ISO 9001: The value of upgrading to the latest Quality Management Revision

By **Andrew Rosenblatt***

Many ISO standards are being updated this year. This article will help you understand what these changes are and how they affect your organisation. The article discusses the benefits of quality management systems and 9001 certification, the greatest impacts of the recent changes to ISO 9001 and the effects of these changes on other management systems certifications such as AS9100 (aerospace), ISO/TS 16949 (automotive) and ISO 13485 (medical devices). We also cover how to transition your certification from ISO 9001:2008 to ISO 9001:2015 and provide a brief history of ISO.

History

ISO, or the International Organisation for Standardisation, is the independent, non-governmental organisation responsible for developing and maintaining international standards. Since its official launch in 1947, ISO has published more than 19,000 globally recognised international standards in a variety of industries, helping to ensure product, service and systems quality, safety and efficiency.

Among the most well-known ISO standards is ISO 9001 – Quality Management Systems ISO 9001, which provides a set of uniform requirements for a quality management system (QMS) and can be used by any organisation, large or small, in any industry.

In 2013 alone, over one million ISO 9001 certificates were issued, across 187 countries. The most recent revision of the standard, which was published in September 2015, continues to be based on a number of quality management principles including a strong customer focus, support of top management, the process approach and continual improvement.

Using ISO 9001:2015 helps ensure that customers get consistent, good quality products and services, which in turn brings many business benefits.

Benefits of ISO 9001

A focus on quality management is essential in sustaining business success. With over a million ISO 9001 certificates issued around the world each year, certification is no longer "a nice to have," but a required business tool. An effective management system is based on good management principles and supports the implementation of progressive business strategies. When successfully implemented, it can help an organisation reach its strategic goals using a systematic approach.

For both service and manufacturing organisations, an effective QMS improves product, process and service quality while reducing waste. Independent studies have shown that ISO 9001 certified companies have recognised improved organisational performance after implementing a QMS system. Implementation of ISO 9001 has been shown to improve the performance of employees by providing clear expectations, tools and actionable feedback on performance.

Not only is implementation of ISO 9001 a beneficial tool for improving internal practices, but there are external benefits as well. A documented QMS allows entry into industry segments that require, or expect, certification and drives a focus on customer satisfaction, aligning performance objectives to customer expectations. Additionally, the costs that are associated with poor quality are significantly reduced.

Numerous studies have found a positive relationship between quality and operational performance, resulting in key financial metric improvements. Organisations have documented both greater value for customers (building market share and revenue) and lower costs (increasing margins and asset utilisation). Better quality products, processes and operations lead to higher customer satisfaction, and ultimately increased sales. No matter the industry, a QMS can be an integral component of an organisation's overall continuous improvement efforts.

A successful management system drives the development of an organisation toward sustained success and pushes it to be one the best performing, efficient and profitable organisations in its sector. Organisations that work to align their processes and ensure they are known by everyone in the business will be more efficient, bring internal costs down and see greater levels of success.

Recent Changes to ISO 9001

ISO standards are reviewed every five years to determine if a revision is required to make sure it remains relevant in the marketplace. The newly revised ISO 9001 is designed to respond to the latest trends and be compatible with other management systems, such as ISO 14001. The new standard is less prescriptive than the previous version; instead focusing on performance through a combination of risk-based thinking and a process approach, as well as employment of the "Plan-Do-Check-Act" cycle at all levels in the organisation.

At first glance, the changes introduced in the 2015 version of the standard may seem to be significant, but organisations may come to realise they are already doing many of the activities described in the standard, and will just need to integrate them into their QMS.

Among the most significant updates to the standard is the increased importance given to risk. With the introduction of ISO 9001:2015, risk-based thinking has

*Global Business Development Director, NSF-ISR and NSF Sustainability, contact NSF-ISR at information@nsf-isr.org

become a "new" compliance requirement. However, this significant change from the previous version of the standard is actually not so new at all. The 2008 version of ISO 9001 required organisations to gather and analyse data from their processes to continually improve upon them, and to implement actions to prevent recurrence of nonconformities. Taken a step further, data analysis was also required to prevent the occurrence of potential nonconformities from happening in the first place.

The approaches to demonstrating risk-based thinking in the QMS will likely be as unique and varied as the organisations seeking registration to ISO 9001:2015. However, there are some common fundamental elements of the process: identification of the risks, analysis of the risks and their impact on the QMS (or organisation itself), qualification or quantification of risks in order to prioritise, determination of actions to mitigate risks, implementation of actions to mitigate risks and analysis of the results of actions taken.

There are many risks to an organisation's QMS that are considered and dealt with every day by top management. ISO 9001:2015 now requires that the identification, review, mitigation and analysis be formalised in order to demonstrate compliance with the various clauses in the standard that refer to risks. Organisations' top management is encouraged to take a leadership role in making the entire organisation sensitive to risk, communicating risk, and reducing or eliminating the potential impact these risks have on the overall organisation and the successful operation of the QMS.

Another significant update to the standard is greater emphasis on leadership. Traditionally, the QMS development, implementation and maintenance have been the domain of the quality management representatives of your organisation. This has also required top management involvement in the past, but the new version of the standard has more far-reaching requirements for all facets of your organisation. Top management is considered to be the senior-most persons in your organisation who are the decision makers. Top management will need to be actively involved in the decision process for determining the scope of the QMS, determining the internal and external factors that influence the performance of your organisation's QMS, determining and managing risks, and providing leadership and resources to ensure that the QMS is successfully implemented and maintained.

How to Prepare for ISO 9001:2015

There are seven main steps that can guide your organisation to a successful transition or implementation of ISO 9001:2015:

1. Learn/understand ISO 9001:2015 – Become familiar with the new standard and its structure.

2. Engage top management – The new revision of the standard involves an organisation's top leaders who should also become familiar with the standard requirements.

3. Plan – Change management is strongly emphasised, so be sure to develop a process to plan for the transition in a fashion consistent with the change.

4. Do – Once established, the plan should be put into action to implement changes to the requirements of the standard, while making sure to continue compliance with ISO 9001:2008.

5. Check – Before the certification body performs the transition audit, the lead auditor will need to confirm that your organisation has performed a full-system internal audit and management review to ISO 9001:2015.

6. Act - Corrective actions resulting from the internal audit will need to be closed, and the details reviewed at management review. Top management will need to confirm that resources for the maintenance of the QMS are adequate, or if changes are necessary.

7. Undergo upgrade audit – Once the certification body successfully completes the upgrade audit, and any resulting corrective action requests (CARs) are closed, your organisation will be granted with an ISO 9001:2015 certificate, beginning a new, full three-year cycle.

ISO 9001:2015 Impact on AS9100, TS 16949 and ISO 13485

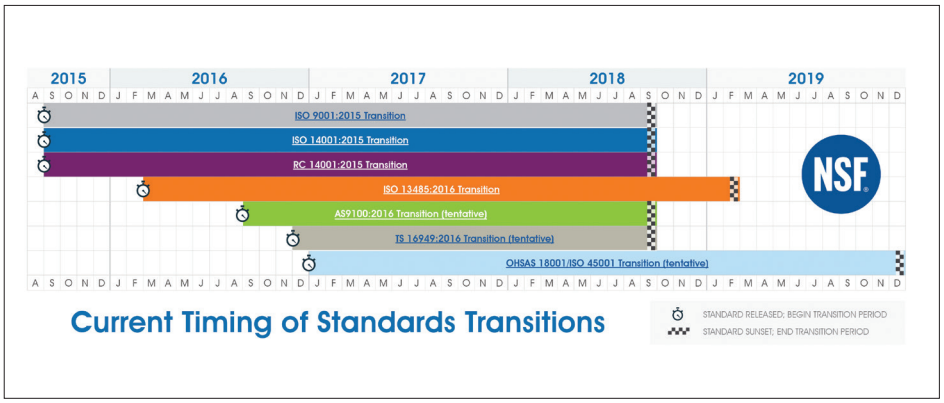
Many management systems based on ISO 9001 are currently undergoing revisions to bring them into alignment with the new version of the QMS standard. Two of the most significant are the AS9100 standard for the aerospace industry and ISO/TS 16949 for the automotive industry.

The updated AS9100 series standards are due for release during Q4 2016. A revised version of ISO/TS 16949 called IATF 16949:2016 is due for release in December, 2016.

The updated ISO 13485 medical devices quality management systems standard was published on March 1, 2016, but is not based on the new high-level structure that underpins the other revised management systems. However, a clause structure comparison to ISO 9001:2015 (Annex B) is provided.

Many of the changes brought about by the revisions may be elements that you will find to be already in place within your QMS. Terminology or presentation may need some adjustment, but the fundamental changes to your QMS could be quite minimal.

At www.nsf.org/info/iso-updates, you will find links to tools and resources such as webinars, upgrade planners, readiness assessments, transition guides and white papers – all designed to help your organisation through the transition.



About NSF-ISR

NSF International Strategic Registrations (NSF-ISR) is an experienced global leader in certification, verification, inspection and testing services. With our international reach, NSF-ISR can meet your operational needs wherever you are around the world.

We assist large and small organisations in navigating market complexities, reducing risk, improving performance, meeting stakeholder expectations and operating more sustainably. NSF-ISR can tailor business solutions that work for you.

NSF-ISR is a leading global certification body, known for its superior technical expertise and customer satisfaction. Through the highest level of integrity, the NSF-ISR mark is recognised as the gold standard of the certification industry.

Quality products and services require effective management systems. Our global team can not only help organisations comply with regulatory requirements through our certification programs, but also ensure effective performance of processes and systems. Whatever your business challenge, NSF-ISR has resources to help. ■