

# **ISO 9001 Revision Approaches Draft International Standard (DIS) Level**

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*(Author's Note: ISO 9001 is still in the revision process. Information in this article should not be used by organizations to make changes to its quality management system or for legal agreements. Information in this article will be useful in helping organizations understand the level of change that is coming.)*

The revision to ISO 9001 was published as a Committee Draft (CD) in June 2013. Subsequent meetings to review comments on the draft have continued the progression of the revision with an anticipated release of the Draft International Standard (DIS) in June or July 2014. While there is still a long way to go in the process, keeping current on what is going on with the ISO standard that has over one million users is important to organizations that use ISO 9001 as the foundation to their quality management system.

The biggest change to users is the structure. Both the 1987 and 1994 versions of ISO 9001 used a “20-element” model that had familiarity to manufacturing industries. In the year 2000, ISO 9001 transitioned to a process approach and moved from the “20-element” model to a structure of five clauses. This structure was used for both the 2000 and 2008 versions of the standard.

The ISO Technical Management Board has adopted a standardized format and common core text for use in all new and revised ISO management system standards, to promote greater ease of use for organizations that seek to integrate the requirements of (for example) ISO 9001, ISO 14001, ISO 50001 into a single, coherent system. This standardized format is referred to as

Annex SL. Table I compares the clause titles of ISO 9001:2008 to the clause titles in the proposed version of ISO 9001.

Table 1

<b><u>Annex SL</u></b>	<b><u>ISO 9001:2008</u></b>
4 Context of Organization	4 Quality Management System
5 Leadership Planning	5 Management Responsibility
6 Planning	6 Resource Management
7 Support	7 Product Realization
8 Operation	8 Measurement, Analysis, Improvement
9 Performance & Evaluation	
10 Improvement	

While there is not an ISO 9001 requirement for an organization to develop its quality management system and document architecture using the structure of ISO 9001, many organizations chooses to do so because it is easier to understand and maintain compliance as well as demonstrate compliance to external parties. As a result, many organizations structured their quality management systems around the ISO 9001:2008 structure.

Organizations that see the structure change might be overwhelmed. Before making any quality management system structure changes, it is important to consider the opportunities and issues associated with making such a change. Any change should add value. Making a change for the sake of lining up a quality management system to a structure of any kind adds unneeded cost and overhead to the organization.

To avoid making a structure change, organizations can develop a cross reference of procedures and methods of compliance from whatever structure they are using to the requirements in the revised standard. It is anticipated that the revised version of ISO 9001 will include a cross reference of existing requirements in ISO 9001:2008 to ISO 9001:2015

(estimated). Clarifying information will also be added to the Annex of ISO 9001:2015 to help emphasize that structure changes will not be required for the revision.

If an organization chooses to make a structure change, they should focus on creating a structure that is unique from any standard or governing document or that is easy to change. For example, don't change document numbers, but create a filter in your quality management system that aligns documents with whatever standard you are using. This method can meet the needs of the organization but be more cost effective in managing long term.

Organizations can expect to see other requirements change in the standard as well. It is highly likely that there will be changes to the specific requirements in the ISO 9001 draft. However, it can be anticipated some of the general themes for the revision will carry through until publication. Some of these themes include the following:

- More generic – There has always been feedback that the standard is difficult to apply to all types of industries, specifically the service industry. For that reason, the language in the standard is being modified to make ISO 9001 easier to use for these types of industries. Currently the CD of ISO 9001 uses the phrase “products and services” instead of product when specifically referring to the deliverables to the customer. Definitions are being added to ISO 9000, the terminology document for ISO 9001, to clarify the terms being used.

Another proposed change to make the standard more generic revolves around some of the requirements that were focused on manufacturing industries. Specifically, the clauses related to 7.1.5 Monitoring and Measuring Devices (previously clause 7.6) and 8.5 Development of goods and services (previously clause 7.3). Both of these clauses included very specific requirements for demonstrating

compliance. Clarifying statements have been added to these clauses to make the requirements more general in order to make the clauses easier to implement for all industries.

- Context of the organization – The required high level structure and identical text requires the management system standard to have clauses related to 4.1 Understanding the organization and its context and 4.2 Understanding the needs and expectations of interested parties. These requirements, while new in the text of the standard, were included in 0.1 General in ISO 9001:2008 which indicated that the quality management system is influenced by the environment that the organization is in, including changes and risks. The new language may cause confusion to users, but the intent is basically the same. One of the concerns with the core text relates to the term interested parties. The interpretation for this phrase is that there is no new requirement to ensure that products and services meet the requirements of interested parties because this would go beyond the scope of the quality management system. These caveats have been added to the text of ISO 9001 in order to make this distinction clear.
- Process approach – Both the 2000 and 2008 versions of ISO 9001 promoted the process approach in the quality management system. The requirements in 4.4.2 Process Approach (previously Clause 4.1) include specific requirements for adopting the process approach. However, one might argue that these specific requirements go outside the boundaries of making the standard more generic. The balance between improving the requirements for the process approach while maintaining generic requirements is critical as the standard advances.

- Risk-Based Thinking and Preventive Action – One of the emphasis areas for the revision to ISO 9001:2015 is risk-based thinking. This is an approach where an organization can analyze the risk associated with implementation of a specific requirement and based on that analysis make a determination of the level of implementation required. The revision does not require a formal risk management program but consideration of risks.

In alignment with risk-based thinking, the CD for ISO 9001 does not use the term preventive action. This is consistent with the core text from Annex SL. The language in the standard looks at how an organization determines the risks and opportunities that need to be addressed for an effective quality management system. Clause 6.1 Actions to address risks and opportunities includes requirements to make sure that the quality management system can achieve its intended outputs. It also addresses taking action appropriate to the potential effect of conformity to goods and services. This requirement is consistent with traditional requirements of preventive action. However, it is expected that even those organizations that struggled with preventive action will find the concept of incorporating preventive action as a significant change. This change is an opportunity to better align the organization and standard with management philosophies since managing risks is typically the language that leadership uses when making decisions about the organization.

- Documented Information – Since the original version of ISO 9001, the terms “documents” and “records” were used. The core text required by Annex SL adopts the terminology of documented information. The business world and the technology used to run it has changed significantly. It is important for the standard to move

forward and be consistent with those business changes. In the past, documents and records relied on paper objective evidence. Today the manner in which we control information is typically electronic and the difference between the documents and records is more seamless. There will be challenges to organization since the standard no longer differentiates with the term document or record, and it instead uses documented information in both instances.

Now that the ISO 9001 revision is nearing the DIS level, comments will be submitted and reviewed by the working group experts. After the review the standard will advance through the following stages.

- FDIS –Once the DIS has been approved we move to the publication stage. The document is finalized by the staff in Geneva and submitted for final ballot to the SC 2 participating members. This stage is generally considered to be a simple check for editing errors and only minor changes and edits can be made. (July 2015)
- IS—After approval of the FDIS, the document is published and provided to member bodies for National adoption purposes. In the USA, ASQ normally adopts these standards as American National Standards as a part of the American National Standards Institute (ANSI) national adoption process. (September 2015)

It is important to note that the final publication of the standard relies on its successful advancement at each specific stage. Estimated dates may shift based on progress and results of ballots. During this timeframe, the International Accreditation Forum will develop any specific guidelines for how organizations that are certified to ISO 9001 will transition to the revised standard. Until the final draft of the standard is published, organizations should not make any

change to their management system based on the content of the draft versions of the standard alone.

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