



GUIDE 72

Guidelines for the justification and development of management system standards

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO Guide 72:2001

<https://standards.iteh.ai/catalog/standards/sist/cecdd9c9-3f1c-4ba3-b9a9-bafd2be2a5e9/iso-guide-72-2001>

First edition 2001

© ISO 2001

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO Guide 72:2001

<https://standards.iteh.ai/catalog/standards/sist/cecdd9c9-3f1c-4ba3-b9a9-bafd2be2a5e9/iso-guide-72-2001>

© ISO 2001

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Normative references	2
3 Terms and definitions	2
4 Abbreviated terms	4
5 General principles	4
6 Justification study process and criteria	5
6.1 General	5
6.2 Justification study process	5
6.3 Justification study criteria	6
7 Guidance on the development process and structure of an MSS	6
7.1 General	6
7.2 MSS development process	7
7.3 Management system standard model, structure and common elements	11
Annex A (informative) Justification criteria questions	13
Annex B (informative) Common elements of ISO MSSs	16
Bibliography	18

ISO Guide 72:2001

<https://standards.iteh.ai/catalog/standards/sist/cecdd9c9-3f1c-4ba3-b9a9-bafd2be2a5e9/iso-guide-72-2001>

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Guides are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft Guides adopted by the responsible Committee or Group are circulated to the member bodies for voting. Publication as a Guide requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this Guide may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO Guide 72 was prepared by the ad hoc group on Management System Standards of the ISO Technical Management Board.

Annexes A and B of this Guide are for information only.

ITIH STANDARD PREVIEW
(standards.iteh.ai)

ISO Guide 72:2001

<https://standards.iteh.ai/catalog/standards/sist/cecdd9c9-3f1c-4ba3-b9a9-bafd2be2a5e9/iso-guide-72-2001>

Introduction

ISO management system standards are increasingly being used worldwide by organizations of all types and sizes.

For them to remain useful, authoritative and respected, it is of key importance that they reflect demonstrated market needs and that they are mutually compatible to facilitate their joint implementation.

The ISO Technical Management Board has recognized the need to ensure market relevance of and compatibility between management systems standards and has acknowledged that this could be facilitated by a common methodology for drafting such standards and by covering issues such as the economic cost and benefits of such standards. As a result, this Guide on the justification and development of management systems standards has been developed as additional guidance to the ISO/IEC Directives.

The objective of this Guide is to assist those involved in the writing of management system standards, whether new or revised, to ensure that these standards meet the above-mentioned key criteria of market relevance and compatibility.

Use of these guidelines should result in the development of management system standards that meet demonstrated market needs, and should avoid the development of management system standards that cause unnecessary burden and complexity in the market.

Use of these guidelines should also help ensure compatibility and enhance alignment between management system standards with a view to facilitating the combined application of the standards by organizations that wish to do so.

The ISO technical committees responsible for generic management system standards are responsible for maintaining the integrity of their standards. These technical committees can establish a sector policy and provide further guidance and procedures for the development of sector-specific standards related to their scope. Such guidance is additional to that provided in this Guide (as has already been done by ISO/TC 176).

iTeh STANDARD PREVIEW **(standards.iteh.ai)**

ISO Guide 72:2001

<https://standards.iteh.ai/catalog/standards/sist/cecdd9c9-3f1c-4ba3-b9a9-bafd2be2a5e9/iso-guide-72-2001>

Guidelines for the justification and development of management system standards

1 Scope

This Guide provides

- guidance for justifying and evaluating a proposed management system standard project with a view to assessing market relevance,
- guidance on the methodology (process) of developing and maintaining (i.e. reviewing and revising) management system standards with a view to ensuring compatibility and enhancing alignment, and
- guidance on the terminology, structure and common elements of management system standards with a view to ensuring compatibility as well as enhancing alignment and ease of use.

This guidance is in addition to the procedures for technical work and the methodology for the development of International Standards established by the ISO/IEC Directives.

This Guide makes a distinction between three different types of management system standard (MSS), as follows.

- Type A: management system requirements standards, both generic and sector-specific.
- Type B: management system guidelines standards, both generic and sector-specific.
- Type C: management system related standards.

Whilst this Guide is aimed primarily at Type A MSSs, it is equally applicable to Type B.

This Guide is also applicable to Type C with the exception of 7.3 relating to the MSS structure and common elements.

This Guide is intended to be used by all ISO bodies involved in the development of management system requirements and guidelines standards, and management system related standards. It can also be used by non-ISO standards development organizations at the international, regional or national level that are considering or are in the process of developing management system standards and/or comparable documents.

It should be emphasized that this Guide does not serve as an integrated management system standard. It is intended to be used by standards writers. It is not intended to be used by organizations implementing management system standards, nor used for certification purposes.

NOTE 1 Whenever in this Guide the term "standard" is used, the whole range of ISO deliverables is meant [i.e. International Standards, ISO/IEC) Guides, Technical Specifications, Technical Reports, Publicly Available Specifications and International Workshop Agreements] unless a specific type of document is referred to.

NOTE 2 Throughout this Guide the abbreviation MSS is used to cover a Type A, B and C standard.

NOTE 3 Whenever in this Guide the term technical committee (TC) is used, all ISO bodies developing MSSs are included.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this Guide. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this Guide are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO/IEC Directives, Part 1, 2001, *Procedures for the technical work*

ISO/IEC Directives, Part 2, 2001, *Rules for the structure and drafting of International Standards*

ISO/IEC Guide 2:1996, *Standardization and related activities — General vocabulary*

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

ISO 14050:1998, *Environmental management — Vocabulary*

3 Terms and definitions

For the purposes of this Guide, the terms and definitions given in ISO/IEC Guide 2, ISO 9000, ISO 14050 and the following apply.

3.1

management system

system to establish policy and objectives and to achieve those objectives

[ISO 9000:2000, definition 3.2.2]

iTeh STANDARD PREVIEW
(standards.iteh.ai)
<https://standards.iteh.ai/catalog/standards/sist/cecdd9c9-3f1c-4ba3-b9a9-b6f2b725fe99/iso-guide-72-2001>

NOTE 1 Management systems are used by organizations to develop their policies and to put these into effect via objectives and targets, using

- an organizational structure where the roles, responsibilities, authorities, etc. of people are defined,
- systematic processes and associated resources to achieve the objectives and targets,
- measurement and evaluation methodology to assess performance against the objectives and targets, with feedback of results used to plan improvements to the system, and
- a review process to ensure problems are corrected and opportunities for improvement are recognized and implemented when justified.

NOTE 2 Every organization possesses (whether consciously or not, and whether documented or not) an overall management system through which the organization's objectives are set, executed and controlled.

3.2 Management system standards

3.2.1

Type A: management system requirements standard

standard that is intended to provide the market place with relevant specifications for the management system of an organization to demonstrate its capability to meet internal and external requirements (e.g. by assessment of that capability by internal or external parties)

EXAMPLES

- Management system requirements standards (specifications).
- Management system sector-specific requirements standards.

3.2.2**Type B: management system guidelines standard**

standard that is intended to assist an organization to implement and/or to enhance its management system by providing additional guidance to the elements of a management system requirements standard, or stand-alone guidance with no equivalence to a management system requirements standard

EXAMPLES

- Guidance on the use of management system requirements standards.
- Guidance on the establishment of a management system.
- Guidance on the improvement/enhancement of a management system.
- Management system sector-specific guidelines standards.

3.2.3**Type C: management system related standard**

standard that is intended to provide further information on specific parts of the management system or guidance on related supporting techniques, in addition to management system standards

EXAMPLES

- Management system terminology documents.
- Standards on auditing, documentation, training, monitoring, measurement and performance evaluation.
- Standards on labelling and life-cycle assessment.

3.3**management system standard family
MSS family**

set of management system requirements and guidelines standards (3.2.1 and 3.2.2) and related standards (3.2.3) developed by the same technical committee

<https://standards.iteh.ai/catalog/standards/sist/cecdd9c9-3f1c-4ba3-b9a9-bafd2be2a5e9/iso-guide-72-2001>

3.4**management system standard project
MSS project**

project to develop initially, review, revise or add new parts to management system requirements and guidelines standards (3.2.1 and 3.2.2) and related standards (3.2.3)

3.5**compatibility**

(of standards) suitability of similar standards for use together under specific conditions to fulfil relevant requirements without causing unacceptable interactions

NOTE 1 Based on ISO/IEC Guide 2.

NOTE 2 In the case of an MSS, “compatibility” means that common elements of the standards can be implemented by organizations in a shared manner, in whole or in part, without unnecessary duplication or the imposition of conflicting requirements. “Compatibility” does not mean that the text of the common elements of the standards needs to be identical, although it should be whenever this is possible in practice. See ISO/TAG 12, Report to the ISO/TMB on ISO 9000 and ISO 14000 compatibility.

3.6**justification study process****JS process**

process for justifying and evaluating the market relevance of MSS projects (3.4)

NOTE The initial justification study is carried out by the proposer of an MSS project. Following evaluation, and if necessary amendment, it forms the input to the subsequent assessment and recommendation report (see 6.2).

4 Abbreviated terms

For the purposes of this Guide, the following abbreviated terms apply.

CASCO	ISO Committee on Conformity Assessment
CD	committee draft
DIS	draft International Standard
JS	justification study
MSS	management system standard(s) (being Type A, B and C as described in 3.2.1 to 3.2.3)
MSS family	management system standard family (3.3)
MSS project	management system standard project (3.4)
NWI	new work item
PDCA	Plan-Do-Check-Act
SC	subcommittee
TC	technical committee
TMB	ISO Technical Management Board
WD	working draft

STANDARD PREVIEW
(standards.iteh.ai)

[ISO Guide 72:2001](https://standards.iteh.ai/catalog/standards/sist/cecdd9c9-3f1c-4ba3-b9a9-bafd2be2a5e9/iso-guide-72-2001)

5 General principles <https://standards.iteh.ai/catalog/standards/sist/cecdd9c9-3f1c-4ba3-b9a9-bafd2be2a5e9/iso-guide-72-2001>

The following general principles provide guidance to assess the market relevance of proposed new work (clause 6) and to the standard development processes carried out by the assigned body (clause 7) once the new work has been accepted.

The justification criteria questions in annex A are based on these principles which provide the criteria against which the answers to the questions should be assessed.

The processes described in clause 7 are similarly based on these principles which provide the criteria for the verification and validation of the resulting MSS.

An MSS should be initiated, developed and maintained only when all of the following principles are observed.

Market relevance	Any MSS should meet the needs of, and add value for, the primary users and other affected parties.
Compatibility	Compatibility between various MSSs and within an MSS family should be maintained.
Ease of use	It should be ensured that the user can easily implement one or more MSS.
Topic coverage	An MSS should have sufficient application coverage to eliminate or minimize the need for sector-specific variances.
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 differentiating from others, or enhancing their management systems beyond the standard.

Technically sound basis	An MSS should be based on proven management practices or existing scientifically validated and relevant data.
Easily understood	An MSS should be easily understood, unambiguous, free from cultural bias, easily translatable, and applicable to businesses in general.
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.
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 joint audits.
Exclusions	An MSS should not include directly related product (including services) specifications, test methods, performance levels (i.e. setting of limits) or other forms of standardization for products produced by the implementing organization.

6 Justification study process and criteria

6.1 General

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

6.2 Justification study process (standards.iteh.ai)

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

- a) the conduct of the JS by (or on behalf of) the proposer of an MSS project;
- b) an independent evaluation to consider whether the justification study is sufficient or whether further work is needed;
- c) an independent assessment of the JS and preparation of a recommendation report; this will include the following information to accompany the proposal during the subsequent ballot:
 - recommendations with summary of rationale, including preferred scope and type of document;
 - methods of conformity assessment, if any, against the proposed standard that are believed to suit the standard users best;
 - summary of the JS assessment, including considered significant factors for and against;
 - relevant geography, sector and contact information made and gathered during the assessment;
 - identification of the authors of the report.

The JS process is followed by the normal ISO balloting procedure for a new field of activity or new work item approval as appropriate.

The objective of the independent assessment is to provide unbiased and objective information as a basis for the recommendation report. It should provide additional useful objective information in a report form for the ISO Member Bodies to make well-informed decisions in the approval process.