



ISO Revisions



Final
Standard

➤ Moving from ISO 9001:2008
to ISO 9001:2015
Transition Guide

Successful businesses understand the value of an effective Quality Management System that ensures the organization is focussed on meeting customer requirements and they are satisfied with the products and services that they receive.

This guide has been designed to help you meet the requirements of the new international standard for Quality Management Systems (QMS) ISO 9001 :2015, which replaces ISO 9001:2008. It specifies the requirements for establishing, implementing, maintaining and continually improving a QMS for any organization, regardless of size.

So why is it 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 committee 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 its customers

NB. *This transition guide is designed to be read in conjunction with the latest available version of ISO 9001 – Quality Management Systems – Requirements with guidance for use. It does not contain the complete content of the standard and should not be regarded as a primary source of reference in place of the published standard itself.*



What's in the new standard and what are the benefits for organizations?

ISO 9001 is the world's most recognized management system standard and is used by over a million organizations across the world. The new version has been written to maintain its relevance in today's marketplace and to continue to offer organizations improved performance and business benefits.

With the 2015 version of ISO 9001 you can:

- Introduce an integrated approach with other management system standards
- Bring quality and continual improvement into the heart of the organization
- Increase involvement of the leadership team
- Introduce risk and opportunity management

It's much less prescriptive than the 2008 version and can be used as a more agile business improvement tool. This means that you can make it relevant to the requirements of your own organization to gain sustainable business improvements.

One of the major changes to ISO 9001 is that it brings quality management and continual improvement into the heart of an organization. This means that the new standard is an opportunity for organizations to align their strategic direction with their quality management system. The starting point of the new version of ISO 9001 is to identify internal and external parties who support the QMS. This means that it can be used to help enhance and monitor the performance of an organization.

Our customers tell us they get multiple benefits as a result of implementing and adopting a system that meets the requirements of ISO 9001. The new version of the standard will continue to do this and provide additional value.

The new standard will:

- Help you become a more consistent competitor in the marketplace
- Provide better quality management that helps you to meet present and identify future customer needs
- Increase efficiency that will save you time, money and resources
- Improve operational performance that will cut errors and improve profits
- Motivate, engage and involve staff with more efficient internal processes
- Win more high value customers, and achieve improved customer retention with better customer service
- Broaden business opportunities by demonstrating compliance

Implementing ISO 9001

ISO 9001 is part of a family of quality management related standards. You may find this section useful for further reference in addition to ISO 9001:

- | | |
|--|--|
| <p>1 ISO 9000, Quality management systems - Fundamentals and vocabulary</p> <p>2 ISO 9004, Managing for the sustained success of an organization - A quality management approach</p> <p>3 ISO 10001, Quality management - Customer satisfaction - Guidelines for codes of conduct for organizations</p> <p>4 ISO 10002, Quality management - Customer satisfaction - Guidelines for complaints handling in organizations</p> | <p>5 ISO 10004, Quality management - Customer satisfaction - Guidelines for monitoring and measuring</p> <p>6 ISO 10014, Quality management - Guidelines for realizing financial and economic benefits</p> <p>7 ISO 19011, Guidelines for auditing management systems</p> |
|--|--|

Comparing ISO 9001:2015 with ISO 9001:2008

ISO 9001:2015 is based on Annex SL – the new high level structure. This is a common framework for all ISO 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. It will be easier for organizations to incorporate their QMS into core business processes and get more involvement from senior management.

The Plan-Do-Check-Act (PDCA) cycle can be applied to all processes and to the quality management system as a whole. The diagram here (Figure 1) illustrates how Clauses 4 to 10 can be grouped in relation to PDCA.

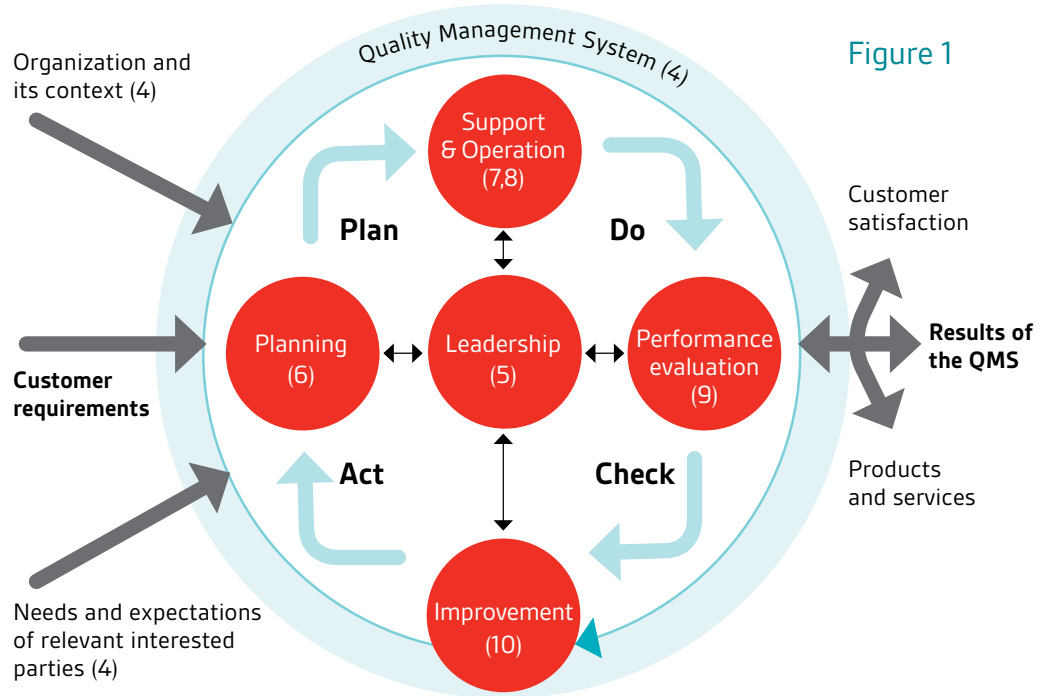


Figure 1

New/updated concept	Comment
Context of the organization	Consider the combination of internal and external factors and conditions that can have an effect on an organization's approach to its products, services, investments and interested parties.
Issues	Issues can be internal or external, positive or negative and include conditions that either affect or are affected by the organization.
Interested parties	Can be a person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity. Examples include suppliers, customers or competitors.
Leadership	Requirements specific to top management who are defined as a person or group of people who directs and controls an organization at the highest level.
Risk associated with threats and opportunities	Refined planning process replaces preventive action and is defined as the 'effect of uncertainty on an expected result.
Communication	There are explicit and more detailed requirements for both internal and external communications.
Documented information	Replaces documents and records.
Performance evaluation	The measurement of quality performance and the effectiveness of the QMS, covering the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results.
Nonconformity and corrective action	More detailed evaluation of both the nonconformities themselves and corrective actions required.
Management review	More detailed requirements relating to inputs and outputs of the review.

The key requirements of ISO 9001:2015

Clause 1: Scope

Clause 1 details the scope of the standard and there has been very little change to this clause from ISO 9001:2008.

Clause 2: Normative references

ISO 9000, Quality Management System - Fundamental and vocabulary is referenced and provides valuable guidance.

Clause 3: Terms and definitions

All the terms and definitions are contained in ISO 9000:2015 – Quality Management – Fundamentals and vocabulary.

Clause 4: Context of the organization

This is a new clause that establishes the context of the QMS and how the business strategy supports this. The 'context of the organization' is the clause that underpins the rest of the new standard. It gives an organization the opportunity to identify and understand the factors and parties in their environment that support the quality management system.

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.

Secondly an organization will also need to identify the "interested parties" that are relevant to their QMS. These groups could include shareholders, employees, customers, suppliers, and even pressure groups and regulatory bodies. Each organization will identify their own unique set of "interested parties" and over time these may change in line with the strategic direction of the organization.

Next the scope of the QMS must be determined. This could include the whole of the organization or specific identified functions. Any outsourced functions or processes will also need to be considered in the organization's scope if they are relevant to the QMS.

The final requirement of Clause 4 is to establish, implement, maintain and continually improve the QMS in accordance with the requirements of the standard. This requires the adoption of a process approach and although every organization will be different, documented information such as process diagrams or written procedures could be used to support this.





Clause 5: Leadership

This clause places requirements on “top management” which is the person or group of people who directs and controls the organization at the highest level. It is no longer the responsibility of an individual or to have a “Management Representative” who is responsible for the QMS. There is an increased emphasis on people “owning” the QMS rather than one individual. The purpose of these requirements is to demonstrate leadership and commitment by leading from the top.

Top management now have greater involvement in the management system and must ensure that the requirements of it are integrated into the organization's processes and that the policy and objectives are compatible with the strategic direction of the organization. The quality policy should be a living document, at the heart of the organization. To ensure this, top management are accountable and have a responsibility to ensure the QMS is made available, communicated, maintained and understood by all parties.

There is also a greater focus on top management to enhance customer satisfaction by identifying and addressing risks and opportunities that could affect this. Top management need to demonstrate consistent customer focus by showing how they meet customer requirements, regulatory and statutory requirements, and also how the organization maintains enhanced customer satisfaction.

In the same context, they need to have a grasp of the organizations internal strengths and weaknesses and how these could have an impact to deliver products or services. This will strengthen the concept of business process management. In addition, top management need to demonstrate an understanding of the key risks associated with each process and the approach taken to manage, reduce or transfer the risk.

Finally, the clause places requirements on top management to assign QMS relevant responsibilities and authorities, but must remain accountable for the effectiveness of the QMS.

Clause 6: Planning

Planning has always been a familiar element of ISO 9001, but now there is an increased focus on ensuring that it is considered with Clause 4.1 ‘context of the organization’ and Clause 4.2 ‘interested parties’.

The first part of this clause concerns risk assessment whilst the second part is concerned with risk treatment. When determining actions to identify risks and opportunities these need to be proportionate to the potential impact they may have on the conformity of products and services. Opportunities could for example include new product launches, geographical expansion, new partnerships, or new technologies.

The organization will need to plan actions to address both risks and opportunities, how to integrate and implement the actions into its management system processes and evaluate the effectiveness of these actions. Actions must be monitored, managed and communicated across the organization.

Another key element of this clause is the need to establish measurable quality objectives. This clause retains some of the requirements contained in Clause 5.4 of the 2008 version but is more specific. Quality objectives now need to be consistent with the quality policy, relevant to the conformity of products and services as well as enhancing customer satisfaction.

The last part of the clause considers planning of changes which must be done in a planned and systemic manner. There is a need to identify the potential consequences of changes, determine who is involved, when changes are to take place, what resource needs to be allocated.

Clause 7: Support

Clause 7 ensures there are the right resources, people and infrastructure to meet the organizational goals. It requires an organization to determine and provide the necessary resources to establish, implement, maintain and continually improve the QMS. Simply expressed, this is a very powerful requirement covering all QMS resource needs and now covers both internal and external resources.

Clause 7.1 builds on Clauses 6.1, 6.2, 6.3 and 7.6 from 2008 and splits into 5 sub-clauses. There are additional requirements to meet applicable statutory and regulatory requirements. The sub-clauses continues to cover requirements for infrastructure and environment for the operation of processes. Monitoring and measuring has been changed to include resources, such as personnel or training.

Organizational knowledge is a new requirement which deals with with requirements for competence, awareness, and communication of the QMS. Personnel must not only be aware of the quality policy, but they must also understand how they contribute to it and what the implications of not conforming are.

There is a key requirement to maintain the knowledge held by an organization to ensure conformity of products and services. This could include the knowledge held by an individual as well as for example, the intellectual property of an organization. Organizations are required to examine whether the current knowledge they have is sufficient when planning changes and whether any additional knowledge is required.

Finally there are the requirements for "documented information". This is a new term, which replaces the references in the 2008 standard to "documents" and "records". Organizations need to determine the level of documented information necessary to control the QMS. This will differ between organizations due to size and complexity. In line with the increased importance of information security in organizations, there is also greater emphasis on controlling access to documented information such as use of passwords. Organizations should also have systems in place to provide a back-up should IT systems crash.

Clause 8: Operation

This clause deals with the execution of the plans and processes that enable the organization to meet customer requirements and design products and services. It includes much of what was previously referred to in Clause 7 of the 2008 version, but there is greater emphasis on the control of processes especially planned changes and review of the consequences of unintended changes, and mitigating any adverse effects as necessary.

The revised version of the standard acknowledges the trend towards greater use of subcontractors and outsourcing. This is demonstrated by the requirement to establish criteria for monitoring the performance of these parties in addition to keeping records used to establish selection criteria.

The Clauses continue to cover 'Requirements for products and services' which remains largely unchanged from the 2008 version. However, it now requires communication with regards to contingency actions where required and also the treatment of customer property. A new requirement for communicating with 'potential' customers is also included, useful for bringing new offerings or solutions to the market.

There are more explicit requirements in terms of the standards or codes of practice that the organization has committed to implement; internal and external resource needs for the design and development of products and services and finally the potential consequences of failure due to the nature of products and services.

There is also a new clause which covers post-delivery activities. This could include activities such as maintenance programmes or work carried out under warranty, and activities covering final disposal or recycling of the product. When determining the extent of these activities organizations must consider the risks associated with a product or service, customer requirements, customer feedback, and any statutory requirements.

Clause 9: Performance evaluation

Performance evaluation covers many of the areas previously featured in Clause 8 of the 2008 version.

Requirements for monitoring, measurement, analysis and evaluation are covered and you will need to consider what needs to be measured, methods employed, when data should be analysed and reported on and at what intervals. Documented information that provides evidence of this must be retained.

There is now an emphasis on directly seeking out information that relates to how customers view the organization. Organizations must actively seek out information on customer perception. This can be achieved in a number of ways including satisfaction surveys, analysis of market share, and through complaints logged. There is now an explicit requirement that organizations must show how the analysis and evaluation of this data is used, especially with regards to the need for improvements to the QMS.

Internal audits must also be conducted and this is largely unchanged from those in the 2008 version. There are additional requirements relating to defining the 'audit criteria' and ensuring the results of the audits are reported to 'relevant' management.

Management reviews are still required but there are additional requirements including the consideration of changes in external and internal issues that are relevant to the QMS. Documented information must be retained as evidence of management reviews.

Clause 10: Improvement

This clause starts with a new section that organizations should determine and identify opportunities for improvement such as improved processes to enhance customer satisfaction. There is also a need to actively look for opportunities to improve processes, products and services, and the QMS, especially with future customer requirements in mind.

Due to the new way of handling preventive actions, there are no preventive action requirements in this clause. However, there are some new corrective action requirements. The first is to react to the nonconformities and take action, as applicable, to control and correct the nonconformities and deal with the consequences. The second is to determine whether similar nonconformities exists or could potentially occur.

The requirement for continual improvement has been extended to cover the suitability and adequacy of the QMS as well as its effectiveness, but it no longer specifies how an organization achieves this.

The change has brought some changes to the terminology used as is shown in the table opposite.

Major differences in terminology between ISO 9001:2008 and ISO 9001:2015

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used – see Clause A.5 for clarification of applicability
Management representative	Not used
Documentation, quality manual, documented procedures, records	Documented information
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider

Documented information

As part of the alignment with other management system standards a common clause on 'Documented Information' has been adopted. The terms "documented procedure" and "record" have both been replaced throughout the requirements text by "documented information". Where ISO 9001:2008 would have referred to documented procedures (e.g. to define, control or support a process) this is now expressed as a requirement to maintain documented information.

Where ISO 9001:2008 would have referred to records this is now expressed as a requirement to retain documented information. Requirements to maintain documented information are detailed throughout the standard and some examples are given. Please read the standard carefully particularly Clause 7.5.

4.3	Scope of the QMS	8.3	Design and development
4.4	QMS and its processes	8.4	Control of externally provided products and services
5.2	QMS policy	8.5	Production and service provision
6.2	QMS objectives	8.6	Release of products and services
7.1	Resources	8.7	Control of non conforming processes
7.2	Evidence of competence	9.1	Control of monitoring, measurement, analysis and evaluation
7.5	Documented information determined by the organization as being necessary for the effectiveness of the QMS	9.2	Evidence of the audit programme(s) and the audit results
8.1	Operational planning and control	9.3	Evidence of the results of management reviews
8.2	Determination of requirements for products and services	10.1	Evidence of the nature of the nonconformities and any subsequent actions taken

Transition guidance

ISO 9001:2015 Transition Timeline



Transition is an opportunity – What do you need to do?

1. Take a completely fresh look at the QMS
2. Attend our suite of transition training courses to understand the differences in more detail
3. Highlight the key changes as opportunity for improvements
4. Make changes to your documentation to reflect new structure (as necessary)
5. Implement new requirements on leadership, risk and context of organization
6. Review effectiveness of current control set
7. Assume every control may have changed
8. Carry out an impact assessment

Your transition journey

BSI has identified a step-by-step journey to help you through the transition and realize the benefits of ISO 9001:2015. We have mapped out a framework which guides you through the options and support available from BSI to ensure you have the knowledge and information you require.

Buy a copy of the International Standard. This will help you become familiar with the new requirements, terminology and layout



Visit the BSI website to access the most up-to-date support and transition material available at bsigroup.com/isorevisions including whitepapers which can help you understand the changes



Look at the wide range of BSI transition training courses available to make sure you fully understand the changes including introduction and implementing courses as well as specific deep-dive modules designed to help you understand core ISO Standard requirements



Download our Implementation Toolkit developed to help you understand, implement and communicate the ISO 9001 revision changes throughout your organization



Consider further services to help implement the changes. BSI has a full range of services available including gap assessments and business improvement tools to help you manage your systems and transition. These can help you transition quickly and gain early adopter advantage.

Compare the differences between ISO 9001:2008 and ISO 9001:2015

Download our Mapping Guide which provides an overview of the changes, deletions, new or enhanced requirements between ISO 9001:2008 and the ISO 9001:2015

Visit bsigroup.com/en-HK

Transition training from BSI

Whatever the specific requirement, BSI has designed a series of training courses that can meet your needs. It's worth noting that all courses have been designed by experts in their fields who have been directly involved in the development of the standards.

Our experienced tutors can help you get to grips with the matters that concern you and your organization directly, whether delivered in-house or as part of an open course where other delegates can share their experience.

The transition courses include:

ISO 9001:2015 Senior management briefing

2 hour face-to-face session

- Understand the purpose of ISO 9001:2015 and the leadership responsibilities outlined in the standard
- Important for top management of organizations transitioning to ISO 9001:2015

ISO 9001:2015 Transition

1 day classroom based training course

- Learn about the new ISO high level structure and the differences between ISO 9001:2008 and ISO 9001:2015
- Essential for anyone involved with an ISO 9001:2015 transition, from managers to implementers and auditors

ISO 9001:2015 Implementing changes

2 day classroom based training course

- Discover how to apply the key changes to ISO 9001:2015 and formulate a transition action plan
- Combines the one day transition course with an additional day of implementation activities
- Recommended for those responsible for transitioning an existing system to ISO 9001:2015

ISO 9001:2015 Auditor transition

2 day classroom based training course

- Learn how to audit the key changes to ISO 9001:2015
- Combines the one day transition course, with a supplementary day of ISO 9001:2015 auditing activities
- Ideal for existing internal and lead auditors who need to convert to ISO 9001:2015

ISO 9001:2015 Deep dive

2 day classroom based training course

- Gain a deeper insight into these important ISO 9001:2015 concepts: process approach, risk-based thinking, control of external provision and auditing leadership.
- Valuable for anyone involved with an ISO 9001:2015 transition, from managers to implementers and auditors.



Additional resources

There are a variety of materials which can be accessed online at www.bsigroup.com/iso-9001 and consists of:

The importance of leadership

The new standard has an entire clause devoted to Leadership and is one of the most significant changes. This whitepaper explains why management are now required to take a more active role in the QMS to ensure it is implemented, embedded, communicated and maintained.

REVISED: ISO 9001 Frequently Asked Questions

Here we aim to address those initial questions that you may have as you begin your journey towards the new standard.

Introducing Annex SL

The new generic framework with core text, common terms and definitions and the blueprint for all management system standards going forward – understand more about the structure in our whitepaper.

ISO 9001 Whitepaper: Managing risk in quality management

This whitepaper explains the background to the revision, how risk is being incorporated into the revised standard and the benefits for ISO 9001 clients.

PLUS:

- Old-to-new ISO 9001 Mapping Guide
- Self-assessment checklist
- Transition journey to the new ISO 9001:2015

Additional services

We also have a wide range of services to help you to implement the changes and understand how well you are doing. These include:

Gap assessment

A transition gap assessment is a pre-assessment service where we take a closer look at your transition plan and quality management system comparing it with the requirements of ISO 9001:2015. As a first step in your transition journey with BSI, the gap assessment can help confirm the areas of your system already compliant and any gaps in your system, saving you time and money.

Business improvement tools

When you implement the revised standard it's extremely important to manage and maintain it in the most efficient manner possible. Best practice organizations do this by deploying business improvement tools such as BSI Action Manager or Entropy software, as one of our clients told us, 'it's literally like having an extra member of the team'. Clients have experienced 50% reduction in the time to implement their management system.

Why BSI?

BSI has been at the forefront of ISO 9001 since the start. And it was originally based on BS 5750 which was developed by BSI. Since 1994 BSI has held the Secretariat of the International Committee developing and evolving ISO 9001 to where it is today. That's why we're best placed to help you understand and transition to the new standard.

At BSI we create excellence by driving the success of our clients through standards. We enable others to perform better, manage risk and achieve sustainable growth.

For over a century our experts have been challenging mediocrity and complacency to help embed excellence into the way people and products work. We make excellence a habit

Our products and services

We provide a unique combination of complementary products and services, managed through our three business streams; Knowledge, Assurance and Compliance.

Knowledge

BSI works with business experts, government bodies, trade associations and consumer groups to capture best practice and structure the knowledge all organizations need to succeed. The majority of the widely used and implemented international standards were originally shaped by BSI, for example ISO 14001, Environmental Management and ISO/IEC 27001 for Information Security.

Assurance

Independent assessment of the conformity of a process or product to a particular standard ensures that our clients perform to a high level of excellence. We help our clients understand how they are performing, thereby identifying areas of improvement from within

Compliance

To experience real, long-term benefits, our clients need to ensure ongoing compliance to a standard so that it becomes an embedded habit. We train our clients to understand standards and how to implement them, as well as provide added value and differentiated management tools to facilitate the process of ongoing compliance.

To find out more visit:
bsigroup.com/en-HK

