



ISO 9001 : 2015 Upgrade Guide

Your detailed guide to upgrading a
Quality Management System



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Please Note: This guide is designed to take you through the key differences that exist between ISO 9001 : 2008 and ISO 9001 : 2015. It does not contain the complete content of the standard and should not be used in place of the standard itself.

Back to Basics...

ISO 9001

ISO 9001 is one of the oldest and best-known ISO management system standards used today. It specifies the requirements for an organisation to improve its processes and customers' satisfaction. Organisations that are certified to **ISO 9001** will have a Quality Management System in place that drives continual improvement and meets the requirements of the current version of the **ISO 9001** standard.

Why has the standard been changed?

In order to ensure that ISO management systems remain useful tools for organisations, they are reviewed every 5 years. When the review takes place, the ISO committee decide whether the changes will be minimal or whether a revision is required, as we have seen with **ISO 9001 : 2015**.

The reason a revision takes place is to keep up with the challenges organisations and businesses face today and in the future. Typical challenges that have been considered with the latest revision include, more complex supply chains as a result of increased globalisation and higher customer expectations as a result of the changes we have seen with the use of social media and other information sources used today.



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How much has changed?

Of the Clauses that exist within ISO 9001 : 2008, seven of them will be seeing changes with regard to **ISO 9001 : 2015**.

Clause 4 (Context of the Organisation) is the first of these, since it's a new clause which requires top management to understand how internal and external issues affect the Organisation's ability to meet the expectations of relevant interested parties.

The Organisation needs to determine who are the relevant interested parties, i.e. stakeholders, and their expectations; whether there are particular requirements relevant to the Quality Management System. Reflecting upon the internal and external issues enables a more accurate definition of the Scope of the Management System.

The guiding principle of Clause 4 is therefore to unite the Management System with the Organisation's strategy; encouraging the development of processes that fit the Organisation's purpose and objectives. The Plan-Do-Check-Act (PDCA) methodology is now intrinsic in all processes, so each one should be monitored to ensure that it fits with the Organisation's purpose and objectives.

Clause 5 (Leadership) describes how top management now need to be able to demonstrate a greater involvement in the Management System. Top management must take leadership of the Management System, not simply manage its implementation. They need to ensure the Management System is at the core of the business, not at the periphery. As part of this process, top management have to encourage participation throughout the Organisation to ensure the Management System is operated effectively and fully integrated into the Organisation's processes.

Meanwhile, **Clause 6 (Planning)** specifies the requirements for addressing risks and opportunities. Replacing the need for preventive action. The Organisation needs to understand the risks and opportunities presented by its operations; to identify the risks faced and decide how they will be addressed. On the other hand, the Organisation needs to consider possible opportunities, such as those which promote improvements in quality, and how to maximise such opportunities.

Clause six also sets out changed requirements for Organisations to manage change in a systematic way.

Next, **Clause 7 (Support)** focuses on improving customer satisfaction and includes a requirement to enhance awareness of the Management System within the Organisation. It also requires the Organisation to determine and share the knowledge necessary for the operation of its processes among its staff.

Clause 8 (Operations) brings a number of new requirements in respect of operational processes to ensure quality outcomes. Firstly, there is a new focus on controlling the outsourcing of products and services, ensuring that all outsourced activity is given consideration for risk management. There are also new and enhanced requirements for customer communication. Change control is being applied to changes in customer requests and the processes for production or service provision. This is because change needs to be managed both in terms of receiving orders, the way a product or service is delivered, as well as the documented information required by the Quality Management System.

Clause 8 also requires the Organisation to consider activities that need to be carried out after it has delivered products or services. These may include the provision of a warranty, ongoing maintenance activities and Environmental considerations, such as recycling or take-back under WEEE Regulations.

Next, **Clause 9 (Performance evaluation)** is an entirely new clause, which is made up of existing clauses. These include 'Monitoring and measurement' and 'Management Review'. This new clause will guide Organisations in the effective collection and assessment of evidence to prove their Quality Management System is meeting business objectives.

Finally, a more structured approach has been suggested for **Clause 10 (Improvement)**. It still retains the principle behind the 'non-conformity and corrective action' clause, but is now more detailed in consideration of non-conformity.

Additional 'Benefit'

It follows the Annex SL framework used for all new ISO Management System Standards. This means new Standards will be easier to understand and far more compatible; saving you time during internal and external audits of your Management Systems.

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What are the Benefits of these Changes?

The 2015 version of the **ISO 9001** standard aims to bring a number of benefits that the 2008 version of the standard either briefly touched on or did not previously offer:

- ✓ It has more focus on risk-based thinking
- ✓ It follows the same structure as other ISO management system standards, making system integration much easier
- ✓ It addresses supply chain management more effectively
- ✓ It now puts more emphasis on leadership engagement
- ✓ It helps address risks/opportunities in a more structured manner within Organisations
- ✓ It now uses a simpler language, with common structure and terms
- ✓ It's been adapted to be more user-friendly for service and knowledge-based organisations

What action should you take following this Revision?

If you are currently certified to **ISO 9001** and you wish to maintain your certification, you will need to upgrade your quality management system to the **2015 version** of the standard and seek certification to it. You have a three-year transition period from the date of publication (September 2015) to move to the 2015 version. **This means that, after the end of September 2018, a certificate to ISO 9001 : 2008 may no longer be accepted by third parties.**

Step by Step Guide for 9001 : 2015 transition

Step 1

You will need to amend your existing Manual to ensure that it meets the requirements of the ISO 9001 : 2015 Standard.



Step 2

You will need to implement the changes brought about by the latest version of the standard.



Step 3

Your Manual, Processes and Procedures will need to be reviewed and approved in order to obtain your new ISO 9001 : 2015 Certificate.

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Do I have to upgrade the System?

Quite simply, the answer is no. QMS are able to do this for you because we are offering new and existing clients a comprehensive upgrade package to guide and support you through the whole process.

If you would like QMS to carry out the upgrade for you, our experienced Consultants will start by delivering a presentation which explains the changes brought about by the upgrade and how these will affect your business. They will then follow this up by re-writing your existing manual to ensure it meets the requirements of **ISO 9001 : 2015**.

During this process they will not only be aiming to incorporate the requirements of the new Standard (e.g. context of the organisation, needs and requirements of interested parties, etc) but they will also be able to incorporate any necessary amendments that have been brought about by changes which have taken place within your organisation since your manual was last updated. Once the manual upgrade is complete, your manual will be reviewed and approved by our Technical Team and your new **ISO 9001 : 2015** certificate issued.

With QMS we like to keep things simple and help our customers get the best value from their ISO management systems and that is why you can be confident that you will receive all the support and guidance you need to successfully implement the changes brought about by the **ISO 9001** standard.

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