
ISO 9001:2015

Information on the revision and insights into the new structure.

The upcoming fifth revision to ISO 9001 provides further opportunity for organizations take stock of their current practices and use standards as the basis for the development of a Business Management System, to unlock the untapped value within their operations.

The ISO 9001 Quality Management Systems standard is under review and an updated version is expected by the end of 2015. All ISO standards are reviewed every five years to make sure they remain helpful and relevant. First published in 1987, ISO 9000 has consistently been ISO'S most popular series of standards. The impending fifth revision provides further opportunity for organizations take stock of their current practices and use standards as the basis for the development of a Business Management System, to unlock the untapped value within their operations. ISO Technical Committee ISO/TC 176 Quality Management and Quality Assurance, sub-committee SC2, Quality Systems is busy laying the groundwork for the next generation of quality management standards. Of significance in this process is the use of the "Annex SL" platform.

What is the New Annex SL Platform?

ISO has recently completed work on a common platform to provide identical structure, text and common terms and definitions for management systems standards of the future. This platform, known as Annex SL, will ensure consistency among future and revised management systems standards, make the standards easier to read and be understood by users, and greatly aid with the integration of multiple standards within one organization.

Annex SL replaces ISO Guide 83 which, while it provided a base structure and standardized text for management systems standards, also received much criticism from organizations integrating multiple management systems, such as ISO 9001, ISO 22000, ISO 14001, etc. While these standards have common elements, they are described and organized differently, making effective integration difficult. The use of the same structure, as well as commonly used terms and definitions, will make it far easier, less time-consuming, and consequently cheaper to implement, integrate, and maintain standards. Annex SL is intended to enable organizations to develop and maintain a single business management system focusing on the organization's core processes rather than individual requirements of a given standard. To this end approximately 30% or so of each new and revised standard will contain identical text.

The intent is that in future all new management system standards will have the same overall look and feel. Current standards will progressively migrate during their next phase. Both ISO 9001 and 14001 will follow the new outline during their revision process.

ISO 9001 2015

Much has been written about the impending fifth revision to ISO 9001. SAI Global is providing the following information to keep organizations informed of the progress of this revision and provide some insight into the new structure and requirements under consideration. The purpose of ISO 9001 is to provide organizations with a foundation upon which to build sound business practices and processes. These requirements, properly applied can bring discipline and consistency to an organization's operating processes. This consistency fosters the development of meaningful metrics to gauge performance. While there are many organizations who understand this concept, there are others who do not fully embrace the constructive and positive benefits to be gained by implementing a disciplined approach to their operations. Some approach conformance as a project to complete, with a definite end point rather than as a journey toward continual improvement and sustainable business success. SAI Global has always approached management system standards as an opportunity for an organization to take stock of its operations and use the standards as the basis for the development of a Business Management System to unlock the hidden value within. SAI Global has always utilized this "holistic approach" when assisting organizations in the development of their management systems and we see ISO 9001:2015 as the next logical step in this journey.

Timing

It would be extremely premature to begin modifying or designing a management system based on the Committee Draft (CD ISO 9001:2015), which was circulated in June of 2013. A Draft International Standard (ISO DIS 9001:2015) should be available by August 2014.. The Final Draft International Standard (ISO FDIS 9001:2015) should be released July to August of 2015 and, the fifth revision should be published in September 2015. History has shown numerous refinements / modifications will occur between now and the official release. In the meantime organizations should devote their resources toward the identification and implementation of continual improvement initiatives within their current management systems. This activity will reap benefits for the organization while the details of the new standard are worked out. A transition period will be defined to allow currently registered organizations to develop and implement their management systems to come into conformance with the requirements of ISO 9001:2015. The general consensus is that the transition period will be set at between two (2) and three (3) years but is subject to modification.

The following represent general observations on the ISO 9001:2015 revision:

- ❖ When ISO 9001:2000 was originally published, the focus of the standard evolved from one of a compliance approach to the present focus in the 2008 version on operating an effective and efficient business management system. This emphasis is planned to continue in ISO 9001:2015, with increased focus on ensuring the Plan Do Check Act (PDCA) cycle of improvement provides confidence to the organization's stakeholders.
- ❖ Annex SL has introduced two new clauses relating to the context of the organization, **4.1 Understanding the organization and its context** and **4.2 Understanding the needs and expectations of interested parties**. Together these clauses will require the organization to determine the issues and requirements that can impact on the planning of the quality management system and can be used as an input into the development of the quality management system. Although there is now reference to determining the requirements of relevant interested parties there is no new requirement to ensure goods and services meet the needs and expectations of external parties other than those already identified in ISO 9001:2008, i.e. the organization's customers, regulatory bodies, relevant industry groups and others as required.
- ❖ The Committee Draft (CD ISO 9001:2015) does not include a specific clause with requirements for "preventive action". The reason given for this change is one of the key purposes of a formal management system is in and of itself, to act as a preventive tool. Consequently, the standard requires "an assessment of the organization's external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended outcome(s) " in clause 4.1, and to "determine the risks and opportunities that need to be addressed to: assure the quality management system can achieve its intended outcome(s); prevent, or reduce, undesired effects; achieve continual improvement." in clause 6.1. These two sets of requirements are considered to cover the concept of "preventive action". The organization is encouraged to take a wider view that looks at risks and opportunities faced by the organization arising from its operations. This approach is continued in the discipline specific text to require risk based thinking and a risk driven approach to preventive action throughout the development, implementation, maintenance and improvement of the quality management system. This has also enabled the reduction in several prescriptive requirements and for their replacement by measurement based requirements. Although risks have to be identified and

acted upon, there is no specific requirement in the present version of the CD for a formal risk management process. Many organizations have such processes already but do not necessarily apply these principles to their quality management systems although it would seem to be a logical and beneficial extension of the risk management process.

- ❖ There is a much welcomed and long needed focus for the quality policy and business objectives to be in alignment with the overall strategic direction of the organization. A much greater emphasis is placed on managing a business with all its intricacies rather than simply product quality. The term interested parties is used, taken from ISO 9004:2009, which is a much boarder consideration than simply the customers of the organization. There is recognition that the success or lack of success of each organization affects a wider audience (e.g. Suppliers, Associates, Stockholders, Customers, Society).
- ❖ The language of the standard was not seen as readily applicable to service industries, therefore ISO 9001:2015 uses the phrase “goods and services” instead of the current term “product.”
- ❖ A process approach when developing, implementing and improving the effectiveness of a quality management system was first introduced in ISO 9001:2000. The proposed 2015 revision to the standard provides for additional focus by including clause 4.4.2 Process approach which specifies requirements considered essential to the adoption of a process approach. The process approach is one of the eight quality management principles upon which ISO 9001:2000 was based. Organizations experienced some confusion regarding the requirements in section 4.1 of ISO 9001:2000 when asked to identify their processes and their sequence and interaction. In its simplest form, the organization was being asked to understand their work flow in order to develop the necessary controls and measurements to allow the leadership to determine if their business processes were operating in an effective and efficient manner. In order to operate at peak efficiency, organizations need to understand and identify what each business process needs to thrive and ensure the necessary conditions and resources are provided in order to contribute to the success of the organization.
- ❖ The terms “document” and “record” have both been replaced throughout the CD document with the term “documented information”. The need for documented procedures is not identified. The CD does have multiple references to requirements for “documented information”. In clause 8.8,

Nonconforming Goods and Services it states documented information must be maintained on the nature of the nonconformity, subsequent actions, and any concessions. This reference implies a record is required for this activity. There is no specific requirement for a documented procedure however as was the case in section 8.3 of ISO 9001:2008.

- ❖ One inconsistency was noted between the definitions and the actual requirements themselves. In the CD, definition 3.17, audit refers to an audit being a “systematic and documented process”. However if one reviews Clause 9.2 covering Internal Audits, the requirement for a documented procedure in order to conduct internal audits is not specified. The clause does include the need for “documented information”. As used in this context, the standard is referring to audit evidence which are records. This inconsistency of course may be modified or resolved in subsequent revisions prior to the final revision of the standard being published.
- ❖ While several of the definitions found in the Committee Draft have retained their current terminology from ISO 9000:2005 such as Conformity and Nonconformity, several others have been revised such as Corrective Action and Continual Improvement. Additional definitions were included in the CD which are not found in ISO 9000:2005. The committee included in the definitions in the CD to assist in the review of the document. It remains to be seen if these definitions will be included in the final version of ISO 9001:2015, or incorporated into a next revision of ISO 9000. Several examples:
 - Documented Information: information required to be controlled and maintained by an organization and the medium on which it is contained.
 - Outsource (verb): make an arrangement where an external organization performs part of an organization’s function or process
 - Risk: effect of uncertainty.

A total of 22 definitions were included in the CD.

One of the expected potential benefits of adopting a common management system structure would be to allow organizations to implement several management systems in an organized and efficient manner. This should allow them to focus their attention on understanding, planning and operating their business processes. A properly designed and implemented management system should provide ample objective evidence of conformance with the relevant management system standards as well as the appropriate regulatory and customer requirements that the organization subscribes to. Organizations may feel the

need to reorganize, restructure and potentially renumber their documents to align with the new framework. This was an all too common activity when previous versions of the standard were initially issued. In fact several organizations labored under the misconception by simply renumbering their documents to match the renumbered ISO 9001 requirements, they would be found in conformance with the standard. SAI Global has always encouraged organizations to develop a document convention numbering system / structure independent of a management system standard. Reorganizing the documentation is not required and actually is not a constructive use of the organization's resources unless the current management system was not adequate.

It should be pointed out not every industry group views the transition to Annex SL as a positive step. The Automotive and Medical Device Industries have expressed their concern and displeasure with this new structure and approach and have decided to develop their own quality management system standards. These industries view the new common requirements from Annex SL as not adding value to the organization. Now, rather than consolidation, organizations may face the prospect of having to conform to multiple management system requirements and undergo multiple external audits to demonstrate their level of conformance to their customers. This development represents a step backwards and it is a situation that certainly warrants continued attention.

We would like to emphasize once again that **ISO 9001:2015 is still evolving** and it is reasonable to assume that numerous modifications will be forthcoming before the document reaches its final version. SAI Global will keep you apprised of any new developments as they become available, and we will be hosting a webinar series covering the ISO 9001:2015 revision, which will start as soon as the draft is finalized and there is more permanence around the specifics of the update.

To receive updates covering the 9001:2015 update you can register for our first webinar on this topic. In the event the finalized draft is not available before the scheduled webinar date, the webinar will be rescheduled to a later date in order to ensure the review process is complete and the standard is finalized enough to provide you with useful and credible information.

For updates on the ISO 9001:2015 release and a schedule of upcoming webinars, visit:

www.saiglobal.com/assurance/iso-9001-2015-revision/

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