





A HARMONISED APPROACH TO MANAGEMENT SYSTEM STANDARDS

The International Standards Organization (ISO) has recently undertaken a limited revision of Annex SL, which forms the basis for nearly all its management system standards. The latest version, published in May 2021 as part of the ISO Supplement to Part 1 of the ISO/IEC Directives, applies to all new ISO Management System Standards as well as the revision of existing ones. Nigel Croft, CQP FCQI, Chair of the ISO Joint Technical Coordination Group (JTCG) for Management System Standards, and Dick Hortensius, Senior Standardization Consultant Management Systems, from the Netherlands Standardization Institute and Secretary of the JTCG, share details of the revisions

The ISO Supplement to the ISO/IEC Directives defines the requirements that have to be followed by ISO Technical Committees for all ISO standards (more than 20,000 of them). “Annex SL” of the Directives is an all-embracing term used to describe the criteria that have to be met in order to ensure a consistent and a harmonised approach to writing the 40-plus MSS that are now within the ISO portfolio.

First published in 2012, and now applied by the vast majority of ISO MSS, Annex SL comprises several components, which in the latest edition are:

- The “body” of Annex SL, which describes among other things the “harmonized approach” to the development of MSS, including the level of autonomy and flexibility that can be exercised by individual ISO Technical Committees when developing their discipline-specific standards.
- Appendix 1, which specifies the justification studies that are required when a proposal is made to develop a new MSS (to avoid overlaps and/or potential conflicts with existing standards).
- Appendix 2 contains the harmonized structure (HS), formerly known as the high-level structure, with the identical core text, common terms and core definitions that MSS writers are required to follow, together with guidance on how to use it (aimed primarily at the standards writers themselves, but which can also be useful to MSS users).

- Appendix 3 contains guidance on the use of terminology.

The ISO’s Joint Technical Coordination Group (JTCG) was established in 2007 and comprises representatives from all of the ISO technical committees with one or more MSS.

Review of Annex SL

All ISO standards are periodically subjected to a systematic review for their relevance and topicality. Although Annex SL is not a “standard” as such, this review was carried out in 2018 by consultation with the various ISO Committees (and their constituent members) with a MSS in their portfolio, and National Standards Bodies (including feedback from users of the standards). That assessment showed that the overall acceptance of Annex SL among standards developers and users had been good, and that there was no need for a major overhaul. However, there were enough points for improvement that justified an update. As a result, a new task force of the JTCG (TF14) was set up at the end of 2018 to prepare a limited review of the high-level structure, as part of a wider revision of Annex SL.

The revision process

Almost 100 representatives of ISO’s Technical Committees and National Member Bodies participated in the revision process, under the leadership of Dr Nigel Croft (Brazilian National Standards Organization) and Dick Hortensius (the Netherlands Standardization Institute). TF14 tried to avoid making changes for change’s sake, and applied a benefit/impact rationale to every individual change. The changes to the high-level structure (now renamed the HS) are therefore quite small and will not have an

immediate impact on users. However, the “Guidance for MSS writers” in Annex SL Appendix 2 has been significantly improved, which should result in enhanced alignment and harmonisation of “discipline-specific” requirements as the changes filter down into the various MSS over time. The revised Annex SL has now been incorporated into the latest version of the Directives, published on 1 May 2021, and will apply to the development of all new MSS (such as the new ISO 42001 for Artificial Intelligence, which is still in its early stages) and any revision of existing standards, such as ISO 9001 (Quality), ISO 14001 (Environment), ISO 45001 (Occupational Health and Safety) and others. However, it should be emphasised that this will occur over time, and the standards are not required to be revised simply as a result of the revision to Annex SL.

The main changes

Scope – link with intended results

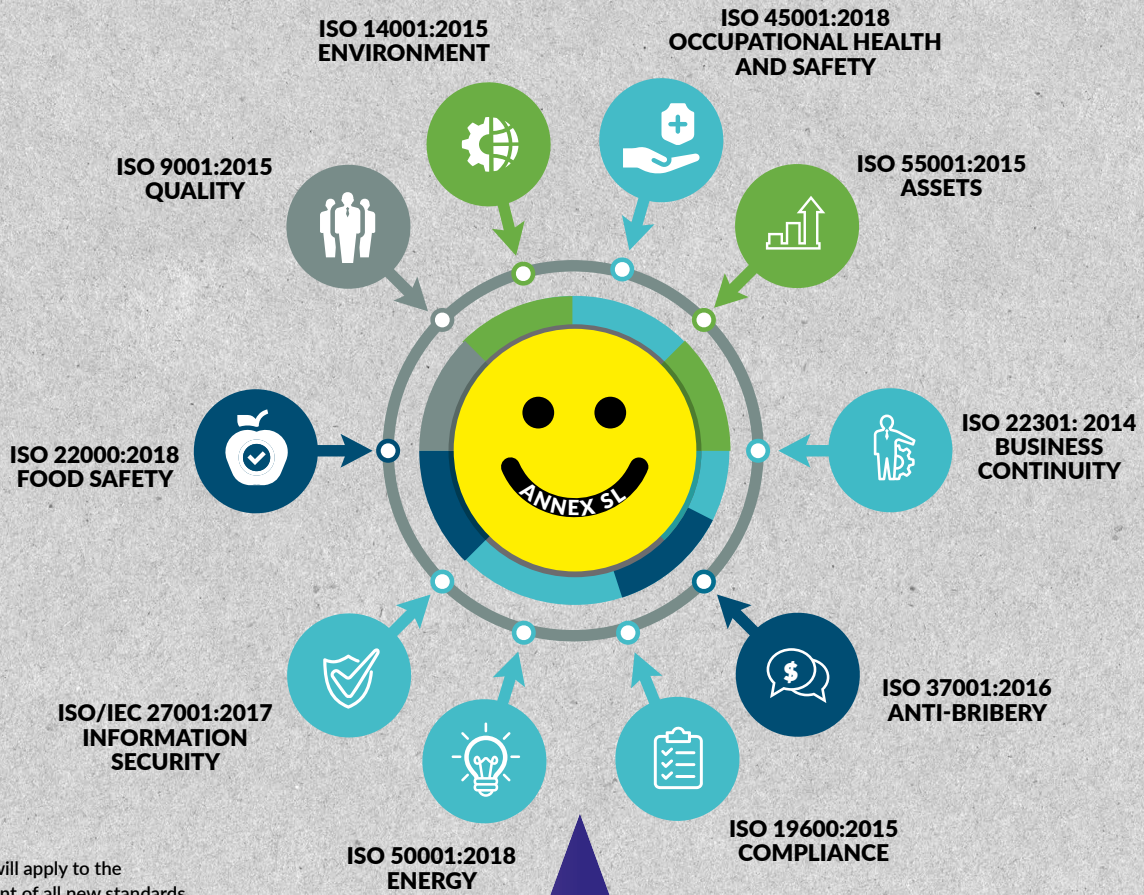
The scope of all MSS (Clause 1) must indicate the intended results of the management system that is specified in the standard. For example, ISO 14001:2015 states that it is about improving environmental performance, meeting compliance obligations and achieving environmental objectives. ISO 9001:2015 is clear that the intended results are to consistently

“THE REVISED ANNEX SL HAS NOW BEEN INCORPORATED INTO THE LATEST VERSION OF THE DIRECTIVES ... AND WILL APPLY TO THE DEVELOPMENT OF ALL NEW MSS”

provide conforming products and services, thereby improving customer satisfaction, and so on. This provides a basis on which organisations can consider the relevant risks and opportunities they need to control or exploit in order to achieve or exceed the goals of the management system.

For auditors and those involved in accredited certification, these intended results are an important reference point for determining the

NEW SITUATION: FULLY ALIGNED STANDARDS



Annex SL will apply to the development of all new standards and revision of existing ones.

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into each MSS, supplemented, if desired, with the specific terms and definitions applicable to that standard.

This is a change for ISO 9001, for example, which so far has not included definitions, instead making a normative reference to ISO 9000 (the Fundamentals and Vocabulary standard). This is important for all users of standards, including auditors, because it has been shown time and again that a good understanding of terminology is essential for a good understanding of a standard as a whole.

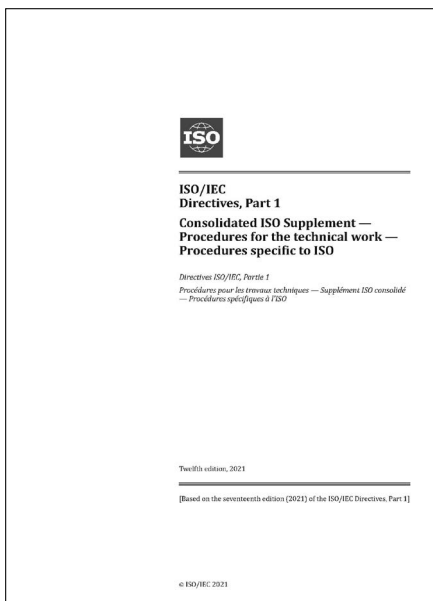
Removal of “outsourcing” and “control of outsourced processes”

The concepts of “outsourcing” and “control of outsourced processes” will no longer be used. In practice, there has often been discussion about what exactly outsourced processes are and what is the difference with (the control of) purchasing and working with outsourced service providers. ▶

overall effectiveness of a management system. “Effectiveness” is defined in Appendix 2 of Annex SL as being “the extent to which planned activities are realised and planned results are achieved”. While an organisation might have other additional expectations for its management system, the MSS will define the minimum that should be achieved as part of the concept that “Output Matters”. This is described further in the joint ISO/IAF/ILAC document “Expected outcomes for accredited certification to ISO management system standards” (https://www.iaf.nu/upFiles/CASCO_Expected_Outcomes2018final.pdf).

Terms and definitions always included in the standard

From now on, the terms and definitions from Appendix 2 must be incorporated



Cover courtesy of ISO

Annex SL is the result of an extensive revision process, with a benefit/rationale impact applied to every change.

That is why it has now been decided in clause 8 to set requirements for the externally provided processes, products and services that are relevant to the management system. This now also requires these processes to be controlled (typically via purchasing), which has not been the case so far.

The organisation determines which stakeholder requirements will be complied with

In Appendix 2 of Annex SL, the term “requirement” is defined as a need or expectation that is stated, generally implied or obligatory. Clause 4.2 has always required an organisation to identify the relevant requirements of relevant interested parties or stakeholders.

This definition of a requirement indicates that it encompasses more than what is mandatory for an organisation, eg, complying with legal requirements. However, it has been unclear how an organisation should deal with the other needs and expectations of stakeholders.

This was already clarified in standards such as ISO 14001 and ISO 45001, and now a similar wording has been added in clause 4.2 (Understanding the needs and expectations of interested parties) of Annex SL, to make it applicable to all MSS. Namely, that the organisation

“FROM NOW ON, THE TERMS AND DEFINITIONS FROM APPENDIX 2 MUST BE INCORPORATED INTO EACH MSS”

shall determine which of the identified requirements of stakeholders will be addressed in the management system. It is logical that these would then become the “applicable requirements” that the organisation commits to meet, as expressed in the policy in accordance with clause 5.2 (XXX Policy), where “XXX” refers to the specific discipline of the MSS, such as quality, environment, etc.

An example in the case of ISO 9001 might be where a potential customer has a series of needs and expectations that the organisation

cannot, or chooses not, to meet. Such needs and expectations become “applicable requirements” for the quality management system only if the organisation offers or accepts an order for products and services that are based on them.

This is consistent with the concept of “compliance obligations” as defined in the newly published ISO 37301:2021 standard for Compliance Management Systems.

Management of change

Clause 6 now includes the new subclause 6.3, which states that the changes to the management system, for whatever reason, shall be carried out in a pre-planned manner. Clause 8 elaborates on this by requiring that the changes that are being planned in clause 6.3 are carried out in a controlled manner. This means that the basics of Management of Change have become an explicit part of Annex SL. This will not affect users of ISO 9001 (there is already a requirement in ISO 9001 to this effect), but this will need to be addressed by all MSS in the future.

Documented information

One important feature in the 2012 version of Annex SL was the departure from the well-known concepts of “documents, procedures and records”, and the introduction of the idea of “documented information”. The purpose of this was to emphasise that it is the information that is important for the effective functioning of the management system, and not so much the way in which that information is captured or documented.

In any case, the JTCG has been very reluctant to include specific requirements for documentation in Annex SL to provide the maximum flexibility for individual MSS writers to define this for their specific discipline, with the minimum of bureaucracy. The extent of documentation is a choice that an organisation makes itself (based on the analysis of its own needs for things like process control, knowledge management, demonstration of conformity and any requirements imposed by relevant interested parties), and not because “ISO requires it to be documented”.

By using different verbs, such as “maintaining” documented information (eg, procedures or work instructions) and “retaining” documented information (for records), some MSS hung on to the old concepts in a roundabout way.

This has led to endless discussions about when a document or record is involved and what specific requirements apply to its management and control, while in modern practice there are all kinds of hybrid forms of making information available in an effective and agile way. Therefore, the new version of Annex SL adopts the idea that documented information needs to “be available”, rather than prescribing how exactly it should happen.

Improvement

There were a number of comments made about clause 10 of the Appendix 2 text (“Improvement”), for instance

“THERE IS NO REQUIREMENT FOR PUBLISHED MSS TO TRANSITION TO THE NEW HARMONIZED STRUCTURE WITHIN A SPECIFIED TIME PERIOD, SO IT IS LIKELY THAT THE 2012 AND 2021 VERSIONS WILL CO-EXIST FOR SOME TIME”

too much emphasis on “learning from mistakes” by taking corrective action on identified nonconformities. This has resulted in the order of the subclauses in clause 10 now being reversed so it now starts with a short section on “continual improvement” in general. This change is unlikely to have a significant impact on users, but it is in line with standards such as ISO 9001 and ISO 14001, in which a separate “general” paragraph on improvement is already included.

Risks and opportunities – no change

The question of “risk” and the ways in which the various MSS address “risks and opportunities” varies significantly between different disciplines and sectors (most notably those that operate in a regulated environment). Therefore, it was not surprising that these topics were the subject of much debate during the revision process. The ISO’s Technical Committee on

Risk Management (TC262), which participated in the work, has since approached ISO to recommend a strategic high-level review on how all ISO and IEC (International Electrotechnical Commission) standards (not only MSS) define and address risk.

As a result, neither the definition of risk nor the text on how to deal with risks and opportunities in clause 6.1 of Appendix 2 has been changed. This was considered to be the best option available within the project time frame – to have made any “quick-fix” changes ahead of the significant discussions that are being initiated at the ISO and IEC level could have caused more confusion than clarity.

However, TF14 did succeed in developing significantly improved guidance for MSS writers, which should provide some flexibility in the application of Appendix 2 when needed within a discipline-specific MSS.

Transition to the new HS

The new core text for MSS prescribed by Appendix 2 of Annex SL applies from 1 May 2021, after which all new MSS and revisions of existing standards must be based on this new version of the HS. A few standards are already ahead of the game, such as the aforementioned ISO 37301:2021, published in April 2021. However, there is no requirement for published MSS to transition to the new HS within a specified time period, so it is likely that the 2012 and 2021 versions will co-exist for some time. However, since there are no fundamental differences between the two, this is not expected to become a major issue.

Summary – socially responsible business operations

In light of this updated version of Annex SL, the ISO has indicated that the path taken in 2012 to improve the alignment and consistency of its portfolio of management system standards is irreversible, and the millions of users of MSS can expect that further steps will be taken in the coming years to support such an approach that facilitates their adoption within a single (“integrated”) management system.

Societal change can be facilitated by the adoption of the appropriate MSS. Examples include business continuity and crisis management (highlighted by Covid-19), resource scarcity, adaptation to climate change, digital transformation, Industry 4.0, the circular economy, sustainability, the sustainable development goals (SDGs), and others. All of these bring both business opportunities and risks that can be addressed within a single, robust, business management model.

The new Annex SL provides the basic elements for this, so that any organisation can easily understand and embed the relevant MSS into its business operations in a way that best fit its strategy and goals, core processes, products and services, and the context in which it operates. ■

The latest version of Annex SL is available to view online at:

bit.ly/3wAzyRT

