



ISO/TMB/JTCG
Joint technical Coordination Group on MSS (TAG 13)

Email of secretary:
Convenorship:

N360 JTCG concept document to support Annex SL

Document type: Other committee document

Date of document: 2013-12-03

Expected action: INFO

Background: Dear all,

Attached please find JTCG N 360 concept document developed by TF4 and approved by JTCG at its Atlanta meeting. Many thank you to TF4 for the substantial work in its development

Kind regards

Anne-Marie

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



-Chair: Anne-Marie Warris

-Secretary: vacant

JTCG Concept document to support of Annex SL

Please find attached Concept document developed by TF4 and approved by JTCG at its meeting.

Please note the Annex SL text in here has not been updated in line with JTCG N362 proposal for minor edits

Please note due to time constraints the format of the table has not been adjusted to remove the breaks that should not be there. It is intended that the table shall be one continues text table with no breaks between clauses.



JTCG/TF4/**N27**

3 December 2013

Annex SL Concepts document

Principle 1: <u>Target audience</u>	Standards Writers of Management System Standards (MSS) , not organizations implementing a MSS based on Annex SL
Principle 2: <u>Clear understanding of the English language</u>	Simple text need not be explained. It is not necessary to provide separate explanations for each sentence and bullet
Principle 3: <u>Reflect intent of Annex SL (as written in 2010)</u>	MSS specific interpretations or applications are not included, but rather avoided.
Principle 4: <u>Additions</u>	Standard writers are obliged to evaluate the sufficiency of the Annex SL requirements for their discipline specific MSS and include additional requirements in any clause, as appropriate to their technical subject.

This guidance is provided in a table format that includes the Annex SL text provides where necessary information on the concept behind the requirement in the Annex SL text, and guidance, examples or comments as appropriate.

<p style="text-align: center;">Annex SL (text) as taken from ISO Directives 2013 editions – not updated in line with JTCG proposal in JTCG N362</p>	<p style="text-align: center;">Concept of the requirement</p>	<p style="text-align: center;">Guidance, examples, or commentary</p>
<p>Introduction</p> <p>NOTE Specific to the discipline.</p>	<p>The intent of the Introduction is to give specific information or commentary about the technical content of the MSS, and about the reasons prompting its preparation. An Introduction is optional. It shall not contain requirements.</p>	<p>Refer to ISO/IEC Directives Part 2: Rules for the structure and drafting of International Standards, for specific requirements, guidance and examples.</p>
<p>1. Scope</p> <p>NOTE Specific to the discipline.</p>	<p>The intent of the Scope clause is to succinctly define without ambiguity the subject of the MSS and the aspects covered, thereby indicating the limits of applicability of the MSS or particular parts of it. It shall not contain requirements.</p> <p>This clause is not to be confused with the scope of the management system (see 4.3)</p>	<p>Refer to ISO/IEC Directives Part 2: Rules for the structure and drafting of International Standards, for specific requirements, guidance and examples.</p>
<p>2. Normative references</p> <p>NOTE Clause Title shall be used. Specific to the discipline.</p>	<p>The intent of the Normative Reference clause is to give a list of the referenced documents which have been cited in the MSS in such a way as to make them indispensable for the application of the MSS. Normative references are optional.</p>	<p>Refer to ISO/IEC Directives Part 2: Rules for the structure and drafting of International Standards, for specific requirements, guidance and examples.</p>
<p>3. Terms and definition</p> <p>NOTE Clause Title shall be used. Terms and definitions may either be within the standard or in a separate document. To reference Common terms and Core definitions + discipline specific</p>	<p>The intent of the Terms and Definitions clause is to provide the common set of harmonized definitions for MSS terminology. Further, standards writers provide additional definitions for the discipline-specific terms, i.e., words used in particular subject fields by</p>	<p>This section should contain only the definitions of words used by specialists in the particular subject field in which the document is written, i.e., these words are called “terms” that are necessary for</p>

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<p>ones.</p> <p>For the purposes of this document, the following terms and definitions apply.</p> <p>NOTE 1 The following terms and definitions constitute an integral part of the “common text” for management systems standards. Additional terms and definitions may be added as needed. Notes may be added or modified to serve the purpose of each standard.</p> <p>NOTE 2 Bold 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.</p> <p>NOTE 3 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”.</p>	<p>specialists that are necessary for understanding the MSS.</p> <p>As per ISO directives, Part 2, D.1.2, arrangement, Terms and definitions should be preferably organized according to the hierarchy of the concepts. Alphabetic order is the least preferred.</p>	<p>understanding the MSS. Words used in general language and ordinary communicative settings are not defined, as the everyday use and meaning of these words can be found in a dictionary.</p> <p><i>For instance, the word “dog” in general language is commonly understood to mean a domestic canine. However, the word “dog” in mechanical engineering has a very specific meaning restricted to this field. The former is a “word”, and the latter is a “term”.</i></p> <p>Terms that are not used in a MSS do not have to be defined.</p> <p>Terms and their associated definitions can be located in this clause of the MSS or included in a referenced document. Suggested references for dictionaries are listed in ISO/IEC Directives, Part 2, Sixth edition, 2011, B.2 Reference works for language.</p> <p>Rules for drafting terms and definitions are given in ISO Directives, Part 2, Annex D, together with special rules for terminology standards, such as vocabularies, nomenclatures or lists of equivalent terms in different languages.</p>

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<p>3.01 organization person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives (3.08)</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>3.02 interested party (preferred term) stakeholder (admitted term) person or organization (3.01) that can affect, be affected by, or perceive themselves to be affected by a decision or activity</p>		<p>Interested parties can include:</p> <ul style="list-style-type: none"> - Customers - Community - Suppliers - Regulators - Nongovernment organizations - Investors - Employees
<p>3.03 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, for example in documented information.</p>		<p>Requirements, other than legal requirements, become obligatory when adopted by the organization.</p>

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<p>3.04 management system set of interrelated or interacting elements of an organization (3.01) to establish policies (3.07) and objectives (3.08) and processes (3.12) 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 system elements include the organization's structure, roles and responsibilities, planning, operation, etc.</p> <p>NOTE 3 to entry: The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.</p>		
<p>3.05 top management person or group of people who directs and controls an organization (3.01) 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 (3.04) covers only part of an organization then top management refers to those who direct and control that part of the organization.</p>		
<p>3.06 effectiveness extent to which planned activities are realized and planned results achieved</p>		
<p>3.07 policy</p>		

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intentions and direction of an organization (3.01) as formally expressed by its top management (3.05)		

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<p>3.08 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 financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and process (3.12)).</p> <p>NOTE 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as an XXX objective or by the use of other words with similar meaning (e.g. aim, goal, or target).</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>		
<p>3.09 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 (ISO Guide 73, 3.5.1.3) and consequences (ISO Guide 73, 3.6.1.3), 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 (ISO Guide 73, 3.6.1.1) of occurrence.</p>		<p>Discipline specific standards can define “risk” in terms that are specific to their discipline. ISO 31000 provides a definition of “risk” that some discipline-specific standards can use (see also definition 3.09).</p>
<p>3.10 competence</p>		

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Ability to apply knowledge and skills to achieve intended results		

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<p>3.11 documented information information required to be controlled and maintained by an organization (3.01) 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 – the management system (3.04), including related processes (3.12); – information created in order for the organization to operate (documentation); – evidence of results achieved (records).</p>		
<p>3.12 process set of interrelated or interacting activities which transforms inputs into outputs</p>		
<p>3.13 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 the management of activities, processes (3.12), products (including services), systems or organizations (3.01).</p>		

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<p>3.14 outsource (verb) make an arrangement where an external organization (3.01) performs part of an organization’s function or process (3.12)</p> <p>NOTE 1 to entry: An external organization is outside the scope of the management system (3.04), although the outsourced function or process is within the scope.</p>		<p>For purposes of Annex SL, an outsourced process is one which</p> <ul style="list-style-type: none"> • the function or process is integral to the organization’s functioning • the function or process is needed for the MS to achieve its intended outcome • liability for the function or process conforming to requirements is retained by the organization • the organization and the external provider have an integral relationship e.g. one where the process is perceived by interested parties as being carried out by the organization
<p>3.15 monitoring determining the status of a system, a process (3.12) or an activity</p> <p>NOTE 1 to entry: To determine the status there may be a need to check, supervise or critically observe.</p>		
<p>3.16 measurement process (3.12) to determine a value</p>		

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<p>3.17 audit systematic, independent and documented process (3.12) for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled</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>Annex SL 9.2 pertains to internal audits.</p> <p>Annex SL requires that internal audits are conducted by the organization or by an external party on its behalf.</p>	<p>Independence can be demonstrated by the freedom from responsibility for the activity being audited or freedom from bias and conflict of interest.</p> <p>“Audit evidence” consists of records, statement of fact and other information relevant to the audit criteria and verifiable, and “audit criteria” are the set of policies, procedures or requirements (3.03) used as a reference against which audit evidence is compared as defined in ISO 19011</p> <p>Audit findings and the audit conclusion may be described collectively as the audit result. “Audit findings” consist of the results of the evaluation of the collected audit evidence against audit criteria and the “audit conclusion” is the outcome of an audit after consideration of the audit objectives and all audit findings, as defined in ISO 19011.</p> <p>A combined audit is an audit of an organization’s management system against two or more sets of audit criteria or standards (for example, quality, safety, etc) and often referred to as an ‘integrated’ audit.</p>

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3.18 conformity fulfilment of a requirement (3.03)		
3.19 nonconformity non-fulfilment of a requirement (3.03)		Nonconformity relates to the requirements specified by the management system standard and to the requirements adopted by the organization
3.20 corrective action action to eliminate the cause of a nonconformity (3.19) and to prevent recurrence		Corrective action is action taken to <u>eliminate the cause</u> of a nonconformity, whereas “correction” is immediate action taken to <u>eliminate</u> a detected nonconformity
3.21 continual improvement recurring activity to enhance performance (3.13)		
4. Context of the organization 4.1 Understanding the organization and its context The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended outcome(s) of its XXX management system.	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. Issues can be e.g. important topics for the organization, problems for debate and discussion, or changing circumstances The knowledge gained is then used to guide the	Examples of issues that may be important to an MS, and may need to be addressed by an MSS include: – 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 objectives; – the external cultural, social, political,

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	<p>efforts to plan, implement and operate the management system.</p> <p>Standards writers may prescribe additional requirements related to understanding the organization and its context in their discipline specific MSS.</p>	<p>legal, regulatory, financial, technological, economic, natural and competitive context, whether international, national, regional or local;</p> <ul style="list-style-type: none"> – characteristics or conditions of the organization, such as <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; ○ the life cycle of the organization's products and services.
<p>4.2 Understanding the needs and expectations of interested parties</p> <p>The organization shall determine — the interested parties that are relevant to the</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</p>	<p>Examples of potential interested parties may include:</p> <ul style="list-style-type: none"> • legal and regulatory authorities (local, regional, state/provincial,

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<p>XXX management system, and</p> <p>The organization shall determine</p> <p>— the relevant requirements of these interested parties</p>	<p>MS and to 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.</p> <p>If an interested party ‘perceives’ themselves to be affected by the management system, they must make it known.</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>The knowledge gained is then used to guide the efforts to plan, implement and operate the management system.</p> <p>Standards writers can prescribe additional requirements related to understanding the needs and expectations of interested parties in their discipline specific MSS.</p>	<p>national or international),</p> <ul style="list-style-type: none"> • parent organizations, • customers, • trade and professional associations, • community groups, • non-governmental organizations, • suppliers, • neighbours, • employees and others working on behalf of the organization. <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

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		commitments; <ul style="list-style-type: none"> • 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, and — the requirements referred to in 4.2. <p>The scope shall be available as documented information.</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>The organization has the freedom and flexibility to define its boundaries and may choose to implement MSS within the entire organization, a specific unit, or particular function(s) within an organization.</p> <p>An understanding of the context (4.1) and the requirements of relevant interested parties (4.2) are considerations when establishing the scope of the management system and in determining which requirements the organization will adopt.</p> <p>Documentation of the scope is created and controlled in accordance with the requirements of <i>Documented information</i> (7.5).</p> <p>Standards writers can prescribe additional requirements for determining the scope of the management system in their discipline specific MSS.</p>	<p>It should be noted that the term scope can be used in three different applications:</p> <ul style="list-style-type: none"> - the Scope of the ISO MSS (clause 1) - the scope of the organization’s management system (as defined by 4.3) - the “scope” of an organization’s certification.
<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,</p>	<p>The intent of the <i>Management System</i> clause is to specify the overarching requirement(s) related to creating the ‘necessary but sufficient’ set of processes that, together, form an effective management system in conformance to the MSS.</p>	<p>The minimum processes required to be established in a MSS include:</p> <ul style="list-style-type: none"> - Management system processes (4.4) - Operational planning and control processes, including outsourced

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<p>in accordance with the requirements of this International Standard.</p>	<p>The 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 business.</p> <p>Standards writers can prescribe additional requirements for the management system or its processes in their discipline specific MSS.</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>processes (8.1)</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 	<p>The intent of the clause on Leadership and Commitment is to identify actions in which top management is personally involved with and directs in the organization.</p> <p>Top management may not perform all of these actions themselves (e.g., they may delegate responsibility to others), but they are accountable for making sure they are performed.</p> <p>Standards writers can prescribe additional requirements related to leadership and commitment in their discipline specific MSS.</p> <p>In the 2nd bullet the importance of “integration ... into</p>	<p>Visible support, involvement and commitment of the organization’s top management is important to the successful implementation of the MSS. It sets the tone and expectations, increases acceptance, and motivates personnel to be engaged in the MS initiatives. It can provide reassurance to external parties that an effective management system is likely in place.</p> <p>An example of a “business process” may be an organization’s central human resource function, which may be responsible for ensuring that the competency requirements of an MSS are met.</p>

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<p>NOTE Reference to “business” in this International Standard should be interpreted broadly to mean those activities that are core to the purposes of the organization’s existence.</p> <ul style="list-style-type: none"> — ensuring that the resources needed for the XXX management system are available — communicating the importance of effective XXX management and of conforming to the XXX management system requirements — ensuring that the XXX management system achieves its intended outcome(s) — promoting continual improvement <p>supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.</p>	<p>the organization’s business processes” is emphasized and it is assigned as one of Top management’s roles.</p> <p>In the 7th bullet “to demonstrate their leadership as it applies to their areas of responsibility” refers to the “relevant management roles”, and not to Top management.</p> <p>The 7th bullet is intended to require Top management to create a culture and environment that encourages people with leadership roles (not necessarily formal management positions, e.g. team leaders) to work actively towards implementing the requirements of the management system and seeking to achieve the XXX objectives.</p> <p>Standards writers can prescribe additional requirements for leadership and commitment in their discipline specific MSS.</p>	
<p>5.2 Policy</p> <p>Top management shall establish a XXX policy that</p> <ul style="list-style-type: none"> — is appropriate to the purpose of the organization — provides a framework for setting XXX objectives — includes a commitment to satisfy applicable requirements, and 	<p>The intent of the clause on Policy is to specify the high level organizational commitments required of the MSS, taking into account the organization’s purpose. It is used to frame the objectives which the organization sets for itself.</p> <p>Documentation of the policy is created and controlled in accordance with the requirements of Documented information (7.5).</p> <p>The policy is communicated internally in accordance with the requirements of the Communication clause</p>	<p>While the policy is expected to contain a commitment to satisfy applicable requirements, in particular laws and regulations, it is understood that even the most effective MS will not guarantee full compliance at any particular point in time. Under such circumstances, it should not be considered out of conformance so long as the MS results in the prompt detection and corrective action of the system deficiencies that contributed to the instance(s) of noncompliance.</p>

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<p>— includes a commitment to continual improvement of the XXX management system.</p> <p>The XXX policy shall</p> <p>— be available as documented information</p> <p>— be communicated within the organization</p> <p>— be available to interested parties, as appropriate</p>	<p>(7.4). It also shall be made available to other interested parties.</p> <p>Standards writers can prescribe additional requirements related to policy in their discipline specific MSS.</p>	
<p>5.3 Organization 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 International Standard: and</p> <p>b) reporting on the performance of the XXX management system to top management.</p>	<p>The intent of the clause on Organization roles, responsibilities and authorities is to assign responsibility and authority for the implementation of the MS requirements to relevant roles within the organization.</p> <p>Top management is accountable for these responsibilities and authorities being assigned and communicated to the respective persons performing those roles.</p> <p>The responsibilities and authorities are communicated in accordance with the requirements of the Communication clause (7.4).</p> <p>Demonstration of conformance to the requirements of the MSS is conducted in accordance with the requirements of the Internal audit clause(9.2)</p> <p>Performance reporting is conducted in accordance</p>	<p>The role of 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. Such individuals should have sufficient access to top management in order to keep management informed of the status and performance of the MS.</p>

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	<p>with the requirements of <i>Management review</i> (9.3)</p> <p>Standards writers can prescribe additional requirements related to policy in their discipline specific MSS.</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"> — assure the XXX management system can achieve its intended outcome(s) — prevent, or reduce, undesired effects — achieve continual improvement. <p>The organization shall plan:</p> <p>a) actions to address these risks and opportunities, and</p> <p>b) how to</p> <ul style="list-style-type: none"> — integrate and implement the actions into its XXX management system processes 	<p>The intent of the clause on <i>Actions to address risks and opportunities</i> is to specify the requirements for the planning needed as a prerequisite to establishing the MS. It specifies what needs to be considered and what needs to be addressed. The planning is performed at a strategic level, versus the tactical planning done for <i>Operational planning and control</i> (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 organization’s applicable requirements identified in (4.3) in order to address any negative or positive consequence posed in a prioritized fashion. Prioritization is based on the three bullet items.</p> <p>Annex SL calls for actions to address risks in 6.1, but does not call for risk management, risk assessment or risk treatment. For those MSS that need to address risk 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>The purpose of planning is to anticipate potential scenarios and consequences, and as such is</p>	<p>Reference to ‘Risks and Opportunities’ is intended to broadly describe something that poses a threat having detrimental or negative effect, or alternatively, something that has the potential for a beneficial or positive effect. It is not intended to be the same as the technical, statistical, or scientific interpretation of the term risk.</p> <p>Threat and opportunity determination may be through informal means, or may be through formal qualitative or quantitative methodologies</p>

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<p>evaluate the effectiveness of these actions.</p>	<p>preventive in addressing undesired effects before they occur. Similarly, it looks for favourable conditions or circumstances that can offer a potential advantage or beneficial outcome and includes planning for those worthy of pursuit.</p> <p>Planning also includes determining how to incorporate the actions deemed necessary or beneficial into the MS, either through objective setting (6.2), operational control (8.1) or other specific clauses of the MS, e.g. resource provisions (7.1), competence (7.2).</p> <p>The mechanism for evaluating the effectiveness of the preventive action taken is also planned, and can include monitoring, measurement techniques (9.1), internal audit (9.2) or management review (9.3).</p> <p>Standards writers can prescribe additional requirements related to actions to address risks and opportunities in their discipline specific MSS.</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> <ul style="list-style-type: none"> — be consistent with the XXX policy — be measurable (if practicable) 	<p>The text is self-explanatory; readers should note linkages to Leadership and commitment (5.1) and Policy (5.2).</p> <p>Objectives should be specified in a way that allows determination of their fulfilment to be made. By including the caveat “where practicable”, it is acknowledged that there may be situations when it may not be feasible to measure an objective.</p> <p>The status and progress on objectives are periodically</p>	<p><i>Intentionally left blank</i></p>

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<ul style="list-style-type: none"> — take into account applicable requirements — be monitored — be communicated, and — be updated as appropriate. <p>The organization shall retain documented information on the XXX objectives.</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>checked in accordance with the requirements of Monitoring, measurement, analysis and evaluation (9.1) and updated as appropriate, consistent with the requirements of Continual improvement (10.2).</p> <p>Objectives are communicated in accordance with the requirements of the Communication clause (7.4).</p> <p>Documentation of the objectives is created and controlled in accordance with the requirements of Documented information (7.5).</p> <p>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 roles, responsibilities and authorities (5.3). 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> <p>Standards writers can prescribe additional requirements related to objectives and planning to achieve to them in their discipline specific MSS.</p>	

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<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>The intent of the clause on Resources is to anticipate, determine and allocate the resources needed for creating and implementing the MS (including its operations and controls), as well as those needed for its ongoing maintenance and improvement.</p> <p>Standards writers can prescribe additional requirements related to resources in their discipline specific MSS.</p>	<p>Resources may include</p> <ul style="list-style-type: none"> • human resources • specialized skills or knowledge • organizational infrastructure (i.e., buildings, communication lines, etc) • technology <p>financial resources</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, and — 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, and <p>NOTE Applicable actions may 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> <ul style="list-style-type: none"> — retain appropriate documented information as evidence of competence. 	<p>The text is self-explanatory when read in conjunction with the definition of competence (3.10).</p> <p>Documentation providing objective evidence of competence is created and controlled in accordance with the requirements of Documented information (7.5).</p> <p>Standards writers can prescribe additional requirements related to competence in their discipline specific MSS.</p>	<p><i>Intentionally left blank</i></p>
<p>7.3 Awareness</p>	<p>The intent of the clause is self-explanatory.</p>	<p>Awareness of the policy should not be taken to mean that it needs to be memorized;</p>

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<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 — the implications of not conforming with the XXX management system requirements. 	<p>Standards writers can prescribe additional requirements related to awareness in their discipline specific MSS.</p>	<p>rather, persons should be aware of the key policy commitments, and their role in achieving them.</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. <p>how to communicate</p>	<p>The intent of the clause is self-explanatory.</p> <p>Annex SL requires communication on the following:</p> <ul style="list-style-type: none"> -importance of effective XXX management and of conforming to the MS requirements -policy -responsibilities and authorities -performance of the MS -objectives <p>[-contribution to the effectiveness of the MS, including the benefits of improved performance</p> <ul style="list-style-type: none"> -implications of not conforming with the MS requirements] -results of audits <p>Standards writers can include specific requirements for communication, including information that is necessary to communicate, either in this clause, or in the other clauses.</p>	<p>Communications should adhere to the principles of transparency, appropriateness, credibility, responsiveness and clarity.</p> <p>Communication can be verbal or written, one-way or two-way, internal or external.</p>

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<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"> — documented information required by this International Standard — 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, and — the competence of persons. 	<p>The intent of the clause General, Documented Information is to provide a description of the types of information that must be created, controlled, and maintained in a management system. This includes that which is</p> <ul style="list-style-type: none"> - required for all MSS (as presented in clause 7.5.1 and in the respective clauses of Annex SL), - required by a particular MSS, and - any additional information the organization determines necessary to be documented. <p>The phrase “documented information as evidence of ...” implies the former term “record”.</p> <p>It is the responsibility of the organization to determine what documented information it needs beyond that which is required by the MSS. The factors it should take into account are listed in the note.</p> <p>The term “documented information” refers to information that a MSS determines is necessary to control and maintain in any format or media (see 7.5.3)</p> <p>Documented information is created and controlled in accordance with the requirements of 7.5.2 and 7.5.3.</p> <p>Standard writers may include specific examples of appropriate documented information.</p>	<p>The minimum documented information required to be created, controlled and/or maintained in a MSS includes:</p> <ul style="list-style-type: none"> - Scope of the management system - Policy - Objectives - Evidence of competence - Documented information of external origin necessary for the planning and operation of the management system - Documented information necessary to have confidence that the processes have been carried out as planned - Monitoring, measurement, analysis and evaluation results - Evidence of internal audit programme implementation - Internal audit results - Management review results - Nature of nonconformities and actions taken - Corrective action results <p>Documented information, originally created for purposes other than the MSS, may be used.</p>

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<p>7.5.2 Creating and updating</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>The intent of the clause <i>Creating and Updating Documented Information</i> is to specify the requirements for uniquely identifying the information, defining the format and media it will be maintained in, and for its approval.</p> <p>Standards writers can prescribe additional requirements related to creating and updating documented information in their discipline specific MSS.</p>	<p>The identification, format and media used for documented information are the choice of the organization implementing the MSS; it need not be in the form of a textual format or a paper manual.</p>
<p>7.5.3 Control of documented information</p> <p>Documented information required by the XXX management system and by this International Standard shall be controlled to ensure</p> <ul style="list-style-type: none"> — it is available and suitable for use, where and when it is needed — it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). — distribution, access, retrieval and use, <p>NOTE Access implies a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information, etc.</p> <ul style="list-style-type: none"> — storage and preservation, including 	<p>The intent of the clause on <i>Control of documented information</i> is to specify the internal controls that need to be considered and implemented for information that is required to be documented. Not all internal controls are applicable to all types of documented information.</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>Standards writers can prescribe additional requirements related to control of documented information in their discipline specific MSS.</p>	<p>The information required to be documented by the MSS may be integrated with other information management or documentation systems established by an organization.</p>

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<p>preservation of legibility</p> <ul style="list-style-type: none"> — control of changes (e.g. version control) — retention and disposition <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>8. Operation</p> <p>8.1 Operational planning and control</p> <p>The organization shall plan, implement and control the processes needed to meet requirements, and to implement the actions determined in 6.1, by</p> <ul style="list-style-type: none"> — establishing criteria for the processes — implementing control of the processes in accordance with the criteria — keeping documented information to the extent necessary to have confidence that the processes have been carried out as planned. <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 intent of the clause on <i>Operational planning and control</i> is to specify the requirements that need to be implemented within the organization’s operations to make sure the MSS requirements are fulfilled, and the priority risks and opportunities are being addressed.</p> <p>Operational control includes the methods implemented to make sure business operations, activities or equipment do not exceed specified conditions or performance standards or violate regulatory compliance limits, and thereby effectively achieve the intended outcome of the MS. These controls establish technical requirements necessary to achieve the desired optimal functionality for business processes, such as technical specifications or operating parameters or a prescribed methodology.</p> <p>Operational control is required for situations related to business processes where absence of controls could lead to deviations from the policy and objectives or poses unacceptable risk. These situations can be related to business operations,</p>	<p>Operational planning can be more detailed than the planning done in 6.1 and at the tactical level focused on the business operations in support of those actions determined in <i>Actions to address risks and opportunities</i> (6.1).</p>

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<p>The organization shall ensure that outsourced processes are controlled.</p>	<p>activities or processes; production, installation or servicing; maintenance; or contractors, suppliers or vendors. The degree of control exercised will vary depending on many factors, including the functions performed; their importance or complexity; the potential consequences of deviation or variability; or, the technical competency involved versus what is available.</p> <p>Documentation needed to have confidence that the operational control processes have been carried out as planned is created and controlled in accordance with the requirements of Documented information (7.5).</p> <p>Requirements for management of change, both planned and unintended changes, are required to prevent or otherwise minimize the chance technical requirements are not fulfilled, or new risks are introduced.</p> <p>When operational controls fail, action is necessary to address any resultant undesired effect(s).</p> <p>Control of outsourced processes is not unlike the control of operations; however the degree of control can be limited to partial control or influence. It is not intended to change any legal relationship with the external entity performing the outsourced process.</p> <p>Standards writers can prescribe additional requirements related to operational planning and</p>	

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<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 results from monitoring and measurement shall be analysed and evaluated. <p>The organization shall retain appropriate documented information as evidence of the results.</p> <p>The organization shall evaluate the XXX performance and the effectiveness of the XXX management system.</p>	<p>control in their discipline specific MSS.</p> <p>The intent of the clause on Monitoring, measurement, analysis and evaluation is to specify the requirements for implementing checks to be sure the intended results of the MS are achieved as planned.</p> <p>Checking can be qualitative (monitoring) or quantitative (measurement).</p> <p>The characteristics that are monitored or measured, analyzed and evaluated 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 or measurement, analysis and evaluation is presented to top management in accordance with the requirements of Management Review (9.3).</p> <p>Documentation of the monitoring, measurement, analysis and evaluation results is created and controlled in accordance with the requirements of Documented information (7.5).</p> <p>Standards writers can prescribe additional requirements related to monitoring, measurement, analysis and evaluation in their discipline specific MSS.</p>	<p><i>Intentionally left blank</i></p>
<p>9.2 Internal audit</p>	<p>The intent of the clause on Internal audit is to specify the requirements for planning, implementing and</p>	<p>The management and conduct of internal audits should abide by the principles of</p>

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<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 International Standard; <p>b) is effectively implemented and maintained.</p> <p>The organization shall:</p> <p>a) plan, establish, implement and maintain an audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting. The audit programme(s) shall take into consideration the importance of the processes concerned and the results of previous audits;</p> <p>b) define the audit criteria and scope for each audit;</p> <p>c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;</p> <p>d) ensure that the results of audits are reported to relevant management, and</p> <p>e) retain documented information as evidence of the implementation of the audit programme and the audit results.</p>	<p>maintaining an internal audit programme for purposes of checking that the organization’s MS conforms to both the MSS requirements and any additional MS related requirements the organization self imposes, and that the MS is being effectively implemented and maintained as planned.</p> <p>An internal audit programme requires that</p> <ul style="list-style-type: none"> -internal audits be planned and scheduled based on the importance of the processes audited and the results of previous audits -a methodology for planning and conducting internal audits be established -roles and responsibilities within the audit programme be assigned taking into account the integrity and independence of the internal audit process -the audit criteria (i.e., policies, procedures or requirements used as a reference against which relevant and verifiable records, statements of fact or other information will be compared) and audit scope (i.e., description of the physical locations, organizational units, activities and processes, as well as the time period covered) for each audit planned. <p>The internal audit programme is planned and implemented and maintained by internal personnel, or can be managed by external persons acting on the organization’s behalf. In either case the selection of internal audit programme personnel needs to meet Competence (7.2) requirements.</p>	<p>integrity, fair presentation, due professional care, confidentiality, independence and an evidence-based approach.</p> <p>Guidance on establishing an internal audit programme, performing management system audits and evaluating the competence of audit personnel is given in ISO 19011.</p>

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	<p>The results of internal audits are reported to the management responsible for the functions/unit audited, and any other individuals deemed appropriate in accordance with the requirements of the Communication clause (7.4).</p> <p>Documentation providing evidence of internal audit programme implementation and audit results is created and controlled in accordance with the requirements of Documented information (7.5).</p> <p>Information, including trends, on internal audit results is reviewed in accordance with the requirements of Management review (9.3).</p> <p>Standards writers can prescribe additional requirements related to internal audit in their discipline specific MSS.</p>	
<p>9.3 Management review</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>The management review shall include consideration of:</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) information on the XXX performance, 	<p>The intent of the clause on Management review is 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 outputs.</p> <p>Top management is required to be personally engaged in this review. It is their 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</p>	<p><i>Intentionally left blank</i></p>

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<p>including trends in:</p> <ul style="list-style-type: none"> — nonconformities and corrective actions — monitoring and measurement results, and — audit results; <p>d) opportunities for continual improvement.</p> <p>The outputs of the management review shall include decisions related to continual improvement opportunities and any need for changes to the XXX management system.</p> <p>The organization shall retain documented information as evidence of the results of management reviews.</p>	<p>outcome.</p> <p>Documentation of the management review results is created and controlled in accordance with the requirements of Documented information (7.5).</p> <p>Standards writers can prescribe additional requirements related to management review in their discipline specific MSS.</p>	

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<p>10. Improvement</p> <p>10.1 Nonconformity and corrective action</p> <p>When a nonconformity occurs, the organization shall:</p> <p>a) react to the nonconformity, and as applicable</p> <ul style="list-style-type: none"> — take action to control and correct it, and — deal with the consequences; <p>b) evaluate the need for action to eliminate the causes of the nonconformity, in order that it does not recur or occur elsewhere, by</p> <ul style="list-style-type: none"> — reviewing the nonconformity — determining the causes of the nonconformity, and — determining if similar nonconformities exist, or could potentially occur; <p>c) implement any action needed;</p> <p>d) review the effectiveness of any corrective action taken; and</p> <p>e) make changes to the XXX management system, if necessary.</p> <p>Corrective actions shall be appropriate to the effects of the nonconformities encountered.</p>	<p>The intent of the clause on Nonconformity and corrective action is to specify the requirements for responding when the MSS and MS (including operational) requirements are not satisfied. It includes taking action to correct the situation, examine the cause and determine if other occurrences exist or potentially exist elsewhere so that action can be taken to prevent reoccurrence. Further, it requires evaluation of the action taken to confirm that the intended result was achieved, and evaluation of the MS to determine if changes are warranted to avoid future occurrences of similar nonconformities.</p> <p>Documentation of the nonconformity, corrective action and the results is created and controlled in accordance with the requirements of Documented information (7.5).</p> <p>Standards writers can prescribe additional requirements related to nonconformity and corrective action in their discipline specific MSS.</p>	<p>Intentionally left blank</p>

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<p>The organization shall retain documented information as evidence of:</p> <ul style="list-style-type: none"> — the nature of the nonconformities and any subsequent actions taken, and — the results of any corrective action 		
<p>10.2 Continual improvement</p> <p>The organization shall continually improve the suitability, adequacy and effectiveness of the XXX management system.</p>	<p>The intent of the clause on Continual improvement is to specify the requirements to improve the Management System (MS). Improvement is focused in three main areas:</p> <p><u>Suitability</u> – the extent to which the MS ‘fits’ and is right for the organization’s purpose, its operations, culture, and business systems</p> <p><u>Adequacy</u> – the extent to which the MS is sufficient in meeting the applicable requirements; and</p> <p><u>Effectiveness</u> – the extent to which planned activities are realized and planned results achieved.</p> <p>Continual improvement involves making changes to the design and implementation of the MS in order to improve the organization’s ability to achieve conformity with the requirements of the MSS and meet its objectives and policy commitments. Although there may be value in improving the system elements alone, the intended outcome of planned actions and other MS changes is an improvement in the organization’s performance.</p> <p>Several clauses of a MSS can assist in achieving continual improvement. A coordinated</p>	<p>Continual implies occurrence over a period of time, but with intervals of interruption (unlike ‘continuous’ which indicates occurrence without interruption). In the context of continual improvement, the expectation is that improvements occur periodically, over time. The rate, extent and timescale of actions that support continual improvement are determined by the organization, in light of its context, economic factors, and other circumstances.</p>

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	<p>implementation of these clauses may help to develop a robust way to achieve this improvement, including, but not limited to:</p> <ul style="list-style-type: none"> - taking actions to address risks and opportunities (6.1); - establishing objectives (6.2); - upgrading operational controls (8.1), taking into consideration new technologies, methods or information; - analyzing and evaluating performance (9.1); - conducting internal audits (9.2); - conducting management reviews (9.3); and - detecting nonconformity(ies) and implementing corrective action(s) (10.1). <p>The organization periodically evaluates and reviews its MS in accordance with the requirements of Monitoring, measurement, analysis and evaluation (9.1) and Internal Audit (9.2) and Management Review (9.3) to identify opportunities for improvement, and plans appropriate actions to be taken in accordance with Actions to address risks and opportunities (6.1), Objectives and planning to achieve them (6.2), and Operational planning and controls (8.1).</p> <p>Standards writers can prescribe additional requirements related to continual improvement in their discipline specific MSS.</p>	