Annex SL – Harmonized Structure (HS)

for Management System Standards

In the identical text proposals:

–   XXX = a Management System Standard (MSS) discipline specific qualifier (e.g. energy, road traffic safety, IT security, food safety, environment, quality) that needs to be inserted

Red italicized text is given as advisory notes to MSS writers.

Introduction

DRAFTING INSTRUCTION: Specific to the discipline.

This text has been prepared using the harmonized structure (i.e. identical clause numbers, clause titles, text and common terms and core definitions) intended to enhance alignment among MSS and to facilitate their implementation for organizations that need to meet the requirements of two or more such standards.

1.   Scope

DRAFTING INSTRUCTION: Specific to the discipline.

DRAFTING INSTRUCTION: The scope of the document shall address the intended result(s) of the management system.

2.   Normative references

DRAFTING INSTRUCTION: Specific to the discipline.

Include generic text specified in ISO/IEC Directives, Part 2.

3.   Terms and definitions

DRAFTING INSTRUCTION 1: Common terms and core definitions shall be included in the MSS and they may also be included in a separate vocabulary standard.

In Clause 3, discipline specific terms and definitions may also be included.

Include generic text specified in ISO/IEC Directives, Part 2.

The arrangement of terms and definitions should preferably be in systematic order, but may differ from the order given below in Clause 3. Alphabetical order is the least preferred order.

DRAFTING INSTRUCTION 2: The following terms and definitions constitute an integral part of the harmonized structure for management systems standards. Additional terms and definitions may be added as needed. Notes to entry may be added to serve the purpose of each standard.

When drafting terms and definitions, MSS writers are advised to make use of the flowcharts given in Annex SL Appendix 3.

DRAFTING INSTRUCTION 3: Italic 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* (3.6)

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

Note 2 to entry: If the organization is part of a larger entity, the term "organization" refers only to the part of the larger entity that is within the scope of the XXX *management system* (3.4).

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
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.

3.4
management system
set of interrelated or interacting elements of an *organization* (3.1) to establish *policies* (3.5) and *objectives* (3.6), as well as *processes* (3.8) to achieve those objectives

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

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

3.5
policy
intentions and direction of an *organization* (3.1) as formally expressed by its *top management* (3.3)

3.6
objective
result to be achieved

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

Note 2 to entry: Objectives can relate to different disciplines (such as finance, health and safety, and environment). They can be, for example, organization-wide or specific to a project, product or *process* (3.8).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended result, as a purpose, as an operational criterion, as an 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* (3.4), XXX objectives are set by the *organization* (3.1), consistent with the XXX *policy* (3.5), to achieve specific results.

3.7
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) and consequences (as defined in ISO Guide 73), 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) of occurrence.

3.8
process
set of interrelated or interacting activities that uses or transforms inputs to deliver a result

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

3.9
competence
ability to apply knowledge and skills to achieve intended results

3.10
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* (3.8);

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

–   evidence of results achieved (records).

3.11
performance
measurable result

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

Note 2 to entry: Performance can relate to managing activities, *processes* (3.8), products, services, systems or *organizations* (3.1).

3.12
continual improvement
recurring activity to enhance *performance* (3.11)

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

3.14
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, e.g. in *documented information* (3.10).

3.15
conformity
fulfilment of a *requirement* (3.14)

3.16
nonconformity
non-fulfilment of a *requirement* (3.14)

3.17
corrective action
action to eliminate the cause(s) of a *nonconformity* (3.16) and to prevent recurrence

3.18
audit
systematic and independent *process* (3.8) for obtaining evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

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

Note 2 to entry: An internal audit is conducted by the *organization* (3.1) itself, or by an external party on its behalf.

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

3.19
measurement
process (3.8) to determine a value

3.20
monitoring
determining the status of a system, a *process* (3.8) or an activity

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

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 XXX management system.

The organization shall determine whether climate change is a relevant issue.

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;

– which of these requirements will be addressed through the XXX management system.

NOTE: Relevant interested parties can have requirements related to climate change.

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 document.

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 result(s);

– directing and supporting persons to contribute to the effectiveness of the XXX management system;

– promoting continual improvement;

– supporting other relevant 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 XXX 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 meet 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 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 document;

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 result(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;

g)   be available as documented information.

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.

6.3   Planning of changes

When the organization determines the need for changes to the XXX management system, the changes shall be carried out in a planned manner.

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.

Appropriate documented information shall be available 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 document;

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 documented information

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 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 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 Clause 6, by:

–   establishing criteria for the processes;

–   implementing control of the processes in accordance with the criteria.

Documented information shall be available 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 externally provided processes, products or services that are relevant to the XXX management system 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.

Documented information shall be available as evidence of the results.

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

9.2 Internal audit

9.2.1 General

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 document;

b) is effectively implemented and maintained.

9.2.2 Internal audit programme

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

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

The organization shall:

a) define the audit objectives, criteria and scope for each audit;

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

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

Documented information shall be available as evidence of the implementation of the audit programme(s) and the audit results.

9.3 Management review

9.3.1 General

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

9.3.2 Management review inputs

The management review shall include:

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)   changes in needs and expectations of interested parties that are relevant to the XXX management system;

d)   information on the XXX performance, including trends in:

–   nonconformities and corrective actions;

–   monitoring and measurement results;

–   audit results;

e)   opportunities for continual improvement.

9.3.3 Management review results

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

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

10   Improvement

10.1   Continual improvement

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

10.2   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 can 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.

Documented information shall be available as evidence of:

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

–   the results of any corrective action.