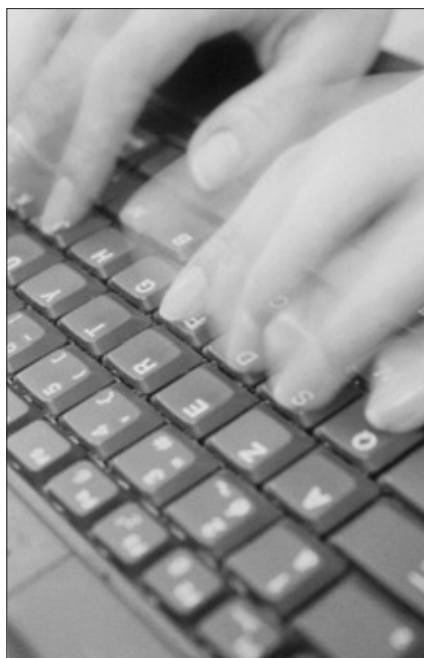


ISO Guide 72 on justification and drafting of management system standards

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ISO management system standards, such as ISO 9001 and ISO 14001, are increasingly being used worldwide by organizations of all types and sizes. For them to remain useful, authoritative and respected, it is important that they reflect demonstrated market needs and that they are mutually compatible to facilitate their joint implementation. Guide 72 is intended to improve the interface between the standards-developing committees and the markets they serve, as well as to make the optimal use of resources by only developing management system standards for which there is a clear market requirement.



Over the last couple of years a number of critical issues related to ISO management system standards have been identified:

- *Mutual compatibility and alignment*

A rapidly growing number of organizations apply ISO management system standards in a combined way. They implement both quality and environmental management systems in a partially or wholly integrated manner. To be able to do so without too many difficulties, mutual compatibility and alignment of management system standards is of extreme importance to the user community.

- *Meeting real market needs*

Given the wide-ranging implications of management system standards for organizations in all economic sectors all over the world, their development should be justified by real and international market needs to ensure that

the costs of implementation are balanced by economic and societal benefits.

- *Transparent and inclusive development process*

Many different stakeholders with a variety of backgrounds have an interest in the development and use of management system standards. This raises specific issues for the standards-development process. It needs to be transparent and inclusive, based on principles of sound project management, as well as cost- and time-effective.

In 1998, the Netherlands Standardization Institute NEN proposed to the ISO Technical Management Board to develop a guide that should provide the common principles and framework for management system standards to assist ISO Technical Committees in developing fully compatible standards. ISO TMB acknowledged that the continuing authority of ISO in the area of management systems is dependent on the presence of mechanisms in the ISO system that not only address compatibility but all the critical issues mentioned above. TMB thus established an ad hoc group charged with the task of developing guidelines for the drafting of management system standards. The secretariat and convenership of this group were entrusted to the Netherlands. It took this ad hoc group about one year to develop a draft Guide that was circulated for ballot in 2000. After review of the ballot results, a revised text was submitted and Guide 72 was published in its final form towards the end of 2001.

Purpose and contents of ISO Guide 72

ISO Guide 72 is intended to be used by standards writers to assist them in the development of management system standards with a view to ensuring that these meet justified market needs and are mutually compatible.

ISO Guide 72 covers the following main subjects:

- general principles of management system standards;
- guidance on justifying and evaluating proposals for management system standards with a view to assessing market relevance;
- guidance on the development process of management system standards with a view to strong management of complex projects;
- guidance on the structure of management system standards with a view to enhancing compatibility and alignment.

General principles of management system standards

Guide 72 describes a number of principles that should be observed when management system standards (MSS) are initiated, developed and maintained:

- **market relevance:** MSS should meet the needs of and add value to potential users;
- **technically sound basis:** MSS should be based on proven practices;
- **compatibility:** MSS should be able to be used together without imposing conflicting requirements;
- **flexibility:** MSS should be applicable to organizations of all types and sizes in a wide variety of situations;
- **topic coverage:** MSS should be sufficiently generic to prevent sector specific variances;

- **exclusions:** MSS should not include product specifications or specific performance levels;
- **ease of use:** MSS should enable easy implementation by their users;
- **easily understood:** MSS should be unambiguous, free from cultural bias and translatable;
- **free trade:** MSS should facilitate free trade in line with the principles of the WTO;
- **conformity assessment:** MSS should clearly address suitability of use for conformity assessment and facilitate joint audits.

These principles should assist ISO in developing MSS that remain useful, authoritative and respected.

Justifying and evaluating proposals for management system standards

Given the wide-ranging potential impact of management system standards, it is considered important that proposals for MSS projects are carefully justified and subsequently evaluated. Guide 72 therefore describes the following process:

- a) The proposer of an MSS project should conduct a so-called justification study;
- b) An independent body should evaluate whether the justification study is sufficient or whether further work is needed;
- c) The independent body should assess the justification study and prepare a recommendation report that should accompany the proposal during the subsequent ballot to assist ISO members to make well-informed decisions.

This process is followed by the normal ISO balloting procedure that is applicable (new work item or new field of activity).

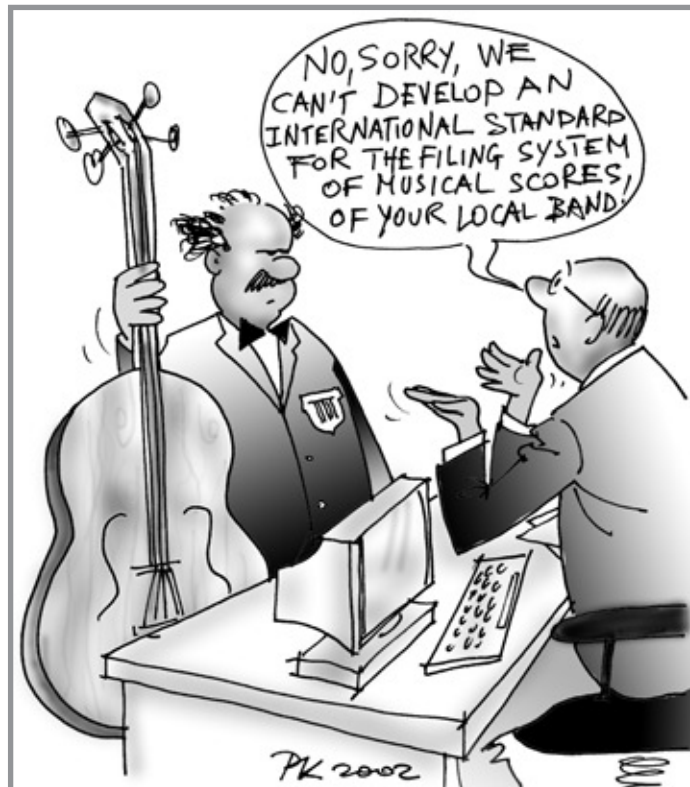
Guide 72 provides a list of questions that should be addressed in a justification study and that provide criteria to assess the results of such studies. The questions build upon the criteria for justification of new work item proposals given in the ISO/IEC Directives, and are subdivided into eight categories:

1. Basic information on the proposal; e.g. purpose and scope of the proposed MSS, the preferred publication format (IS [International Standard], TS [Technical Specification], TR [Technical Report]..), anticipated completion date;

2. Affected parties; which parties will be affected by the proposed MSS, e.g. primary users that should implement and achieve conformance to the standard, their customers and suppliers, regulatory bodies, non-governmental organizations;

3. Need for an MSS; what is the need for the proposed MSS? Is it local, national, regional or global? Does the need differ between developing and developed countries, between small, medium and large organizations? How are the need and its importance determined?

4. Sector-specific MSS proposals; how is the proposed



MSS related to any generic MSS (such as ISO 9000 and ISO 14000)?

5. *Value of an MSS*; what are the expected costs (including methods for demonstration of conformity) and benefits for the primary users, as well as for other affected parties including society at large? How are these costs and benefits determined and how do they differentiate within and between the various stakeholder groups?
6. *Risk of trade barriers*; how will the proposed MSS facilitate or impact global trade? Will it be used in government regulations?
7. *Risk of incompatibility, redundancy and proliferation*; is there potential overlap or conflict with any existing or planned standards (ISO and non-ISO); are there any alternatives for the proposed MSS? Will it staunch or promote proliferation of standards at national or regional level or in industry sectors?
8. *Other risk factors*

It is acknowledged that the significance and relevance of the questions will vary according to the nature of the proposed MSS. It is important that they are all considered; the extent to which they can or should be answered will depend on the specific case.

Standards development process

Guide 72 provides guidance for the management system standards development process to assist ISO committees in managing these often complex projects. It is important that the final standard adequately responds to the market needs as identified in the justification study; a design specification process, therefore, as well as verification and validation processes are important. Given the high interest of many stakeholders in these types of standard, special attention for managing large numbers of participants and communication processes is key to achieving successful results in an efficient manner.

Guide 72 recommends that for each MSS project a design specification is developed and approved before a working

draft is prepared. The design specification should ensure that the results of the justification study are translated correctly into requirements for – and an outline of – the management system standard. The design specification for management system standards should typically address user needs and compatibility issues. The design specification is the basis for verification of the various interim results (such as Working Draft, Committee Draft, Draft International Standard) during the development process. Validation of interim results against the intended use of the standard is also important. Validation techniques can include surveys amongst and pilot projects with organizations that intend to implement the standard.

Guide 72 recommends paying special attention to managing human resources, e.g. with a view to the composition of drafting groups, where a balance between expertise and representation of various stakeholder groups is important, as well as continuation of membership. Guidance is given for communication during the development process, e.g. via regular communiqués and press releases, designating contact points for information and listings of frequently asked questions and answers.

Structure and common elements

It is acknowledged that compatibility and ease of use of management system standards can be enhanced by increasing the commonality between these standards. Important factors in this respect are the overall management system model applied, the structure of the standard and the common system elements and their wording. The authors of Guide 72 did not consider it feasible to recommend one model for all management system standards, because existing models, such as PDCA (Plan, Do, Check, Act) and the process model, will evolve over time and new models may emerge. Guide 72, however, does recommend that any management system standard be based on a recognized model, and that the structure of the standard (i.e. the logical arrangement of the requirements) follows that model. In addition, Guide 72 identifies a number of common manage-

ment system elements and recommends a specific logical order of these elements in any management system standard and the use of the same wording when the same meaning is expressed. This recommendation for alignment, that goes beyond compatibility in its narrow sense, is intended to facilitate ease of use and joint implementation of ISO management system standards.

Target group for Guide 72: primarily ISO itself

The request for Guide 72 and an ISO policy on management system standards came from the user community and especially the primary users (i.e. organizations that implement management system standards to demonstrate sound management of business aspects to internal and external stakeholders). The target group for Guide 72 is primarily ISO itself: the technical committees that develop or consider developing management system standards. The secondary target group is the user community of standards: to show that ISO takes their problems seriously and implements mechanisms to ensure compatibility/alignment, market need and a sound, inclusive and transparent standards development process.

The sound implementation and use of ISO Guide 72 by the ISO standards development committees is key for the future successes and achievements of ISO in this important and visible field of standardization.

Management system standards development is still under way. Recently the development of a food safety management system standard by TC 34 has been started. COPOLCO (ISO Committee for Consumer Policy) is studying the feasibility of a standard for corporate social responsibility that might take shape as a management system standard as well. Given the worldwide application of OHSAS 18001, it seems to be just a matter of time before ISO will develop its own standard for an occupational health and safety management system standard.

These developments show that a clear ISO policy on management system standards is needed, and ISO Guide 72 provides the basis for that. □