ISO Revisions

ISO 9001 Whitepaper

The history and future of ISO 9001

Approaching change

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Introduction

ISO has recently released the results of their 2012 survey of certificates. This annual study shows that over one million certificates for ISO 9001 have now been issued globally – proving that the standard remains in high demand. Certified organizations feel the standard helps them to become a more consistent competitor in the marketplace and with a strong focus on quality management, allows them to attract and meet the needs of high value customers better. With a certified system in place, they can save time, money and resources while optimizing their operational performance with fewer errors and higher profits. The standard also helps them to set up efficient internal processes that motivate staff.

With a revision for 2015 underway, this whitepaper looks at the history of the standard, how it has developed over the years and the changes companies can expect to see in ISO 9001:2015.

The history of **ISO 9001**

The UK's very first quality management standard was known as BS 5750. Driven by the Ministry of Defence, this standard specified how the manufacturing process should be managed, instead of looking at what was manufactured. In 1987, BSI convinced ISO to adopt BS 5750 as an international standard. It was named ISO 9001 with variants developed to cover different types of business.

Although ISO 9001:1987 followed BS 5750's structure, it also came with three models for quality management systems. One looked at quality assurance in design, development, production, installation and servicing for companies creating new products. The second model focused on production, installation and servicing, while the third covered final inspection and testing with no concern for how the product was made.

From 1994 to 2008

ISO 9001:1994 placed particular emphasis on product assurance using preventive actions, instead of just checking the final product. It also required companies to comply with documented procedures – recognizing the trend to manage quality by control rather than assurance.

ISO 9001:2000 placed quality and process management at its core, changing the previous versions radically. It aimed to first understand the client's requirements before designing processes that would help them to deliver on these. The standard also looked at how to continuously improve processes and track customer satisfaction. Where previous versions focused on quality control, ISO 9001:2000 was built on quality management.

ISO 9001:2008 only made the existing requirements of the 2000 version specification clearer. It also incorporated some changes to make it more consistent with ISO 14001:2004, the environmental management system standard.

Later in 2009, ISO 9004 (which accompanied ISO 9001:2000 for the first time) was revised to promote a sustainable business approach. This version focused on all stakeholders and not just customers and social conditions.

Making **ISO 9001** work in every industry

ISO 9001's requirements are generic and must be carefully interpreted to make sense within specific organizations. Manufacturing is not like a service industry, for example. So, over time various industry sectors wanted to standardize their interpretations of the guidelines specifically for their marketplace. These include:

- **Information technology:** TickIT interprets ISO 9000 for the software development industry.
- **Aviation:** AS 9100 is an Aerospace Basic Quality System Standard that was developed by major manufacturers, including Boeing, Lockheed-Martin, McDonnell Douglas and Pratt & Whitney.
- **Automotive:** ISO/TS 16949 is an interpretation that was developed by the IATF, a group of motor manufacturers including GM, Ford and Chrysler.
- **Telecommunications:** TL 9000, the Telecom Quality Management and Measurement System Standard, was developed by the telecom consortium, QuEST Forum. Unlike ISO 9001 and other sector-specific standards, TL 9000 sets out standardized product and process measurements that allow companies to benchmark their performance in key process areas against peer organizations.
- **Medical:** ISO 13485:2012 is the medical industry's equivalent of ISO 9001:2008. Unlike the standards it replaces, ISO 13485:2003 is a stand-alone specification. That means compliance with ISO 13485 doesn't necessarily mean compliance with ISO 9001:2008 and vice versa.
- **Oil and gas:** ISO/TS 29001 looks at the design, development, production, installation and service of products for the petroleum, petrochemical and natural gas industries.

Why **ISO 9001** is changing

All ISO standards are reviewed every five years to make sure they are still current and relevant in the marketplace. That is why ISO 9001 is currently under review – at Committee Draft stage – and an updated version is due towards the end of 2015. The Committee Draft stage is the first consultation in the development of an ISO standard where members who have chosen to take part in the revision, will form a national position on the draft and comment on it. This normally takes between two to four months.

Once the national positions have been submitted, experts – all nominated by the ISO members of the participating countries – meet regularly to discuss issues or answer questions that have been raised. These meetings will continue until a Draft International Standard is published and goes out for public comment. This will happen during the second quarter of 2014. Once the new draft has been finalized and accepted, it is published with a new date following the standard's number. In this case, the revised ISO 9001 standard will be published next year as ISO 9001:2015.

The changes

All ISO management systems share common elements. But despite this, these systems come in many different shapes and structures which can lead to confusion and difficulties when they are implemented.

ISO has already completed some initial work to provide an identical structure, text and common terms and definitions for all management system standards of the future. This means that both future and revised management system standards will be consistent and simpler to integrate. The revised structure will also make the standards easier to read – leading to a better understanding for those tasked with implementing them.

This new high-level structure is sometimes referred to as Annex SL and all ISO technical committees who develop management system standards in future will use this as their blueprint. The high level structure is designed to align format, text, terms and definitions, while still giving standards developers all the flexibility they need to integrate their technical topics and requirements. ISO 9001:2015 will adopt the new high level structure and will have the following outline:

Clause 1:	Scope
Clause 2:	Normative references
Clause 3:	Terms and definitions
Clause 4:	Context of the organization
Clause 5:	Leadership
Clause 6:	Planning
Clause 7:	Support
Clause 8:	Operation
Clause 9:	Performance evaluation
Clause 10:	Improvement

Key changes in detail

Clause 4 refers to the context of the organization. This is a brand-new requirement and highlights the need for senior managers to understand the expectations of all relevant parties. They'll also need to know how internal and external challenges could affect their ability to meet these. This clause is closely linked to leadership which means management systems can no longer be held at arm's length, but should form part of the strategic direction of the business. This will help to raise the standards in the boardroom and align management systems with the needs of the business.

Clause 4 also looks at process management. From now on organizations need to determine process risk and have measures in place to ensure effective operation. They'll also need to allocate responsibilities for particular processes or sets of processes.

Clause 5 is about leadership. As mentioned before, this requirement has been set in place to ensure quality policies are aligned with strategic direction. This will help organizations to identify, assess and manage all risks that could stand in the way of meeting product requirements. Clause 5 also highlights the need to allocate responsibility for process management.

There are significant changes in **Clause 6**. This section will now replace the need for preventive action and focus on risk and opportunities that relate to product conformity and customer satisfaction. Clause 6 also sets out better requirements to help organizations manage change in a systematic manner.

Clause 7 looks at how to manage changes to resources more effectively. It also includes a new requirement to determine, present and maintain knowledge to continuously meet customer needs and improve their overall satisfaction. The third change to Clause 7 refers to the competence requirements that relate to every process or set of processes within organizations.

Clause 8 has two new requirements. The first is contingency planning to improve customer communication, while the second looks at ways to assess the suitability of a design before it reaches operations. Clause 8 also specifies the importance of controlling all outsourced activities through efficient risk management.

Clause 9 includes stronger monitoring and measurement requirements and also introduces how this works in relation to risk and the effectiveness of an organization's quality management system.

Finally, **Clause 10** sets out a more structured approach for Continual Improvement Internal Audits.

ISO 9001: 2015

In summary

According to the draft design specification, the revised standard will provide a stable, core set of requirements for the next ten years or more. These will stay generic, but be relevant to organizations of all types and sizes operating in any sector. While maintaining its current focus on effective process management, the standard will also reflect the changes in quality management system practices and technology since the last major revision in 2000. By applying Annex SL, the revised standard will improve compatibility and alignment with other ISO management system standards.

ISO 9001:2015 will also improve implementation and conformity assessments for first, second and third parties. Using simplified language and writing styles, the new updated standard will help all stakeholders to understand and interpret key areas better.

More about **PAS 99:2012**

PAS 99 is a Publicly Available Specification designed to integrate common management systems. With many BSI clients choosing to have their integrated management systems (IMS) certified against this specification, much of the thinking in PAS 99 had an impact on the development, structure and content of Annex SL.

PAS 99 was introduced in 2006 and revised in 2012. This revised version therefore reflects Annex SL and uses its text where it is appropriate – providing a future-proof approach for integrating new management systems.

Certification

When ISO 9001:2000 was first introduced, there was a three-year transition period for certified organizations to make the necessary changes and retain their certification. It has been confirmed by the International Accreditation Forum that ISO 9001: 2015 will have the same transition period of three years.

Support from BSI

BSI will carry on monitoring the proposed changes and keep all clients updated throughout the development process. This information will be available on bsigroup.com and webinars, as well as regular newsletters, workshops, publications and training courses. BSI will also make sure that all their client managers are fully briefed on the changes, so they can advise their clients in advance about the impact these revisions will have on their organization.

Getting ready for change

Certified organizations should talk to their client managers to keep up-to-date on the proposed changes. It's worth considering purchasing PAS 99 to understand the implications and opportunities of Annex SL – especially since BSI will continue to issue certificates against PAS 99. Anyone adopting PAS 99 will find the transition to the revised ISO 9001:2015 much smoother due to its similarities found within Annex SL. All certified organizations must also start making senior management aware of the coming changes and ensure a transition plan is in place. When the draft becomes available for public comment in 2014, organizations can buy it to become familiar with the changes before the official publication in 2015.

Organizations that are still considering getting ISO 9001:2008 certified, should not delay implementation – the business benefits are significant. It takes between six to 12 months from starting a project to getting certified, so there is still enough time to achieve this and then take advantage of the transition period. BSI and other certification bodies will continue to issue existing certificates up until September 2015. Once certified, these companies have until September 2018 to make the necessary changes and get ISO 9001:2015 certified.

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