



➤ ISO 9001 Whitepaper

Understanding the changes

Approaching change

ISO 9001 at a glance

How does ISO 9001 work?

ISO 9001 can be applied to all types and sizes of organizations and helps them put systems and processes in place to ensure that the organization is focussed on understanding and meeting customers' requirements. In order to do this it requires the organization to identify, manage, control and improve those business processes that can have an impact on customer satisfaction.

More about ISO 9001's structure

As an internationally recognized standard for Quality Management, ISO 9001 is built on the Plan-Do-Check-Act (PDCA) approach. This is the operating principle of all ISO management system standards.

Put in the context of quality management, the PDCA approach works as follows:

- **Plan.** Understand your business environment and customer requirements and identify how they affect your organization. Define your objectives, targets and action plans to improve your customer satisfaction – all in line with your company's policy
- **Do.** Implement your quality and management action plans.
- **Check.** Monitor and measure your processes and operations against the company's objectives and report the results.
- **Act.** Take actions to improve your customer satisfaction performance on an ongoing basis.

➤ ISO 9001:2015 The impact on organizations

There are 3 key areas which we believe will have a significant impact.

Many of our clients acknowledge that standards perform better when they are aligned to the business strategies of an organization and therefore the role of top management in their deployment is key. This is the first key change in the new standard. Greater emphasis on the objectives and goal

setting – ensures the new standard puts Leadership at the centre of its thinking

Secondly it's all about integration, a new high level structure has been introduced to ensure that differing standards support each other. Future standards will be consistent in their structure and better integrated to

ISO 9001 resulting in linked processes and activities that deliver value and efficiency.

And thirdly its about managing change in your business, understanding the risks and challenges which may impact on your organizations ability to meet customer requirements and taking a preventative approach.

Who can benefit from **ISO 9001?**

Organizations new to ISO 9001

The new version is more compatible with service organizations both in language and content. With a greater emphasis on risk and opportunity management, its approach is in line with the current thinking of many senior managers.

It is interesting to note that initially during the early stages of the development – the term 'products' was going to be changed to become 'goods' but it hasn't. It remains 'Products and Services'

Organizations already certified.

Many certified organizations will appreciate that it has fewer prescriptive requirements

Remember – this version does not ask or require for ANY procedures – BUT what it does ask you to show is control. You need to demonstrate that you have identified areas and can control the outcomes. How you do that, is up to you.

One of the key objectives of the revision was to enable organizations using multiple management system standards to develop an integrated business management system. Going forward all management system standards will have an identical structure to ISO 9001 enabling easier integration and improved management.

For all organizations this is an opportunity to review your approach, engage with management and deliver a system that is aligned to and supports the achievement of your overall business and quality objectives.

➤ Why ISO 9001 is changing

All ISO management system standards are subject to a regular review under the rules by which they are written. Following a substantial user survey the ISO Committee responsible for ISO 9001 decided that a review was appropriate and created the following objectives to maintain its relevance in today's market place:

- Integrate with other management systems
- Provide an integrated approach to organizational management
- Provide a consistent foundation for the next 10 years
- Reflect the increasingly complex environments in which organizations' operate
- Ensure the new standard reflects the needs of all potential user groups
- Enhance an organization's ability to satisfy it's customers.

➤ ISO 9001: 2015

ISO 9001:2015 will be based on Annex SL – the new high level structure (HLS) that brings a common framework to all management systems. This helps to keep consistency, align different management system standards, offer matching sub-clauses against the top-level structure and apply common language across all standards. Based on the PDCA approach, ISO 9001:2015 will follow this structure.

With the new standard in place, organizations will find it easier to incorporate their quality management system into the core business processes and get more involvement from senior management.

Clause 0:	Introduction
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

➤ What are the significant proposed changes?

The key changes in the proposed standard for 2015 based on the Draft International Standard, published in May 2014, are:

- The emphasis on leadership
- The focus on risk management
- Emphasis on objectives, measurement and change
- Communication and awareness
- Fewer prescriptive requirements.

Leadership and business context

Firstly, the organization will need to determine external and internal issues that are relevant to its purpose, i.e. what are the relevant issues, both inside and out, that have an impact on what the organization does, or that would affect its ability to achieve the intended outcome(s) of its management system. It should be noted that the term 'issue' covers not only problems, which would have been the subject of preventive action in previous standards, but also important topics for the management system to address, such as

any market assurance and governance goals that the organization might set for its management system.

This means that senior managers need to be able to demonstrate an understanding of the wider business environment, social, cultural and regulatory and how that impacts or could impact on the organization's ability to meet customer requirements. In the same context they need to have a grasp of the organization's internal strengths and weaknesses and how these could impact on the ability to deliver their products or services. This will strengthen the concept of business process management including the need now to allocate specific responsibilities for processes, and demonstrate an understanding of the key risks associated with each process and the approach taken to manage, reduce or transfer the risk.

Top management now have a greater involvement in the management system. They have to make sure that the requirements of the management system are integrated into the organization's processes and that the policy and objectives are compatible with the strategic direction of the organization.

➤ What are the significant proposed changes?

Focus on Risk management

Senior management must be able to demonstrate an understanding of business risks and how they could impact on the ability to meet customer requirements. An effective risk management process will be critical for successful certification to the new version.

It must ensure the management system can achieve its intended outcomes and achieve continual improvement. **Clause 6.1 Actions to address risks and opportunities**, is where this is covered and it addresses the 'what, who, how and when' of risk management.

The organization should plan actions to address these risks and opportunities, how to integrate and implement the actions into its management system processes and evaluate the effectiveness of these actions.

SO Risk replaces preventive action. You will need to identify where risk arises and ensure controls are in place to manage it. Remember that risk is defined as 'the effect of uncertainty on an expected result and the new standard makes risk-based thinking more explicit throughout.

Objectives and measurement

The requirements around quality objectives have also been made more detailed. They need to be consistent with the quality policy, measurable (if practicable), monitored, communicated, and updated as appropriate. They also have to be established at relevant functions and levels.

Objectives should include plans on how to achieve them as well as how the results will be evaluated. The organization must determine who will be responsible for the delivery of the objectives, resources required, what needs to be done and by when.

So remember that when establishing quality objectives you need to demonstrate how you plan to achieve them.

And remember that the objectives (results to be achieved) – can be technical, strategic or operational.

Communication and awareness

Clause 7.3 Awareness is now a clause in its own right: people working under an organization's control should be aware of the quality policy, objectives, their contributions to QMS, implications of non-conformities etc. There is an increased emphasis on awareness to ensure that everyone knows the implications of not conforming to the management system requirements.

Which leads into **Clause 7.4 Communication** – internal and external communications are now a requirement. It's up to you to decide what/who/when and how you are communicating. Communication is important for both internal and external stakeholders and an organization must develop a communication plan. It is important to decide who will own the communication and ensure that they have the appropriate authority, competencies and knowledge.

The communication plan can include a variety of mediums including briefings, meetings, seminars, conferences and newsletters

Fewer prescriptive requirements

Much will be made of the fact that the new version of the standard has no requirements for procedures but it does have requirements for documentation. **Clause 7.5 Documented Information** deals with documented information and is split into 3 sub-clauses – general, creating and updating and control.

An organization must decide what information they wish to retain, how these are updated and controlled and adequately protected

Clause 8 Operations includes:

- Requirements for customer communication (from information on products to contracts and invoicing)
- Review of design and development changes
- Information for external providers
- Identification and traceability
- Release of products and services now part of operational controls
- Non-conforming processes, outputs and product and services

All feature a requirement for them to be controlled and you must consider how best to implement these requirements within your own organization.

➤ The revision and transition timeline



Above is the expected timeline for the publication of ISO 9001:2015.

We are currently at the DIS (draft international standard) stage. Following feedback on this an FDIS (final draft

international standard) will be published Summer 2015 and the final publication date is scheduled for September 2015. Organizations will then have 3 years to complete the transition to the new

requirements. Although this sounds a long time our experience suggests that now is the time to start the process!

➤ Where to from here?

Purchase Draft

If you haven't already done so, we recommend that you start preparing now by purchasing a copy of the draft which is available from the BSI online shop.

Training Opportunities

We will be encouraging our customers to begin the transition process as soon as possible with a view to having plenty of time to complete the process before the deadline.

Now would be a good time to start talking about the revision in your business and educating those who need to be aware or involved in the transition – you may want to start thinking about who may require training – for example, anyone involved in the implementation process or internal auditing.

We will be offering various training courses following publication of the FDIS. These will include both requirements training and lead auditor transition training. Also, with such an emphasis on leadership in the new standard, we are looking to offer senior management workshops to help businesses understand the role of leadership in the new revision and what they need to do to prepare.

Some of these training courses are available for booking immediately and all will be advertised on the BSI website so please keep checking.

And remember to talk to your client manager - we are increasing our client manager's training by 25% this year to ensure they have all the knowledge to support you through the transition.

We will be working closely with clients to track how they are progressing and to analyse the need for training and supporting materials.

And also, something that is unique to BSI – when the time comes for you to transition, you will have access to our Client Portal which will give you much better visibility of Non-Conformance actions raised during your BSI assessment. It will also give you more information and better communication with your BSI Client Manager, helping you to drive performance through your management systems. This will be delivered as part of your certification services and therefore comes at no additional cost.

We are also in the process of enhancing a number of applications in our Business Improvement Software which will support clients in their transition activities. This will give you tools to support audit management, document control, corrective action management and risk management.