



ISO/TMBG/JTCG-TF 14
Revision of the High Level Structure for MSS

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Draft revised guidance ('Appendix 3 of Annex SL') to the revised identical core text and common terms and core definitions for a MSS ('Appendix 2 of Annex SL')

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Background: This document includes the draft of the revised guidance ("Appendix 3 of Annex SL") to the revised identical core text and common terms and core definitions for a MSS ("Appendix 2 of Annex SL"). In this document N 101 the draft revised guidance is presented alongside the revised core text (circulated and approved as DGuide 83) for easy reference. In document N 102 a separate line numbered plain version of the draft guidance is circulated. N 102 should be used for providing comments with reference to line numbers and (sub)clauses.

This draft is circulated for comment by **November 10th 2020**, using the ISO/IEC commenting template.

Committee URL: <https://isotc.iso.org/livelink/livelink/open/>

Identical core text, common terms and core definitions for a MSS	Guidance for MSS Writers and ISO Editors
<p>NOTE 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.</p> <p>Blue italicized text is given as advisory notes to MSS writers</p>	
<p>Introduction</p> <p><i>Drafting instruction Specific to the discipline.</i></p> <p><i>This text has been prepared using the harmonized approach (i.e. clause sequence, identical core text and common terms and core definitions) provided in Annex L, Appendix 2 of the ISO/IEC Directives, Part 1). This is intended to enhance alignment among ISO and IEC management system standards, and to facilitate their implementation for organizations that need to meet the requirements of two or more such standards.</i></p> <p><i>HLS is highlighted in the text (clauses 1 to 10) by the use of blue font. Black represents the ISO or IEC specific discipline text. Strikeout is used to show agreed deletions within the HLS 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>This guidance is aimed at 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, and to the ISO/CS editorial team. It does not add to or change any requirements of the Directives.</p> <p>The objectives of this Guidance are to promote a common understanding of the harmonized approach for writing MSS (including the identical core text, common terms and core definitions), reduce the need for deviations, and indicate opportunities for further harmonization and alignment between the various discipline-specific requirements that each MSS committee may choose to add. Such additions are at the discretion of the individual committee, provided they do not contradict any of the identical core text, common terms or core definitions.</p> <p>Whilst 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 discipline-specific guidance to their standards, and to provide such guidance as appropriate.</p> <p>Where references are made to other ISO standards in this Guidance, or where examples are provided, this does not imply that reference to such standards (or text contained therein) is mandatory for discipline-specific MSS. MSS writers are, however, encouraged to consult these standards and consider them as potential inputs when drafting their own MSS.</p> <p>Attention of MSS Writers is drawn to 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>

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<p>1. Scope</p> <p><i>Drafting instruction</i> <i>Specific to the discipline.</i></p> <p><i>Drafting instruction</i> <i>The scope of the document shall address the intended result(s) of the management system.</i></p>	<p>.</p> <p>This drafting instruction provides a basis on which the effectiveness of the XXX management system can be judged (see Clause 3.1.6.1).</p>
<p>2. Normative references</p> <p><i>Drafting instruction</i> <i>Clause Title shall be used. Specific to the discipline.</i></p>	
<p>3. Terms and definitions</p> <p><i>Drafting instruction 1</i> <i>Common terms and core definitions shall be included in the MS standard, and they may also be included in a separate vocabulary standard.</i></p> <p><i>In Clause 3, discipline specific terms and definitions may also be included.</i></p> <p><i>The arrangement of terms and definitions should preferably be listed according to the hierarchy of the concepts (i.e. systematic order), but may differ from the order given below in clause 3. Alphabetical order is the least preferred order.</i></p> <p>For the purposes of this document, the following terms and definitions apply.</p>	<p>Language and terminology reference documents are as follows: ISO/IEC Directives, Part 2:2018, clause 16, ISO 704:2009 “<i>Terminology principles and methods</i>” and ISO 10241-1:2011 “<i>Terminological entries in standards - Part 1: General requirements and examples of presentation</i>”.</p> <p>Drafting Instruction 1</p> <p>When terms and their associated definitions that are located in this clause of the MSS are also included in a separate vocabulary standard, this vocabulary standard should be included as Normative Reference in Clause 2 of the MS standard.</p> <p>The harmonized approach recommends that terms and definitions in the MSS to be organized according to the hierarchy of concepts in line with the guidelines provided in ISO 704. As a consequence, term entries in an MS standard may have different numbers from the ones in the harmonized approach because of the addition of discipline specific concepts.</p> <p>An alphabetical index may be added to the MS standard as an appendix, for ease of reference.</p> <p>MSS Writers should choose one of the two following introductory wordings (ISO/IEC Directives, Part 2:2018, 16.5.3):</p> <ul style="list-style-type: none"> – when all the terms and definitions are within the MS standard, “For the purposes of this document, the following terms and definitions apply”; – when some terms and definitions are in another standard (e.g. a vocabulary standard), “For the purposes of this document, the terms

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<p><i>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 to entry may be added or modified to serve the purpose of each standard.</i></p> <p><i>When drafting terms and definitions, MSS writers are advised to make use of the flowcharts given in the JTCG terminology guidance (part of appendix 3).</i></p>	<p>and definitions given in [external document reference xxx] and the following apply.”</p> <p>Drafting Instruction 2 <u>General.</u> Term entries (i.e. terms, definitions and all associated notes) stated in clause 3 of the identical core text for MSS should be included in all MS standards.</p> <p>MSS Writers should be aware that any changes made to these term entries in discipline-specific MSS can in effect change requirements in the remainder of the MSS. Therefore if a modification of a definition or note to entry is made by a committee, this is regarded as a deviation for which a justification is required.</p> <p><u>Additional notes to entry</u> Notes to entry may be added to serve the purpose of each MS standard, on condition that they do not contradict, or deviate from, the defined concept.</p> <p><u>Additional terms and definitions</u> When drafting a new definition corresponding to a discipline-specific term, the guideline of ISO 704 should be followed.</p> <p>When a new definition corresponding to a subordinate concept (i.e. xxx MS standard concept) is drafted, the definition should begin with the term of the concept defined in clause 3 of the identical core text for MSS, followed by the specific characteristics of the subject field in question (See JTCG Terminology Guidance in support of Annex SL).</p> <p>Example: policy intentions and direction of an <i>organization</i> (3.1) as formally expressed by its <i>top management</i> (3.1.2)</p> <p>occupational health and safety policy OH&S policy <i>policy</i> (3.14) to prevent work-related <i>injury and ill health</i> (3.18) <i>to workers</i> (3.3) <i>and to provide safe and healthy workplaces</i> (3.6) [SOURCE: ISO 45001:2018, 3.15]</p>

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	<i>objective</i> (3.2.5) set by the <i>organization</i> (3.1.4) consistent with its <i>environmental policy</i> (3.1.3) [SOURCE: ISO 14001:2015]

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<p>3.1 organization person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives (3.1.3.2)</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 XX management system</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>3.1.1 interested party (preferred term) stakeholder (admitted term)</p> <p>person or organization (3.1) that can affect, be affected by, or perceive itself to be affected by a decision or activity</p>	<p>The term entry “interested party” includes the term “stakeholder” as an alternative. It is recommended to use the term “interested party”, in which case “stakeholder” may be deleted from the term entry.</p> <p>The use of “stakeholder” is not considered a deviation. When choosing to use “stakeholder”, however, the committee should be aware of the translation issue to find an equivalent in other languages.</p> <p>If the committee chooses to use the term “stakeholder” (e.g. for reasons of tradition in their specific discipline) , the term “interested party” may be deleted from the term entry.</p> <p>It is not permitted to use both “interested party” and “stakeholder” as synonyms or representing different concepts in the same MSS</p> <p>Interested parties can include, but are not limited to:</p> <ul style="list-style-type: none"> – employees; – customers; – investors; – suppliers; – regulators; – competitors; – trade and professional associations; – academia and researchers; – communities; – nongovernmental organizations.

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<p>3.1.2 top management person or group of people who directs and controls an organization (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 management system (3.1.3) covers only part of an organization then top management refers to those who direct and control that part of the organization.</p>	No guidance needed
<p>3.1.3 management system set of interrelated or interacting elements of an organization (3.1) to establish policies (3.1.3.1) and objectives (3.1.3.2) as well as processes (3.1.4) 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 a management system 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 to the MSS.</p>
<p>3.1.3.1 policy intentions and direction of an organization (3.1) as formally expressed by its top management (3.1.2)</p>	No guidance needed

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<p>3.1.3.2 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 (3.1.4).</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 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 management systems XXX objectives are set by the organization, consistent with the XXX policy, to achieve specific results.</p>	No guidance needed

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<p>3.1.3.3 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>The harmonized approach to MSS introduces a risk-based approach, whether formal or informal. MSS writers should remember that such an approach (also referred to as risk-based thinking or an approach based on risk management) addresses both positive and negative effects of uncertainty. The approach needs to consider any event, scenario, or circumstance (whether planned or unplanned) that may result in a deviation from the expected. Deviations happen. It is the effect of a deviation that can be positive or negative (or both), not the deviation itself.</p> <p>If MSS writers wish to (or due to discipline-specific or sector-specific requirements have to) target a risk group, category or type for their users, in addition to the general concepts specified here, they may define this subset as XXX risk.</p> <p>If a risk (or XXX risk) potentially generates a negative effect, it is usual to concentrate on eliminating or mitigating the risk. However, if the risk (or the mitigating action) generates a potential positive effect, then it is prudent to recognize and consider leveraging this opportunity.</p> <p>The harmonized approach to risks and opportunities makes it easier for an organization's management system to incorporate and conform to multiple MSSs. Where the potential exists to adopt a multi-criteria assessment process (e.g. where there is some combination of financial, social, environmental, reputational risk etc.), it is possible that some criteria may have positive effects and others negative. MSS writers may need to alert their users that they will need to 'balance' or find an acceptable trade-off across the various criteria in order to determine what is acceptable or desirable overall.</p> <p>MSS writers may also wish to refer to ISO 31000 (Risk management — Guidelines) for a more thorough understanding of risk management.</p>
<p>3.1.4 process set of interrelated or interacting activities that uses or transforms inputs to deliver a result</p> <p>Note 1 to entry: Whether the result of a process is called output, product or service depends on the context of the reference.</p>	<p>No guidance needed</p>

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<p>3.1.4.1 competence Ability to apply knowledge and skills to achieve intended results</p>	No guidance needed
<p>3.1.5 documented information information required to be controlled and maintained by an organization (3.1) and the medium on which it is contained</p> <p>Note 1 to entry: Documented information can be in any format and media and from any source.</p> <p>Note 2 to entry: Documented information can refer to</p> <ul style="list-style-type: none"> – the management system (3.1.3), including related processes (3.1.4); – information created in order for the organization to operate (documentation); – evidence of results achieved (records). 	<p>“Documented information” is a broad 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 MS standard as well as requirements that the organization has to or chooses to comply with.</p> <p>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.</p> <p>“Documented information” replaces the nouns “documentation”, “documents” “records” and “documented procedures” used in previous editions of some MS standards.</p> <p>Whenever reference is made to “documented information” throughout the Identical core text, common terms and core definitions, this means that such information shall be managed in accordance with Clause 7.5.</p>
<p>3.1.6 performance measurable result</p> <p>Note 1 to entry: Performance can relate either to quantitative or qualitative findings.</p> <p>Note 2 to entry: Performance can relate to managing activities, processes (3.1.4), products, services, systems or organizations (3.1).</p>	No guidance needed
<p>3.1.6.1 continual improvement recurring activity to enhance performance (3.1.6)</p>	No guidance needed
<p>3.1.6.2 effectiveness extent to which planned activities are realized and planned results are achieved</p>	<p>MSS writers should only use the terms "effectiveness" and "effective" when referring to the ability to deliver measurable results. It is important not to confuse the concept of "effectiveness" with the one of "efficiency", which is defined as the “relationship between the result achieved and the resources used” [SOURCE: ISO 9000:2015, 3.7.10]</p>

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<p>3.1.7 requirement need or expectation that is stated, generally implied or obligatory</p> <p>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.</p> <p>Note 2 to entry: A specified requirement is one that is stated, e.g. in documented information.</p>	<p>Requirements other than legal and corporate requirements are not necessarily obligatory for the organization. They become obligatory when the organization decides to adopt them as applicable requirements (see 4.2, 3rd indent).</p>
<p>3.1.7.1 conformity fulfilment of a requirement (3.1.7)</p>	<p>The terms “conformity” applies to all requirements, either mandatory or voluntary, including the ones specified in the relevant MS standards.</p> <p>The term “compliance” has a different meaning from the term “conformity”. According to ISO/DIS 37301 <i>“Compliance management systems – Requirements with guidance for use”</i>:</p> <p>compliance the outcome of meeting all the organization’s compliance obligations</p> <p>[SOURCE: ISO/DIS 37301:2020, 3.27]</p> <p>compliance obligation requirements that an organization mandatorily has to comply with as well as those that an organization voluntarily chooses to comply with</p> <p>[SOURCE: ISO/DIS 37301:2020, 3.26]</p> <p>A TC/SC/PC who wants to introduce the term “compliance”, should provide appropriate guidance on how to interpret it with respect to “conformity” in the specific discipline, e.g. by qualifying the associated compliance, such as “compliance to applicable regulations”, etc.</p>

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<p>3.1.7.2 nonconformity non-fulfilment of a <i>requirement</i> (3.1.7)</p>	<p>Nonconformity relates to the non-fulfilment of requirements specified by the MSS and to requirements adopted by the organization as an integral part of its management system (e.g. on products, processes, agreements with interested parties, management system) and resulting from legal requirements.</p> <p>According to the definition of "compliance" and "compliance obligation" a "nonconformity" is not necessarily a "noncompliance" (i.e. "non-fulfilment of a compliance obligation", ISO/DIS 37301:2020, 3.28), while a "noncompliance" is always a "nonconformity".</p>
<p>3.1.7.2.1 corrective action action to eliminate the cause(s) of a nonconformity (3.1.7.2) and to prevent recurrence</p>	<p>Although the aim of corrective action is 'to eliminate the cause of a nonconformity and to prevent recurrence', MSS writers need to be aware of the fact that it is not always possible, technically feasible, or cost effective to identify or fully eliminate the cause.</p>
<p>3.1.8 audit systematic and independent process (3.1.4) for obtaining evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled</p> <p>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).</p> <p>Note 2 to entry: An internal audit is conducted by the organization itself, or by an external party on its behalf.</p> <p>Note 3 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.</p>	<p>MS standards writers should refer to ISO 19011:2018 "<i>Guidelines for auditing management systems</i>" for guidance on auditing.</p> <p>The audit conclusion is the result of an audit after consideration and review of the audit objectives and all audit findings, as defined in ISO 19011 .</p>

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<p>3.1.9 Measurement process (3.1.4) to determine a value</p>	<p>Measurement consists on the determination of a value (e.g. physical quantity, property) using a measuring, instrument, equipment or system.</p> <p>The reference document regarding metrology (“the science of measurement”) is ISO/IEC Guide 99:2007 <i>International Vocabulary of Metrology VIM</i>.</p> <p>Useful information regarding monitoring and measuring resources can be found in the ISO 9001 Auditing Practices Group Guidance documents.</p> <p>https://committee.iso.org/home/tc176/iso-9001-auditing-practices-group.html</p>
<p>3.1.10 monitoring determining the status of a system, a process (3.1.4) or an activity</p> <p>Note 1 to entry: To determine the status there can be a need to check, supervise or critically observe.</p>	<p>Monitoring is to determine the status of something, which implies observing, supervising, keeping under review. It can, but does not necessarily, involve <i>measurement</i> (3.1.9) at intervals, especially for the purpose of regulation or control.</p> <p>See the references mentioned in 3.1.9.</p>

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<p>4. Context of the organization</p> <p>4.1 Understanding the organization and its context</p> <p>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.</p>	<p>Intent of the requirement(s)</p> <p>The intent of the clause on <i>Understanding the organization and its context</i> is to specify the requirements for a high-level (e.g. strategic) understanding of the important issues that can affect, either positively or negatively, the MS.</p> <p>Guidance for MSS Writers & ISO Editors</p> <p>MSS writers may prescribe additional requirements related to understanding the organization and its context that are specific to their discipline. According to the “Guidance on selected words used in the ISO 9000 family of standards”, (https://www.iso.org/files/live/sites/isoorg/files/standards/docs/en/terminology-ISO9000-family.pdf) use of the word "determine" means to “find out one or more characteristics and their characteristic values”.</p> <p>If documented information is required for a specific MSS discipline, for example in the legal, medical or financial sectors then standard writers can add appropriate additional requirements.</p> <p>Examples of application</p> <p>Examples of issues that may be important to a MS, and may need to be addressed by an MSS may include:</p> <ul style="list-style-type: none"> – environmental characteristics or conditions related to climate, pollution, resource availability, and biodiversity, and the effect these conditions may have on the organization’s ability to achieve its intended results; – the external cultural, social, political, legal, regulatory, financial, technological, economic, natural and competitive context, whether international, national, regional or local. <p>There are many other characteristics or conditions that might be relevant for some discipline-specific MSS that could influence an organization’s context, such as:</p> <ul style="list-style-type: none"> – organizational governance, information flows and decision-making processes; – organizational policies, objectives, and the strategies that are in place to achieve them; – the capabilities of the organization, understood in terms of resources (e.g. capital, time, people, knowledge, processes, systems and technologies); – the organization's culture; – standards, guidelines and models adopted by the organization;

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<p>4.2 Understanding the needs and expectations of interested parties</p> <p>The organization shall determine:</p> <ul style="list-style-type: none"> — 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. 	<ul style="list-style-type: none"> – the life cycle of the organization's products and services. <p>Intent of the requirement(s)</p> <p>The intent of the clause on <i>Understanding the needs and expectations of interested parties</i> is to specify the requirements for a high-level (e.g. strategic) understanding of the needs and expectations of relevant interested parties that are applicable to the MS within the scope of the MSS.</p> <p>Not all interested party requirements are requirements of the organization. Some are not applicable to the organization or relevant to the management system. Others are mandatory because they have been incorporated into laws, regulations, permits and licenses by governmental or court action. There may be others that an organization may decide to voluntarily adopt or decide to enter into an agreement or contract. Once adopted or agreed to, it must comply. These are sometimes referred to as an organization's "compliance obligations"</p> <p>Guidance for MSS Writers and ISO Editors</p> <p>MSS writers can prescribe additional requirements related to understanding the needs and expectations of interested parties in their discipline specific MSS.</p> <p>Apart from legal requirements, the needs and expectations of an interested party become obligations when they are specified, and the organization decides that it will adopt them. Once the organization subscribes, then they become organizational requirements (see 4.3).</p> <p>Examples of Application</p> <p>Examples of potential interested parties may include:</p> <ul style="list-style-type: none"> – legal and regulatory authorities (local, regional, state/provincial, national or international); – parent organizations; – customers; – trade and professional associations; – community groups; – non-governmental organizations; – suppliers; – neighbours; – partners; – employees, their representatives and other people working on behalf of the organization.

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	<p>Examples of Application</p> <p>Examples of interested party requirements may include:</p> <ul style="list-style-type: none"> – law; – permits, licences or other forms of authorization; – orders issued by regulatory agencies; – judgments of courts or administrative tribunals; – treaties, conventions and protocols; – relevant industry codes and standards; and – contracts which have been entered into; – agreements with community groups or non-governmental organizations; – agreements with public authorities and customers; – organizational requirements; – voluntary principles or codes of practice; – voluntary labelling or environmental commitments; – obligations arising under contractual arrangements with the organization.
<p>4.3 Determining the scope of the XXX management system</p> <p>The organization shall determine the boundaries and applicability of the XXX management system to establish its scope.</p> <p>When determining this scope, the organization shall consider:</p> <ul style="list-style-type: none"> — the external and internal issues referred to in 4.1, — the requirements referred to in 4.2. <p>The scope shall be available as documented information.</p>	<p>Intent of the requirement(s)</p> <p>The intent of the clause on <i>Determining the scope of the management system</i> is to establish the physical and organizational boundaries to which the management system will apply.</p> <p>Guidance for MSS Writers and ISO Editors</p> <p>Standards writers can prescribe additional requirements for determining the scope of the management system in their discipline specific MSS.</p> <p>Note that 4.3 addresses the scope of the management system for the specific discipline, not the scope of the organisation’s overall management system.</p>
<p>4.4 XXX management system</p> <p>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.</p>	<p>Intent of the requirement(s)</p> <p>The intent of the this clause is to specify the overarching requirement(s) related to the set of processes that, together, form an effective management system (See 3.1.3) in conformance to the MSS</p> <p>The processes that are typically included as part of an MSS include:</p> <ul style="list-style-type: none"> – management system processes (4.4);

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	<ul style="list-style-type: none"> - operational planning and control processes; - performance evaluation processes externally provided processes, where applicable (8.1). <p>Guidance for MSS Writers and ISO Editors</p> <p>Standards writers can prescribe additional requirements for the management system or its processes in their discipline specific MSS..</p> <p>Prior to drafting additional discipline-specific requirements, MSS Writers need to consider to what extent an organization retains authority, accountability, and autonomy to decide how it will fulfil the management system requirements, including the level of detail and extent to which it will integrate the management system requirements into its organization.</p> <p>Note when drafting an MSS, reference to this clause may avoid the need to keep repeating phrases such as “establish, maintain, and continually improve ...”, for e.g. a process, a procedure, a management system, in multiple clauses.</p>
<p>5. Leadership</p> <p>5.1 Leadership and commitment</p> <p>Top management shall demonstrate leadership and commitment with respect to the XXX management system by:</p> <ul style="list-style-type: none"> — 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) 	<p>Intent of the requirement(s)</p> <p>To identify actions in which top management is directly involved and directs the organization.</p> <p>Visible support, involvement and commitment of the organization’s top management is important to the successful implementation of the MS. It sets the attitude and expectations, increases acceptance, and motivates personnel to be engaged in the MS initiatives. It can provide reassurance to interested parties that an effective management system is likely in place.</p> <p>Guidance for MSS writers and ISO Editors</p> <p>MSS Writers should note that the word "ensuring" used in parts of this clause means that top management does not necessarily perform all of these actions themselves (e.g., they may delegate responsibility to others), but they are accountable for making sure they are performed. Any additional discipline-specific requirements should use a similar rationale for activities that can be delegated by top management</p> <p>Examples of application</p>

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<p>— directing and supporting persons to contribute to the effectiveness of the XXX management system</p> <p>— promoting continual improvement</p> <p>— supporting other relevant roles to demonstrate their leadership as it applies to their areas of responsibility.</p> <p>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.</p>	<p>An example of a “business process” can be an organization’s central human resource function, which may be responsible for ensuring that the competency requirements of an MS are met.</p> <p>Examples of additional actions in which top management is directly involved in some discipline-specific MS standards include:</p> <ul style="list-style-type: none"> – taking accountability for the effectiveness of the XXX management system; – promoting the use of the process approach and risk-based thinking; – ensuring that the XXX MS scope and boundaries are established; – promoting cross-functional collaboration within the organization; – developing, leading and promoting a culture in the organization that supports the intended results of the XXX management system. <p>The governance function includes setting and being accountable for the purpose and parameters for the organization. Where this function is provided by a role other than top management (for example, by a governing body) then requirements related to that role should also be included in this clause.</p> <p>References to other ISO Documents</p> <p>Examples of sources of information on the concept governance in relationship with management systems can be found in:</p> <p>ISO 18091:2019 - Quality management systems — Guidelines for the application of ISO 9001 in local government</p> <p>ISO 19600:2014 - Compliance management systems — Guidelines</p> <p>ISO/IEC 38500:2015 - Information technology — Governance of IT for the organization</p> <p>ISO/DIS 37000:2020 - Guidance for the Governance of Organizations</p> <p>ISO/IEC 27014:2013 - Information technology — Security techniques — Governance of information security.</p>
<p>5.2 XXX Policy</p> <p>Top management shall establish a XXX policy that:</p> <ol style="list-style-type: none"> 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; 	<p>Intent of the requirement(s)</p> <p>To specify the organizational commitments that are needed as part of the effective implementation of the MS, taking into account the organization’s purpose. It is used to frame the objectives which the organization sets for itself.</p> <p>Guidance for MSS writers and ISO Editors</p> <p>While the policy is expected to contain a commitment to meet applicable requirements of the MSS (including legal requirements), it is understood that even the most effective MS will not ensure full conformity at any particular point in time.</p>

<p align="center">Identical core text, common terms and core definitions for a MSS</p>	<p align="center">Guidance for MSS Writers and ISO Editors</p>
<p>d) includes a commitment to continual improvement of the XXX management system.</p> <p>The XXX policy shall:</p> <ul style="list-style-type: none"> — be available as documented information; — be communicated within the organization; — be available to interested parties, as appropriate. 	<p>In the case of MSS that are used as a basis for technical regulations," to ensure and maintain the suitability, adequacy and effectiveness of MS" can be considered to be included in Clause 10 Continual Improvement.</p>

Identical core text, common terms and core definitions for a MSS	Guidance for MSS Writers and ISO Editors
<p>5.3 Roles, responsibilities and authorities</p> <p>Top management shall ensure that the responsibilities and authorities for relevant roles are assigned and communicated within the organization.</p> <p>Top management shall assign the responsibility and authority for:</p> <p>a) ensuring that the XXX management system conforms to the requirements of this document;</p> <p>b) reporting on the performance of the XXX management system to top management.</p>	<p>Intent of the requirement(s)</p> <p>Require top management to assign and communicate responsibility and authority for the implementation of the management system requirements to relevant roles within the organization.</p> <p>Guidance for MSS writers and ISO Editors</p> <p>Ensuring that the management system conforms with the requirements of the MSS can be assigned to an individual, shared by several individuals, or assigned to a team, several functions or roles.</p>
<p>6. Planning</p> <p>6.1 Actions to address risks and opportunities</p> <p>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:</p> <ul style="list-style-type: none"> — give assurance that the XXX management system can achieve its intended result(s); — prevent, or reduce, undesired effects; — achieve continual improvement. 	<p>Intent of the clause</p> <p>The purpose of planning is to anticipate potential scenarios and consequences, and as such is preventive in addressing undesired effects before they occur. Similarly, it looks for favourable conditions or circumstances that can offer a potential advantage or benefit, and includes planning for those that are considered worthy of pursuit.</p> <p>Intent of the requirement(s)</p> <p>The intent of the clause on Actions to address risks and opportunities (6.1) is to specify the requirements for the planning needed as a prerequisite to establishing the discipline-specific MS. It specifies what needs to be considered and what needs to be addressed. MS Writers should keep in mind that the planning referred to in 6.1 is performed at a strategic level, versus the tactical planning done for Operational planning and control (8.1).</p> <p>At a minimum, planning needs to consider the issues relevant to the organization's context identified in (4.1) and the requirements identified in (4.2) to determine positive and negative effects that need to be addressed to prioritize and achieve the 3 bullet points in 6.1 of assurance, prevention, and continual improvement.</p> <p>Guidance for MSS Writers and ISO editors</p> <p>The harmonized approach calls for actions to address risks and opportunities in 6.1 at a strategic planning level. These are then required to be deployed at a tactical level in 8.1.</p> <p>The harmonized approach does not specifically refer to risk management, risk assessment or risk treatment. For those disciplines that need to address risk</p>

Identical core text, common terms and core definitions for a MSS	Guidance for MSS Writers and ISO Editors
<p>The organization shall plan:</p> <ul style="list-style-type: none"> a) actions to address these risks and opportunities; b) how to <ul style="list-style-type: none"> — integrate and implement the actions into its XXX management system processes; — evaluate the effectiveness of these actions. 	<p>formally, the MSS should clarify its need for a “risk management” approach, and agree on the positioning of risk assessment and risk treatment text (i.e. should it go in clause 6 or clause 8, or in both).</p> <p>MSS writers can prescribe additional requirements related to actions to address risks and opportunities in their discipline-specific MSS. MSS writers may decide how and where to integrate their discipline specific requirements (i.e. clause 6 or 8) as best fits their discipline specific needs, and insert such discipline specific requirements into the harmonized text or immediately following the harmonized text.</p> <p>For some XXX management systems planning also needs to address emergency preparedness and response. Such planning should acknowledge the interaction with the organization’s overall contingency and continuity planning.</p> <p>In addressing opportunities, MSS writers should bear in mind that while a risk can generate a positive effect, risk is only one source of opportunity that users can leverage. Other sources of opportunity which may be identified or discovered can include:</p> <ul style="list-style-type: none"> – review of the organization’s context (4.1); – review of the needs and expectations of interested parties (4.2); – a positive outcome of a negative effect; – cause analysis; – unplanned events; – innovation; – audit findings (internal or external); – management review; – continuous improvement. <p>Note: ‘identified’ opportunities are known and planned, ‘discovered’ opportunities are previously unforeseen (or unplanned) deviations from expected as sources of risk or opportunity.</p> <p>MSS writers may wish to provide users with requirements or guidance in managing opportunities within their MSS. One approach is to mirror or invert the guidance provided by ISO 31000, to create a framework to manage opportunities</p>
<p>6.2 XXX objectives and planning to achieve them</p> <p>The organization shall establish XXX objectives at relevant functions and levels.</p> <p>The XXX objectives shall:</p>	<p>Intent of the requirement(s)</p> <p>The intent of objectives and planning to achieve them is to ensure all functions and levels within the organization can give support to the intended results of the discipline-specific MS.</p>

Identical core text, common terms and core definitions for a MSS	Guidance for MSS Writers and ISO Editors
<p>a) be consistent with the XXX policy;</p> <p>b) be measurable (if practicable);</p> <p>c) take into account applicable requirements;</p> <p>d) be monitored;</p> <p>e) be communicated;</p> <p>f) be updated as appropriate;</p> <p>g) be available as documented information.</p> <p>When planning how to achieve its XXX objectives, the organization shall determine:</p> <ul style="list-style-type: none"> — what will be done; — what resources will be required; — who will be responsible; — when it will be completed; — how the results will be evaluated. 	<p>Guidance for MSS Writers and ISO Editors</p> <p>MSS writers should be aware of the following linkages with other clauses, and ensure that any additional discipline-specific requirements are consistent with them:</p> <ul style="list-style-type: none"> – Objectives are communicated in accordance with the requirements of the Communication clause (7.4); – Documentation of the objectives is created and controlled in accordance with the requirements of Documented information (7.5); – The actions required to achieve the objectives (i.e., ‘what’) and the associated timeframe (i.e., ‘when’) are determined. In addition, assignment of responsibility for doing it (i.e., ‘who’) is established in accordance with the requirements of Organization’s policy and objectives; – Any need for budgets, specialized skills, technology or infrastructure, for example, are determined and provided in accordance with the requirements of Resources (7.1); – Lastly, a mechanism for evaluating the overall results of what was accomplished is determined in accordance with the requirements of Monitoring, measurement, analysis and evaluation (9.1) and reported in accordance with Management Review (9.3). <p>Standards writers can prescribe additional requirements related to objectives and planning to achieve them in their discipline specific MSS.</p> <p>Objectives are to be measurable and verifiable, but not necessarily quantified. Qualitative results may also be relevant, e.g. an answer of “yes/no” regarding achieving objectives is acceptable, providing it is supported by evidence. take into account applicable consider the organization’s requirements</p> <p>Examples of application</p> <p>The text is self-explanatory; MSS writers should note linkages to Leadership and commitment (5.1) and Policy (5.2).</p> <p>Any discipline-specific requirements related to objectives should be stated in a way that allows determination of their fulfilment to be made. By including the caveat “where practicable”, it is acknowledged that there can be situations when it may not be feasible to measure the achievement of an objective. However, some discipline-specific MSS can include specific requirements in this respect, or a NOTE to clarify the intent.</p>

Identical core text, common terms and core definitions for a MSS	Guidance for MSS Writers and ISO Editors
	For specific MS disciplines, MSS Writers can make reference to other MSS clauses when the status and progress on objectives need to be periodically checked and updated.
<p>6.3 Planning of changes</p> <p>When the organization determines the need for changes to the XXX management system, the changes shall be carried out in a planned manner.</p>	<p>Intent of the requirement(s)</p> <p>Planning of changes is an important part of ensuring the organization can achieve the intended results of its XXX management system on an ongoing basis.</p> <p>As part of managing change, the organization should address planned and unplanned changes to ensure that the unintended consequences of these changes do not have a negative effect on the intended results or the integrity of the XXX management system.</p> <p>Examples of change include:</p> <ul style="list-style-type: none"> – planned changes to products, processes, services, operations, equipment or facilities; – changes in staff or external providers, including contractors; – changes in requirements. <p>Guidance for MSS writers and ISO Editors</p> <p>Planning of changes can vary, depending on the complexity and severity of the changes. A minor change such a policy update could be captured in a verbal conversation, whereas a design in new factory building would need formal sign off from relevant stakeholders. Therefore, MSS should be flexible to allow for this and for local, governmental or industry-specific requirements.</p> <p>MSS Writers should make reference to Clause 8.1 for controlling planned changes.</p>
<p>7. Support</p> <p>7.1 Resources</p> <p>The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the XXX management system.</p>	<p>Intent of the requirement(s)</p> <p>To determine and provide the resources needed to implement, maintain and improve the MS. Resources should be appropriate to ensure that the operation of the MS is effective in achieving its intended results.</p> <p>Guidance for standards writers and ISO Editors</p> <p>Resources may include, for example:</p>

<p>Identical core text, common terms and core definitions for a MSS</p>	<p>Guidance for MSS Writers and ISO Editors</p>
	<ul style="list-style-type: none"> - human resources; - specialized skills or knowledge; - organizational knowledge; - organizational infrastructure (i.e., buildings, communication lines, etc); - technology; - financial resources; - work environment or environment for the operation of the processes. <p>Examples of application</p> <p>Some MSS have introduced in clause 7 additional requirements that could be seen as non-discipline-specific and could, eventually, be applicable to all MSS.</p> <p>For example, this is the case of a type of resource “organizational knowledge”, introduced by ISO 9001:2015 in clause 7.1.5.</p> <p>ISO 30401 provides information on the importance of organizational knowledge and describes a holistic approach to its management.</p> <p>References to other ISO Documents</p> <p>Examples of \sources of information on the concept of organizational knowledge as a resource with can be found in: ISO 9001:2015 - Quality management systems — Requirements ISO 30401:2018 - Knowledge management systems — Requirements</p>
<p>7.2 Competence</p> <p>The organization shall:</p> <ul style="list-style-type: none"> — 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. <p>Appropriate documented information shall be available as evidence of competence.</p>	<p>Intent of the requirement(s)</p> <p>To determine the competence necessary for persons to meet the requirements of the MSS and achieve the MS’s objectives.</p> <p>Guidance for standards writers and ISO Editors</p> <p>The text should be read in conjunction with the definition of competence (3.1.4.1).</p> <p>As mentioned in the Note to Clause 7.2, MSS writers should be aware that training is not the only mean to achieve competence.</p> <p>For some MSS, the meaning of the phrase ‘xxx performance’ changes the meaning of the requirement. In this case, the MSS writers can provide</p>

<p>Identical core text, common terms and core definitions for a MSS</p>	<p>Guidance for MSS Writers and ISO Editors</p>
<p>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.</p>	<p>alternative text to provide clarification as long as the intent of the requirement does not change.</p> <p>Examples of application</p> <p>MSS writers who wish to add more text on ‘competence’ can find information in ISO 10015</p> <p>If a discipline-specific MSS needs to mention training as a way to ensure competence, an example of an additional requirement could read e.g.: ‘determine training needs associated with its xxx aspects and its xxx management system’</p> <p>References to other ISO Documents</p> <p>Examples of sources of information on competence in relationship with management systems can be found in:</p> <p>ISO 10015:2019 - Quality management — Guidelines for competence management and people development. ISO 14001:2015 - Environmental management systems — Requirements with guidance for use</p>
<p>7.3 Awareness</p> <p>Persons doing work under the organization's control shall be aware of:</p> <ul style="list-style-type: none"> — the XXX policy; — their contribution to the effectiveness of the XXX management system, including the benefits of improved XXX performance; <p>the implications of not conforming with the XXX management system requirements.</p>	<p>Intent of the requirement(s)</p> <p>To ensure that persons in the organization are aware of relevant MSS requirements and any situation or aspect that can have an effect on the intended results of the MS.</p> <p>Guidance for MSS writers and ISO Editors</p> <p>Awareness of listed topics should not be taken to mean that these should be memorized. Rather, persons should be aware of the XXX MS intended results and their role in achieving them.</p> <p>For some MSS, the meaning of the phrase ‘xxx performance’ changes the meaning of the requirement. In this case, the MSS can provide alternative text to provide clarification as long as the intent of the requirement does not change.</p> <p>Examples of application</p> <p>Additional items that persons can be required to be aware of could be:</p>

Identical core text, common terms and core definitions for a MSS	Guidance for MSS Writers and ISO Editors
	<ul style="list-style-type: none"> - the xxx objectives and their impact on achieving them and on risk exposure; - XXX culture and specific desired behaviours, mindsets related to it. <p>References to other ISO Documents</p> <p>Sources of information on culture and specific desired behaviours related to management systems can be found in:</p> <p>ISO 56002:2019 - Innovation management — Innovation management system — Guidance ISO 9004:2018 - Quality management — Quality of an organization — Guidance to achieve sustained success ISO 19600:2014 - Compliance management systems — Guidelines ISO/DIS 37301:2020 - Compliance management systems – Requirements with guidance for use</p>
<p>7.4 Communication</p> <p>The organization shall determine the internal and external communications relevant to the XXX management system including:</p> <ul style="list-style-type: none"> — on what it will communicate; — when to communicate; — with whom to communicate; — how to communicate. 	<p>Intent of the requirement(s)</p> <p>To ensure that information concerning the XXX MS is communicated effectively both to and from the relevant interested parties.</p> <p>Guidance for MSS writers and ISO Editors</p> <p>Examples of topics where other clauses of the harmonized approach require effective communication include:</p> <ul style="list-style-type: none"> - importance of effective XXX management and of conforming to the MSS requirements (see 5.1); - policy (see 5.2); - responsibilities and authorities (see 5.3); - performance of the MS (see 5.3); - objectives (see 6.2); - results of audits (see 9.2.2). <p>Examples of application</p> <p>Explicit requirements may be added in an MSS to ensure that the internal and external communication are covering essential topics related to a specific MS and/or to whom to communicate what.</p> <p>Examples for such additional requirements could be:</p>

Identical core text, common terms and core definitions for a MSS	Guidance for MSS Writers and ISO Editors
	<ul style="list-style-type: none"> – the organization shall take into account diversity aspects (e.g. gender, language, culture, literacy, disability) when considering its communication needs; – the organization shall ensure that the views of internal and external interested parties are considered in establishing its communication process(es). <p>References to other ISO Documents</p> <p>Examples of sources of information on requirements for communication related to management systems can be found in: ISO 14001:2015 - Environmental management systems — Requirements with guidance for use ISO 45001:2018 - Occupational health and safety — Occupational health and safety management systems — Requirements with guidance for use ISO 22000:2018 - Food safety management systems — Requirements for any organization in the food chain.</p>
<p>7.5 Documented information</p> <p>7.5.1 General</p> <p>The organization's XXX management system shall include:</p> <ul style="list-style-type: none"> 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. <p>NOTE The extent of documented information for a XXX management system can differ from one organization to another due to:</p> <ul style="list-style-type: none"> – the size of organization and its type of activities, processes, products and services; – the complexity of processes and their interactions; – the competence of persons. 	<p>Intent of the requirement(s)</p> <p>To provide a description of the types of documented information that need to be created, controlled, and maintained in a management system. This includes those which are:</p> <ul style="list-style-type: none"> – required for all MSS (as presented in clause 7.5.1 and in the respective clauses of the harmonized approach); – required by a particular MS; and – any additional information the organization determines necessary to be documented. <p>-</p> <p>The intent of the NOTE is to indicate the factors that should be taken into account when the extent of documented information is defined, such as size, type, complexity, persons competence (risks can be also viewed as a factor)</p> <p>Guidance for standards writers and ISO Editors</p> <p>The text should be read in conjunction with the definition of documented information (3.1.5).</p>

Identical core text, common terms and core definitions for a MSS	Guidance for MSS Writers and ISO Editors
	<p>References to other ISO Documents</p> <p>Examples of sources of information on documentation related to management systems can be found in: ISO 30301:2019 - Information and documentation — Management systems for records — Requirements</p>
<p>7.5.2 Creating and updating documented information</p> <p>When creating and updating documented information the organization shall ensure appropriate:</p> <ul style="list-style-type: none"> — 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. 	<p>Intent of the requirement(s)</p> <p>To specify the requirements for uniquely identifying the information, defining the format and media it will be maintained in, and for its review and approval.</p> <p>References to other ISO Documents</p> <p>Examples of sources of information on documentation related to management systems can be found in: ISO 30301:2019 - Information and documentation — Management systems for records — Requirements</p>
<p>7.5.3 Control of documented information</p> <p>Documented information required by the XXX management system and by this document shall be controlled to ensure:</p> <ol style="list-style-type: none"> 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). <p>For the control of documented information, the organization shall address the following activities, as applicable:</p> <ul style="list-style-type: none"> — distribution, access, retrieval and use; — storage and preservation, including preservation of legibility; — control of changes (e.g. version control); — retention and disposition 	<p>Intent of the requirement(s)</p> <p>To specify the internal controls that need to be considered and implemented for information that is required to be documented. Different internal controls may be needed for different types of documented information.</p> <p>Guidance for MSS writers and ISO Editors</p> <p>In addition to internal information that is required to be documented, information created by external parties may be required for the MSS. The identification and control of such information is also required.</p> <p>The information required to be documented by the MS may be integrated with other information management or documentation systems established by an organization.</p> <p>References to other ISO Documents</p> <p>Examples of sources of information on documentation related to management systems can be found in: ISO 30301:2019 - Information and documentation — Management systems for records — Requirements</p>

<p>Identical core text, common terms and core definitions for a MSS</p>	<p>Guidance for MSS Writers and ISO Editors</p>
<p>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.</p> <p>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.</p>	
<p>8 Operation</p>	
<p>8.1 Operational planning and control</p> <p><i>Drafting instruction: This subclause heading will be deleted if no additional subclauses are added to Clause 8.</i></p> <p>The organization shall plan, implement and control the processes needed to meet requirements, and to implement the actions determined in Clause 6, by:</p> <ul style="list-style-type: none"> — establishing criteria for the processes; — implementing control of the processes in accordance with the criteria. <p>Documented information shall be available to the extent necessary to have confidence that the processes have been carried out as planned.</p> <p>The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.</p> <p>The organization shall ensure that externally provided processes, products or services that are relevant to the XXX management system are controlled.</p>	<p>Intent of the requirement(s)</p> <p>To enable the organization to plan, implement and control the processes related to the scope of the MS. This includes any externally provided processes. By mentioning clause 6, this requirement includes the consideration of risks and opportunities when determining the extent of control for the processes.</p> <p>Guidance for MSS writers and ISO editors</p> <p>MSS writers may add requirements that are related to the MSS in order to provide requirements that control the related processes.</p> <p>Clause 8 is typically the area of the harmonized approach where MSS writers add the most discipline-specific requirements. For this reason, Clause 8 may be longer than other clauses in many MSS.</p> <p>Operational planning can be more detailed than the planning done in Clause 6, focused on the business operations in support of those planned actions determined in Clause 6.</p> <p>External providers include providers of processes, product or services that have an effect on the MS. External providers could include the organization’s corporate headquarters, associate companies, suppliers, or someone to whom the organization has requested to provide a process, a product or a service. An external provider is outside the scope of the management system, although the control over the externally provided processes, products or services relevant to the intended results of the XXX management system are within the scope.</p> <p>For some XXX management systems the concept of emergency preparedness and response is important as part of operational planning and control. This concept needs to be linked to the requirements related to planning of unintended changes as described in Clause 6.3. If a MSS Committee considers it relevant to include specific requirements on emergency preparedness and response in their MSS, they should do so as part of Clause 8. These specific requirements may be related to the organization’s contingency planning or business continuity planning. A committee</p>

Identical core text, common terms and core definitions for a MSS	Guidance for MSS Writers and ISO Editors
	<p>can use the following suggested text that may be supplemented with discipline-specific requirements:</p> <p>8.x Emergency preparedness and response</p> <p>The organization shall establish, implement and maintain the process(es) needed to prepare for and respond to potential emergency situations identified in 6.1.x.</p> <p>The organization shall:</p> <ul style="list-style-type: none"> a) establish a planned response to emergency situations, taking into account the needs and capabilities of all relevant interested parties; b) provide relevant information and training, as appropriate, to relevant interested parties, including persons working under its control; c) periodically test and exercise the planned response capability, where practicable; d) respond to actual emergency situations; e) take action to prevent or mitigate the consequences of emergency situations, appropriate to the magnitude of the emergency and the potential impact; f) evaluate performance of planned response and revise it as necessary, including after the occurrence of emergency situations and after testing and exercising. <p>Examples of application</p> <p>Clause 8 of ISO 9001:2015 includes requirements for determining customer requirements, design and development, externally provided processes, products, and services, control of production and service provision, release of product and service delivery, and control of nonconforming output.</p> <p>ISO 9001:2015 has requirements for controlling externally provided processes, products or services. These controls include the evaluation, selection and monitoring of performance of the external provider, based on established criteria.</p> <p>ISO 9001:2015 considers the interactions with the organizations when determining controls. An associate organization might have different controls imposed on it compared to other external providers.</p> <p>ISO 50001:2018 requires the organization to establish the control over the processes, only to those where absence of control could lead to deviations from the XXX policy or XXX objectives.</p>

<p>Identical core text, common terms and core definitions for a MSS</p>	<p>Guidance for MSS Writers and ISO Editors</p>
	<p>ISO 55001:2014 has linked the requirements of Clause 8 to requirements in 10.2, considering that when controls fail, organizations may need to take actions as described in 10.2.</p> <p>ISO 22000:2018 applies the concept of risk when defining the degree of control over the externally provided products, processes or services.</p> <p>References to other ISO documents</p> <p>Examples of sources of information can be found in: ISO 9001:2015 - <i>Quality management systems — Requirements</i> ISO/TS 9002:2016 - <i>Quality management systems — Guidelines for the application of ISO 9001:2015</i> ISO 22000:2018 - <i>Food safety management systems — Requirements for any organization in the food chain</i> ISO 50001:2018 - <i>Energy management systems — Requirements with guidance for use</i> ISO 55001:2014 - <i>Asset management — Management systems — Requirements</i></p>
<p>9 Performance evaluation</p>	
<p>9.1 Monitoring, measurement, analysis, and evaluation</p> <p>The organization shall determine:</p> <ul style="list-style-type: none"> — 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. <p>Documented information shall be available as evidence of the results. The organization shall evaluate the XXX performance and the effectiveness of the XXX management system.</p>	<p>Intent of the requirement(s)</p> <p>To specify the requirements on processes that provide the information needed to demonstrate whether or not the intended results of the MS are being achieved as planned.</p> <p>The results of the analysis and evaluation of what is monitored and measured provide the 'necessary and sufficient' information to judge the extent to which the MS planned activities are realized and its planned results are achieved.</p> <p>The information gained through monitoring, measurement, analysis and evaluation is intended to be used at different levels of the organization, as appropriate, to support decision making related to the respective activities.</p> <p>Guidance for MSS writers and ISO editors</p> <p>MSS writers should consult 3.1.9 and 3.1.9.1 to understand the difference between 'monitoring' and 'measurement' and ensure that any discipline-specific text they develop respects this difference.</p> <p>When determining what to monitor and measure, the MSS may address the need to evaluate the fulfilment of specific requirements within the scope of MSS (see 4.3) and/or related processes.</p>

Identical core text, common terms and core definitions for a MSS	Guidance for MSS Writers and ISO Editors
	For some MSS, the meaning of XXX performance changes the meaning of the requirement. In this case, the MSS can provide alternative text to provide clarification as long as the intent of the requirement does not change.
9.2 Internal audit	
<p>9.2.1 General</p> <p>The organization shall conduct internal audits at planned intervals to provide information on whether the XXX management system:</p> <p>a) conforms to:</p> <ul style="list-style-type: none"> — the organization's own requirements for its XXX management system; — the requirements of this document; <p>b) is effectively implemented and maintained.</p>	<p>Intent of the requirement(s)</p> <p>To specify the requirements for planning, implementing and maintaining an internal audit programme to facilitate the provision of the necessary information for the performance evaluation.</p> <p>Guidance for MSS writers and ISO editors</p> <p>Several MSS refer to ISO 19011, that provides guidance on auditing management systems. If a TC/SC/PC includes a reference to ISO 19011, they can use the following suggested text:</p> <p>NOTE ISO 19011 provides guidance on auditing management systems, including the principles of auditing, managing an audit programme and conducting management system audits, as well as guidance on the evaluation of competence of individuals involved in the audit process. These activities include the individual(s) managing the audit programme, auditors and audit teams.</p> <p>References to other ISO documents</p> <p>Examples of sources of information on the concept of internal auditing in relationship with management systems can be found in:</p> <p>ISO 19011:2018 - <i>Guidelines for auditing management systems</i></p>
<p>9.2.2 Internal audit programme</p> <p>The organization shall plan, establish, implement and maintain an audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting.</p> <p>When establishing the internal audit programme(s), the organization shall consider the importance of the processes concerned and the results of previous audits.</p> <p>The organization shall:</p> <p>a) define the audit objectives, criteria and scope for each audit;</p> <p>b) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;</p> <p>c) ensure that the results of audits are reported to relevant managers.</p>	No additional guidance necessary

Identical core text, common terms and core definitions for a MSS	Guidance for MSS Writers and ISO Editors
Documented information shall be available as evidence of the implementation of the audit programme(s) and the audit results.	
9.3 Management review	
<p>9.3.1 General</p> <p>Top management shall review the organization's XXX management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.</p>	<p>Intent of the requirement(s)</p> <p>To specify the requirements related to the conduct of a holistic review of the MS by top management, including the information to be covered and the expected results.</p> <p>Top management engagement in this review is the mechanism to drive changes to the MS and direct continual improvement priorities, particularly in relation to the changing circumstances in the organization's context, deviations from intended results, or favourable conditions that offer an advantage with beneficial results.</p> <p>Guidance for MSS writers and ISO editors</p> <p>For some MSS, the meaning of XXX performance changes the meaning of the requirement. In this case, the MSS can provide alternative text to provide clarification as long as the intent of the requirement does not change.</p>
<p>9.3.2 Management review inputs</p> <p>This management review shall include:</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> — nonconformities and corrective actions; — monitoring and measurement results; — audit results; e) opportunities for continual improvement. 	No additional guidance needed
<p>9.3.3 Management review results</p> <p>The results of the management review shall include decisions related to continual improvement opportunities and any need for changes to the XXX management system.</p> <p>Documented information shall be available as evidence of the results of management reviews.</p>	No additional guidance needed
10 Improvement	

Identical core text, common terms and core definitions for a MSS	Guidance for MSS Writers and ISO Editors
<p>10.1 Continual improvement</p> <p>The organization shall continually improve the suitability, adequacy and effectiveness of the XXX management system.</p>	<p>Intent of the requirement(s)</p> <p>To specify the requirements to improve the MS.</p> <p>MSS writers should be aware that the term adopted by the Harmonized Approach is 'continual improvement' (see 3.1.6.1) and not 'continuous improvement'. These terms are not synonymous; therefore, the introduction of the term 'continuous improvement' into discipline-specific MSS should be avoided.</p> <p>Guidance for MSS writers and ISO editors</p> <p>Some discipline-specific MSS supporting documents provide guidance about suitability, adequacy and effectiveness. If a MSS Committee considers it relevant to include guidance about these terms, they can use the following suggested text:</p> <p>NOTE The three main areas of improving the XXX management system are defined as follows:</p> <ul style="list-style-type: none"> — suitability: the extent to which the XXX management system 'fits' and is right for the organization's purpose, its operations, culture, and business systems; — adequacy: the extent to which the XXX management system is sufficient in meeting the applicable requirements; — effectiveness: the extent to which planned activities are realized and planned results achieved. <p>Examples of application</p> <p>In the identical core text, clause 10 focuses on corrective actions and continual improvement. ISO 14001:2015 opted to add as guidance to this clause other forms of improvement like breakthrough improvement and innovation. These were also added as notes in ISO 9001:2015.</p> <p>References to other ISO documents</p> <p>Examples of sources of information on the concept of continual improvement in relationship with management systems can be found in:</p> <p>ISO 14001:2015 - <i>Environmental management systems — Requirements with guidance for use</i></p> <p>ISO 45001:2018 - <i>Occupational health and safety management systems — Requirements with guidance for use</i></p> <p>ISO 9001:2015 - <i>Quality management systems — Requirements</i></p> <p>ISO 56002:2019 - <i>Innovation management — Innovation management system — Guidance</i></p>

Identical core text, common terms and core definitions for a MSS	Guidance for MSS Writers and ISO Editors
<p>10.2 Nonconformity and corrective action</p> <p>When a nonconformity occurs, the organization shall:</p> <ul style="list-style-type: none"> a) react to the nonconformity, and as applicable: <ul style="list-style-type: none"> — 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: <ul style="list-style-type: none"> — 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. <p>Corrective actions shall be appropriate to the effects of the nonconformities encountered.</p> <p>Documented information shall be available as evidence of:</p> <ul style="list-style-type: none"> — the nature of the nonconformities and any subsequent actions taken; — the results of any corrective action. 	<p>Intent of the requirement(s)</p> <p>To specify the requirements for responding, if and when needed, when the MSS and MS requirements (including operational requirements) are not satisfied. It applies to the non-fulfilment of a requirement related to process, product, service, system, and to any other requirement that affects the ability of the MS to achieve its intended result.</p>