Security.Improved

ISO 9001:2008 and ISO 9001:2015 Compared

AN NSI GUIDE FOR APPROVED COMPANIES

Introduction:

This comparison guide has been developed to help you understand the changes in BS EN ISO 9001:2015 (ISO 9001:2015) published on 22nd September 2015. It attempts to identify the key changes and criteria specific changes approved companies need to take into account.

Summary of the principal changes between ISO 9001:2008 and ISO 9001:2015

- The new standard adopts the high-level structure and terminology of Annex SL. Annex SL was developed to ensure all future ISO management system standards would share a common format, irrespective of the specific discipline to which they relate. Annex SL prescribes a high-level structure, identical core text, and common terms and definitions. This means that even when requirements are essentially unchanged between ISO 9001:2008 and ISO 9001:2015, these are frequently found under a new clause/sub-clause heading.
- Clause 5, previously “Management Responsibility”, now becomes “Leadership”. Top management are required to demonstrate they engage in key quality management system activities as opposed to simply ensuring these activities occur. This further reinforces the ISO9001:2008 requirements for top management to be able to demonstrate they are actively involved in the operation of their quality management system. The removal of all references to the role of “management representative” reinforces a desire to see quality management systems embedded into routine business operations, rather than operating as an independent system in its own right with its own dedicated management structure. It does not, however preclude an organisation from having such a role (see below)
- Two new clauses (4.1 and 4.2) are introduced relating to the context of the organisation. Organisations will be required to identify explicitly any internal and external issues that may impact their quality management system’s ability to deliver its intended results. They must also understand the needs and expectations of “interested parties” i.e. those individuals and organisations that can affect, be affected by, or perceive themselves to be affected by, the organisation’s decisions or activities.
- ISO 9001:2015 places a greater emphasis on the definition of scope of the quality management system than ISO 9001:2008 does. Scope sets the boundaries for, and identifies the applicability of, an organisation’s quality management system. Clause 4.3 requires scope to be determined in consideration of the organisation’s context.
- While ISO 9001:2008 promoted the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, clause 4.4 of ISO 9001:2015 sets out specific requirements designed to enforce its adoption.
- References to preventive action have disappeared. However, the core concept of identifying and addressing potential mistakes before they happen very much remains. ISO 9001:2015 talks in terms of risk and opportunities. Organisations must evidence they have determined, considered and, where necessary, taken action to address any risks or opportunities that may impact (either positively or negatively) their quality management system’s ability to deliver its intended outcomes or that could impact customer satisfaction.
- The term “product” is replaced by “products and services”. Previously, the inclusion of services as products was implicit. By including explicit reference to services, the standard writers are attempting to reinforce that ISO 9001 is applicable to all suppliers, not just those providing physical products. Note: a subcontractor is considered a supplier.
- ISO 9001:2015 clause 10 recognises that incremental (continual) improvement is not the only improvement profile. Improvement can also arise as a result of periodic breakthroughs,

reactive change or as a result of reorganisation. Thus, the title of this clause is now "Improvement" as opposed to ISO 9001:2008 8.5.1 referring to "Continual improvement".

- The phrase "externally provided products and services" replaces "Purchasing". Clause 8.4 addresses all forms of external provision, whether it is by purchasing from a supplier, through an arrangement with an associate company, through the outsourcing of processes and functions of the organisation, or by any other means. Organisations are required to take a risk-based approach to determine the type and extent of controls appropriate to each external provider and all external provision of products and services.
- References to a documented quality manual, documented procedures and to quality records have been removed. Instead, throughout ISO 9001:2015 there are specific references to "Documented Information". This is information the organisation is required to keep, control and maintain. How it wishes to record this information is up to the organisation itself; formats and storage methods are not prescribed.
- The phrase "documented information shall be maintained" within the new standard is the equivalent of the previous need for procedures, manuals or other forms of documented systems etc. Organisations should ensure they have this information available.
- The phrase "documented information shall be retained" within the new standard is the equivalent of the previous need for records to be maintained. Organisations should ensure they can provide evidence to their auditor.
- There has been a conscious attempt to revisit the wording of the standard with a view to making the requirements easier to understand and to aid its translation.
- Where requirements were previously implied, the wording of the standard has been amended to make them explicit. Understanding the organisation and its context, and the adoption of a process-based approach, are perhaps the most significant examples but these are not the only instances.
- Terms and definitions continue to reside in a separate standard, ISO 9000:2015. It is important organisations have a copy of this document.
- ISO 9001:2015 has three informative annexes which we would recommend organisations ensure they are familiar with.
    - Annex A provides clarification on the new structure, terminology and concepts underpinning the standard
    - Annex B details refreshed Quality Management Principles, drawn across from ISO 9004.
    - Annex C details related quality management system standards from ISO's 10000 series. These are designed to provide assistance to organisations seeking to establish or improve their quality management performance.

Key changes approved companies do not need to make

Organisations do not need to:

- Remove their management representatives. While there is no requirement in ISO 9001:2015 for a management representative, this does not prevent organisations from choosing to retain this role if they so wish. Be aware, however, some of the duties traditionally assigned to the management representative by top management may, in future, need to be undertaken directly by top management themselves.
- Throw out their Quality Manuals and Documented Procedures. While ISO 9001:2015 sets out no requirement for organisations to hold either a Quality Manual or Documented Procedures, if this documentation is in place, needed and working well, there is no need for it to be

withdrawn although some updating to reference the new requirements of ISO 9001:2015 will be required.

NSI recommended changes

- Renumber existing QMS documentation to correspond to the new clause references. Should you wish not to do this reference needs to be made to compliance with ISO 9001:2015, if the organisation wishes to demonstrate compliance to this standard.
- Restructure management systems to follow the sequence of requirements as set out in the Standard.
- Refresh existing documentation to use the new terms and definitions contained within ISO 9001:2015.

Clause 1: Scope

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Scope	1.	1.	Scope	The overall purpose of the standard remains unchanged from ISO 9001:2008. It is still intended as a means by which organisations can demonstrate their ability to supply products and services that consistently meet customer and applicable statutory and regulatory requirements. It is also for use where an organisation is seeking to enhance its customers' satisfaction as a result of it operating a QMS. KEY POINTS: • All references to "exclusions" in ISO 9001:2008 sub-clause 1.2 "Application" have been removed as all of the requirements in ISO 9001:2015 are intended to be applicable to all types and size of organisation. If a particular clause of ISO 9001:2015 is not carried this would need a full justification (see clause 4.3) • ISO 9001:2015 Annex A A.5 recognises there may be circumstances where it is impossible for an organisation to conform to a specific requirement, for example, where it does not operate a "required" process. In these instances, the organisation can deem the requirement "not applicable" providing this does not affect the ability to supply conforming products or services, or compromise its aim to enhance customer satisfaction. • Within Note 1, the ISO 9001:2008 reference to "output resulting from product realisation" has been removed.
		1.1	General	
		1.2	Application	

Clause 2: Normative References

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Normative references	2	2	Normative references	ISO 9001:2008 cited ISO 9000:2005 'QMSs – Fundamentals and Vocabulary' as a normative reference. This means that these two documents were intended to be used as a pair. ISO 9001:2015 cites ISO 9000:2015 'Quality Management Systems – Fundamentals and Vocabulary. Approved companies should hold a copy of ISO 9000:2015 since this is indispensable for the application of ISO 9001:2015

Clause 3: Terms and Definitions

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Terms and definitions	3	3	Terms and definitions	The terms and definitions for ISO 9001:2008 were contained within a supplementary standard, ISO 9000:2005. The terms and definitions for ISO 9001:2015 are now contained within ISO 9001:2015 'Quality Management Systems – Fundamentals and Vocabulary KEY POINTS: • Some of the current definitions have changed, • Some terms not defined in ISO 9000:2005 (e.g. monitoring, performance) are now defined in ISO 9000:2105 • There are definitions for some of the new terms used in ISO 9000:2015 (e.g. risk, innovation)

Clause 4: Context of the Organisation

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Context of the organisation	4	4	Quality management system	Title Only
Understanding the organisation & its context	4.1	4.1	General requirements	NEW CLAUSE ISO 9001:2015 requires organisations to identify, monitor and review internal and external issues that are relevant to its purpose and strategic direction, and that have the ability to impact the QMS's intended results. KEY POINTS: • This is a new clause and relates to "Context". • Most NSI Approved Companies will already be successfully monitoring internal and external issues that have the potential to affect not only their QMS, but also the company's very existence. ISO 9001:2015 requires this is conducted to a more robust level and the way this is done will need to be demonstrated.
Understanding the needs and expectations of interested parties	4.2	4.2	Documentation requirements	NEW CLAUSE The organisation is required to determine "the relevant requirements" of "relevant interested parties" Once determined, the organisation must then monitor and review the information it holds about these parties and their requirements.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				KEY POINTS: • This is a new clause • "Relevant interested parties" are groups or individuals with the ability to impact (or potentially impact) the organisation's ability to supply consistently products and services that meet customer and applicable statutory and regulatory requirements. • Customers, shareholders, board members, members of the public, other contractors working on site and competitors etc. would all fit into this classification. Each organisation will have its own set of relevant interested parties which will change over time. • Very few of the relevant interested parties' total requirements will be relevant to the operation of a particular organisation's QMS. Only the relevant ones need to be captured.
Determining the scope of the QMS	4.3			NEW CLAUSE The scope of a QMS sets its boundaries, identifying what the requirements of the QMS are applicable to, and to what they are not. This should be defined by the organisation. When defining the scope of its QMS, the organisation needs to take into account its context (e.g. the internal and external issues it faces and the requirements of relevant interested parties), and also the products and/or services it intends to deliver. The scope must be made available and be maintained as documented information stating the products and services covered by the QMS, and justification for any instance where a requirement of the standard cannot be applied.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				The scope needs to state the products and services covered by the QMS and must also include any justifications or instances where specific elements of ISO 9001:2015 cannot be applied (for example, where a required process is not undertaken). KEY POINTS: • An NSI Approved Company has always been required to specify the scope of its QMS. However, this must now be done in explicit consideration of the organisation's context, as well as in terms of the products and services it intends to supply. • If a requirement of the standard can be applied, given the organisation's determined scope, then it must be included. Only in cases where meeting the requirement is impossible (and where the absence of meeting the requirement does not adversely impact the organisation's ability to supply conforming products and services) is it permissible not to apply the requirement • This replaces "exclusions", which are referenced in ISO 9001:2008 clause 1.2 (Application) which acknowledges there may be instances where it is impossible to apply a specific requirement, but limits these to requirements appearing in clause 7 "Product realisation"
QMS & its Processes	4.4			NEW CLAUSE ISO 9001:2015 requires the organisation to establish a process-based QMS. Once in place this needs to be maintained and continually improved. Clause 4.4 sets out high-level requirements for the design of a process-based management system. Most of what is given in clause 4.4 was in ISO 9001:2008, but the requirements were less clear and were fragmented across a number of clauses, including "General requirements" (clauses 4.1 and 8.1) and "Monitoring and measurement of processes" (sub-clause 8.2.3).

				KEY POINTS:
				• The principal change from ISO 9001:2008 is an increased focus on processes, something that appears throughout ISO 9001:2015. Whereas ISO 9001:2008 "promoted" the adoption of a process approach, ISO 9001:2015 mandates it.
				• NSI Approved Companies need to:
				  • determine performance indicators that allow for the effective operation and control of their processes
				  • determine responsibilities and authorities for processes
				  • identify risks and opportunities for processes
				  • plan to address these risks and opportunities
				• The 9001:2008 requirement to determine opportunities to continually improve processes has been expanded to include "continually improve processes and the QMS".
				• Organisations are required to maintain the documented information necessary to support the operation of its processes. They must also retain documented information that evidences processes are being carried out as planned.
				• For NSI Gold Approved Companies the key factor(s) in meeting these requirements will be the extent to which the process approach has truly been embraced and adopted already. This includes:
				  • the effectiveness of QMS planning carried out under ISO 9001:2008 sub-clause 5.4.2,
				  • the effectiveness of planning of processes needed for product realisation carried out under ISO 9001:2008 clause 7.1,
				  • the effectiveness of process monitoring, measurement, analysis and improvement carried out under ISO 9001:2008 sub-clause 8.2.3.
				• These will be key areas for review when conducting transition audits.

Clause 5: Leadership

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Leadership	5	5	Management responsibility	Title Only
Leadership & commitment	5.1			Title Only ISO 9001:2015 replaces “Management responsibility” with “Leadership”, and repositions a number of ISO 9001:2008 requirements as leadership activities.
General	5.1.1			**Sub-clause 5.1.1** identifies specific aspects of the QMS where top management are expected to demonstrate both leadership and commitment. This starts with the top management taking accountability for the effectiveness of their organisation’s QMS. They must ensure their organisation’s quality policy and quality objectives are consistent with the organisation’s overall strategic direction and the context in which the organisation is operating. They must also work alongside their people in order to ensure the quality objectives are achieved. In addition, top management must ensure the quality policy is communicated, understood and applied across the organisation. Top management must also ensure that QMS requirements are integral to the organisation’s business processes – that is, the QMS must not be just a “bolt on”. They must promote awareness and the adoption of the “process approach” and risk-based thinking, and must make sure the resources required for the effective operation of the QMS are made available. Top management must stress the importance of effective quality management and of conforming to the requirements of the QMS. They must make sure the QMS is achieving the results intended and must lead people to contribute to the effective operation of the

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				system. They must drive improvement and innovation, and develop leadership in their managers. KEY POINTS: • Together with a process based approach and risk-based thinking the change from management commitment to **leadership and commitment** is perhaps the most significant change contained within ISO 9001:2015. The impact felt by individual NSI companies will vary greatly depending on where each organisation is starting from. • For those where the most senior members of the organisation currently play an active role in driving its QMS forward, the changes will simply be a formalisation of what is happening now. However, for those organisations where top management have effectively devolved responsibility for their QMS to their Management Representative, the ramifications of the ISO 9001:2015 changes will be significantly greater. • ISO 9001:2015 requires top management to be much more “hands on” with respect to their QMS than ISO 9001:2008 does. While this does not mean the top management cannot delegate, implementers will need to make top management aware of the new requirements, and the fact that they will now be audited as a matter of routine. Note: when ISO 9001:2015 uses the term “top management”, it is referring to a person or a group of people at the highest level within an organisation, i.e. the people who coordinate, direct, and control the organisation.
Customer Focus	5.1.2	5.2	Customer Focus	**Sub-clause 5.1.2** requires top management to take the lead in demonstrating the organisation’s commitment to its customers.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				They must ensure customer and applicable statutory and regulatory requirements are identified, understood and met. They must consider and address any risks that threaten the organisation's ability to provide conforming products and/or services, or which may negatively impact customer satisfaction. In addition, top management must also ensure the organisation remains focused on enhancing its customers' satisfaction. KEY POINTS: • Sub-clause 5.1.2 expands on ISO 9001:2008 clause 5.2 by requiring top management to ensure risks and opportunities that could affect the organisation's ability to supply conforming products and services, and to enhance customer satisfaction, are identified and addressed. • The requirement to determine customer and applicable statutory and regulatory requirements is moved to this clause from ISO 9001:2008 sub-clause 7.2.1c. • Top management are now explicitly required to "maintain" a focus on enhancing customer satisfaction.
Policy	5.2			Title Only
Establishing the a quality policy	5.2.1	5.3	Quality policy	**Sub-clause 5.2.1** sets out the requirements of top management in respect of the organisation's quality policy. Top management must establish a quality policy consistent with the purpose and context of the organisation. It must additionally provide a framework for the setting and review of

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				quality objectives, including commitments to satisfy any applicable requirements and continually improve their QMS. It is the responsibility of top management to review and maintain the quality policy. KEY POINTS: • ISO 9001:2008 requires top management to “establish” the quality policy (5.1), and to “ensure” it is reviewed for continuing suitability. ISO 9001:2015 requires the top management to “establish, review and maintain” a quality policy. • ISO 9001:2015 requires the quality policy is appropriate to the context of the organisation, not just its purpose. This will require the review of the organisation’s quality policy after having decided on the context of the organisation and having considered the relevant requirements of the relevant interested parties. • The quality policy must include a commitment to continually improve the QMS. ISO 9001:2008 only required a commitment to continually improve the effectiveness of the QMS. • The quality policy must now provide a framework for the setting and reviewing of quality objectives.
Communicating the quality policy	5.2.2	5.1	Management commitment	**Sub-clause 5.2.2** sets out specific requirements in respect of the organisation’s quality policy. The policy must be available as documented information. It must be communicated, understood and applied across the organisation and must be available to relevant interested parties as appropriate. KEY POINTS: • As an item of documented information, the quality policy can now be held in any manner that meets the requirements of ISO 9001:2015 clause 7.5.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• There is now an explicit requirement for the quality policy to be applied throughout the organisation. This can have some implications for implementers of the QMS. • The new requirement for the quality policy to be available to relevant interested parties, as appropriate, means that some organisations will need to demonstrate how this is done if they are not already making the policy available.
Organisational roles, responsibilities & authorities	5.3			NEW CLAUSE This is largely a clarification of requirements given in clause 5.5 of ISO 9001:2008. The top management of the organisation need to ensure assignment of the necessary responsibilities and authorities to individuals within the organisation to carry out quality-related activities. Specifically, they need to assign responsibility and authority for ensuring that: • the requirements set out in ISO 9001:2015 are met; • QMS processes are delivering their intended outcomes; • reporting on the operation of the QMS and identifying any opportunities for improvement is taking place; • customer focus is promoted throughout the organisation; • whenever changes to the QMS are planned and implemented, the integrity of the system is maintained. Top management need to ensure responsibilities and authorities relating to an organisation's QMS are communicated within the organisation and that they are understood within the organisation.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				KEY POINTS: • ISO 9001:2015 requires that not only are responsibilities and authorities assigned, but they are also communicated and understood within the organisation. • The role of Management Representative has disappeared in ISO 9001:2015. This is an attempt to ensure that ownership of the QMS does not centre around a single individual. Duties assigned to the Management Representative in ISO 9001:2008, including ensuring QMS processes are established and maintained, the reporting of QMS performance and promotion of customer requirements across the organisation, can now be assigned to any role or split across several roles. • There is a new requirement for top management to ensure that someone is tasked with preserving the integrity of the QMS while it is in the process of revision. • The quality professionals within the organisation may have to revisit existing responsibilities and authorities with regards to the QMS, especially the responsibilities of top management. The review may identify gaps, including gaps of knowledge and skills, which will then need to be addressed before a compliant system can be established.

Clause 6: Planning

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Planning	6			NEW CLAUSE Title Only
Actions to address risks & opportunities	6.1			NEW CLAUSE Title Only
	6.1.1			NEW CLAUSE **Sub-clause 6.1.1** is a new requirement. Organisations are required to consider their context when planning for their QMSs. This means thinking about the internal and external issues they face and the relevant requirements of their relevant interested parties, and how this may impact on their QMS design. The organisation must then determine the risks and opportunities that need to be addressed within its given context. This is in order to provide assurance the QMS can achieve its intended outcomes, enhance desirable effects, prevent or reduce undesired effects, and to achieve improvement.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				KEY POINTS: • This sub-clause introduces a new requirement for organisations to determine those risks and opportunities that have the potential to impact the operation and performance of their QMS, both positively and negatively. • While no specific risk-management methodology is prescribed, risk management as an activity must now be carried out. **Note:** that 'risk' is specifically defined (Terms and Definitions in ISO 9000:2015). • Once the organisation has identified the risks and opportunities it faces, it must determine how it wishes to address these.
	6.1.2			NEW CLAUSE **Sub-clause 6.1.2** requires a planned approach with respect to these actions, with them initially being integrated into the QMS prior to a subsequent evaluation to determine whether the action was effective in reducing the risk or realising the opportunity. KEY POINTS: • This new requirement requires organisations to have robust risk management methodologies in place. These need to allow risks and opportunities relating to the QMS to be captured and assessed. • Depending on the outcome of this assessment, action needs to be taken to mitigate the risk or to realise the opportunity. The standard requires the extent of this action to be proportionate to the risk or opportunity itself, i.e. major risks requiring major action(s). • Subsequently, organisations need to evaluate the effectiveness of the actions they took.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• Organisations are free to decide on the most appropriate risk management method to use. • This clause is related to several other clauses within the standard with regards to its outcomes i.e. what are the risks and opportunities for the organisation, and how are they to be addressed. • Consequently organisations truly need to understand the risk management methodology and apply it effectively. It is clear that wrong assessment will not result in a suitable QMS, and hence not effective. • There is a statement regarding proportionality to the effect that actions taken to address risks and opportunities should be in line with the potential impact of the risk or opportunity on the conformity of products and/or services, as well as on customer satisfaction. An associated note set out potential strategies for mitigating risks, and recognises **not all** risks and opportunities need actions. For example, the organisation may take an informed decision to keep the risk, in effect taking no action beyond identifying and evaluating the risk or opportunity. A second note sets out strategies that could arise from opportunities such as the development of new products or the introduction of new technology.
Quality objectives & planning to achieve them	6.2			NEW CLAUSE Title Only

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
	6.2.1	5.4.1	Quality objectives	**Sub-clause 6.2.1** is an enhancement and extension of ISO 9001:2008 requirements. It requires an organisation to set quality objectives for relevant functions, levels and processes within its QMS. It is for the organisation itself to decide which functions, levels and processes are relevant. The quality objectives must be consistent with the organisation's quality policy and be relevant to the conformity of products and services, and the enhancement of customer satisfaction. Quality objectives must be measurable, take into account applicable customer and statutory and regulatory requirements, and be monitored in order to determine whether they are being met. They must also be communicated across the organisation and be updated as and when the need arises. Information on the quality objectives needs to be retained by the organisation as documented information. KEY POINTS: • This is an extension of ISO 9001:2008 sub-clause 5.4.1 "Quality objectives". • The requirement for quality objectives to be measurable and consistent with the organisation's quality policy is carried across, as is the requirement for objectives to be set for relevant functions and levels. • New for ISO 9001:2015 are requirements to set quality objectives for applicable processes, to set objectives relevant to the enhancement of customer satisfaction, and to monitor progress against the achievement of objectives. • For organisations that simply created the minimum amount of quality objectives necessary to conform to the requirements of ISO 9001:2008, this clause will mean

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				some additional work to demonstrate the value of the quality objectives at relevant functions, levels and processes within the organisation.
	6.2.2	5.4.2	Quality management system planning	**Sub-clause 6.2.2** is an enhancement of ISO 9001:2008 sub-clause 5.4.2, which now clearly states requirements previously inferred within ISO 9001:2008. The organisation must undertake planning in order to determine how its quality objectives will be achieved. Sub-clause 6.2.2 requires an organisation to determine the work required in order to realise its quality objectives, the resources necessary to undertake this work, who will be responsible for ensuring that the work is done and when the work needs to be completed by. Additionally, the organisation must determine how it will evaluate the work done to determine whether it has led to the objective being realised. KEY POINTS: • Sub-clause 6.2.2 focuses not just on what needs to be done, but also asks organisations to identify what resources will be required to do it, who will do it, when it will be completed and how it will be evaluated in order to determine if it has realised the objective. • The target set on completion of quality objectives means more robust monitoring of the objectives will need to take place. • It may be necessary for the organisation to revisit its existing quality objectives in order to ensure that the enhanced planning requirements of clause 6.2.2 have been applied.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Planning of changes	6.3	5.4.2b		Clause 6.3 is an enhancement of ISO 9001:2008 clause 5.4.2b. When the organisation determines there is a need to change the QMS, clause 6.3.3 of ISO 9001:2015 requires such changes to be carried out in a controlled manner. Changes need to be planned first and then logically implemented. The organisation needs to be clear as to what it is attempting to achieve by implementing the proposed change and what the consequences (both positive and negative) of proceeding may be. It needs to assess whether the integrity of the QMS could be compromised or improved as a result of making the change. The organisation must also consider whether there are sufficient resources available to effect the change and whether any changes in responsibilities or authority levels are necessary to drive the change through. The organisation is required to retain documented information relating to planned changes that impact its QMS. KEY POINTS: • This is an extension of ISO 9001:2008 sub-clause 5.4.2b, which requires the integrity of the QMS to be preserved whenever changes to it are planned or implemented. • The new requirements in ISO 9001:2015 build on this, adding in specific considerations that an organisation must undertake when planning and implementing QMS changes.

Clause 7: Support

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Support	7			Title Only
Resources	7.1			Title Only
General	7.1.1	6.1	Provision of resources	Sub-clause 7.1.1 updates ISO 9001:2008 clause 6.1 “Provision of resources”. An organisation must initially determine and then provide the resources necessary to establish, implement, maintain and continually improve its QMS. In doing so, the organisation is required to consider both the capabilities and constraints on its existing internal resources as well as what needs to be sourced from external providers. KEY POINTS: • The ISO 9001:2008 clause 6.1b reference to “identifying resources needed to enhance customer satisfaction” has been removed from ISO 9001:2015 sub-clause 7.1.1. although this is still implied through ISO 9001:2015 5.1.1 f. • There is now an explicit requirement to consider both internal and external QMS resource requirements.
People	7.1.2			NEW CLAUSE Sub-clause 7.1.2 requires an organisation to provide those people necessary for the effective operation of its QMS and its processes in order to consistently meet customer and applicable statutory and regulatory requirements.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				KEY POINTS: • This is essentially an existing requirement separated out from ISO 9001:2008 clause 6.1 “Provision of resources”. Whereas the reference to meeting statutory and regulatory requirements was implicit in clause 6.1, it is now explicit.
Infrastructure	7.1.3	6.3	Infrastructure	Sub-clause 7.1.3 updates ISO 9001:2008 clause 6.3 “Infrastructure”. As is the case for ISO 9001:2008, the requirements for infrastructure in ISO 9001:2015 are centred around identifying, providing and maintaining the means to enable processes to operate effectively and to achieve conformity of products and services. The examples of infrastructure in the standard are essentially the same as those in ISO 9001:2008, with some minor revisions to wording: • “buildings, workspace and associated utilities” becomes “buildings and associated utilities”; • “process equipment (both hardware and software)” becomes “equipment including hardware and software”; • “supporting services (such as transport, communication or information systems)” becomes “transportation resources”, and “information and communication technology” KEY POINTS: • No action required.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Environment for the operation of processes	7.1.4	6.4	Work environment	Sub-clause 7.1.4 updates ISO 9001:2008 clause 6.4 “Work environment” ISO 9001:2015 requires organisations to “determine, provide and maintain” a suitable environment for the operation of processes. This is a little more prescriptive than the ISO 9001:2008 wording, which simply required organisations to “determine and manage” their work environment. The note highlights a suitable environment can be a combination of human and physical factors such as physical, social, and psychological and gives examples. It recognises these factors will differ from organisation to organisation depending on the products and services provided. KEY POINTS: • The “work environment” now becomes “environment” necessary for the operation of processes reflecting an increased focus throughout the standard on a process-based approach. • As is the case for sub-clause 7.1.3 “Infrastructure” in ISO 9001:2015, the purpose of maintaining the process environment is to assure conformity of products and services. • The note to sub-clause 7.1.4 in ISO 9001:2015 explains that a suitable environment can be a combination of human and physical factors such as physical, social, and psychological and gives examples
Monitoring & measuring resources	7.1.5	7.6	Control of monitoring and measuring equipment	Sub-clause 7.1.5 updates ISO 9001:2008 clause 7.6 “Control of monitoring and measuring equipment” split into two sub- clauses

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				KEY POINTS: • ISO 9001:2015 sub-clause 7.1.5 relates to monitoring and measuring “resources” whereas ISO 9001:2008 clause 7.6 is concerned solely with monitoring and measuring “equipment”. This change is an acknowledgement that, in certain instances, humans also carry out monitoring or measurement activity without reliance on equipment.
General	7.1.5.1			Where an organisation uses monitoring or measuring to demonstrate its products and services conform to requirements, it must make sure it provides the necessary resources to ensure its monitoring and measuring results are valid. These resources need to be suitable to the type of monitoring or measurement being undertaken and must be maintained in order to ensure they remain fit for purpose. The organisation must maintain appropriate documented information as evidence that monitoring and measuring resources are fit for purpose. KEY POINTS: • The organisation is now required to retain documented information as evidence the measuring and monitoring resources are fit for purpose.
Measurement traceability	7.1.5.2			In instances where measurement traceability has been identified as a requirement, or is considered by the organisation as essential in order to provide confidence in the measurement results, measuring equipment must be verified or calibrated against international or national measurement standards at specific intervals or prior to their use.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				If no such standards exist, the organisation must record the basis it is using for calibrating or verifying the measuring instrument in the form of documented information. Measuring equipment must be identified in such a way that their calibration status can be determined. They must also be protected to prevent them being adjusted, damaged or subjected to deterioration. If measuring equipment is found to be defective, previous results need to be revisited and any necessary corrective action implemented. KEY POINTS: • If measurement traceability is required then measuring equipment are subject to additional controls. These are, however, just a reworking of those currently contained in ISO 9001:2008 clause 7.6 “Control of monitoring and measuring equipment”.
Organisational knowledge	7.1.6			NEW CLAUSE A new requirement aimed at ensuring organisations take steps to capture and preserve knowledge and learning, which is necessary for the effective operation of their processes and for ensuring the conformity of their products and services. This is a broad requirement directed primarily at ensuring the organisation has or obtains the knowledge resources necessary to respond to: • changing business environments referred to in clause 4.1, • changing customer and interested party needs and expectations referred to in clause 4.2 • related improvement initiatives where applicable.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				This knowledge needs to be maintained and made available to the extent necessary. The organisation can choose how best to do this; there is no explicit requirement for organisational knowledge to be held as documented information. The organisation must re-assess the extent of its organisational knowledge if it is considering making changes to its QMSs in response to changing needs or trends in its operational environment. If the current level of knowledge is deemed insufficient the organisation must take steps to enhance it. This is an attempt to ensure that organisations make informed decisions in respect of updates to their QMSs. Note 1 recognises organisational knowledge is specific to each organisation and is information that is used and shared to achieve objectives while Note 2 identifies potential sources of organisational knowledge. KEY POINTS: • This is a new requirement. • Organisations should ensure they introduce new processes to address the requirements above. • This requirement has strong links with management review activities. • The notes to clause 7.1.6 give good examples of what “organisational knowledge” can include as well as to how additional knowledge and updates can be obtained.
Competence	7.2	6.2.1 & 6.2.2	Human resources – general & competence, training and awareness	Clause 7.2 is essentially an amalgamation of ISO 9001:2008 sub-clause 6.2.1 “Human Resources – General” and sub-clause 6.2.2 “Competence, training and awareness” (save for requirement 6.2.2d, which now transfers to ISO 9001:2015 clause 7.3 “Awareness”). The organisation must determine the competency requirements for those people performing work under its control. Once these competency requirements have been determined, the

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				organisation must then ensure those people possess the necessary competencies, either on the basis of their education, training or experience. If those people are found not to be competent, action must be taken to make them competent or to gain the necessary competencies from other sources. An assessment needs to be subsequently undertaken to determine whether this has been successful in raising competence to the required level. The Note in this clause gives examples of applicable actions, such as training, recruitment or use of external people. Organisations must retain appropriate documented information to evidence the competence of its people. Note: clause 7.2 refers to “People performing work under its control”. This embraces contract and agency people, as well as people performing processes and functions outsourced to external providers. These are operating under the control of the organisation, recognised in ISO 9001:2015 by a specific reference in clause 8.4.3 to the need to communicate to external providers’ competence and qualification requirements as applicable. In practice this requirement is likely to be addressed through procurement processes. KEY POINTS: • Competence is defined as the “ability to apply knowledge and skills to achieve intended results”. Competence now needs to be considered in terms of its potential impact on “quality performance”, as opposed to “its ability to affect conformity to product requirements”. • Organisations are still required to take action to address any competency issues and subsequently to check this action has been effective.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• Organisations are still required to maintain evidence to demonstrate that people doing work under its control are competent. This evidence needs to be maintained as documented information. • While clause 6.2.2 of ISO 9001:2008 requires records of education, training, skills, and experience, clause 7.2.5 ISO 9001:2015 requires documented information as evidence of competence.
Awareness	7.3	6.2.2	Competency, Training and Awareness	NEW CLAUSE Awareness has now been elevated from a constituent element of sub-clause 6.2.2 "Competency, training and awareness" in ISO 9001:2008 to a separate sub-clause in its own right. The requirements contained in the new clause 7.3 apply to "all persons doing work under the organisation's control". This is more expansive than under ISO 9001:2008 where the organisation needed to ensure that "its personnel" were aware. What individuals need to be aware of has also been extended. Under ISO 9001:2008, the awareness requirement for personnel was quite limited; necessitating only an awareness of the relevance and importance of the work they were conducting, and an appreciation as to how this contributed to the organisation's quality objectives. Now there are explicit requirements for people doing work under the organisation's control to be aware of the organisation's quality policy, any quality objectives relevant to them, how they are contributing to the effectiveness of the QMS and what the implications are of them not conforming to QMS requirements.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				KEY POINTS: • Clause 7.3 contains expanded requirements. • The people who need to be made aware now extends to **all** persons doing work on the organisation's behalf not just the organisation's personnel. • Additional information as set out above must be communicated to these individuals. • The important factor here is the addition of the requirement to make persons doing work under the organisation's control aware of the implications of not conforming to the QMS.
Communication	7.4	5.5.3	Internal communication	This expands on the current ISO 9001:2008 sub-clause 5.5.3 by extending its scope to include external communications as well as internal ones. Clause 7.4 "Communication" encompasses all internal and external communication relating to an organisation's QMS. Each organisation must determine those QMS-related matters on which it wishes to communicate. Once this has been done, consideration must then be given as to the timing of such communications, their target audience their method of delivery and who communicates. Note: reference to external communication in this clause **does not** encompass specific customer communication requirements of ISO 9001:2008 sub-clause 7.2.3, which are largely retained in ISO 9001:2015 sub-clause 8.2.1. KEY POINTS: • The new wording is more prescriptive in respect of the mechanics of the communication; sub-clause 5.5.3 refers to the need for "communication to take

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				place" whereas ISO 9001:2015 clause 7.4 requires organisations to determine on what it will communicate, when it will communicate, with whom it will communicate how it will communicate and who should do the communicating. • Organisations should be prepared to evidence these considerations.
Documented information	7.5			Title Only
General	7.5.1	4.2	Documentation requirements	Sub-clause 7.5.1 confirms an organisation's QMS includes both documented information required in ISO 9001:2015 and documented information identified by the organisation as necessary for the effective operation of its QMS. The note to the clause advises the extent of documented information present can differ between organisations due to their size and the types of activities, processes, products and services KEY POINTS: • No change required. These requirements are already contained in ISO 9001:2008 clause 4.2.
Creating & updating	7.5.2	4.2	Documentation requirements	When documented information is created or updated, the organisation must ensure it is appropriately identified and described (e.g. title, date, author, reference number). It must be in an appropriate format (e.g. language, software version, graphics) and on appropriate media (e.g. paper, electronic). Documented information must be reviewed and approved for suitability and adequacy.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				KEY POINTS: • No further action is required. These requirements are already contained within the sub-clauses that comprise ISO 9001:2008 clause 4.2.
Control of documented information	7.5.3	4.2.3	Control of Documents	Title Only ISO 9001:2015 Splits the control of documented information into 2 sub clauses
	7.5.3.1			The organisation is required to control documented information in order to ensure it is available where and when needed and that it is suitable for use. It must also be adequately protected against improper use, loss of integrity and loss of confidentiality. KEY POINTS: • Although the requirement for a documented procedure setting out how documents are to be controlled has been removed, the need to control documented information remains. • The requirements in sub-clause **7.5.3.1** mirror current requirements in ISO 9001:2008 4.2.3
	7.5.3.2			The organisation must determine how it will distribute, access, retrieve and use documented information. It must decide how it will store and preserve documented information, and how it will control any changes to the documented information. It must also decide its retention and disposal arrangements.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				The organisation is also required to identify any documented information of external origin to the organisation it considers necessary for the planning and operation of the organisation's QMS. Such documentation must be identified and controlled. KEY POINTS: • While ISO 9001:2008 contains requirements for controls in respect of the distribution and retrieval of documents, ISO 9001:2015 extends these also to cover the "access" and "usage" of documented information required by the organisation's QMS and by ISO 9001:2015 • Where organisations chose to hold their documented information in electronic forms, there may be a need to revisit access controls (passwords/logins) and authorisation levels in order to ensure current controls are appropriate. • Organisations will need to consider how such systems are to be protected when passwords are lost and how access to the documented information can be preserved in the event of system unavailability. • Organisations will be required to demonstrate how the integrity of their documented information is maintained. • With most organisations moving to electronic documents maintained and accessed remotely using passwords, etc. this can mean more controls that need to be demonstrated if claiming compliance. The Note in clause 7.5.3.2 states access can imply "permission to view only", or "permission to view and authority to change".

Clause 8: Operations

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Operation	8			Title Only
Operational planning & control	8.1	7.1	Planning of product realisation	Clause 8.1 requires the organisation to plan, implement and control those processes it has previously identified (see clause 4.4) as necessary in order for it to meet product or service requirements. It must additionally plan how it will address any risks and opportunities that may impact these processes and, therefore, its ability to achieve these requirements. The planning process commences with the organisation establishing its product/service requirements. Once this has been completed, the organisation must then consider its processes and for each it must establish the criteria for the process, how it will control the process, the acceptance criteria for the outputs of each process and the resources necessary to support each process. This means the inputs (triggers for the process), outputs (products and/or services), and resources and controls (to ensure that the required outputs are achieved) should be determined. In addition, what makes the output acceptable also needs to be determined; this can be targets, measures, values, KPIs, specifications and other criteria as relevant to the output. Subsequently, the organisation is required to create and keep documented information to the extent it determines is necessary to allow it to ensure its processes are being carried out as planned, and that the products and services being produced conform to the identified requirements and acceptance criteria. The extent of planning for the provision of products and services must be proportionate to the size, nature and complexity of the organisation's operations. The output from operational planning and control must be suitable for the organisation's operation.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				The organisation must control planned changes to the provision of product and services, and must review the consequences of any unintended changes. Where necessary, the organisation should take action to address or mitigate any adverse effects. Any outsourced processes must be controlled in accordance with clause 8.4 “Control of externally provided products and services”. KEY POINTS: • The requirement to plan and develop processes is not new. For ISO 9001:2105 this has been extended also to include “implementation and control”. • The term “product realization” has been withdrawn and replaced by “operation”. • The requirement for “Planning of product realization” has been replaced by “Operational planning and control”. • The ISO 9001:2008 clause 7.1a requirement to determine quality objectives for products or services has been relocated to ISO 9001:2015 sub-clause 6.2.1, which calls for quality objectives to be established at relevant functions, levels and processes. • ISO 9001:2008 clause 7.1b refers to providing “resources specific to the product”. ISO 9001:2015 refers to “resources needed to achieve conformity to product and service requirements”. • The requirement for planning proportionate to the organisation’s size, nature and complexity comes straight across from ISO 9001:2008. • The requirement for the output from operational planning and control to be in a form that is suitable for use by the organisation comes straight across from ISO 9001:2008.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• The new control-focused requirements centre on ensuring that processes are implemented as planned, including actions to address risks and opportunities. This needs to be evidenced by means of documented information.
Requirements for products & services	8.2			Title Only
Customer communication	8.2.1	7.2.3	Customer Communication	Sub-clause **8.2.1** requires an organisation to ensure it has processes in place to allow it to communicate with its customers on matters relating to its products and services, enquiries, contracts or order handling (including amendments); customer views and perceptions (including customer complaints), the handling or treatment of customer property if applicable; and specific requirements for contingency actions when relevant. KEY POINTS: • These requirements are essentially the same as for ISO 9001:2008 sub-clause 7.2.3 “Customer communication”, but with the addition of new requirements to communicate in respect of the handling or treatment of customer property and specific requirements for contingency actions where relevant. • The ISO 9001:2008 requirement to obtain “customer feedback” has been amended to obtain “customer views and perceptions”. • A change here that may have implications for organisations is the clause on customer communication now appears **before** the determination and reviewing of requirements. This is to demonstrate the importance of communicating with the customer on understanding the requirements before determining what the organisation intends to offer them.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Determining the requirements for products & services	8.2.2	7.2.1	Determination of requirements related to product	The organisation is required to ensure requirements for the products and services it intends to offer to customers have been defined. This includes the capture of any applicable statutory and regulatory requirements. The organisation must ensure it has the ability to meet the defined requirements and substantiate the claims it is making for the products and services it intends to supply. KEY POINTS: • This replaces ISO 9001:2008 sub-clause 7.2.1. • The new clause represents a subtle change in emphasis in the nature of the interaction between supplier and customer in respect of determining customer requirements. • In ISO 9001:2008, the organisation determines customer requirements before reviewing these and then proceeding to design or develop a product or service. ISO 9001:2015 starts from the position that the organisation has already determined the products and services it intends to offer to customers, taking into account customer requirements. • This reflects the way much of business takes place these days, with organisations effectively setting out their product portfolios from which customers must choose. • An organisation will need to be able to substantiate any claims it makes about its products or services in respect of them meeting defined requirements.
Review of requirements related to products & services	8.2.3			Title Only

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
	8.2.3.1	7.2.1 & 7.2.2	Determination of requirements related to product and Review of requirements related to the product	The organisation needs to ensure it has the ability to meet the requirements for products and services being offered. In order to do this the organisation is required to conduct a review before committing to supply the product or service. This review needs to consider requirements set by the customer, including ones relating to delivery and post-delivery. It must also include consideration of any requirements not stated by the customer but are known to be necessary for the product or service to be suitable for the customer's intended use. The review must consider any statutory or regulatory requirements relating to the product or service, and any new or changed requirements that differ from those previously determined. Where contract or order requirements differ the organisation must seek to resolve any differences. If the customer does not provide a documented statement of their requirements the organisation must confirm the customer's requirements with the customer prior to the order/ contract being accepted. The note recognises that a formal review is impractical for each order and allows for the review to cover relevant product information such as catalogues. KEY POINTS: • This sub-clause amalgamates ISO 9001:2008 sub-clauses 7.2.1 and 7.2.2. • There is no substantive change to content, though there is recognition that when reviewing requirements relating to products or services, these requirements could now include those arising from relevant interested parties – not just from customers.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
	8.2.3.2			Documented information relating to requirement reviews must be retained by the organisation. Where requirements have been revised as a result of review, this must be identified in the documented information.
Changes to requirements for products and services	8.2.4			Where product or service requirements have been changed, the organisation must ensure any relevant documents are amended and relevant personnel are made aware of the changed requirements.
Design & development of products & services	8.3			Title Only
General	8.3.1			New Clause The organisation must establish, implement and maintain a design and development process appropriate to ensure the provision of products and services. KEY POINTS: • Sub-clause 8.3.1 is a new clause that mandates the introduction of a design and development process.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Design & development planning	8.3.2	7.3.1	Design and development planning	The organisation is required to plan and control the design and development of its products and services. The design and development process will comprise a number of stages, each of which will be subject to controls. When determining the stages and controls to be applied to its design and development process, the organisation must consider: • the complexity, nature and duration of the design and development activities; • the required process stages including design and development reviews where applicable; • the design and development verification and validation required at each stage; • the responsibilities and authorities of those involved in the design and development process; • the internal and external resource needs for the design and development process; • the need to ensure the interfaces between individuals and parties involved in the design and development process are appropriately controlled; • whether it is necessary to involve the customer and/or user groups in the design and development process; • what is required to subsequently provide the product or service; • the level of control expected by the customer and/or other relevant interested parties in the design and development process; • the documented information necessary to demonstrate the design and development requirements have been met.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation

				KEY POINTS:
				• ISO 9001:2015 sub-clause 8.3.2 builds on the existing ISO 9001:2008 sub-clause 7.3.1 “Design and development planning”.
				• Sub-clause 8.3.2 is more explicit than its predecessor in terms of what needs to be taken into consideration when planning the design and development process. However, it is likely that organisations complying with ISO 9001:2008 will already be undertaking these activities anyway.
				• Additional examples of what to take in to consideration could be:
				  • involving the customer and/or user groups in the design and development process where appropriate;
				  • ensuring the organisation’s design and development process takes into account any identified requirement to include specific stages, such as design or a development review.
				• The requirement to retain documented information that confirms that the design and development requirements have been met is a new addition to this clause.

Design & development inputs	8.3.3	7.3.2	Design and development inputs	ISO 9001:2015 sub-clause 8.3.3 requires the organisation to determine any requirements essential for the specific type of product or service being designed and developed. These include: • any functional or performance requirements • information gained from similar design and development activities • any applicable statutory or regulatory requirements • any standards and/or codes of practice the organisation has agreed to implement

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• potential consequences of failure due to the nature of the product or service. The organisation must ensure that design and development inputs are adequate, complete and unambiguous. If there are any conflicts between design inputs, then these must be resolved. The organisation needs to retain documented information on the design and development inputs. KEY POINTS: • These are amended requirements. This sub-clause builds on the previous requirements of ISO 9001:2008 sub-clause 7.3.2 “Design and development inputs”. • There are 2 new requirements to include as a design and development input: “the potential consequences of design or development failure” based on the nature of the product or service and “standards and/or codes of practice” the organisation is committed to working to. • The remaining ISO 9001:2008 design and development input requirements are essentially unchanged.
Design & development controls	8.3.4	7.3.3; 7.3.4; 7.3.5 and 7.3.6		The organisation is required to apply controls to its design and development process in order to ensure: • the results from undertaking the design and development process are clearly defined; • design and development reviews take place to ensure the results of design and development can meet the requirements; • design and development outputs do meet the input requirements (verification);

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• the resulting products and services are fit for their intended use or specified application (validation); • issues identified through the review, verification or validation activities are resolved; • documented information is retained. The note recognises the activities of review, verification and validation have distinct purposes within the design and development process and that they can be conducted separately or combined as suits the products and services. KEY POINTS: • This sub-clause draws in a number of existing requirements from ISO 9001:2008 sub-clauses 7.3.3, 7.3.4, 7.3.5 and 7.3.6. • There are no new requirements.
Design & development outputs	8.3.5	7.3.3	Design and development outputs	The organisation must ensure the outputs from design and development meet the input requirements for design and development, and are suitable for use in subsequent processes. As applicable, design outputs must include or reference any related monitoring or measuring requirements and acceptance criteria. The organisation must ensure the products to be produced or the services to be delivered are fit for their intended purpose and are safe to use. The organisation is required to retain documented information resulting from the design and development process. KEY POINTS: • This sub-clause corresponds to ISO 9001:2008 sub-clause 7.3.3 “Design and development outputs”.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• It is essentially unchanged, except that the requirement to "include or reference monitoring and measuring requirements" has been added to ISO 9001:2008 sub-clause 7.3.3c. • A requirement to retain documented information resulting from the design and development process has also been added into this sub-clause.
Design & development changes	8.3.6	7.3.7	Control of design and development changes	If changes are made to either design inputs or design outputs, the organisation must identify, review, and control these in order to ensure that conformity to requirements is maintained. The requirement to review and exercise control applies at all stages during the development of products or services and, subsequently, for example, after the product or service has been delivered. The organisation is required to retain documentary information relating to: • design and development changes; • the result of reviews; • authorisation for the changes; • actions taken to prevent adverse impacts; KEY POINTS: • This sub-clause is essentially unchanged from ISO 9001:2008 sub-clause 7.3.7 "Control of design and development changes". • "Control" has been added. • The ISO 9001:2008 requirement to "review, verify, validate and, as appropriate, approve design changes before implementation" is no longer explicitly defined but is implied in the wording of sub-clause 8.3.6.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• The impact of the new requirement for "post-delivery activities in sub-clause 8.5.5 needs careful consideration. • There are specific requirements as to what documentary information is to be retained.
Control of externally provided products & services	8.4			Title Only
General	8.4.1	7.4.1 & 7.4.3		The organisation must ensure externally provided processes, products or services meet their specified requirements. They must determine what controls need to be applied to externally provided processes, products or services to ensure when: • products and services from the external providers are to be incorporated into the organisation's own products and services; • products and services to be provided directly to the customer by the external provider on the organisation's behalf; • outsourced processes or parts of processes from an external provider. The organisation must determine and implement criteria that allow it to evaluate and select external providers, and subsequently to monitor their performance. Criteria relating to the re-evaluation of external providers also need to be established and implemented. Documented information needs to be retained evidencing these activities have taken place and of any actions taken following the evaluations.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				KEY POINTS: • The implications of this sub-clause are broadly in line with the requirements of ISO 9001:2008 sub-clauses 7.4.1 and 7.4.3. • However, ISO 9001:2015 sub-clause 8.4.1 now explicitly sets out those instances in which the organisation must apply controls to external providers (see the bullet points above). • The new requirement here is to establish criteria to monitor the performance of external providers and to have the results of the evaluation, re-evaluation and performance as documented information. This would include but not exclusively ARC's and RVRCs, subcontractors etc. • In ISO 9001:2008 sub-clause 7.4.1, it is required to keep records of the "criteria" for selection, evaluation and re-evaluation of the suppliers. In ISO 9001:2015 organisations are required to record not only the criteria, but also the results of these activities, including performance. • If previously the organisation has not maintained records of the "results" of these activities above, they need to do so, meaning more documented information than before. Note: an "external provider" is a provider external to the scope of the QMS. If the organisation is part of a group but has its own QMS then any products or services delivered by other members of the group would be consider as externally provided and subject to this clause.
Type & extent of control	8.4.2	7.4.1 & 7.4.3	Purchasing process & Verification of	The organisation must ensure externally provided processes, products or services do not impact its ability to supply conforming products and services to its customers. The organisation must also ensure the externally provided processes remain within the control of the QMS and define the controls it needs to apply to the external provider and the outputs.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
			purchased product	The organisation should consider: • the impact of these processes, products and services on their ability to meet customer requirements; • applicable statutory and regulatory requirements and; • how effective it considers the controls applied by the provider are. The organisation needs to determine the verification activities needed to ensure externally provided processes, products and services meet their requirements or those of the customer. KEY POINTS: • This clause brings in elements from ISO 9001:2008 sub-clauses 7.4.1 “Purchasing process” and 7.4.3 “Verification of purchased product”. • In ISO 9001:2008 sub-clause 7.4.1, when determining the nature and extent of controls to be employed to suppliers, the organisation needed to consider “the effect of the purchased product on subsequent product realization or the final product”. In ISO 9001:2015 this has been amended to “the potential impact of the externally provided processes, products or services on the organisation’s ability consistently to meet customer and applicable statutory and regulatory requirements”. • The requirement to verify externally provided processes, products or services remains in sub-clause 8.4.2. However, in ISO 9001:2008 the verification was to ensure “the purchased product met specified purchase requirements”. In ISO 9001:2015, the verification is to ensure “the externally provided processes, products and services meet requirements”.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Information for external providers	8.4.3	7.4.1, 7.4.2 & 7.4.3	Purchasing processes; Purchasing information & Verification of purchased product	Sub-clause 8.4.3 sets out the information the organisation is required to communicate to external providers of processes, products and services. The organisation is required to ensure the requirements it intends to communicate to the external provider are adequate prior to being communicated. The organisation must communicate its requirements for: • the processes, products or services to be provided by the external provider on behalf of the organisation; • the approval of the products and services, methods, processes or equipment used and the release of the product or service; • the competence of the external provider including any necessary qualifications required by their personnel; • how the external provider will interacts with the organisation; • how the external provider's performance will be monitored and controlled by the organisation; • verification/validation activities that the organisation (or its customer) intends to perform at the external provider's premises. KEY POINTS: • ISO 9001:2015 sub-clause 8.4.3 draws in existing requirements from ISO 9001:2008 sub-clauses 7.4.1 "Purchasing processes", 7.4.2 "Purchasing information" and 7.4.3 "Verification of purchased product". • Essentially, these requirements are unchanged. There is an acknowledgement organisations may need to communicate not just the products or services they wish to receive, but also any processes they want the external provider to undertake on their behalf.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• The requirement for the organisation to communicate, as applicable, the necessary qualification of personnel has been expanded and also included the overall competence of the external provider. • The requirement for the organisation to communicate any “QMS requirements”, as applicable, has been expanded to “interactions with the organisation”.
Production & service provision	8.5			Title Only

Control of production & service provision	8.5.1	7.5.1 & 7.5.2	Control of production and service provision
			
			&
			
			Validation of processes from production and service provision”.
				Sub-clause 8.5.1 requires organisations to control the way in which they provide their products and services.
				
				These controlled conditions must include, as appropriate,:
				• documented information that defines:
				  • the characteristics of the product or service to be provided or activity to be performed;
				  • the results to be achieved;
				• the availability and use of suitable monitoring and measurement resources;
				• the implementation of monitoring and measurement activities to ensure both the processes themselves and the process outputs meet the organisation’s acceptance criteria;
				• a suitable environment and infrastructure for the operation of processes;
				• the appointment of competent personnel and, where necessary, the qualifications required;

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• for processes where the results cannot be verified by subsequent monitoring or measurement, the process itself is initially validated and then periodically re-evaluated; • actions to prevent human error; • product and service release, delivery and post-delivery activities are implemented. KEY POINTS: • This sub-clause is an amalgamation and expansion of ISO 9001:2008 sub-clauses 7.5.1 “Control of production and service provision” and 7.5.2 “Validation of processes from production and service provision”. • The reference to “work instructions” has been replaced by a reference to “documented information” that defines the activities to be performed and the results achieved”. • “The results achieved” is an important addition; these may not appear in existing documentation describing the activities to be performed or in records generated from them. • Reference is made to monitoring and measuring “resources” as opposed to “monitoring and measuring equipment”, reflecting the fact that monitoring may be being carried out by humans. • There is now an explicit requirement to ensure monitoring and measurement activities are undertaken at appropriate points. This is in order to verify processes are being controlled and that process outputs, products and services are meeting their acceptance criteria. This is an expansion on ISO 9001:2008 sub-clause 7.5.1e. • The “use of suitable equipment” has been replaced by the “use of suitable infrastructure and environment”.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• The ISO 9001:2008 sub-clause 7.5.2b reference to the “qualification of personnel” has modified to “appointment of competent persons, including any required qualifications”.
Identification & traceability	8.5.2	7.5.3	Identification and traceability	The organisation is required to put arrangements in place to allow its process outputs to be identified where this is necessary, in order for it to be able to demonstrate they conform to requirements. The organisation must be able to identify the status of process outputs in respect of any monitoring and measurement requirements it has set, at all stages of production or service provision. In cases where traceability is a requirement, the organisation must additionally ensure its process outputs are uniquely identifiable. Documented information that enables product outputs to be traced back through the QMS must be retained. KEY POINTS: • Essentially, this sub-clause is unchanged from ISO 9001:2008 sub-clause 7.5.3 “Identification and traceability”. • ISO 9001:2015 sub-clause 8.5.2 states that identification and traceability is to be employed “where necessary to ensure the conformity of products and services”. However, ISO 9001:2008 simply states that it is to be employed “where appropriate”. • There are some terminology changes. ISO 9001:2015 refers to “process outputs”, the “provision of products and services” and “documented information”, whereas ISO 9001:2008 refers to “products”, “product realization” and “records”. However, the substance of the requirements is identical.
Property belonging to	8.5.3	7.5.4	Customer property	Sub-clause 8.5.3 requires the organisation to take care of property supplied to it for incorporation into its products or services by customers or by external providers. As such

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
customers or external providers				the organisation must ensure any such property is identified, verified, protected and safeguarded. If the property is incorrectly used, lost or damaged, the organisation must make sure that this is reported back to the customer or external provider and retain documented information on what has happened. A note provides examples of the types of property that this clause is intended to cover. KEY POINTS: • This requirement is essentially unchanged from ISO 9001:2008 sub-clause 7.5.4. • However, it has now been extended to cover not just customer property, but also property belonging to the external providers provided to the organisation for use or incorporation into the products and services. As such, existing arrangements must be revised to reflect this. • For organisations that use external providers' property, this can impact on their QMS in relation to gaps in controls needed, and these organisations need to ensure compliance with this requirement.
Preservation	8.5.4	7.5.5	Preservation of product	Sub-clause 8.5.4 requires the organisation to take appropriate measures during production and service provision to safeguard process outputs, in order to maintain their conformity to requirements. The note to sub-clause 8.5.4 provides examples of "preservation". These include identification, handling, packaging, storage, transmission or transportation and protection. KEY POINTS: • Although this sub-clause refers to "process outputs" as opposed to "product", its requirements are essentially the same as for ISO 9001:2008 sub-clause 7.5.5 "Preservation of product".

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• Examples of what preservation could include now appear in a note to sub-clause 8.5.4 instead of in the body of the sub-clause itself. • "Transportation" and "Transmission" have been added to the original ISO 9001:2008 preservation examples.
Post-delivery activities	8.5.5			NEW CLAUSE Sub-clause 8.5.5 requires the organisation to determine the nature and extent of any post-delivery activities it needs to undertake. The organisation must consider any potential undesired consequences associated with the product or service. the nature of the product or service, how the product or service will be used and what the product or service's intended lifetime is. In addition, consideration of any post-delivery activities also needs to take into account customer requirements, customer feedback and any applicable statutory or legal requirements. KEY POINTS: • This is a new clause. • These are new requirements and the QMS will need to be amended to address this clause. • Note should be taken of any necessary considerations relating to undesired consequences, the nature of the product or service, its intended lifetime, customer requirements and feedback and applicable statutory or legal requirements. • This is especially important if the products or services are of high risk and have a large or indefinite lifetime.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Control of changes	8.5.6			NEW CLAUSE The organisation is required to review and control any changes considered essential in order to ensure products or services continue to meet their specified requirements. In such instances, the organisation must retain documented information describing the results of the review of the changes, the person(s) authorising the changes and any necessary actions. KEY POINTS: • This is a new clause. • If the organisation determines it must make changes to its processes in order to ensure its products or services continue to conform to their specified requirements, then these changes must be made in a controlled manner. • There are several implications if an organisation regularly makes unplanned changes as a result of market or customer needs, or lack of supplier performance.
Release of products & services	8.6	8.2.4	Monitoring and measurement of product	Clause 8.6 requires the organisation to carry out predetermined verification at appropriate points in the production/delivery process to verify that products and services meet agreed acceptance criteria. Products or services must not normally be released to the customer until all of the planned tests and checks have been satisfactorily completed, unless someone with the relevant authority agrees to their early release. Where applicable, permission for early release must also be obtained from the customer. Documented information needs to be retained including: • evidence that the product or service meets the acceptance criteria needs to be retained

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• identification of the individual authorising the release. KEY POINTS: • Sub-clause 8.6 refers to “products and services” instead of “products”, and to the need to retain “documented information” as opposed to “evidence” of conformity to requirements. • Apart from this, it is otherwise equivalent to ISO 9001:2008 sub-clause 8.2.4.
Control of non-conforming outputs	8.7			Title Only ISO 9001:2008 has been split into 2 sub-clauses in ISO9001:2015.
	8.7.1	8.3	Control of nonconforming product	The organisation is required to identify any outputs, products or services that do not conform to their intended requirements. Controls need to be established and implemented to ensure that these “nonconforming” outputs, products or services are not delivered to the customer or used unintentionally. Where nonconforming outputs, products or services are identified, the organisation is required to take action to correct the fault. This corrective action must be proportionate, reflecting both the nature of the nonconformity and its ability to impact the organisation’s intended product or service. This requirement also applies to nonconforming products or services that are identified after delivery to the customer. The organisation is required to deal with nonconforming outputs, products or services in one or more of the following ways: • by correcting the fault;

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• by segregation or containment of the outputs, products or service; • by securing the return or suspension of provision of product or service • by informing the customer • by obtaining authorisation for acceptance under a concession. If the organisation decides to correct a nonconforming process output, product or service it must verify the corrective action it has taken has restored the output, product or service's conformity to requirements. KEY POINTS: • This clause contains minor changes in requirements from ISO 9001:2008 clause 8.3 "Control of nonconforming product". • ISO 9001:2015 includes reference to "outputs" and "services" as well as to products. • There is no longer a requirement for a documented procedure that defines the controls and related responsibilities and authorities for dealing with nonconforming products.
	8.7.2			The organisation is required to retain documented information that describes the nonconformity and the actions taken. This also needs to include details of any concessions obtained and details of the person or authority that made decisions in respect of dealing with the nonconformity.

Clause 9: Performance Evaluation

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Performance evaluation	9			Title Only
Monitoring, measurement, analysis & evaluation	9.1			Title Only
General	9.1.1			NEW CLAUSE Sub-clause 9.1.1 requires the organisation initially to determine what it needs to monitor and measure. Once this has been done it must then decide how it is going to carry out these activities in order to ensure the results obtained are valid. The requirement for methods to ensure valid results also extends to the organisation's analysis and evaluation activities. In addition, the organisation must also determine when monitoring and measurement should be carried out and at what stage the results of monitoring and measurement should be analysed and evaluated. There is a requirement for organisations to evaluate the quality performance and effectiveness of their QMSs. Documented information is to be retained to evidence the results. KEY POINTS: • The decision on whether to monitor or to measure, and what to monitor and measure, can have a significant impact on the effectiveness of the QMS, its implementation and its results.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation

				• The decision whether to monitor or to measure, and what to monitor and measure will be based on:
				  • the degree of confidence in the operational controls established for its processes, and their effectiveness. Historical data on performance can be used to establish what should be monitored and what should be measured;
				  • the degree of confidence the organisation needs to have in the operational controls it has established for its processes, and their effectiveness. This can use the output from the organisation's approach to addressing risks and opportunities; as well as the needs and expectations of its customers and interested parties.
				• In the absence of data for either of the above points, the organisation may have to have a comprehensive set of monitoring and measurement activities until such time that it can build enough information and/or data to help inform its decision making for future monitoring and measurement activities.
				• This is all about the assessment of risk.

Customer satisfaction	9.1.2	8.2.1	Customer satisfaction	Sub-clause 9.1.2 requires the organisation to put in place arrangements to monitor the degree to which customers **believe** their requirements for products and services have been met. The organisation needs to identify how this information is to be secured and the way in which it is to be used. Guidance is provided by means of the Note similar to that in 9001:2008 clause 8.2.1 as to the methods that could be employed to obtain customer views. KEY POINTS: • This clause supersedes ISO 9001:2008 sub-clause 8.2.1.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• The organisation must decide how it is going to obtain and use customer satisfaction information.
Analysis & evaluation	9.1.3	8.1 & 8.4	General & analysis of data	Sub-clause 9.1.3 requires the organisation to analyse and evaluate appropriate data and information it has obtained through its monitoring and measurement processes. The data and information should be analysed to determine: • the organisation's products and services conform to requirements; • the degree of customer satisfaction;; • the performance and effectiveness of the QMS • that planning has been successfully implemented; • effectiveness of actions to address risks and opportunities; • performance of external providers; • the need for improvements within the QMS. KEY POINTS: • Sub-clause 9.1.3 refers to analysis "and evaluation" of data, rather than just "analysis" as in ISO 9001:2008 clause 8.4. • There is a new requirement for data and information to demonstrate planning has been effective. • The ISO 9001:2008 clause 8.4c reference to preventive action has been removed. • Sub-clause 9.1.3 refers to evaluating the performance and effectiveness of the QMS as a whole, whereas ISO 9001:2008 refers to providing information relating to the characteristic and trends of processes.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• The ISO 9001:2008 clause 8.1 reference to “statistical techniques and the extent of their use” has been removed.
Internal audit	9.2			
	9.2.1	8.2.2	Internal audit	Sub-clause 9.2.1 confirms the requirement for the organisation to carry out internal audits at planned intervals in order to determine whether the QMS conforms to both the organisation’s own requirements and the requirements of ISO 9001:2015. Internal audits must also identify whether the QMS is being effectively implemented and maintained. KEY POINTS: • These requirements are essentially unchanged from ISO 9001:2008 sub-clause 8.2.2.
	9.2.2	8.2.2	Internal audit	Sub-clause 9.2.2 sets out a series of requirements relating to how audit programmes must be structured, what audits must cover, who should undertake audits and how audits are to be reported. When designing an audit programme, organisations need to consider the importance of the processes concerned, changes within the organisation, and the results of previous audits. Each audit needs to have a defined scope and its own audit criteria. Audits and auditors need to be impartial and objective and the findings from audits need to be fed back to the relevant management with any required corrections or corrective actions being taken in a timely manner.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				Documented information needs to be retained to provide evidence that the audit programme has been implemented. Documentary information must also exist to provide evidence of the results of audits. KEY POINTS: • There is no longer a requirement for organisations to establish a documented internal audit procedure. However, organisations may still chose to operate one if they so wish. • There is a need to retain documented information evidencing the implementation of an audit programme and also the results of audits. • When designing the internal audit programme organisational changes now need to be considered explicitly • The results of the audits should be reported to the relevant management versus ISO 9001:2008 where the “nonconformities are reported to the management of the area audited”
Management review	9.3			Title Only
General	9.3.1	5.6.1	General	Sub-clause 9.3.1 requires reviews of the QMS to be undertaken by top management at planned intervals in order to ensure the QMS’s continuing suitability, adequacy and effectiveness. This is essentially unchanged from the existing ISO 9001:2008 sub-clause 5.6.1. However, ISO 9001:2015 requires management reviews additionally to consider the degree of alignment between the QMS and the strategic direction of the organisation.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Management review inputs	9.3.2	5.6.2	Review input	Sub-clause 9.3.2 details the items that top management must (as a minimum) consider during a management review: • revisit the status of any actions identified at previous reviews; • the changes in both internal and external issues relevant to the QMS; • performance and effectiveness of the QMS. Specific reference is made to the need for trends and indicators relating to nonconformities and corrective action, monitoring and measurement results, audit results and customer satisfaction and feedback from relevant interested parties, process performance and conformity of products and services. Also contained within this section is a requirement to consider the performance of external providers; • the adequacy of resources; • effectiveness of actions to address risks and opportunities (as identified in clause 6.1); • any opportunities for improvement. KEY POINTS: • This sub-clause supersedes ISO 9008:2008 sub-clause 5.6.2 “Review input”. • The overall purpose of management reviews remains unchanged, there are now new “strategic” items relating to external and internal issues and risk and opportunities to be included on the agenda. • There is a requirement that “trends and indicators” be used to monitor specific elements of quality performance. This contrasts with ISO 9001:2008, where the requirement is simply to “include information” on these items. • The implication is a more comprehensive review process.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				NOTE: a lot of the information listed will already be available in some organisations, but may not have been addressed under 'quality management' in the past.
Management review outputs	9.3.3	5.6.3	Review output	Sub-clause 9.3.3 sets out specific requirements in respect of the outputs from management reviews. These must include decisions as to whether there is a need to change any aspect of the QMS, the level of resources needed to support the operation of the QMS, as well as any decisions relating to improvement opportunities. The organisation must retain documented information to provide evidence as to the results of management reviews. KEY POINTS: • This sub-clause supersedes ISO 9001:2008 sub-clause 5.6.3 "Review output". The requirements of both sub-clauses are, however, essentially the same. • Organisations are required to retain documented information as evidence of the results of the management reviews rather than records of management review as stated in 9001:2008.

Clause 10: Improvement

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Improvement	10			
General	10.1			NEW CLAUSE It sets out the headline requirement for organisations actively to seek out and realise improvement opportunities that will better enable the organisation to meet customer requirements and enhance their customers' satisfaction. When looking to improve, organisations should seek to improve their products and services to meet requirements and to prepare for future needs and expectations, correct, prevent or reduce undesired results and seek to improve the performance and effectiveness of their QMS. It is recognised improvement does not always take place on a continual basis. Sometimes it occurs as a result of corrective action, sometimes through innovation and sometimes as a result of re-organisation. Preventive action no longer exists as a concept in ISO 9001:2015 and all references to it have been removed. It has been replaced by risk-based thinking. The explicit requirement to improve the QMS through the use of the quality policy, quality objectives, audit results, analysis of data and corrective actions, and management review that appears in ISO 9001:2008 sub-clause 8.5.1 "Continual improvement" has been removed from ISO 9001:2015. KEY POINTS: • Organisations should ensure they have systems in place to review their products and services, reduce undesired results and the performance of their QMS as a whole, with the objective of making improvements.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				• There are no longer any requirements to be fulfilled relating to preventive action (previously ISO 9001:2008 sub-clause 8.5.3). • It is no longer necessary to have a documented procedure for preventive action. • Pay attention when improving products and services not only to meet known requirements, but also the “future needs and expectations”.
Nonconformity & corrective action	10.2			Heading Only ISO 9001:20015 splits the requirements into 2 sub clauses.
	10.2.1	8.5.2	Corrective action	Sub-clause 10.2.1 sets out how the organisation is required to act when nonconformity is identified. The organisation is required to take whatever action is necessary to control and correct the nonconformity, and to deal with any resultant consequences. Once completed, the organisation can then move on to consider whether any further action is required to prevent a similar nonconformity occurring at some point in the future. This requires the organisation to determine what caused the nonconformities (root cause analysis) and then to consider whether the potential for a similar problem remains. The organisation is required to implement any actions identified as needed, review their effectiveness and make changes to the QMS if necessary. This clause also recognises the actions organisations take on nonconformities should be appropriate to the effect of those nonconformities.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
				This sub-clause was previously ISO 9001:2008 sub-clause 8.5.2“Corrective action”. KEY POINTS: • There is now an explicit requirement for organisations on discovering nonconformity to determine whether other similar nonconformities actually do or potentially could exist. • There is also a requirement for the organisation to determine whether changes are required to the wider QMS in order to prevent a reoccurrence. • Sub-clause 8.5.3 “Preventive action” has been removed.
	10.2.2			NEW CLAUSE Sub-clause 10.2.2 requires the organisation to keep documented information detailing the nature of any nonconformity identified and the action that the organisation decided to take to address it. This documented information must also record the results of the corrective action. KEY POINTS: • The ISO 9001:2008 sub-clause 8.5.2 requirement for a documented corrective action procedure has been removed. Instead, the organisation is now required to retain “documented information”. • If organisations wish to retain their existing documented corrective action procedure, then providing it meets the requirements of sub-clause 10.2.2, it will be accepted as documented information. • Please note the documented information will require the nature of the nonconformities to be recorded as well as any subsequent actions taken. This was not an explicit requirement of 9001:2008 sub clause 8.5.2.and is a new requirement.

ISO 9001:2015	Clause Number	Clause Number	ISO 9001:2008	ISO 9001:2015 Interpretation
Continual improvement	10.3	8.5.1	Continual improvement	Clause 10.3 requires the organisation to work continually to improve its QMS in terms of its suitability, adequacy and effectiveness. As part of the continual improvement process, the organisation is specifically required to use the outputs from analysis and evaluation (see sub-clause 9.1.3) and from management review (see clause 9.3) to determine areas of underperformance and to identify any opportunities for improvement. KEY POINTS: • The ISO 9001:2008 sub-clause 8.5.1 requirement continually to improve the effectiveness of the QMS has been extended to include its adequacy and suitability. • Organisations now need to demonstrate they are using the outputs from their analysis and evaluation processes to identify areas of underperformance and opportunities for improvement.