



**ISO/IEC
Directives, Part 1
Consolidated ISO Supplement —
Procedures for the technical work —
Procedures specific to ISO**

Directives ISO/IEC, Partie 1

*Procédures pour les travaux techniques — Supplément ISO consolidé
— Procédures spécifiques à l'ISO*

Twelfth edition, 2021

[Based on the seventeenth edition (2021) of the ISO/IEC Directives, Part 1]



COPYRIGHT PROTECTED DOCUMENT

© ISO/IEC 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

International Organization for Standardization

CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

International Electrotechnical Commission

CP 131 • 3, rue de Varembe
CH-1211 Geneva 20
Phone: + 41 22 919 02 11
Fax: + 41 22 919 03 00
Email: inmail@iec.org
Website: www.iec.org

Published in Switzerland

Annex SL
(normative)

Harmonized approach for management system standards

SL.1 General

The harmonized approach for developing management system standards (MSS) includes this annex, a justification study (see Appendix 1), the harmonized structure (identical clause numbers with the same sequence, clause titles, text, common terms and core definitions) with guidance for use (see Appendix 2) and terminology guidance (see Appendix 3).

A new management system standard (MSS) or revision of an existing MSS by a TC/SC/PC shall be developed in accordance with this annex (see SL.8.2).

NOTE 1 TC/SC/PC is hereafter referred to as “committee” in this annex.

NOTE 2 The committees responsible for MSS are members of the Joint Technical Coordination Group on MSS (JTCG).

SL.2 Terms and definitions

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

SL.2.1

management system

set of interrelated or interacting elements of an organization to establish policies and objectives, as well as processes to achieve those objectives

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

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

Note 3 to entry: This definition corresponds to definition 3.4 in Appendix 2.

SL.2.2

management system standard

MSS

standard for a *management system* (SL.2.1)

Note 1 to entry: For the purposes of this annex, this definition also applies to other ISO deliverables (e.g. TS, PAS, IWA).

SL.2.3

generic MSS

MSS (SL.2.2) designed to be widely applicable across economic sectors, various types and sizes of organizations and diverse languages, geographical, cultural and social conditions

SL.2.4

sector-specific MSS

MSS (SL.2.2) that provides additional requirements or guidance for the application of a *generic MSS* (SL.2.3) to a specific economic or business sector

SL.2.5

Type A MSS

MSS (SL.2.2) providing requirements

EXAMPLE Management system requirements standards (specifications); management system sector-specific requirements standards.

SL.2.6

Type B MSS

MSS (SL.2.2) providing guidelines

Note to entry 1: There are different categories of Type B MSS, including on:

- the use, application or implementation of a *Type A MSS* (SL.2.5);
- the establishment, improvement or enhancement of a management system;
- a specific topic, requirement or set of requirements related to a Type A MSS;
- other guidance not directly related to a Type A MSS.

SL.2.7

harmonized approach for MSS

methodology applied to development of MSS (SL.2.2) including justification study, identical clause numbers, clause titles, text and common terms and core definitions

Note 1 to entry: See Appendix 2 and Appendix 3.

SL.3 Requirements to submit a Justification Study

A justification study (JS) shall be carried out in accordance with Appendix 1 and is needed for:

- new MSS including Type A , Type B or sector-specific MSS;
- revisions of MSS that do not have an approved JS.

All MSS proposals [including sector-specific MSS (SL.2.4), see Annex SP] and their JS shall be identified by the relevant committee leadership and the JS shall be sent to the TMB (or its MSS task force) for evaluation and approval before the NP ballot takes place. It is the responsibility of the relevant committee secretariat to identify all MSS proposals.

No JS is required for:

- a Type B MSS providing guidance on a specific Type A MSS for which a JS has already been submitted and approved;
- a revision of an MSS with an approved JS and scope that has been confirmed.

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

SL.4 Cases where no JS have been submitted

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

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

SL.5 Applicability of this annex

The procedures in this annex apply to all ISO deliverables, including TS, PAS and IWA.

SL.6 General criteria

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

- 1) **Market relevance** — MSS meets the needs of, and add value for, the primary users and other affected parties.
- 2) **Compatibility** — There is compatibility between various MSS and within an MSS family.
- 3) **Topic coverage** — A generic MSS (SL.2.3) should have sufficient application coverage to eliminate or minimize the need for sector-specific variances.
- 4) **Flexibility** — An MSS should be applicable to organizations in all relevant sectors and cultures and of every size. An MSS should not prevent organizations from competitively adding to or enhancing their management systems beyond the standard or differentiating themselves from others.
- 5) **Free trade** — An MSS should permit the free trade of goods and services in line with the principles included in the WTO Agreement on Technical Barriers to Trade.
- 6) **Applicability of conformity assessment** — The market need for first-, second- or third-party conformity assessment, or any combination thereof, should be assessed. The resulting MSS should clearly address the suitability of use for conformity assessment in its scope. An MSS should facilitate combined audits against multiple MSS.
- 7) **Exclusions** — An MSS shall not include directly related product or service specifications, test methods, performance levels (i.e. setting of limits) or other forms of standardization for products or services provided by the implementing organization.
- 8) **Ease of use** — It should be ensured that the user can easily implement one or more MSS. An MSS should be easily understood, unambiguous, free from cultural bias, easily translatable, and applicable to businesses in general.

SL.7 Justification study process and criteria

SL.7.1 General

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

SL.7.2 Justification study process

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

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

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

SL.7.3 Justification study criteria

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

SL.8 Identical clause titles, identical core text and common terms and core definitions for use in management systems standards (the “harmonized structure”)

SL.8.1 Introduction

The aim of this document is to enhance the consistency and alignment of MSS by providing a unifying and agreed upon harmonized approach. The aim is that all Type A MSS (and Type B MSS where appropriate) are aligned and the compatibility of these standards is enhanced. It is envisaged that individual MSS will add additional “discipline-specific” requirements as required.

NOTE In SL.8.3 and SL.8.4, “discipline-specific” is used to indicate specific subject(s) to which a management system standard refers, e.g. energy, quality, records, environment etc.

The intended audience for this document is committees and others that are involved in the development of MSS.

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

Appendix 2 sets out the harmonized structure that form the nucleus of future and revised Type A MSS, and Type B MSS when possible, together with guidance on its use for MSS Writers and ISO Editors.

SL.8.2 Application of the harmonized structure by different types of MSS

Type A MSS shall apply the harmonized structure detailed in Appendix 2.

Type B MSS providing guidance on the use, application or implementation of a Type A MSS shall follow the same clause sequence down to the two-digit clause level (e.g. 10.2) of that Type A MSS.

For other Type B MSS, the committee may choose to use the harmonized structure clause sequence or take a different approach.

SL.8.3 Using Appendix 2 to this annex

Discipline-specific text additions to requirements in Appendix 2 shall be managed as follows.

1. Discipline-specific additions shall be made by the individual committee or other group that is developing the specific MSS.
2. Discipline-specific text shall not affect harmonization or contradict or undermine the intent of the harmonized structure.
3. Additional subclauses, or sub-subclauses (etc.) may be inserted either ahead of an identical text subclause (or sub-subclause etc.), or after such a subclause (etc.), renumbered accordingly and with the necessary adjustments to cross referencing.

NOTE 1 Hanging paragraphs are not permitted (see ISO/IEC Directives, Part 2).

4. Clause 3 of the MSS shall include the terms and definitions from Clause 3 of Appendix 2. If a modification or deletion of a definition or note to entry is made by a committee, a justification for deviation is required. Addition of notes to entry are not considered deviations. These terms and definitions may be repeated in a vocabulary standard. Insertions of discipline specific terms and definitions and renumbering accordingly is permitted.

NOTE 2 Appendix 2 presents the definitions in systematic order, which is preferred due to translation (see Appendix 3 on terminology).

5. A committee may add or insert discipline-specific text within Appendix 2. Examples of additions include:
 - a) new bullet points;
 - b) discipline-specific explanatory text (e.g. Notes or Examples), in order to clarify requirements;
 - c) discipline-specific new paragraphs to subclauses (etc.) within the identical text;
 - d) additional text that enhances the existing requirements in Appendix 2.
6. A committee shall avoid repeating requirements between identical core text and discipline-specific text by adding text to the identical core text, taking account of point 2 above.
7. In order to distinguish between discipline-specific text and identical core text from Appendix 2, a committee shall, from the start of the drafting process, use blue for text from the harmonized structure and black for the committee discipline-specific text. This aids identification of the different types of text during the development and balloting stages.

NOTE 3 Identification of distinguishing text is not necessarily carried into the published version.

8. Understanding of the concept of “risk” may be more specific than that given in definition 3.7 of Appendix 2. In this case, a discipline-specific definition may be needed. The discipline-specific terms and definitions are differentiated from the core definitions, e.g. (XXX) risk.

NOTE 4 The above can also apply to a number of other definitions.

9. If due to exceptional discipline specific circumstances, text from the harmonized structure cannot be applied in the management system standard, then the committee may amend the text and introduce a deviation.
10. If there are non-discipline specific circumstances, the committee shall raise the issue within JTCG.

SL.8.4 Deviation reports

When a committee has a deviation, it shall justify the deviation based on discipline specific information by:

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

The Committee shall use the ISO commenting template to provide its deviation reports. The deviation report shall contain the changes to the Appendix 2 text or notes to entry and any deletions. The report should also contain additions to facilitate trend analysis for future revisions.

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

NOTE 2 The Committee strives to avoid any non-applicability of the harmonized structure.

The Committee receives comments from ISO/CS regarding the deviations. The committee resolves the comments in dialogue with the editorial staff. The deviation reports are retained by JTCC. JTCC reviews the deviation reports for trends and other information for future revisions of Annex SL.

Appendix 1

(normative)

Justification criteria questions

1 General

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

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

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

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

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

Basic information on the MSS proposal

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

Principle 1: Market relevance

7	<p>Have all the affected parties been identified? For example:</p> <ul style="list-style-type: none"> a) organizations (of various types and sizes): the decision-makers within an organization who approve work to implement and achieve conformance to the MSS; b) customers/end-users, i.e. individuals or parties that pay for or use a product (including service) from an organization; c) supplier organizations, e.g. producer, distributor, retailer or vendor of a product, or a provider of a service or information; d) MSS service provider, e.g. MSS certification bodies, accreditation bodies or consultants; e) regulatory bodies; f) non-governmental organizations.
8	<p>What is the need for this MSS? Does the need exist at a local, national, regional or global level? Does the need apply to developing countries? Does it apply to developed countries? What is the added value of having an ISO document (e.g. facilitating communication between organizations in different countries)?</p>
9	<p>Does the need exist for a number of sectors and is thus generic? If so, which ones? Does the need exist for small, medium or large organizations?</p>
10	<p>Is the need important? Will the need continue? If yes, will the target date of completion for the proposed MSS satisfy this need? Are viable alternatives identified?</p>
11	<p>Describe how the need and importance were determined. List the affected parties consulted and the major geographical or economical regions in which they are located.</p>
12	<p>Is there known or expected support for the proposed MSS? List those bodies that have indicated support. Is there known or expected opposition to the proposed MSS? List those bodies that have indicated opposition.</p>
13	<p>What are the expected benefits and costs to organizations, differentiated for small, medium and large organizations if applicable?</p> <p>Describe how the benefits and the costs were determined. Provide available information on geographic or economic focus, industry sector and size of the organization. Provide information on the sources consulted and their basis (e.g. proven practices), premises, assumptions and conditions (e.g. speculative or theoretical), and other pertinent information.</p>
14	<p>What are the expected benefits and costs to other affected parties (including developing countries)?</p> <p>Describe how the benefits and the costs were determined. Provide any information regarding the affected parties indicated.</p>
15	<p>What will be the expected value to society?</p>
16	<p>Have any other risks been identified (e.g. timeliness or unintended consequences to a specific business)?</p>

Principle 2: Compatibility

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

Principle 3: Topic coverage

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

Principle 4: Flexibility

23	Will the MSS allow an organization competitively to add to, differentiate or encourage innovation of its management system beyond the standard?
----	---

Principle 5: Free trade

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

Principle 6: Applicability of conformity

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

Principle 7: Exclusions

30	Does the proposed scope of the MSS include product or service specifications, test methods, (product or service) performance levels, or other forms of guidance or requirements directly related to products or services produced or provided by the implementing organization?
----	---

Appendix 2

(normative)

Harmonized structure for MSS with guidance for use

The harmonized structure for MSS (identical clause numbers, clause titles, text and common terms and core definitions), together with guidance on its use for writers and editors of MSS, is provided at the following URL:

(<https://isotc.iso.org/livelink/livelink?func=ll&objId=16347818&objAction=browse&viewType=1>)

Appendix 3

(informative)

Terminology guidance in support of Annex SL

Guidance that is intended to help writers and editors of MSS to understand the approach to terminology in Appendix 2 is provided at the following URL:

(<https://isotc.iso.org/livelink/livelink?func=ll&objId=16347818&objAction=browse&viewType=1>).