

➤ ISO 9001:2015 Readiness Review

ISO Revisions
Latest update



Company Name	Contact Name
Address	Job Title
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Certification No.	Email

BSI is committed to ensuring a smooth assessment for all clients wishing to certify to ISO 9001:2015, whether you are new to the standard or transitioning from ISO 9001:2008.

This document should be used in conjunction with ISO 9001:2015 and allows you to detail how you intend to meet the requirements of the new standard. In addition, ISO 9000 is the normative document containing Terms and Definitions, it is recommend that ISO 9000 is used in conjunction with ISO 9001.

Guidance has been provided within each of the clauses as well as within the standard itself.

Please complete this form at least 8 weeks before your assessment to allow us to review the contents before your on-site assessment.

Please do not provide supplementary documentation, please list your processes, procedures, documents or records that support the way in which you meet the intent of the requirements.

Your client manager or assessor is here to support you on your journey, so please talk to them about your plans.

Clause 4 – Context of the organization

This is a new clause that underpins ISO 9001:2015 and establishes the context of the Quality Management System (QMS). It gives you the opportunity to identify all internal and external issues that are relevant, and may affect, the strategic direction of the organization and the QMS. You will also need to identify 'interested parties' that are relevant to the QMS. These groups can include shareholders, customers, regulatory groups etc.

Finally, you'll need to establish, implement, maintain and continually improve the QMS.

Clause 4.1 – Understanding the organization and its context – **NEW REQUIREMENT**

There is no equivalent clause in ISO 9001:2008, however guidance is provided within the notes supporting Clause 4.1. You will need to be able to demonstrate that you have identified external and internal issues, which you monitor and review. Please provide information:

- about the internal and external issues relevant to your organization
- the process of monitoring the internal and external issues
- how you have considered the impact of any changes to the issues

Clause 4.2 – Understanding the needs and expectations of interested parties – NEW REQUIREMENT

Again there is no equivalent clause in ISO 9001:2008 but guidance is provided within the notes supporting Clause 4.2 and within Annex A3. You will need to be able to demonstrate that you have identified, monitor and review all interested parties that are relevant to the QMS and their requirements. Please provide:

- Information about interested parties who affect or could affect your QMS
- Information about their needs and expectations
- The process of monitoring and reviewing interested parties and their needs.

Clause 4.3 – Determining the scope of the quality management system – ENHANCED REQUIREMENT

There was already a requirement in ISO 9001:2008 to document the scope of the QMS. The new standard now requires you to consider the 'context of the organization' (Clause 4.1) and 'interested parties' (Clause 4.2). You'll need to identify any boundaries and applicability of the QMS. This could include the whole organization or specific functions. Please provide information on:

- The boundary and applicability information on the scope of your QMS
- The products and / or services included in your quality management system
- Has the scope of your QMS changed and if so how?

Clause 4.4 – Quality management system and its processes – OTHER CHANGES

The final requirement is for you to establish, implement, maintain and continually improve your QMS. Whilst there was a similar clause (Clause 4.1) in the 2008 version, this now requires the adoption of a process approach. Although every organization will be different, documented information such as process diagrams or written procedures could support this. Please provide information on the process-based QMS including:

- List of processes, process sequences and interactions, methods to manage the processes, resources to support processes, process responsibilities and authorities, risks and opportunities of each process and how you ensure the system improves the processes and the quality management system.

Clause 5 – Leadership

Clause 5 is a new clause, but covers some requirements that were in ISO 9001:2008. Top management are now required to have greater involvement in the QMS and must ensure that the requirements are integrated into the organization's processes and that the policy and objectives are compatible with the strategic direction of the organization.

There is also greater focus on top management to enhance customer satisfaction and they have a grasp of the organizations internal strengths and weaknesses and how these can impact the delivery of products or services.

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 5.1 – Leadership and commitment – **NEW REQUIREMENT**

There is no equivalent clause in ISO 9001:2008 however the requirements within the clause are generally self-explanatory. You'll need to provide information on how top management ensure the QMS is compatible with the strategic direction as well as taking responsibility and promoting risk based thinking, customer focus and improvement. Please provide information on how top management ensures the QMS achieves the intended results.

Clause 5.2 – Policy – **OTHER CHANGES**

This clause represents only minor changes from Clause 5.3 in ISO 9001:2008. Top management need to establish, implement and maintain a quality policy and ensure it is communicated both within the organization but also to relevant interested parties as appropriate. Additional guidance is provided within the clause. Please provide information on when you policy was reviewed/amended and details of any changes that were required.

Clause 5.3 – Organizational roles, responsibilities, and authorities – **OTHER CHANGES**

The requirements within this clause are broader than those specified in the 2008 version. They now apply to all "relevant roles" rather than only to 'those involved in the management system'. Top management need to ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood throughout the organization. However there is no fundamental change in approach when taking into account the guidance provided with the clause. Annex B also provides information on additional standards which may help. Please provide information on how top management have established and communicated responsibilities and authorities for the effective operation 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 the 'context of the organization' and 'interested parties'. Now there is a requirement to identify risks and opportunities, the impact these may have on the conformity of products and services and how you plan to address these. Finally you will need to consider planning for changes in a systematic manner.

Clause 6.1 – Actions to address risks and opportunities – **ENHANCED REQUIREMENT**

This clause requires you to identify the risks and opportunities that need to be managed. You need to consider the outputs from 'understanding the context of the organization' (Clause 4.1) and 'interested parties' (Clause 4.2). The requirements in relation to contingency planning and preventive action from the 2008 version are now addressed within this clause.

This is not a risk assessment; it is risk-based thinking. Annex A4 provides more guidance. Please provide information on how the risks and opportunities have been identified and how actions to address these have been managed.

Clause 6.2 – Quality objectives and planning to achieve them – **OTHER CHANGES**

This clause retains some of the requirements contained in Clause 5.4 of the 2008 version but is more specific. Quality objectives need to be consistent with the quality policy, relevant to the conformity of products and services as well as enhancing customer satisfaction. Once defined, the objectives need to be monitored, communicated and updated as appropriate.

Whilst this clause is more specific than previous, there is no fundamental change in the approach. Guidance is contained within the clause contents.

Please provide information on how the organization ensures objectives are relevant to the organizations policy, how they are communicated and monitored.

Clause 6.3 – Planning of changes – **ENHANCED REQUIREMENT**

There is little change to Clause 5.4.2 of ISO 9001:2008 in that the integrity of the QMS must be maintained when planning changes. However you now need to consider the purpose of change, why it's being made, potential consequences and the resources and (re) allocation of responsibilities. Please provide information on how the organization manages and implements change.

Clause 7 – Support

Clause 7 ensures that you have the right resources, people and infrastructure required to meet your organizational goals. Organizational knowledge is a new requirement for competence, awareness and communication of the QMS. A key requirement is to ensure that knowledge is held to ensure conformity of the products or service. Finally there are the requirements for 'documented information' which replaces 'documents' and 'records' in the 2008 version.

Clause 7.1 – Resources – **ENHANCED REQUIREMENT**

This clause builds on Clauses 6.1, 6.2, 6.3 and 7.6 from 2008 and splits into 6 sub-clauses. You now need to consider internal and external providers and meet customer and applicable statutory and regulatory requirements. Monitoring and measuring equipment has been changed to resource; this could be visual inspection, largely the same requirements as the 2008 standard.

A new sub-clause requires you to identify what information you need and how knowledge can be updated and maintained within the organization, for example by addressing succession planning.

Additional guidance is included within the clause and Annex A7.

Please provide information on how internal and external resource requirements are considered for the establishment, implementation and improvement of the management system. Also on how knowledge required has been determined for the operation of its processes and achievement of conformity of products and services.

Clause 7.2 – Competence – **OTHER CHANGES**

There are no significant changes within this clause; it's a combination of Clauses 6.2.1 and 6.2.2 from 2008. You will need to determine the competency of people and ensure that these are met and maintained. This applies to any person affecting the organizations quality performance including contractors. Within this clause you are required to retain documented information as evidence of competence.

Please provide information on those persons who can affect the performance of the QMS are competent on the basis of appropriate education, training, or experience, and how the information required for the effective implementation and operation of the QMS have been determined.

Clause 7.3 – Awareness – **OTHER CHANGES**

This clause covers awareness of the quality policy, objectives and the implications of not conforming to the requirements. However there is no fundamental change in approach when taking into account the guidance provided within the clause. Please provide information on how you have raised awareness of the policy and the QMS requirements.

Clause 7.4 – Communication – ENHANCED REQUIREMENT

Similar to the requirements within the 2008 version, however this has now been expanded to include both internal and external communications relevant to the quality management system. You will need to think about what you need to communicate, when, to whom and how. Please provide information on how this is achieved.

Clause 7.5 – Documented information – OTHER CHANGES

Clause 7 replaces 'documented procedures' and 'records' from the 2008 version with 'documented information'. Additional requirements now include the activity to control 'distribution' of necessary documented information, especially with regards to permission to view and authority to change. However there is no fundamental change in approach when taking into account the guidance provided within the clause contents of 7.5.3. Please provide information on how you control the distribution of necessary documentation

Clause 8 - Operation

This clause deals with the execution of the plans and process that meet the requirements for the provision of products and services and is the clause that covers most QMS specific requirements. The standard acknowledges the trend towards a greater use of sub-contractors and outsourcing and these must be monitored effectively.

There is also a new clause covering post-delivery activities such as maintenance programmes or work carried out under warranty.

Clause 8.1 – Operational planning and control – ENHANCED REQUIREMENT

This clause is comparable with the requirements in Clause 7.1 of the 2008 version but is more specifically defined. For example processes needed to meet requirements, need to be planned, implemented and controlled, as do the actions identified in 6.1. Requirements in relation to change control and outsourced processes have also been introduced. Please provide information on how this is achieved.

Clause 8.2 – Requirements for products and services – OTHER CHANGES

Although these requirements have been enhanced from the previous version, Clause 8.2.1 remains largely unchanged. However, it now requires communication with regards to contingency actions where required and also the treatment of customer property. The requirements cover communication in Clause 8.2.2 Communication to 'potential' customers which is useful for bringing new offerings or solutions to the market place. It has the ability to meet the defined requirements and substantiate the claims for the products and services it offers. Please provide information on how this is achieved.

Clause 8.3 – Design and development of products and services – OTHER CHANGES

This clause requires the organization to establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services. Where the detailed requirements of the organization's products and services are not already established or not defined by the customer or by other interested parties, the organization shall establish, implement and maintain a design and development process. Clause 8.3.3 is more explicit in terms of c) standards or codes of practice that the organization has committed to implement; d) internal and external resource needs for the design and development of products and services; e) the potential consequences of failure due to the nature of the products and services Please provide information on how this is achieved.

Finally Clause 8.3.5 is largely unchanged in relation to Clause 7.3.3 in the 2008 version, but with additional requirements to include or reference monitoring and measuring requirements, and acceptance criteria, as applicable.

Clause 8.4 – Control of externally provided processes, products and service – OTHER CHANGES

This clause is very similar to Clauses 7.4.1, 7.4.2 and 7.4.3 of 2008 covering the control of externally provided processes, products and services. You need to ensure personnel are competent and have the necessary qualifications, their interactions with the QMS and control the external provider's performance.

An additional requirement from the 2008 version is the need to establish specific criteria for monitoring performance of and communicate with external providers. Please provide information to address these changes.

Clause 8.5 – Production and service provision – OTHER CHANGES

Clause 8.5.1 can be aligned to a combination of Clauses 7.5.1 and 7.5.2 of 2008, and focuses on activities to be performed and achieved results. There are no significant changes to 'identification and traceability' (Clause 8.5.2), although it should be noted that process outputs are the results of any activities which are ready for delivery to the organization's customer or to the next phase in the process.

The requirement of Clause 8.5.3 is enhanced and now covers property belonging to customers and external providers. This must be identified, verified, protected and safeguarded and if damaged, unsuitable or lost must be reported to the customer or external provider. Please provide information how you comply with this change.

Part of the original Cause 7.5.5 in 2008 is now included within the notes.

Clause 8.6 – Release of products and services – OTHER CHANGES

This clause largely remains unchanged from the 2008 versions and now covers the arrangements for the release of products and services. You will need to verify that the products and services have met the customer requirements and retain documented information on the release.

Clause 8.7 – Control of nonconforming output – OTHER CHANGES

Again, largely unchanged other than process outputs and services now included. You are required to ensure that outputs that do not conform to their requirements are identified and controlled. There are no requirements for a procedure but you are required to retain documented information that describes the nonconformity, the actions taken and the concessions obtained.

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'll need to consider what needs to be measured, methods employed, when data should be analysed and reported on. Documented information that provides evidence of this must now be retained.

Clause 9.1 – Monitoring, measurement, analysis and evaluation – OTHER CHANGES

The requirements within this clause are now defined more specifically than those in 2008 version. For example you will need to determine when monitoring and measurement shall be performed and when the results will be analysed and evaluated. However, there is no fundamental change in the approach when taking into account the guidance provided within the clause contents and the Quality Management Principles.

Clause 9.2 – Internal Audit – OTHER CHANGES

Additional requirements are now specified relating to defining the 'audit criteria' and ensuring that the results of the audits are reported to "relevant management", however there is no fundamental change in approach when taking into account the guidance provided within the clause contents. Please provide information on how your organization addresses internal audit requirements and details of any changes that have had to be made to the existing provision if required.

Clause 9.3 – Management Review – OTHER CHANGES

The management review process contained within Clause 5.6 of the 2008 version remain, however there are additional requirements including the consideration of changes in external and internal issues that are relevant to the QMS; however there is no fundamental change in approach when taking into account the guidance provided within the clause contents. Please provide information on how your organization addresses these changes.

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.

Clause 10.1 – General – OTHER CHANGES

This clause covers the general need for improvement, whether to meet existing and future customer requirements, correcting or reducing undesired effects or improving the performance or effectiveness of the system. Please provide information on how your organization has addressed these changes

Clause 10.2 – Nonconformity and corrective action – OTHER CHANGES

There are now additional requirements specified relating to nonconformity management requiring the organization to make changes to the QMS, if necessary. However there is no fundamental change in approach when taking into account the guidance provided within the clause contents. Note that preventive action requirements are now addressed within Cause 6.1. Please provide information on how your organization has addressed these changes.

Clause 10.3 – Continual Improvement – OTHER CHANGES

Finally, there are additional requirements specifically related to continually improving the 'suitability' and 'adequacy' of the QMS and not just the 'effectiveness'. Notes within the clause provide further guidance. Please provide information on the process for determining the suitability and adequacy to address this clause.