Training Manual

Internal Auditor Training Course on ISO/IEC 17065:2012, ISO/IEC 17067:2013 ISO 45001:2018, ISO 22000:2018 ISO 9001:2015 & ISO 14001:2015

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Content

INTERNATIONAL STANDARD

ISO/IEC 17065

First edition
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Conformity assessment — Requirements for bodies certifying products, processes and services

Évaluation de la conformité — Exigences pour les organismes certifiant les produits, les procédés et les services

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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

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

ISO/IEC 17065 was prepared by the ISO Committee on conformity assessment (CASCO).

It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This first edition of ISO/IEC 17065 cancels and replaces ISO/IEC Guide 65:1996, which has been technically revised.

The following major changes have been made compared with ISO/IEC Guide 65:1996:

— restructuring of this International Standard based on the common structure adopted by ISO/CASCO;

— modifications based on ISO/PAS 17001, ISO/PAS 17002, ISO/PAS 17003, ISO/PAS 17004 and ISO/PAS 17005;

— introduction of the ISO/IEC 17000 functional approach in the process requirements of Clause 7;

— information on the application of this International Standard for processes and services in Annex B;

— revision of the terms and definitions in Clause 3;

— improvement of the impartiality requirements (mechanism);

— consolidation of the management system requirements in Clause 8;

— inclusion of principles for product certification bodies and their activities in Annex A;

— improvement by taking into account IAF GD 5;

— inclusion of a reference to certification schemes, for which further information is provided in ISO/IEC 17067.

Introduction

The overall aim of certifying products, processes or services is to give confidence to all interested parties that a product, process or service fulfils specified requirements. The value of certification is the degree of confidence and trust that is established by an impartial and competent demonstration of fulfilment of specified requirements by a third party. Parties that have an interest in certification include, but are not limited to:

a) the clients of the certification bodies;

b) the customers of the organizations whose products, processes or services are certified;

c) governmental authorities;

d) non-governmental organizations; and

e) consumers and other members of the public.

Interested parties can expect or require the certification body to meet all the requirements of this International Standard as well as when relevant, those of the certification scheme.

Certification of products, processes or services is a means of providing assurance that they comply with specified requirements in standards and other normative documents. Some product, process or service certification schemes may include initial testing or inspection and assessment of its suppliers' quality management systems, followed by surveillance that takes into account the quality management system and the testing or inspection of samples from the production and the open market. Other schemes rely on initial testing and surveillance testing, while still others comprise type testing only.

This International Standard specifies requirements, the observance of which is intended to ensure that certification bodies operate certification schemes in a competent, consistent and impartial manner, thereby facilitating the recognition of such bodies and the acceptance of certified products, processes and services on a national and international basis and so furthering international trade. This International Standard can be used as a criteria document for accreditation or peer assessment or designation by governmental authorities, scheme owners and others.

The requirements contained in this International Standard are written, above all, to be considered as general criteria for certification bodies operating product, process or service certification schemes; they may have to be amplified when specific industrial or other sectors make use of them, or when particular requirements such as health and safety have to be taken into account. Annex A contains principles relating to certification bodies and certification activities that they provide.

This International Standard does not set requirements for schemes and how they are developed and is not intended to restrict the role or choice of scheme owners, however scheme requirements should not contradict or exclude any of the requirements of this International Standard.

Statements of conformity to the applicable standards or other normative documents can be in the form of certificates and/or marks of conformity. Schemes for certifying particular products or product groups, processes and services to specified standards or other normative documents will, in many cases, require their own explanatory documentation.

While this International Standard is concerned with third parties providing product, process or service certification, many of its provisions may also be useful in first- and second-party product conformity assessment procedures.

In this International Standard, the following verbal forms are used:

— "shall" indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

Conformity assessment — Requirements for bodies certifying products, processes and services

1 Scope

This International Standard contains requirements for the competence, consistent operation and impartiality of product, process and service certification bodies. Certification bodies operating to this International Standard need not offer all types of products, processes and services certification. Certification of products, processes and services is a third-party conformity assessment activity (see ISO/IEC 17000:2004, definition 5.5).

In this International Standard, the term "product" can be read as "process" or "service", except in those instances where separate provisions are stated for "processes" or "services" (see Annex B).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17020, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

ISO/IEC 17021, *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the following apply.

3.1
client
organization or person responsible to a certification body for ensuring that **certification requirements** (3.7), including **product requirements** (3.8), are fulfilled

NOTE Whenever the term "client" is used in this International Standard, it applies to both the "applicant" and the "client", unless otherwise specified.

3.2
consultancy
participation in

a) the designing, manufacturing, installing, maintaining or distributing of a certified product or a product to be certified, or

b) the designing, implementing, operating or maintaining of a certified process or a process to be certified, or

c) the designing, implementing, providing or maintaining of a certified service or a service to be certified

NOTE In this International Standard, the term "consultancy" is used in relation to activities of certification bodies, personnel of certification bodies and organizations related or linked to certification bodies.

3.3
evaluation
combination of the selection and determination functions of conformity assessment activities

NOTE The selection and determination functions are specified in ISO/IEC 17000:2004, Clauses A.2 and A.3.

3.4
product
result of a process

NOTE 1 Four generic product categories are noted in ISO 9000:2005:

— services (e.g. transport) (see definition in 3.6);

— software (e.g. computer program, dictionary);

— hardware (e.g. engine, mechanical part);

— processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element.

NOTE 2 Products include results of natural processes, such as growth of plants and formation of other natural resources.

NOTE 3 Adapted from ISO/IEC 17000:2004, definition 3.3.

3.5
process
set of interrelated or interacting activities which transforms inputs into outputs

EXAMPLES Welding engineering processes; heat treatment processes; manufacturing processes requiring confirmation of process capability (e.g. operating or producing product within specified tolerances); food production processes; plant growth processes.

NOTE Adapted from ISO 9000:2005, definition 3.4.1.

3.6
service
result of at least one activity necessarily performed at the interface between the supplier and the customer, which is generally intangible

NOTE 1 Provision of a service can involve, for example, the following:

— an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);

— an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);

— the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);

— the creation of ambience for the customer (e.g. in hotels and restaurants).

NOTE 2 Adapted from ISO 9000:2005, definition 3.4.2.

3.7
certification requirement
specified requirement, including **product requirements** (3.8), that is fulfilled by the **client** (3.1) as a condition of establishing or maintaining certification

NOTE Certification requirements include requirements imposed on the client by the certification body (usually via the certification agreement (see 4.1.2)) to meet this International Standard, and can also include requirements imposed on the client by the certification scheme. "Certification requirements", as used in this International Standard, do not include requirements imposed on the certification body by the certification scheme.

EXAMPLE The following are certification requirements that are not product requirements:

— completing the certification agreement;

— paying fees;

— providing information about changes to the certified product;

— providing access to certified products for surveillance activities.

3.8
product requirement
requirement that relates directly to a product, specified in standards or in other normative documents identified by the certification scheme

NOTE Product requirements can be specified in normative documents such as regulations, standards and technical specifications.

3.9
certification scheme
certification system related to specified products, to which the same specified requirements, specific rules and procedures apply

NOTE 1 Adapted from ISO/IEC 17000:2004, definition 2.8.

NOTE 2 A "certification system" is a "conformity assessment system", which is defined in ISO/IEC 17000:2004, definition 2.7.

NOTE 3 The rules, procedures and management for implementing product, process and service certification are stipulated by the certification scheme.

NOTE 4 General guidance for the development of schemes is given in ISO/IEC 17067, in combination with ISO/IEC Guide 28 and ISO/IEC Guide 53.

3.10
scope of certification
identification of

— the product(s), process(es) or service(s) for which the certification is granted,

— the applicable certification scheme, and

— the standard(s) and other normative document(s), including their date of publication, to which it is judged that the product(s), process(es) or service(s) comply

3.11
scheme owner
person or organization responsible for developing and maintaining a specific **certification scheme** (3.9)

NOTE The scheme owner can be the certification body itself, a governmental authority, a trade association, a group of certification bodies or others.

3.12
certification body
third-party conformity assessment body operating certification schemes

NOTE A certification body can be non-governmental or governmental (with or without regulatory authority).

3.13
impartiality
presence of objectivity

NOTE 1 Objectivity is understood to mean that conflicts of interest do not exist, or are resolved so as not to adversely influence the activities of the body.

NOTE 2 Other terms that are useful in conveying the element of impartiality are independence, freedom from conflicts of interest, freedom from bias, freedom from prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment and balance.

4 General requirements

4.1 Legal and contractual matters

4.1.1 Legal responsibility

The certification body shall be a legal entity, or a defined part of a legal entity, such that the legal entity can be held legally responsible for all its certification activities.

NOTE A governmental certification body is deemed to be a legal entity on the basis of its governmental status.

4.1.2 Certification agreement

4.1.2.1 The certification body shall have a legally enforceable agreement for the provision of certification activities to its clients. Certification agreements shall take into account the responsibilities of the certification body and its clients.

4.1.2.2 The certification body shall ensure its certification agreement requires that the client comply at least, with the following:

a) the client always fulfils the certification requirements (see 3.7), including implementing appropriate changes when they are communicated by the certification body (see 7.10);

b) if the certification applies to ongoing production, the certified product continues to fulfil the product requirements (see 3.8);

c) the client makes all necessary arrangements for

   1) the conduct of the evaluation (see 3.3) and surveillance (if required), including provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and client's subcontractors;

   2) investigation of complaints;

   3) the participation of observers, if applicable;

d) the client makes claims regarding certification consistent with the scope of certification (see 3.10);

e) the client does not use its product certification in such a manner as to bring the certification body into disrepute and does not make any statement regarding its product certification that the certification body may consider misleading or unauthorized;

f) upon suspension, withdrawal, or termination of certification, the client discontinues its use of all advertising matter that contains any reference thereto and takes action as required by the certification scheme (e.g. the return of certification documents) and takes any other required measure;

g) if the client provides copies of the certification documents to others, the documents shall be reproduced in their entirety or as specified in the certification scheme;

h) in making reference to its product certification in communication media such as documents, brochures or advertising, the client complies with the requirements of the certification body or as specified by the certification scheme;

i) the client complies with any requirements that may be prescribed in the certification scheme relating to the use of marks of conformity, and on information related to the product;

NOTE See also ISO/IEC 17030, ISO/IEC Guide 23 and ISO Guide 27.

j) the client keeps a record of all complaints made known to it relating to compliance with certification requirements and makes these records available to the certification body when requested, and

1) takes appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification;

2) documents the actions taken;

NOTE Verification of item j) by the certification body can be specified in the certification scheme.

k) the client informs the certification body, without delay, of changes that may affect its ability to conform with the certification requirements.

NOTE Examples of changes can include the following:

— the legal, commercial, organizational status or ownership,

— organization and management (e.g. key managerial, decision-making or technical staff),

— modifications to the product or the production method,

— contact address and production sites,

— major changes to the quality management system.

4.1.3 Use of license, certificates and marks of conformity

4.1.3.1 The certification body shall exercise the control as specified by the certification scheme over ownership, use and display of licenses, certificates, marks of conformity, and any other mechanisms for indicating a product is certified.

NOTE 1 Guidance on the use of certificates and marks permitted by the certification body can be obtained from ISO/IEC Guide 23.

NOTE 2 ISO/IEC 17030 provides requirements for the use of third-party marks.

4.1.3.2 Incorrect references to the certification scheme, or misleading use of licenses, certificates, marks, or any other mechanism for indicating a product is certified, found in documentation or other publicity, shall be dealt with by suitable action.

NOTE Such actions are addressed in ISO Guide 27 and can include corrective actions, withdrawal of certificate, publication of the transgression and, if necessary, legal action.

4.2 Management of impartiality

4.2.1 Certification activities shall be undertaken impartially.

4.2.2 The certification body shall be responsible for the impartiality of its certification activities and shall not allow commercial, financial or other pressures to compromise impartiality.

4.2.3 The certification body shall identify risks to its impartiality on an ongoing basis. This shall include those risks that arise from its activities, from its relationships, or from the relationships of its personnel (see 4.2.12). However, such relationships may not necessarily present a certification body with a risk to impartiality.

NOTE 1 A relationship presenting a risk to impartiality of the certification body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new clients, etc.

NOTE 2 Identifying risks does not imply risk assessments as stated in ISO 31000.

4.2.4 If a risk to impartiality is identified, the certification body shall be able to demonstrate how it eliminates or minimizes such risk. This information shall be made available to the mechanism specified in 5.2.

4.2.5 The certification body shall have top management commitment to impartiality.

4.2.6 The certification body and any part of the same legal entity and entities under its organizational control (see 7.6.4) shall not:

a) be the designer, manufacturer, installer, distributer or maintainer of the certified product;

b) be the designer, implementer, operator or maintainer of the certified process;

c) be the designer, implementer, provider or maintainer of the certified service;

d) offer or provide consultancy (see 3.2) to its clients;

e) offer or provide management system consultancy or internal auditing to its clients where the certification scheme requires the evaluation of the client's management system.

NOTE 1 This does not preclude the following:

— the possibility of exchange of information (e.g. explanations of findings or clarifying requirements) between the certification body and its clients;

— the use, installing and maintaining of certified products which are necessary for the operations of the certification body.

NOTE 2 "Management system consultancy" is defined in ISO/IEC 17021:2011, definition 3.3.

4.2.7 The certification body shall ensure that activities of separate legal entities, with which the certification body or the legal entity of which it forms a part has relationships, do not compromise the impartiality of its certification activities.

NOTE See 4.2.3, Note 1.

4.2.8 When the separate legal entity in 4.2.7 offers or produces the certified product (including products to be certified) or offers or provides consultancy (see 3.2), the certification body's management personnel and personnel in the review and certification decision-making process shall not be involved in the activities of the separate legal entity. The personnel of the separate legal entity shall not be involved in the management of the certification body, the review, or the certification decision.

NOTE For the evaluation personnel, impartiality requirements are stipulated in Clause 6 and additional requirements are given in the other relevant International Standards cited in 6.2.1 and 6.2.2.1.

4.2.9 The certification body's activities shall not be marketed or offered as linked with the activities of an organization that provides consultancy (see 3.2). A certification body shall not state or imply that certification would be simpler, easier, faster or less expensive if a specified consultancy organization were used.

4.2.10 Within a period specified by the certification body, personnel shall not be used to review or make a certification decision for a product for which they have provided consultancy (see 3.2).

NOTE 1 The period can be specified in the certification scheme or, if specified by the certification body, it reflects a period that is long enough to ensure that the review or decision does not compromise impartiality. A specified period of two years is often used.

NOTE 2 For the evaluation personnel, impartiality requirements are stipulated in Clause 6 and additional requirements are given in the other relevant International Standards cited in 6.2.1 and 6.2.2.1.

4.2.11 The certification body shall take action to respond to any risks to its impartiality, arising from the actions of other persons, bodies or organizations, of which it becomes aware.

4.2.12 All certification body personnel (either internal or external) or committees who could influence the certification activities shall act impartially.

4.3 Liability and financing

4.3.1 The certification body shall have adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations.

4.3.2 The certification body shall have the financial stability and resources required for its operations.

4.4 Non-discriminatory conditions

4.4.1 The policies and procedures under which the certification body operates, and the administration of them, shall be non-discriminatory. Procedures shall not be used to impede or inhibit access by applicants, other than as provided for in this International Standard.

4.4.2 The certification body shall make its services accessible to all applicants whose activities fall within the scope of its operations.

4.4.3 Access to the certification process shall not be conditional upon the size of the client or membership of any association or group, nor shall certification be conditional upon the number of certifications already issued. There shall not be undue financial or other conditions.

NOTE A certification body can decline to accept an application or maintain a contract for certification from a client when fundamental or demonstrated reasons exist, such as the client participating in illegal activities, having a history of repeated non-compliances with certification/product requirements, or similar client-related issues.

4.4.4 The certification body shall confine its requirements, evaluation, review, decision and surveillance (if any) to those matters specifically related to the scope of certification.

4.5 Confidentiality

4.5.1 The certification body shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of certification activities. Except for information that the client makes publicly available, or when agreed between the certification body and the client (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential. The certification body shall inform the client, in advance, of the information it intends to place in the public domain.

4.5.2 When the certification body is required by law or authorized by contractual arrangements to release confidential information, the client or person concerned shall, unless prohibited by law, be notified of the information provided.

4.5.3 Information about the client obtained from sources other than the client (e.g. from the complainant or from regulators) shall be treated as confidential.

4.6 Publicly available information

The certification body shall maintain (through publications, electronic media or other means), and make available upon request, the following:

a) information about (or reference to) the certification scheme(s), including evaluation procedures, rules and procedures for granting, for maintaining, for extending or reducing the scope of, for suspending, for withdrawing or for refusing certification;

b) a description of the means by which the certification body obtains financial support and general information on the fees charged to applicants and to clients;

c) a description of the rights and duties of applicants and clients, including requirements, restrictions or limitations on the use of the certification body's name and certification mark and on the ways of referring to the certification granted;

d) information about procedures for handling complaints and appeals.

5 Structural requirements

5.1 Organizational structure and top management

5.1.1 Certification activities shall be structured and managed so as to safeguard impartiality.

5.1.2 The certification body shall document its organizational structure, showing duties, responsibilities and authorities of management and other certification personnel and any committees. When the certification body is a defined part of a legal entity, the structure shall include the line of authority and the relationship to other parts within the same legal entity.

5.1.3 The management of the certification body shall identify the board, group of persons, or person having overall authority and responsibility for each of the following:

a) development of policies relating to the operation of the certification body;

b) supervision of the implementation of the policies and procedures;

c) supervision of the finances of the certification body;

d) development of certification activities;

e) development of certification requirements;

f) evaluation (see 7.4);

g) review (see 7.5);

h) decisions on certification (see 7.6);

i) delegation of authority to committees or personnel, as required, to undertake defined activities on its behalf;

j) contractual arrangements;

k) provision of adequate resources for certification activities;

l) responsiveness to complaints and appeals;

m) personnel competence requirements;

n) management system of the certification body (see Clause 8).

5.1.4 The certification body shall have formal rules for the appointment, terms of reference and operation of any committees that are involved in the certification process (see Clause 7). Such committees shall be free from any commercial, financial and other pressures that might influence decisions. The certification body shall retain authority to appoint and withdraw members of such committees.

5.2 Mechanism for safeguarding impartiality

5.2.1 The certification body shall have a mechanism for safeguarding its impartiality. The mechanism shall provide input on the following:

a) the policies and principles relating to the impartiality of its certification activities;

b) any tendency on the part of a certification body to allow commercial or other considerations to prevent the consistent impartial provision of certification activities;

c) matters affecting impartiality and confidence in certification, including openness.

NOTE 1 Other tasks or duties (e.g. taking part in the decision-making process) can be assigned to the mechanism, provided these additional tasks or duties do not compromise its essential role of ensuring impartiality.

NOTE 2 A possible mechanism can be a committee established by one or more certification bodies, a committee implemented by a scheme owner, a governmental authority or an equivalent party.

NOTE 3 A single mechanism for several certification schemes can satisfy this requirement.

NOTE 4 If the certification body also provides management systems certification, a committee that fulfils ISO/IEC 17021:2011, 6.2, can also fulfil this subclause (5.2) providing that all the requirements of 5.2 have been met.

5.2.2 The mechanism shall be formally documented to ensure the following:

a) a balanced representation of significantly interested parties, such that no single interest predominates (internal or external personnel of the certification body are considered to be a single interest, and shall not predominate);

b) access to all the information necessary to enable it to fulfil all its functions.

5.2.3 If the top management of the certification body does not follow the input of this mechanism, the mechanism shall have the right to take independent action (e.g. informing authorities, accreditation bodies, stakeholders). In taking appropriate action, the confidentiality requirements of 4.5 relating to the client and certification body shall be respected.

Input that is in conflict with the operating procedures of the certification body or other mandatory requirements should not be followed. Management should document the reasoning behind the decision to not follow the input and maintain the document for review by appropriate personnel.

5.2.4 Although every interest cannot be represented in the mechanism, a certification body shall identify and invite significantly interested parties.

NOTE 1 Such interested parties can include clients of the certification body, customers of clients, manufacturers, suppliers, users, conformity assessment experts, representatives of industry trade associations, representatives of governmental regulatory bodies or other governmental services, and representatives of non-governmental organizations, including consumer organizations. It can be sufficient to have one representative of each interested party in the mechanism.

NOTE 2 These interests can be limited, depending on the nature of the certification scheme.

6 Resource requirements

6.1 Certification body personnel

6.1.1 General

6.1.1.1 The certification body shall employ, or have access to, a sufficient number of personnel to cover its operations related to the certification schemes and to the applicable standards and other normative documents.

NOTE The personnel include those normally working for the certification body, as well as persons working under an individual contract or a formal agreement that places them within the management control and systems/procedures of the certification body (see 6.1.3).

6.1.1.2 The personnel shall be competent for the functions they perform, including making required technical judgments, defining policies and implementing them.

6.1.1.3 Personnel, including any committee members, personnel of external bodies, or personnel acting on the certification body's behalf, shall keep confidential all information obtained or created during the performance of the certification activities, except as required by law or by the certification scheme.

6.1.2 Management of competence for personnel involved in the certification process

6.1.2.1 The certification body shall establish, implement and maintain a procedure for management of competencies of personnel involved in the certification process (see Clause 7). The procedure shall require the certification body to:

a) determine the criteria for the competence of personnel for each function in the certification process, taking into account the requirements of the schemes;

b) identify training needs and provide, as necessary, training programmes on certification processes, requirements, methodologies, activities and other relevant certification scheme requirements;

c) demonstrate that the personnel have the required competencies for the duties and responsibilities they undertake;

d) formally authorize personnel for functions in the certification process;

e) monitor the performance of the personnel.

6.1.2.2 The certification body shall maintain the following records on the personnel involved in the certification process (see Clause 7):

a) name and address;

b) employer(s) and position held;

c) educational qualification and professional status;

d) experience and training;

e) the assessment of competence;

f) performance monitoring;

g) authorizations held within the certification body;

h) date of most recent updating of each record.

6.1.3 Contract with the personnel

The certification body shall require personnel involved in the certification process to sign a contract or other document by which they commit themselves to the following:

a) to comply with the rules defined by the certification body, including those relating to confidentiality (see 4.5) and independence from commercial and other interests;

b) to declare any prior and/or present association on their own part, or on the part of their employer, with:

   1) a supplier or designer of products, or

   2) a provider or developer of services, or

   3) an operator or developer of processes

   to the evaluation or certification of which they are to be assigned;

c) to reveal any situation known to them that may present them or the certification body with a conflict of interest (see 4.2).

Certification bodies shall use this information as input into identifying risks to impartiality raised by the activities of such personnel, or by the organizations that employ them (see 4.2.3).

6.2 Resources for evaluation

6.2.1 Internal resources

When a certification body performs evaluation activities, either with its internal resources or with other resources under its direct control, it shall meet the applicable requirements of the relevant International Standards and, as specified by the certification scheme, of other documents. For testing, it shall meet the applicable requirements of ISO/IEC 17025; for inspection, it shall meet the applicable requirements of ISO/IEC 17020; and for management system auditing, it shall meet the applicable requirements of ISO/IEC 17021. The impartiality requirements of the evaluation personnel stipulated in the relevant standard shall always be applicable.

NOTE Examples of reasons as to why some requirements are not applicable include the following:

— expertise is available within the certification body when using the results of the evaluation activity;

— the extent of control the certification body has over testing (including witnessing the testing), inspection (e.g. specifying inspection methods or parameters) or management system assessment (e.g. requiring specific details of a management system);

— a particular requirement is covered in an equivalent way by this International Standard, or is not needed to give confidence in the certification decision.

6.2.2 External resources (outsourcing)

6.2.2.1 The certification body shall outsource evaluation activities only to bodies that meet the applicable requirements of the relevant International Standards and, as specified by the certification scheme, of other documents. For testing, it shall meet the applicable requirements of ISO/IEC 17025; for inspection, it shall meet the applicable requirements of ISO/IEC 17020; and for management system auditing, it shall meet the applicable requirements of ISO/IEC 17021. The impartiality requirements of the evaluation personnel stipulated in the relevant standard shall always be applicable.

NOTE 1 Examples of reasons as to why some requirements are not applicable include the following:

— expertise is available within the certification body when using the results of the evaluation activity;

— the extent of control the certification body has over testing (including witnessing the testing), inspection (e.g. specifying inspection methods or parameters) or management system assessment (e.g. requiring specific details of a management system);

— a particular requirement is covered in an equivalent way by this International Standard, or is not needed to give confidence in the certification decision.

NOTE 2 This can include outsourcing to other certification bodies. Use of external personnel under contract is not outsourcing.

NOTE 3 For the purposes of this International Standard, the terms "outsourcing" and "subcontracting" are considered to be synonyms.

6.2.2.2 Where evaluation activities are outsourced to non-independent bodies (e.g. client laboratories), the certification body shall ensure that the evaluation activities are managed in a manner which provides confidence in the results, and that records are available to justify the confidence.

6.2.2.3 The certification body shall have a legally binding contract with the body that provides the outsourced service, including provisions for confidentiality and conflict of interest as specified in 6.1.3, item c).

6.2.2.4 The certification body shall:

a) take responsibility for all activities outsourced to another body;

b) ensure that the body that provides outsourced services, and the personnel that it uses, are not involved, either directly or through any other employer, in such a way that the credibility of the results could be compromised;

c) have documented policies, procedures and records for the qualification, assessing and monitoring of all bodies that provide outsourced services used for certification activities;

d) maintain a list of approved providers of outsourced services;

e) implement corrective actions for any breaches of the contract in 6.2.2.3 or other requirements in 6.2.2 of which it becomes aware;

f) inform the client in advance of outsourcing activities, in order to provide the client with an opportunity to object.

NOTE If the qualification, assessing and monitoring of the bodies that provide outsourced services are performed by other organizations (e.g. by accreditation bodies, peer assessment bodies or governmental authorities), the certification body can take this qualification and monitoring into account provided that:

— it is provided for within the scheme requirements;

— the scope is applicable to the work being undertaken;

— the validity of the qualification, assessing and monitoring arrangements is verified at a periodicity determined by the certification body.

7 Process requirements

7.1 General

7.1.1 The certification body shall operate one or more certification scheme(s) covering its certification activities.

NOTE 1 The elements of such schemes can be coupled with surveillance of production, or with the assessment and surveillance of the client's management system, or both.

NOTE 2 General guidance on the development of schemes is given in ISO/IEC 17067, in combination with ISO/IEC Guide 28 and ISO/IEC Guide 53.

7.1.2 The requirements against which the products of a client are evaluated shall be those contained in specified standards and other normative documents.

NOTE Guidance for developing normative documents suitable for this purpose is contained in ISO/IEC 17007.

7.1.3 If explanations are required as to the application of these documents (see 7.1.2) for a specific certification scheme, they shall be formulated by relevant and impartial persons or committees, possessing the necessary technical competence, and shall be made available by the certification body upon request.

7.2 Application

For application, the certification body shall obtain all the necessary information to complete the certification process in accordance with the relevant certification scheme.

NOTE 1 The following are examples of necessary information:

— the product(s) to be certified;

— the standards and/or other normative documents for which the client is seeking certification (see 7.1.2);

— the general features of the client, including its name and the address(es) of its physical location(s), significant aspects of its process and operations (if required by the relevant certification scheme), and any relevant legal obligations;

- general information concerning the client, relevant to the field of certification for which the application is made, such as the client's activities, its human and technical resources, including laboratories and/or inspection facilities, and its functions and relationship in a larger corporation, if any;
- information concerning all outsourced processes used by the client that will affect conformity to requirements; if the client has identified a legal entity/entities for producing the certified product(s) that is different from the client, then the certification body can establish appropriate contractual controls over the legal entity/entities concerned, if necessary for effective surveillance; if such contractual controls are needed, they can be established prior to providing formal certification documentation (see 7.7);
- all other information needed in accordance with the relevant certification requirements, such as information for initial evaluation and surveillance activities, e.g. the locations where the certified product(s) are produced and contact personnel at these locations.

NOTE 2 A variety of media and mechanisms can be used to collect this information at various times, including an application form. Such information gathering can be in conjunction with, or separate from, the completion of the legally binding agreement (the certification agreement) specified in 4.1.2.

NOTE 3 Application for an extension of the certification scope could involve similar products, different locations, etc.

7.3 Application review

7.3.1 The certification body shall conduct a review of the information obtained (see 7.2) to ensure that:

a) the information about the client and the product is sufficient for the conduct of the certification process;

b) any known difference in understanding between the certification body and the client is resolved, including agreement regarding standards or other normative documents;

c) the scope of certification (see 3.10) sought is defined;

d) the means are available to perform all evaluation activities;

e) the certification body has the competence and capability to perform the certification activity.

7.3.2 The certification body shall have a process to identify when the client's request for certification includes

- a type of product, or
- a normative document, or
- a certification scheme

with which the certification body has no prior experience.

NOTE Products can be considered to be of the same type when the knowledge of the requirements, characteristics and technology related to one product is sufficient to understand the requirements, characteristics and technology of another product.

7.3.3 In these cases (see 7.3.2), the certification body shall ensure it has the competence and capability for all the certification activities it is required to undertake, and it shall maintain a record of the justification for the decision to undertake certification.

7.3.4 The certification body shall decline to undertake a specific certification if it lacks any competence or capability for the certification activities it is required to undertake.

7.3.5 If the certification body relies on certifications it has already granted to the client, or has already granted to other clients, to omit any activities, then the certification body shall reference the existing certification(s) in its records. If requested by the client, the certification body shall provide justification for omission of activities.

7.4 Evaluation

7.4.1 The certification body shall have a plan for the evaluation activities to allow for the necessary arrangements to be managed.

NOTE Depending on the characteristics of the certification scheme and the product requirements, the plan can be either a generic plan applicable to all activities, including evaluation of the quality management system, when applicable, or a specific one for a particular activity, or a combination of both.

7.4.2 The certification body shall assign personnel to perform each evaluation task that it undertakes with its internal resources (see 6.2.1).

NOTE Outsourced tasks are completed by personnel usually assigned by the organization to which the task is outsourced. Such personnel are not normally assigned by the certification body.

7.4.3 The certification body shall ensure all necessary information and/or documentation is made available for performing the evaluation tasks.

NOTE The evaluation tasks can include activities such as design and documentation review, sampling, testing, inspection and audit.

7.4.4 The certification body shall carry out the evaluation activities that it undertakes with its internal resources (see 6.2.1) and shall manage outsourced resources (see 6.2.2) in accordance with the evaluation plan (see 7.4.1). The products shall be evaluated against the requirements covered by the scope of certification and other requirements specified in the certification scheme.

7.4.5 The certification body shall only rely on evaluation results related to certification completed prior to the application for certification, where it takes responsibility for the results and satisfies itself that the body that performed the evaluation fulfils the requirements contained in 6.2.2 and those specified by the certification scheme.

NOTE This can include work carried out under recognition agreements between certification bodies.

7.4.6 The certification body shall inform the client of all nonconformities.

7.4.7 If one or more nonconformities have arisen, and if the client expresses interest in continuing the certification process, the certification body shall provide information regarding the additional evaluation tasks needed to verify that nonconformities have been corrected.

7.4.8 If the client agrees to completion of the additional evaluation tasks, the process specified in 7.4 shall be repeated to complete the additional evaluation tasks.

7.4.9 The results of all evaluation activities shall be documented prior to review (see 7.5).

NOTE 1 This documentation can provide an opinion as to whether product requirements (including requirements such as those for the quality management system under which the product is produced, if required by the certification scheme) have been fulfilled.

NOTE 2 The certification scheme can indicate whether the evaluation is performed by the certification body, under its responsibility, or is performed prior to the application (see 7.2) for the certification process. In the latter case, the requirements of 7.4 are not applicable.

7.5 Review

7.5.1 The certification body shall assign at least one person to review all information and results related to the evaluation. The review shall be carried out by person(s) who have not been involved in the evaluation process.

7.5.2 Recommendations for a certification decision based on the review shall be documented, unless the review and the certification decision are completed concurrently by the same person.

7.6 Certification decision

7.6.1 The certification body shall be responsible for, and shall retain authority for, its decisions relating to certification.

7.6.2 The certification body shall assign at least one person to make the certification decision based on all information related to the evaluation, its review, and any other relevant information. The certification decision shall be carried out by a person or group of persons [e.g. a committee (see 5.1.4)] that has not been involved in the process for evaluation (see 7.4).

NOTE The review and the certification decision can be completed concurrently by the same person or group of persons.

7.6.3 The person(s) [excluding members of committees (see 5.1.4)] assigned by the certification body to make a certification decision shall be employed by, or shall be under contract with, one of the following:

— the certification body (see 6.1);

— an entity under the organizational control of the certification body (see 7.6.4).

7.6.4 A certification body's organizational control shall be one of the following:

— whole or majority ownership of another entity by the certification body;

— majority participation by the certification body on the board of directors of another entity;

— a documented authority by the certification body over another entity in a network of legal entities (in which the certification body resides), linked by ownership or board of director control.

NOTE For governmental certification bodies, other parts of the same government can be considered to be "linked by ownership" to the certification body.

7.6.5 The persons employed by, or under contract with, entities under organizational control shall fulfil the same requirements of this International Standard as persons employed by, or under contract with, the certification body.

7.6.6 The certification body shall notify the client of a decision not to grant certification, and shall identify the reasons for the decision.

NOTE If the client expresses interest in continuing the certification process, the certification body can resume the process for evaluation from 7.4.

7.7 Certification documentation

7.7.1 The certification body shall provide the client with formal certification documentation that clearly conveys, or permits identification of the following:

a) the name and address of the certification body;

b) the date certification is granted (the date shall not precede the date on which the certification decision was completed);

c) the name and address of the client;

d) the scope of certification (see 3.10);

NOTE Where the standard(s) or other normative document(s) (see 7.1.2) to which conformity is being certified include reference to other standards or normative documents, these do not need to be included in the formal certification documentation.

e) the term or expiry date of certification, if certification expires after an established period;

f) any other information required by the certification scheme.

7.7.2 The formal certification documentation shall include the signature or other defined authorization of the person(s) of the certification body assigned such responsibility.

NOTE The name and title of an individual whose agreement to be responsible for certification documentation is on record at the certification body is an example of a "defined authorization" other than a signature.

7.7.3 Formal certification documentation (see 7.7) shall only be issued after, or concurrent with, the following:

a) the decision to grant or extend the scope of certification (see 7.6.1) has been made;

b) certification requirements have been fulfilled;

c) the certification agreement (see 4.1.2) has been completed/signed.

7.8 Directory of certified products

The certification body shall maintain information on certified products which contains at least the following:

a) identification of the product;

b) the standard(s) and other normative document(s) to which conformity has been certified;

c) identification of the client.

The parts of this information that need to be published or made available upon request in a directory (through publications, electronic media or other means) are stipulated by the relevant scheme(s). As a minimum, the certification body shall provide information, upon request, about the validity of a given certification.

NOTE Where the certification body provides the information to a scheme, the scheme directory would satisfy this requirement.

7.9 Surveillance

7.9.1 If surveillance is required by the certification scheme, or as specified in 7.9.3 or 7.9.4, the certification body shall initiate surveillance of the product(s) covered by the certification decision in accordance with the certification scheme.

NOTE 1 ISO/IEC 17067 provides examples of surveillance activities in certification schemes.

NOTE 2 The criteria and process for surveillance activities are defined by each certification scheme.

7.9.2 When surveillance utilizes evaluation, review or a certification decision, the requirements in 7.4, 7.5 or 7.6, respectively, shall be fulfilled.

7.9.3 When continuing use of a certification mark is authorized for placement on a product (or its packaging, or information accompanying it) (for process or service, see 7.9.4) of a type which has been certified, surveillance shall be established and shall include periodic surveillance of marked products to ensure ongoing validity of the demonstration of fulfilment of product requirements.

7.9.4 When continuing use of a certification mark is authorized for a process or service, surveillance shall be established and shall include periodic surveillance activities to ensure ongoing validity of the demonstration of fulfilment of process or service requirements.

7.10 Changes affecting certification

7.10.1 When the certification scheme introduces new or revised requirements that affect the client, the certification body shall ensure these changes are communicated to all clients. The certification body shall verify the implementation of the changes by its clients and shall take actions required by the scheme.

NOTE Contractual arrangements with clients can be necessary to ensure implementation of these requirements. A model of a license agreement for the use of certification, including the aspects related to a notice of changes, as far as applicable, is given in ISO/IEC Guide 28:2004, Annex E.

7.10.2 The certification body shall consider other changes affecting certification, including changes initiated by the client, and shall decide upon the appropriate action.

NOTE Changes affecting certification can include new information related to the fulfilment of certification requirements obtained by the certification body after certification has been established.

7.10.3 The actions to implement changes affecting certification shall include, if required, the following:

— evaluation (see 7.4);

— review (see 7.5);

— decision (see 7.6);

— issuance of revised formal certification documentation (see 7.7) to extend or reduce the scope of certification;

— issuance of certification documentation of revised surveillance activities (if surveillance is part of the certification scheme).

These actions shall be completed in accordance with applicable parts of 7.4, 7.5, 7.6, 7.7 and 7.8. Records (see 7.12) shall include the rationale for excluding any of the above activities (e.g. when a certification requirement that is not a product requirement changes, and no evaluation, review or decision activities are necessary).

7.11 Termination, reduction, suspension or withdrawal of certification

7.11.1 When a nonconformity with certification requirements is substantiated, either as a result of surveillance or otherwise, the certification body shall consider and decide upon the appropriate action.

NOTE Appropriate action can include the following:

a) continuation of certification under conditions specified by the certification body (e.g. increased surveillance);

b) reduction in the scope of certification to remove nonconforming product variants;

c) suspension of the certification pending remedial action by the client;

d) withdrawal of the certification.

7.11.2 When the appropriate action includes evaluation, review or a certification decision, the requirements in 7.4, 7.5 or 7.6, respectively, shall be fulfilled.

7.11.3 If certification is terminated (by request of the client), suspended or withdrawn, the certification body shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure it provides no indication that the product continues to be certified. If a scope of certification is reduced, the certification body shall take actions specified by the certification scheme and shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

7.11.4 If certification is suspended, the certification body shall assign one or more persons to formulate and communicate the following to the client:

— actions needed to end suspension and restore certification for the product(s) in accordance with the certification scheme;

— any other actions required by the certification scheme.

These persons shall be competent in their knowledge and understanding of all aspects of the handling of suspended certifications (see 6.1).

7.11.5 Any evaluations, reviews or decisions needed to resolve the suspension, or that are required by the certification scheme, shall be completed in accordance with the applicable parts of 7.4, 7.5, 7.6, 7.7.3, 7.9 and 7.11.3.

7.11.6 If certification is reinstated after suspension, the certification body shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure all appropriate indications exist that the product continues to be certified. If a decision to reduce the scope of certification is made as a condition of reinstatement, the certification body shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the client and clearly specified in certification documentation and public information.

7.12 Records

7.12.1 The certification body shall retain records to demonstrate that all certification process requirements (those in this International Standard and those of the certification scheme) have been effectively fulfilled (see also 8.4).

7.12.2 The certification body shall keep records confidential. Records shall be transported, transmitted and transferred in a way that ensures confidentiality is maintained (see also 4.5).

7.12.3 If the certification scheme involves complete re-evaluation of the product(s) within a determined cycle, records shall be retained at least for the current and the previous cycle. Otherwise, records shall be retained for a period defined by the certification body.

NOTE In defining retention times, legal circumstances and recognition arrangements can be considered.

7.13 Complaints and appeals

7.13.1 The certification body shall have a documented process to receive, evaluate and make decisions on complaints and appeals. The certification body shall record and track complaints and appeals, as well as actions undertaken to resolve them.

7.13.2 Upon receipt of a complaint or appeal, the certification body shall confirm whether the complaint or appeal relates to certification activities for which it is responsible and, if so, shall address it.

7.13.3 The certification body shall acknowledge receipt of a formal complaint or appeal.

7.13.4 The certification body shall be responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision.

7.13.5 The decision resolving the complaint or appeal shall be made by, or reviewed and approved by, person(s) not involved in the certification activities related to the complaint or appeal.

7.13.6 To ensure that there is no conflict of interest, personnel (including those acting in a managerial capacity) who have provided consultancy (see 3.2) for a client, or been employed by a client, shall not be used by the certification body to review or approve the resolution of a complaint or appeal for that client within two years following the end of the consultancy or employment.

7.13.7 Whenever possible, the certification body shall give formal notice of the outcome and the end of the complaint process to the complainant.

7.13.8 The certification body shall give formal notice of the outcome and the end of the appeal process to the appellant.

7.13.9 The certification body shall take any subsequent action needed to resolve the complaint or appeal.

8 Management system requirements

8.1 Options

8.1.1 General

The certification body shall establish and maintain a management system that is capable of achieving the consistent fulfilment of the requirements of this International Standard in accordance with either Option A or Option B.

8.1.2 Option A

The management system of the certification body shall address the following:

— general management system documentation (e.g. manual, policies, definition of responsibilities, see 8.2);

— control of documents (see 8.3);

— control of records (see 8.4);

— management review (see 8.5);

— internal audit (see 8.6);

— corrective actions (see 8.7);

— preventive actions (see 8.8).

8.1.3 Option B

A certification body that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of this International Standard, fulfils the management system clause requirements (see 8.2 to 8.8).

NOTE Option B is included to enable a certification body which operates a management system in accordance with ISO 9001 to use that system to demonstrate fulfilment of the management system requirements in 8.2 to 8.8 of this International Standard. Option B does not require that the certification body's management system is certified to ISO 9001.

8.2 General management system documentation (Option A)

8.2.1 The certification body's top management shall establish, document, and maintain policies and objectives for fulfilment of this International Standard and the certification scheme and shall ensure the policies and objectives are acknowledged and implemented at all levels of the certification body's organization.

8.2.2 The certification body's top management shall provide evidence of its commitment to the development and implementation of the management system and its effectiveness in achieving consistent fulfilment of this International Standard.

8.2.3 The certification body's top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that include the following:

a) ensuring that processes and procedures needed for the management system are established, implemented and maintained;

b) reporting to top management on the performance of the management system and any need for improvement.

8.2.4 All documentation, processes, systems, records, etc. related to the fulfilment of the requirements of this International Standard shall be included, referenced, or linked to documentation of the management system.

8.2.5 All personnel involved in certification activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3 Control of documents (Option A)

8.3.1 The certification body shall establish procedures to control the documents (internal and external) that relate to the fulfilment of this International Standard.

8.3.2 The procedures shall define the controls needed to:

a) approve documents for adequacy prior to issue;

b) review and update (as necessary) and re-approve documents;

c) ensure that changes and the current revision status of documents are identified;

d) ensure that relevant versions of applicable documents are available at points of use;

e) ensure that documents remain legible and readily identifiable;

f) ensure that documents of external origin are identified and their distribution controlled;

g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

NOTE Documentation can be in any form or type of medium.

8.4 Control of records (Option A)

8.4.1 The certification body shall establish procedures to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of its records related to the fulfilment of this International Standard.

8.4.2 The certification body shall establish procedures for retaining records (see 7.12) for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements.

8.5 Management review (Option A)

8.5.1 General

8.5.1.1 The certification body's top management shall establish procedures to review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this International Standard.

8.5.1.2 These reviews shall be conducted at least once a year. Alternatively, a complete review broken up into segments shall be completed within a 12-month time frame. Records of reviews shall be maintained.

8.5.2 Review inputs

The input to the management review shall include information related to the following:

a) results of internal and external audits;

b) feedback from clients and interested parties related to the fulfilment of this International Standard;

NOTE Interested parties can include scheme owners.

c) feedback from the mechanism for safeguarding impartiality;

d) the status of preventive and corrective actions;

e) follow-up actions from previous management reviews;

f) the fulfilment of objectives;

g) changes that could affect the management system;

h) appeals and complaints.

8.5.3 Review outputs

The outputs from the management review shall include decisions and actions related to the following:

a) improvement of the effectiveness of the management system and its processes;

b) improvement of the certification body related to the fulfilment of this International Standard;

c) resource needs.

8.6 Internal audits (Option A)

8.6.1 The certification body shall establish procedures for internal audits to verify that it fulfils the requirements of this International Standard and that the management system is effectively implemented and maintained.

NOTE ISO 19011 provides guidelines for conducting internal audits.

8.6.2 An audit programme shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits.

8.6.3 Internal audits shall normally be performed at least once every 12 months, or completed within a 12-month time frame for segmented (or rolling) internal audits. A documented decision-making process shall be followed to change (reduce or restore) the frequency of internal audits or the time frame in which internal audits shall be completed. Such changes shall be based on the relative stability and ongoing effectiveness of the management system. Records of decisions to change the frequency of internal audits, or the time frame in which they will be completed, including the rationale for the change, shall be maintained.

8.6.4 The certification body shall ensure that:

a) internal audits are conducted by personnel knowledgeable in certification, auditing and the requirements of this International Standard;

b) auditors do not audit their own work;

c) personnel responsible for the area audited are informed of the outcome of the audit;

d) any actions resulting from internal audits are taken in a timely and appropriate manner;

e) any opportunities for improvement are identified.

8.7 Corrective actions (Option A)

8.7.1 The certification body shall establish procedures for identification and management of nonconformities in its operations.

8.7.2 The certification body shall also, where necessary, take actions to eliminate the causes of nonconformities in order to prevent recurrence.

8.7.3 Corrective actions shall be appropriate to the impact of the problems encountered.

8.7.4 The procedures for corrective actions shall define requirements for the following:

a) identifying nonconformities (e.g. from complaints and internal audits);

b) determining the causes of nonconformity;

c) correcting nonconformities;

d) evaluating the need for actions to ensure that nonconformities do not recur;

e) determining and implementing the actions needed in a timely manner;

f) recording the results of actions taken;

g) reviewing the effectiveness of corrective actions.

8.8 Preventive actions (Option A)

8.8.1 The certification body shall establish procedures for taking preventive actions to eliminate the causes of potential nonconformities.

8.8.2 Preventive actions taken shall be appropriate to the probable impact of the potential problems.

8.8.3 The procedures for preventive actions shall define requirements for the following:

a) identifying potential nonconformities and their causes;

b) evaluating the need for action to prevent the occurrence of nonconformities;

c) determining and implementing the action needed;

d) recording the results of actions taken;

e) reviewing the effectiveness of the preventive actions taken.

NOTE The procedures for corrective and preventive actions do not necessarily have to be separate.

Annex A
(informative)

Principles for product certification bodies and their certification activities

A.1 General

A.1.1 The overall aim of certification is to give confidence to all interested parties that a product fulfils specified requirements. The value of certification is the degree of confidence and trust that is established by an impartial and competent demonstration of fulfilment of specified requirements by a third party. Parties that have an interest in certification include, but are not limited to the following:

a) the clients of the certification bodies;

b) the customers of the organizations whose products are certified;

c) governmental authorities;

d) non-governmental organizations;

e) consumers and other members of the public.

A.1.2 The principles for inspiring confidence are those specified in Clauses A.2 to A.6.

A.2 Impartiality

A.2.1 It is necessary for certification bodies and their personnel to be impartial, and to be perceived as impartial, in order to give confidence in their activities and their outcomes.

A.2.2 Risks to impartiality include bias that may arise from the following:

a) self-interest (e.g. overdependence on a contract for service or the fees, or fear of losing the client or fear of becoming unemployed, to an extent that adversely affects impartiality in carrying out conformity assessment activities);

b) self-review (e.g. performing a conformity assessment activity in which the certification body evaluates the results of other services it has already provided, such as consultancy);

c) advocacy (e.g. a certification body or its personnel acting in support of, or in opposition to, a given company which is at the same time its client);

d) over-familiarity, i.e. risks that arise from a certification body or its personnel being overly familiar or too trusting, instead of seeking evidence of conformity (in the product certification context, this risk is more difficult to manage because the need for personnel with very specific expertise often limits the availability of qualified personnel);

e) intimidation (e.g. the certification body or its personnel can be deterred from acting impartiality by risks from, or fear of, a client or other interested party);

f) competition (e.g. between the client and a contracted person).

A.3 Competence

The competence of the personnel supported by the management system of the certification body is necessary in order to deliver certification that provides confidence.

A.4 Confidentiality and openness

A.4.1 General

Managing the balance between requirements related to confidentiality (see A.4.2) and openness (see A.4.3) affects the trust of stakeholders and their perception of value in the conformity assessment activities being performed.

A.4.2 Confidentiality

To gain access to the information needed to conduct effective conformity assessment activities, the certification body needs to provide confidence that confidential information will not be disclosed.

All organizations and personnel have the right to ensure the protection of any proprietary information that they provide, unless the law or the certification scheme that has been applied for requires disclosure of proprietary information (see 4.5).

A.4.3 Openness

A certification body needs to provide access to, and disclosure of, appropriate and timely information about its evaluation and certification processes, as well as about the certification status of any product (i.e. granting, maintaining, extending or reducing the scope of, suspending, withdrawing or refusing certification), in order to gain confidence in the integrity and credibility of certification. Openness is a principle of access to, or disclosure of, appropriate information.

A.4.4 Access to information

Any information held by the certification body on a product that is the subject of an evaluation and/or certification should be made accessible, upon request, to the person or organization that contracted the certification body to undertake the certification activity.

A.5 Responsiveness to complaints and appeals

The effective resolution of complaints and appeals is an important means of protection for the certification body, its clients and other users of conformity assessment against errors, omissions or unreasonable behaviour. Confidence in conformity assessment activities is safeguarded when complaints and appeals are processed appropriately.

A.6 Responsibility

A.6.1 The client, not the certification body, has the responsibility of fulfilling the certification requirements.

A.6.2 The certification body has the responsibility to obtain sufficient objective evidence upon which to base a certification decision. Based on a review of the evidence, it makes a decision to grant certification if there is sufficient evidence of conformity, or a decision not to grant certification if there is not sufficient evidence of conformity, or a decision not to maintain certification.

Annex B
(informative)

Application of this International Standard for processes and services

B.1 Explanations of how to apply this International Standard to the certification of processes

When applying this International Standard to the certification of processes:

— replace “product(s)” with “process(es)”;

— replace “production” with “operation”;

— replace “produced” with “operated”;

— replace “producing” with “operating”.

B.2 Explanations of how to apply this International Standard to the certification of services

When applying this International Standard to the certification of services:

— replace “product(s)” with “service(s)”;

— replace “production” with “provision”;

— replace “produced” with “provided”;

— replace “producing” with “providing”.

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[6] ISO/PAS 17003, *Conformity assessment — Complaints and appeals — Principles and requirements*

[7] ISO/PAS 17004, *Conformity assessment — Disclosure of information — Principles and requirements*

[8] ISO/PAS 17005, *Conformity assessment — Use of management systems — Principles and requirements*

[9] ISO/IEC 17007, *Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment*

[10] ISO/IEC 17030, *Conformity assessment — General requirements for third-party marks of conformity*

[11] ISO/IEC 17067[1], *Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes*

[12] ISO 19011[2], *Guidelines for auditing management systems*

[13] ISO 31000, *Risk management — Principles and guidelines*

[14] ISO/IEC Guide 23, *Methods of indicating conformity with standards for third-party certification systems*

[15] ISO Guide 27, *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*

[16] ISO/IEC Guide 28:2004, *Conformity assessment — Guidance on a third-party certification system for products*

[17] ISO/IEC Guide 53, *Conformity assessment — Guidance on the use of an organization's quality management system in product certification*

[18] IAF GD 5, *IAF Guidance on the Application of ISO/IEC Guide 65:1996*

1) Revision of ISO/IEC Guide 67:2004.

2) References in this International Standard to the relevant guidance in ISO 19011 apply to the auditing of all other types of management systems.

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee CAS/1, Conformity assessment.

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Foreword

This document (EN ISO/IEC 17067:2013) has been prepared by Technical Committee ISO/CASCO "Committee on conformity assessment" in collaboration with Technical Committee CEN/CLC/TC 1 "Criteria for conformity assessment bodies" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2014, and conflicting national standards shall be withdrawn at the latest by February 2014.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO/IEC 17067:2013 has been approved by CEN as EN ISO/IEC 17067:2013 without any modification.

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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

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

ISO/IEC 17067 was prepared by the *ISO Committee on conformity assessment* (CASCO).

It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This first edition of ISO/IEC 17067 cancels and replaces ISO/IEC Guide 67:2004, which has been technically revised.

The following major changes have been made compared with ISO/IEC Guide 67:2004:

— a new Clause 6 has been added, providing guidelines on setting up and operating a product certification scheme;

— some of the text originally in the main body of ISO/IEC Guide 67 has been moved to the Introduction;

— the functional approach to conformity assessment has been emphasised;

— Table 1 has been extended to reflect the functional approach;

— explicit provision has been made for type and batch certification schemes;

— references to ISO/IEC 17065:2012 have replaced references to ISO/IEC Guide 65:1996;

— the text has been made more concise in places.

Introduction

This International Standard describes the fundamentals of product certification and provides guidelines for product certification schemes. In this International Standard references to the term "product" can also be read to mean "services" or "processes".

As products are designed, produced, distributed, used and ultimately disposed of, they can give rise to concerns with purchasers, users and society in general. Such concerns could relate to safety, health or environmental impacts, durability, compatibility, suitability for intended purposes or for stated conditions.

Generally, these concerns are addressed by specifying the required product attributes in a normative document such as a standard.

The supplier of the product then has the task of demonstrating that the product conforms to the requirements of the normative document.

It might be sufficient for the supplier to assess and declare its product's conformity, but in other cases the user or a regulatory authority might require that conformity be assessed by a competent and impartial third party.

Assessment and impartial third party attestation that fulfilment of specified requirements has been demonstrated for the product is referred to as product certification.

This International Standard outlines how schemes for product certification can be structured and managed. It identifies common assessment techniques that are used as a basis for product certification, such as product testing, inspection and auditing.

This International Standard is intended for use by those involved with product certification, particularly those who are, or who are considering becoming, product certification scheme owners. Product certification scheme owners can include:

a) product certification bodies;

b) government and regulators;

c) purchasing agencies;

d) non-government organizations;

e) industry and retail associations; and

f) consumer organizations.

This International Standard provides only guidance and does not contain requirements. It is compatible with ISO/IEC 17065, which specifies requirements for product certification bodies.

In this International Standard, the following verbal forms are used:

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

The modal verb "shall", which indicates a requirement, is not used because this International Standard only provides guidelines.

Further details can be found in the ISO/IEC Directives, Part 2.

Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes

1 Scope

This International Standard describes the fundamentals of product certification and provides guidelines for understanding, developing, operating or maintaining certification schemes for products, processes and services.

It is intended for use by all with an interest in product certification, and especially by certification scheme owners.

NOTE 1 In this International Standard the term "product" can also be read as "process" or "service", except in those instances where separate provisions are stated for "processes" or "services". Definitions of product, process and service are given in ISO/IEC 17065.

NOTE 2 The certification of products, processes and services is a third-party conformity assessment activity (see ISO/IEC 17000) carried out by product certification bodies. The requirements for product certification bodies are specified in ISO/IEC 17065.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17065:2012, *Conformity assessment — Requirements for bodies certifying products, processes and services*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 17065 and the following apply.

3.1
certification system
rules, procedures and management for carrying out certification

[SOURCE: ISO/IEC 17000:2004, 2.7, modified]

3.2
certification scheme
certification system (3.1) related to specified products, to which the same specified requirements, specific rules and procedures apply

Note 1 to entry: The rules, procedures and management for implementing product, process and service certification are stipulated by the certification scheme.

[SOURCE: ISO/IEC 17065:2012, 3.9, modified]

3.3
scheme owner
person or organization responsible for developing and maintaining a specific *certification scheme* (3.2)

Note 1 to entry: The scheme owner can be the certification body itself, a governmental authority, a trade association, a group of certification bodies or others.

[SOURCE: , 3.11]

4 Product certification

4.1 Concept of product certification

4.1.1 Product certification is the provision of assessment and impartial third-party attestation that fulfilment of specified requirements has been demonstrated. Product certification is carried out by product certification bodies which should conform to ISO/IEC 17065. Specified requirements for products are generally contained in standards or other normative documents.

4.1.2 Product certification is an established conformity assessment activity that provides confidence to consumers, regulators, industry and other interested parties that products conform to specified requirements, including for example product performance, safety, interoperability and sustainability.

4.1.3 Product certification can facilitate trade, market access, fair competition and consumer acceptance of products on a national, regional and international level.

4.2 Objectives of product certification

4.2.1 The fundamental objectives of product certification are:

a) to address the needs of consumers, users and, more generally, all interested parties by giving confidence regarding fulfilment of specified requirements;

b) to allow suppliers to demonstrate to the market that their product has been attested to fulfil specified requirements by an impartial third party body.

4.2.2 Product certification should provide the following:

— confidence for those with an interest in fulfilment of requirements, and

— sufficient value so that suppliers can effectively market products.

5 Product certification schemes

5.1 Basics

5.1.1 Product certification schemes should implement the functional approach as described in ISO/IEC 17000:2004, Annex A. The functions are:

— **selection**, which includes planning and preparation activities in order to collect or produce all the information and input needed for the subsequent determination function;

— **determination**, which may include conformity assessment activities such as testing, measuring, inspection, design appraisal, assessment of services and processes and auditing to provide information regarding the product requirements as input to the review and attestation functions;

— **review**, which means verification of the suitability, adequacy and effectiveness of selection and determination activities, and the results of these activities, with regard to fulfilment of specified requirements (see ISO/IEC 17000:2004, 5.1);

— **decision** on certification;

— **attestation**, which means issue of a statement of conformity, based on a decision following review, that fulfilment of specified requirements has been demonstrated (see ISO/IEC 17000:2004, 5.2);

— **surveillance** (where needed), which means systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity (see ISO/IEC 17000:2004, 6.1).

NOTE 1 Further information about the functions is given in ISO/IEC 17000.

NOTE 2 In ISO/IEC 17065, the functions of "selection" and "determination" have been combined and are referred to as "evaluation".

NOTE 3 In ISO/IEC 17065, the function of "attestation" is related to the subclause on "certification documentation" (see ISO/IEC 17065:2012, 7.7).

5.1.2 Whenever product certification is performed, a certification scheme (see 3.2) is in place.

5.2 Functions and activities in product certification schemes

5.2.1 Product certification schemes are developed by defining specific activities for each of the applicable functions described in 5.1.1. Table 1 shows how to build a product certification scheme by using these functions, and outlines some of the combinations of activities in use in the wide range of fields where product certification is employed. The types of product certification schemes in Table 1 are further described in 5.3.

5.2.2 Clause 6 describes the process for deciding which activities to use for a given situation and the factors to be taken into account in making the decision.

Table 1 — Building a product certification scheme

	Conformity assessment functions and activities[a] within product certification schemes	Types of product certification schemes[b]							
		1a	1b	2	3	4	5	6	N[c,d]
I	**Selection**, including planning and preparation activities, specification of requirements, e.g. normative documents, and sampling, as applicable	x	x	x	x	x	x	x	x
II	**Determination of characteristics**, as applicable, by: a) testing b) inspection c) design appraisal d) assessment of services or processes e) other determination activities, e.g. verification	x	x	x	x	x	x	x	x
III	**Review** Examining the evidence of conformity obtained during the determination stage to establish whether the specified requirements have been met	x	x	x	x	x	x	x	x
IV	**Decision on certification** Granting, maintaining, extending, reducing, suspending, withdrawing certification	x	x	x	x	x	x	x	x
V	**Attestation, licensing**								
	a) issuing a certificate of conformity or other statement of conformity (attestation)	x	x	x	x	x	x	x	x
	b) granting the right to use certificates or other statements of conformity	x	x	x	x	x	x	x	
	c) issuing a certificate of conformity for a batch of products		x						
	d) granting the right to use marks of conformity (licensing) is based on surveillance (VI) or certification of a batch.		x	x	x	x	x	x	
VI	**Surveillance**, as applicable (see 5.3.4 to 5.3.8), by:								
	a) testing or inspection of samples from the open market			x		x	x		
	b) testing or inspection of samples from the factory				x	x	x		
	c) assessment of the production, the delivery of the service or the operation of the process				x	x	x	x	
	d) management system audits combined with random tests or inspections						x	x	

[a] Where applicable, the activities can be coupled with initial audit and surveillance audit of the applicant's management system (an example is given in ISO/IEC Guide 53) or initial assessment of the production process. The order in which the assessments are performed may vary and will be defined within the scheme.

[b] An often used and well-tried model for a product certification scheme is described in ISO/IEC Guide 28; it is a product certification scheme corresponding to scheme type 5.

[c] A product certification scheme includes at least the activities I, II, III, IV and V a).

[d] The symbol *N* has been added to show an undefined number of possible other schemes, which can be based on different activities.

5.3 Types of product certification schemes

5.3.1 General

The examples given in 5.3.2 to 5.3.8 do not represent all possible types of product certification schemes. They may be used with many types of requirements and may use a wide variety of statements of conformity (see ISO/IEC 17000:2004, 5.2, Note 1). All types of product certification schemes involve selection, determination, review, decision and attestation. One or more determination activities should be selected from among those in Table 1, taking into account the product and the specified requirements. The types of schemes referred to in Table 1 differ according to which surveillance activities (if applicable)

are carried out. For scheme types 1a and 1b, no surveillance is required since the attestation relates only to the product items which have been subjected to the determination activities. For the other scheme types, 5.3.4 to 5.3.8 outline the way in which the different surveillance activities can be used and the circumstances to which they could be applicable.

5.3.2 Scheme type 1a

In this scheme, one or more samples of the product are subjected to the determination activities. A certificate of conformity or other statement of conformity (e.g. a letter) is issued for the product type, the characteristics of which are detailed in the certificate or a document referred to in the certificate. Subsequent production items are not covered by the certification body's attestation of conformity.

The samples are representative of subsequent production items which could be referred to by the manufacturer as being manufactured in accordance with the certified type.

The certification body may grant to the manufacturer the right to use the type certificate or other statement of conformity (e.g. letter) as a basis for the manufacturer to declare that subsequent production items conform to the specified requirements.

5.3.3 Scheme type 1b

This scheme type involves the certification of a whole batch of products, following selection and determination as specified in the scheme. The proportion to be tested, which can include testing of all the units in the batch (100% testing), would be based, for example, on the homogeneity of the items in the batch and the application of a sampling plan, where appropriate. If the outcome of the determination, review and decision is positive, all items in the batch may be described as certified and may have a mark of conformity affixed, if that is included in the scheme.

5.3.4 Scheme type 2

The surveillance part of this scheme involves periodically taking samples of the product from the market and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements.

While this scheme may identify the impact of the distribution channel on conformity, the resources it requires can be extensive. Also, when significant nonconformities are found, effective corrective measures may be limited since the product has already been distributed to the market.

5.3.5 Scheme type 3

The surveillance part of this scheme involves periodically taking samples of the product from the point of production and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements. The surveillance includes periodic assessment of the production process.

This scheme does not provide any indication of the impact the distribution channel plays on conformity. When serious nonconformities are found, the opportunity may exist to resolve them before widespread market distribution occurs.

5.3.6 Scheme type 4

The surveillance part of this scheme allows for the choice between periodically taking samples of the product from the point of production, or from the market, or from both, and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements. The surveillance includes periodic assessment of the production process.

This scheme can both indicate the impact of the distribution channel on conformity and provide a pre-market mechanism to identify and resolve serious nonconformities. Significant duplication of effort may take place for those products whose conformity is not affected during the distribution process.

5.3.7 Scheme type 5

The surveillance part of this scheme allows for the choice between periodically taking samples of the product either from the point of production, or from the market, or from both, and subjecting them to determination activities to check that items produced subsequent to the initial attestation fulfil the specified requirements. The surveillance includes periodic assessment of the production process, or audit of the management system, or both. The extent to which the four surveillance activities are conducted may be varied for a given situation, as defined in the scheme. If the surveillance includes audit of the management system, an initial audit of the management system will be needed.

5.3.8 Scheme type 6

This scheme is mainly applicable to certification of services and processes.

Although services are considered as being generally intangible, the determination activities are not limited to the evaluation of intangible elements (e.g. effectiveness of an organization's procedures, delays and responsiveness of the management). In some situations, the tangible elements of a service can support the evidence of conformity indicated by the assessment of processes, resources and controls involved. For example, inspection of the cleanliness of vehicles for the quality of public transportation.

As far as processes are concerned, the situation is very similar. For example, the determination activities for welding processes can include testing and inspection of samples of the resultant welds, if applicable.

For both services and processes, the surveillance part of this scheme should include periodic audits of the management system and periodic assessment of the service or process.

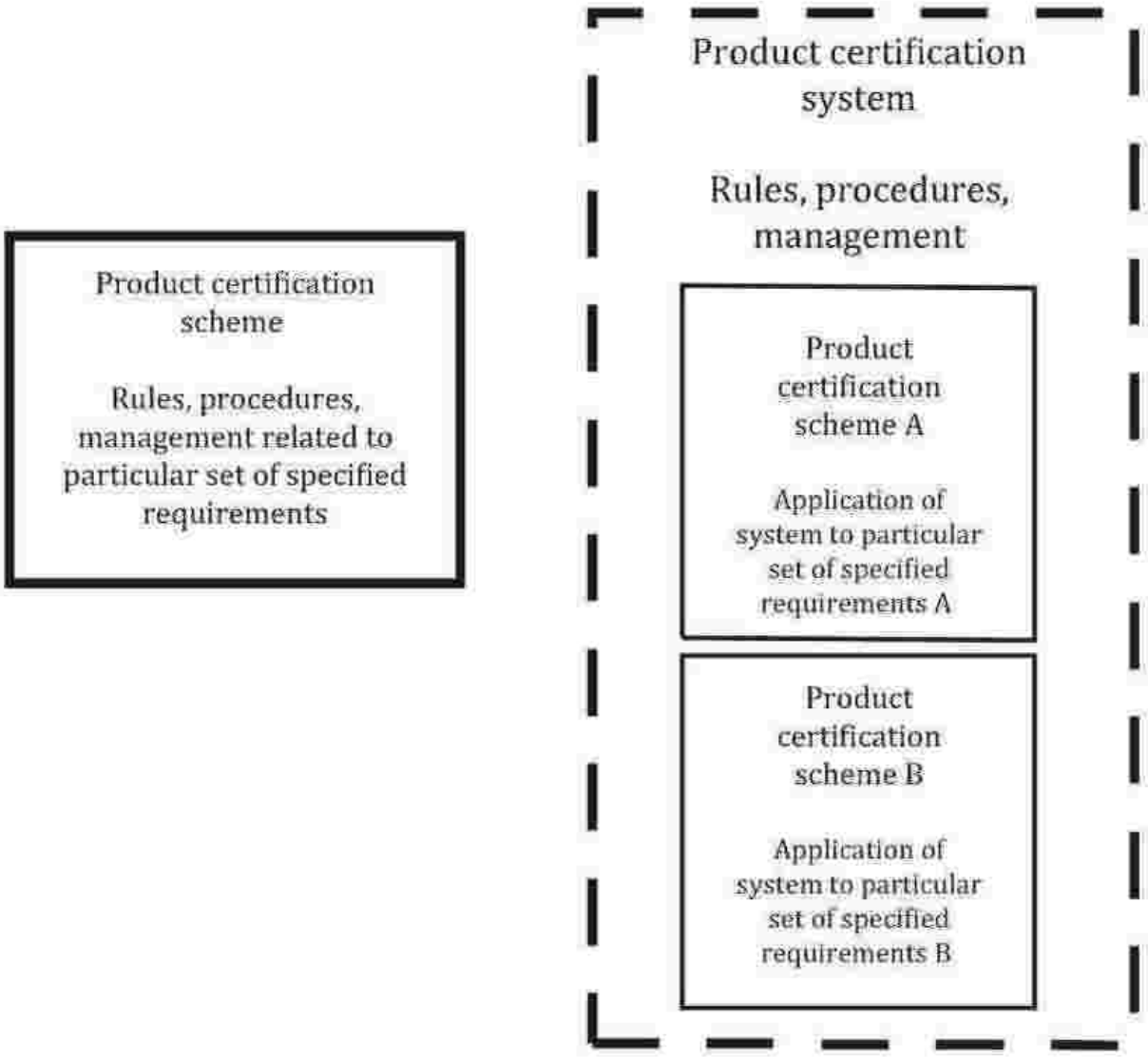
6 Development and operation of a product certification scheme

6.1 General

This clause provides guidelines on how to develop and operate a product certification scheme. It is particularly relevant to those persons and organizations that are considering the establishment of a scheme or acting as a stakeholder (e.g. manufacturer, service provider, certification body, customer or public authority).

6.2 Relationship between product certification scheme and product certification system

The product certification scheme will use defined rules, procedures and management, which could be unique to the scheme or could be defined in a product certification system applicable to a number of schemes. It is always necessary to have a product certification scheme, but only necessary to separately define a product certification system if the same rules, procedures and management are to be used for more than one scheme. Figure 1 illustrates the relationship between a product certification scheme and a product certification system.



a) Unique product certification scheme

b) Product certification system relating to several schemes

Figure 1 — Relationship between product certification scheme and product certification system

6.3 Scheme owner

6.3.1 The following main types of scheme owners can be identified:

a) certification bodies which develop a product certification scheme for the sole use of their clients;

b) organizations such as a regulatory body or a trade association not being a certification body, which develop a product certification scheme in which one or more certification bodies participate.

NOTE A group of certification bodies, perhaps in different countries, can together set up a certification scheme. In that case, it would be necessary for the certification bodies, as joint owners of the scheme, to create a management structure so that the scheme could be operated effectively by all participating certification bodies.

6.3.2 If a scheme owner operates several schemes, the scheme owner may combine common procedures and management into a product certification system. In that case, the scheme owner would become the system owner and would be responsible for the management of the system and the schemes operating within it.

6.3.3 The scheme owner should be a legal entity.

NOTE A governmental scheme owner is deemed to be a legal entity on the basis of its governmental status.

6.3.4 The scheme owner should be able to take on full responsibility for the objectives, the content and the integrity of the scheme.

6.3.5 The scheme owner should maintain the scheme and provide guidance when required.

6.3.6 The scheme owner should set up a structure for the operation and management of the scheme.

6.3.7 The scheme owner should document the content of the scheme.

6.3.8 The scheme owner should ensure that the scheme is developed by persons competent in both technical and conformity assessment aspects.

6.3.9 The scheme owner should make arrangements to protect the confidentiality of information provided by the parties involved in the scheme.

6.3.10 The scheme owner should evaluate and manage the risks/liabilities arising from its activities.

NOTE Evaluating risks does not imply risk assessments in accordance with ISO 31000.

6.3.11 The scheme owner should have adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its activities. Arrangements should be appropriate e.g. for the range of activities and schemes undertaken and in the geographic regions in which the scheme operates.

6.3.12 The scheme owner should have the financial stability and resources required for it to fulfil its role in the operation of the scheme.

6.4 Development of product certification schemes

6.4.1 Product certification schemes can be developed for different purposes. Such purposes may include schemes established by regulators to achieve health, safety or environmental outcomes. Other schemes may have the purpose of assisting clients and consumers to differentiate products in the market place and make informed purchasing decisions.

6.4.2 Irrespective of the purpose, scheme owners should understand the assumptions, influences and consequences involved in establishing, operating and maintaining a scheme on an ongoing basis.

6.4.3 In developing a scheme, the scheme owner should have a clear understanding of the objectives of the scheme and the assumptions that underlie the need for, and the acceptance of, the scheme. To assist in this, the scheme owner should identify stakeholders and seek their opinions and participation in scheme development.

6.4.4 Before developing the specific content of the scheme (see 6.5), fundamental scheme principles should be agreed among the stakeholders. Such principles may include:

— confirmation of the ownership,

— confirmation of the governance and decision making mechanisms that may or may not provide for direct involvement of stakeholders,

— confirmation of the underlying business and funding model, and

— providing an outline for monitoring and periodic review of the scheme.

6.4.5 Once developed, the scheme owner should ensure that information about the scheme is made publicly available to ensure transparency, understanding and acceptance. The scheme owner should ensure that the scheme is regularly reviewed, including confirmation that it is fulfilling its objectives, in accordance with a process that includes stakeholders.

6.5 Content of a scheme

6.5.1 General

A product certification scheme should specify the following elements:

a) the scope of the scheme, including the type of products covered;

b) the requirements against which the products are evaluated, by reference to standards or other normative documents; where it is necessary to elaborate upon the requirements to remove ambiguity, the explanations should be formulated by competent people and should be made available to all interested parties;

NOTE Further guidance on how to formulate specified requirements is provided in ISO/IEC 17007.

c) the selection of the activities (see Table 1) appropriate to the purpose and the scope of the scheme; as a minimum, a certification scheme should include the functions and activities I, II, III, IV and V a);

d) other requirements to be met by the client, e.g. the operation of a management system or process control activities to assure the demonstration of fulfilment of specified requirements is valid for the ongoing production of certified products;

e) the requirements for certification bodies and other conformity assessment bodies involved in the certification process; these requirements should not be in contradiction to the requirements of the applicable standards for conformity assessment bodies;

f) whether conformity assessment bodies involved in the scheme (e.g. testing laboratories, inspection bodies, product certification bodies, bodies auditing manufacturers' management systems) are to be accredited, participate in peer assessment or qualified in another manner; if the scheme is to require that conformity assessment bodies are accredited, the appropriate references should be specified, e.g. that the accreditation body is a member of a mutual recognition arrangement between accreditation bodies;

g) the methods and procedures to be used by the conformity assessment bodies and other organizations involved in the certification process, so as to assure the integrity and consistency of the outcome of the conformity assessment process;

h) the information to be supplied to the certification body by an applicant for certification;

i) the content of the statement of conformity (e.g. certificate) which unambiguously identifies the product to which it applies;

j) the conditions under which the client may use the statement of conformity or marks of conformity;

k) where marks of conformity may be used, the ownership, use and control of the marks; the requirements of ISO/IEC 17030 should be applied;

l) the resources required for the operation of the scheme, including impartiality and competence of the personnel (internal and external), the evaluation resources, and the use of subcontractors;

m) how the results of the determination (evaluation) and surveillance stages are to be reported and used by the certification body and the scheme owner;

n) the question of how non-conformities with the certification requirements, which include product requirements, are to be dealt with and resolved;

o) surveillance procedures, where surveillance is part of the scheme;

p) the criteria for access of conformity assessment bodies to the scheme and for the access of clients to the scheme;

q) content, conditions and responsibility for publication of the directory of certified products by the certification body or the scheme owner;

r) the need for, and content of, contracts, e.g. between scheme owner and certification body, scheme owner and clients, certification body and clients: the rights, responsibilities and liabilities of the various parties should be defined in contracts;

NOTE An example contract between a certification body and its clients can be found in ISO/IEC Guide 28:2004, Annex B.

s) general conditions for granting, maintaining, continuing, extending the scope of, reducing the scope of, suspending and withdrawing certification: this includes requirements for discontinuation of advertising and return of certification documents and any other action if the certification is suspended, withdrawn or terminated;

t) the way in which the clients' complaints records are to be verified if such verification is part of the scheme;

u) the way in which the clients make reference to the scheme in their publicity material;

v) retention of records by scheme owner and certification bodies.

6.5.2 Sampling

Where applicable, the scheme should define the extent to which sampling of the product to be certified is required, and on what basis such sampling should be undertaken both at the selection and surveillance stages. The scheme should define when sampling is required and who is permitted to undertake it.

NOTE Useful information on this topic is given in ISO 10576-1, ISO 2859-10, ISO 3951-1 and ISO 22514-1.

6.5.3 Acceptance of conformity assessment results

In some cases, clients might have obtained the results of determination activities, such as testing, inspection or auditing, prior to making an application for certification. In such a situation, the conformity assessment result may be from a source not within the contractual control of the certification body. The scheme should define whether and under what conditions such conformity assessment results can be considered in the certification process.

6.5.4 Outsourcing of the conformity assessment activities

If the scheme permits outsourcing (subcontracting) of conformity assessment activities such as testing, inspection or auditing, then the scheme should require these bodies to meet the applicable requirements of the relevant International Standards. For testing, it should meet the applicable requirements of ISO/IEC 17025; for inspection, it should meet the applicable requirements of ISO/IEC 17020; and for management system auditing, it should meet the applicable requirements of ISO/IEC 17021. The scheme should state the degree to which prior agreement to outsourcing needs to be obtained from the scheme owner or the client whose products are being certified under the scheme.

6.5.5 Complaints and appeals to the scheme owner

The scheme owner should define the complaints and appeals process and who is responsible for undertaking this process.

Appeals against the decision of the certification body and complaints about the certification body should be addressed to the certification body in the first instance.

Appeals and complaints that have not been, or cannot be, resolved by the certification body can be addressed to the scheme owner.

6.5.6 Licensing and control of the mark

Where the scheme provides for the use of certificates, marks or other statements of conformity, there should be a license or other form of enforceable agreement to control such use. Licenses can include provisions related to use of the certificate, mark or other statement of conformity in communications about the certified product, and requirements to be fulfilled when certification is no longer valid. Such licenses may be between two or more of the following:

- scheme owner;
- certification body;
- client of the certification body.

6.5.7 Surveillance

If surveillance is included, the scheme should define the set of activities (see function 6 in Table 1) that make up the surveillance functions. When deciding upon the appropriate surveillance activities, the scheme owner should consider the nature of the product, the consequences and probability of non-conforming products and the frequency of the activities.

6.5.8 Non-conforming products

The scheme should define requirements that apply when a product no longer fulfils certification requirements, such as product recall or providing information to the market.

NOTE See also ISO Guide 27.

6.5.9 Reporting to the scheme owner

When reporting to the scheme owner is required, the content and frequency of reporting should be defined. Such reporting may be for the purpose of scheme improvement, for control purposes and for monitoring the extent of conformity by clients.

6.5.10 Subcontracting of the operation of the scheme

If the scheme owner subcontracts all or part of the operation of the scheme to another party, it should have a legally binding contract defining the duties and responsibilities of both parties. A governmental scheme owner can subcontract operation of the scheme by regulatory provisions.

6.5.11 Marketing

The scheme should define the policies and procedures related to marketing, including the extent to which certification bodies and clients can make reference to the scheme.

6.5.12 Fraudulent claim of certification

Actions and responsibilities for situations where certification under the scheme is being claimed fraudulently should be described.

6.6 Maintenance and improvement of a scheme

6.6.1 Review of scheme operation

The scheme owner should define a process for reviewing the operation of the scheme on a periodic basis in order to confirm its validity and to identify aspects requiring improvement, taking into account feedback from stakeholders. The review should include provisions for ensuring that the scheme requirements are being applied in a consistent manner.

6.6.2 Changes in specified requirements

The scheme owner should monitor the development of the standards and other normative documents which define the specified requirements used in the scheme. Where changes in these documents occur, the scheme owner should have a process for making the necessary changes in the scheme, and for managing the implementation of the changes (e.g. transition period) by the certification bodies, clients and, where necessary, other stakeholders.

6.6.3 Other changes to the scheme

The scheme owner should define a process for managing the implementation of other changes to the rules, procedures and management of the scheme.

6.7 Scheme documentation

The scheme owner should create, control and maintain adequate documentation for the operation, maintenance and improvement of the scheme. The documentation should specify the rules and the operating procedures of the scheme, and in particular the responsibilities for governance of the scheme.

Bibliography

[1] ISO 2859-10, *Sampling procedures for inspection by attributes — Part 10: Introduction to the ISO 2859 series of standards for sampling for inspection by attributes*

[2] ISO 3951-1, *Sampling procedures for inspection by variables — Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL*

[3] ISO 10576-1, *Statistical methods — Guidelines for the evaluation of conformity with specified requirements — Part 1: General principles*

[4] ISO/IEC 17007, *Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment*

[5] ISO/IEC 17020, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

[6] ISO/IEC 17021 (all parts), *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

[7] ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

[8] ISO/IEC 17030, *Conformity assessment — General requirements for third-party marks of conformity*

[9] ISO 22514-1, *Statistical methods in process management — Capability and performance — Part 1: General principles and concepts*

[10] ISO 31000, *Risk management — Principles and guidelines*

[11] ISO Guide 27:1983, *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*

[12] ISO/IEC Guide 28:2004, *Conformity assessment — Guidance on a third-party certification system for products*

[13] ISO/IEC Guide 53, *Conformity assessment — Guidance on the use of an organization's quality management system in product certification*

[14] ISO/IEC Guide 68, *Arrangements for the recognition and acceptance of conformity assessment results*

INTERNATIONAL STANDARD

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Occupational health and safety management systems — Requirements with guidance for use

Systèmes de management de la santé et de la sécurité au travail — Exigences et lignes directrices pour leur utilisation

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Contents

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Project Committee ISO/PC 283, *Occupational health and safety management systems*.

Introduction

0.1 Background

An organization is responsible for the occupational health and safety of workers and others who can be affected by its activities. This responsibility includes promoting and protecting their physical and mental health.

The adoption of an OH&S management system is intended to enable an organization to provide safe and healthy workplaces, prevent work-related injury and ill health, and continually improve its OH&S performance.

0.2 Aim of an OH&S management system

The purpose of an OH&S management system is to provide a framework for managing OH&S risks and opportunities. The aim and intended outcomes of the OH&S management system are to prevent work-related injury and ill health to workers and to provide safe and healthy workplaces; consequently, it is critically important for the organization to eliminate hazards and minimize OH&S risks by taking effective preventive and protective measures.

When these measures are applied by the organization through its OH&S management system, they improve its OH&S performance. An OH&S management system can be more effective and efficient when taking early action to address opportunities for improvement of OH&S performance.

Implementing an OH&S management system conforming to this document enables an organization to manage its OH&S risks and improve its OH&S performance. An OH&S management system can assist an organization to fulfil its legal requirements and other requirements.

0.3 Success factors

The implementation of an OH&S management system is a strategic and operational decision for an organization. The success of the OH&S management system depends on leadership, commitment and participation from all levels and functions of the organization.

The implementation and maintenance of an OH&S management system, its effectiveness and its ability to achieve its intended outcomes are dependent on a number of key factors, which can include:

a) top management leadership, commitment, responsibilities and accountability;

b) top management developing, leading and promoting a culture in the organization that supports the intended outcomes of the OH&S management system;

c) communication;

d) consultation and participation of workers, and, where they exist, workers' representatives;

e) allocation of the necessary resources to maintain it;

f) OH&S policies, which are compatible with the overall strategic objectives and direction of the organization;

g) effective process(es) for identifying hazards, controlling OH&S risks and taking advantage of OH&S opportunities;

h) continual performance evaluation and monitoring of the OH&S management system to improve OH&S performance;

i) integration of the OH&S management system into the organization's business processes;

j) OH&S objectives that align with the OH&S policy and take into account the organization's hazards, OH&S risks and OH&S opportunities;

k) compliance with its legal requirements and other requirements.

Demonstration of successful implementation of this document can be used by an organization to give assurance to workers and other interested parties that an effective OH&S management system is in place. Adoption of this document, however, will not in itself guarantee prevention of work-related injury and ill health to workers, provision of safe and healthy workplaces and improved OH&S performance.

The level of detail, the complexity, the extent of documented information and the resources needed to ensure the success of an organization's OH&S management system will depend on a number of factors, such as:

— the organization's context (e.g. number of workers, size, geography, culture, legal requirements and other requirements);

— the scope of the organization's OH&S management system;

— the nature of the organization's activities and the related OH&S risks.

0.4 Plan-Do-Check-Act cycle

The OH&S management system approach applied in this document is founded on the concept of Plan-Do-Check-Act (PDCA).

The PDCA concept is an iterative process used by organizations to achieve continual improvement. It can be applied to a management system and to each of its individual elements, as follows:

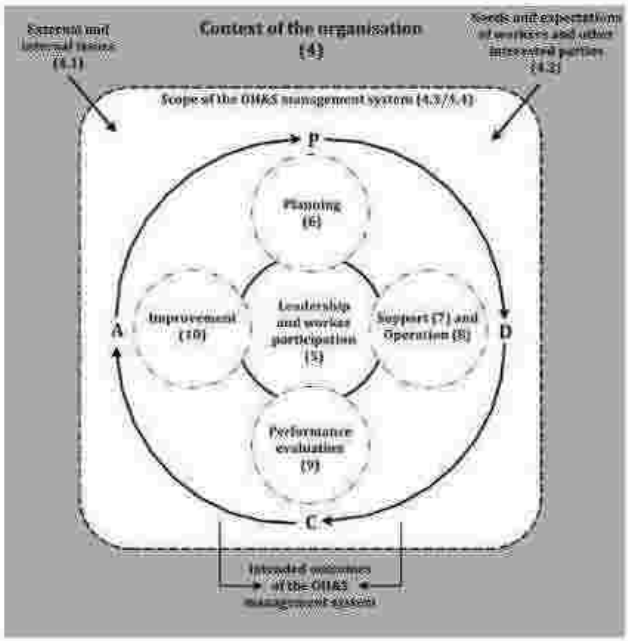
a) Plan: determine and assess OH&S risks, OH&S opportunities and other risks and other opportunities, establish OH&S objectives and processes necessary to deliver results in accordance with the organization's OH&S policy;

b) Do: implement the processes as planned;

c) Check: monitor and measure activities and processes with regard to the OH&S policy and OH&S objectives, and report the results;

d) Act: take actions to continually improve the OH&S performance to achieve the intended outcomes.

This document incorporates the PDCA concept into a new framework, as shown in Figure 1.



NOTE The numbers given in brackets refer to the clause numbers in this document.

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

0.5 Contents of this document

This document conforms to ISO's requirements for management system standards. These requirements include a high level 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 subjects, such as those for quality, social responsibility, environmental, security or financial management, though its elements can be aligned or integrated with those of other management systems.

This document contains requirements that can be used by an organization to implement an OH&S management system and to assess conformity. An organization that wishes to demonstrate conformity to this document can do so by:

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

— seeking confirmation of its conformity 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 OH&S management system by an external organization.

Clauses 1 to 3 in this document set out the scope, normative references and terms and definitions which apply to the use of this document, while Clauses 4 to 10 contain the requirements to be used to assess conformity to this document. Annex A provides informative explanations to these requirements. The terms and definitions in Clause 3 are arranged in conceptual order, with an alphabetical index provided at the end of this document.

In this document, the following verbal forms are used:

a) "shall" indicates a requirement;

b) "should" indicates a recommendation;

c) "may" indicates a permission;

d) "can" indicates a possibility or a capability.

Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement. "Notes to entry" used in Clause 3 provide additional information that supplements the terminological data and can contain provisions relating to the use of a term.

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Occupational health and safety management systems — Requirements with guidance for use

1 Scope

This document specifies requirements for an occupational health and safety (OH&S) management system, and gives guidance for its use, to enable organizations to provide safe and healthy workplaces by preventing work-related injury and ill health, as well as by proactively improving its OH&S performance.

This document is applicable to any organization that wishes to establish, implement and maintain an OH&S management system to improve occupational health and safety, eliminate hazards and minimize OH&S risks (including system deficiencies), take advantage of OH&S opportunities, and address OH&S management system nonconformities associated with its activities.

This document helps an organization to achieve the intended outcomes of its OH&S management system. Consistent with the organization's OH&S policy, the intended outcomes of an OH&S management system include:

a) continual improvement of OH&S performance;

b) fulfilment of legal requirements and other requirements;

c) achievement of OH&S objectives.

This document is applicable to any organization regardless of its size, type and activities. It is applicable to the OH&S risks under the organization's control, taking into account factors such as the context in which the organization operates and the needs and expectations of its workers and other interested parties.

This document does not state specific criteria for OH&S performance, nor is it prescriptive about the design of an OH&S management system.

This document enables an organization, through its OH&S management system, to integrate other aspects of health and safety, such as worker wellness/wellbeing.

This document does not address issues such as product safety, property damage or environmental impacts, beyond the risks to workers and other relevant interested parties.

This document can be used in whole or in part to systematically improve occupational health and safety management. However, claims of conformity to this document are not acceptable unless all its requirements are incorporated into an organization's OH&S 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 terminological databases for use in standardization at the following addresses:

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

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

3.1
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.16)

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: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.2
interested party (preferred term)
stakeholder (admitted term)
person or *organization* (3.1) that can affect, be affected by, or perceive itself to be affected by a decision or activity

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.3
worker
person performing work or work-related activities that are under the control of the *organization* (3.1)

Note 1 to entry: Persons perform work or work-related activities under various arrangements, paid or unpaid, such as regularly or temporarily, intermittently or seasonally, casually or on a part-time basis.

Note 2 to entry: Workers include *top management* (3.12), managerial and non-managerial persons.

Note 3 to entry: The work or work-related activities performed under the control of the organization may be performed by workers employed by the organization, workers of external providers, contractors, individuals, agency workers, and by other persons to the extent the organization shares control over their work or work-related activities, according to the context of the organization.

3.4
participation
involvement in decision-making

Note 1 to entry: Participation includes engaging health and safety committees and workers' representatives, where they exist.

3.5
consultation
seeking views before making a decision

Note 1 to entry: Consultation includes engaging health and safety committees and workers' representatives, where they exist.

3.6
workplace
place under the control of the *organization* (3.1) where a person needs to be or to go for work purposes

Note 1 to entry: The organization's responsibilities under the *OH&S management system* (3.11) for the workplace depend on the degree of control over the workplace.

3.7
contractor
external *organization* (3.1) providing services to the organization in accordance with agreed specifications, terms and conditions

Note 1 to entry: Services may include construction activities, among others.

3.8
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) and *interested parties* (3.2) that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, for example in *documented information* (3.24).

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.9
legal requirements and other requirements
legal requirements that an *organization* (3.1) has to comply with and other *requirements* (3.8) that an organization has to or chooses to comply with

Note 1 to entry: For the purposes of this document, legal requirements and other requirements are those relevant to the *OH&S management system* (3.11).

Note 2 to entry: "Legal requirements and other requirements" include the provisions in collective agreements.

Note 3 to entry: Legal requirements and other requirements include those that determine the persons who are *workers'* (3.3) representatives in accordance with laws, regulations, collective agreements and practices.

3.10
management system
set of interrelated or interacting elements of an *organization* (3.1) to establish *policies* (3.14) and *objectives* (3.16) and *processes* (3.25) to achieve those objectives

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

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

Note 3 to entry: The scope of a management system may 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.

Note 4 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. Note 2 to entry has been modified to clarify some of the wider elements of a management system.

3.11
occupational health and safety management system
OH&S management system
management system (3.10) or part of a management system used to achieve the *OH&S policy* (3.15)

Note 1 to entry: The intended outcomes of the OH&S management system are to prevent *injury and ill health* (3.18) to *workers* (3.3) and to provide safe and healthy *workplaces* (3.6).

Note 2 to entry: The terms "occupational health and safety" (OH&S) and "occupational safety and health" (OSH) have the same meaning.

3.12
top management
person or group of people who directs and controls an *organization* (3.1) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization, provided ultimate responsibility for the *OH&S management system* (3.11) is retained.

Note 2 to entry: If the scope of the *management system* (3.10) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. Note 1 to entry has been modified to clarify the responsibility of top management in relation to an OH&S management system.

3.13
effectiveness
extent to which planned activities are realized and planned results achieved

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.14
policy
intentions and direction of an *organization* (3.1), as formally expressed by its *top management* (3.12)

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.15
occupational health and safety policy
OH&S policy
policy (3.14) to prevent work-related *injury and ill health* (3.18) to *workers* (3.3) and to provide safe and healthy *workplaces* (3.6)

3.16
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 financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and *process* (3.25)).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as an *OH&S objective* (3.17), or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original Note 4 to entry has been deleted as the term "OH&S objective" has been defined separately in 3.17.

3.17
occupational health and safety objective
OH&S objective
objective (3.16) set by the *organization* (3.1) to achieve specific results consistent with the *OH&S policy* (3.15)

3.18
injury and ill health
adverse effect on the physical, mental or cognitive condition of a person

Note 1 to entry: These adverse effects include occupational disease, illness and death.

Note 2 to entry: The term "injury and ill health" implies the presence of injury or ill health, either on their own or in combination.

3.19
hazard
source with a potential to cause *injury and ill health* (3.18)

Note 1 to entry: Hazards can include sources with the potential to cause harm or hazardous situations, or circumstances with the potential for exposure leading to injury and ill health.

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" (as defined in ISO Guide 73:2009, 3.5.1.3) and "consequences" (as defined in ISO Guide 73:2009, 3.6.1.3), 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" (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence.

Note 5 to entry: In this document, where the term "risks and opportunities" is used this means *OH&S risks* (3.21), *OH&S opportunities* (3.22) and other risks and other opportunities for the management system.

Note 6 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. Note 5 to entry has been added to clarify the term "risks and opportunities" for its use within this document.

3.21
occupational health and safety risk
OH&S risk
combination of the likelihood of occurrence of a work-related hazardous event(s) or exposure(s) and the severity of *injury and ill health* (3.18) that can be caused by the event(s) or exposure(s)

3.22
occupational health and safety opportunity
OH&S opportunity
circumstance or set of circumstances that can lead to improvement of *OH&S performance* (3.28)

3.23
competence
ability to apply knowledge and skills to achieve intended results

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.24
documented information
information required to be controlled and maintained by an *organization* (3.1) 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:

a) the *management system* (3.10), including related *processes* (3.25);

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

c) evidence of results achieved (records).

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.25
process
set of interrelated or interacting activities which transforms inputs into outputs

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.26
procedure
specified way to carry out an activity or a *process* (3.25)

Note 1 to entry: Procedures may be documented or not.

[SOURCE: ISO 9000:2015, 3.4.5, modified — Note 1 to entry has been modified.]

3.27
performance
measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings. Results can be determined and evaluated by qualitative or quantitative methods.

Note 2 to entry: Performance can relate to the management of activities, *processes* (3.25), products (including services), systems or *organizations* (3.1).

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. Note 1 to entry has been modified to clarify the types of methods that may be used for determining and evaluating results.

3.28
occupational health and safety performance
OH&S performance
performance (3.27) related to the *effectiveness* (3.13) of the prevention of *injury and ill health* (3.18) to *workers* (3.3) and the provision of safe and healthy *workplaces* (3.6)

3.29
outsource, verb
make an arrangement where an external *organization* (3.1) performs part of an organization's function or *process* (3.25)

Note 1 to entry: An external organization is outside the scope of the *management system* (3.10), although the outsourced function or process is within the scope.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.30
monitoring
determining the status of a system, a *process* (3.25) or an activity

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

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.31
measurement
process (3.25) to determine a value

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.32
audit
systematic, independent and documented *process* (3.25) for obtaining audit 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) 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: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.33
conformity
fulfilment of a *requirement* (3.8)

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.34
nonconformity
non-fulfilment of a *requirement* (3.8)

Note 1 to entry: Nonconformity relates to requirements in this document and additional *OH&S management system* (3.11) requirements that an *organization* (3.1) establishes for itself.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. Note 1 to entry has been added to clarify the relationship of nonconformities to the requirements of this document and to the organization's own requirements for its OH&S management system.

3.35
incident
occurrence arising out of, or in the course of, work that could or does result in *injury and ill health* (3.18)

Note 1 to entry: An incident where injury and ill health occurs is sometimes referred to as an "accident".

Note 2 to entry: An incident where no injury and ill health occurs, but has the potential to do so, may be referred to as a "near-miss", "near-hit" or "close call".

Note 3 to entry: Although there can be one or more *nonconformities* (3.34) related to an incident, an incident can also occur where there is no nonconformity.

3.36
corrective action
action to eliminate the cause(s) of a *nonconformity* (3.34) or an *incident* (3.35) and to prevent recurrence

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The definition has been modified to include reference to "incident", as incidents are a key factor in occupational health and safety, yet the activities needed for resolving them are the same as for nonconformities, through corrective action.

3.37
continual improvement
recurring activity to enhance *performance* (3.27)

Note 1 to entry: Enhancing performance relates to the use of the *OH&S management system* (3.11) in order to achieve improvement in overall *OH&S performance* (3.28) consistent with the *OH&S policy* (3.15) and *OH&S objectives* (3.12).

Note 2 to entry: Continual does not mean continuous, so the activity does not need to take place in all areas simultaneously.

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. Note 1 to entry has been added to clarify the meaning of "performance" in the context of an OH&S management system; Note 2 to entry has been added to clarify the meaning of "continual".

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 outcome(s) of its OH&S management system.

4.2 Understanding the needs and expectations of workers and other interested parties

The organization shall determine:

a) the other interested parties, in addition to workers, that are relevant to the OH&S management system;

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

c) which of these needs and expectations are, or could become, legal requirements and other requirements.

4.3 Determining the scope of the OH&S management system

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

When determining this scope, the organization shall:

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

b) take into account the requirements referred to in 4.2;

c) take into account the planned or performed work-related activities.

The OH&S management system shall include the activities, products and services within the organization's control or influence that can impact the organization's OH&S performance.

The scope shall be available as documented information.

4.4 OH&S management system

The organization shall establish, implement, maintain and continually improve an OH&S management system, including the processes needed and their interactions, in accordance with the requirements of this document.

5 Leadership and worker participation

5.1 Leadership and commitment

Top management shall demonstrate leadership and commitment with respect to the OH&S management system by:

a) taking overall responsibility and accountability for the prevention of work-related injury and ill health, as well as the provision of safe and healthy workplaces and activities;

b) ensuring that the OH&S policy and related OH&S objectives are established and are compatible with the strategic direction of the organization;

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

d) ensuring that the resources needed to establish, implement, maintain and improve the OH&S management system are available;

e) communicating the importance of effective OH&S management and of conforming to the OH&S management system requirements;

f) ensuring that the OH&S management system achieves its intended outcome(s);

g) directing and supporting persons to contribute to the effectiveness of the OH&S management system;

h) ensuring and promoting continual improvement;

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

j) developing, leading and promoting a culture in the organization that supports the intended outcomes of the OH&S management system;

k) protecting workers from reprisals when reporting incidents, hazards, risks and opportunities;

l) ensuring the organization establishes and implements a process(es) for consultation and participation of workers (see 5.4);

m) supporting the establishment and functioning of health and safety committees, [see 5.4 e) 1)].

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

5.2 OH&S policy

Top management shall establish, implement and maintain an OH&S policy that:

a) includes a commitment to provide safe and healthy working conditions for the prevention of work-related injury and ill health and is appropriate to the purpose, size and context of the organization and to the specific nature of its OH&S risks and OH&S opportunities;

b) provides a framework for setting the OH&S objectives;

c) includes a commitment to fulfil legal requirements and other requirements;

d) includes a commitment to eliminate hazards and reduce OH&S risks (see 8.1.2);

e) includes a commitment to continual improvement of the OH&S management system;

f) includes a commitment to consultation and participation of workers, and, where they exist, workers' representatives.

The OH&S policy shall:

— be available as documented information;

— be communicated within the organization;

— be available to interested parties, as appropriate;

— be relevant and appropriate.

5.3 Organizational roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles within the OH&S management system are assigned and communicated at all levels within the organization and maintained as documented information. Workers at each level of the organization shall assume responsibility for those aspects of the OH&S management system over which they have control.

NOTE While responsibility and authority can be assigned, ultimately top management is still accountable for the functioning of the OH&S management system.

Top management shall assign the responsibility and authority for:

a) ensuring that the OH&S management system conforms to the requirements of this document;

b) reporting on the performance of the OH&S management system to top management.

5.4 Consultation and participation of workers

The organization shall establish, implement and maintain a process(es) for consultation and participation of workers at all applicable levels and functions, and, where they exist, workers' representatives, in the development, planning, implementation, performance evaluation and actions for improvement of the OH&S management system.

The organization shall:

a) provide mechanisms, time, training and resources necessary for consultation and participation;

NOTE 1 Worker representation can be a mechanism for consultation and participation.

b) provide timely access to clear, understandable and relevant information about the OH&S management system;

c) determine and remove obstacles or barriers to participation and minimize those that cannot be removed;

NOTE 2 Obstacles and barriers can include failure to respond to worker inputs or suggestions, language or literacy barriers, reprisals or threats of reprisals and policies or practices that discourage or penalize worker participation.

d) emphasize the consultation of non-managerial workers on the following:

1) determining the needs and expectations of interested parties (see 4.2);

2) establishing the OH&S policy (see 5.2);

3) assigning organizational roles, responsibilities and authorities, as applicable (see 5.3);

4) determining how to fulfil legal requirements and other requirements (see 6.1.3);

5) establishing OH&S objectives and planning to achieve them (see 6.2);

6) determining applicable controls for outsourcing, procurement and contractors (see 8.1.4);

7) determining what needs to be monitored, measured and evaluated (see 9.1);

8) planning, establishing, implementing and maintaining an audit programme(s) (see 9.2.2);

9) ensuring continual improvement (see 10.3);

e) emphasize the participation of non-managerial workers in the following:

1) determining the mechanisms for their consultation and participation;

2) identifying hazards and assessing risks and opportunities (see 6.1.1 and 6.1.2);

3) determining actions to eliminate hazards and reduce OH&S risks (see 6.1.4);

4) determining competence requirements, training needs, training and evaluating training (see 7.2);

5) determining what needs to be communicated and how this will be done (see 7.4);

6) determining control measures and their effective implementation and use (see 8.1, 8.1.3 and 8.2);

7) investigating incidents and nonconformities and determining corrective actions (see 10.2).

NOTE 3 Emphasizing the consultation and participation of non-managerial workers is intended to apply to persons carrying out the work activities, but is not intended to exclude, for example, managers who are impacted by work activities or other factors in the organization.

NOTE 4 It is recognized that the provision of training at no cost to workers and the provision of training during working hours, where possible, can remove significant barriers to worker participation.

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 General

When planning for the OH&S management system, the organization shall consider the issues referred to in 4.1 (context), the requirements referred to in 4.2 (interested parties) and 4.3 (the scope of its OH&S management system) and determine the risks and opportunities that need to be addressed to:

a) give assurance that the OH&S management system can achieve its intended outcome(s);

b) prevent, or reduce, undesired effects;

c) achieve continual improvement.

When determining the risks and opportunities for the OH&S management system and its intended outcomes that need to be addressed, the organization shall take into account:

— hazards (see 6.1.2.1);

— OH&S risks and other risks (see 6.1.2.2);

— OH&S opportunities and other opportunities (see 6.1.2.3);

— legal requirements and other requirements (see 6.1.3).

The organization, in its planning process(es), shall determine and assess the risks and opportunities that are relevant to the intended outcomes of the OH&S management system associated with changes in the organization, its processes or the OH&S management system. In the case of planned changes,

permanent or temporary, this assessment shall be undertaken before the change is implemented (see 8.1.3).

The organization shall maintain documented information on:

— risks and opportunities;

— the process(es) and actions needed to determine and address its risks and opportunities (see 6.1.2 to 6.1.4) to the extent necessary to have confidence that they are carried out as planned.

6.1.2 Hazard identification and assessment of risks and opportunities

6.1.2.1 Hazard identification

The organization shall establish, implement and maintain a process(es) for hazard identification that is ongoing and proactive. The process(es) shall take into account, but not be limited to:

a) how work is organized, social factors (including workload, work hours, victimization, harassment and bullying), leadership and the culture in the organization;

b) routine and non-routine activities and situations, including hazards arising from:

   1) infrastructure, equipment, materials, substances and the physical conditions of the workplace;

   2) product and service design, research, development, testing, production, assembly, construction, service delivery, maintenance and disposal;

   3) human factors;

   4) how the work is performed;

c) past relevant incidents, internal or external to the organization, including emergencies, and their causes;

d) potential emergency situations;

e) people, including consideration of:

   1) those with access to the workplace and their activities, including workers, contractors, visitors and other persons;

   2) those in the vicinity of the workplace who can be affected by the activities of the organization;

   3) workers at a location not under the direct control of the organization;

f) other issues, including consideration of:

   1) the design of work areas, processes, installations, machinery/equipment, operating procedures and work organization, including their adaptation to the needs and capabilities of the workers involved;

   2) situations occurring in the vicinity of the workplace caused by work-related activities under the control of the organization;

   3) situations not controlled by the organization and occurring in the vicinity of the workplace that can cause injury and ill health to persons in the workplace;

g) actual or proposed changes in organization, operations, processes, activities and the OH&S management system (see 8.1.3);

h) changes in knowledge of, and information about, hazards.

6.1.2.2 Assessment of OH&S risks and other risks to the OH&S management system

The organization shall establish, implement and maintain a process(es) to:

a) assess OH&S risks from the identified hazards, while taking into account the effectiveness of existing controls;

b) determine and assess the other risks related to the establishment, implementation, operation and maintenance of the OH&S management system.

The organization's methodology(ies) and criteria for the assessment of OH&S risks shall be defined with respect to their scope, nature and timing to ensure they are proactive rather than reactive and are used in a systematic way. Documented information shall be maintained and retained on the methodology(ies) and criteria.

6.1.2.3 Assessment of OH&S opportunities and other opportunities for the OH&S management system

The organization shall establish, implement and maintain a process(es) to assess:

a) OH&S opportunities to enhance OH&S performance, while taking into account planned changes to the organization, its policies, its processes or its activities and:

   1) opportunities to adapt work, work organization and work environment to workers;

   2) opportunities to eliminate hazards and reduce OH&S risks;

b) other opportunities for improving the OH&S management system.

NOTE OH&S risks and OH&S opportunities can result in other risks and other opportunities for the organization.

6.1.3 Determination of legal requirements and other requirements

The organization shall establish, implement and maintain a process(es) to:

a) determine and have access to up-to-date legal requirements and other requirements that are applicable to its hazards, OH&S risks and OH&S management system;

b) determine how these legal requirements and other requirements apply to the organization and what needs to be communicated;

c) take these legal requirements and other requirements into account when establishing, implementing, maintaining and continually improving its OH&S management system.

The organization shall maintain and retain documented information on its legal requirements and other requirements and shall ensure that it is updated to reflect any changes.

NOTE Legal requirements and other requirements can result in risks and opportunities for the organization.

6.1.4 Planning action

The organization shall plan:

a) actions to:

   1) address these risks and opportunities (see 6.1.2.2 and 6.1.2.3);

   2) address legal requirements and other requirements (see 6.1.3);

3) prepare for and respond to emergency situations (see 8.2);

b) how to:

1) integrate and implement the actions into its OH&S management system processes or other business processes;

2) evaluate the effectiveness of these actions.

The organization shall take into account the hierarchy of controls (see 8.1.2) and outputs from the OH&S management system when planning to take action.

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

6.2 OH&S objectives and planning to achieve them

6.2.1 OH&S objectives

The organization shall establish OH&S objectives at relevant functions and levels in order to maintain and continually improve the OH&S management system and OH&S performance (see 10.3).

The OH&S objectives shall:

a) be consistent with the OH&S policy;

b) be measurable (if practicable) or capable of performance evaluation;

c) take into account:

1) applicable requirements;

2) the results of the assessment of risks and opportunities (see 6.1.2.2 and 6.1.2.3);

3) the results of consultation with workers (see 5.4) and, where they exist, workers' representatives;

d) be monitored;

e) be communicated;

f) be updated as appropriate.

6.2.2 Planning to achieve OH&S objectives

When planning how to achieve its OH&S 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;

f) how the actions to achieve OH&S objectives will be integrated into the organization's business processes.

The organization shall maintain and retain documented information on the OH&S objectives and plans to achieve them.

7 Support

7.1 Resources

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

7.2 Competence

The organization shall:

a) determine the necessary competence of workers that affects or can affect its OH&S performance;

b) ensure that workers are competent (including the ability to identify hazards) on the basis of appropriate education, training or experience;

c) where applicable, take actions to acquire and maintain the necessary competence, and evaluate the effectiveness of the actions taken;

d) retain appropriate documented information as evidence of competence.

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.

7.3 Awareness

Workers shall be made aware of:

a) the OH&S policy and OH&S objectives;

b) their contribution to the effectiveness of the OH&S management system, including the benefits of improved OH&S performance;

c) the implications and potential consequences of not conforming to the OH&S management system requirements;

d) incidents and the outcomes of investigations that are relevant to them;

e) hazards, OH&S risks and actions determined that are relevant to them;

f) the ability to remove themselves from work situations that they consider present an imminent and serious danger to their life or health, as well as the arrangements for protecting them from undue consequences for doing so.

7.4 Communication

7.4.1 General

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

a) on what it will communicate;

b) when to communicate;

c) with whom to communicate:

1) internally among the various levels and functions of the organization;

2) among contractors and visitors to the workplace;

3) among other interested parties;

d) how to communicate.

The organization shall take into account diversity aspects (e.g. gender, language, culture, literacy, disability) when considering its communication needs.

The organization shall ensure that the views of external interested parties are considered in establishing its communication process(es).

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

— take into account its legal requirements and other requirements;

— ensure that OH&S information to be communicated is consistent with information generated within the OH&S management system, and is reliable.

The organization shall respond to relevant communications on its OH&S management system.

The organization shall retain documented information as evidence of its communications, as appropriate.

7.4.2 Internal communication

The organization shall:

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

b) ensure its communication process(es) enables workers to contribute to continual improvement.

7.4.3 External communication

The organization shall externally communicate information relevant to the OH&S management system, as established by the organization's communication process(es) and taking into account its legal requirements and other requirements.

7.5 Documented information

7.5.1 General

The organization's OH&S 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 OH&S management system.

NOTE The extent of documented information for an OH&S 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 legal requirements and other requirements;

— the complexity of processes and their interactions;

— the competence of workers.

7.5.2 Creating and updating

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 OH&S 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.

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

NOTE 1 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.

NOTE 2 Access to relevant documented information includes access by workers, and, where they exist, workers' representatives.

8 Operation

8.1 Operational planning and control

8.1.1 General

The organization shall plan, implement, control and maintain the processes needed to meet requirements of the OH&S management system, and to implement the actions determined in Clause 6, by:

a) establishing criteria for the processes;

b) implementing control of the processes in accordance with the criteria;

c) maintaining and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned;

d) adapting work to workers.

At multi-employer workplaces, the organization shall coordinate the relevant parts of the OH&S management system with the other organizations.

8.1.2 Eliminating hazards and reducing OH&S risks

The organization shall establish, implement and maintain a process(es) for the elimination of hazards and reduction of OH&S risks using the following hierarchy of controls:

a) eliminate the hazard;

b) substitute with less hazardous processes, operations, materials or equipment;

c) use engineering controls and reorganization of work;

d) use administrative controls, including training;

e) use adequate personal protective equipment.

NOTE In many countries, legal requirements and other requirements include the requirement that personal protective equipment (PPE) is provided at no cost to workers.

8.1.3 Management of change

The organization shall establish a process(es) for the implementation and control of planned temporary and permanent changes that impact OH&S performance, including:

a) new products, services and processes, or changes to existing products, services and processes, including:

   — workplace locations and surroundings;

   — work organization;

   — working conditions;

   — equipment;

   — work force;

b) changes to legal requirements and other requirements;

c) changes in knowledge or information about hazards and OH&S risks;

d) developments in knowledge and technology.

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

NOTE Changes can result in risks and opportunities.

8.1.4 Procurement

8.1.4.1 General

The organization shall establish, implement and maintain a process(es) to control the procurement of products and services in order to ensure their conformity to its OH&S management system.

8.1.4.2 Contractors

The organization shall coordinate its procurement process(es) with its contractors, in order to identify hazards and to assess and control the OH&S risks arising from:

a) the contractors' activities and operations that impact the organization;

b) the organization's activities and operations that impact the contractors' workers;

c) the contractors' activities and operations that impact other interested parties in the workplace.

The organization shall ensure that the requirements of its OH&S management system are met by contractors and their workers. The organization's procurement process(es) shall define and apply occupational health and safety criteria for the selection of contractors.

NOTE It can be helpful to include the occupational health and safety criteria for the selection of contractors in the contractual documents.

8.1.4.3 Outsourcing

The organization shall ensure that outsourced functions and processes are controlled. The organization shall ensure that its outsourcing arrangements are consistent with legal requirements and other requirements and with achieving the intended outcomes of the OH&S management system. The type and degree of control to be applied to these functions and processes shall be defined within the OH&S management system.

NOTE Coordination with external providers can assist an organization to address any impact that outsourcing has on its OH&S performance.

8.2 Emergency preparedness and response

The organization shall establish, implement and maintain a process(es) needed to prepare for and respond to potential emergency situations, as identified in 6.1.2.1, including:

a) establishing a planned response to emergency situations, including the provision of first aid;

b) providing training for the planned response;

c) periodically testing and exercising the planned response capability;

d) evaluating performance and, as necessary, revising the planned response, including after testing and, in particular, after the occurrence of emergency situations;

e) communicating and providing relevant information to all workers on their duties and responsibilities;

f) communicating relevant information to contractors, visitors, emergency response services, government authorities and, as appropriate, the local community;

g) taking into account the needs and capabilities of all relevant interested parties and ensuring their involvement, as appropriate, in the development of the planned response.

The organization shall maintain and retain documented information on the process(es) and on the plans for responding to potential emergency situations.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and performance evaluation

9.1.1 General

The organization shall establish, implement and maintain a process(es) for monitoring, measurement, analysis and performance evaluation.

The organization shall determine:

a) what needs to be monitored and measured, including:

1) the extent to which legal requirements and other requirements are fulfilled;

2) its activities and operations related to identified hazards, risks and opportunities;

3) progress towards achievement of the organization's OH&S objectives;

4) effectiveness of operational and other controls;

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

c) the criteria against which the organization will evaluate its OH&S performance;

d) when the monitoring and measuring shall be performed;

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

The organization shall evaluate the OH&S performance and determine the effectiveness of the OH&S management system.

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

NOTE There can be legal requirements or other requirements (e.g. national or international standards) concerning the calibration or verification of monitoring and measuring equipment.

The organization shall retain appropriate documented information:

— as evidence of the results of monitoring, measurement, analysis and performance evaluation;

— on the maintenance, calibration or verification of measuring equipment.

9.1.2 Evaluation of compliance

The organization shall establish, implement and maintain a process(es) for evaluating compliance with legal requirements and other requirements (see 6.1.3).

The organization shall:

a) determine the frequency and method(s) for the evaluation of compliance;

b) evaluate compliance and take action if needed (see 10.2);

c) maintain knowledge and understanding of its compliance status with legal requirements and other requirements;

d) retain documented information 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 OH&S management system:

a) conforms to:

1) the organization's own requirements for its OH&S management system, including the OH&S policy and OH&S objectives;

2) the requirements of this document;

b) is effectively implemented and maintained.

9.2.2 Internal audit programme

The organization shall:

a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, consultation, planning requirements and reporting, which shall take into consideration the importance of the processes concerned and the results of previous audits;

b) define the audit criteria and scope for each audit;

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

d) ensure that the results of the audits are reported to relevant managers; ensure that relevant audit results are reported to workers, and, where they exist, workers' representatives, and other relevant interested parties;

e) take action to address nonconformities and continually improve its OH&S performance (see Clause 10);

f) retain documented information as evidence of the implementation of the audit programme and the audit results.

NOTE For more information on auditing and the competence of auditors, see ISO 19011.

9.3 Management review

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

The management review shall include consideration of:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the OH&S management system, including:

   1) the needs and expectations of interested parties;

   2) legal requirements and other requirements;

   3) risks and opportunities;

c) the extent to which the OH&S policy and the OH&S objectives have been met;

d) information on the OH&S performance, including trends in:

   1) incidents, nonconformities, corrective actions and continual improvement;

   2) monitoring and measurement results;

   3) results of evaluation of compliance with legal requirements and other requirements;

   4) audit results;

   5) consultation and participation of workers;

   6) risks and opportunities;

e) adequacy of resources for maintaining an effective OH&S management system;

f) relevant communication(s) with interested parties;

g) opportunities for continual improvement.

The outputs of the management review shall include decisions related to:

— the continuing suitability, adequacy and effectiveness of the OH&S management system in achieving its intended outcomes;

— continual improvement opportunities;

— any need for changes to the OH&S management system;

— resources needed;

— actions, if needed;

— opportunities to improve integration of the OH&S management system with other business processes;

— any implications for the strategic direction of the organization.

Top management shall communicate the relevant outputs of management reviews to workers, and, where they exist, workers' representatives (see 7.4).

The organization shall retain documented information as evidence of the results of management reviews.

10 Improvement

10.1 General

The organization shall determine opportunities for improvement (see Clause 9) and implement necessary actions to achieve the intended outcomes of its OH&S management system.

10.2 Incident, nonconformity and corrective action

The organization shall establish, implement and maintain a process(es), including reporting, investigating and taking action, to determine and manage incidents and nonconformities.

When an incident or a nonconformity occurs, the organization shall:

a) react in a timely manner to the incident or nonconformity and, as applicable:

   1) take action to control and correct it;

   2) deal with the consequences;

b) evaluate, with the participation of workers (see 5.4) and the involvement of other relevant interested parties, the need for corrective action to eliminate the root cause(s) of the incident or nonconformity, in order that it does not recur or occur elsewhere, by:

   1) investigating the incident or reviewing the nonconformity;

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

   3) determining if similar incidents have occurred, if nonconformities exist, or if they could potentially occur;

c) review existing assessments of OH&S risks and other risks, as appropriate (see 6.1);

d) determine and implement any action needed, including corrective action, in accordance with the hierarchy of controls (see 8.1.2) and the management of change (see 8.1.3);

e) assess OH&S risks that relate to new or changed hazards, prior to taking action;

f) review the effectiveness of any action taken, including corrective action;

g) make changes to the OH&S management system, if necessary.

Corrective actions shall be appropriate to the effects or potential effects of the incidents or nonconformities encountered.

The organization shall retain documented information as evidence of:

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

— the results of any action and corrective action, including their effectiveness.

The organization shall communicate this documented information to relevant workers, and, where they exist, workers' representatives, and other relevant interested parties.

NOTE The reporting and investigation of incidents without undue delay can enable hazards to be eliminated and associated OH&S risks to be minimized as soon as possible.

10.3 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the OH&S management system, by:

a) enhancing OH&S performance;

b) promoting a culture that supports an OH&S management system;

c) promoting the participation of workers in implementing actions for the continual improvement of the OH&S management system;

d) communicating the relevant results of continual improvement to workers, and, where they exist, workers' representatives;

e) maintaining and retaining documented information as evidence of continual improvement.

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.

The requirements in this document need to be viewed from a systems perspective and should not be taken in isolation, i.e. there can be an interrelationship between the requirements in one clause with the requirements in other clauses.

A.2 Normative references

There are no normative references in this document. Users can refer to the documents listed in the Bibliography for further information on OH&S guidelines and other ISO management system standards.

A.3 Terms and definitions

In addition to the terms and definitions given in Clause 3, and in order to avoid misunderstanding, clarifications of selected concepts are provided below.

a) "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 in the context of improvement.

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

c) 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 shall be done.

d) This document uses the term "interested party"; the term "stakeholder" is a synonym as it represents the same concept.

e) The word "ensure" means the responsibility can be delegated, but not the accountability to make sure that an action is performed.

f) "Documented information" is used to include both documents and records. This document uses the phrase "retain documented information as evidence of..." to mean records, and "shall be maintained as documented information" to mean documents, including procedures. The phrase "to retain documented information as evidence of..." is not intended to require that the information retained will meet legal evidentiary requirements. Instead, it is intended to define the type of records that need to be retained.

g) Activities that are "under the shared control of the organization" are activities for which the organization shares control over the means or methods, or shares direction of the work performed with respect to its OH&S performance, consistent with its legal requirements and other requirements.

Organizations can be subject to requirements related to the OH&S management system that mandate the use of specific terms and their meaning. If these other terms are used, conformity to this document is still required.

A.4 Context of the organization

A.4.1 Understanding the organization and its context

An understanding of the context of an organization is used to establish, implement, maintain and continually improve its OH&S management system. Internal and external issues can be positive or negative and include conditions, characteristics or changing circumstances that can affect the OH&S management system, for example:

a) external issues, such as:

   1) the cultural, social, political, legal, financial, technological, economic and natural surroundings and market competition, whether international, national, regional or local;

   2) introduction of new competitors, contractors, subcontractors, suppliers, partners and providers, new technologies, new laws and the emergence of new occupations;

   3) new knowledge on products and their effect on health and safety;

   4) key drivers and trends relevant to the industry or sector having impact on the organization;

   5) relationships with, as well as perceptions and values of, its external interested parties;

   6) changes in relation to any of the above;

b) internal issues, such as:

   1) governance, organizational structure, roles and accountabilities;

   2) policies, objectives and the strategies that are in place to achieve them;

   3) the capabilities, understood in terms of resources, knowledge and competence (e.g. capital, time, human resources, processes, systems and technologies);

   4) information systems, information flows and decision-making processes (both formal and informal);

   5) introduction of new products, materials, services, tools, software, premises and equipment;

   6) relationships with, as well as perceptions and values of, workers;

   7) the culture in the organization;

   8) standards, guidelines and models adopted by the organization;

   9) the form and extent of contractual relationships, including, for example, outsourced activities;

   10) working time arrangements;

   11) working conditions;

   12) changes in relation to any of the above.

A.4.2 Understanding the needs and expectations of workers and other interested parties

Interested parties, in addition to workers, can include:

a) legal and regulatory authorities (local, regional, state/provincial, national or international);

b) parent organizations;

c) suppliers, contractors and subcontractors;

d) workers' representatives;

e) workers' organizations (trade unions) and employers' organizations;

f) owners, shareholders, clients, visitors, local community and neighbours of the organization and the general public;

g) customers, medical and other community services, media, academia, business associations and non-governmental organizations (NGOs);

h) occupational health and safety organizations, occupational safety and health-care professionals.

Some needs and expectations are mandatory, for example, because they have been incorporated into laws and regulations. The organization may also decide to voluntarily agree to, or adopt, other needs and expectations (e.g. subscribing to a voluntary initiative). Once the organization adopts them, they are addressed when planning and establishing the OH&S management system.

A.4.3 Determining the scope of the OH&S management system

An organization has the freedom and flexibility to define the boundaries and applicability of the OH&S management system. The boundaries and applicability may include the whole organization, or a specific part(s) of the organization, provided that the top management of that part of the organization has its own functions, responsibilities and authorities for establishing an OH&S management system.

The credibility of the organization's OH&S management system will depend upon the choice of the boundaries. The scope should not be used to exclude activities, products and services that have or can impact the organization's OH&S performance, or to evade its legal requirements and other requirements. The scope is a factual and representative statement of the organization's operations included within its OH&S management system boundaries that should not mislead interested parties.

A.4.4 OH&S management system

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

a) establishes one or more processes to have confidence that they are controlled, carried out as planned and achieve the intended outcomes of the OH&S management system;

b) integrates requirements of the OH&S management system into its various business processes (e.g. design and development, procurement, human resources, sales and marketing).

If this document is implemented for a specific part(s) of an organization, the policies and processes developed by other parts of the organization can be used to meet the requirements of this document, provided that they are applicable to the specific part(s) that will be subject to them and that they conform to the requirements of this document. Examples include corporate OH&S policies, education, training and competency programmes, and procurement controls.

A.5 Leadership and worker participation

A.5.1 Leadership and commitment

Leadership and commitment from the organization's top management, including awareness, responsiveness, active support and feedback, are critical for the success of the OH&S management system and achievement of its intended outcomes; therefore, top management has specific responsibilities for which they need to be personally involved or which they need to direct.

A culture that supports an organization's OH&S management system is largely determined by top management and is the product of individual and group values, attitudes, managerial practices, perceptions, competencies and patterns of activities that determine the commitment to, and the style and proficiency of, its OH&S management system. It is characterized by, but not limited to, active participation of workers, cooperation and communications founded on mutual trust, shared perceptions of the importance of the OH&S management system by active involvement in detection of OH&S opportunities and confidence in the effectiveness of preventive and protective measures. An important way top management demonstrates leadership is by encouraging workers to report incidents, hazards, risks and opportunities and by protecting workers against reprisals, such as the threat of dismissal or disciplinary action, when they do so.

A.5.2 OH&S policy

The OH&S policy is a set of principles stated as commitments in which top management outlines the long-term direction of the organization to support and continually improve its OH&S performance. The OH&S policy provides an overall sense of direction, as well as a framework for the organization to set its objectives and take actions to achieve the intended outcomes of the OH&S management system.

These commitments are then reflected in the processes an organization establishes to ensure a robust, credible and reliable OH&S management system (including addressing the specific requirements in this document).

The term "minimize" is used in relation to OH&S risks to set out the organization's aspirations for its OH&S management system. The term "reduce" is used to describe the process to achieve this.

In developing its OH&S policy, an organization should consider its consistency and coordination with other policies.

A.5.3 Organizational roles, responsibilities and authorities

Those involved in the organization's OH&S management system should have a clear understanding of their role, responsibility(ies) and authority(ies) for achieving the intended outcomes of the OH&S management system.

While top management has overall responsibility and authority for the OH&S management system, every person in the workplace needs to take account not only of their own health and safety, but also the health and safety of others.

Top management being accountable means being answerable for decisions and activities to the organization's governing bodies, legal authorities and, more broadly, its interested parties. It means having ultimate responsibility and relates to the person who is held to account if something is not done, is not done properly, does not work or fails to achieve its objective.

Workers should be enabled to report about hazardous situations so that action can be taken. They should be able to report concerns to responsible authorities as required, without the threat of dismissal, disciplinary action or other such reprisals.

The specific roles and responsibilities identified in 5.3 may be assigned to an individual, shared by several individuals, or assigned to a member of top management.

A.5.4 Consultation and participation of workers

The consultation and participation of workers, and, where they exist, workers' representatives, can be key factors of success for an OH&S management system and should be encouraged through the processes established by the organization.

Consultation implies a two-way communication involving dialogue and exchanges. Consultation involves the timely provision of the information necessary for workers, and, where they exist, workers' representatives, to give informed feedback to be considered by the organization before making a decision.

Participation enables workers to contribute to decision-making processes on OH&S performance measures and proposed changes.

Feedback on the OH&S management system is dependent upon worker participation. The organization should ensure workers at all levels are encouraged to report hazardous situations, so that preventive measures can be put in place and corrective action taken.

The reception of suggestions will be more effective if workers do not fear the threat of dismissal, disciplinary action or other such reprisals when making them.

A.6 Planning

A.6.1 Actions to address risks and opportunities

A.6.1.1 General

Planning is not a single event, but an ongoing process, anticipating changing circumstances and continually determining risks and opportunities, both for the workers and for the OH&S management system.

Undesired effects can include work-related injury and ill health, noncompliance with legal requirements and other requirements, or damage to reputation.

Planning considers the relationships and interactions between the activities and requirements for the management system as a whole.

OH&S opportunities address the identification of hazards, how they are communicated, and the analysis and mitigation of known hazards. Other opportunities address system improvement strategies.

Examples of opportunities to improve OH&S performance:

a) inspection and auditing functions;

b) job hazard analysis (job safety analysis) and task-related assessments;

c) improving OH&S performance by alleviating monotonous work or work at a potentially hazardous pre-determined work rate;

d) permit to work and other recognition and control methods;

e) incident or nonconformity investigations and corrective actions;

f) ergonomic and other injury prevention-related assessments.

Examples of other opportunities to improve OH&S performance:

— integrating occupational health and safety requirements at the earliest stage in the life cycle of facilities, equipment or process planning for facilities relocation, process re-design or replacement of machinery and plant;

— integrating occupational health and safety requirements at the earliest stage of planning for facilities relocation, process re-design or replacement of machinery and plant;

— using new technologies to improve OH&S performance;

— improving the occupational health and safety culture, such as by extending competence related to occupational health and safety beyond requirements or encouraging workers to report incidents in a timely manner;

— improving the visibility of top management's support for the OH&S management system;

— enhancing the incident investigation process(es);

— improving the process(es) for worker consultation and participation;

— benchmarking, including consideration of both the organization's own past performance and that of other organizations;

— collaborating in forums that focus on topics dealing with occupational health and safety.

A.6.1.2 Hazard identification and assessment of risks and opportunities

A.6.1.2.1 Hazard identification

The ongoing proactive identification of hazard begins at the conceptual design stage of any new workplace, facility, product or organization. It should continue as the design is detailed and then comes into operation, as well as being ongoing during its full life cycle to reflect current, changing and future activities.

While this document does not address product safety (i.e. safety to end-users of products), hazards to workers occurring during manufacture, construction, assembly or testing of products should be considered.

Hazard identification helps the organization recognize and understand the hazards in the workplace and to workers, in order to assess, prioritize and eliminate hazards or reduce OH&S risks.

Hazards can be physical, chemical, biological, psychosocial, mechanical, electrical or based on movement and energy.

The list given in 6.1.2.1 is not exhaustive.

NOTE The numbering of the following list items a) to l) does not correspond exactly to the numbering of the list items given in 6.1.2.1.

The organization's hazard identification process(es) should consider:

a) routine and non-routine activities and situations:

   1) routine activities and situations create hazards through day-to-day operations and normal work activities;

   2) non-routine activities and situations are occasional or unplanned;

   3) short-term or long-term activities can create different hazards;

b) human factors:

   1) relate to human capabilities, limitations and other characteristics;

   2) information should be applied to tools, machines, systems, activities and environment for safe, comfortable human use;

3) should address three aspects: the activity, the worker and the organization, and how these interact with and impact on occupational health and safety;

c) new or changed hazards:

1) can arise when work processes are deteriorated, modified, adapted or evolved as a result of familiarity or changing circumstances;

2) understanding how work is actually performed (e.g. observing and discussing hazards with workers) can identify if OH&S risks are increased or reduced;

d) potential emergency situations:

1) unplanned or unscheduled situations that require an immediate response (e.g. a machine catching fire in the workplace, or a natural disaster in the vicinity of the workplace or at another location where workers are performing work-related activities);

2) include situations such as civil unrest at a location at which workers are performing work-related activities which requires their urgent evacuation;

e) people:

1) those in the vicinity of the workplace who could be affected by the activities of the organization (e.g. passers-by, contractors or immediate neighbours);

2) workers at a location not under the direct control of the organization, such as mobile workers or workers who travel to perform work-related activities at another location (e.g. postal workers, bus drivers, service personnel travelling to and working at a customer's site);

3) home-based workers, or those who work alone;

f) changes in knowledge of, and information about, hazards.

1) sources of knowledge, information and new understanding about hazards can include published literature, research and development, feedback from workers, and review of the organization's own operational experience;

2) these sources can provide new information about the hazards and OH&S risks.

A.6.1.2.2 Assessment of OH&S risks and other risks to the OH&S management system

An organization can use different methods to assess OH&S risks as part of its overall strategy for addressing different hazards or activities. The method and complexity of assessment does not depend on the size of the organization, but on the hazards associated with the activities of the organization.

Other risks to the OH&S management system should also be assessed using appropriate methods.

Processes for the assessment of risk to the OH&S management system should consider day-to-day operations and decisions (e.g. peaks in work flow, restructuring) as well as external issues (e.g. economic change). Methodologies can include ongoing consultation of workers affected by day-to-day activities (e.g. changes in work load), monitoring and communication of new legal requirements and other requirements (e.g. regulatory reform, revisions to collective agreements regarding occupational health and safety), and ensuring resources meet existing and changing needs (e.g. training on, or procurement of, new improved equipment or supplies).

A.6.1.2.3 Assessment of OH&S opportunities and other opportunities for the OH&S management system

The process for assessment should consider the OH&S opportunities and other opportunities determined, their benefits and potential to improve OH&S performance.

A.6.1.3 Determination of legal requirements and other requirements

a) Legal requirements can include:

   1) legislation (national, regional or international), including statutes and regulations;

   2) decrees and directives;

   3) orders issued by regulators;

   4) permits, licences or other forms of authorization;

   5) judgments of courts or administrative tribunals;

   6) treaties, conventions, protocols;

   7) collective bargaining agreements.

b) Other requirements can include:

   1) the organization's requirements;

   2) contractual conditions;

   3) employment agreements;

   4) agreements with interested parties;

   5) agreements with health authorities;

   6) non-regulatory standards, consensus standards and guidelines;

   7) voluntary principles, codes of practice, technical specifications, charters;

   8) public commitments of the organization or its parent organization.

A.6.1.4 Planning action

The actions planned should primarily be managed through the OH&S management system and should involve integration with other business processes, such as those established for the management of the environment, quality, business continuity, risk, financial or human resources. The implementation of the actions taken is expected to achieve the intended outcomes of the OH&S management system.

When the assessment of OH&S risks and other risks has identified the need for controls, the planning activity determines how these are implemented in operation (see Clause 8); for example, determining whether to incorporate these controls into work instructions or into actions to improve competence. Other controls can take the form of measuring or monitoring (see Clause 9).

Actions to address risks and opportunities should also be considered under the management of change (see 8.1.3) to ensure there are no resulting unintended consequences.

A.6.2 OH&S objectives and planning to achieve them

A.6.2.1 OH&S objectives

Objectives are established to maintain and improve OH&S performance. The objectives should be linked to risks and opportunities and performance criteria which the organization has identified as being necessary for the achievement of the intended outcomes of the OH&S management system.

OH&S objectives can be integrated with other business objectives and should be set at relevant functions and levels. Objectives can be strategic, tactical or operational:

a) strategic objectives can be set to improve the overall performance of the OH&S management system (e.g. to eliminate noise exposure);

b) tactical objectives can be set at facility, project or process level (e.g. to reduce noise at source);

c) operational objectives can be set at the activity level (e.g. the enclosure of individual machines to reduce noise).

The measurement of OH&S objectives can be qualitative or quantitative. Qualitative measures can be approximations, such as those obtained from surveys, interviews and observations. The organization is not required to establish OH&S objectives for every risk and opportunity it determines.

A.6.2.2 Planning to achieve OH&S objectives

The organization can plan to achieve objectives individually or collectively. Plans can be developed for multiple objectives where necessary.

The organization should examine the resources required (e.g. financial, human, equipment, infrastructure) to achieve its objectives.

When practicable, each objective should be associated with an indicator which can be strategic, tactical or operational.

A.7 Support

A.7.1 Resources

Examples of resources include human, natural, infrastructure, technology and financial.

Examples of infrastructure include the organization's buildings, plant, equipment, utilities, information technology and communications systems, and emergency containment systems.

A.7.2 Competence

The competence of workers should include the knowledge and skills needed to appropriately identify the hazards and deal with the OH&S risks associated with their work and workplace.

In determining the competence for each role, the organization should take into account things such as:

a) the education, training, qualification and experience necessary to undertake the role and the re-training necessary to maintain competence;

b) the work environment;

c) the preventive and control measures resulting from the risk assessment process(es);

d) the requirements applicable to the OH&S management system;

e) legal requirements and other requirements;

f) the OH&S policy;

g) the potential consequences of compliance and noncompliance, including the impact on the worker's health and safety;

h) the value of participation of workers in the OH&S management system based on their knowledge and skill;

i) the duties and responsibilities associated with the roles;

j) individual capabilities, including experience, language skills, literacy and diversity;

k) the relevant updating of the competence made necessary by context or work changes.

Workers can assist the organization in determining the competence needed for roles.

Workers should have the necessary competence to remove themselves from situations of imminent and serious danger. For this purpose, it is important that workers are provided with sufficient training on hazards and risks associated with their work.

As appropriate, workers should receive the training required to enable them to carry out their representative functions for occupational health and safety effectively.

In many countries, it is a legal requirement to provide training at no cost to workers.

A.7.3 Awareness

In addition to workers (especially temporary workers), contractors, visitors and any other parties should be aware of the OH&S risks to which they are exposed.

A.7.4 Communication

The communication process(es) established by the organization should provide for the gathering, updating and dissemination of information. It should ensure that relevant information is provided, is received and is understandable to all relevant workers and interested parties.

A.7.5 Documented information

It is important to keep the complexity of the documented information at the minimum level possible to ensure effectiveness, efficiency and simplicity at the same time.

This should include documented information regarding planning to address legal requirements and other requirements and on evaluations of the effectiveness of these actions.

The actions described in 7.5.3 are particularly aimed at preventing unintended use of obsolete documented information.

Examples of confidential information include personal and medical information.

A.8 Operation

A.8.1 Operational planning and control

A.8.1.1 General

Operational planning and control of the processes need to be established and implemented as necessary to enhance occupational health and safety, by eliminating hazards or, if not practicable, by reducing the OH&S risks to levels as low as reasonably practicable for operational areas and activities.

Examples of operational control of the processes include:

a) the use of procedures and systems of work;

b) ensuring the competence of workers;

c) establishing preventive or predictive maintenance and inspection programmes;

d) specifications for the procurement of goods and services;

e) application of legal requirements and other requirements, or manufacturers' instructions for equipment;

f) engineering and administrative controls;

g) adapting work to workers; for example, by:

   1) defining, or redefining, how the work is organized;

   2) the induction of new workers;

   3) defining, or redefining, processes and working environments;

   4) using ergonomic approaches when designing new, or modifying, workplaces, equipment, etc.

A.8.1.2 Eliminating hazards and reducing OH&S risks

The hierarchy of controls is intended to provide a systematic approach to enhance occupational health and safety, eliminate hazards, and reduce or control OH&S risks. Each control is considered less effective than the one before it. It is usual to combine several controls in order to succeed in reducing the OH&S risks to a level that is as low as reasonably practicable.

The following examples are given to illustrate measures that can be implemented at each level.

a) Elimination: removing the hazard; stopping using hazardous chemicals; applying ergonomics approaches when planning new workplaces; eliminating monotonous work or work that causes negative stress; removing fork-lift trucks from an area.

b) Substitution: replacing the hazardous with less hazardous; changing to answering customer complaints with online guidance; combating OH&S risks at source; adapting to technical progress (e.g. replacing solvent-based paint by water-based paint; changing slippery floor material; lowering voltage requirements for equipment).

c) Engineering controls, reorganization of work, or both: isolating people from hazard; implementing collective protective measures (e.g. isolation, machine guarding, ventilation systems); addressing mechanical handling; reducing noise; protecting against falls from height by using guard rails; reorganizing work to avoid people working alone, unhealthy work hours and workload, or to prevent victimization.

d) Administrative controls including training: conducting periodic safety equipment inspections; conducting training to prevent bullying and harassment; managing health and safety coordination with subcontractors' activities; conducting induction training; administrating forklift driving licences; providing instructions on how to report incidents, nonconformities and victimization without fear of retribution; changing the work patterns (e.g. shifts) of workers; managing a health or medical surveillance programme for workers who have been identified as at risk (e.g. related to hearing, hand-arm vibration, respiratory disorders, skin disorders or exposure); giving appropriate instructions to workers (e.g. entry control processes).

e) Personal protective equipment (PPE): providing adequate PPE, including clothing and instructions for PPE utilization and maintenance (e.g. safety shoes, safety glasses, hearing protection, gloves).

A.8.1.3 Management of change

The objective of a management of change process is to enhance occupational health and safety at work, by minimizing the introduction of new hazards and OH&S risks into the work environment as changes occur (e.g. with technology, equipment, facilities, work practices and procedures, design specifications, raw materials, staffing, standards or regulations). Depending on the nature of an expected change, the organization can use an appropriate methodology(ies) (e.g. design review) for assessing the OH&S risks and the OH&S opportunities of the change. The need to manage change can be an outcome of planning (see 6.1.4).

A.8.1.4 Procurement

A.8.1.4.1 General

The procurement process(es) should be used to determine, assess and eliminate hazards, and to reduce OH&S risks associated with, for example, products, hazardous materials or substances, raw materials, equipment, or services before their introduction into the workplace.

The organization's procurement process(es) should address requirements including, for example, supplies, equipment, raw materials, and other goods and related services purchased by the organization to conform to the organization's OH&S management system. The process should also address any needs for consultation (see 5.4) and communication (see 7.4).

The organization should verify that equipment, installations and materials are safe for use by workers by ensuring:

a) equipment is delivered according to specification and is tested to ensure it works as intended;

b) installations are commissioned to ensure they function as designed;

c) materials are delivered according to their specifications;

d) any usage requirements, precautions or other protective measures are communicated and made available.

A.8.1.4.2 Contractors

The need for coordination recognizes that some contractors (i.e. external providers) possess specialized knowledge, skills, methods and means.

Examples of contractor activities and operations include maintenance, construction, operations, security, cleaning and a number of other functions. Contractors can also include consultants or specialists in administrative, accounting and other functions. Assignment of activities to contractors does not eliminate the organization's responsibility for the occupational health and safety of workers.

An organization can achieve coordination of its contractors' activities through the use of contracts that clearly define the responsibilities of the parties involved. An organization can use a variety of tools for ensuring contractors' OH&S performance in the workplace (e.g. contract award mechanisms or pre-qualification criteria which consider past health and safety performance, safety training, or health and safety capabilities, as well as direct contract requirements).

When coordinating with contractors, the organization should give consideration to the reporting of hazards between itself and its contractors, controlling worker access to hazardous areas, and procedures to follow in emergencies. The organization should specify how the contractor will coordinate its activities with the organization's own OH&S management system processes (e.g. those used for controlling entry, for confined space entry, exposure assessment and process safety management) and for the reporting of incidents.

The organization should verify that contractors are capable of performing their tasks before being allowed to proceed with their work; for example, by verifying that:

a) OH&S performance records are satisfactory;

b) qualification, experience and competence criteria for workers are specified and have been met (e.g. through training);

c) resources, equipment and work preparations are adequate and ready for the work to proceed.

A.8.1.4.3 Outsourcing

When outsourcing, the organization needs to have control of the outsourced functions and process(es) to achieve the intended outcome(s) of the OH&S management system. In the outsourced functions and process(es), the responsibility for conforming to the requirements of this document is retained by the organization.

The organization should establish the extent of control over outsourced function(s) or process(es) based upon factors such as:

— the ability of the external organization to meet the organization's OH&S management system requirements;

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

— the potential effect the outsourced process or function will have on the organization's ability to achieve the intended outcome of its OH&S management system;

— the extent to which the outsourced process or function is shared;

— the capability of the organization to achieve the necessary control through the application of its procurement process;

— opportunities for improvement.

In some countries, legal requirements address outsourced functions or processes.

A.8.2 Emergency preparedness and response

Emergency preparedness plans can include natural, technical and man-made events that occur inside and outside normal working hours.

A.9 Performance evaluation

A.9.1 Monitoring, measurement, analysis and performance evaluation

A.9.1.1 General

In order to achieve the intended outcomes of the OH&S management system, the processes should be monitored, measured and analysed.

a) Examples of what could be monitored and measured can include, but are not limited to:

   1) occupational health complaints, health of workers (through surveillance) and work environment;

   2) work-related incidents, injuries and ill health, and complaints, including trends;

   3) the effectiveness of operational controls and emergency exercises, or the need to modify or introduce new controls;

   4) competence.

b) Examples of what could be monitored and measured to evaluate the fulfilment of legal requirements can include, but are not limited to:

   1) identified legal requirements (e.g. whether all legal requirements have been determined, and whether the organization's documented information of them is kept up-to-date);

   2) collective agreements (when legally binding);

3) the status of identified gaps in compliance.

c) Examples of what could be monitored and measured to evaluate the fulfilment of other requirements can include, but are not limited to:

1) collective agreements (when not legally binding);

2) standards and codes;

3) corporate and other policies, rules and regulations;

4) insurance requirements.

d) Criteria are what the organization can use to compare its performance against.

1) Examples are benchmarks against:

i) other organizations;

ii) standards and codes;

iii) the organization's own codes and objectives;

iv) OH&S statistics.

2) To measure criteria, indicators are typically used; for example:

i) if the criterion is a comparison of incidents, the organization may choose to look at frequency, type, severity or number of incidents; then the indicator could be the determined rate within each one of these criteria;

ii) if the criterion is a comparison of completions of corrective actions, then the indicator could be the percentage completed on time.

Monitoring can involve continual checking, supervising, critically observing or determining the status in order to identify change from the performance level required or expected. Monitoring can be applied to the OH&S management system, to processes or to controls. Examples include the use of interviews, reviews of documented information and observations of work being performed.

Measurement generally involves the assignment of numbers to objects or events. It is the basis for quantitative data and is generally associated with the performance evaluation of safety programmes and health surveillance. Examples include the use of calibrated or verified equipment to measure exposure to a hazardous substance or the calculation of the safe distance from a hazard.

Analysis is the process of examining data to reveal relationships, patterns and trends. This can mean the use of statistical operations, including information from other similar organizations, to help draw conclusions from the data. This process is most often associated with measurement activities.

Performance evaluation is an activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve the established objectives of the OH&S management system.

A.9.1.2 Evaluation of compliance

The frequency and timing of compliance evaluations can vary depending on the importance of the requirement, variations in operating conditions, changes in legal requirements and other requirements and the organization's past performance. An organization can use a variety of methods to maintain its knowledge and understanding of its compliance status.

A.9.2 Internal audit

The extent of the audit programme should be based on the complexity and level of maturity of the OH&S management system.

An organization can establish objectivity and impartiality of the internal audit by creating a process(es) that separates auditors' roles as internal auditors from their normal assigned duties, or the organization can also use external people for this function.

A.9.3 Management review

The terms used in relation to management review should be understood as follows:

a) "suitability" refers to how the OH&S management system fits the organization, its operation, its culture and business systems;

b) "adequacy" refers to whether the OH&S management system is implemented appropriately;

c) "effectiveness" refers to whether the OH&S management system is achieving the intended outcome.

The management review topics listed in 9.3 a) to g) need not be addressed all at once; the organization should determine when and how the management review topics are addressed.

A.10 Improvement

A.10.1 General

The organization should consider the results from analysis and evaluation of OH&S performance, evaluation of compliance, internal audits and management review when taking action to improve.

Examples of improvement include corrective action, continual improvement, breakthrough change, innovation and re-organization.

A.10.2 Incident, nonconformity and corrective action

Separate processes may exist for incident investigations and nonconformities reviews, or these may be combined as a single process, depending on the organization's requirements.

Examples of incidents, nonconformities and corrective actions can include, but are not limited to:

a) incidents: same level fall with or without injury; broken leg; asbestosis; hearing loss; damage to buildings or vehicles where they can lead to OH&S risks;

b) nonconformities: protective equipment not functioning properly; failure to fulfil legal requirements and other requirements; prescribed procedures not being followed;

c) corrective actions (as indicated by the hierarchy of controls; see 8.1.2): eliminating hazards; substituting with less hazardous materials; redesigning or modifying equipment or tools; developing procedures; improving the competence of affected workers; changing the frequency of use; using personal protective equipment.

Root cause analysis refers to the practice of exploring all the possible factors associated with an incident or nonconformity by asking what happened, how it happened and why it happened, to provide the input for what can be done to prevent it from happening again.

When determining the root cause of an incident or nonconformity, the organization should use methods appropriate to the nature of the incident or nonconformity being analysed. The focus of root cause analysis is prevention. This analysis can identify multiple contributory failures, including factors related to communication, competence, fatigue, equipment or procedures.

Reviewing the effectiveness of corrective actions [see 10.2 f)] refers to the extent to which the implemented corrective actions adequately control the root cause(s).

A.10.3 Continual improvement

Examples of continual improvement issues include, but are not limited to:

a) new technology;

b) good practices, both internal and external to the organization;

c) suggestions and recommendations from interested parties;

d) new knowledge and understanding of occupational health and safety-related issues;

e) new or improved materials;

f) changes in worker capabilities or competence;

g) achieving improved performance with fewer resources (i.e. simplification, streamlining, etc.).

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Alphabetical index of terms

INTERNATIONAL STANDARD

ISO 22000

Second edition
2018-06

Food safety management systems — Requirements for any organization in the food chain

Systèmes de management de la sécurité des denrées alimentaires — Exigences pour tout organisme appartenant à la chaîne alimentaire

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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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 34, *Food products*, Subcommittee SC 17, *Management systems for food safety*.

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.

This second edition cancels and replaces the first edition (ISO 22000:2005), which has been technically revised through the adoption of a revised clause sequence. It also incorporates the Technical Corrigendum ISO 22000:2005/Cor.1:2006.

The following annexes are included to provide the users of this document with further information:

— Annex A: cross references between the CODEX HACCP principles and this document;

— Annex B: cross reference between this document and ISO 22000:2005.

Introduction

0.1 General

The adoption of a food safety management system (FSMS) is a strategic decision for an organization that can help to improve its overall performance in food safety. The potential benefits to an organization of implementing a FSMS based on this document are:

a) the ability to consistently provide safe foods and products and services that meet customer and applicable statutory and regulatory requirements;

b) addressing risks associated with its objectives;

c) the ability to demonstrate conformity to specified FSMS requirements.

This document employs the process approach (see 0.3), which incorporates the Plan-Do-Check-Act (PDCA) cycle (see 0.3.2) and risk-based thinking (see 0.3.3).

This process approach enables an organization to plan its processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its FSMS to deviate from the planned results, and to put in place controls to prevent or minimize adverse effects.

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

"NOTES" provide guidance in understanding or clarifying the requirements in this document.

0.2 FSMS principles

Food safety is related to the presence of food safety hazards at the time of consumption (intake by the consumer). Food safety hazards can occur at any stage of the food chain. Therefore, adequate control throughout the food chain is essential. Food safety is ensured through the combined efforts of all the parties in the food chain. This document specifies the requirements for a FSMS that combines the following generally recognized key elements:

— interactive communication;

— system management;

— prerequisite programmes;

— hazard analysis and critical control point (HACCP) principles.

In addition, this document is based on the principles that are common to ISO management system standards. The management principles are:

— customer focus;

— leadership;

— engagement of people;

— process approach;

— improvement;

— evidence-based decision making;

— relationship management.

0.3 Process approach

0.3.1 General

This document adopts a process approach when developing and implementing a FSMS and improving its effectiveness to enhance production of safe products and services while meeting applicable requirements. Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the food safety policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle, with an overall focus on risk-based thinking aimed at taking advantage of opportunities and preventing undesirable results.

The recognition of the organization's role and position within the food chain is essential to ensure effective interactive communication throughout the food chain.

0.3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be described briefly as follows:

Plan: establish the objectives of the system and its processes, provide the resources needed to deliver the results, and identify and address risks and opportunities;

Do: implement what was planned;

Check: monitor and (where relevant) measure processes and the resulting products and services, analyse and evaluate information and data from monitoring, measuring and verification activities, and report the results;

Act: take actions to improve performance, as necessary.

In this document, and as illustrated in Figure 1, the process approach uses the concept of the PDCA cycle at two levels. The first covers the overall frame of the FSMS (Clause 4 to Clause 7 and Clause 9 to Clause 10). The other level (operational planning and control) covers the operational processes within the food safety system as described in Clause 8. Communication between the two levels is therefore essential.

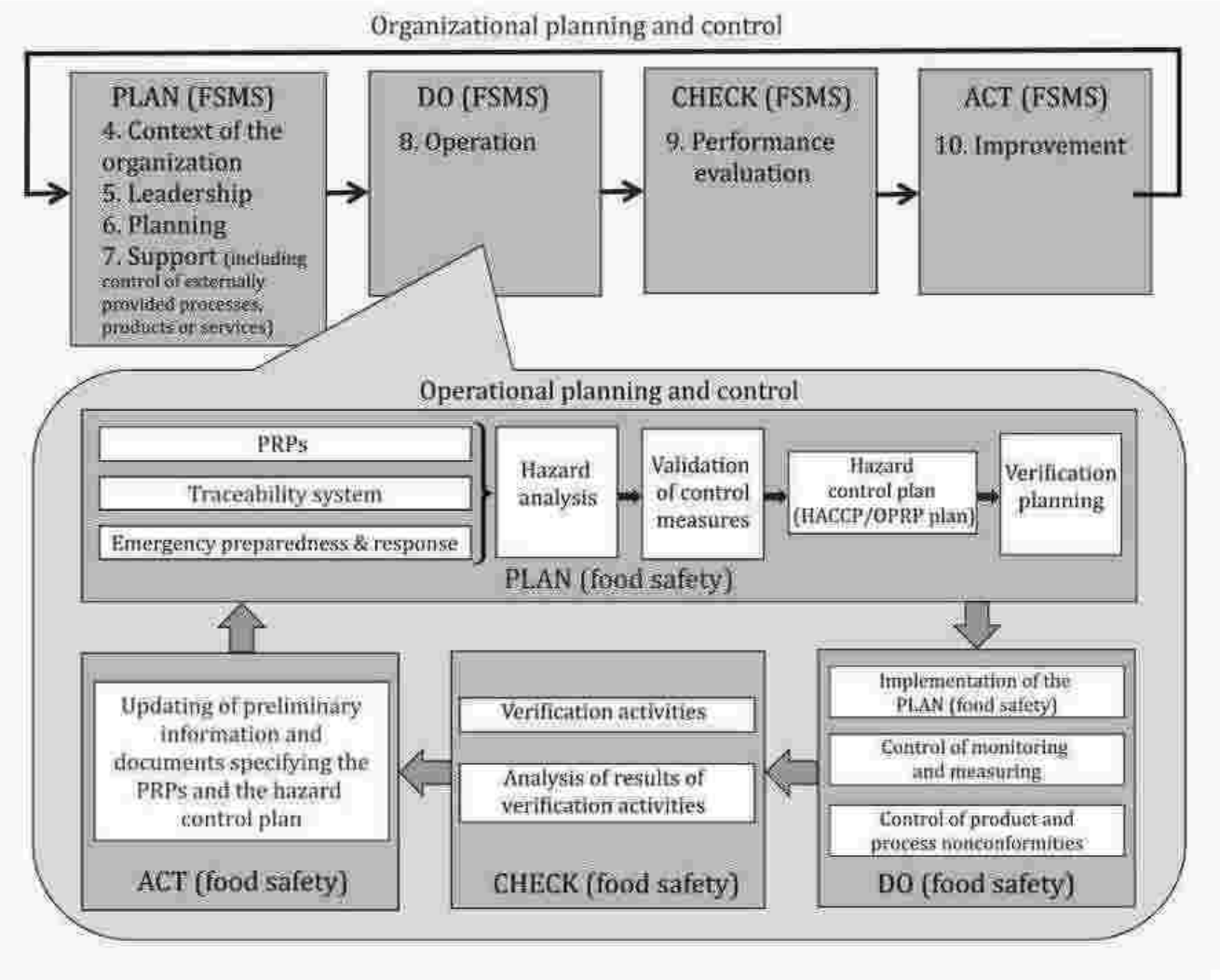

Figure 1 — Illustration of the Plan-Do-Check-Act cycle at the two levels

0.3.3 Risk-based thinking

0.3.3.1 General

Risk-based thinking is essential for achieving an effective FSMS. In this document, risk-based thinking is addressed on two levels, organizational (see 0.3.3.2) and operational (see 0.3.3.3), which is consistent with the process approach described in 0.3.2.

0.3.3.2 Organizational risk management

Risk is the effect of uncertainty, and any such uncertainty can have positive or negative effects. In the context of organizational risk management, a positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

To conform to the requirements of this document, an organization plans and implements actions to address organizational risks (Clause 6). Addressing risks establishes a basis for increasing the effectiveness of the FSMS, achieving improved results and preventing negative effects.

0.3.3.3 Hazard analysis — Operational processes

The concept of risk-based thinking based on the HACCP principles at the operational level is implicit in this document.

The subsequent steps in HACCP can be considered as the necessary measures to prevent hazards or reduce hazards to acceptable levels to ensure food is safe at the time of consumption (Clause 8).

Decisions taken in the application of HACCP should be based on science, free from bias and documented. The documentation should include any key assumptions in the decision-making process.

0.4 Relationship with other management system standards

This document has been developed within the ISO high level structure (HLS). The objective of the HLS is to improve alignment between ISO management system standards. This document enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its FSMS approach with the requirements of other management systems and supporting standards.

This document is the core principle and framework for FSMSs and sets out the specific FSMS requirements for organizations throughout the food chain. Other guidance related to food safety, specifications and/or requirements specific to food sectors can be used together with this framework.

In addition, ISO has developed a family of associated documents. These include documents for:

— prerequisite programmes (ISO/TS 22002 series) for specific sectors of the food chain;

— requirements for auditing and certification bodies;

— traceability.

ISO also provides guidance documents for organizations on how to implement this document and related standards. Information is available on the ISO website.

Food safety management systems — Requirements for any organization in the food chain

1 Scope

This document specifies requirements for a food safety management system (FSMS) to enable an organization that is directly or indirectly involved in the food chain:

a) to plan, implement, operate, maintain and update a FSMS providing products and services that are safe, in accordance with their intended use;

b) to demonstrate compliance with applicable statutory and regulatory food safety requirements;

c) to evaluate and assess mutually agreed customer food safety requirements and to demonstrate conformity with them;

d) to effectively communicate food safety issues to interested parties within the food chain;

e) to ensure that the organization conforms to its stated food safety policy;

f) to demonstrate conformity to relevant interested parties;

g) to seek certification or registration of its FSMS by an external organization, or make a self-assessment or self-declaration of conformity to this document.

All requirements of this document are generic and are intended to be applicable to all organizations in the food chain, regardless of size and complexity. Organizations that are directly or indirectly involved include, but are not limited to, feed producers, animal food producers, harvesters of wild plants and animals, farmers, producers of ingredients, food manufacturers, retailers, and organizations providing food services, catering services, cleaning and sanitation services, transportation, storage and distribution services, suppliers of equipment, cleaning and disinfectants, packaging materials and other food contact materials.

This document allows any organization, including small and/or less developed organizations (e.g. a small farm, a small packer-distributor, a small retail or food service outlet) to implement externally-developed elements in their FSMS.

Internal and/or external resources can be used to meet the requirements of this document.

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 terminological databases for use in standardization at the following addresses:

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

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

3.1
acceptable level
level of a *food safety hazard* (3.22) not to be exceeded in the *end product* (3.15) provided by the *organization* (3.31)

3.2
action criterion
measurable or observable specification for the *monitoring* (3.27) of an *OPRP* (3.30)

Note 1 to entry: An action criterion is established to determine whether an OPRP remains in control, and distinguishes between what is acceptable (criterion met or achieved means the OPRP is operating as intended) and unacceptable (criterion not met nor achieved means the OPRP is not operating as intended).

3.3
audit
systematic, independent and documented *process* (3.36) for obtaining audit 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 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: Relevant disciplines are, for example, food safety management, quality management or environmental management.

3.4
competence
ability to apply knowledge and skills to achieve intended results

3.5
conformity
fulfilment of a *requirement* (3.38)

3.6
contamination
introduction or occurrence of a contaminant including a *food safety hazard* (3.22) in a *product* (3.37) or processing environment

3.7
continual improvement
recurring activity to enhance *performance* (3.33)

3.8
control measure
action or activity that is essential to prevent a significant *food safety hazard* (3.22) or reduce it to an *acceptable level* (3.1)

Note 1 to entry: See also *significant food safety hazard* (3.40).

Note 2 to entry: Control measure(s) is (are) identified by hazard analysis.

3.9
correction
action to eliminate a detected *nonconformity* (3.28)

Note 1 to entry: A correction includes the handling of potentially unsafe products and can therefore be made in conjunction with a *corrective action* (3.10).

Note 2 to entry: A correction may be, for example, reprocessing, further processing and/or elimination of the adverse consequences of the nonconformity (such as disposal for other use or specific labelling).

3.10
corrective action
action to eliminate the cause of a *nonconformity* (3.28) and to prevent recurrence

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action includes cause analysis.

3.11
critical control point
CCP
step in the *process* (3.36) at which *control measure(s)* (3.8) is (are) applied to prevent or reduce a *significant food safety hazard* (3.40) to an acceptable level, and defined *critical limit(s)* (3.12) and *measurement* (3.26) enable the application of *corrections* (3.9)

3.12
critical limit
measurable value which separates acceptability from unacceptability

Note 1 to entry: Critical limits are established to determine whether a *CCP* (3.11) remains in control. If a critical limit is exceeded or not met, the products affected are to be handled as potentially unsafe products.

[SOURCE: CAC/RCP 1-1969, modified — The definition has been modified and Note 1 to entry has been added.]

3.13
documented information
information required to be controlled and maintained by an *organization* (3.31) 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 (3.25), including related processes (3.36);

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

— evidence of results achieved (records).

3.14
effectiveness
extent to which planned activities are realized and planned results achieved

3.15
end product
product (3.37) that will undergo no further processing or transformation by the *organization* (3.31)

Note 1 to entry: A product that undergoes further processing or transformation by another organization is an end product in the context of the first organization and a raw material or an ingredient in the context of the second organization.

3.16
feed
single or multiple product(s), whether processed, semi-processed or raw, which is (are) intended to be fed to food-producing animals

Note 1 to entry: Distinctions are made in this document between the terms *food* (3.18), *feed* (3.16) and *animal food* (3.19):

— food is intended for consumption by humans and animals, and includes feed and animal food;

— feed is intended to be fed to food-producing animals;

— animal food is intended to be fed to non-food-producing animals, such as pets.

[SOURCE: CAC/GL 81-2013, modified — The word “materials” has been changed to “products” and “directly” has been deleted.]

3.17
flow diagram
schematic and systematic presentation of the sequence and interactions of steps in the process

3.18
food
substance (ingredient), whether processed, semi-processed or raw, which is intended for consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances (ingredients) used only as drugs

Note 1 to entry: Distinctions are made in this document between the terms *food* (3.18), *feed* (3.16) and *animal food* (3.19):

— food is intended for consumption by humans and animals, and includes feed and animal food**;**

— feed is intended to be fed to food-producing animals;

— animal food is intended to be fed to non-food-producing animals, such as pets.

[SOURCE: CAC/GL 81-2013, modified — The word “human” has been deleted.]

3.19
animal food
single or multiple product(s), whether processed, semi-processed or raw, which is (are) intended to be fed to non-food-producing animals

Note 1 to entry: Distinctions are made in this document between the terms *food* (3.18), *feed* (3.16) and *animal food* (3.19):

— food is intended for consumption by humans and animals, and includes feed and animal food**;**

— feed is intended to be fed to food-producing animals;

— animal food is intended to be fed to non-food-producing animals, such as pets.

[SOURCE: CAC/GL 81-2013, modified — The word “materials” has been changed to “products”, “non” has been added and “directly” has been deleted.]

3.20
food chain
sequence of the stages in the production, processing, distribution, storage and handling of a *food* (3.18) and its ingredients, from primary production to consumption

Note 1 to entry: This includes the production of *feed* (3.16) and *animal food* (3.19).

Note 2 to entry: The food chain also includes the production of materials intended to come into contact with food or raw materials.

Note 3 to entry: The food chain also includes service providers.

3.21
food safety
assurance that food will not cause an adverse health effect for the consumer when it is prepared and/or consumed in accordance with its intended use

Note 1 to entry: Food safety is related to the occurrence of *food safety hazards* (3.22) in *end products* (3.15) and does not include other health aspects related to, for example, malnutrition.

Note 2 to entry: It is not to be confused with the availability of, and access to, food ("food security").

Note 3 to entry: This includes feed and animal food.

[SOURCE: CAC/RCP 1-1969, modified — The word "harm" has been changed to "adverse health effect" and notes to entry have been added.]

3.22
food safety hazard
biological, chemical or physical agent in *food* (3.18) with the potential to cause an adverse health effect

Note 1 to entry: The term "hazard" is not to be confused with the term "*risk*" (3.39) which, in the context of food safety, means a function of the probability of an adverse health effect (e.g. becoming diseased) and the severity of that effect (e.g. death, hospitalization) when exposed to a specified hazard.

Note 2 to entry: Food safety hazards include allergens and radiological substances.

Note 3 to entry: In the context of feed and feed ingredients, relevant food safety hazards are those that can be present in and/or on feed and feed ingredients and that can through animal consumption of feed be transferred to food and can thus have the potential to cause an adverse health effect for the animal or the human consumer. In the context of operations other than those directly handling feed and food (e.g. producers of packaging materials, disinfectants), relevant food safety hazards are those hazards that can be directly or indirectly transferred to food when used as intended (see 8.5.1.4).

Note 4 to entry: In the context of animal food, relevant food safety hazards are those that are hazardous to the animal species for which the food is intended.

[SOURCE: CAC/RCP 1-1969, modified — The phrase "or condition of" has been deleted from the definition and notes to entry have been added.]

3.23
interested party (preferred term)
stakeholder (admitted term)
person or *organization* (3.31) that can affect, be affected by, or perceive itself to be affected by a decision or activity

3.24
lot
defined quantity of a *product* (3.37) produced and/or processed and/or packaged essentially under the same conditions

Note 1 to entry: The lot is determined by parameters established beforehand by the organization and may be described by other terms, e.g. batch.

Note 2 to entry: The lot may be reduced to a single unit of product.

[SOURCE: CODEX STAN 1, modified — Reference to "and/or processed and/or packaged" has been included in the definition and notes to entry have been added.]

3.25
management system
set of interrelated or interacting elements of an *organization* (3.31) to establish *policies* (3.34) and *objectives* (3.29) and *processes* (3.36) to achieve those objectives

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

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

Note 3 to entry: The scope of a management system may 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.

Note 4 to entry: Relevant disciplines are, for example, a quality management system or an environmental management system.

3.26
measurement
process (3.36) to determine a value

3.27
monitoring
determining the status of a system, a *process* (3.36) or an activity

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

Note 2 to entry: In the context of food safety, monitoring is conducting a planned sequence of observations or measurements to assess whether a process is operating as intended.

Note 3 to entry: Distinctions are made in this document between the terms *validation* (3.44), *monitoring* (3.27) and *verification* (3.45):

— validation is applied prior to an activity and provides information about the capability to deliver intended results;

— monitoring is applied during an activity and provides information for action within a specified time frame;

— verification is applied after an activity and provides information for confirmation of conformity.

3.28
nonconformity
non-fulfilment of a *requirement* (3.38)

3.29
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 financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and *process* (3.36)).

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

Note 4 to entry: In the context of FSMS, objectives are set by the organization, consistent with the food safety policy, to achieve specific results.

3.30
operational prerequisite programme
OPRP
control measure (3.8) or combination of control measures applied to prevent or reduce a *significant food safety hazard* (3.40) to an *acceptable level* (3.1), and where *action criterion* (3.2) and *measurement* (3.26) or observation enable effective control of the *process* (3.36) and/or *product* (3.37)

3.31
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.29)

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.

3.32
outsource, verb
make an arrangement where an external *organization* (3.31) performs part of an organization's function or *process* (3.36)

Note 1 to entry: An external organization is outside the scope of the *management system* (3.25), although the outsourced function or process is within the scope.

3.33
performance
measurable result

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

Note 2 to entry: Performance can relate to the management of activities, *processes* (3.36), *products* (3.37) (including services), systems or *organizations* (3.31).

3.34
policy
intentions and direction of an *organization* (3.31) as formally expressed by its *top management* (3.41)

3.35
prerequisite programme
PRP
basic conditions and activities that are necessary within the *organization* (3.31) and throughout the *food chain* (3.20) to maintain food safety

Note 1 to entry: The PRPs needed depend on the segment of the food chain in which the organization operates and the type of organization. Examples of equivalent terms are: good agricultural practice (GAP), good veterinary practice (GVP), good manufacturing practice (GMP), good hygiene practice (GHP), good production practice (GPP), good distribution practice (GDP) and good trading practice (GTP).

3.36
process
set of interrelated or interacting activities which transforms inputs to outputs

3.37
product
output that is a result of a *process* (3.36)

Note 1 to entry: A product can be a service.

3.38
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, for example in documented information.

3.39
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" (as defined in ISO Guide 73:2009, 3.5.1.3) and "consequences" (as defined in ISO Guide 73:2009, 3.6.1.3), 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" (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence.

Note 5 to entry: Food safety risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to (a) hazard(s) in *food* (3.18), as specified in the Codex Procedural Manual[11].

3.40
significant food safety hazard
food safety hazard (3.22), identified through the hazard assessment, which needs to be controlled by *control measures* (3.8)

3.41
top management
person or group of people who directs and controls an *organization* (3.31) 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* (3.25) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

3.42
traceability
ability to follow the history, application, movement and location of an object through specified stage(s) of production, processing and distribution

Note 1 to entry: Movement can relate to the origin of the materials, processing history or distribution of the *food* (3.18).

Note 2 to entry: An object can be a *product* (3.37), a material, a unit, equipment, a service, etc.

[SOURCE: CAC/GL 60-2006, modified — Notes to entry have been added.]

3.43
update
immediate and/or planned activity to ensure application of the most recent information

Note 1 to entry: Update is different from the terms "maintain" and "retain":

— "maintain" is to keep something on-going/to keep in good condition;

— "retain" is to keep something that is retrievable.

3.44
validation
<food safety> obtaining evidence that a *control measure* (3.8) (or combination of control measures) will be capable of effectively controlling the *significant food safety hazard* (3.40)

Note 1 to entry: Validation is performed at the time a control measure combination is designed, or whenever changes are made to the implemented control measures.

Note 2 to entry: Distinctions are made in this document between the terms *validation* (3.44), *monitoring* (3.27) and *verification* (3.45):

— validation is applied prior to an activity and provides information about the capability to deliver intended results;

— monitoring is applied during an activity and provides information for action within a specified time frame;

— verification is applied after an activity and provides information for confirmation of conformity.

3.45
verification
confirmation, through the provision of objective evidence, that specified *requirements* (3.38) have been fulfilled

Note 1 to entry: Distinctions are made in this document between the terms *validation* (3.44), *monitoring* (3.27) and *verification* (3.45):

— validation is applied prior to an activity and provides information about the capability to deliver intended results;

— monitoring is applied during an activity and provides information for action within a specified time frame;

— verification is applied after an activity and provides information for confirmation of conformity.

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 result(s) of its FSMS.

The organization shall identify, review and update information related to these external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the context can be facilitated by considering external and internal issues, including, but not limited to, legal, technological, competitive, market, cultural, social and economic environments, cybersecurity and food fraud, food defence and intentional contamination, knowledge and performance of the organization, whether international, national, regional or local.

4.2 Understanding the needs and expectations of interested parties

To ensure that the organization has the ability to consistently provide products and services that meet applicable statutory, regulatory and customer requirements with regard to food safety, the organization shall determine:

a) the interested parties that are relevant to the FSMS;

b) the relevant requirements of the interested parties of the FSMS.

The organization shall identify, review and update information related to the interested parties and their requirements.

4.3 Determining the scope of the food safety management system

The organization shall determine the boundaries and applicability of the FSMS to establish its scope. The scope shall specify the products and services, processes and production site(s) that are included in the FSMS. The scope shall include the activities, processes, products or services that can have an influence on the food safety of its end products.

When determining this scope, the organization shall consider:

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

b) the requirements referred to in 4.2.

The scope shall be available and maintained as documented information.

4.4 Food safety management system

The organization shall establish, implement, maintain, update and continually improve a FSMS, including the processes needed and their interactions, in accordance with the requirements of this document.

5 Leadership

5.1 Leadership and commitment

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

a) ensuring that the food safety policy and the objectives of the FSMS are established and are compatible with the strategic direction of the organization;

b) ensuring the integration of the FSMS requirements into the organization's business processes;

c) ensuring that the resources needed for the FSMS are available;

d) communicating the importance of effective food safety management and conforming to the FSMS requirements, applicable statutory and regulatory requirements, and mutually agreed customer requirements related to food safety;

e) ensuring that the FSMS is evaluated and maintained to achieve its intended result(s) (see 4.1);

f) directing and supporting persons to contribute to the effectiveness of the FSMS;

g) promoting continual improvement;

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

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

5.2 Policy

5.2.1 Establishing the food safety policy

Top management shall establish, implement and maintain a food safety policy that:

a) is appropriate to the purpose and context of the organization;

b) provides a framework for setting and reviewing the objectives of the FSMS;

c) includes a commitment to satisfy applicable food safety requirements, including statutory and regulatory requirements and mutually agreed customer requirements related to food safety;

d) addresses internal and external communication;

e) includes a commitment to continual improvement of the FSMS;

f) addresses the need to ensure competencies related to food safety.

5.2.2 Communicating the food safety policy

The food safety policy shall:

a) be available and maintained as documented information;

b) be communicated, understood and applied at all levels within the organization;

c) be available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and authorities

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

Top management shall assign the responsibility and authority for:

a) ensuring that the FSMS conforms to the requirements of this document;

b) reporting on the performance of the FSMS to top management;

c) appointing the food safety team and the food safety team leader;

d) designating persons with defined responsibility and authority to initiate and document action(s).

5.3.2 The food safety team leader shall be responsible for:

a) ensuring the FSMS is established, implemented, maintained and updated;

b) managing and organizing the work of the food safety team;

c) ensuring relevant training and competencies for the food safety team (see 7.2);

d) reporting to top management on the effectiveness and suitability of the FSMS.

5.3.3 All persons shall have the responsibility to report problem(s) with regards to the FSMS to identified person(s).

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 When planning for the FSMS, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and 4.3 and determine the risks and opportunities that need to be addressed to:

a) give assurance that the FSMS can achieve its intended result(s);

b) enhance desirable effects;

c) prevent, or reduce, undesired effects;

d) achieve continual improvement.

NOTE In the context of this document, the concept of risks and opportunities is limited to events and their consequences relating to the performance and effectiveness of the FSMS. Public authorities are responsible for addressing public health risks. Organizations are required to manage food safety hazards (see 3.22) and the requirements related to this process that are laid down in Clause 8.

6.1.2 The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

   1) integrate and implement the actions into its FSMS processes;

   2) evaluate the effectiveness of these actions.

6.1.3 The actions taken by the organization to address risks and opportunities shall be proportionate to:

a) the impact on food safety requirements;

b) the conformity of food products and services to customers;

c) requirements of interested parties in the food chain.

NOTE 1 Actions to address risks and opportunities can include: avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or accepting the presence of risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices (modification of products or processes), using new technology and other desirable and viable possibilities to address the food safety needs of the organization or its customers.

6.2 Objectives of the food safety management system and planning to achieve them

6.2.1 The organization shall establish objectives for the FSMS at relevant functions and levels.

The objectives of the FSMS shall:

a) be consistent with the food safety policy;

b) be measurable (if practicable);

c) take into account applicable food safety requirements, including statutory, regulatory and customer requirements;

d) be monitored and verified;

e) be communicated;

f) be maintained and updated as appropriate.

The organization shall retain documented information on the objectives for the FSMS.

6.2.2 When planning how to achieve its objectives for the FSMS, 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.

6.3 Planning of changes

When the organization determines the need for changes to the FSMS, including personnel changes, the changes shall be carried out and communicated in a planned manner.

The organization shall consider:

a) the purpose of the changes and their potential consequences;

b) the continued integrity of the FSMS;

c) the availability of resources to effectively implement the changes;

d) the allocation or re-allocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance, update and continual improvement of the FSMS.

The organization shall consider:

a) the capability of, and any constraints on, existing internal resources;

b) the need for external resources.

7.1.2 People

The organization shall ensure that persons necessary to operate and maintain an effective FSMS are competent (see 7.2).

Where the assistance of external experts is used for the development, implementation, operation or assessment of the FSMS, evidence of agreement or contracts defining the competency, responsibility and authority of external experts shall be retained as documented information.

7.1.3 Infrastructure

The organization shall provide the resources for the determination, establishment and maintenance of the infrastructure necessary to achieve conformity with the requirements of the FSMS.

NOTE Infrastructure can include:

— land, vessels, buildings and associated utilities;

— equipment, including hardware and software;

— transportation;

— information and communication technology.

7.1.4 Work environment

The organization shall determine, provide and maintain the resources for the establishment, management and maintenance of the work environment necessary to achieve conformity with the requirements of the FSMS.

NOTE A suitable environment can be a combination of human and physical factors such as:

a) social (e.g. non-discriminatory, calm, non-confrontational);

b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);

c) physical (e.g. temperature, heat, humidity, light, air flow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

7.1.5 Externally developed elements of the food safety management system

When an organization establishes, maintains, updates and continually improves its FSMS by using externally developed elements of a FSMS, including PRPs, the hazard analysis and the hazard control plan (see 8.5.4), the organization shall ensure that the provided elements are:

a) developed in conformance with requirements of this document;

b) applicable to the sites, processes and products of the organization;

c) specifically adapted to the processes and products of the organization by the food safety team;

d) implemented, maintained and updated as required by this document;

e) retained as documented information.

7.1.6 Control of externally provided processes, products or services

The organization shall:

a) establish and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers of processes, products and/or services;

b) ensure adequate communication of requirements to the external provider(s);

c) ensure that externally provided processes, products or services do not adversely affect the organization's ability to consistently meet the requirements of the FSMS;

d) retain documented information of these activities and any necessary actions as a result of the evaluations and re-evaluations.

7.2 Competence

The organization shall:

a) determine the necessary competence of person(s), including external providers, doing work under its control that affects its food safety performance and effectiveness of the FSMS;

b) ensure that these persons, including the food safety team and those responsible for the operation of the hazard control plan, are competent on the basis of appropriate education, training and/or experience;

c) ensure that the food safety team has a combination of multi-disciplinary knowledge and experience in developing and implementing the FSMS (including, but not limited to, the organization’s products, processes, equipment and food safety hazards within the scope of the FSMS);

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

e) retain appropriate documented information as evidence of competence.

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.

7.3 Awareness

The organization shall ensure that all relevant persons doing work under the organization’s control shall be aware of:

a) the food safety policy;

b) the objectives of the FSMS relevant to their task(s);

c) their individual contribution to the effectiveness of the FSMS, including the benefits of improved food safety performance;

d) the implications of not conforming with the FSMS requirements.

7.4 Communication

7.4.1 General

The organization shall determine the internal and external communications relevant to the FSMS, including:

a) on what it will communicate;

b) when to communicate;

c) with whom to communicate;

d) how to communicate;

e) who communicates.

The organization shall ensure that the requirement for effective communication is understood by all persons whose activities have an impact on food safety.

7.4.2 External communication

The organization shall ensure that sufficient information is communicated externally and is available for interested parties of the food chain.

The organization shall establish, implement and maintain effective communications with:

a) external providers and contractors;

b) customers and/or consumers, in relation to:

   1) product information related to food safety, to enable the handling, display, storage, preparation, distribution and use of the product within the food chain or by the consumer;

   2) identified foods safety hazards that need to be controlled by other organizations in the food chain and/or by consumers;

   3) contractual arrangements, enquiries and orders, including their amendments;

   4) customer and/or consumer feedback, including complaints;

c) statutory and regulatory authorities;

d) other organizations that have an impact on, or will be affected by, the effectiveness or updating of the FSMS.

Designated persons shall have defined responsibility and authority for the external communication of any information concerning food safety. Where relevant, information obtained through external communication shall be included as input for management review (see 9.3) and for updating the FSMS (see 4.4 and 10.3).

Evidence of external communication shall be retained as documented information.

7.4.3 Internal communication

The organization shall establish, implement and maintain an effective system for communicating issues having an impact on food safety.

To maintain the effectiveness of the FSMS, the organization shall ensure that the food safety team is informed in a timely manner of changes in the following:

a) products or new products;

b) raw materials, ingredients and services;

c) production systems and equipment;

d) production premises, location of equipment and surrounding environment;

e) cleaning and sanitation programmes;

f) packaging, storage and distribution systems;

g) competencies and/or allocation of responsibilities and authorizations;

h) applicable statutory and regulatory requirements;

i) knowledge regarding food safety hazards and control measures;

j) customer, sector and other requirements that the organization observes;

k) relevant enquiries and communications from external interested parties;

l) complaints and alerts indicating food safety hazards associated with the end product;

m) other conditions that have an impact on food safety.

The food safety team shall ensure that this information is included when updating the FSMS (see 4.4 and 10.3).

Top management shall ensure that relevant information is included as input to the management review (see 9.3).

7.5 Documented information

7.5.1 General

The organization's FSMS shall include:

a) documented information required by this document;

b) documented information determined by the organization as being necessary for the effectiveness of the FSMS;

c) documented information and food safety requirements required by statutory, regulatory authorities and customers.

NOTE The extent of documented information for a FSMS can differ from one organization to another due to:

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

— the complexity of processes and their interactions;

— the competence of persons.

7.5.2 Creating and updating

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

7.5.3.1 Documented information required by the FSMS 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).

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

a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;

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

d) retention and disposition.

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

Documented information retained as evidence of conformity shall be protected from unintended alterations.

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.

8 Operation

8.1 Operational planning and control

The organization shall plan, implement, control, maintain and update the processes needed to meet requirements for the realization of safe products, and to implement the actions determined in 6.1, by:

a) establishing criteria for the processes;

b) implementing control of the processes in accordance with the criteria;

c) keeping documented information to the extent necessary to have the confidence to demonstrate that the processes have been carried out as planned.

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 outsourced processes are controlled (see 7.1.6).

8.2 Prerequisite programmes (PRPs)

8.2.1 The organization shall establish, implement, maintain and update PRP(s) to facilitate the prevention and/or reduction of contaminants (including food safety hazards) in the products, product processing and work environment.

8.2.2 The PRP(s) shall be:

a) appropriate to the organization and its context with regard to food safety;

b) appropriate to the size and type of the operation and the nature of the products being manufactured and/or handled;

c) implemented across the entire production system, either as programmes applicable in general or as programmes applicable to a particular product or process;

d) approved by the food safety team.

8.2.3 When selecting and/or establishing PRP(s), the organization shall ensure that applicable statutory, regulatory and mutually agreed customer requirements are identified. The organization should consider:

a) the applicable part of the ISO/TS 22002 series;

b) applicable standards, codes of practice and guidelines.

8.2.4 When establishing PRP(s) the organization shall consider:

a) construction, lay-out of buildings and associated utilities;

b) lay-out of premises, including zoning, workspace and employee facilities;

c) supplies of air, water, energy and other utilities;

d) pest control, waste and sewage disposal and supporting services;

e) the suitability of equipment and its accessibility for cleaning and maintenance;

f) supplier approval and assurance processes (e.g. raw materials, ingredients, chemicals and packaging);

g) reception of incoming materials, storage, dispatch, transportation and handling of products;

h) measures for the prevention of cross contamination;

i) cleaning and disinfecting;

j) personal hygiene;

k) product information/consumer awareness;

l) others, as appropriate.

Documented information shall specify the selection, establishment, applicable monitoring and verification of the PRP(s).

8.3 Traceability system

The traceability system shall be able to uniquely identify incoming material from the suppliers and the first stage of the distribution route of the end product. When establishing and implementing the traceability system, the following shall be considered as a minimum:

a) relation of lots of received materials, ingredients and intermediate products to the end products;

b) reworking of materials/products;

c) distribution of the end product.

The organization shall ensure that applicable statutory, regulatory and customer requirements are identified.

Documented information as evidence of the traceability system shall be retained for a defined period to include, as a minimum, the shelf life of the product. The organization shall verify and test the effectiveness of the traceability system.

NOTE Where appropriate, the verification of the system is expected to include the reconciliation of quantities of end products with the quantity of ingredients as evidence of effectiveness.

8.4 Emergency preparedness and response

8.4.1 General

Top management shall ensure procedures are in place to respond to potential emergency situations or incidents that can have an impact on food safety which are relevant to the role of the organization in the food chain.

Documented information shall be established and maintained to manage these situations and incidents.

8.4.2 Handling of emergencies and incidents

The organization shall:

a) respond to actual emergency situations and incidents by:

   1) ensuring applicable statutory and regulatory requirements are identified;

   2) communicating internally;

   3) communicating externally (e.g. suppliers, customers, appropriate authorities, media);

b) take action to reduce the consequences of the emergency situation, appropriate to the magnitude of the emergency or incident and the potential food safety impact;

c) periodically test procedures where practical;

d) review and, where necessary, update the documented information after the occurrence of any incident, emergency situation or tests.

NOTE Examples of emergency situations that can affect food safety and/or production are natural disasters, environmental accidents, bioterrorism, workplace accidents, public health emergencies and other accidents, e.g. interruption of essential services such as water, electricity or refrigeration supply.

8.5 Hazard control

8.5.1 Preliminary steps to enable hazard analysis

8.5.1.1 General

To carry out the hazard analysis, preliminary documented information shall be collected, maintained and updated by the food safety team. This shall include, but not be limited to:

a) applicable statutory, regulatory and customer requirements;

b) the organization's products, processes and equipment;

c) food safety hazards relevant to the FSMS.

8.5.1.2 Characteristics of raw materials, ingredients and product contact materials

The organization shall ensure that all applicable statutory and regulatory food safety requirements are identified for all raw materials, ingredients and product contact materials.

The organization shall maintain documented information concerning all raw materials, ingredients and product contact materials to the extent needed to conduct the hazard analysis (see 8.5.2), including the following, as appropriate:

a) biological, chemical and physical characteristics;

b) composition of formulated ingredients, including additives and processing aids;

c) source (e.g. animal, mineral or vegetable);

d) place of origin (provenance);

e) method of production;

f) method of packaging and delivery;

g) storage conditions and shelf life;

h) preparation and/or handling before use or processing;

i) acceptance criteria related to food safety or specifications of purchased materials and ingredients appropriate to their intended use.

8.5.1.3 Characteristics of end products

The organization shall ensure that all applicable statutory and regulatory food safety requirements are identified for all the end products intended to be produced.

The organization shall maintain documented information concerning the characteristics of end products to the extent needed to conduct the hazard analysis (see 8.5.2), including information on the following, as appropriate:

a) product name or similar identification;

b) composition;

c) biological, chemical and physical characteristics relevant for food safety;

d) intended shelf life and storage conditions;

e) packaging;

f) labelling relating to food safety and/or instructions for handling, preparation and intended use;

g) method(s) of distribution and delivery.

8.5.1.4 Intended use

The intended use, including reasonably expected handling of the end product and any unintended use but reasonably expected mishandling and misuse of the end product, shall be considered and shall be maintained as documented information to the extent needed to conduct the hazard analysis (see 8.5.2).

Where appropriate, groups of consumers/users shall be identified for each product.

Groups of consumers/users known to be especially vulnerable to specific food safety hazards shall be identified.

8.5.1.5 Flow diagrams and description of processes

8.5.1.5.1 Preparation of the flow diagrams

The food safety team shall establish, maintain and update flow diagrams as documented information for the products or product categories and the processes covered by the FSMS.

Flow diagrams provide a graphic representation of the process. Flow diagrams shall be used when conducting the hazard analysis as a basis for evaluating the possible occurrence, increase, decrease or introduction of food safety hazards.

Flow diagrams shall be clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis. Flow diagrams shall, as appropriate, include the following:

a) the sequence and interaction of the steps in the operation;

b) any outsourced processes;

c) where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow;

d) where reworking and recycling take place;

e) where end products, intermediate products, by-products and waste are released or removed.

8.5.1.5.2 On-site confirmation of flow diagrams

The food safety team shall confirm on-site the accuracy of the flow diagrams, update the flow diagrams where appropriate and retain as documented information.

8.5.1.5.3 Description of processes and process environment

The food safety team shall describe, to the extent needed to conduct the hazard analysis:

a) the layout of premises, including food and non-food handling areas;

b) processing equipment and contact materials, processing aids and flow of materials;

c) existing PRPs, process parameters, control measures (if any) and/or the strictness with which they are applied, or procedures that can influence food safety;

d) external requirements (e.g. from statutory and regulatory authorities or customers) that can impact the choice and the strictness of the control measures.

The variations resulting from expected seasonal changes or shift patterns shall be included as appropriate.

The descriptions shall be updated as appropriate and maintained as documented information.

8.5.2 Hazard analysis

8.5.2.1 General

The food safety team shall conduct a hazard analysis, based on the preliminary information, to determine the hazards that need to be controlled. The degree of control shall ensure food safety and, where appropriate, a combination of control measures shall be used.

8.5.2.2 Hazard identification and determination of acceptable levels

8.5.2.2.1 The organization shall identify and document all food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and process environment.

The identification shall be based on:

a) the preliminary information and data collected in accordance with 8.5.1;

b) experience;

c) internal and external information including, to the extent possible, epidemiological, scientific and other historical data;

d) information from the food chain on food safety hazards related to the safety of the end products, intermediate products and the food at the time of consumption;

e) statutory, regulatory and customer requirements.

NOTE 1 Experience can include information from staff and external experts who are familiar with the product and/or processes in other facilities.

NOTE 2 Statutory and regulatory requirements can include food safety objectives (FSOs). The Codex Alimentarius Commission defines FSOs as "The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)".

Hazards should be considered in sufficient detail to enable hazard assessment and the selection of appropriate control measures.

8.5.2.2.2 The organization shall identify step(s) (e.g. receiving raw materials, processing, distribution and delivery) at which each food safety hazard can be present, be introduced, increase or persist.

When identifying hazards, the organization shall consider:

a) the stages preceding and following in the food chain;

b) all steps in the flow diagram;

c) the process equipment, utilities/services, process environment and persons.

8.5.2.2.3 The organization shall determine the acceptable level in the end product of each food safety hazard identified, whenever possible.

When determining acceptable levels, the organization shall:

a) ensure that applicable statutory, regulatory and customer requirements are identified;

b) consider the intended use of end products;

c) consider any other relevant information.

The organization shall maintain documented information concerning the determination of acceptable levels and the justification for the acceptable levels.

8.5.2.3 Hazard assessment

The organization shall conduct, for each identified food safety hazard, a hazard assessment to determine whether its prevention or reduction to an acceptable level is essential.

The organization shall evaluate each food safety hazard with regard to:

a) the likelihood of its occurrence in the end product prior to application of control measures;

b) the severity of its adverse health effects in relation to the intended use (see 8.5.1.4).

The organization shall identify any significant food safety hazards.

The methodology used shall be described, and the result of the hazard assessment shall be maintained as documented information.

8.5.2.4 Selection and categorization of control measure(s)

8.5.2.4.1 Based on the hazard assessment, the organization shall select an appropriate control measure or combination of control measures that will be capable of preventing or reducing the identified significant food safety hazards to defined acceptable levels.

The organization shall categorize the selected identified control measure(s) to be managed as OPRP(s) (see 3.30) or at CCPs (see 3.11).

The categorization shall be carried out using a systematic approach. For each of the control measures selected, there shall be an assessment of the following:

a) the likelihood of failure of its functioning;

b) the severity of the consequence in the case of failure of its functioning; this assessment shall include:

   1) the effect on identified significant food safety hazards;

   2) the location in relation to other control measure(s);

   3) whether it is specifically established and applied to reduce the hazards to an acceptable level;

   4) whether it is a single measure or is part of combination of control measure(s).

8.5.2.4.2 In addition, for each control measure, the systematic approach shall include an assessment of the feasibility of:

a) establishing measurable critical limits and/or measurable/observable action criteria;

b) monitoring to detect any failure to remain within critical limit and/or measurable/observable action criteria;

c) applying timely corrections in case of failure.

The decision-making process and results of the selection and categorization of the control measures shall be maintained as documented information.

External requirements (e.g. statutory, regulatory and customer requirements) that can impact the choice and the strictness of the control measures shall also be maintained as documented information.

8.5.3 Validation of control measure(s) and combinations of control measures

The food safety team shall validate that the selected control measures are capable of achieving the intended control of the significant food safety hazard(s). This validation shall be done prior to implementation of control measure(s) and combinations of control measures to be included in the hazard control plan (see 8.5.4) and after any change therein (see 7.4.2, 7.4.3, 10.2 and 10.3).

When the result of validation shows that the control measures(s) is (are) not capable of achieving the intended control, the food safety team shall modify and re-assess the control measure(s) and/or combination(s) of control measure(s).

The food safety team shall maintain the validation methodology and evidence of capability of the control measure(s) to achieve the intended control as documented information.

NOTE Modification can include changes in control measure(s) (i.e. process parameters, rigour and/or their combination) and/or change(s) in the manufacturing technologies for raw materials, end product characteristics, methods of distribution and intended use of the end products.

8.5.4 Hazard control plan (HACCP/OPRP plan)

8.5.4.1 General

The organization shall establish, implement and maintain a hazard control plan. The hazard control plan shall be maintained as documented information and shall include the following information for each control measure at each CCP or OPRP:

a) food safety hazard(s) to be controlled at the CCP or by the OPRP;

b) critical limit(s) at CCP or action criteria for OPRP;

c) monitoring procedure(s);

d) correction(s) to be made if critical limits or action criteria are not met;

e) responsibilities and authorities;

f) records of monitoring.

8.5.4.2 Determination of critical limits and action criteria

Critical limits at CCPs and action criteria for OPRPs shall be specified. The rationale for their determination shall be maintained as documented information.

Critical limits at CCPs shall be measurable. Conformance with critical limits shall ensure that the acceptable level is not exceeded.

Action criteria for OPRPs shall be measurable or observable. Conformance with action criteria shall contribute to the assurance that the acceptable level is not exceeded.

8.5.4.3 Monitoring systems at CCPs and for OPRPs

At each CCP, a monitoring system shall be established for each control measure or combination of control measure(s) to detect any failure to remain within the critical limits. The system shall include all scheduled measurements relative to the critical limit(s).

For each OPRP, a monitoring system shall be established for the control measure or combination of control measure(s) to detect failure to meet the action criterion.

The monitoring system, at each CCP and for each OPRP, shall consist of documented information, including:

a) measurements or observations that provide results within an adequate time frame;

b) monitoring methods or devices used;

c) applicable calibration methods or, for OPRPs, equivalent methods for verification of reliable measurements or observations (see 8.7);

d) monitoring frequency;

e) monitoring results;

f) responsibility and authority related to monitoring;

g) responsibility and authority related to evaluation of monitoring results.

At each CCP, the monitoring method and frequency shall be capable of timely detection of any failure to remain within critical limits, to allow timely isolation and evaluation of the product (see 8.9.4).

For each OPRP, the monitoring method and frequency shall be proportionate to the likelihood of failure and the severity of consequences.

When monitoring an OPRP is based on subjective data from observations (e.g. visual inspection), the method shall be supported by instructions or specifications.

8.5.4.4 Actions when critical limits or action criteria are not met

The organization shall specify corrections (see 8.9.2) and corrective actions (see 8.9.3) to be taken when critical limits or action criterion are not met and shall ensure that:

a) the potentially unsafe products are not released (see 8.9.4);

b) the cause of nonconformity is identified;

c) the parameter(s) controlled at the CCP or by the OPRP is (are) returned within the critical limits or action criteria;

d) recurrence is prevented.

The organization shall make corrections in accordance with 8.9.2 and corrective actions in accordance with 8.9.3.

8.5.4.5 Implementation of the hazard control plan

The organization shall implement and maintain the hazard control plan, and retain evidence of the implementation as documented information.

8.6 Updating the information specifying the PRPs and the hazard control plan

Following the establishment of the hazard control plan, the organization shall update the following information, if necessary:

a) characteristics of raw materials, ingredients and product-contact materials;

b) characteristics of end products;

c) intended use;

d) flow diagrams and descriptions of processes and process environment.

The organization shall ensure that the hazard control plan and/or the PRP(s) are up to date.

8.7 Control of monitoring and measuring

The organization shall provide evidence that the specified monitoring and measuring methods and equipment in use are adequate for the monitoring and measuring activities related to the PRP(s) and the hazard control plan.

The monitoring and measuring equipment used shall be:

a) calibrated or verified at specified intervals prior to use;

b) adjusted or re-adjusted as necessary;

c) identified to enable the calibration status to be determined;

d) safeguarded from adjustments that would invalidate the measurement results;

e) protected from damage and deterioration.

The results of calibration and verification shall be retained as documented information. The calibration of all the equipment shall be traceable to international or national measurement standards; where no standards exist, the basis used for calibration or verification shall be retained as documented information.

The organization shall assess the validity of the previous measurement results when the equipment or process environment is found not to conform to requirements. The organization shall take appropriate action in relation to the equipment or process environment and any product affected by the non-conformance.

The assessment and resulting action shall be maintained as documented information.

Software used in monitoring and measuring within the FSMS shall be validated by the organization, software supplier or third party prior to use. Documented information on validation activities shall be maintained by the organization and the software shall be updated in a timely manner.

Whenever there are changes, including software configuration/modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.

NOTE Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

8.8 Verification related to PRPs and the hazard control plan

8.8.1 Verification

The organization shall establish, implement and maintain verification activities. The verification planning shall define purpose, methods, frequencies and responsibilities for the verification activities.

The verification activities shall confirm that:

a) the PRP(s) are implemented and effective;

b) the hazard control plan is implemented and effective;

c) hazard levels are within identified acceptable levels;

d) input to the hazard analysis is updated;

e) other actions determined by the organization are implemented and effective.

The organization shall ensure that verification activities are not carried out by the person responsible for monitoring the same activities.

Verification results shall be retained as documented information and shall be communicated.

Where verification is based on testing of end product samples or direct process samples and where such test samples show nonconformity with the acceptable level of the food safety hazard (see 8.5.2.2), the organization shall handle the affected lot(s) of product as potentially unsafe (see 8.9.4.3) and apply corrective actions in accordance with 8.9.3.

8.8.2 Analysis of results of verification activities

The food safety team shall conduct an analysis of the results of verification that shall be used as an input to the performance evaluation of the FSMS (see 9.1.2).

8.9 Control of product and process nonconformities

8.9.1 General

The organization shall ensure that data derived from the monitoring of OPRPs and at CCPs are evaluated by designated persons who are competent and have the authority to initiate corrections and corrective actions.

8.9.2 Corrections

8.9.2.1 The organization shall ensure that when critical limits at CCP(s) and/or action criteria for OPRPs are not met, the products affected are identified and controlled with regard to their use and release.

The organization shall establish, maintain and update documented information that includes:

a) a method of identification, assessment and correction for affected products to ensure their proper handling;

b) arrangements for review of the corrections carried out.

8.9.2.2 When critical limits at CCPs are not met, affected products shall be identified and handled as potentially unsafe products (see 8.9.4).

8.9.2.3 Where action criteria for an OPRP are not met, the following shall be carried out:

a) determination of the consequences of that failure with respect to food safety;

b) determination of the cause(s) of failure;

c) identification of the affected products and handling in accordance with 8.9.4.

The organization shall retain results of the evaluation as documented information.

8.9.2.4 Documented information shall be retained to describe corrections made on nonconforming products and processes, including:

a) the nature of the nonconformity;

b) the cause(s) of the failure;

c) the consequences as a result of the nonconformity.

8.9.3 Corrective actions

The need for corrective actions shall be evaluated when critical limits at CCP(s) and/or action criteria for OPRPs are not met.

The organization shall establish and maintain documented information that specifies appropriate actions to identify and eliminate the cause of detected nonconformities, to prevent recurrence, and to return the process to control after a nonconformity is identified.

These actions shall include:

a) reviewing nonconformities identified by customer and/or consumer complaints and/or regulatory inspection reports;

b) reviewing trends in monitoring results that can indicate loss of control;

c) determining the cause(s) of nonconformities;

d) determining and implementing actions to ensure that nonconformities do not recur;

e) documenting the results of corrective actions taken;

f) verifying corrective actions taken to ensure that they are effective.

The organization shall retain documented information on all corrective actions.

8.9.4 Handling of potentially unsafe products

8.9.4.1 General

The organization shall take action(s) to prevent potentially unsafe products from entering the food chain, unless it can demonstrate that:

a) the food safety hazard(s) of concern is (are) reduced to the defined acceptable levels;

b) the food safety hazard(s) of concern will be reduced to identified acceptable levels prior to entering the food chain; or

c) the product still meets the defined acceptable level(s) of the food safety hazard(s) of concern despite the nonconformity.

The organization shall retain products that have been identified as potentially unsafe under its control until the products have been evaluated and the disposition has been determined.

If products that have left the control of the organization are subsequently determined to be unsafe, the organization shall notify relevant interested parties and initiate a withdrawal/recall (see 8.9.5).

The controls and related responses from relevant interested parties and authorization for dealing with potentially unsafe products shall be retained as documented information.

8.9.4.2 Evaluation for release

Each lot of products affected by the nonconformity shall be evaluated.

Products affected by failure to remain within critical limits at CCPs shall not be released, but shall be handled in accordance with 8.9.4.3.

Products affected by failure to meet action criterion for OPRPs shall only be released as safe when any of the following conditions apply:

a) evidence other than the monitoring system demonstrates that the control measures have been effective;

b) evidence shows that the combined effect of the control measures for that particular product conforms to the performance intended (i.e. identified acceptable levels);

c) the results of sampling, analysis and/or other verification activities demonstrate that the affected products conform to the identified acceptable levels for the food safety hazard(s) concerned.

Results of evaluation for release of products shall be retained as documented information.

8.9.4.3 Disposition of nonconforming products

Products that are not acceptable for release shall be:

a) reprocessed or further processed within or outside the organization to ensure that the food safety hazard is reduced to acceptable levels; or

b) redirected for other use as long as food safety in the food chain is not affected; or

c) destroyed and/or disposed as waste.

Documented information on the disposition of nonconforming products, including the identification of the person(s) with approving authority shall be retained.

8.9.5 Withdrawal/recall

The organization shall be able to ensure the timely withdrawal/recall of lots of end products that have been identified as potentially unsafe, by appointing competent person(s) having the authority to initiate and carry out the withdrawal/recall.

The organization shall establish and maintain documented information for:

a) notifying relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers);

b) handling withdrawn/recalled products as well as products still in stock;

c) performing the sequence of actions to be taken.

Withdrawn/recalled products and end products still in stock shall be secured or held under the control of the organization until they are managed in accordance with 8.9.4.3.

The cause, extent and result of a withdrawal/recall shall be retained as documented information and reported to the top management as input for the management review (see 9.3).

The organization shall verify the implementation and effectiveness of withdrawals/recalls through the use of appropriate techniques (e.g. mock withdrawal/recall or practice withdrawal/recall) and retain documented information.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization shall determine:

a) what needs to be monitored and measured;

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

c) when the monitoring and measuring shall be performed;

d) when the results from monitoring and measurement shall be analysed and evaluated;

e) who shall analyse and evaluate the results from monitoring and measurement.

The organization shall retain appropriate documented information as evidence of the results.

The organization shall evaluate the performance and the effectiveness of the FSMS.

9.1.2 Analysis and evaluation

The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement, including the results of verification activities related to PRPs and the hazard control plan (see 8.8 and 8.5.4), the internal audits (see 9.2) and external audits.

The analysis shall be carried out:

a) to confirm that the overall performance of the system meets the planned arrangements and the FSMS requirements established by the organization;

b) to identify the need for updating or improving the FSMS;

c) to identify trends which indicate a higher incidence of potentially unsafe products or process failures;

d) to establish information for planning of the internal audit programme related to the status and importance of areas to be audited;

e) to provide evidence that corrections and corrective actions are effective.

The results of the analysis and the resulting activities shall be retained as documented information. The results shall be reported to top management and used as input to the management review (see 9.3) and the updating of the FSMS (see 10.3).

NOTE Methods to analyse data can include statistical techniques.

9.2 Internal audit

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the FSMS:

a) conforms to:

   1) the organization's own requirements for its FSMS;

   2) the requirements of this document;

b) is effectively implemented and maintained.

9.2.2 The organization shall:

a) plan, establish, implement and maintain (an) audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes in the FSMS, and the results of monitoring, measurement and previous audits;

b) define the audit criteria and scope for each audit;

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

d) ensure that the results of the audits are reported to the food safety team and relevant management;

e) retain documented information as evidence of the implementation of the audit programme and the audit results;

f) make the necessary correction and take the necessary corrective action within the agreed time frame;

g) determine if the FSMS meets the intent of the food safety policy (see 5.2) and objectives of the FSMS (see 6.2).

Follow-up activities by the organization shall include the verification of the actions taken and the reporting of the verification results.

NOTE ISO 19011 provides guidelines for auditing management systems.

9.3 Management review

9.3.1 General

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

9.3.2 Management review input

The management review shall consider:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the FSMS, including changes in the organization and its context (see 4.1);

c) information on the performance and the effectiveness of the FSMS, including trends in:

   1) result(s) of system updating activities (see 4.4 and 10.3);

   2) monitoring and measurement results;

   3) analysis of the results of verification activities related to PRPs and the hazard control plan (see 8.8.2);

   4) nonconformities and corrective actions;

   5) audit results (internal and external);

   6) inspections (e.g. regulatory, customer);

   7) the performance of external providers;

   8) the review of risks and opportunities and of the effectiveness of actions taken to address them (see 6.1);

   9) the extent to which objectives of the FSMS have been met;

d) the adequacy of resources;

e) any emergency situation, incident (see 8.4.2) or withdrawal/recall (see 8.9.5) that occurred;

f) relevant information obtained through external (see 7.4.2) and internal (see 7.4.3) communication, including requests and complaints from interested parties;

g) opportunities for continual improvement.

The data shall be presented in a manner that enables top management to relate the information to stated objectives of the FSMS.

9.3.3 Management review output

The outputs of the management review shall include:

a) decisions and actions related to continual improvement opportunities;

b) any need for updates and changes to the FSMS, including resource needs and revision of the food safety policy and objectives of the FSMS.

The organization shall retain documented information as evidence of the results of management reviews.

10 Improvement

10.1 Nonconformity and corrective action

10.1.1 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;

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 causes of the nonconformity;

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

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) make changes to the FSMS, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

10.1.2 The organization shall retain documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;

b) the results of any corrective action.

10.2 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the FSMS.

Top management shall ensure that the organization continually improves the effectiveness of the FSMS through the use of communication (see 7.4), management review (see 9.3), internal audit (see 9.2), analysis of results of verification activities (see 8.8.2), validation of control measure(s) and combination(s) of control measure(s) (see 8.5.3), corrective actions (see 8.9.3) and FSMS updating (see 10.3).

10.3 Update of the food safety management system

Top management shall ensure that the FSMS is continually updated. To achieve this, the food safety team shall evaluate the FSMS at planned intervals. The team shall consider whether it is necessary to review the hazard analysis (see 8.5.2), the established hazard control plan (see 8.5.4) and the established PRPs (see 8.2). The updating activities shall be based on:

a) input from communication, external as well as internal (see 7.4);

b) input from other information concerning the suitability, adequacy and effectiveness of the FSMS;

c) output from the analysis of results of verification activities (see 9.1.2);

d) output from management review (see 9.3).

System updating activities shall be retained as documented information and reported as input to the management review (see 9.3).

Annex A
(informative)

Cross references between the CODEX HACCP and this document

Table A.1 — Cross references between the CODEX HACCP principles and application steps and clauses of this document

CODEX HACCP Principles	CODEX HACCP application steps[a]		This document	
	Assemble HACCP team	Step 1	5.3	Food safety team
	Describe product	Step 2	8.5.1.2	Characteristics of raw materials, ingredients and product-contact materials
			8.5.1.3	Characteristics of end products
	Identify intended use	Step 3	8.5.1.4	Intended use
	Construct flow diagram	Step 4	8.5.1.5	Flow diagrams and descriptions of processes
	On-site confirmation of flow diagram	Step 5		
Principle 1 Conduct a hazard analysis	List all potential hazards	Step 6	8.5.2	Hazard analysis
	Conduct a hazard analysis Consider control measures		8.5.3	Validation of control measure(s) and combinations of control measure(s)
Principle 2 Determine the critical control points (CCPs)	Determine CCPs	Step 7	8.5.4	Hazard control plan
Principle 3 Establish critical limit(s)	Establish critical limits for each CCP	Step 8	8.5.4	Hazard control plan
Principle 4 Establish a system to monitor control of the CCP	Establish a monitoring system for each CCP	Step 9	8.5.4.3	Monitoring systems at CCPs and for OPRPs
Principle 5 Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control	Establish corrective actions	Step 10	8.5.4	Hazard control plan
			8.9.2	Corrections
			8.9.3	Corrective actions
Principle 6 Establish procedures for verification to confirm that the HACCP system is working effectively	Establish verification procedures	Step 11	8.7	Control of monitoring and measuring
			8.8	Verification related to PRPs and the hazard control plan
			9.2	Internal audit
Principle 7 Establish documentation concerning all procedures and records appropriate to these principles and their application	Establish documentation and record keeping	Step 12	7.5	Documented information

[a] CODEX publications are available via Reference [12].

Annex B
(informative)

Cross references between this document and ISO 22000:2005

Table B.1 — Main structure

This document	ISO 22000:2005
4 Context of the organization	New heading
4.1 Understanding the organization and its context	New
4.2 Understanding the needs and expectations of interested parties	New
4.3 Determining the scope of the food safety management system	4.1 (and new)
4.4. Food safety management system	4.1
5 Leadership	New heading
5.1 Leadership and commitment	5.1, 7.4.3 (and new)
5.2 Policy	5.2 (and new)
5.3 Organizational roles, responsibilities and authorities	5.4, 5.5, 7.3.2 (and new)
6 Planning	New heading
6.1 Actions to address risks and opportunities	New
6.2 Objectives of the food safety management system and planning to achieve them	5.3 (and new)
6.3 Planning of changes	5.3 (and new)
7 Support	New heading
7.1 Resources	1, 4.1, 6.2, 6.3, 6.4 (and new)
7.2 Competence	6.2, 7.3.2 (and new)
7.3 Awareness	6.2.2
7.4 Communication	5.6, 6.2.2
7.5 Documented information	4.2, 5.6.1
8 Operation	New heading
8.1 Operational planning and control	New
8.2 Prerequisite programmes (PRPs)	7.2
8.3 Traceability system	7.9 (and new)
8.4 Emergency preparedness and response	5.7 (and new)
8.5 Hazard control	7.3, 7.4, 7.5, 7.6, 8.2 (and new)
8.6 Updating the information specifying the PRPs and the hazard control plan	7.7
8.7 Control of monitoring and measuring	8.3
8.8 Verification related to PRPs and the hazard control plan	7.8, 8.4.2
8.9 Control of product and process nonconformities	7.10
9 Performance evaluation	New heading
9.1 Monitoring, measurement, analysis and evaluation	New heading
9.1.1 General	New
9.1.2 Analysis and evaluation	8.4.2, 8.4.3
9.2 Internal audit	8.4.1
9.3 Management review	5.8 (and new)
9.3.1 General	5.2, 5.8.1

Table B.1 *(continued)*

This document	ISO 22000:2005
9.3.2 Management review input	5.8.2 (and new)
9.3.3 Management review output	5.8.1, 5.8.3
10 Improvement	New heading
10.1 Nonconformity and corrective action	New
10.2 Continual improvement	8.1, 8.5.1
10.3 Update of the food safety management system	8.5.2

Table B.2 — Clause 7: Support

This document	ISO 22000:2005
7 Support	New heading
7.1. Resources	6
7.1.1 General	6.1
7.1.2 People	6.2, 6.2.2 (and new)
7.1.3 Infrastructure	6.3
7.1.4 Work environment	6.4
7.1.5 Externally developed elements of the food safety management system	1 (and new)
7.1.6 Control of externally provided processes, products or services	4.1 (and new)
7.2 Competence	6.2.1, 6.2.2, 7.3.2
7.3 Awareness	6.2.2
7.4 Communication	5.6
7.4.1 General	6.2.2 (and new)
7.4.2 External communication	5.6.1
7.4.3 Internal communication	5.6.2
7.5 Documented information	4.2
7.5.1 General	4.2.1, 5.6.1
7.5.2 Creating and updating	4.2.2
7.5.3 Control of documented information	4.2.2, 4.2.3 (and new)

Table B.3 — Clause 8: Operation

This document	ISO 22000:2005
8 Operation	New heading
8.1 Operational planning and control	7.1 (and new)
8.2 Prerequisite programmes (PRPs)	7.2
8.3 Traceability system	7.9 (and new)
8.4 Emergency preparedness and response	5.7
8.4.1 General	5.7
8.4.2 Handling of emergencies and incidents	New
8.5 Hazard control	New heading
8.5.1 Preliminary steps to enable hazard analysis	7.3
8.5.1.1 General	7.3.1
8.5.1.2 Characteristics of raw materials, ingredients and product contact materials	7.3.3.1
8.5.1.3 Characteristics of end products	7.3.3.2
8.5.1.4 Intended use	7.3.4

Table B.3 *(continued)*

This document	ISO 22000:2005
8.5.1.5 Flow diagrams and description of processes	7.3.5.1
8.5.1.5.1 Preparation of flow diagrams	7.3.5.1
8.5.1.5.2 On-site confirmation of flow diagrams	7.3.5.1
8.5.1.5.3 Description of processes and process environment	7.2.4, 7.3.5.2 (and new)
8.5.2 Hazard analysis	7.4
8.5.2.1 General	7.4.1
8.5.2.2 Hazard identification and determination of acceptable levels	7.4.2
8.5.2.3 Hazard assessment	7.4.3, 7.6.2 (and new)
8.5.2.4 Selection and categorization of control measure(s)	7.3.5.2, 7.4.4 (and new)
8.5.3 Validation of control measure(s) and combination(s) of control measure(s)	8.2
8.5.4 Hazard control plan (HACCP/OPRP plan)	New heading
8.5.4.1 General	7.5, 7.6.1
8.5.4.2 Determination of critical limits and action criteria	7.6.3 (and new)
8.5.4.3 Monitoring systems at CCPs and for OPRPs	7.6.3, 7.6.4 (and new)
8.5.4.4 Actions when critical limits or action criteria are not met	7.6.5
8.5.4.5 Implementation of the hazard control plan	New
8.6 Updating the information specifying the PRPs and the hazard control plan	7.7
8.7 Control of monitoring and measuring	8.3
8.8 Verification related to PRPs and the hazard control plan	New heading
8.8.1 Verification	7.8, 8.4.2
8.8.2 Analysis of results of verification activities	8.4.3
8.9 Control of product and process nonconformities	7.10
8.9.1 General	7.10.1, 7.10.2
8.9.2 Corrections	7.10.1
8.9.3 Corrective actions	7.10.2
8.9.4 Handling of potentially unsafe products	7.10.3
8.9.4.1 General	7.10.3.1
8.9.4.2 Evaluation for release	7.10.3.2
8.9.4.3 Disposition of nonconforming products	7.10.3.3
8.9.5 Withdrawal/recall	7.10.4

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FINAL DRAFT

INTERNATIONAL STANDARD

ISO/FDIS 9001

ISO/TC 176/SC 2

Secretariat: BSI

Voting begins on:
2015-07-09

Voting terminates on:
2015-09-09

Quality management systems — Requirements

Systèmes de management de la qualité — Exigences

Please see the administrative notes on page iii

Reference number
ISO/FDIS 9001:2015(E)

ISO/CEN PARALLEL PROCESSING

This final draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement. The final draft was established on the basis of comments received during a parallel enquiry on the draft.

This final draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel two-month approval vote in ISO and formal vote in CEN.

Positive votes shall not be accompanied by comments.

Negative votes shall be accompanied by the relevant technical reasons.

Contents

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Foreword

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

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This fifth edition cancels and replaces the fourth edition (ISO 9001:2008), which has been technically revised, through the adoption of a revised clause sequence and the adaptation of the revised quality management principles and of new concepts.

Introduction

0.1 General

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

The potential benefits to an organization of implementing a quality management system based on this International Standard are:

a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;

b) facilitating opportunities to enhance customer satisfaction;

c) addressing risks and opportunities associated with its context and objectives;

d) the ability to demonstrate conformity to specified quality management system requirements.

This International Standard can be used by internal and external parties.

It is not the intent of this International Standard to imply the need for:

— uniformity in the structure of different quality management systems;

— alignment of documentation to the clause structure of this International Standard;

— the use of the specific terminology of this International Standard within the organization.

The quality management system requirements specified in this International Standard are complementary to requirements for products and services.

This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

The process approach enables an organization to plan its processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see Clause A.4).

Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

In this International Standard, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.

0.2 Quality management principles

This International Standard is based on the quality management principles described in ISO 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of typical actions to improve the organization's performance when applying the principle.

The quality management principles are:

— customer focus;

— leadership;

— engagement of people;

— process approach;

— improvement;

— evidence-based decision making;

— relationship management.

0.3 Process approach

0.3.1 General

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Specific requirements considered essential to the adoption of a process approach are included in 4.4.

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results.

The application of the process approach in a quality management system enables:

a) understanding and consistency in meeting requirements;

b) the consideration of processes in terms of added value;

c) the achievement of effective process performance;

d) improvement of processes based on evaluation of data and information.

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring checkpoints, which are necessary for control, are specific to each process and will vary depending on the related risks.

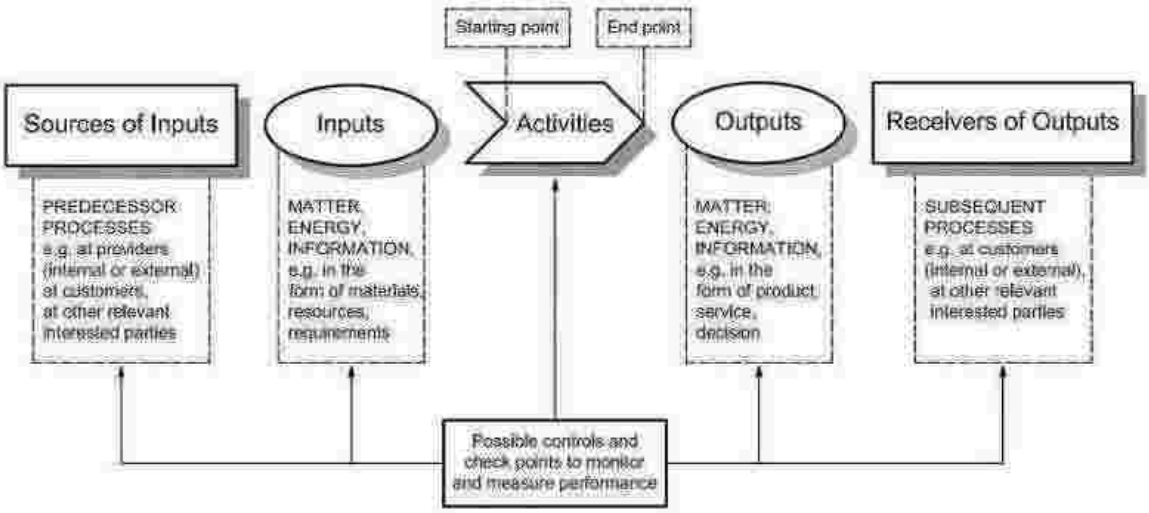

Figure 1 — Schematic representation of the elements of a single process

0.3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle.

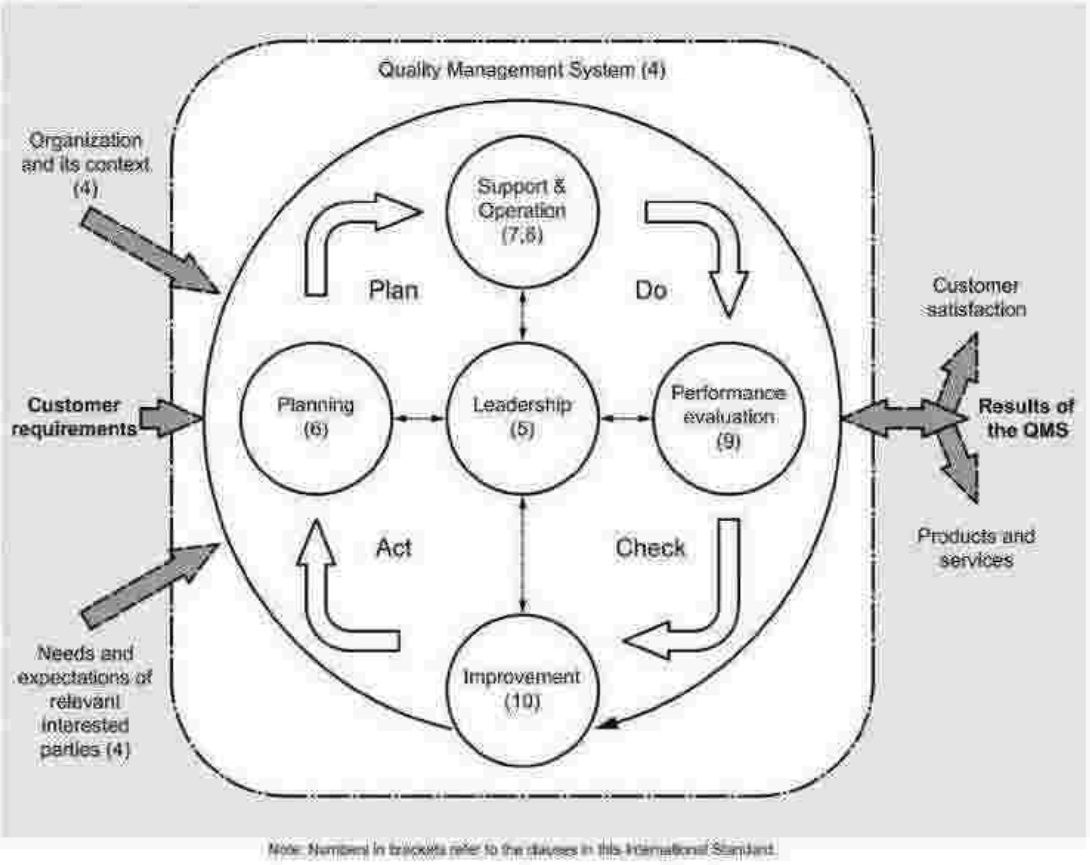

Figure 2 — Representation of the structure of this International Standard in the PDCA cycle

The PDCA cycle can be briefly described as follows:

— **Plan**: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies;

— **Do**: implement what was planned;

— **Check**: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives and requirements and report the results;

— **Act**: take actions to improve performance, as necessary.

0.3.3 Risk-based thinking

Risk-based thinking (see Clause A.4) is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of this International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analysing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.

Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

0.4 Relationship with other management system standards

This International Standard applies the framework developed by ISO to improve alignment among its International Standards for management systems (see Clause A.1).

This International Standard enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its quality management system with the requirements of other management system standards.

This International Standard relates to ISO 9000 and ISO 9004 as follows:

— ISO 9000 *Quality management systems — Fundamentals and vocabulary* provides essential background for the proper understanding and implementation of this International Standard;

— ISO 9004 *Managing for the sustained success of an organization — A quality management approach* provides guidance for organizations that choose to progress beyond the requirements of this International Standard.

Annex B provides details of other International Standards on quality management and quality management systems that have been developed by ISO/TC 176.

This International Standard does not include requirements specific to other management systems, such as those for environmental management, occupational health and safety management, or financial management.

Sector-specific quality management system standards based on the requirements of this International Standard have been developed for a number of sectors. Some of these standards specify additional quality management system requirements, while others are limited to providing guidance to the application of this International Standard within the particular sector.

A matrix showing the correlation between the clauses of this edition of this International Standard and the previous edition (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access web site at: www.iso.org/tc176/sc02/public.

Quality management systems — Requirements

1 Scope

This International Standard specifies requirements for a quality management system when an organization:

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1 In this International Standard, the terms "product" or "service" only apply to products and services intended for, or required by, a customer.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

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 its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

The organization shall monitor and review information about these external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

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

b) the requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.

4.3 Determining the scope of the quality management system

The organization shall determine the boundaries and applicability of the quality 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 requirements of relevant interested parties referred to in 4.2;

c) the products and services of the organization.

The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

4.4 Quality management system and its processes

4.4.1 The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

a) determine the inputs required and the outputs expected from these processes;

b) determine the sequence and interaction of these processes;

c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

d) determine the resources needed for these processes and ensure their availability;

e) assign the responsibilities and authorities for these processes;

f) address the risks and opportunities as determined in accordance with the requirements of 6.1;

g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;

h) improve the processes and the quality management system.

4.4.2 To the extent necessary, the organization shall:

a) maintain documented information to support the operation of its processes;

b) retain documented information to have confidence that the processes are being carried out as planned.

5 Leadership

5.1 Leadership and commitment

5.1.1 General

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

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

b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;

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

d) promoting the use of the process approach and risk-based thinking;

e) ensuring that the resources needed for the quality management system are available;

f) communicating the importance of effective quality management and of conforming to the quality management system requirements;

g) ensuring that the quality management system achieves its intended results;

h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

i) promoting improvement;

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

NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.

5.1.2 Customer focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c) the focus on enhancing customer satisfaction is maintained.

5.2 Policy

5.2.1 Developing the quality policy

Top management shall establish, implement and maintain a quality policy that:

a) is appropriate to the purpose and context of the organization and supports its strategic direction;

b) provides a framework for setting quality objectives;

c) includes a commitment to satisfy applicable requirements;

d) includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the quality policy

The quality policy shall:

a) be available and be maintained as documented information;

b) be communicated, understood and applied within the organization;

c) be available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and authorities

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

Top management shall assign the responsibility and authority for:

a) ensuring that the quality management system conforms to the requirements of this International Standard;

b) ensuring that the processes are delivering their intended outputs;

c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;

d) ensuring the promotion of customer focus throughout the organization;

e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s);

b) enhance desirable effects;

c) prevent, or reduce, undesired effects;

d) achieve improvement.

6.1.2 The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement the actions into its quality management system processes (see 4.4);

2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

6.2 Quality objectives and planning to achieve them

6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives shall:

a) be consistent with the quality policy;

b) be measurable;

c) take into account applicable requirements;

d) be relevant to conformity of products and services and to enhancement of customer satisfaction;

e) be monitored;

f) be communicated;

g) be updated as appropriate.

The organization shall maintain documented information on the quality objectives.

6.2.2 When planning how to achieve its quality 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.

6.3 Planning of changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).

The organization shall consider:

a) the purpose of the changes and their potential consequences;

b) the integrity of the quality management system;

c) the availability of resources;

d) the allocation or reallocation of responsibilities and authorities.

7 Support

7.1 Resources

7.1.1 General

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

The organization shall consider:

a) the capabilities of, and constraints on, existing internal resources;

b) what needs to be obtained from external providers.

7.1.2 People

The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

NOTE Infrastructure can include:

a) buildings and associated utilities;

b) equipment, including hardware and software;

c) transportation resources;

d) information and communication technology.

7.1.4 Environment for the operation of processes

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE A suitable environment can be a combination of human and physical factors, such as:

a) social (e.g. non-discriminatory, calm, non-confrontational);

b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);

c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization shall ensure that the resources provided:

a) are suitable for the specific type of monitoring and measurement activities being undertaken;

b) are maintained to ensure their continuing fitness for their purpose.

The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

b) identified in order to determine their status;

c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

7.1.6 Organizational knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

NOTE 1 Organizational knowledge is knowledge specific to the organization; it is gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE 2 Organizational knowledge can be based on:

a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);

b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

7.2 Competence

The organization shall:

a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

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

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

d) retain appropriate documented information as evidence of competence.

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.

7.3 Awareness

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

a) the quality policy;

b) relevant quality objectives;

c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;

d) the implications of not conforming with the quality management system requirements.

7.4 Communication

The organization shall determine the internal and external communications relevant to the quality management system, including:

a) on what it will communicate;

b) when to communicate;

c) with whom to communicate;

d) how to communicate;

e) who communicates.

7.5 Documented information

7.5.1 General

The organization's quality management system shall include:

a) documented information required by this International Standard;

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

NOTE The extent of documented information for a quality 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 complexity of processes and their interactions;

— the competence of persons.

7.5.2 Creating and updating

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

7.5.3.1 Documented information required by the quality management system and by this International Standard 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).

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

a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;

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

d) retention and disposition.

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

Documented information retained as evidence of conformity shall be protected from unintended alterations.

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.

8 Operation

8.1 Operational planning and control

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

a) determining the requirements for the products and services;

b) establishing criteria for:

   1) the processes;

   2) the acceptance of products and services;

c) determining the resources needed to achieve conformity to the product and service requirements;

d) implementing control of the processes in accordance with the criteria;

e) determining and keeping documented information to the extent necessary:

   1) to have confidence that the processes have been carried out as planned;

2) to demonstrate the conformity of products and services to their requirements.

NOTE "Keeping" implies both the maintaining and the retaining of documented information.

The output of this planning shall be suitable for the organization's operations.

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 outsourced processes are controlled (see 8.4).

8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers shall include:

a) providing information relating to products and services;

b) handling enquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property;

e) establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the requirements related to products and services

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

a) the requirements for the products and services are defined, including:

1) any applicable statutory and regulatory requirements;

2) those considered necessary by the organization;

b) the organization can meet the claims for the products and services it offers.

8.2.3 Review of requirements related to products and services

8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;

b) requirements not stated by the customer, but necessary for the specified or intended use, when known;

c) requirements specified by the organization;

d) statutory and regulatory requirements applicable to the products and services;

e) contract or order requirements differing from those previously expressed.

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues or advertising material.

8.2.3.2 The organization shall retain documented information, as applicable:

a) on the results of the review;

b) on any new requirements for the products and services.

8.2.4 Changes to requirements for products and services

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and development of products and services

8.3.1 General

The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.2 Design and development planning

In determining the stages and controls for design and development, the organization shall consider:

a) the nature, duration and complexity of the design and development activities;

b) the required process stages, including applicable design and development reviews;

c) the required design and development verification and validation activities;

d) the responsibilities and authorities involved in the design and development process;

e) the internal and external resource needs for the design and development of products and services;

f) the need to control interfaces between persons involved in the design and development process;

g) the need for involvement of customers and users in the design and development process;

h) the requirements for subsequent provision of products and services;

i) the level of control expected for the design and development process by customers and other relevant interested parties;

j) the documented information needed to demonstrate that design and development requirements have been met.

8.3.3 Design and development inputs

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

a) functional and performance requirements;

b) information derived from previous similar design and development activities;

c) statutory and regulatory requirements;

d) standards or codes of practice that the organization has committed to implement;

e) potential consequences of failure due to the nature of the products and services.

Inputs shall be adequate for design and development purposes, complete and unambiguous.

Conflicting design and development inputs shall be resolved.

The organization shall retain documented information on design and development inputs.

8.3.4 Design and development controls

The organization shall apply controls to the design and development process to ensure that:

a) the results to be achieved are defined;

b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;

c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;

d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;

e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;

f) documented information of these activities is retained.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

8.3.5 Design and development outputs

The organization shall ensure that design and development outputs:

a) meet the input requirements;

b) are adequate for the subsequent processes for the provision of products and services;

c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organization shall retain documented information on design and development outputs.

8.3.6 Design and development changes

The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The organization shall retain documented information on:

a) design and development changes;

b) the results of reviews;

c) the authorization of the changes;

d) the actions taken to prevent adverse impacts.

8.4 Control of externally provided processes, products and services

8.4.1 General

The organization shall ensure that externally provided processes, products and services conform to requirements.

The organization shall determine the controls to be applied to externally provided processes, products and services when:

a) products and services from external providers are intended for incorporation into the organization's own products and services;

b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;

c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and extent of control

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

The organization shall:

a) ensure that externally provided processes remain within the control of its quality management system;

b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

c) take into consideration:

   1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;

   2) the effectiveness of the controls applied by the external provider;

d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 Information for external providers

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements for:

a) the processes, products and services to be provided;

b) the approval of:

   1) products and services;

   2) methods, processes and equipment;

3) the release of products and services;

c) competence, including any required qualification of persons;

d) the external providers' interactions with the organization;

e) control and monitoring of the external providers' performance to be applied by the organization;

f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

8.5 Production and service provision

8.5.1 Control of production and service provision

The organization shall implement production and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

a) the availability of documented information that defines:

1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

2) the results to be achieved;

b) the availability and use of suitable monitoring and measuring resources;

c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

d) the use of suitable infrastructure and environment for the operation of processes;

e) the appointment of competent persons, including any required qualification;

f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) the implementation of actions to prevent human error;

h) the implementation of release, delivery and post-delivery activities.

8.5.2 Identification and traceability

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

8.5.3 Property belonging to customers or external providers

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

NOTE A customer's or external provider's property can include material, components, tools and equipment, premises, intellectual property and personal data.

8.5.4 Preservation

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

8.5.5 Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization shall consider:

a) statutory and regulatory requirements;

b) the potential undesired consequences associated with its products and services;

c) the nature, use and intended lifetime of its products and services;

d) customer requirements;

e) customer feedback.

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.6 Control of changes

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of products and services

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

The organization shall retain documented information on the release of products and services. The documented information shall include:

a) evidence of conformity with the acceptance criteria;

b) traceability to the person(s) authorizing the release.

8.7 Control of nonconforming outputs

8.7.1 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

The organization shall deal with nonconforming outputs in one or more of the following ways:

a) correction;

b) segregation, containment, return or suspension of provision of products and services;

c) informing the customer;

d) obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 The organization shall retain documented information that:

a) describes the nonconformity;

b) describes the actions taken;

c) describes any concessions obtained;

d) identifies the authority deciding the action in respect of the nonconformity.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization shall determine:

a) what needs to be monitored and measured;

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

c) when the monitoring and measuring shall be performed;

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

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

The organization shall retain appropriate documented information as evidence of the results.

9.1.2 Customer satisfaction

The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.

NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

9.1.3 Analysis and evaluation

The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used to evaluate:

a) conformity of products and services;

b) the degree of customer satisfaction;

c) the performance and effectiveness of the quality management system;

d) if planning has been implemented effectively;

e) the effectiveness of actions taken to address risks and opportunities;

f) the performance of external providers;

g) the need for improvements to the quality management system.

NOTE Methods to analyse data can include statistical techniques.

9.2 Internal audit

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

a) conforms to:

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

2) the requirements of this International Standard;

b) is effectively implemented and maintained.

9.2.2 The organization shall:

a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

b) define the audit criteria and scope for each audit;

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

d) ensure that the results of the audits are reported to relevant management;

e) take appropriate correction and corrective actions without undue delay;

f) retain documented information as evidence of the implementation of the audit programme and the audit results.

NOTE See ISO 19011 for guidance.

9.3 Management review

9.3.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the quality management system;

c) information on the performance and effectiveness of the quality management system, including trends in:

   1) customer satisfaction and feedback from relevant interested parties;

   2) the extent to which quality objectives have been met;

   3) process performance and conformity of products and services;

   4) nonconformities and corrective actions;

   5) monitoring and measurement results;

   6) audit results;

   7) the performance of external providers;

d) the adequacy of resources;

e) the effectiveness of actions taken to address risks and opportunities (see 6.1);

f) opportunities for improvement.

9.3.3 Management review outputs

The outputs of the management review shall include decisions and actions related to:

a) opportunities for improvement;

b) any need for changes to the quality management system;

c) resource needs.

The organization shall retain documented information as evidence of the results of management reviews.

10 Improvement

10.1 General

The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include:

a) improving products and services to meet requirements as well as to address future needs and expectations;

b) correcting, preventing or reducing undesired effects;

c) improving the performance and effectiveness of the quality management system.

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall:

a) react to the nonconformity and, as applicable:

   1) take action to control and correct it;

   2) deal with the consequences;

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 and analysing the nonconformity;

   2) determining the causes of the nonconformity;

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

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the quality management system, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

10.2.2 The organization shall retain documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;

b) the results of any corrective action.

10.3 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

Annex A
(informative)

Clarification of new structure, terminology and concepts

A.1 Structure and terminology

The clause structure (i.e. clause sequence) and some of the terminology of this edition of this International Standard, in comparison with the previous edition (ISO 9001:2008), have been changed to improve alignment with other management systems standards.

There is no requirement in this International Standard for its structure and terminology to be applied to the documented information of an organization's quality management system.

The structure of clauses is intended to provide a coherent presentation of requirements, rather than a model for documenting an organization's policies, objectives and processes. The structure and content of documented information related to a quality management system can often be more relevant to its users if it relates to both the processes operated by the organization and information maintained for other purposes.

There is no requirement for the terms used by an organization to be replaced by the terms used in this International Standard to specify quality management system requirements. Organizations can choose to use terms which suit their operations (e.g. using "records", "documentation" or "protocols" rather than "documented information"; or "supplier", "partner" or "vendor" rather than "external provider"). Table A.1 shows the major differences in terminology between this edition of this International Standard and the previous edition.

Table A.1 — Major differences in terminology between ISO 9001:2008 and ISO 9001:2015

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used (See Clause A.5 for clarification of applicability)
Management representative	Not used (Similar responsibilities and authorities are assigned but no requirement for a single management representative)
Documentation, quality manual, documented procedures, records	Documented information
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider

A.2 Products and services

ISO 9001:2008 used the term "product" to include all output categories. This edition of this International Standard uses "products and services". The term "products and services" includes all output categories (hardware, services, software and processed materials).

The specific inclusion of "services" is intended to highlight the differences between products and services in the application of some requirements. The characteristic of services is that at least part of the output is realized at the interface with the customer. This means, for example, that conformity to requirements cannot necessarily be confirmed before service delivery.

In most cases, products and services are used together. Most outputs that organizations provide to customers, or are supplied to them by external providers, include both products and services. For example, a tangible or intangible product can have some associated service or a service can have some associated tangible or intangible product.

A.3 Understanding the needs and expectations of interested parties

Subclause 4.2 specifies requirements for the organization to determine the interested parties that are relevant to the quality management system and the requirements of those interested parties. However, 4.2 does not imply extension of quality management system requirements beyond the scope of this International Standard. As stated in the scope, this International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.

There is no requirement in this International Standard for the organization to consider interested parties where it has decided that those parties are not relevant to its quality management system. It is for the organization to decide if a particular requirement of a relevant interested party is relevant to its quality management system.

A.4 Risk-based thinking

The concept of risk-based thinking has been implicit in previous editions of this International Standard, e.g. through requirements for planning, review and improvement. This International Standard specifies requirements for the organization to understand its context (see 4.1) and determine risks as a basis for planning (see 6.1). This represents the application of risk-based thinking to planning and implementing quality management system processes (see 4.4) and will assist in determining the extent of documented information.

One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this International Standard does not have a separate clause or subclause on preventive action. The concept of preventive action is expressed through the use of risk-based thinking in formulating quality management system requirements.

The risk-based thinking applied in this International Standard has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements. There is greater flexibility than in ISO 9001:2008 in the requirements for processes, documented information and organizational responsibilities.

Although 6.1 specifies that the organization shall plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Organizations can decide whether or not to develop a more extensive risk management methodology than is required by this International Standard, e.g. through the application of other guidance or standards.

Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its objectives, and the effects of uncertainty are not the same for all organizations. Under the requirements of 6.1, the organization is responsible for its application of risk-based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks.

A.5 Applicability

This International Standard does not refer to "exclusions" in relation to the applicability of its requirements to the organization's quality management system. However, an organization can review the applicability of requirements due to the size or complexity of the organization, the management model it adopts, the range of the organization's activities and the nature of the risks and opportunities it encounters.

The requirements for applicability are addressed in 4.3, which defines conditions under which an organization can decide that a requirement cannot be applied to any of the processes within the scope of its quality management system. The organization can only decide that a requirement is not applicable if its decision will not result in failure to achieve conformity of products and services.

A.6 Documented information

As part of the alignment with other management system standards, a common clause on "documented information" has been adopted without significant change or addition (see 7.5). Where appropriate, text elsewhere in this International Standard has been aligned with its requirements. Consequently, "documented information" is used for all document requirements.

Where ISO 9001:2008 used specific terminology such as "document" or "documented procedures", "quality manual" or "quality plan", this edition of this International Standard defines requirements to "maintain documented information".

Where ISO 9001:2008 used the term "records" to denote documents needed to provide evidence of conformity with requirements, this is now expressed as a requirement to "retain documented information". The organization is responsible for determining what documented information needs to be retained, the period of time for which it is to be retained and the media to be used for its retention.

A requirement to "maintain" documented information does not exclude the possibility that the organization might also need to "retain" that same documented information for a particular purpose, e.g. to retain previous versions of it.

Where this International Standard refers to "information" rather than "documented information" (e.g. in 4.1: "The organization shall monitor and review the information about these external and internal issues"), there is no requirement that this information is to be documented. In such situations, the organization can decide whether or not it is necessary or appropriate to maintain documented information.

A.7 Organizational knowledge

In 7.1.6, this International Standard addresses the need to determine and manage the knowledge maintained by the organization, to ensure that it can achieve conformity of products and services.

Requirements regarding organizational knowledge were introduced for the purpose of:

a) safeguarding the organization from loss of knowledge, e.g.
   - through staff turnover;
   - failure to capture and share information;

b) encouraging the organization to acquire knowledge, e.g.
   - learning from experience;
   - mentoring;
   - benchmarking.

A.8 Control of externally provided processes, products and services

All forms of externally provided processes, products and services are addressed in 8.4, e.g. whether through:

a) purchasing from a supplier;

b) an arrangement with an associate company;

c) outsourcing processes to an external provider.

Outsourcing always has the essential characteristic of a service, since it will have at least one activity necessarily performed at the interface between the provider and the organization.

The controls required for external provision can vary widely depending on the nature of the processes, products and services. The organization can apply risk-based thinking to determine the type and extent of controls appropriate to particular external providers and externally provided processes, products and services.

Annex B
(informative)

Other International Standards on quality management and quality management systems developed by ISO/TC 176

The International Standards described in this annex have been developed by ISO/TC 176 to provide supporting information for organizations that apply this International Standard, and to provide guidance for organizations that choose to progress beyond its requirements. Guidance or requirements contained in the documents listed in this annex do not add to, or modify, the requirements of this International Standard.

Table B.1 shows the relationship between these standards and the relevant clauses of this International Standard.

This annex does not include reference to the sector-specific quality management system standards developed by ISO/TC 176.

This International Standard is one of the three core standards developed by ISO/TC 176.

— ISO 9000 *Quality management systems — Fundamentals and vocabulary* provides an essential background for the proper understanding and implementation of this International Standard. The quality management principles are described in detail in ISO 9000 and have been taken into consideration during the development of this International Standard. These principles are not requirements in themselves, but they form the foundation of the requirements specified by this International Standard. ISO 9000 also defines the terms, definitions and concepts used in this International Standard.

— ISO 9001 (this International Standard) specifies requirements aimed primarily at giving confidence in the products and services provided by an organization and thereby enhancing customer satisfaction. Its proper implementation can also be expected to bring other organizational benefits, such as improved internal communication, better understanding and control of the organization's processes.

— ISO 9004 *Managing for the sustained success of an organization — A quality management approach* provides guidance for organizations that choose to progress beyond the requirements of this International Standard, to address a broader range of topics that can lead to improvement of the organization's overall performance. ISO 9004 includes guidance on a self-assessment methodology for an organization to be able to evaluate the level of maturity of its quality management system.

The International Standards outlined below can provide assistance to organizations when they are establishing or seeking to improve their quality management systems, their processes or their activities.

— ISO 10001 *Quality management — Customer satisfaction — Guidelines for codes of conduct for organizations* provides guidance to an organization in determining that its customer satisfaction provisions meet customer needs and expectations. Its use can enhance customer confidence in an organization and improve customer understanding of what to expect from an organization, thereby reducing the likelihood of misunderstandings and complaints.

— ISO 10002 *Quality management — Customer satisfaction — Guidelines for complaints handling in organizations* provides guidance on the process of handling complaints by recognizing and addressing the needs and expectations of complainants and resolving any complaints received. ISO 10002 provides an open, effective and easy-to-use complaints process, including training of people. It also provides guidance for small businesses.

— ISO 10003 *Quality management — Customer satisfaction — Guidelines for dispute resolution external to organizations* provides guidance for effective and efficient external dispute resolution for product-related complaints. Dispute resolution gives an avenue of redress when organizations

do not remedy a complaint internally. Most complaints can be resolved successfully within the organization, without adversarial procedures.

— ISO 10004 *Quality management — Customer satisfaction — Guidelines for monitoring and measuring* provides guidelines for actions to enhance customer satisfaction and to determine opportunities for improvement of products, processes and attributes that are valued by customers. Such actions can strengthen customer loyalty and help retain customers.

— ISO 10005 *Quality management systems — Guidelines for quality plans* provides guidance on establishing and using quality plans as a means of relating requirements of the process, product, project or contract, to work methods and practices that support product realization. Benefits of establishing a quality plan are increased confidence that requirements will be met, that processes are in control and the motivation that this can give to those involved.

— ISO 10006 *Quality management systems — Guidelines for quality management in projects* is applicable to projects from the small to large, from simple to complex, from an individual project to being part of a portfolio of projects. ISO 10006 is to be used by personnel managing projects and who need to ensure that their organization is applying the practices contained in the ISO quality management system standards.

— ISO 10007 *Quality management systems — Guidelines for configuration management* is to assist organizations applying configuration management for the technical and administrative direction over the life cycle of a product. Configuration management can be used to meet the product identification and traceability requirements specified in this International Standard.

— ISO 10008 *Quality management — Customer satisfaction — Guidelines for business-to-consumer electronic commerce transactions* gives guidance on how organizations can implement an effective and efficient business-to-consumer electronic commerce transaction (B2C ECT) system, and thereby provide a basis for consumers to have increased confidence in B2C ECTs, enhance the ability of organizations to satisfy consumers and help reduce complaints and disputes.

— ISO 10012 *Measurement management systems — Requirements for measurement processes and measuring equipment* provides guidance for the management of measurement processes and metrological confirmation of measuring equipment used to support and demonstrate compliance with metrological requirements. ISO 10012 provides quality management criteria for a measurement management system to ensure metrological requirements are met.

— ISO/TR 10013 *Guidelines for quality management system documentation* provides guidelines for the development and maintenance of the documentation necessary for a quality management system. ISO/TR 10013 can be used to document management systems other than those of the ISO quality management system standards, e.g. environmental management systems and safety management systems.

— ISO 10014 *Quality management — Guidelines for realizing financial and economic benefits* is addressed to top management. It provides guidelines for realizing financial and economic benefits through the application of quality management principles. It facilitates application of management principles and selection of methods and tools that enable the sustainable success of an organization.

— ISO 10015 *Quality management — Guidelines for training* provides guidelines to assist organizations in addressing issues related to training. ISO 10015 can be applied whenever guidance is required to interpret references to "education" and "training" within the ISO quality management system standards. Any reference to "training" includes all types of education and training.

— ISO/TR 10017 *Guidance on statistical techniques for ISO 9001:2000* explains statistical techniques which follow from the variability that can be observed in the behaviour and results of processes, even under conditions of apparent stability. Statistical techniques allow better use of available data to assist in decision making, and thereby help to continually improve the quality of products and processes to achieve customer satisfaction.

— ISO 10018 *Quality management — Guidelines on people involvement and competence* provides guidelines which influence people involvement and competence. A quality management system

depends on the involvement of competent people and the way that they are introduced and integrated into the organization. It is critical to determine, develop and evaluate the knowledge, skills, behaviour and work environment required.

— ISO 10019 *Guidelines for the selection of quality management system consultants and use of their services* provides guidance for the selection of quality management system consultants and the use of their services. It gives guidance on the process for evaluating the competence of a quality management system consultant and provides confidence that the organization's needs and expectations for the consultant's services will be met.

— ISO 19011 *Guidelines for auditing management systems* provides guidance on the management of an audit programme, on the planning and conducting of an audit of a management system, as well as on the competence and evaluation of an auditor and an audit team. ISO 19011 is intended to apply to auditors, organizations implementing management systems, and organizations needing to conduct audits of management systems.

Table B.1 — Relationship between other International Standards on quality management and quality management systems and the clauses of this International Standard

Other International Standard	Clause in this International Standard						
	4	5	6	7	8	9	10
ISO 9000	All	All	All	All	All	All	All
ISO 9004	All	All	All	All	All	All	All
ISO 10001					8.2.2, 8.5.1	9.1.2	
ISO 10002					8.2.1,	9.1.2	10.2.1
ISO 10003						9.1.2	
ISO 10004						9.1.2, 9.1.3	
ISO 10005		5.3	6.1, 6.2	All	All	9.1	10.2
ISO 10006	All	All	All	All	All	All	All
ISO 10007					8.5.2		
ISO 10008	All	All	All	All	All	All	All
ISO 10012				7.1.5			
ISO/TR 10013				7.5			
ISO 10014	All	All	All	All	All	All	All
ISO 10015				7.2			
ISO/TR 10017			6.1	7.1.5		9.1	
ISO 10018	All	All	All	All	All	All	All
ISO 10019					8.4		
ISO 19011						9.2	

NOTE "All" indicates that all the subclauses in the specific clause of this International Standard are related to the other International Standard.

Bibliography

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[3] ISO 10002, *Quality management — Customer satisfaction — Guidelines for complaints handling in organizations*

[4] ISO 10003, *Quality management — Customer satisfaction — Guidelines for dispute resolution external to organizations*

[5] ISO 10004, *Quality management — Customer satisfaction — Guidelines for monitoring and measuring*

[6] ISO 10005, *Quality management systems — Guidelines for quality plans*

[7] ISO 10006, *Quality management systems — Guidelines for quality management in projects*

[8] ISO 10007, *Quality management systems — Guidelines for configuration management*

[9] ISO 10008, *Quality management — Customer satisfaction — Guidelines for business-to-consumer electronic commerce transactions*

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[11] ISO/TR 10013, *Guidelines for quality management system documentation*

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[13] ISO 10015, *Quality management — Guidelines for training*

[14] ISO/TR 10017, *Guidance on statistical techniques for ISO 9001:2000*

[15] ISO 10018, *Quality management — Guidelines on people involvement and competence*

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[17] ISO 14001, *Environmental management systems — Requirements with guidance for use*

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[20] ISO 37500, *Guidance on outsourcing*

[21] ISO/IEC 90003, *Software engineering — Guidelines for the application of ISO 9001:2008 to computer software*

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INTERNATIONAL STANDARD

ISO 14001

Third edition
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Environmental management systems — Requirements with guidance for use

Systèmes de management environnemental — Exigences et lignes directrices pour son utilisation

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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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 207, *Environmental management*, Subcommittee SC 1, *Environmental management systems*.

This third edition cancels and replaces the second edition (ISO 14001:2004), which has been technically revised. It also incorporates the Technical Corrigendum ISO 14001:2004/Cor.1:2009.

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, growing pressures on the environment from pollution, inefficient use of resources, improper waste management, climate change, degradation of ecosystems and loss of biodiversity.

This has 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.

0.2 Aim of an environmental management system

The purpose of this International Standard is to provide 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 can provide top management with information to build success over the long term and create options for contributing to sustainable development by:

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

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

— assisting the organization in the fulfilment of compliance obligations;

— enhancing environmental performance;

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

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

— communicating environmental information to relevant interested parties.

This International Standard, like other International Standards, is not intended to increase or change an organization's legal requirements.

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 implications. 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 International Standard can be used to assure interested parties that an effective environmental management system is in place.

Adoption of this International Standard, however, will not in itself guarantee optimal environmental outcomes. Application of this International Standard 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 International Standard.

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 can be 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 introduced in this International Standard could be integrated into a PDCA model, which can help new and existing users to understand the importance of a systems approach.

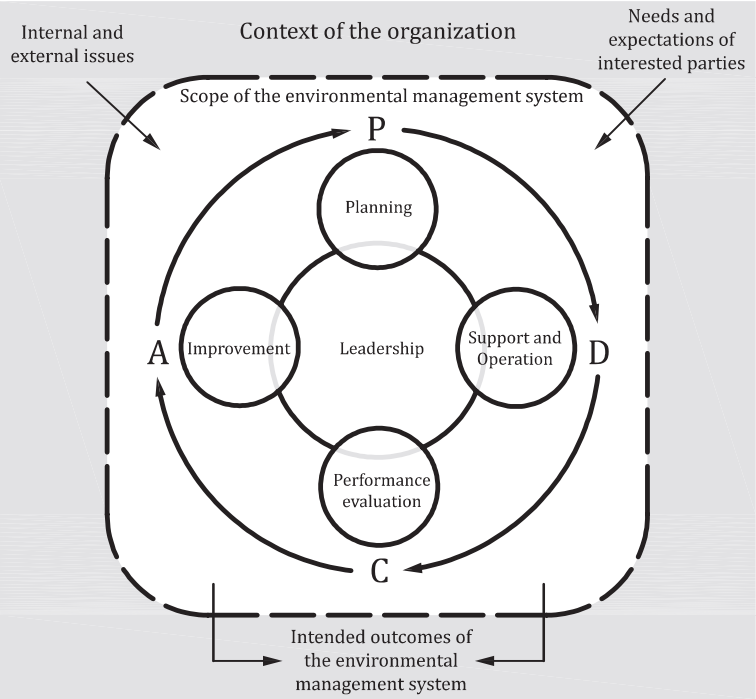

Figure 1 — Relationship between PDCA and the framework in this International Standard

0.5 Contents of this International Standard

This International Standard conforms to ISO's requirements for management system standards. These requirements include a high level structure, identical core text, and common terms with core definitions, designed to benefit users implementing multiple ISO management system standards.

This International Standard does not include requirements specific to other management systems, such as those for quality, occupational health and safety, energy or financial management. However, this International Standard 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 International Standard contains the requirements used to assess conformity. An organization that wishes to demonstrate conformity with this International Standard 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 International Standard. Annex B shows broad technical correspondence between the previous edition of this International Standard and this edition. Implementation guidance on environmental management systems is included in ISO 14004.

In this International Standard, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Information marked as “NOTE” is intended to assist the understanding or use of the document. “Notes to entry” used in Clause 3 provide additional information that supplements the terminological data and can contain provisions relating to the use of a term.

The terms and definitions in Clause 3 are arranged in conceptual order, with an alphabetical index provided at the end of the document.

Environmental management systems — Requirements with guidance for use

1 Scope

This International Standard specifies the requirements for an environmental management system that an organization can use to enhance its environmental performance. This International Standard 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 International Standard helps an organization achieve the intended outcomes of its environmental management system, which provide value for the environment, the organization itself and interested parties. Consistent with the organization's environmental policy, the intended outcomes of an environmental management system include:

— enhancement of environmental performance;

— fulfilment of compliance obligations;

— achievement of environmental objectives.

This International Standard is applicable to any organization, regardless of size, type and 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 International Standard does not state specific environmental performance criteria.

This International Standard can be used in whole or in part to systematically improve environmental management. Claims of conformity to this International Standard, 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.

3 Terms and definitions

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

3.1 Terms related to organization and leadership

3.1.1
management system
set of interrelated or interacting elements of an *organization* (3.1.4) to establish policies and *objectives* (3.2.5) and *processes* (3.3.5) to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines (e.g. quality, environment, occupational health and safety, energy, financial management).

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

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), fulfil *compliance obligations* (3.2.9), and address *risks and opportunities* (3.2.11)

3.1.3
environmental policy
intentions and direction of an *organization* (3.1.4) related to *environmental performance* (3.4.11), as formally expressed by its *top management* (3.1.5)

3.1.4
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.

3.1.5
top management
person or group of people who directs and controls an *organization* (3.1.4) 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.

3.1.6
interested party
person or *organization* (3.1.4) 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* (3.1.4) 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* (3.1.4) 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 one or more 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* (3.1.4) *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 financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product, service and *process* (3.3.5)).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, 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).

3.2.6
environmental objective
objective (3.2.5) set by the *organization* (3.1.4) consistent with its *environmental policy* (3.1.3)

3.2.7
prevention of pollution
use of *processes* (3.3.5), 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* (3.1.4) and *interested parties* (3.1.6) that the need or expectation under consideration is implied.

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

Note 3 to entry: Requirements other than legal requirements become obligatory when the organization decides to comply with them.

3.2.9
compliance obligations (preferred term)
legal requirements and other requirements (admitted term)
legal *requirements* (3.2.8) that an *organization* (3.1.4) 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 or non-governmental organizations.

3.2.10
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"* (as defined in ISO Guide 73:2009, 3.5.1.3) and *"consequences"* (as defined in ISO Guide 73:2009, 3.6.1.3), 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"* (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence.

3.2.11
risks and opportunities
potential adverse effects (threats) and potential beneficial effects (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* (3.1.4) 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 *environmental management system* (3.1.2), including related *processes* (3.3.5);

— information created in order for the organization to operate (can be referred to as documentation);

— evidence of results achieved (can be referred to as 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 — The words "(or service)" have been added to the definition and Note 1 to entry has been added.]

3.3.4
outsource (verb)
make an arrangement where an external *organization* (3.1.4) performs part of an organization's function or *process* (3.3.5)

Note 1 to entry: An external organization is outside the scope of the *management system* (3.1.1), although the outsourced function or process is within the scope.

3.3.5
process
set of interrelated or interacting activities which transforms inputs into outputs

Note 1 to entry: A process can be documented or not.

3.4 Terms related to performance evaluation and improvement

3.4.1
audit
systematic, independent and documented *process* (3.3.5) for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An internal audit is conducted by the *organization* (3.1.4) itself, or by an external party on its behalf.

Note 2 to entry: An audit can be a combined audit (combining two or more disciplines).

Note 3 to entry: Independence can be demonstrated by the freedom from responsibility for the activity being audited or freedom from bias and conflict of interest.

Note 4 to entry: "Audit evidence" consists of records, statements of fact or other information which are relevant to the audit criteria and are verifiable; and "audit criteria" are the set of policies, procedures or *requirements* (3.2.8) used as a reference against which audit evidence is compared, as defined in ISO 19011:2011, 3.3 and 3.2 respectively.

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 International Standard and additional *environmental management system* (3.1.2) requirements that an *organization* (3.1.4) establishes for itself.

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

Note 1 to entry: There can be more than one cause for a nonconformity.

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* (3.1.4) *environmental policy* (3.1.3).

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

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

3.4.7
indicator
measurable representation of the condition or status of operations, management or conditions

[SOURCE: ISO 14031:2013, 3.15]

3.4.8
monitoring
determining the status of a system, a *process* (3.3.5) or an activity

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

3.4.9
measurement
process (3.3.5) 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 the management of activities, *processes* (3.3.5), products (including services), systems or *organizations* (3.1.4).

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* (3.1.4) *environmental policy* (3.1.3), *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. Such issues shall include environmental conditions being affected by or capable of affecting the organization.

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.

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.

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

The scope shall be maintained as documented information and 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 International Standard.

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;

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 management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence.

5.2 Environmental policy

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

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 sustainable resource use, climate change mitigation and adaptation, and protection of biodiversity and ecosystems.

d) includes a commitment to fulfil its compliance obligations;

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

The environmental policy shall:

— be maintained as documented information;

— be communicated within the organization;

— be available to interested parties.

5.3 Organizational 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 International Standard;

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 the process(es) needed to meet the requirements in 6.1.1 to 6.1.4.

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

a) the issues referred to in 4.1;

b) the requirements referred to in 4.2;

c) the scope of its environmental management system;

and determine the risks and opportunities, related to its environmental aspects (see 6.1.2), compliance obligations (see 6.1.3) and other issues and requirements, 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.

Within the scope of the environmental management system, the organization shall determine potential emergency situations, including those that can have an environmental impact.

The organization shall maintain documented information of its:

— risks and opportunities that need to be addressed;

— process(es) needed in 6.1.1 to 6.1.4, to the extent necessary to have confidence 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.

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

a) change, including planned or new developments, and new or modified activities, products and services;

b) abnormal conditions and reasonably foreseeable 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.

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

The organization shall maintain documented information of its:

— environmental aspects and associated environmental impacts;

— criteria used to determine its significant environmental aspects;

— significant environmental aspects.

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

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.

The organization shall maintain documented information of its compliance obligations.

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

6.1.4 Planning action

The organization shall plan:

a) to take actions to address its:

1) significant environmental aspects;

2) compliance obligations;

3) risks and opportunities identified in 6.1.1;

b) how to:

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

The organization shall maintain documented information on the environmental objectives.

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.

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 fulfil 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.

The organization shall retain appropriate documented information 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 fulfilling 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.

The organization shall retain documented information as evidence of its communications, as appropriate.

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 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 International Standard;

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

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 International Standard 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.

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.

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.

8 Operation

8.1 Operational planning and control

The organization shall establish, implement, control and maintain the processes needed to meet environmental management system requirements, and to implement the actions identified in 6.1 and 6.2, 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 outsourced processes are controlled or influenced. The type and extent of control or influence to be applied to the process(es) 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 organization shall maintain documented information to the extent necessary to have confidence that the processes have been 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 potential emergency situations identified in 6.1.1.

The organization shall:

a) prepare to respond by planning actions 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 actions, where practicable;

e) periodically review and revise the process(es) and planned response actions, 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 organization shall maintain documented information to the extent necessary to have confidence that the process(es) is (are) carried out as planned.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization shall monitor, measure, analyse and evaluate its environmental performance.

The organization shall determine:

a) what needs to be monitored and measured;

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 evaluate its environmental performance and the effectiveness of the environmental management system.

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.

The organization shall retain appropriate documented information 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 fulfilment of 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.

The organization shall retain documented information 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 International Standard;

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, the organization shall take into consideration the environmental importance of the processes concerned, changes affecting the organization and the results of previous audits.

The organization shall:

a) define the 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 the audits are reported to relevant management.

The organization shall retain documented information as evidence of the implementation of the audit programme and the audit results.

9.3 Management review

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

The management review shall include consideration of:

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, 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) fulfilment of its compliance obligations;

   4) audit results;

e) adequacy of resources;

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

g) opportunities for continual improvement.

The outputs of the management review shall include:

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

— decisions related to continual improvement opportunities;

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

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

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

— any implications for the strategic direction of the organization.

The organization shall retain documented information as evidence of the results of management reviews.

10 Improvement

10.1 General

The organization shall determine opportunities for improvement (see 9.1, 9.2 and 9.3) and implement 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 causes of the nonconformity, in order that it does not recur or occur elsewhere, by:

   1) reviewing the nonconformity;

   2) determining the causes of the nonconformity;

   3) determining if similar nonconformities exist, or could 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 the environmental impact(s).

The organization shall retain documented information as evidence of:

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

— the results of any corrective action.

10.3 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the environmental management system to enhance environmental performance.

Annex A
(informative)

Guidance on the use of this International Standard

A.1 General

The explanatory information given in this annex is intended to prevent misinterpretation of the requirements contained in this International Standard. 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.

The requirements in this International Standard need to be viewed from a systems or holistic perspective. The user should not read a particular sentence or clause of this International Standard in isolation from other clauses. There is an interrelationship between the requirements in some clauses and the requirements in other clauses. For example, the organization needs to understand the relationship between the commitments in its environmental policy and the requirements that are specified in other clauses.

Management of 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. Management of change is addressed in various requirements of this International Standard, including

— maintaining the environmental management system (see 4.4),

— environmental aspects (see 6.1.2),

— internal communication (see 7.4.2),

— operational control (see 8.1),

— internal audit programme (see 9.2.2), and

— management review (see 9.3).

As part of managing change, the organization should address planned and unplanned changes to ensure that the unintended consequences of these changes do not have a negative effect on the intended outcomes of the environmental management system. Examples of change include:

— planned changes to products, processes, operations, equipment or facilities;

— changes in staff or external providers, including contractors;

— new information related to environmental aspects, environmental impacts and related technologies;

— changes in compliance obligations.

A.2 Clarification of structure and terminology

The clause structure and some of the terminology of this International Standard have been changed to improve alignment with other management systems standards. There is, however, no requirement in this International Standard for its clause structure or terminology to be applied to an organization's environmental management system documentation. There is no requirement to replace the terms used by an organization with the terms used in this International Standard. Organizations can choose to use terms that suit their business, e.g. "records", "documentation", or "protocols", 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 International Standard, 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 needs 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.

— In this International Standard, 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.

— This International Standard uses the term "interested party"; the term "stakeholder" is a synonym as it represents the same concept.

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

— The phrase "compliance obligations" replaces the phrase "legal requirements and other requirements to which the organization subscribes" used in the previous edition of this International Standard. The intent of this new phrase does not differ from that of the previous edition.

— "Documented information" replaces the nouns "documentation", "documents" and "records" used in previous editions of this International Standard. To distinguish the intent of the generic term "documented information", this International Standard now uses the phrase "retain documented information as evidence of…." to mean records, and "maintain documented information" to mean documentation other than records. The phrase "as evidence of…." is not a requirement to meet legal evidentiary requirements; its intent is only to indicate objective evidence needs to be retained.

— The phrase "external provider" means an external supplier organization (including a contractor) that provides a product or a service.

— The change from "identify" to "determine" is intended to harmonize with the standardized management system terminology. The word "determine" implies a discovery process that results in knowledge. The intent does not differ from that of previous editions.

— The phrase "intended outcome" is what the organization intends to achieve by implementing its environmental management system. The minimal intended outcomes include enhancement of environmental performance, fulfilment of compliance obligations and achievement of 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.

— 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). It replaces the phrase "persons working for it or on its behalf" and "persons working for or on behalf of the organization" used in the previous edition of this International Standard. The intent of this new phrase does not differ from that of the previous edition.

— The concept of "target" used in previous editions of this International Standard is captured within the term "environmental objective".

A.4 Context of the organization

A.4.1 Understanding the organization and its context

The intent of 4.1 is to provide a high-level, conceptual understanding of the important issues 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 internal and external 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 and biodiversity, that can either affect the organization's purpose, or be affected by its environmental aspects;

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

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

An understanding of the context of an organization is used to establish, implement, maintain and continually improve its environmental management system (see 4.4). The internal and external issues that are determined in 4.1 can result in risks and opportunities to the organization or to the environmental management system (see 6.1.1 to 6.1.3). The organization determines those that need to be addressed and managed (see 6.1.4, 6.2, Clause 7, Clause 8 and 9.1).

A.4.2 Understanding the needs and expectations of interested parties

An organization is expected to gain a general (i.e. high-level, not detailed) understanding of the expressed needs and expectations of those internal and external 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 6.1.1).

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.

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.

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 this International Standard throughout the entire

organization, or only in (a) specific part(s) of the organization, as long as the 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 upon 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. Scoping should not be used to exclude activities, products, services, or facilities that have or can have significant environmental aspects, or to evade its compliance obligations. The scope is a factual and representative statement of the organization's operations included within its environmental management system boundaries that should not mislead interested parties.

Once the organization asserts it conforms to this International Standard, 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 International Standard, including the level of detail and extent to which it:

a) establishes one or more processes to have confidence that it (they) is (are) controlled, carried out as planned and achieve the desired results;

b) integrates environmental management system requirements into its various business processes, such as design and development, procurement, human resources, sales and marketing;

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.

If this International Standard is implemented for (a) specific part(s) of an organization, policies, processes and documented information developed by other parts of the organization can be used to meet the requirements of this International Standard, provided they are applicable to that (those) specific part(s).

For information on maintaining the environmental management system as part of management of change, see Clause A.1.

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 should be personally involved or which top management should direct. Top management may delegate responsibility for these actions to others, but it retains accountability for ensuring the actions are performed.

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).

Three basic commitments for the environmental policy are specified in this International Standard to:

a) protect the environment;

b) fulfil 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 International Standard, 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 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, recycling, or air quality, and can also include commitments related to 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 fulfil its compliance obligations, particularly applicable legal requirements. This International Standard specifies a number of interconnected requirements related to this commitment. These include the need to:

— determine compliance obligations;

— ensure operations are carried out in accordance with these compliance obligations;

— evaluate fulfilment of the compliance obligations;

— correct nonconformities.

A.5.3 Organizational 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 International Standard and achieving the intended outcomes.

The specific roles and responsibilities identified in 5.3 may 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 in 6.1.1 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. The organization can ensure this by determining its risks and opportunities that need to be addressed and planning action to address them. These risks and opportunities can be related to environmental aspects, compliance obligations, other issues or other needs and expectations of interested parties.

Environmental aspects (see 6.1.2) can create risks and opportunities associated with adverse environmental impacts, beneficial environmental impacts, and other effects on the organization. The risks and opportunities related to environmental aspects can be determined as part of the significance evaluation or determined separately.

Compliance obligations (see 6.1.3) can create risks and opportunities, such as failing to comply (which can damage the organization's reputation or result in legal action) or performing beyond its compliance obligations (which can enhance the organization's reputation).

The organization can also have risks and opportunities related to other issues, including environmental conditions or needs and expectations of interested parties, which can affect the organization's ability to achieve the intended outcomes of its environmental management system, e.g.

a) environmental spillage due to literacy or language barriers among workers who cannot understand local work procedures;

b) increased flooding due to climate change that could affect the organizations premises;

c) lack of available resources to maintain an effective environmental management system due to economic constraints;

d) introducing new technology financed by governmental grants, which could improve air quality;

e) water scarcity during periods of drought that could affect the organization's ability to operate its emission control equipment.

Emergency situations are unplanned or unexpected events that need the 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. When determining potential emergency situations (e.g. fire, chemical spill, 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).

Although risks and opportunities need to be determined and addressed, there is no requirement for formal risk management or a documented risk management process. It is up to the organization to select the method it will use to determine its risks and opportunities. The method may involve a simple qualitative process or a full quantitative assessment depending on the context in which the organization operates.

The risks and opportunities identified (see 6.1.1 to 6.1.3) are inputs for planning actions (see 6.1.4) and for establishing the environmental objectives (see 6.2).

A.6.1.2 Environmental aspects

An organization determines its environmental aspects and associated environmental impacts, and determines those that are significant and, therefore, need to 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.

When determining environmental aspects, the organization considers a life cycle perspective. This does not require a detailed life cycle assessment; thinking carefully about the life cycle stages that can be controlled or influenced by the organization is sufficient. Typical stages of a product (or service) life cycle include raw material acquisition, design, production, transportation/delivery, use, end-of-life treatment and final disposal. The life cycle stages that are applicable will vary depending on the activity, product or service.

An organization needs to determine the environmental aspects within the scope of its environmental management system. It takes into account the inputs and outputs (both intended and unintended) that are associated with its current and relevant past activities, products and services; planned or new developments; and new or modified activities, products and services. The method used should consider normal and abnormal operating conditions, shut-down and start-up conditions, as well as the reasonably foreseeable emergency situations identified in 6.1.1. Attention should be paid to prior

occurrences of emergency situations. For information on environmental aspects as part of managing change, see Clause A.1.

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

When determining its environmental aspects, the organization can consider:

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 (noise), light);

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

h) use of space.

In addition to the environmental aspects that it can control 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, as well as products and services that it provides to others, including those associated with (an) outsourced process(es). With respect to those 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, however, 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.

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 and maintenance of facilities, organizational assets and infrastructure;

— environmental performance and practices of external providers;

— product transportation and service delivery, including packaging;

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

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

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). Other criteria may also be used. An environmental aspect might not be significant when only considering environmental criteria. It 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. These other criteria are not intended to be used to downgrade an aspect that is significant based on its environmental impact.

A significant environmental aspect can result 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, licenses or other forms of authorization;

d) orders, rules or guidance from regulatory agencies;

e) judgements 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 with the organization;

— relevant organizational or industry standards.

A.6.1.4 Planning action

The organization plans, at a high level, the actions that have to be taken within the environmental management system to address its significant environmental aspects, its compliance obligations, and the risks and opportunities identified in 6.1.1 that are a priority for the organization to achieve the intended outcomes of its environmental management system.

The actions planned may include establishing environmental objectives (see 6.2) or may be incorporated into other environmental management system processes, either individually or in combination. Some actions may be addressed through other management systems, such as those related to occupational health and safety or business continuity, or through other business processes related to risk, financial or human resource management.

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 may 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 should be 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.

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, it is important that the organization is able to determine whether or not an environmental objective has been achieved.

For additional information on environmental indicators, see ISO 14031.

A.7 Support

A.7.1 Resources

Resources are needed for the effective functioning and improvement of the environmental management system and to enhance environmental performance. Top management should ensure that those with environmental management system responsibilities are supported with the necessary resources. Internal resources may be supplemented by (an) external provider(s).

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.

A.7.2 Competence

The competency requirements of this International Standard 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

Awareness of the environmental policy should not be taken to mean that the commitments need to be 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 fulfil 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 and recommendations for continual improvement. Communication is a two-way process, in and out of 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 of many different interested parties, or multiple approaches might be necessary to address specific needs of individual interested parties.

The information received by the organization can contain requests from interested parties for specific information related to the management of its environmental aspects, or can contain general impressions or views on the way the organization carries out that management. These impressions or views can be positive or negative. In the latter case (e.g. complaints), it is important that a prompt and clear answer is provided by the organization. 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 appropriate, so that information meets the needs of relevant interested parties, enabling them to participate;

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

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

e) not exclude relevant information;

f) be understandable to interested parties.

For information on communication as part of managing change, see Clause A.1. For additional information on communication, see ISO 14063.

A.7.5 Documented information

An organization should create and maintain documented information in a manner sufficient to ensure a suitable, adequate and effective environmental management system. The primary focus should be 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 International Standard, an organization may choose to create additional documented information for purposes of transparency, accountability, continuity, consistency, training, or ease in auditing.

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

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, the risks and opportunities, significant environmental aspects and compliance obligations. 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 error 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 needed within its own business processes (e.g. procurement process) to control or influence (an) outsourced process(es) or (a) provider(s) of products and services. Its decision should 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 outcome 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 a process is outsourced, or when products and 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, an outsourced process performed onsite might be under the direct control of an organization; in other cases, an organization's ability to influence an outsourced process or external supplier might be limited.

When determining the type and extent of operational controls related to external providers, including contractors, the organization may 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.

For information on operational control as part of managing change, see Clause A.1. For information on life cycle perspective, see A.6.1.2.

An outsourced process is one that fulfils all of the following:

— it is within the scope of the environmental management system;

— it is integral to the organization's functioning;

— it is needed for the environmental management system to achieve its intended outcome;

— liability for conforming to requirements is retained by the organization;

— the organization and the external provider have a relationship where the process is perceived by interested parties as being carried out by the organization.

Environmental requirements are the organization's environmentally-related needs and expectations that it establishes for, 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.

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 its particular needs. For information on determining emergency situations, see A.6.1.1.

When planning 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 should be 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 should be 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 and 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, see ISO 14031.

A.9.1.2 Evaluation of 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 need to be evaluated periodically.

If compliance evaluation results indicate a failure to fulfil a legal requirement, the organization needs to determine and implement the actions necessary to achieve compliance. This might require communication with a regulatory agency and agreement on a course of action to fulfil its legal requirements. 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 need to be corrected, even if those nonconformities have not resulted in actual non-compliance with legal requirements.

A.9.2 Internal audit

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:

a) previously identified nonconformities and the effectiveness of the actions taken;

b) results of internal and external audits.

For additional information on establishing an internal audit programme, performing environmental management system audits and evaluating the competence of audit personnel, see ISO 19011. For information on internal audit programme as part of managing change, see Clause A.1.

A.9.3 Management review

The management review should be high-level; it does not need to be an exhaustive review of detailed information. The management review topics need not be addressed all at once. The review may take place over a period of time and can be part of regularly scheduled management activities, such as board or operational meetings; it does not need to be a separate activity.

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

For information on management review as part of managing change, see Clause A.1.

"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 International Standard and is implemented appropriately. "Effectiveness" refers to whether it is achieving the desired results.

A.10 Improvement

A.10.1 General

The organization should consider the results from analysis and evaluation of environmental performance, evaluation of compliance, internal audits and management review when taking action to improve.

Examples of improvement include corrective action, continual improvement, breakthrough change, innovation and re-organization.

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 (i.e. actions to address risks and opportunities).

A.10.3 Continual improvement

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.

Annex B
(informative)

Correspondence between ISO 14001:2015 and ISO 14001:2004

Table B.1 shows the correspondence between this edition of this International Standard (ISO 14001:2015) and the previous edition (ISO 14001:2004).

Table B.1 — Correspondence between ISO 14001:2015 and ISO 14001:2004

ISO 14001:2015		ISO 14001:2004	
Clause title	**Clause number**	**Clause number**	**Clause title**
Introduction			Introduction
Scope	1	1	Scope
Normative references	2	2	Normative references
Terms and definitions	3	3	Terms and definitions
Context of the organization (title only)	4		
		4	Environmental management system requirements (title only)
Understanding the organization and its context	4.1		
Understanding the needs and expectations of interested parties	4.2		
Determining the scope of the environmental management system	4.3	4.1	General requirements
Environmental management system	4.4	4.1	General requirements
Leadership (title only)	5		
Leadership and commitment	5.1		
Environmental policy	5.2	4.2	Environmental policy
Organizational roles, responsibilities and authorities	5.3	4.4.1	Resources, roles, responsibility and authority
Planning (title only)	6	4.3	Planning (title only)
Actions to address risks and opportunities (title only)	6.1		
General	6.1.1		
Environmental aspects	6.1.2	4.3.1	Environmental aspects
Compliance obligations	6.1.3	4.3.2	Legal and other requirements
Planning action	6.1.4		
Environmental objectives and planning to achieve them (title only)	6.2	4.3.3	Objectives, targets and programme(s)
Environmental objectives	6.2.1		
Planning actions to achieve environmental objectives	6.2.2		
Support (title only)	7	4.4	Implementation and operation (title only)
Resources	7.1	4.4.1	Resources, roles, responsibility and authority
Competence	7.2	4.4.2	Competence, training and awareness
Awareness	7.3		
Communication (title only)	7.4	4.4.3	Communication
General	7.4.1		
Internal communication	7.4.2		
External communication	7.4.3		

Table B.1 *(continued)*

ISO 14001:2015		ISO 14001:2004	
Clause title	**Clause number**	**Clause number**	**Clause title**
Documented information (title only)	7.5	4.4.4	Documentation
General	7.5.1		
Creating and updating	7.5.2	4.4.5	Control of documents
		4.5.4	Control of records
Control of documented information	7.5.3	4.4.5	Control of documents
		4.5.4	Control of records
Operation (title only)	8	4.4	Implementation and operation (title only)
Operational planning and control	8.1	4.4.6	Operational control
Emergency preparedness and response	8.2	4.4.7	Emergency preparedness and response
Performance evaluation (title only)	9	4.5	Checking (title only)
Monitoring, measurement, analysis and evaluation (title only)	9.1	4.5.1	Monitoring and measurement
General	9.1.1		
Evaluation of compliance	9.1.2	4.5.2	Evaluation of compliance
Internal audit (title only)	9.2	4.5.5	Internal audit
General	9.2.1		
Internal audit programme	9.2.2		
Management review	9.3	4.6	Management review
Improvement (title only)	10		
General	10.1		
Nonconformity and corrective action	10.2	4.5.3	Nonconformity, corrective action and preventive action
Continual improvement	10.3		
Guidance on the use of this International Standard	Annex A	Annex A	Guidance on the use of this International Standard
Correspondence between ISO 14001:2015 and ISO 14001:2004	Annex B		
		Annex B	Correspondence between ISO 14001:2004 and ISO 9001:2008
Bibliography			Bibliography
Alphabetical index of terms			

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