to:
a) plan the audit and assign audit tasks according to the specific competence of individual audit team members;
b) discuss strategic issues with top management of the auditee to determine whether they have considered these issues when evaluating their risks and opportunities;
c) develop and maintain a collaborative working relationship among the audit team members;
d) manage the audit process, including:
1) making effective use of resources during the audit;
2) managing the uncertainty of achieving audit objectives;
3) taking into account the health and safety of the audit team members during the audit, including ensuring that they meet the relevant health, safety and security arrangements;
4) directing the audit team members;
5) providing direction and guidance to auditors-in-training;
6) preventing and resolving conflicts and problems that can occur during the audit, including those within the audit team, as necessary;
e) represent the audit team in communications with the individual(s) managing the audit programme, the audit client and the auditee;
f) lead the audit team to reach the audit conclusions;
g) prepare and complete the audit report.

7.2.3.5 Knowledge and skills for auditing multiple disciplines
When auditing multiple discipline management systems, the audit team member should have an understanding of the interactions and synergy among the different management systems.
Audit team leaders should understand the requirements of each of the management system standards being audited and recognize the limits of their competence in each of the disciplines.
NOTE Audits of multiple disciplines done simultaneously can be done as a combined audit or as an audit of an integrated management system that covers multiple disciplines.

7.2.4 Achieving auditor competence
Auditor competence can be acquired using a combination of the following:
a) successfully completing training programmes that cover generic auditor knowledge and skills;
b) experience in a relevant technical, managerial or professional position involving the exercise of judgement, decision-making, problem solving and communication with managers, professionals, peers, customers and other relevant interested parties;

c) education/training and experience in a specific management system discipline and sector;
d) audit experience acquired under the supervision of an auditor competent in the same discipline.
NOTE Successful completion of a training course will depend on the type of course. For courses with an examination component, it can mean successfully passing the examination. For other courses, it can mean participating in and completing the course.

7.2.5 Achieving audit team leader competence
An audit team leader should have acquired additional audit experience to develop the competence described in 7.2.3.4. This additional experience should have been gained by working under the direction and guidance of a different audit team leader.

7.3 Establishing the auditor evaluation criteria
The criteria used to evaluate auditors should be qualitative (e.g. demonstrating desired behaviour, knowledge or the performance of skills, in training or in the workplace) and quantitative (e.g. years of work experience and education, number of audits conducted, hours of audit training).

7.4 Selecting the appropriate auditor evaluation method
The evaluation should be conducted using two or more of the methods given in Table 2. When using Table 2, the following should be noted:
a) the methods outlined represent a range of options and do not always apply in all situations;
b) the various methods outlined can differ in their reliability;
c) a combination of methods should be used to ensure an outcome that is objective, consistent, fair and reliable.

Table 2 — Auditor evaluation methods

Evaluation method	Objectives	Examples
Review of records	To verify the background of the auditor	Analysis of records of education, training, employment, professional credentials and auditing experience
Feedback	To provide information about how the performance of the auditor is perceived	Surveys, questionnaires, personal references, testimonials, complaints, performance evaluation, peer review
Interview	To evaluate desired professional behaviour and communication skills, to verify information and test knowledge and to acquire additional information	Personal interviews
Observation	To evaluate desired professional behaviour and the ability to apply knowledge and skills	Role playing, witnessed audits, on-the-job performance
Testing	To evaluate desired professional behaviour and knowledge and skills and their application	Oral and written exams, psychometric testing
Post-audit review	To provide information on the auditor's performance during the auditing activities, identifying strengths and opportunities for improvement	Review of the audit report, interviews with the audit team leader, the audit team and, if appropriate, feedback from the auditee

7.5 Conducting the auditor evaluation

The information collected about the auditor under evaluation should be compared against the criteria set in 7.2.3. When an auditor under evaluation who is expected to participate in the audit programme does not

fulfil the criteria, additional training, work or audit experience should be undertaken and a subsequent re-evaluation should be performed.

7.6 Maintaining and improving auditor competence

Auditors and audit team leaders should continually improve their competence. Auditors should maintain their auditing competence through regular participation in management system audits and continual professional development. This can be achieved through means such as additional work experience, training, personal study, coaching, attendance at meetings, seminars and conferences, or other relevant activities.

The individual(s) managing the audit programme should establish suitable mechanisms for the continual evaluation of the performance of the auditors and audit team leaders.

The continual professional development activities should take into account the following:

a) changes in the needs of the individual and the organization responsible for the conduct of the audit;
b) developments in the practice of auditing including the use of technology;
c) relevant standards including guidance/supporting documents and other requirements;
d) changes in disciplines or sectors;
e) analysis of feedback from auditees and stakeholders.