

ISO/IEC Directives, Part 1 — Consolidated ISO Supplement — Procedures specific to ISO

Directives ISO/IEC, Partie 1 — Supplément ISO consolidé — Procédures spécifiques à l'ISO

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Annex SL **(normative)**

Proposals for management system standards

SL.1 General

Whenever a proposal is made to prepare a new management system standard (MSS), including sector-specific MSS, a justification study (JS) shall be carried out in accordance with Appendix 1 to this Annex SL.

NOTE No JS is needed for the revision of an existing MSS whose development has already been approved and provided the scope is confirmed (unless it was not provided during its first development).

To the extent possible, the proposer shall endeavour to identify the full range of deliverables which will constitute the new or revised MSS family, and a JS shall be prepared for each of the deliverables.

SL.2 Terms and definitions

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

SL.2.1 management system

See definition contained in Appendix 2 (clause 3.4) of this Annex SL.

SL.2.2 Management System Standard MSS

Standard for *management systems* (SL.5.1).

Note to entry: For the purposes of this document, this definition also applies to other ISO deliverables (e.g. TS, PAS).

SL.2.3 generic MSS

MSS designed to be widely applicable across economic sectors, various types and sizes of organizations and diverse geographical, cultural and social conditions.

SL.2.4 sector-specific MSS

MSS that provides additional requirements or guidance for the application of a generic MSS to a specific economic or business sector.

SL.2.5 Type A MSS

MSS providing requirements

EXAMPLES

- Management system requirements standards (specifications).
- Management system sector-specific requirements standards.

SL.2.6

Type B MSS

MSS providing guidelines

EXAMPLES

- Guidance on the use of management system requirements standards.
- Guidance on the establishment of a management system.
- Guidance on the improvement/enhancement of a management system.

SL.2.7

High Level Structure

HLS

outcome of the work of the ISO/TMB/JTCG “Joint technical Coordination Group on MSS” which refers to high level structure (HLS), identical subclause titles, identical text and common terms and core definitions. See Appendix 2 to this Annex SL.

SL.3 Obligation to submit a JS

All MSS [including sector-specific MSS (SL.5.4), see Annex SP] proposals and their JS shall be identified by the relevant TC/SC/PC leadership and the JS shall be sent to the ISO/TMB (or its MSS task force) for evaluation and approval before the NWI ballot takes place. It is the responsibility of the relevant TC/SC/PC secretariat to identify all MSS proposals, without exception, so that there will be no MSS proposals which fail (with knowledge or without knowledge) to carry out the JS or which fail to be sent to the ISO/TMB for evaluation.

No JS is required for a Type B MSS providing guidance on a specific Type A MSS for which a JS has already been submitted and approved.

EXAMPLE ISO/IEC 27003:2010 (Information technology — Security techniques — Information security management system implementation guidance) does not need to have JS submitted as ISO/IEC 27001:2013 (Information technology — Security techniques — Information security management systems — Requirements) has already had a JS submitted and approved.

SL.4 Cases where no JS have been submitted

MSS proposals which have not been submitted for ISO/TMB evaluation before the NWI ballot will be sent to the ISO/TMB for evaluation and no new ballot should take place before the ISO/TMB decision (project on hold). It is considered good practice that the TC/SC/PC members endorse the JS prior it is sent to the ISO/TMB.

NOTE Already published MSS which did not have a JS submitted will be treated as new MSS at the time of revision, i.e. a JS is to be presented and approved before any work can begin.

SL.5 Applicability of Annex SL

The above procedures apply to all ISO deliverables including IWAs.

SL.6 General principles

All projects for new MSS (or for MSS which are already published but for which no JS was completed) shall undergo a JS (see SL.1 and Note to SL.3). The following general principles provide guidance to assess the market relevance of proposed MSS and for the preparation of a JS. The justification criteria questions in Appendix 1 to this Annex SL are based on these principles. The answers to the questions will form part of the JS. An MSS should be initiated, developed and maintained only when all of the following principles are observed.

- 1) **Market relevance** — Any MSS should meet the needs of, and add value for, the primary users and other affected parties.
- 2) **Compatibility** — Compatibility between various MSS and within an MSS family should be maintained.
- 3) **Topic coverage** — A generic MSS (SL.5.3) should have sufficient application coverage to eliminate or minimize the need for sector-specific variances.
- 4) **Flexibility** — An MSS should be applicable to organizations in all relevant sectors and cultures and of every size. An MSS should not prevent organizations from competitively adding to or differentiating from others, or enhancing their management systems beyond the standard.
- 5) **Free trade** — An MSS should permit the free trade of goods and services in line with the principles included in the WTO Agreement on Technical Barriers to Trade.
- 6) **Applicability of conformity assessment** — The market need for first-, second- or third-party conformity assessment, or any combination thereof, should be assessed. The resulting MSS should clearly address the suitability of use for conformity assessment in its scope. An MSS should facilitate joint audits.
- 7) **Exclusions** — An MSS should not include directly related product (including services) specifications, test methods, performance levels (i.e. setting of limits) or other forms of standardization for products produced by the implementing organization.
- 8) **Ease of use** — It should be ensured that the user can easily implement one or more MSS. An MSS should be easily understood, unambiguous, free from cultural bias, easily translatable, and applicable to businesses in general.

SL.7 Justification study process and criteria

SL.7.1 General

This clause describes the justification study (JS) process for justifying and evaluating the market relevance of proposals for an MSS. Appendix 1 to this Annex SL provides a set of questions to be addressed in the justification study.

SL.7.2 Justification study process

The JS process applies to any MSS project and consists of the following:

- a) the development of the JS by (or on behalf of) the proposer of an MSS project;
- b) an approval of the JS by the ISO/TMB (or ISO/TMB MSS task force).

The JS process is followed by the normal ISO balloting procedure for new work item approval as appropriate.

SL.7.3 Justification study criteria

Based on Annex C of the ISO/IEC Directives, Part 1, 2012, and the general principles stated above, a set of questions (see Appendix 1 to this Annex SL) shall be used as criteria for justifying and assessing a proposed MSS project and shall be answered by the proposer. This list of questions is not exhaustive and any additional information that is relevant to the case should be provided. The JS should demonstrate that all questions have been considered. If it is decided that they are not relevant or appropriate to a particular situation, then the reasons for this decision should be clearly stated. The unique aspect of a particular MSS may require consideration of additional questions in order to assess objectively its market relevance.

SL.8 Guidance on the development process and structure of an MSS

SL.8.1 General

The development of an MSS will have effects in relation to

- the far-reaching impact of these standards on business practice,
- the importance of worldwide support for the standards,
- the practical possibility for involvement by many, if not all, ISO Member Bodies, and
- the market need for compatible and aligned MSS.

This clause provides guidance in addition to the procedures laid down in the ISO/IEC Directives, in order to take these effects into account.

All MSS (whether they are Type A or Type B MSS, generic or sector-specific) shall, in principle, use consistent structure, common text and terminology so that they are easy to use and compatible with each other. The guidance and structure given in Appendix 2 to this Annex SL shall, in principle, also be followed (based on ISO/TMB Resolution 18/2012).

A Type B MSS which provides guidance on another MSS of the same MSS family should follow the same structure (i.e. clauses numbering). Where MSS providing guidance (Type B MSS) are involved, it is important that their functions be clearly defined together with their relationship with the MSS providing requirements (Type A MSS), for example:

- guidance on the use of the requirements standard;
- guidance on the establishment/implementation of the management system;
- guidance on improvement/enhancement of the management system.

Where the proposed MSS is sector-specific:

- it should be compatible and aligned with the generic MSS;
- rules and principles specified in Annex SP shall be followed;
- the relevant committee responsible for the generic MSS may have additional requirements to be met or procedures to be followed (see Annex SP);
- other committees may need to be consulted, as well as CASCO on conformity assessment issues.

In the case of sector specific documents, their function and relationship with the generic MSS should be clearly defined (e.g. additional sector-specific requirements; elucidation; or both as appropriate).

Sector-specific documents should always show clearly (e.g. by using different typographical styles) the kind of sector-specific information being provided.

NOTE 1 Where the identical text or any of the requirements cannot be applied in a specific MSS, due to special circumstances, this should be reported to the ISO/TMB through the TMB Secretary at tmb@iso.org (see SL.9.3).

SL.8.2 MSS development process

SL.8.2.1 General

In addition to the JS, the development of an MSS should follow the same requirements as other ISO deliverables (ISO/IEC Directives, Part 1, Clause 2).

SL.8.2.2 Design specification

To ensure that the intention of the standard, as demonstrated by the justification study, will be maintained, a design specification may be developed before a working draft is prepared.

The responsible committee will decide whether the design specification is needed and in case it is felt necessary, it will decide upon its format and content that is appropriate for the MSS and should set up the necessary organization to carry out the task.

The design specification should typically address the following.

User needs	The identification of the users of the standard and their associated needs, together with the costs and benefits for these users.
Scope	The scope and purpose of the standard, the title and the field of application.
Compatibility	How compatibility within this and with other MSS families will be achieved, including identification of the common elements with similar standards, and how these will be included in the recommended structure (see Appendix 2 to this Annex SL).
Consistency	Consistency with other documents (to be) developed within the MSS family.

NOTE Most, if not all of the information on user needs and scope will be available from the justification study.

The design specification should ensure that

- a) the outputs of the justification study are translated correctly into requirements for the MSS,
- b) the issues of compatibility and alignment with other MSS are identified and addressed,
- c) a basis for verification of the final MSS exists at appropriate stages during the development process,
- d) the approval of the design specification provides a basis for ownership throughout the project by the members of the TC/SC(s),
- e) account is taken of comments received through the NWI ballot phase, and
- f) any constraints are taken into account.

The Committee developing the MSS should monitor the development of the MSS against the design specification in order to ensure that no deviations happen in the course of the project.

SL.8.2.3 Producing the deliverables

SL.8.2.3.1 Monitoring output

In the drafting process, the output should be monitored for compatibility and ease of use with other MSS, by covering issues such as

- the high level structure (HLS), identical subclause titles, identical text and common terms and core definitions the need for clarity (both in language and presentation), and
- avoiding overlap and contradiction.

SL.8.2.4 Transparency of the MSS development process

MSS have a broader scope than most other types of standard. They cover a large field of human endeavour and have an impact on a wide range of user interests.

Committees preparing MSS should accordingly adopt a highly transparent approach to the development of the standards, ensuring that

- possibilities for participation in the process of developing standards are clearly identified, and
- the development processes being used are understood by all parties.

Committees should provide information on progress throughout the life cycle of the project, including

- the status of the project to date (including items under discussion),
- contact points for further information,
- communiqués and press releases on plenary meetings, and
- regular listings of frequently asked questions and answers.

In doing this, account needs to be taken of the distribution facilities available in the participating countries.

Where it may be expected that users of a Type A MSS are likely to demonstrate conformity to it, the MSS shall be so written that conformity can be assessed by a manufacturer or supplier (first party, or self-declaration), a user or purchaser (second party) or an independent body (third party, also known as certification or registration).

Maximum use should be made of the resources of the ISO Central Secretariat to facilitate the transparency of the project and the committee should, in addition, consider the establishment of a dedicated open-access website.

Committees should involve the national member bodies to build up a national awareness of the MSS project, providing drafts as appropriate for different interested and affected parties, including accreditation bodies, certification bodies, enterprises and the user community, together with additional specific information as needed.

The committee should ensure that technical information on the content of the MSS under development is readily available to participating members, especially those in developing countries.

SL.8.2.5 Process for interpretation of a standard

The committee may establish a process to handle interpretation questions related to their standards from the users, and may make the resulting interpretations available to others in an expedient manner.

Such a mechanism can effectively address possible misconceptions at an early stage and identify issues that may require improved wording of the standard during the next revision cycle. Such processes are considered to be “committee specific procedures” [see Foreword f)].

SL.9 High level structure, identical core text and common terms and core definitions for use in Management Systems Standards

SL.9.1 Introduction

The aim of this document is to enhance the consistency and alignment of ISO MSS by providing a unifying and agreed upon high level structure, identical core text and common terms and core definitions. The aim being that all ISO Type A MSS (and B where appropriate) are aligned and the compatibility of these standards is enhanced. It is envisaged that individual MSS will add additional “discipline-specific” requirements as required.

NOTE In Annex SL.9.1 and Annex SL.9.4 “discipline-specific” is used to indicate specific subject(s) to which a management system standard refers, e.g. energy, quality, records, environment etc.

The intended audience for this document is ISO Technical Committees (TC), Subcommittees (SC) and Project Committees (PC) and others that are involved in the development of MSS.

This common approach to new MSS and future revisions of existing standards will increase the value of such standards to users. It will be particularly useful for those organizations that choose to operate a single (sometimes called “integrated”) management system that can meet the requirements of two or more MSS simultaneously.

Appendix 2 to this Annex SL sets out the high level structure, identical core text and common terms and core definitions that form the nucleus of future and revised ISO Type A MSS and Type B MSS when possible.

Appendix 3 to this Annex SL sets out guidance to the use of Appendix 2 to this Annex SL.

SL.9.2 Use

ISO MSS include the high level structure and identical core text as found in Appendix 2 to this Annex SL. The common terms and core definitions are either included or normatively reference an international standard where they are included.

NOTE The high level structure includes the main clauses (1 to 10) and their titles, in a fixed sequence. The identical core text includes numbered sub-clauses (and their titles) as well as text within the sub-clauses.

SL.9.3 Non applicability

If due to exceptional circumstances the high level structure or any of the identical core text, common terms and core definitions cannot be applied in the management system standard then the TC/PC/SC needs to explain their rationale for review by:

- a) providing an initial deviation report to ISO/CS with the DIS submission;
- b) providing a final deviation report to ISO/TMB (through the ISO/TMB Secretary at tmb@iso.org) upon submission of the final text of the standard for publication.

TC/PC/SC shall use the ISO commenting template to provide their deviation reports.

NOTE 1 The final deviation report can be an updated version of the initial deviation report.

NOTE 2 TC/PC/SC strive to avoid any non-applicability of the high level structure or any of the identical core text, common terms and core definitions.

SL.9.4 Using Annex SL Appendix 2

Discipline-specific text additions to Annex SL Appendix 2 are managed as follows.

1. Discipline-specific additions are made by the individual ISO/TC, PC, SC or other group that is developing the specific ISO management system standard.
2. Discipline-specific text does not affect harmonization or contradict or undermine the intent of the high level structure, identical core text, common terms and core definitions.
3. Insert additional sub-clauses, or sub-sub-clauses (etc.) either ahead of an identical text sub-clause (or sub-sub-clause etc.), or after such a sub-clause (etc.) and renumbered accordingly.

NOTE 1 Hanging paragraphs are not permitted — see ISO/IEC Directives, Part 2, clause 22.3.3.

NOTE 2 Attention is drawn to the need to check cross referencing.

4. Add or insert discipline-specific text within Appendix 2 to this Annex SL. Examples of additions include:
 - a) new bullet points
 - b) discipline-specific explanatory text (e.g. Notes or Examples), in order to clarify requirements
 - c) discipline-specific new paragraphs to sub-clauses (etc.) within the identical text
 - d) adding text that enhances the existing requirements in Appendix 2 to this Annex SL
5. Avoid repeating requirements between identical core text and discipline-specific text by adding text to the identical core text taking account of point 2 above.
6. Distinguish between discipline-specific text and identical core text from the start of the drafting process. This aids identification of the different types of text during the development and balloting stages.

NOTE 1 Distinguishing options include by colour, font, font size, italics, or by being boxed separately, etc.

NOTE 2 Identification of distinguishing text is not necessarily carried into the published version.

7. Understanding of the concept of “risk” may be more specific than that given in the definition under 3.9 of Appendix 2 to this Annex SL. In this case a discipline-specific definition may be needed. The discipline-specific terms and definitions are differentiated from the core definition, e.g. (XXX) risk.

NOTE The above can also apply to a number of other definitions.

8. Common terms and core definitions will be integrated into the listing of terms and definitions in the discipline-specific management system standard consistent with the concept system of that standard.

SL.9.5 Implementation

Follow the sequence, high level structure, identical core text, common terms and core definitions for any new management system standard and for any revisions to existing management system standard.

SL.9.6 Guidance

Find supporting guidance in Appendix 3 to this Annex SL.

Appendix 1

(normative)

Justification criteria questions

1. General

The list of questions to be addressed in the justification study are in line with the principles listed in SL.6. This list is not exhaustive. Additional information not covered by the questions should be provided if it is relevant to the case.

Each general principle should be given due consideration and ideally when preparing the JS, the proposer should provide a general rationale for each principle, prior to answering the questions associated with the principle.

The principles the proposer of the MSS should pay due attention to when preparing the justification study are:

1. Market relevance
2. Compatibility
3. Topic coverage
4. Flexibility
5. Free trade
6. Applicability of conformity assessment
7. Exclusions

NOTE No questions directly refer to the principle 8 “ease of use”, but it should guide the development of the deliverable.

Basic information on the MSS proposal

1	What is the proposed purpose and scope of the MSS? Is the document supposed to be a guidance document or a document with requirements?
2	Does the proposed purpose or scope include product (including service) specifications, product test methods, product performance levels, or other forms of guidance or requirements directly related to products produced or provided by the implementing organization?
3	Is there one or more existing ISO committee or non-ISO organization that could logically have responsibility for the proposed MSS? If so, identify.
4	Have relevant reference materials been identified, such as existing guidelines or established practices?
5	Are there technical experts available to support the standardization work? Are the technical experts direct representatives of the affected parties from the different geographical regions?
6	What efforts are anticipated as being necessary to develop the document in terms of experts needed and number/duration of meetings?
7	Is the MSS intended to be a guidance document, contractual specification or regulatory specification for an organization?

Principle 1: market relevance

8	<p>Have all the affected parties been identified? For example:</p> <p>a) organizations (of various types and sizes): the decision-makers within an organization who approve work to implement and achieve conformance to the MSS;</p> <p>b) customers/end-users, i.e. individuals or parties that pay for or use a product (including service) from an organization;</p> <p>c) supplier organizations, e.g. producer, distributor, retailer or vendor of a product, or a provider of a service or information;</p> <p>d) MSS service provider, e.g. MSS certification bodies, accreditation bodies or consultants;</p> <p>e) regulatory bodies;</p> <p>f) non-governmental organizations.</p>
9	<p>What is the need for this MSS? Does the need exist at a local, national, regional or global level? Does the need apply to developing countries? Does it apply to developed countries? What is the added value of having an ISO document (e.g. facilitating communication between organizations in different countries)?</p>
10	<p>Does the need exist for a number of sectors and is thus generic? If so, which ones? Does the need exist for small, medium or large organizations?</p>
11	<p>Is the need important? Will the need continue? If yes, will the target date of completion for the proposed MSS satisfy this need? Are viable alternatives identified?</p>
12	<p>Describe how the need and importance were determined. List the affected parties consulted and the major geographical or economical regions in which they are located.</p>
13	<p>Is there known or expected support for the proposed MSS? List those bodies that have indicated support. Is there known or expected opposition to the proposed MSS? List those bodies that have indicated opposition.</p>
14	<p>What are the expected benefits and costs to organizations, differentiated for small, medium and large organizations if applicable?</p> <p>Describe how the benefits and the costs were determined. Provide available information on geographic or economic focus, industry sector and size of the organization. Provide information on the sources consulted and their basis (e.g. proven practices), premises, assumptions and conditions (e.g. speculative or theoretical), and other pertinent information.</p>
15	<p>What are the expected benefits and costs to other affected parties (including developing countries)?</p> <p>Describe how the benefits and the costs were determined. Provide any information regarding the affected parties indicated.</p>
16	<p>What will be the expected value to society?</p>
17	<p>Have any other risks been identified (e.g. timeliness or unintended consequences to a specific business)?</p>

Principle 2: compatibility

18	<p>Is there potential overlap or conflict with (or what is the added value in relation to) other existing or planned ISO or non-ISO international standards, or those at the national or regional level? Are there other public or private actions, guidance, requirements and regulations that seek to address the identified need, such as technical papers, proven practices, academic or professional studies, or any other body of knowledge?</p>
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19	Is the MSS or the related conformity assessment activities (e.g. audits, certifications) likely to add to, replace all or parts of, harmonize and simplify, duplicate or repeat, conflict with, or detract from the existing activities identified above? What steps are being considered to ensure compatibility, resolve conflict or avoid duplication?
20	Is the proposed MSS likely to promote or stem proliferation of MSS at the national or regional level, or by industry sectors?

Principle 3: topic coverage

21	Is the MSS for a single specific sector?
22	Will the MSS reference or incorporate an existing, non-industry-specific ISO MSS (e.g. from the ISO 9000 series of quality management standards)? If yes, will the development of the MSS conform to the ISO/IEC Sector Policy (see 34.2 of ISO/IEC Directives, Part 2), and any other relevant policy and guidance procedures (e.g. those that may be made available by a relevant ISO committee)?
23	What steps have been taken to remove or minimize the need for particular sector-specific deviations from a generic MSS?

Principle 4: flexibility

24	Will the MSS allow an organization competitively to add to, differentiate or encourage innovation of its management system beyond the standard?
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Principle 5: free trade

25	How would the MSS facilitate or impact global trade? Could the MSS create or prevent a technical barrier to trade?
26	Could the MSS create or prevent a technical barrier to trade for small, medium or large organizations?
27	Could the MSS create or prevent a technical barrier to trade for developing or developed countries?
28	If the proposed MSS is intended to be used in government regulations, is it likely to add to, duplicate, replace, enhance or support existing governmental regulations?

Principle 6: applicability of conformity

29	If the intended use is for contractual or regulatory purposes, what are the potential methods to demonstrate conformance (e.g. first party, second party or third party)? Does the MSS enable organizations to be flexible in choosing the method of demonstrating conformance, and to accommodate for changes in its operations, management, physical locations and equipment?
30	If third-party registration/certification is a potential option, what are the anticipated benefits and costs to the organization? Will the MSS facilitate joint audits with other MSS or promote parallel assessments?

Principle 7: exclusions

31	Does the proposed purpose or scope include product (including service) specifications, product test methods, product performance levels, or other forms of guidance or requirements directly related to products produced or provided by the implementing organization?
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Appendix 2

(normative)

High level structure, identical core text, common terms and core definitions

NOTE In the Identical text proposals, XXX = an MSS discipline specific qualifier (e.g. energy, road traffic safety, IT security, food safety, societal security, environment, quality) that needs to be inserted. *Blue italicized text is given as advisory notes to standards drafters.*

Introduction

DRAFTING INSTRUCTION Specific to the discipline.

1. Scope

DRAFTING INSTRUCTION Specific to the discipline.

2. Normative references

DRAFTING INSTRUCTION Clause Title shall be used. Specific to the discipline.

3. Terms and definitions

DRAFTING INSTRUCTION 1 Clause Title shall be used. Terms and definitions may either be within the standard or in a separate document. To reference Common terms and Core definitions + discipline specific ones. The arrangement of terms and definitions shall be according to the concept systems of each standard.

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

DRAFTING INSTRUCTION 2 The following terms and definitions constitute an integral part of the “common text” for management systems standards. Additional terms and definitions may be added as needed. Notes may be added or modified to serve the purpose of each standard.

DRAFTING INSTRUCTION 3 Italics type in a definition indicates a cross-reference to another term defined in this clause, and the number reference for the term is given in parentheses.

DRAFTING INSTRUCTION 4 Where the text “XXX” appears throughout this clause, the appropriate reference should be inserted depending on the context in which these terms and definitions are being applied. For example: “an XXX objective” could be substituted as “an information security objective”.

3.1

organization

person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.8)

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.

3.2

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

3.3

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.

3.4

management system

set of interrelated or interacting elements of an *organization* (3.1) to establish *policies* (3.7) and *objectives* (3.8) and *processes* (3.12) 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.

3.5

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.

Note 2 to entry: If the scope of the *management system* (3.4) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

3.6

effectiveness

extent to which planned activities are realized and planned results achieved

3.7

policy

intentions and direction of an *organization* (3.1), as formally expressed by its *top management* (3.5)

3.8

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* (3.12)).

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 XXX 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 XXX management systems, XXX objectives are set by the organization, consistent with the XXX policy, to achieve specific results.

3.9

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.

3.10

competence

ability to apply knowledge and skills to achieve intended results

3.11

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:

- the *management system* (3.4), including related *processes* (3.12);
- information created in order for the organization to operate (documentation);
- evidence of results achieved (records).

3.12

process

set of interrelated or interacting activities which transforms inputs into outputs

3.13

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* (3.12), products (including services), systems or *organizations* (3.1).

3.14

outsource (verb)

make an arrangement where an external *organization* (3.1) performs part of an organization's function or *process* (3.12)

Note 1 to entry: An external organization is outside the scope of the *management system* (3.4), although the outsourced function or process is within the scope.

3.15

monitoring

determining the status of a system, a *process* (3.12) or an activity

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

3.16

measurement

process (3.12) to determine a value

3.17

audit

systematic, independent and documented *process* (3.12) 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.

3.18

conformity

fulfilment of a *requirement* (3.3)

3.19

nonconformity

non-fulfilment of a *requirement* (3.3)

3.20

corrective action

action to eliminate the cause of a *nonconformity* (3.19) and to prevent recurrence

3.21

continual improvement

recurring activity to enhance *performance* (3.13)

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 XXX management system.

4.2 Understanding the needs and expectations of interested parties

The organization shall determine:

- the interested parties that are relevant to the XXX management system;
- the relevant requirements of these interested parties.

4.3 Determining the scope of the XXX management system

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

When determining this scope, the organization shall consider:

- the external and internal issues referred to in 4.1;
- the requirements referred to in 4.2.

The scope shall be available as documented information.

4.4 XXX management system

The organization shall establish, implement, maintain and continually improve an XXX management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard/this part of ISO XXXX/this Technical Specification.

5. Leadership

5.1 Leadership and commitment

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

- ensuring that the XXX policy and XXX objectives are established and are compatible with the strategic direction of the organization;
- ensuring the integration of the XXX management system requirements into the organization's business processes;
- ensuring that the resources needed for the XXX management system are available;
- communicating the importance of effective XXX management and of conforming to the XXX management system requirements;
- ensuring that the XXX management system achieves its intended outcome(s);
- directing and supporting persons to contribute to the effectiveness of the XXX management system;
- promoting continual improvement;
- 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/this part of ISO XXXX/this Technical Specification can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence.

5.2 Policy

Top management shall establish a XXX policy that:

- a) is appropriate to the purpose of the organization;
- b) provides a framework for setting XXX objectives;
- c) includes a commitment to satisfy applicable requirements;
- d) includes a commitment to continual improvement of the XXX management system.

The XXX policy shall:

- be available as documented information;
- be communicated within the organization;
- be available to 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 and communicated within the organization.

Top management shall assign the responsibility and authority for:

- a) ensuring that the XXX management system conforms to the requirements of this International Standard/this part of ISO XXXX/this Technical Specification;
- b) reporting on the performance of the XXX management system to top management.

6. Planning

6.1 Actions to address risks and opportunities

When planning for the XXX 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:

- give assurance that the XXX management system can achieve its intended outcome(s);
- prevent, or reduce, undesired effects;
- achieve continual improvement.

The organization shall plan:

- a) actions to address these risks and opportunities;
- b) how to:
 - integrate and implement the actions into its XXX management system processes;
 - evaluate the effectiveness of these actions.

6.2 XXX objectives and planning to achieve them

The organization shall establish XXX objectives at relevant functions and levels.

The XXX objectives shall:

- a) be consistent with the XXX policy;
- b) be measurable (if practicable);
- c) take into account applicable requirements;
- d) be monitored;
- e) be communicated;
- f) be updated as appropriate.

The organization shall retain documented information on the XXX objectives.

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

- what will be done;
- what resources will be required;
- who will be responsible;
- when it will be completed;
- how the results will be evaluated.

7. Support

7.1 Resources

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

7.2 Competence

The organization shall:

- determine the necessary competence of person(s) doing work under its control that affects its XXX performance;
- ensure that these persons are competent on the basis of appropriate education, training, or experience;
- where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- 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

Persons doing work under the organization's control shall be aware of:

- the XXX policy;

- their contribution to the effectiveness of the XXX management system, including the benefits of improved XXX performance;
- the implications of not conforming with the XXX management system requirements.

7.4 Communication

The organization shall determine the internal and external communications relevant to the XXX management system, including:

- on what it will communicate;
- when to communicate;
- with whom to communicate;
- how to communicate.

7.5 Documented information

7.5.1 General

The organization's XXX management system shall include:

- a) documented information required by this International Standard/this part of ISO XXXX/this Technical Specification;
- b) documented information determined by the organization as being necessary for the effectiveness of the XXX management system.

NOTE The extent of documented information for a XXX 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:

- identification and description (e.g. a title, date, author, or reference number);
- format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
- review and approval for suitability and adequacy.

7.5.3 Control of documented information

Documented information required by the XXX management system and by this International Standard/this part of ISO XXXX/this Technical Specification 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 XXX 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

DRAFTING INSTRUCTION This subclause heading will be deleted if no additional subclauses are added to Clause 8.

The organization shall plan, implement and control the processes needed to meet requirements, and to implement the actions determined in 6.1, by:

- establishing criteria for the processes;
- implementing control of the processes in accordance with the criteria;
- keeping documented information to the extent necessary to have confidence 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.

9. Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

The organization shall determine:

- what needs to be monitored and measured;
- the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results;
- when the monitoring and measuring shall be performed;
- when the results from monitoring and measurement shall be analysed and evaluated.

The organization shall retain appropriate documented information as evidence of the results.

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

9.2 Internal audit

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

- a) conforms to:
 - the organization's own requirements for its XXX management system;
 - the requirements of this International Standard/this part of ISO XXXX/this Technical Specification;
- 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 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) 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 XXX 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 XXX management system;
- c) information on the XXX performance, including trends in:
 - nonconformities and corrective actions;
 - monitoring and measurement results;
 - audit results;
- d) opportunities for continual improvement.

The outputs of the management review shall include decisions related to continual improvement opportunities and any need for changes to the XXX management system.

The organization shall retain documented information as evidence of the results of management reviews.

10. Improvement

10.1 Nonconformity and corrective action

When a nonconformity occurs, the organization shall:

- a) react to the nonconformity and, as applicable:
 - take action to control and correct it;
 - 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:
 - reviewing the nonconformity;
 - determining the causes of the nonconformity;
 - 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 XXX management system, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

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.

10.2 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the XXX management system.