ISO 9001 Transition guide

ISO Revisions

Moving from ISO 9001:2008 to ISO 9001:2015

The new international standard for quality management systems

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

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 the previous version ISO 9001:2008. It specifies the requirements for establishing, implementing, maintaining and continually improving a QMS for any organization, regardless of type or 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 ISO user survey the committee decided that a review was appropriate and created the following objectives to maintain its relevance in today's market place and in the future:

- Integrate with other management systems
- Provide an integrated approach to organizational management
- Reflect the increasingly complex environments in which organizations operate
- Enhance an organization's ability to satisfy it's 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.*

Why adopt a Quality Management System standard?

Manage quality whatever the size of your business with a standard that's recognized the world over and used by over one million organizations.

With ISO 9001 Quality Management you can;

- Consistently meet customers' expectations
- Differentiate your company and win more business
- Improve company performance (increasing efficiency and bottom line)

An ISO 9001 quality management system will help you to continually monitor and manage quality whether you run a single site operation or a global business. As the world's most widely recognized quality management standard, it outlines ways to achieve, as well as benchmark, consistent performance and service.

These are some of the benefits that our customers tell us they have received as a result of adopting and implementing a system that meets the requirements of ISO 9001.

The standard allows:

- You to become a more consistent competitor in your marketplace
- Better quality management helps you meet customer needs
- More efficient ways of working will save time, money and resources
- Improved operational performance will cut errors and increase profits
- Motivate and engage staff with more efficient internal processes
- Win more high value customers 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:

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

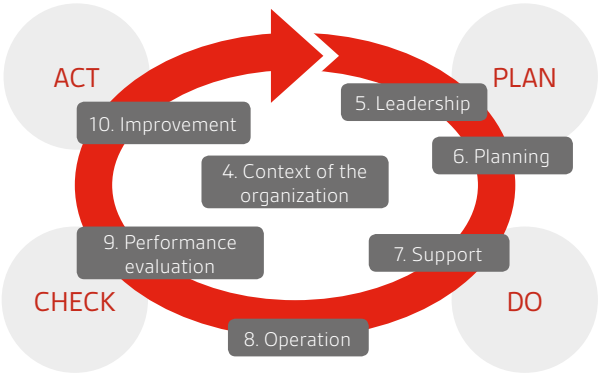
Comparing the latest version of ISO 9001 with ISO 9001:2008

ISO 9001:2015 will be based on Annex SL – the new high level structure (HLS) that brings a common framework to 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.

With the new standard structure 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.

Based on Annex SL, Fig. 1 shows how the clauses of the new high level structure could also be applied to the Plan-Do-Check-Act cycle. The PDCA cycle can be applied to all processes and to the quality management system as a whole.

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 and 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

Clause 4: Context of the organization

This is a new clause that establishes the context for the QMS. 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.

The final requirement in clause 4 is to establish, implement, maintain and continually improve the QMS in accordance with the requirements the standard.

Clause 5: Leadership

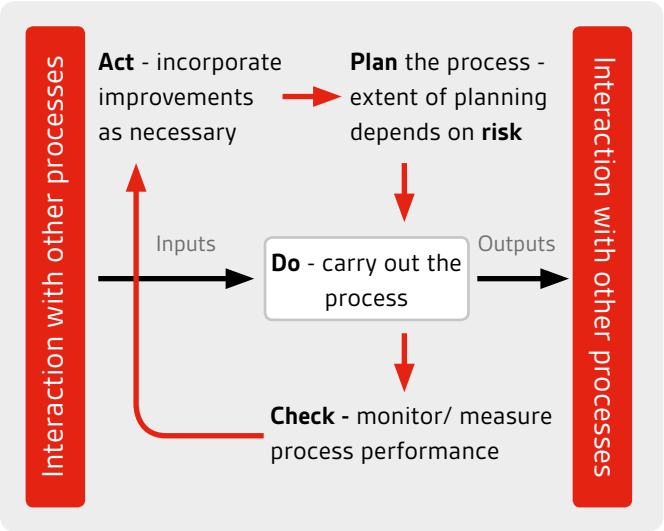
This clause places requirements on 'top management' which is the person or group of people who directs and controls the organization at the highest level. The purpose of these requirements is to demonstrate leadership and commitment by leading from the top.

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. 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.

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

This clause works with Clauses 4.1 and 4.2 to complete the new way of dealing with preventive actions. The first part of this clause concerns risk assessment whilst the second part is concerned with risk treatment. 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.



Clause 7: Support

This clause begins with a requirement that organizations shall 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. The clause continues with requirements for competence, awareness and communication.

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'.

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.

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 analyzed and reported on and at what intervals.

Internal audits must also be conducted at planned intervals with management reviews taking place to review the organization's management system and ensure its continuing suitability, adequacy and effectiveness.

Clause 10: Improvement

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 nonconformities and take action, as applicable, to control and correct the nonconformity and deal with the consequences. The second is to determine whether similar nonconformities exist, 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 shown in the table below:

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 Annex 4 for clarification of applicability
Documentation, records	Documentated information
Work environment	Environment for the operation of processes
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 7.5.

4.3	Scope of the QMS
4.4	QMS and its processes
5.2	QMS policy
6.2	QMS objectives
7.1.5	Monitoring and measuring resources
7.2	Evidence of competence
7.5	Documented information determined by the organization as being necessary for the effectiveness of the QMS
8.1	Operational planning and control
8.2	Determination of requirements for products and services
8.3.5	Design and development
8.4	Control of externally provided products and services
8.5.1	Production and service provision
8.5.2	Identification and traceability
8.5.6	Control of changes
8.7	Control of non conforming processes
9.1	Control of monitoring, measurement, analysis and evaluation
9.2	Evidence of the audit programme(s) and the audit results
9.3	Evidence of the results of management reviews
10.1	Evidence of the nature of the nonconformities and any subsequent actions taken
10.3	Evidence of continual improvement

Mapping table

The table below is a clause by clause comparison between the requirements of the proposed 2015 version and the current 2008 standard.

ISO DIS 9001	ISO 9001:2008
4 Context of the organization	**1.0** Scope
4.1 Understanding the organization and its context	**1.1** General
4.2 Understanding the needs and expectations of interested parties	**1.1** General
4.3 Determining the scope of the quality management system	**1.2** Application **4.2.2** Quality manual
4.4 Quality management system and its processes	**4** Quality management system **4.1** General requirements
5 Leadership	**5** Management responsibility
5.1 Leadership and commitment	**5.1** Management commitment
5.1.1 Leadership and commitment for the quality management system	**5.1** Management commitment
5.1.2 Customer focus	**5.2** Customer focus

Continued >>

Mapping table – continued

ISO DIS 9001	ISO 9001:2008
5.2 Quality policy	**5.3** Quality policy
5.3 Organizational roles, responsibilities and authorities	**5.5.1** Responsibility and authority **5.5.2** Management representative
6 Planning for the quality management system	**5.4.2** Quality management system planning
6.1 Actions to address risks and opportunities	**5.4.2** Quality management system planning **8.5.3** Preventive action
6.2 Quality objectives and planning to achieve them	**5.4.1** Quality objectives
6.3 Planning of changes	**5.4.2** Quality management system planning
7 Support	**6** Resource management
7.1 Resources	**6** Resource management
7.1.1 General	**6.1** Provision of resources
7.1.2 People	**6.1** Provision of resources
7.1.3 Infrastructure	**6.3** Infrastructure
7.1.4 Environment for the operation of processes	**6.4** Work environment
7.1.5 Monitoring and measuring resources	**7.6** Control of monitoring and measuring equipment
7.1.6 Organizational knowledge	**New**
7.2 Competence	**6.2.1** General **6.2.2** Competence, training and awareness
7.3 Awareness	**6.2.2** Competence, training and awareness
7.4 Communication	**5.5.3** Internal communication
7.5 Documented information	**4.2** Documentation requirements
7.5.1 General	**4.2.1** General
7.5.2 Creating and updating	**4.2.3** Control of documents **4.2.4** Control of records
7.5.3 Control of documented Information	**4.2.3** Control of documents **4.2.4** Control of records
8 Operation	**7** Product realization
8.1 Operational planning and control	**7.1** Planning of product realization
8.2 Determination of requirements for products and services	**7.2** Customer-related processes
8.2.1 Customer communication	**7.2.3** Customer communication

Continued >>

Mapping table – continued

ISO DIS 9001	ISO 9001:2008
8.2.2 Determination of requirements related to products and services	**7.2.1** Determination of requirements related to the product
8.2.3 Review of requirements related to the products and services	**7.2.2** Review of requirements related to the product
8.3 Design and development of products and services	**7.3** Design and development
8.3.1 General	**New**
8.3.2 Design and development planning	**7.3.1** Design and development planning
8.3.3 Design and development Inputs	**7.3.2** Design and development inputs
8.3.4 Design and development controls	**7.3.4** Design and development review **7.3.5** Design and development verification **7.3.6** Design and development validation
8.3.5 Design and development outputs	**7.3.3** Design and development outputs
8.3.6 Design and development changes	**7.3.7** Control of design and development changes
8.4 Control of externally provided products and services	**7.4.1** Purchasing process
8.4.1 General	**7.4.1** Purchasing process
8.4.2 Type and extent of control of external provision	**7.4.1** Purchasing process **7.4.3** Verification of purchased product
8.4.3 Information for external providers	**7.4.2** Purchasing information
8.5 Production and service provision	**7.5** Production and service provision
8.5.1 Control of production and service provision	**7.5.1** Control of production and service provision
8.5.2 Identification and traceability	**7.5.3** Identification and traceability
8.5.3 Property belonging to customers or external providers	**7.5.4** Customer property
8.5.4 Preservation	**7.5.5** Preservation of product
8.5.5 Post-delivery activities	**7.5.1** Control of production and service provision
8.5.6 Control of changes	**7.3.7** Control of design and development changes
8.6 Release of products and services	**8.2.4** Monitoring and measurement of processes **7.4.3** Verification of purchased product
8.7 Control of nonconforming process outputs, products and services	**8.3** Control of nonconforming product
9 Performance evaluation	**New**
9.1 Monitoring, measurement, analysis and evaluation	**8** Measurement, analysis and improvement
9.1.1 General	**8.1** General
9.1.2 Customer satisfaction	**8.2.1** Customer satisfaction

Continued >>

Mapping table – continued

ISO DIS 9001		ISO 9001:2008	
9.1.3	Analysis and evaluation	**8.4**	Analysis of data
9.2	Internal audit	**8.2.2**	Internal audit
9.3	Management review	**5.6**	Management review
10	Improvement	**8.5**	Improvement
10.1	General	**8.5.1**	Continual improvement
10.2	Nonconformity and corrective action	**8.3** **8.5.2**	Control of nonconforming product Corrective action
10.3	Continual Improvement	**8.5.1**	Continual improvement

Transition guidance

ISO 9001:2015 Transition Timeline

September 2015 publication

September 2015 start of three years transition period to September 2018

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

1. Take a completely fresh look at the QMS
2. Attend a one–day transition course to understand the differences
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 Final Draft International Standard (FDIS) and/or International Standard on publication. 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, Entropy software to help you manage your systems and transition assessments for organizations keen to transition quick and gain early adopter advantage

ISO Revisions

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 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/Lead 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 Leadership Auditing
- Valuable for anyone involved with an ISO 9001:2015 transition, including managers to implementers and auditors

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 Revisions

Additional resources

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

NEW: ISO 9001 Whitepaper - Understanding the changes

With the key changes in the proposed standard for 2015 based on the Draft International Standard, published in May 2014, this Whitepaper looks at those changes in detail, the timeline and what you can do now to prepare.

NEW: ISO 9001 Frequently Asked Questions

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

ISO 9001:2015 Revision Webinar

Learn more about the new ISO 9001 revision and how the changes will affect your business.

ISO 9001 Whitepaper - The history and future of ISO 9001

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.

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
- Old-to-new ISO 9001 Transition Guide
- Self-assessment checklists for the new ISO 9001
- Your Transition Journey to the new ISO 9001:2015

We know ISO 9001; BSI shaped the original standard.

BSI...

- Shaped the original BS 5750 which was the original standard
- Has the most highly trained and knowledgeable assessors
- Offers the widest range of support solutions in the market place
- Is the number one certification body in the UK, USA and Korea
- Looks after more than 70,000 global clients
- Has an unrivalled international reputation for excellence

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