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Harmonized structure for MSS with guidance for use

Structure-harmonisée pour les NSM avec préconisations relatives à l'utilisation

ICS: ISO ics

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REVISION OF ISO SUPPLEMENT TO THE ISO/IEC DIRECTIVES PART 1, ANNEX SL, APPENDIX 2 (HARMONIZED STRUCTURE FOR MSS WITH GUIDANCE FOR USE)

Background

In September 2021, ISO members have signed the London Declaration to combat climate change through standards. To help deliver on ISO commitments, the TMB has developed an action plan that will support the ISO technical community. One of the focus of the TMB action plan is for committees to include climate considerations in their works.

Because ISO Management Systems Standards (MSS) are widespread, well enshrined in business organizations, and respected, they have the capacity to induce change. For this reason, the TMB action plan requested the TMB/JTCG (Joint Technical Coordination Group, gathering all leaders of committees in charge of MSS) to submit change proposal to the Appendix 2 of the Annex SL of the ISO Supplement to the ISO/IEC Directives Part 1. This Appendix 2 is also known as "Harmonized Structure" (formerly known as "High Level Structure", or "HLS") and provides identical clause numbers, clause titles, text and common terms and core definitions for all MSS. Change in the Harmonized Structure will therefore have repercussions in all ISO MSS, and it is expected that the proposed changes will support the delivery of the ISO climate commitment.

Change proposal

The TMB (through a dedicated Task Force in charge of implementing the TMB action plan) has asked the JTCG to provide recommendations for the revision of the Harmonized Structure. Via dedicated plenary meetings, the JTCG has reached consensus on the changes to the Harmonized Structure. These proposed changes were reviewed and accepted by TMB and are outlined below (additions highlighted):

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.

The full Appendix 2 is provided as an Annex for your convenience.

DGuide approval process

Because the Harmonized Structure is the part of the Annex SL that is the basis for all MSS and because it is technical text, the same level of approval as for an International Standard is needed. The use of the DGuide approval process ensures that the change proposal will be balloted to all ISO members, in the exact same way as for Draft International Standards (DIS): the vehicle

(DGuide ballot) is different but the process is the same. This guarantees that all ISO members are consulted, they are asked to vote and comment, and the resulting Harmonized Structure benefits from the same member consensus as International Standards do, hence providing the same legitimacy.

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Annex SL Appendix 2
(normative)

Harmonized structure for MSS with guidance for use

Harmonized structure (identical clause numbers, clause titles, text and common terms and core definitions) for MSS (normative)	Guidance for MSS writers (informative)
<p>In the identical text proposals:</p> <ul style="list-style-type: none">— 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 <p><i>Red italicized text is given as advisory notes to MSS writers</i></p>	<p>Throughout this guidance:</p> <ul style="list-style-type: none">— MS = Management System— MSS = Management System Standard— MSS writers = ISO TC/SC/PCs that are responsible for writing discipline-specific MSS based on Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1, as well as editors of MSS— HS = Harmonized structure - that part of the Harmonized Approach that defines the identical clause numbers, clause titles, text and common terms and core definitions
	<p>General</p> <ul style="list-style-type: none">a) This guidance is intended for MSS writers. It does not add to or change any requirement of the ISO/IEC Directives, Part 1 or Part 2 (including the HS). The objectives of the guidance are to promote a common understanding of the HS, reduce the need for deviations, and indicate opportunities for further alignment between the various discipline-specific requirements that an MSS committee may choose to add.b) MSS writers should be aware that an organization may address the requirements of several MSS within a single MS. They should therefore aim to ensure that any additional discipline-specific requirements can be integrated into such a system.c) If MSS writers are considering additional discipline-specific requirements, they can consult other MSS to verify if similar additions have been made and, wherever possible, use identical or similar text and positioning to ensure ongoing alignment of these additional requirements. A complete list of MSS can be found at https://www.iso.org/management-system-standards-list.html. MSS writers should liaise with their Committee Manager to arrange access to relevant documents including an editable template of the Harmonized Structure available from the JTCG Secretariat. Further advice is also available via participation in the ISO/TMBG/JTCG (Joint Technical Coordination Group on MSS).d) Where references are made in this guidance to other documents, or where examples are provided, these references are offered to provide MSS writers with a better understanding and context of the use of discipline-specific elements of an MSS. The references and examples are not intended for inclusion in discipline-specific MSS. MSS writers can consult these standards and consider them as potential inputs when drafting their own MSS.

Harmonized structure (identical clause numbers, clause titles, text and common terms and core definitions) for MSS (normative)	Guidance for MSS writers (informative)
<p style="text-align: center; color: #e91e63; font-size: 2em; opacity: 0.3;">iTeh STANDARD PREVIEW (standards.iteh.ai)</p> <p style="text-align: center; color: #e91e63; font-size: 1.2em; opacity: 0.3;">ISO/DGuide 83 https://standards.iteh.ai/catalog/standards/sist/c7778f32-bd4a-4d48-ac0d-42a6118be9cb/iso-dguide-83</p>	<p>e) MSS writers should be aware of the ISO Policy on references to legal requirements in standards, and in particular to TMB Resolution 70/2018 and the additional “Guidance on legal statements in ISO standards” (see https://www.iso.org/drafting-standards.html).</p> <p>f) There are many requirements in the HS that use the verb “determine”. MSS writers should be aware that this does not specifically require documented information to be available as evidence of conformity.</p> <p>g) If MSS writers need to include discipline-specific requirements for documented information (see 3.10) in any clause of their MSS, they should base such requirements on the same phrases that are used in the HS:</p> <ul style="list-style-type: none"> — “... shall be available ...” = the documented information is available for use — “... shall be available as evidence of ...” = the documented information is to provide evidence of conformity <p>h) While this guidance can also be of interest for users of discipline-specific MSS, it is the responsibility of the relevant MSS writers to decide on the need for any guidance on the implementation of their standards, and to provide such guidance as appropriate.</p> <p>i) For clauses where no additional guidance is deemed necessary, this column is marked as “No additional guidance”.</p>
<p>Introduction</p> <p><i>Drafting instruction: Specific to the discipline.</i></p> <p><i>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.</i></p> <p><i>Text taken from the harmonized structure is highlighted in the text of Clauses 1 to 10 by the use of blue font. Discipline-specific text is given in black. Strikeout is used to show agreed deletions within the HS text. The use of blue text and strikeout is only to facilitate analysis and will not be incorporated after the Draft International Standard stage of development for this document.</i></p>	<p>No additional guidance</p>
<p>1. Scope</p> <p><i>Drafting instruction: Specific to the discipline.</i></p>	<p>The “intended results” refer to the results that are expected to be achieved by implementing the MSS. MSS writers should be aware that throughout the HS, references to the “intended results of the MS” include, but are not limited to, those mentioned by the MSS writers in Clause 1, within the scope of the MS as defined by the organization (see 4.3).</p>

Harmonized structure (identical clause numbers, clause titles, text and common terms and core definitions) for MSS (normative)	Guidance for MSS writers (informative)
<i>Drafting instruction: The scope of the document shall address the intended result(s) of the management system.</i>	To facilitate translation and to provide a better link with the definition of “objective” (see 3.6), MSS writers should avoid introducing new terms such as “outcomes” instead of “results”.
2. Normative references <i>Drafting instruction: Specific to the discipline.</i> <i>Include generic text specified in ISO/IEC Directives, Part 2.</i>	See guidance on Normative references in ISO/IEC Directives, Part 2.
3. Terms and definitions <i>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.</i> <i>In Clause 3, discipline specific terms and definitions may also be included.</i> <i>Include generic text specified in ISO/IEC Directives, Part 2.</i> <i>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.</i> <i>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.</i> <i>When drafting terms and definitions, MSS writers are advised to make use of the flowcharts given in Annex SL Appendix 3.</i>	See guidance on Terms and definitions in ISO/IEC Directives, Part 2, as well as Appendix 3. Drafting Instruction 1 When the terms and their associated definitions that are located in Clause 3 of the MSS are also included in a separate vocabulary standard, in accordance with ISO/IEC Directives, Part 2, the vocabulary standard is required to be listed as a Normative reference in Clause 2 of the MSS. Depending on the way in which terms and definitions are given for the standard, MSS writers should choose the appropriate introductory wording specified in ISO/IEC Directives, Part 2. ISO/IEC Directives, Part 2 recommends that terms and definitions are organized according to the hierarchy of concepts (i.e. systematic order). Term entries in an MSS may be numbered differently from those in the HS because of the addition of discipline-specific concepts. Drafting Instruction 2 <u>General</u> The term entries (i.e. terms, definitions and all associated notes) stated in Clause 3 of the HS are mandatory in all MSS. MSS writers should be aware that any changes made to these term entries in discipline-specific MSS can change requirements in the remainder of the MSS. If a modification of a definition or note to entry is made, this is regarded as a deviation for which a justification is required (see Annex SL 8.3.4). <u>Additional notes to entry</u> Notes to entry may be added to serve the purpose of a discipline-specific MSS provided they do not contradict, or deviate from, the defined concept. <u>Additional terms and definitions</u> When drafting a new definition corresponding to a discipline-specific term, the guidelines of ISO 10241-1 should be followed.

Harmonized structure (identical clause numbers, clause titles, text and common terms and core definitions) for MSS (normative)	Guidance for MSS writers (informative)
<p style="text-align: center; color: #e91e63; font-weight: bold;">iTeh STANDARD PREVIEW (standards.iteh.ai)</p> <p style="text-align: center; color: #e91e63;">ISO/DGuide 83 https://standards.iteh.ai/catalog/standards/sist/c7778f32-bd4a-4048-ac0d-42a6118be9cb/iso-dguide-83</p> <p><i>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.</i></p> <p><i>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”.</i></p>	<p>When a new definition corresponding to a subordinate (i.e. XXX MSS) concept is drafted, the definition should begin with the term of the concept defined in Clause 3 of the HS, followed by the specific characteristics of the subject field in question (see Annex SL Appendix 3).</p> <p>Example from ISO 45001:2018:</p> <p>3.14 policy intentions and direction of an organization as formally expressed by its top management</p> <p>3.15 occupational health and safety policy OH&S policy <i>policy</i> (3.14) to prevent work-related injury and ill health to workers and to provide safe and healthy workplaces</p> <p>Drafting Instruction 3</p> <p>Example:</p> <p>3.20 monitoring determining the status of a system, a <i>process</i> (3.8) or an activity</p> <p>Drafting Instruction 4</p> <p>“XXX” in the Notes to entry should be substituted with the appropriate reference. These additional terms (subordinate concepts) may be included as new term entries.</p> <p>Example from ISO 14001:2015:</p> <p>3.2.5 objective result to be achieved</p> <p>Note 1 to entry: An objective can be strategic, tactical, or operational.</p> <p>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.</p>

Harmonized structure (identical clause numbers, clause titles, text and common terms and core definitions) for MSS (normative)	Guidance for MSS writers (informative)
<p style="text-align: center; color: #e91e63; font-weight: bold;">iTeh STANDARD PREVIEW (standards.iteh.ai)</p> <p style="text-align: center; color: #e91e63; font-weight: bold;">ISO/DGuide 83 https://standards.iteh.ai/catalog/standards/sist/c7778f32-bd4a-4412-6d181-6161c1d1d183</p>	<p>Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended result, a purpose, an operational criterion, as an <i>environmental objective</i> (3.2.6) or by the use of other words with similar meaning (e.g. aim, goal, or target).</p> <p>Note 4 to entry: In the context of environmental management systems objectives are set by the organization, consistent with the environmental policy, to achieve specific results.</p> <p>3.2.6 environmental objective <i>objective</i> (3.2.5) set by the organization consistent with its environmental policy</p>
<p>3.1 organization person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its <i>objectives</i> (3.6)</p> <p>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.</p> <p>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 <i>management system</i> (3.4).</p>	<p>MSS writers should ensure that any use of the term “organization” with a different intent from that described in Note 2 to entry is clearly distinguished.</p>
<p>3.2 interested party (preferred term) stakeholder (admitted term)</p> <p>person or <i>organization</i> (3.1) that can affect, be affected by, or perceive itself to be affected by a decision or activity</p>	<p>MSS writers should use the term “interested party”, in which case “stakeholder” may be deleted from the term entry.</p> <p>The use of the term “stakeholder” is not considered a deviation, but if MSS writers choose to use that term (e.g. for reasons of tradition in their specific discipline), they should be aware of potential translation problems to find an equivalent in other languages. If MSS writers choose to use the term “stakeholder”, the term “interested party” may be deleted from the term entry.</p> <p>MSS writers should not use the terms “interested party” and “stakeholder” as synonyms or representing different concepts in the same MSS.</p>
<p>3.3 top management person or group of people who directs and controls an <i>organization</i> (3.1) at the highest level</p> <p>Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.</p> <p>Note 2 to entry: If the scope of the <i>management system</i> (3.4) covers only part of an organization, then top management refers to those who direct and control that part of the organization.</p>	<p>No additional guidance</p>

<p>Harmonized structure (identical clause numbers, clause titles, text and common terms and core definitions) for MSS</p> <p>(normative)</p>	<p>Guidance for MSS writers</p> <p>(informative)</p>
<p>3.4 management system set of interrelated or interacting elements of an <i>organization</i> (3.1) to establish <i>policies</i> (3.5) and <i>objectives</i> (3.6), as well as <i>processes</i> (3.8) to achieve those objectives</p> <p>Note 1 to entry: A management system can address a single discipline or several disciplines.</p> <p>Note 2 to entry: The management system elements include the organization's structure, roles and responsibilities, planning and operation.</p>	<p>The scope of an MS may include the whole of the organization, specific and identified functions or activities of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.</p> <p>MSS writers should take care not to confuse the scope of the MSS, the scope of the MS, and the scope of any eventual certification of the MS.</p>
<p>3.5 policy intentions and direction of an <i>organization</i> (3.1) as formally expressed by its <i>top management</i> (3.3)</p>	<p>No additional guidance</p>
<p>3.6 objective result to be achieved</p> <p>Note 1 to entry: An objective can be strategic, tactical, or operational.</p> <p>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 <i>process</i> (3.8).</p> <p>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).</p> <p>Note 4 to entry: In the context of XXX <i>management systems</i> (3.4), XXX objectives are set by the <i>organization</i> (3.1), consistent with the XXX <i>policy</i> (3.5), to achieve specific results.</p>	<p>No additional guidance</p>
<p>3.7 risk effect of uncertainty</p> <p>Note 1 to entry: An effect is a deviation from the expected — positive or negative.</p> <p>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.</p> <p>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.</p> <p>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.</p>	<p>It is recognized that some MSS disciplines have their own understanding of risk, which is not exactly aligned with that of others, but which has been adopted over many years.</p> <p>MSS writers need to be aware that the main advantage of the HS is to make it easier for an organization to incorporate the requirements of multiple MSS into its management system. They should therefore be aware of the need to maintain alignment wherever possible when introducing discipline-specific term entries or requirements related to risk.</p> <p>If MSS writers (due to discipline-specific or sector-specific requirements) need to address a particular risk group, category or type for their users, in addition to the general concept specified here, they should consult Annex SL 8.3.8.</p> <p>For further information, MSS writers can refer to ISO 31000 (<i>Risk management – Guidelines</i>).</p>

Harmonized structure (identical clause numbers, clause titles, text and common terms and core definitions) for MSS (normative)	Guidance for MSS writers (informative)
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.	No additional guidance
3.9 competence ability to apply knowledge and skills to achieve intended results	No additional guidance
3.10 documented information information required to be controlled and maintained by an <i>organization</i> (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 <i>management system</i> (3.4), including related <i>processes</i> (3.8); – information created in order for the organization to operate (documentation); – evidence of results achieved (records).	MSS writers need to be aware that “documented information” is a term to represent any information that needs to be documented for the effective implementation of the MS, and to demonstrate conformity to the MS requirements. This includes requirements specified by the relevant MSS as well as requirements that the organization has to, or chooses to, comply with. The term “documented information” is used to convey the fact that the focus should be primarily on the delivery of information rather than the medium used to convey it. “Documented information” replaces the nouns “documentation”, “documents” “records” and “documented procedures” used in previous editions of some MSS. MSS writers need to be aware that whenever reference is made to “documented information” throughout the HS, the requirements specified in 7.5 apply.
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, <i>processes</i> (3.8), products, services, systems or <i>organizations</i> (3.1).	No additional guidance
3.12 continual improvement recurring activity to enhance <i>performance</i> (3.11)	No additional guidance
3.13 effectiveness extent to which planned activities are realized and planned results are achieved	MSS writers should only use the terms “effectiveness” and “effective” when referring to the ability to deliver intended results. It is important not to confuse the concept of “effectiveness” with that of “efficiency”, which relates the result achieved compared to the resources used.
3.14	No additional guidance

Harmonized structure (identical clause numbers, clause titles, text and common terms and core definitions) for MSS (normative)	Guidance for MSS writers (informative)
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 <i>organization</i> (3.1) and <i>interested parties</i> (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 <i>documented information</i> (3.10).	
3.15 conformity fulfilment of a <i>requirement</i> (3.14)	The term "conformity" applies to all requirements, including those specified in the relevant MSS. The term "compliance" can have a different meaning from the term "conformity" and is not used in the HS. MSS writers who want to introduce the term "compliance" should provide appropriate guidance on how to interpret it with respect to "conformity" in their specific discipline. MSS writers should consult ISO 37301 (<i>Compliance management systems – Requirements with guidance for use</i>) for more information if they need to include discipline-specific requirements relating to compliance.
3.16 nonconformity non-fulfilment of a <i>requirement</i> (3.14)	Nonconformity relates to the non-fulfilment of requirements (see 3.14) including those specified by the MSS or adopted by the organization as an integral part of its MS (e.g. for products, processes, agreements with interested parties).
3.17 corrective action action to eliminate the cause(s) of a <i>nonconformity</i> (3.16) and to prevent recurrence	No additional guidance
3.18 audit systematic and independent <i>process</i> (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 <i>organization</i> (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.	This definition of "audit" differs slightly from the definition given in ISO 19011:2018 (<i>Guidelines for auditing management systems</i>), in that the definition in 3.18 does not specifically state that the audit process is to be "documented". If MSS writers need to include additional discipline-specific definitions related to audit, they should consult ISO 19011.
3.19 measurement <i>process</i> (3.8) to determine a value	Measurement consists of determining a value (e.g. physical quantity, property) using measurement resources such as a measuring instrument, equipment, system or surveys.