

ISO 9001:2015 Audit Procedures

Fourth edition

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The content and requirements of the ISO 9001:2015 standard

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2.1 WHAT ARE THE CURRENT ISO 9000 STANDARDS?

The ISO 9000 family of standards consists of three primary standards supported by a number of technical reports. These are:

- **ISO 9000:2015 Quality Management Systems: fundamentals and vocabulary** – which describes the fundamentals of QMSs and specifies the terminology for QMSs.
- **ISO 9004:2009 Managing for the sustained success of an organisation. A Quality Management approach** – which provides guidance on QMSs, including the processes for continual improvement that will contribute to the satisfaction of an organisation's customers and other interested parties.
- **ISO 9001:2015 Quality Management Systems. Requirements** – which is the most important Quality Management 'requirements' standard that is applicable to all organisations, products and services.

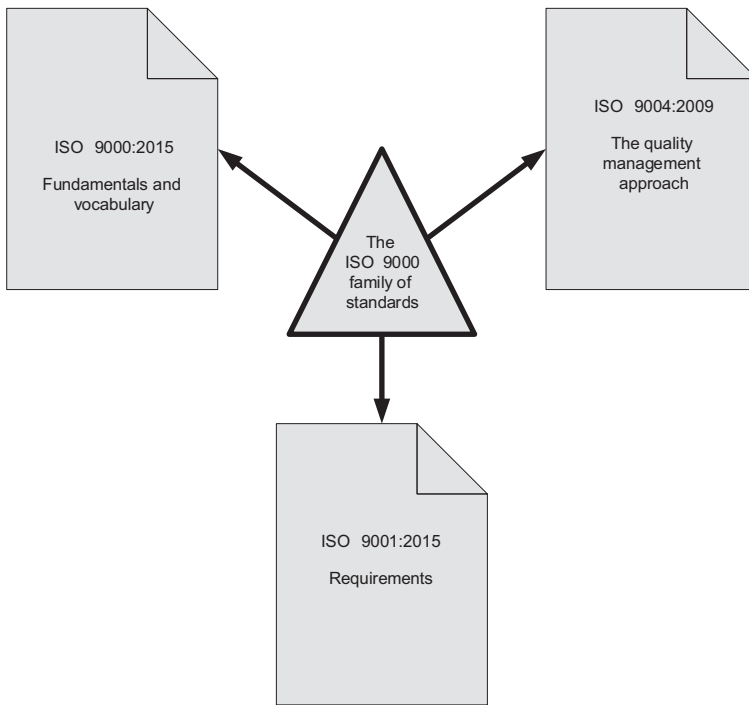


FIG. 2.1 The ISO 9000 family

2.1.1 ISO 9000:2005 Quality Management Systems: fundamentals and vocabulary

To ensure a more harmonised approach to standardisation (and the hopeful(!) achievement of coherent terminology within the ISO 9000 family), ISO 9000:2015 was developed in order to assist:

- those concerned with enhancing the mutual understanding of the terminology used in Quality Management (e.g. suppliers, customers, regulators);
- internal or external auditors, regulators, certification and/or registration bodies;
- developers of related standards;
- organisations that provide advice or training on the quality matters.

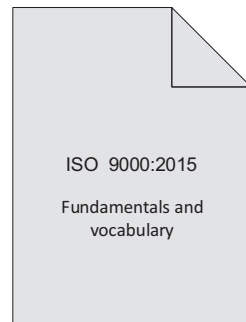


FIG. 2.2
The way to ISO
9000:2015

ISO 9000:2015 also provides:

- an introduction to the fundamentals of Quality Management Systems;
- terms and definitions;
- the methodology used in the development of the vocabulary.

2.1.2 ISO 9004:2009 Managing for the sustained success of an organisation. A Quality Management approach



Author's Hint

This third edition of ISO 9004 contains up-to-date information on achieving sustainable business success through Quality Management.

It provides guidance on QMSs, including the processes that are required for continual improvement and, ultimately, customer satisfaction. It outlines the importance of self-assessment to identify areas of strength within organisations and areas where improvements can be made.



Author's Hint

ISO 9004 will help you achieve and maintain business objectives in the long term; however, it is not intended to provide certification or regulatory requirements. Instead, it builds on ISO 9001 to widen the scope of your Quality Management and give you greater confidence in how you assess, maintain and improve it.



FIG. 2.3
The reason for ISO 9004:2009

ISO 9004 outlines a systematic approach to continual improvement of your organisation's overall performance. This includes best practice advice on quality strategy and policy, as well as managing resources and processes.

ISO 9004:2009 also provides:

- Quality Management Principles;
- managing for the sustained success of an organisation;
- strategy and policy;
- resource management;
- process management;
- monitoring, measurement, analysis and reviews;
- improvement, innovation and learning;
- self-assessment tools;
- normative references;
- terms and definitions.

2.1.3 ISO 9001:2015 Quality Management Systems. Requirements

ISO 9001:2015 is a single Quality Management *requirements* standard that is applicable to all organisations, products and services. It is the only standard that can be used for the certification of a QMS, and its generic requirements can be used by *any* organisation to:

- address customer satisfaction;
- meet customer and applicable regulatory requirements;
- enable internal and external parties (including certification bodies) to assess the organisation's ability to meet these customer and regulatory requirements.

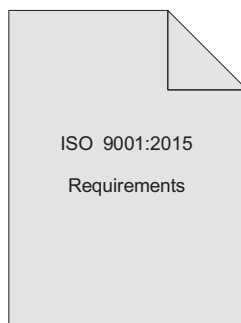


FIG. 2.4
The benefits of gaining ISO 9001:2015

For certification purposes, your organisation will now have to possess a documented management system which takes the inputs and transforms them into targeted outputs, something that effectively:

- says what they are going to do;
- does what they have said they are going to do;
- keeps records of everything that they do – especially when things go wrong.

The basic process used to achieve these targeted outputs will encompass:

- the client's requirements;
- the inputs from management and Staff;
- documented controls for any activities that are needed to produce the finished article; and, of course
- delivering a product or service which satisfies the customer's original requirements.

2.2 WHAT IS THE STRUCTURE OF ISO 9001:2008?

ISO 9001:2015 commences with an introductory section, which is then followed by the seven sections that make up ISO 9001:2015 and which are summarised below.

Clause 1 Scope

The Scope is 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.

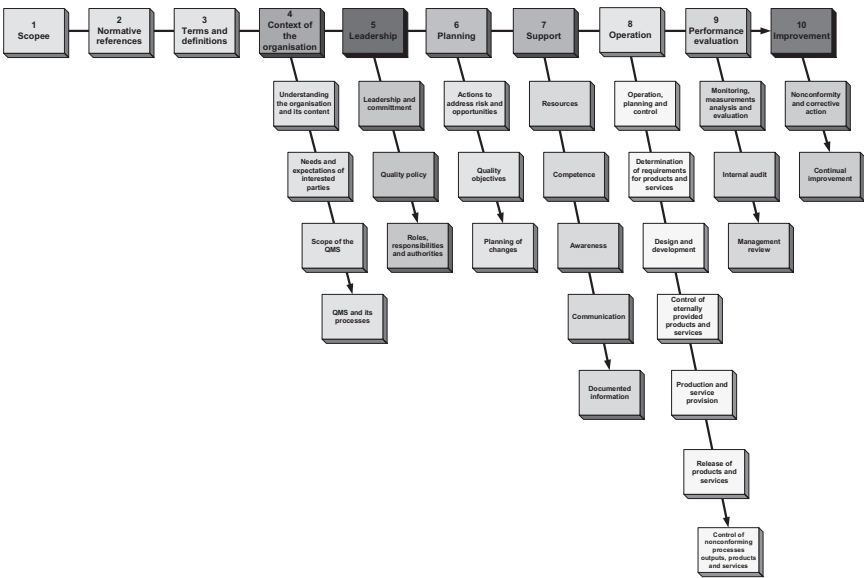


FIG. 2.5 The major clauses

Clause 2 Normative references

This section lists any standards that form a mandatory input to ISO 9001:2015.

💡 ISO 9001:2015 does not contain any additional normative references.

Clause 3 Terms and definitions

This section contains a description of the ISO 9001:2015 standard-specific terms and definitions.

💡 For ISO 9001:2015, all relevant terms and conditions have been brought directly into the primary standard.

Clause 4 Context of the organisation

This clause is broken down into four separate sub-clauses which address the scope of the organisation’s Quality Management System, with particular emphasis on the needs and expectations of interested parties.

It provides the basic foundation of *any* management system for identifying, monitoring and reviewing internal and external issues that are relevant to its purpose and strategic direction, and that have the ability to impact the Quality Management System’s intended results.

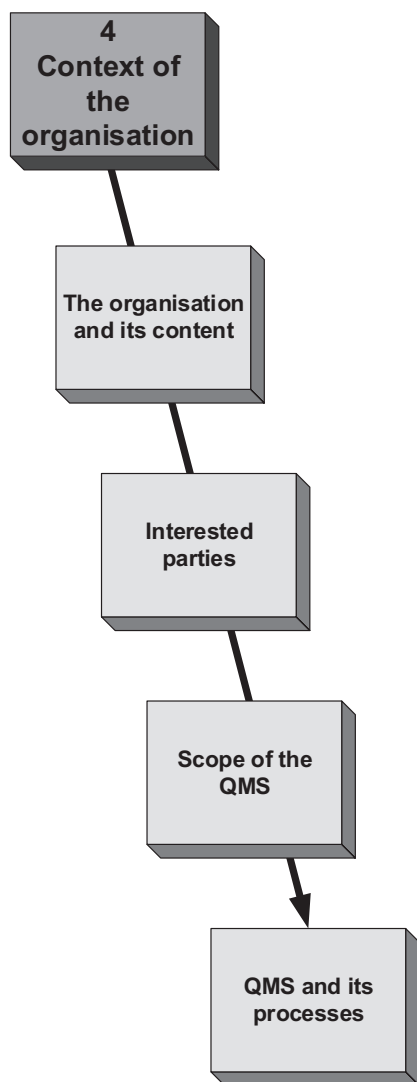


FIG. 2.6 Clause 4: Context



Author's Hint

The list of interested parties that the organisation needs to consider must include: direct customers, end users, suppliers, distributors, retailers (or others involved in the supply chain), regulators, etc.

The organisation and its context

ISO 9001:2015 Clause 4.1 ‘Understanding the organisation and its context’	‘The organisation shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its Quality Management System’
--	--

This is a new clause introduced into ISO 9001:2015 relating to ‘Context’, which requires organisations to identify, monitor and review all external and internal issues that could influence the requirements of the organisation’s QMSs.

The needs and expectations of interested parties

ISO 9001:2015 Clause 4.2 ‘Understanding the needs and expectations of interested parties’	‘The organisation shall determine: • the interested parties that are relevant to the Quality Management System; • the requirements of these interested parties that are relevant to the Quality Management System’
--	---

Another new clause introduced for ISO 9001:2015, which requires organisations to identify ‘relevant interested parties’ (groups or individuals) who have the ability to impact (or potentially impact) the organisation’s capability to consistently supply products and services that meet customer *and* applicable statutory and regulatory requirements.

The scope of the Quality Management System

ISO 9001:2015 Clause 4.3 ‘Determining the scope of the Quality Management System’	‘The organisation shall determine the boundaries and applicability of the Quality Management System to establish its scope’
--	--

The organisation must establish, implement, maintain and improve its Quality Management System (including the necessary processes and their interactions) in accordance with the requirements of this standard.

Quality Management System and its processes

ISO 9001:2015 Clause 4.4 'Quality Management System and its processes'	'The organisation shall: • establish, implement, maintain and continually improve a Quality Management System, including the processes needed and their interactions; • maintain and retain documented information to support the operation of its processes'
---	---

ISO 9001:2015 has now made it a *mandatory* requirement for an organisation to establish a process-based Quality Management System. Once this is in place and fully implemented, it needs to be maintained and continually improved.

Clause 5 Leadership



'Management responsibility' is replaced by 'Leadership' in the 2015 edition of ISO 9001.

Although 'Leadership' would seem at first glance to be just a reiteration of what's gone before regarding policy, organisational roles, responsibilities, authorities and so on, in the 2015 edition there is now much more emphasis on this being seen as a 'hands on' Leadership as opposed to just 'management'.

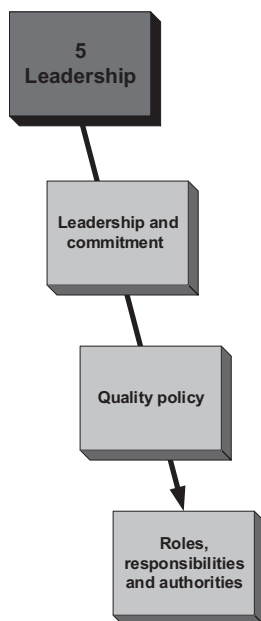


FIG. 2.7 Clause 5: Leadership

Leadership and commitment

ISO 9001:2015 Clause 5. ‘Leadership and commitment’	‘Top Management shall demonstrate Leadership and commitment with respect to: • the Quality Management System; • customer focus’
--	--

ISO 9001:2015 specifically *requires* Top Management to accept responsibility for, and demonstrate their commitment to, their organisation’s QMS.



It is also now a *mandatory requirement* for Top Management to guarantee that their organisation consistently provides products and services that conform to customer requirements, that meet applicable statutory and regulatory requirements and (of prime importance!) enhance customer satisfaction.

Policy

ISO 9001:2015 Clause 5.2 ‘Policy’	‘Top Management shall establish, implement and maintain a Quality Policy that: • is appropriate to the purpose and context of the organisation and supports its strategic direction; • provides a framework for setting quality objectives; • includes a commitment to satisfy applicable requirements and continual improvement of the Quality Management System; • is available and maintained as documented information; • is communicated, understood and applied within the organisation; • is available to relevant interested parties, as appropriate’
--	--

Top Management are now required to ensure that their organisation’s Quality Policy and quality objectives are consistent with the organisation’s overall strategic direction, and the situation in which the organisation is currently operating or intending to operate in.

Organisational roles, responsibilities and authorities

ISO 9001:2015 Clause 5.3 ‘Organisational roles, responsibilities and authorities’	‘Top Management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organisation’
--	---

Top Management need to assign roles, responsibilities and authorities that are appropriate to the necessary people who can be trusted to ensure that the organisation’s QMS is capable of covering *and* meeting all of the requirements from ISO 9001:2015 that are necessary for their type of business.

Clause 6 Planning

This clause is all about how the organisation will prevent, or reduce, undesired effects (i.e. risks). How will it ensure that it can achieve the aims of its QMS and ensure continual improvement?

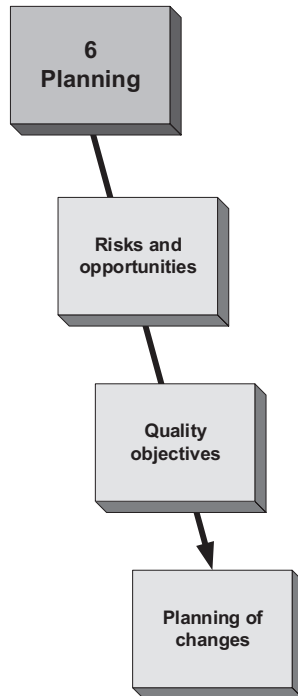


FIG. 2.8 Clause 6: Planning

Risks and opportunities

ISO 9001:2015 Clause 6.1 ‘Actions to address risks and opportunities’	‘When planning the Quality Management System, the organisation shall consider the issues concerning the organisation and its context and the requirements concerning the needs and expectations of interested parties (referred to in 4.1 and 4.2) and: • determine the risks and opportunities that need to be addressed; • plan actions to address these risks and opportunities; • integrate and implement the actions into its Quality Management System processes; • evaluate the effectiveness of these actions’
--	---

This is a new requirement (brought about by the introduction of Annex SL) which requires organisations to adopt a risk-based approach when planning the workflow of their business, and which means that they will have to decide those risks and opportunities that will have the potential to impact the operation and performance of their Quality Management System, both positively and negatively.

**Author’s Hint**

This risk-based methodology will incorporate much of what was previously called ‘preventive action’.

Quality objectives and planning to achieve them

ISO 9001:2015 Clause 6.2 ‘Quality objectives and planning to achieve them’	‘The organisation shall establish quality objectives at relevant functions, levels and processes needed for the Quality Management System’, which shall: • be consistent with the Quality Policy; • be measurable; • take into account applicable requirements; • be relevant to conformity of products and services and to enhancement of customer satisfaction; • be monitored; • be communicated; • be updated as appropriate’
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Clause 6.2 continued	'The organisation shall also determine: • what will be done; • what resources will be required'
---------------------------------	---

Top Management need to document a set of quality objectives that the organisation must meet, particularly with respect to the conformity of products and services and the enhancement of customer satisfaction.

Planning of changes

ISO 9001:2015 Clause 6.3 'Planning of changes'	'When the organisation determines the need for changes to the Quality Management System, the changes shall be carried out in a planned manner'
---	---

When there is a need to make a change to the QMS, then this must be completed in a controlled manner and any changes proposed must be thoroughly reviewed.

Clause 7 Support

This clause considers what resources are required to meet the goals, policies, objectives and ambitions of an organisation.

Resources

ISO 9001:2015 Clause 7.1 'Resources'	'The organisation shall determine and provide: • the resources needed for the establishment, implementation, maintenance and continual improvement of the Quality Management System; • the persons necessary for the effective implementation of its Quality Management System and for the operation and control of its processes; • the infrastructure necessary for the operation of its processes and to achieve conformity of products and services; • the environment necessary for the operation of its processes and to achieve conformity of products and services;
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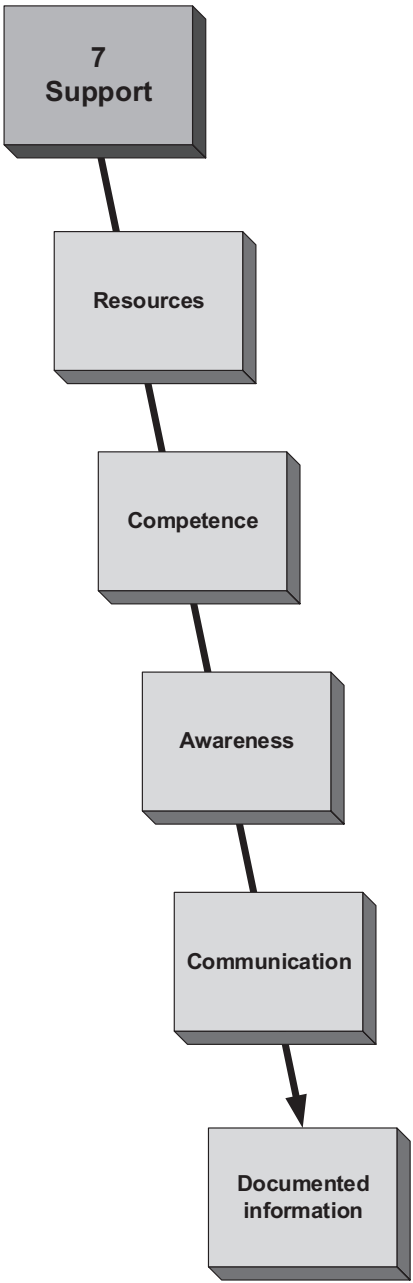


FIG. 2.9 Clause 7: Support

Clause 7.1 <i>continued</i>	• the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements'
--	--



Author's Hint

When measurement traceability is a requirement (or has become an essential part of providing confidence in the validity of measurement results), then all necessary measuring equipment should be identified, calibrated (or certified) and safeguarded from adjustments, damage or deterioration prior to use.

There are a number of specifics that an organisation is required to consider when providing resources. For example, it will have to decide and then subsequently provide the knowledge-based resources necessary to establish, implement, maintain and continually improve its QMS, taking into consideration whether this can be provided from its existing internal resources or whether it needs to be outsourced from an external provider.

It will also need to provide the necessary infrastructure to support process operations and properly maintain a suitable environment for the operation of its processes, to assure conformity of products and services.

Competence

ISO 9001:2015 Clause 7.2 'Competence'	'The organisation shall determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the Quality Management System'
--	--

The organisation must ensure that those people performing work under its control possess the necessary competencies, either on the basis of their education, training or experience.

Awareness

ISO 9001:2015 Clause 7.3 'Awareness'	'The organisation shall ensure that persons doing work under the organisation's control are aware of: • the Quality Policy; • relevant quality objectives; • their contribution to the effectiveness of the Quality Management System; • the implications of not conforming with the Quality Management System requirements'
---	--

ISO 9001:2015 now makes it a *requirement* for people completing work under the organisation’s control (including subcontractors) to be aware of the organisation’s Quality Policy, any quality objectives that are relevant to them, how they will be contributing to the effectiveness of the QMS and what implications there will be if they don’t conform to these QMS requirements.

Communication

ISO 9001:2015 Clause 7.4 ‘Communication’	‘The organisation shall determine the internal and external communications relevant to the Quality Management System’
---	--

Organisations need to decide on what they will communicate, when they will communicate, with whom they will communicate and how they will communicate – taking into consideration whether this is internal, external or third party communication.

Documented information

ISO 9001:2015 Clause 7.5 ‘Documented information’	‘The organisation’s Quality Management System shall include documented information required by this International Standard in addition to that necessary for the effectiveness of their Quality Management System. This documented information shall be controlled to ensure that: • it is available and suitable for use, where and when it is needed; • it is adequately protected; • it includes all the relevant information concerning description format, type of media to be used, and how it should be reviewed and approved for suitability and adequacy’
--	---

Similar to the previous edition of the standard, the organisation must document all the information detailed in ISO 9001:2015 that is necessary for the effective operation of its QMS.

Furthermore, this information must be properly identified and described (e.g. title, date, author, reference number, etc.) in an appropriate format (e.g. language, software version, graphics, etc.); and made available throughout the organisation (e.g. via paper and/or electronic means) when and where needed.

It must also ensure that this information is protected against improper use, loss of integrity, loss of confidentiality and (in this day and age) has adequate anti-virus protection, of course!



Author's Hint

As previously mentioned, the terms 'document' and 'record' have both been replaced throughout the requirements text by 'documented information'.

Clause 8 Operations

The requirement to plan and develop processes has now been expanded for the organisation to plan, *implement and control* the processes that it needs.



Author's Hint

In addition, the term 'product realisation' has been replaced by 'operation', and the requirement for 'Planning of product realisation' has been replaced by 'Operational planning and control'.

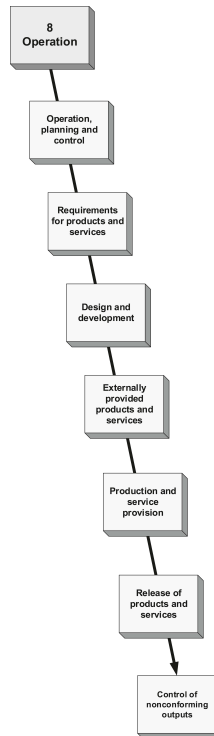


FIG. 2.10 Clause 8 Operations

Planning and control

ISO 9001:2015 Clause 8.1 'Operational planning and control'	'The organisation shall plan, implement and control the processes needed to meet the requirements for the provision of products and services'
--	--

In addition to an organisation having to plan, implement and control its processes in order for it to meet the product and service requirements of ISO 9001:2015, it must now also plan how to address any risks and opportunities that may impact these processes and, therefore, its ability to achieve these requirements.

Requirements for products and services

There are four separate subsections to this particular clause, as shown below:

ISO 9001:2015 Clause 8.2.1	'Requirements for products and services'
'Customer communication'	'Communication with customers shall include: • providing information relating to products and services; • handling enquiries, contracts or orders, including changes; • obtaining customer feedback relating to products and services, including customer complaints; • handling or controlling customer property; • establishing specific requirements for contingency actions, when relevant'
'Determining the requirements for products and services'	'The organisation shall ensure that: • the requirements for the products and services are defined, including: – any applicable statutory and regulatory requirements; – those considered necessary by the organisation; • the organisation can meet the claims for the products and services it offers'

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'Review of requirements for products and services'	'The organisation shall ensure that it has the ability to meet the requirements for products and services to be offered to customers and shall retain documented information, as applicable: • on the results of the review; • on any new requirements for the products and services'
'Changes to requirements for products and services'	'The organisation shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed'

Similarly, ISO 9001:2015 now requires the organisation to have a process in place to try to gain 'customer feedback', and now also to be able to gain and discuss the views and perceptions of the customer with respect to (for example) the handling and/or treatment of customer property and specific requirements.

Design and development of products and services

ISO 9001:2015 Clause 8.3 'Design and development of products and services'	'The organisation shall: • establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services; • determine the requirements essential for the specific types of products and services to be designed and developed; • apply controls to the design and development process and verify that the design output meets the design and development inputs; • ensure that design and development outputs are capable of meeting the input requirements; • identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements'
---	--

 This is a *new mandatory clause* that requires the introduction of a design and development process, and is particularly aimed at organisations that have not established detailed requirements for their products or services, or where these have not been defined by the customer or other interested parties. Thus, in future, organisations will be required to plan and control the design and development of their products and services and describe a process comprising a number of stages, each of which will be subject to controls, and they *must* ensure the adequacy of requirements prior to their communication to the external provider.

Externally provided processes, products and services

ISO 9001:2015 Clause 8.4 ‘Control of externally provided processes, products and services’	‘The organisation shall ensure that externally provided processes, products and services conform to requirements and do not adversely affect the organisation’s ability to consistently deliver conforming products and services to its customers’
---	---

The organisation must ensure that externally provided processes, products and services (including training) satisfy specified requirements.

Production and service provision

ISO 9001:2015 Clause 8.5.1 ‘Production and service provision’	‘The organisation shall: • implement production and service provision under controlled conditions; • use suitable means to identify outputs when it is necessary to ensure the conformity of products and services; • exercise care with property belonging to customers or external providers while it is under the organisation’s control or being used by the organisation; • preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements; • meet requirements for post-delivery activities associated with the products and services; • review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements’
--	--

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This clause requires the organisation to control the way in which it provides its products and services and what activities need to be performed to produce the product or deliver the service.

Release of products and services

ISO 9001:2015 Clause 8.6 'Release of products and services'	'The organisation shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met'
--	--

Before a product or service may be released to a customer, the organisation must verify that all customer- and product/service-specific requirements have been met.

Nonconforming outputs

ISO 9001:2015 Clause 8.7.1 'Control of nonconforming process outputs'	'The organisation shall: • ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery; • retain documented information that: – describes the nonconformity; – describes the actions taken; – describes any concessions obtained; – identifies the authority deciding the action in respect of the nonconformity'
--	---

The organisation needs to develop controls to identify any process outputs, products and/or services that do not conform to their intended requirements, are not delivered to the customer or are used unintentionally.

Clause 9 Performance evaluation

This new clause includes a lot of what was in Clause 8 in the previous ISO 9001:2008 – ‘Measurement, analysis and improvement’, with the addition of evaluation, internal audit and management review.

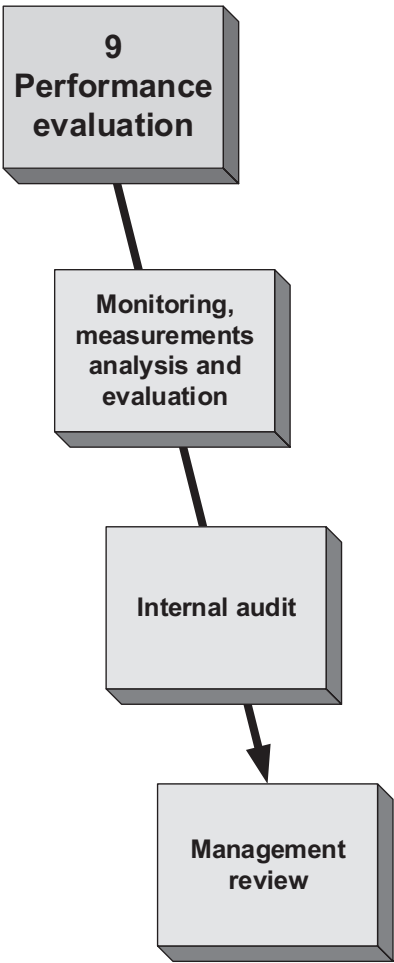


FIG. 2.11 Clause 9: Performance evaluation

Monitoring, measurement, analysis and evaluation

ISO 9001:2015 Clause 9.1 ‘Monitoring, measurement, analysis and evaluation’	‘The organisation shall: • determine what needs to be monitored and measured; • determine the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results; • determine when the monitoring and measuring shall be performed; • determine when the results from monitoring and measurement shall be analysed and evaluated; • monitor customers’ perceptions of the degree to which their needs and expectations have been fulfilled; • determine the methods for obtaining, monitoring and reviewing this information; • analyse and evaluate appropriate data and information arising from monitoring and measurement’
--	---

Basically this clause is all about risk assessment where, having initially determined when, how and what the organisation needs to monitor and measure, it must also decide how best to carry out these activities in order to improve the quality performance and effectiveness of its Quality Management System.



Author’s Hint

One of the principal changes here is that the organisation can no longer make its own decision (perception) as to whether it has satisfied its customers’ requirements; it now needs to find out exactly what the customer thinks of the organisation, its products and services.

Internal audit

ISO 9001:2015 ‘Clause 9.2 Internal audit’	‘The organisation shall plan, establish and conduct internal audits at planned intervals to provide information on whether the Quality Management System conforms to: • the organisation’s own requirements for its Quality Management System; • the requirements of this International Standard’
--	---

This is reiteration of the previous ISO 9001:2008 standard whereby the organisation must carry out internal audits at planned intervals in order to determine whether its Quality Management System meets the requirements of its own documented QMS, as well as those of ISO 9001:2015.

Management review

ISO 9001:2015 Clause 9.3 'Management review'	'Top Management shall review the organisation's Quality Management System, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness and alignment with the strategic direction of the organisation taking into consideration: • actions from previous management reviews; • changes in external and internal issues relevant to the QMS; • customer satisfaction and feedback from relevant interested parties; • process performance and conformity of products and services; • nonconformities and corrective actions; • monitoring and measurement results; • audit results; • performance of external providers; • adequacy of resources; • effectiveness of actions taken to address risks; • opportunities for improvement. The outputs from these reviews shall include decisions and actions related to: • opportunities for improvement; • any need for changes to the Quality Management System; • resource needs'
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While the overall purpose of management reviews remains unchanged and Top Management still needs to conduct regular reviews of the QMS at planned intervals, there are now new items relating to context, risk and opportunities that need to be considered.

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Clause 10 Improvement



Author's Hint

All references to 'preventive action' have been removed in ISO 9001:2015, as these have been replaced by 'risk-based thinking'.

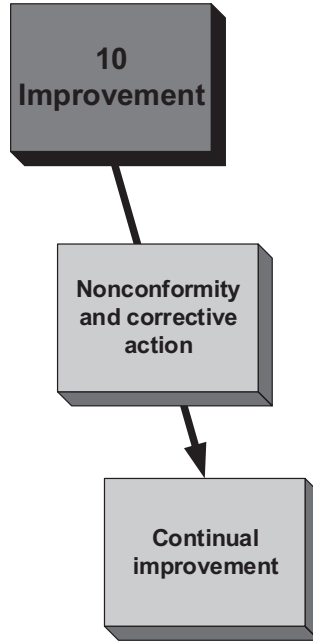


FIG. 2.12 Clause 10: Improvement

The main requirement of this new clause is for the organisation to address nonconformity, corrective action and improvement and, in doing so, not only continue to meet customer requirements but also improve customer satisfaction.

Nonconformity and corrective action

ISO 9001:2015 Clause 10.2 'Nonconformity and corrective action'	'When a nonconformity, including any arising from complaints, occurs, the organisation shall take action to control and correct it'
--	--

When a nonconformity is identified, the organisation needs to take whatever action is necessary to control and correct the nonconformity and to make changes to the Quality Management System if necessary.

Continual improvement

ISO 9001:2015 Clause 10.3 'Continual improvement'	'The organisation shall continually improve the suitability, adequacy and effectiveness of the Quality Management System'
--	--

Although the previous version of ISO 9001 required an organisation ‘continually to improve the effectiveness of their Quality Management System’, this has now been changed to a requirement for the organisation to work ‘continually to improve its Quality Management System in terms of its suitability, adequacy and effectiveness’.

2.3 WHAT IS THE DIFFERENCE BETWEEN ISO 9001:2015
AND ISO 9001:2008?

It is important to realise that *not* everything in the 2015 version of ISO 9001 has changed from the previous version!

However, as ISO 9001:2015 was written in accordance with Annex SL (with text and terminology common to all other management system standards), the structure has changed quite dramatically as can be seen from the following table.

ISO 9001:2015 Clause		Equivalent ISO 9001:2008 Clause	
1	Scope	1	
2	Normative Reference	2	
3	Terms and Definitions	3	
4	Context of the Organisation (Section title)	1.0	Scope
4.1	Understanding the organisation and its context	1.1	General
4.2	Understanding the needs and expectations of interested parties	1.1 4.2.2	General Quality Manual
4.3	Determining the scope of the Quality Management System	1.2 4.2.2	Application Quality Manual
4.4	Quality Management System and its processes	4 4.1	Quality Management System General requirements

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ISO 9001:2015 Clause		Equivalent ISO 9001:2008 Clause	
5	Leadership (Section title)	5	Management responsibility
5.1	Leadership and commitment	5.1	Management commitment
5.2	Policy	5.3	Quality Policy
5.3	Organisational roles, responsibilities and authorities	5.5.1	Responsibility and authority
		5.5.2	Management representative
6	Planning (Section title)	5.4.2	Quality Management System planning
6.1	Actions to address risks and opportunities	5.4.2	Quality Management System planning
		8.5.3	Preventive action
6.2	Quality objectives and planning to achieve them	5.4.1	Quality objectives
6.3	Planning of changes	5.4.2	Quality Management System planning
7	Support (Section title)	6	Resource management
7.1	Resources	6	Resource management
7.1.1	General	6.1	Provision of resources
7.1.2	People	6.1	Provision of resources
7.1.3	Infrastructure	6.3	Infrastructure
7.1.4	Environment for the operation of processes	6.4	Work environment
7.1.5	Monitoring and measuring resources	7.6	Control of monitoring and measuring equipment
7.1.6	Organisational knowledge		New
7.2	Competence	6.2.1	General
		6.2.2	Competence, training and awareness
7.3	Awareness	6.2.2	Competence, training and awareness
7.4	Communication	5.5.3	Internal communication
7.5	Documented Information	4.2	Documentation requirements
7.5.1	General	4.2.1	General
7.5.2	Creating and Updating	4.2.3	Control of documents
		4.2.4	Control of records

ISO 9001:2015 Clause		Equivalent ISO 9001:2008 Clause	
7.5.3	Control of Documented Information	4.2.3 4.2.4	Control of documents Control of records
8	Operation (Section title)	7	Product realisation
8.1	Operational planning and control	7.1	Planning of product realisation
8.2	Requirements for products and services	7.2.2	Customer-related processes
8.2.1	Customer communication	7.2.3	Customer communication
8.2.2	Determination of requirements related to products and services	7.2.1	Determination of requirements related to the product
8.2.3	Review of requirements related to products and services	7.2.2	Review of requirements related to the product
8.2.4	Changes to requirements for products and services	7.2.2	Review of requirements related to the product
8.3	Design and development of products and services	7.3	Design and development
8.3.1	General		New
8.3.2	Design and development planning	7.3.1	Design and development planning
8.3.3	Design and development inputs	7.3.2	Design and development inputs
8.3.4	Design and development controls	7.3.4 7.3.5 7.3.6	Design and development review Design and development verification Design and development validation
8.3.5	Design and development outputs	7.3.3	Design and development outputs
8.3.6	Design and development changes	7.3.7	Control of design and development changes
8.4	Control of externally provided processes, products and services	7.4.1	Purchasing process
8.4.1	General	7.4.1	Purchasing process

ISO 9001:2015 Clause		Equivalent ISO 9001:2008 Clause	
8.4.2	Type and extent of control	7.4.1 7.4.3	Purchasing process Verification of purchased product
8.4.3	Information for external providers	7.4.2	Purchasing information
8.5	Production and service provision	7.5	Production and service provision
8.5.1	Control of production and service provision	7.5.1	Control of production and service provision
8.5.2	Identification and traceability	7.5.3	Identification and traceability
8.5.3	Property belonging to customers or external providers	7.5.4	Customer property
8.5.4	Preservation	7.5.5	Preservation of product
8.5.5	Post-delivery activities	7.5.1	Control of production and service provision
8.5.6	Control of changes	7.3.7	Control of design and development changes
8.6	Release of products and services	8.2.4 7.4.3	Monitoring and measurement of processes Verification of purchased product
8.7	Control of nonconforming outputs	8.3	Control of nonconforming product
9	Performance evaluation (Section title)		New
9.1	Monitoring, measurement, analysis and evaluation	8	Measurement, analysis and improvement
9.1.1	General	8.1	General
9.1.2	Customer satisfaction	8.2.1	Customer satisfaction
9.1.3	Analysis and evaluation	8.4	Analysis of data
9.2	Internal audit	8.2.2	Internal audit
9.3	Management review	5.6	Management review
10	Improvement (Section title)	8.5	Improvement
10.1	General	8.5.1	Continual improvement
10.2	Nonconformity and Corrective Action	8.3 8.5.2	Control of nonconforming product Corrective action
10.3	Continual Improvement	8.5.1	Continual improvement