

THE ROUTE TO ISO 9001:2015

THE ART OF MANAGEMENT:

CUSTOMER REQUIREMENTS;

**BUILDING SYSTEMS AND
PROCESSES; DEVELOPING A**

CULTURE OF
BUSINESS IMPROVEMENT;

STRIVING FOR **EXCELLENCE.**

MORE THAN **CREATING
PROCEDURES** AND

TICK BOXES. ISO 9001

WILL HELP YOUR BUSINESS DEVELOP

CUSTOMER FOCUSED

MANAGEMENT SYSTEMS; REMAIN COMPETITIVE;

QUICKLY ADAPT

IN A CHANGING WORLD...

READ ON...

SGS

FOREWORD

The purpose of this booklet is to provide a simple introduction to ISO 9001 Quality Management Systems. It is not intended to be a full explanation of the standard nor of its implementation, rather, it aims to promote understanding and to help the reader profit from the experience of third-party auditors, and the problems encountered by others.

It is hoped that this simple approach will cut through some of the 'fog' and 'management speak' that so often overcomplicates something that should be reasonably straightforward.

It is not intended as a replacement for the standard, and the reader is strongly advised to purchase a copy of ISO 9001 if planning to implement an ISO 9001 quality management system. A copy of the standard may be purchased at www.iso.org and will also be available from the reader's National Standards publishing authority.

Some of the wording of this booklet is taken from ISO 9001 and SGS acknowledges the permission of the British Standards Institute for use of those extracts.

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TERMS AND DEFINITIONS

All terms and definitions given in the text of the booklet can be found in the reference document:

ISO 9000:2015 Quality Management Systems – Fundamentals and Vocabulary

INTRODUCTION TO ISO 9001:2015

This booklet gives a brief introduction to ISO 9001 and points out some of the common pitfalls in implementation and preparing for third-party audit.

For an organisation the adoption of a quality management system is a strategic decision, made to improve its overall performance and to provide a solid basis for sustainable development initiatives.

Consistently being required to meet and address future needs and expectations can pose a challenge for organisations in an environment that is increasingly dynamic and complex.

The international standard ISO 9001 promotes the adoption of a process approach when planning, developing, implementing and improving the effectiveness of its processes and their interactions with an aim to enhance customer satisfaction by meeting customer requirements.

This international standard can be applied to any type or size of organisation.

Risk-based thinking has been introduced into the International Standard, which has enabled a reduction in prescriptive requirements, being replaced by performance based requirements. The incorporation of the PDCA cycle of

PLAN → DO → CHECK → ACT has been retained.

As one of the key purposes of a quality management system is to act as a preventive tool the need to have a separate clause on preventive action has been removed.

Throughout this booklet the following verbal forms are used:

'shall' indicates a requirement

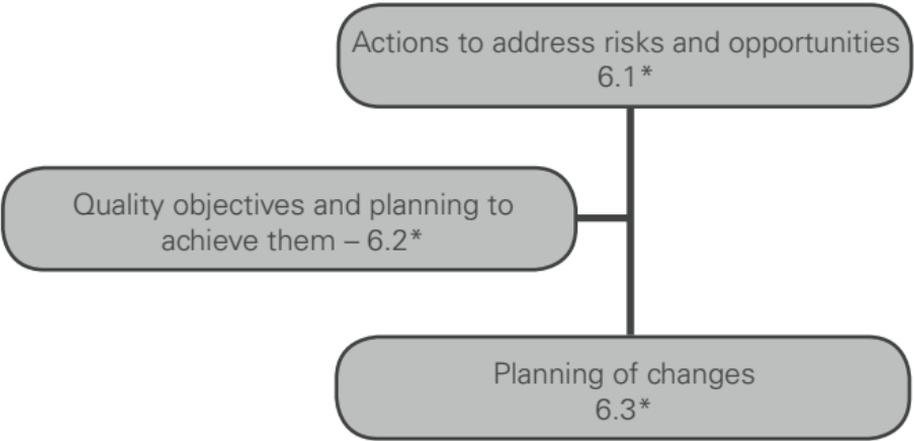
'should' indicates a recommendation

'may' indicates a permission

'can' indicates a possibility or a capability.

The '**PLAN**' part of the process starts by establishing the objectives, looking at risks and opportunities and any associated actions, and planning any changes necessary to deliver results in accordance with customer requirements and the organisation's policies.

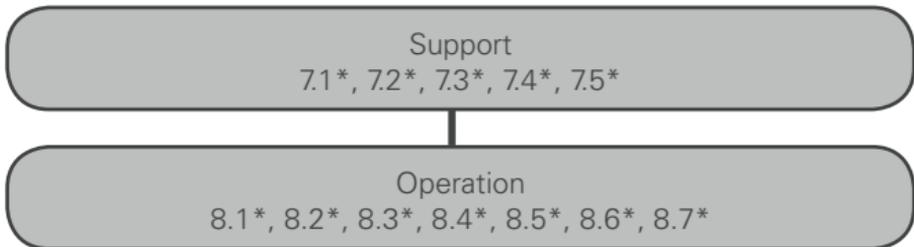
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** clause of ISO 9001:2015*

The organisation will also have to take into account the context of their organisation, the needs and expectations of their interested parties (including all statutory and regulatory requirements that are applicable to the product, service or application to ensure its safe and proper intended use to the customer or end user) and any changes that are required to their quality management system. Therefore the interested parties will play a significant role in defining the requirements as inputs into the '**PLAN**' part of the process.

Now comes the '**DO**' part of the implementation cycle. The objectives and processes now established have to be implemented and managed.



A choice can be made on how this is achieved. Some can be managed through improvement programmes and be subject to Objectives, Targets and Management programmes, or they can be controlled by operational control procedures. In some instances both of these mechanisms can be applied.

An important part of the process, the '**CHECK**' part, comes next. This includes the monitoring and measurement and subsequent results of the quality management system. Inputs will also come from customer satisfaction (interested parties) and from the products and services offered themselves.

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Performance evaluation
9.1*, 9.2*, 9.3*

** clause of ISO 9001:2015*

This ensures that the controls and procedures are functioning as intended. There is a requirement to report all findings and results, normally through the internal audit process and at management review meetings.

The final part of the cycle is for the organisation to '**ACT**' against the findings and results, which may be through nonconformity and/or corrective action.

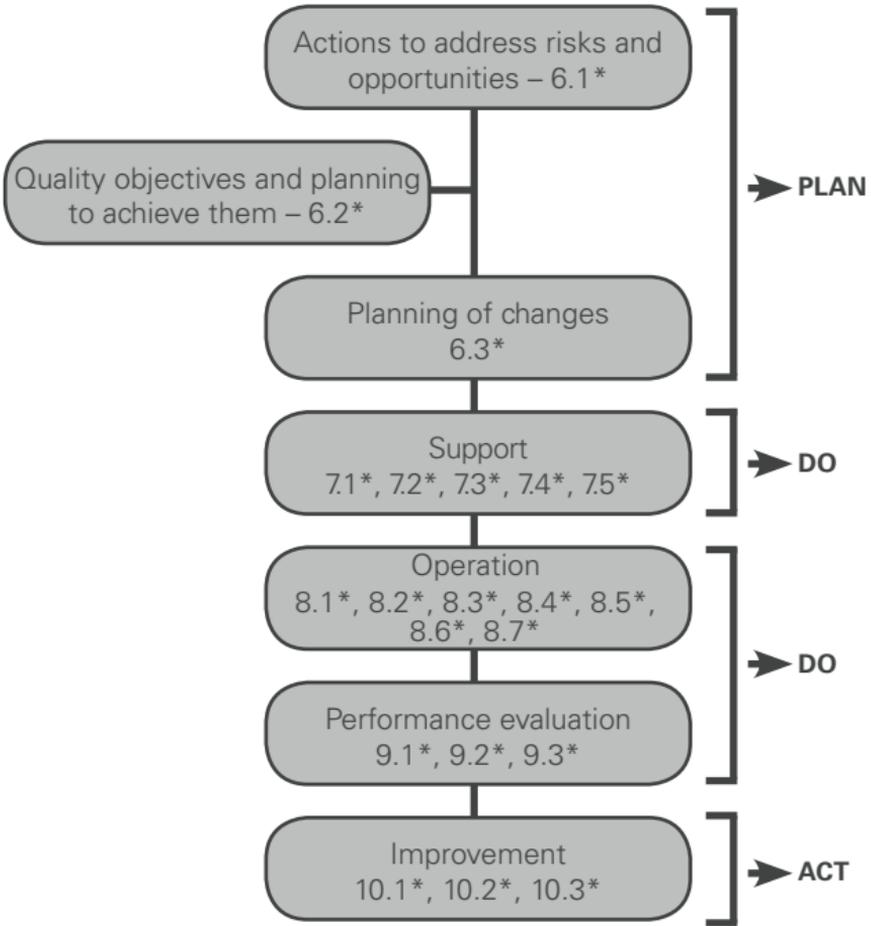
Improvement
10.1*, 10.2*, 10.3*

There will be a requirement to take action to continually improve process performance.

The **PLAN → DO → CHECK → ACT** methodology is designed to operate at all levels through the organisation and can be applied to all processes.

Underpinning the four elements of the PDCA is clause 5 of the International Standard – Leadership (5.1*, 5.2*, 5.3*).

ISO 9001 PROCESS FLOWCHART



**clause of ISO 9001:2015*

ISO 9001:2015 uses the Annex SL template (framework), which is a requirement for all new and revised Management System Standards. It provides the high level structure (i.e. major clause numbers and titles) that are fixed and cannot be changed, core text, common terms and core definitions. Discipline-specific sub-clauses may be added (which is the case for ISO 9001:2015). Similarly, there will be common requirements across all the management system standards, for example the requirement to “..establish, implement, maintain and continually improve the management system”. One of the consequences of adopting the Annex SL template is that some of the requirements of ISO 9001:2008, which are unchanged in ISO 9001:2015, are now located under different headings in different numbered clauses.

Although all of the requirements in ISO 9001:2015 are intended to be applicable to all types of organisation, of whatever size, it is recognised that there may be circumstances where an organisation cannot comply with a specific requirement because it simply does

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not undertake a certain type of activity as part of its business. In such a case the organisation can regard the requirement as 'not applicable'. However, it cannot do this if it would affect its ability to supply products or services that comply with client requirements, or which adversely affect its ability to enhance customer satisfaction. The organisation has to justify designating any elements of ISO 9001:2015 as not applicable.

“QUALITY AUDIT” OR “AUDIT OF QUALITY”

If you simply audit a site or business, identify its quality problems and then fix them you could well return a year later to find that all of the problems have reappeared simply because there is no management system in place.

On the other hand, if you install a quality management system, make it work and then audit that system you deliver real control and genuine ongoing improvement.

An ISO 9001 QMS provides a system of inter-linking processes. It is an effective toolkit of mechanisms for managing quality issues in any kind of organisation. It is only prescriptive in terms of **what** must happen, leaving the **how** to the organisation to decide or devise for itself.

This approach means that ISO 9001 can be applied to any kind and scale of organisation. It also explains why, from time to time, there are misunderstandings of its intent and in its application.

THE ADOPTION OF AN ISO 9001 MANAGEMENT SYSTEM...

...will mean that an organisation will potentially benefit from:

- The ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements
- Facilitating opportunities to enhance customer satisfaction
- Addressing risk and opportunities associated with its context and objectives
- The ability to demonstrate conformity to specified quality management system requirements.

The notes below are preceded by the clause number of ISO 9001:2015 and are presented in the order they appear in the standard.

4.1 UNDERSTANDING THE ORGANISATION AND ITS CONTEXT

The 'context' of the organisation (sometimes called its business or organisational environment) refers to the combination of internal

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and external factors and conditions that can have an effect on an organisation's approach to its products, services and investments. As a result, the design and implementation of an organisation's quality management system will be influenced by its context (and any changes to it).

An organisation's context will include, for example:

- the specific objectives of the organisation;
- the needs and expectations of its customers and any other relevant 'interested parties';
- the products and services it provides;
- the complexity of both the processes that the organisation uses and the way in which they interact;
- its size and organisational structure.

This is not a completely new concept for quality management systems, since the Introduction to ISO 9001:2008 (section 0.1 General) includes a number of references to the examples as given above.

An organisation has to identify those external and internal issues that are relevant to its 'context' and that can affect its ability to achieve the intended outcome(s) of its management system. The organisation must also continue to monitor and review those issues to establish whether any changes to them will affect its QMS, or its purpose.

Although many organisations will already be monitoring internal and external issues, this is a new requirement that all clients will now need to comply with.

There is no specific requirement that these internal and external issues, or their monitoring and review, have to be documented by an organisation. However, in many cases this information could be available from several different sources. It may form part of an organisation's documented business plan or business strategy, for example, or be referenced on the organisation's website, in its annual reports to shareholders, or there may even be simply a section in the management review minutes dealing with this issue.

Senior management will be best placed to explain the organisation's context since the organisation has to consider its 'strategic direction' when identifying internal and external issues. Depending on an organisation's management structure, its quality manager, for example, may not have sufficient knowledge of the issues relevant to the organisation's context and be unable to provide the information necessary to verify compliance with the requirements of this clause.

This table summarises the requirements of clause 4.1.

REQUIREMENTS	✓ or X	COMMENT/PLAN
Has the organisation determined: <ul style="list-style-type: none"> • Internal issues? • External issues? Relevant to its purpose and strategic direction		
Does the organisation monitor and review: <ul style="list-style-type: none"> • Internal issues? • External issues? 		

4.2 UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

An organisation is required to identify the ‘interested parties’ that are relevant to its QMS. By ‘relevant’ ISO 9001 means those parties that can or could have an impact on the organisation’s ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements. The organisation is also required to identify what requirements these interested parties themselves have, which are relevant to the organisation’s QMS. Ongoing monitoring and review of these interested parties and their requirements is also required.

An ‘interested party’ (sometimes referred to as a ‘stakeholder’) is any person or organisation that can affect, be affected by, or perceive themselves to be affected by the decisions or activities of the organisation implementing the QMS. These interested parties could include the organisation’s shareholders, employees, customers, end users, suppliers, regulators, pressure groups, etc.

In order to determine whether an interested party, or its requirements, are relevant to their QMS, the organisation must consider whether or not they have an impact on the organisation’s ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements or enhance customer satisfaction. Every organisation will have its own set of relevant interested parties and these may well change over time. Every interested party will also have its own set of requirements, but not all of these will be relevant to an organisation’s QMS.

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There will need to be some form of evidence that an organisation has been through an initial process that both identifies who its relevant interested parties are, as well as their requirements that are relevant to the organisation's QMS. There will also need to be evidence that the organisation continues to review whether the relevance of these interested parties and/or their requirements change.

Where the organisation has determined that an interested party and/or its requirements are not relevant to its QMS then it does not have to take any action to address them.

Again, as with organisational context, there is no specific requirement that these interested parties or their requirements, or their monitoring and review, have to be documented by an organisation. However, this information could again be available from the same sources that could be used to identify internal and external organisational context issues (documented business plan or business strategy, organisation websites, annual reports, etc. or again even a section in the management review minutes dealing with them).

This table summarises the requirements of clause 4.2.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Has the organisation determined: <ul style="list-style-type: none">• The interested parties?• The requirements of the interested parties?		
Does the organisation: <ul style="list-style-type: none">• Monitor and review information about the interested parties?• Monitor and review their relevant requirements?		

4.3 DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM

This clause covers some of the requirements in ISO 9001:2008 clauses 1.2 'Application' and 4.2.2 'Quality Manual'. However, whilst there is still a requirement that an organisation must establish the scope of its quality management system, there is now a specific requirement that when doing so the organisation must consider:

- a) the external and internal context issues referred to in clause 4.1;
- b) the requirements of relevant interested parties referred to in clause 4.2;

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c) the products and services of the organisation.

An organisation must identify any boundaries and/or limits on the applicability of its QMS. So, for example, the scope can include the whole of the organisation, specific and identified functions of the organisation, specific and identified sections of the organisation, or one or more functions across a group of organisations; any physical limitations to the scope of the QMS will also need to be identified. Outsourced functions or processes are considered within the organisation’s scope.

Although there is no longer any requirement that the scope of an organisation’s QMS must be documented in a quality manual (which is no longer required), it must be available and maintained as ‘documented information’ (ISO 9001 clause 7.5). The scope must include reference to the products and services covered by the QMS.

This table summarises the requirements of clause 4.3.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Has the organisation determined the boundaries and applicability of the QMS to establish its scope?		
Has the organisation considered: <ul style="list-style-type: none"> • External and internal issues referred to in the context? • Requirements of relevant interested parties referred to in the interested parties clause? • Its own products and services? 		
Has the organisation applied all requirements of ISO 9001 that are applicable?		
Is the scope available and maintained as documented information?		
Does the scope state types of products or services covered?		

4.4 QUALITY MANAGEMENT SYSTEMS AND ITS PROCESSES

ISO 9001 requires the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system. As the achievement of consistent and predictable results is more effective and efficient when activities are understood and managed as interrelated processes, ISO 9001 now includes specific requirements necessary for the adoption of a process approach.

This process approach requires an organisation to systematically define and manage processes and their interactions so as to achieve the intended results in accordance with both the quality policy and strategic direction of the organisation. ISO 9001 now requires an organisation to identify:

- the inputs required and the outputs expected from processes;
- the measurements and related performance indicators, needed to ensure the effective operation and control of processes;
- the assignment of the responsibilities and authorities for processes;
- the risks and opportunities associated with processes (ISO 9001 clause 6.1) and planned and implemented appropriate actions to address them.

Although there is no longer any specific requirement to 'document' its QMS, an organisation is required to both maintain documented information necessary to support the operation of processes and retain sufficient documented information to demonstrate these processes are being carried out as planned.

Operational procedures, work instructions, process diagrams, etc. would be examples of documented information used to support the operation of processes, but individual organisations may have different approaches to this. Similarly, an organisation will need to retain documented evidence that shows individual processes are operating in line with the defined criteria (inputs, outputs, measurements, performance indicators, etc.).

This table summarises the requirements of clause 4.4.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Is the QMS established, implemented, maintained and continually improved, including the processes needed and their interactions?		
Have the processes needed for the QMS and their application been determined?		
Has the organisation: <ul style="list-style-type: none"> • Determined the inputs and outputs required? • Determined the sequence and interaction of these processes? • Determined and applied the criteria and methods needed for effective operation and control? • Determined the resources needed and their availability? • Assigned the responsibilities and authorities? • Addressed the risks and opportunities? • Evaluated these processes and implemented any changes? • Improved the processes? 		
Does the organisation: <ul style="list-style-type: none"> • Maintain documented information? • Retain documented information? 		

5.1 LEADERSHIP AND COMMITMENT

Top management are now required to demonstrate a greater direct involvement in the organisation’s QMS and the removal of the need for a specific ‘management representative’ is partly an attempt to ensure that ‘ownership’ of an organisation’s management system is not simply focused on an individual person.

Top management must be able to demonstrate that they have taken responsibility for emphasising the importance of conforming to the requirements of the quality management system. In addition, they must ensure that the QMS is achieving its intended results and drives continual improvement within their organisation.

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In those organisations where top management have effectively delegated responsibility for the QMS down to a management representative, then under ISO 9001 they will now have to demonstrate much more direct involvement in the QMS. They can still delegate tasks to others, such as the MR, but otherwise the specified requirements must be seen to be undertaken by top management themselves.

Top management have to be seen to be 'accountable' for their organisation's QMS and to emphasise the importance of effective quality management and conformance with QMS requirements. They must also ensure that quality management system requirements are integral to the organisation's business processes and be consistent with its overall strategic direction and the context in which it operates.

Several of the ISO 9001 elements that are aimed at top management leadership and commitment require them to 'ensure' that certain activities are undertaken or carried out. This indicates that top management can delegate these tasks to others to carry out. However, where there is a specific requirement that top management must be 'taking', 'promoting', 'communicating', 'engaging' and 'supporting' action(s) this indicates that they must carry out these actions themselves.

The specific requirement is that top management must have 'demonstrated leadership and commitment' and as with the issues relating to organisational context in ISO 9001 clause 4.1, there is no specific requirement that the activities related to this have to be documented.

Although there may be documented evidence available to demonstrate top management's leadership and commitment (internal/external awareness campaigns, communication documentation, adequate QMS resources available, etc.), it is now more likely that senior management will be interviewed in relation to these requirements to establish whether they have the appropriate 'hands-on' approach that is now required.

ISO 9001 has enhanced the requirement that top management shall not only ensure that "...customer requirements are determined and are met with the aim of enhancing customer satisfaction" but they

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also need to demonstrate that any risks and opportunities are being identified and addressed where they:

- could potentially have an impact on the organisation's ability to supply products and services that conform to customer requirements and applicable statutory or regulatory requirements; or
- may affect customer satisfaction.

In addition, top management have to demonstrate that they maintain a focus on consistently providing products and services that

- conform to customer requirements;
- meet applicable statutory and regulatory requirements; and
- enhance customer satisfaction.

The reference to the need to ensure that the focus on enhancing customer satisfaction is 'maintained' indicates that this is an ongoing requirement.

Top management is required to demonstrate leadership and commitment with respect to customer focus 'by ensuring' that these ISO 9001 requirements are carried out. This again suggests that these are tasks that do not have to be directly undertaken by top management and that responsibility for carrying them out can be delegated to other personnel.

Once more, there is no specific documented information required to demonstrate compliance with these requirements and it may be that evidence of compliance can only be found in relation to other ISO 9001 requirements.

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This table summarises the requirements of clause 5.1.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Has top management demonstrated leadership and commitment by: <ul style="list-style-type: none"> • Taking accountability for the effectiveness of the QMS? • Quality policy and quality objectives are established? • Ensuring the integration of the QMS requirements into the business processes? • Promoting the use of the process approach and risk-based thinking? • Ensuring resources needed are available? • Communicating the importance of the QMS and its requirements? • Ensuring the QMS achieves its intended results? • Engaging, directing and supporting persons to contribute to the effectiveness of the QMS? • Promoting improvement? • Supporting other relevant management roles? 		
Customer focus: <ul style="list-style-type: none"> • Customer and applicable statutory and regulatory requirements are determined, understood and consistently met? • Risks and opportunities are determined and addressed? • Focus on enhancing customer satisfaction is maintained? 		

5.2 POLICY

Although the requirements in relation to an organisation’s quality policy are broadly the same as those in ISO 9001:2008, there are some new elements. ISO 9001:2015 now requires that an organisation’s quality policy is appropriate to both its purpose and its ‘context’. This means that once the organisation has determined its context and the relevant requirements of its interested parties, top management will have to review its quality policy in light of that information.

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There is also now a requirement the quality policy includes a commitment to “...continual improvement” of the QMS, which is subtly different to the ISO 9001:2008 requirement to “...continually improve the effectiveness” of the QMS.

The quality policy itself has to be available as ‘documented information’ and verification will be needed to demonstrate that top management were involved in its preparation and that they continue to review it to ensure that any changes in context (including strategic direction), interested parties or their requirements are reflected in the quality policy and whether the organisation’s quality objectives are affected. There is no specific requirement that this ongoing review is documented.

There is also a new requirement that the quality policy is made available to the organisation’s ‘interested parties’ and demonstrations of how this is done for both internal and external interested parties will be required. It may be that the quality policy is available on the organisation’s website, for example, but other methods of ensuring that it is available can be used.

This table summarises the requirements of clause 5.2.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Has top management established, implemented and maintained a quality policy that: <ul style="list-style-type: none"> • 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? • Includes a commitment to continual improvement? 		
Is the quality policy: <ul style="list-style-type: none"> • Available and maintained as documented information? • Communicated, understood and applied? • Available to relevant interested parties? 		

5.3 ORGANISATIONAL ROLES, RESPONSIBILITIES AND AUTHORITIES

There is now a requirement that not only must responsibilities and authorities be assigned and communicated, but also that they are understood within the organisation. Therefore when an organisation’s personnel have been advised of their QMS responsibilities and authorities, they must also verify that personnel understand them. This will mean that the organisation itself will have to ensure that its personnel understand these responsibilities and authorities.

Top management have now also to ensure that specific responsibilities and authorities are assigned, communicated and understood in relation to:

- ensuring that the QMS conforms to the requirements of ISO 9001;
- ensuring that processes are delivering their intended outputs;
- reporting on the need for change or innovation in relation to the QMS;
- reporting to top management in relation to QMS performance, improvement opportunities, change and/or innovation.

Although there is no longer any requirement to appoint a specific management representative, the tasks currently assigned to the MR (in ISO 9001:2008 and those above) must still be carried out by one or more persons. Verification that these responsibilities and authorities in relation to these tasks have been assigned, communicated and understood will be needed.

This table summarises the requirements of clause 5.3.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Has top management ensured that responsibilities and authorities for relevant roles are assigned, communicated and understood?		
Has top management assigned the responsibility and authority for: <ul style="list-style-type: none"> • Ensuring the QMS conforms to ISO 9001? • Ensuring the processes are delivering their intended outputs? • Reporting on performance of the QMS? Ensuring the promotion of customer focus? • Ensuring the integrity of the QMS is maintained through planned changes? 		

6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

An organisation is now required to consider both its 'context' and 'interested parties' when planning and implementing its QMS.

This new requirement obliges organisations to identify those risks and opportunities that have the potential to impact (positively or negatively) on the operation and performance of their QMS.

Having identified those external and internal issues that are relevant to its context, as well as the needs of interested parties, an organisation is required to use that information to determine both the risks and opportunities that need to be addressed to:

- ensure that its management system can achieve its intended outcome(s);
- prevent, or reduce, undesired effects;
- achieve continual improvement.

Based on the results of this assessment, organisations then have to:

- take action to address any risks and opportunities;
- integrate and implement these actions into their QMS processes; and
- evaluate the effectiveness of the actions taken.

Not all of the processes of a QMS represent the same level of risk or opportunity in terms of the organisation's ability to meet its objectives. For that reason, ISO 9001 requires that the actions taken to address any risks and opportunities are "...proportionate to the potential impact on the conformity of products and services". The consequences of failures or nonconformities in relation to processes, systems products and/or services, for example, will not be the same for all organisations. So when deciding how to plan and control its QMS, including its component processes and activities, the organisation needs to consider both the type and level of risk or opportunity associated with them.

Options to address risks and opportunities can include:

- avoiding risk; taking risk in order to pursue an opportunity;
- eliminating the risk source; changing the likelihood or consequences;
- sharing the risk; or
- retaining risk by informed decision.

There needs to be evidence that the organisation has done this and that it continues to review whether these issues and requirements change. It also needs to demonstrate that the action taken is subsequently reviewed to confirm whether it has been effective or not.

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ISO 9001 contains no specific requirements for 'preventive action' but it could be argued that these requirements serve a similar purpose.

Although risks and opportunities have to be determined and addressed, there is no requirement for a formal, documented risk management process and organisations are free to choose the assessment and evaluation mechanism they consider is most appropriate for them. However, organisations must be able to demonstrate that they have a planned methodology in place that allows them to determine all/any risks and opportunities relevant to the planning of their QMS.

Documentation that demonstrates that this process has been carried out may be available (business plans or strategy documents, for example, annual reports, management review minutes, etc.), but there may be occasions where it is not. Again there may need to be an interview of senior management in relation to the organisation's risks and opportunities. Since these may have an influence on, or be influenced by, an organisation's strategic direction or its context, it is likely that discussion of these issues will have to involve senior management. Depending on an organisation's management structure, its quality manager, for example, may not have sufficient knowledge of the all the risks and opportunities relevant to the organisation and so be unable to provide the information necessary to verify compliance with the requirements of this clause.

This table summarises the requirements of clause 6.1.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
When planning the QMS has the organisation considered the issues, risks and opportunities that need to be addressed to: <ul style="list-style-type: none">• Give assurance the QMS can achieve its intended results?• Enhance desirable effects?• Prevent or reduce undesired effects?• Achieve improvement?		

<p>Has the organisation planned:</p> <ul style="list-style-type: none">• Actions to address the risks and opportunities?• Integration and implementation of the actions into the QMS processes?• Evaluation of the effectiveness of these actions?• Actions to be taken to address risk and opportunities are proportionate to the potential impact on the conformity or product or service?		
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6.2 QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM

In addition to the need to establish measurable quality objectives at relevant functions and levels that are consistent with an organisation's quality policy, there are now requirements that they must be established for 'relevant processes' and be relevant to the 'enhancement of customer satisfaction'. The implicit element of these changes is that an organisation will now have to demonstrate that their quality objectives actually 'add value' and not that they been established in order to meet the bare minimum requirements.

An organisation is required to retain documented information on their quality objectives. The requirements related to the planning needed to achieve quality objectives are now more explicitly detailed in ISO 9001. Organisations are now required to determine:

- what resources will be required to achieve quality objectives;
- who will be responsible for them; what will be done and when; and
- how will achievement of the objectives will be evaluated.

In some cases this will require organisations to undertake more detailed monitoring of objectives and targets than they currently do. Verification that the what, when, who and how elements have been satisfactorily planned will be required, but since an organisation has to retain documented information on their quality objectives, this should be available in some documented form or other. Personnel to whom responsibility for quality objectives has been given will have to be aware of what their responsibilities are and will have been given the resources to achieve the objectives.

This table summarises the requirements of clause 6.2.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Has the organisation established quality objectives at relevant functions, levels and processes?		
Are the quality objectives: <ul style="list-style-type: none"> • Consistent with the quality policy? • Measurable? • Taken into account regarding applicable requirements? • Relevant to conformity of products and enhancement of customer satisfaction? • Monitored? • Communicated? • Updated? 		
Is documented information maintained on the quality objectives?		
When planning how to achieve its quality objectives has the organisation determined: <ul style="list-style-type: none"> • What will be done? • What resources will be required? • Who will be responsible? • When it will be completed? • How the results will be evaluated? 		

6.3 PLANNING OF CHANGES

ISO 9001 still contains the key requirement that the integrity of an organisation’s QMS must be maintained when any changes to it are planned and implemented, but also adds further requirements. In addition to a general requirement that all changes to an organisation’s QMS are “...carried out in a planned and systematic manner” this process must include consideration of:

- why the change is being made and the potential consequences of that change;
- any effects on the integrity of the QMS; whether the resources necessary to carry out the change are available;
- the allocation or reallocation of related responsibilities and authorities caused by the change.

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Since ISO 9001 requires organisations to maintain/retain documented information “..to the extent necessary to support the operation of processes” then the activities related to QMS changes, including consideration of the issues above, will need to be documented.

This table summarises the requirements of clause 6.3.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Are changes carried out in a planned and systematic manner?		
Does the organisation consider: <ul style="list-style-type: none">• The purpose of the change and any potential consequences?• The integrity of the QMS?• The availability of resources?• The allocation of responsibilities and authorities?		

7.1 RESOURCES

ISO 9001 makes consideration/evaluation of resource capabilities a specific requirement. Additionally, when identifying the resources needed to establish, implement, maintain and continually improve its QMS, there is now a requirement that an organisation needs to take into account both internal and external resource requirements and capabilities.

There is no specific requirement that documented evidence needs to be available to demonstrate but it will need to be shown that both internal and external resource requirements and capabilities were considered.

Infrastructure – ISO 9001 does now make it clear that ‘infrastructure’ can include:

- buildings and associated utilities;
- equipment including hardware and software;
- transportation;
- information and communication technology.

Environment for the operation of processes – there is now a requirement for organisations to not only determine what is the work environment suitable to ensure conformity of products and services, but also to ‘provide and maintain’ it. The notes to the clause make it clear that ‘environment for the operation of processes’ can

include physical, social, psychological, environmental and other factors (such as temperature, humidity, ergonomics and cleanliness).

The organisation has not only to identify what the necessary environment is for the operation of its processes, but also that they have provided that environment; taking into account the factors listed in the notes to the clause. The organisation must have in place some method for ensuring that the necessary environment is maintained, though the type of monitoring and controls required will vary, depending on the processes involved.

Monitoring and measuring resources – there is now a greater emphasis on monitoring and measuring ‘resources’ rather than simply equipment; in this context, resources would include personnel, training, workplace environment, etc. There is no longer any specific mention of verification of computer software.

The organisation will have to retain documented information to demonstrate that not just monitoring and measuring equipment is fit for purpose, but that all monitoring and measuring resources are.

Organisational knowledge – this is a new requirement that addresses the need for organisations to determine and maintain the knowledge obtained by the organisation, including by its personnel, to ensure that it can achieve conformity of products and services. The primary requirement is that an organisation must establish the knowledge necessary for it to satisfactorily operate the processes it uses and provide products and services that conform to requirements.

The type of ‘organisational knowledge’ that will need to be maintained will vary from one organisation to another. It is likely to include knowledge held by competent personnel within the organisation that they use to carry out their operational tasks, for example, but it may also include bespoke software needed to run process equipment, internal and/or external product and service standards, technical manuals, intellectual property, etc. The amount or level of organisational knowledge needed may be large or small, depending on an individual organisation’s activities, processes and circumstances, but the key question is whether the organisation has identified the knowledge it needs to have in order to carry out its processes and activities.

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This knowledge needs to be maintained and made available where and when necessary. It is up to the organisation to decide how to do this and there is no specific requirement that this knowledge is to be retained as documented information. Additionally, when planning changes to its QMS or operational activities, an organisation is required to assess whether its existing organisational knowledge is sufficient to satisfactorily manage these changes or if it needs to obtain additional knowledge to do so and take steps to get it if necessary.

This table summarises the requirements of clause 7.1.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Have resources been determined and provided to establish, implement, maintain and continually improve the QMS?		
Has the organisation considered: <ul style="list-style-type: none"> • The capabilities and constraints on existing internal resources? • What needs to be obtained from the external providers? 		
Has the organisation determined and provided the persons necessary for effective implementation of the QMS?		
Has the infrastructure necessary been determined, provided and maintained?		
Has the environment necessary been determined, provided and maintained?		
When monitoring and measuring are used have the resources needed to ensure valid and reliable results been determined and provided?		
Are the resources provided: <ul style="list-style-type: none"> • Suitable for the type of monitoring and measurement activities? • Maintained to ensure continued fitness for purpose? • Appropriate documented information retained? 		

<p>Is measuring equipment:</p> <ul style="list-style-type: none"> • Calibrated? • Identified to determine its status? • Safeguarded from adjustment, damage or deterioration? 		
<p>Is validity of previous measurement results determined when measurement equipment is unfit for its intended use?</p>		
<p>Does the organisation:</p> <ul style="list-style-type: none"> • Determine the knowledge necessary for the operation of its processes? • Maintain the knowledge and make available to the extent necessary? • When addressing changing need determine how to acquire necessary additional knowledge or required updates? 		

7.2 COMPETENCE

ISO 9001 now defines ‘competence’ as the ability to apply knowledge and skills to achieve intended results. An organisation needs to demonstrate that it has determined the competency requirements for personnel and then it must:

- ensure that personnel meet those competency requirements; or
- take action to ensure that they acquire the identified competence.

The organisation also needs to demonstrate that any action taken to acquire or maintain competency is subsequently reviewed to establish whether it has been effective in raising personnel competence to the required level(s). Applicable ‘actions’ can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of suitably competent persons.

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A key addition to these requirements is that they now apply to all/ any personnel 'under its control' that affect the organisation's quality performance. This will include any sub-contract/agency personnel, as well as anyone undertaking outsourced processes and functions.

An organisation will now have to retain documented information to demonstrate that all personnel under its control are competent.

This table summarises the requirements of clause 7.2.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Has the organisation: <ul style="list-style-type: none">• Determined the necessary competence of persons doing work under their control?• Ensured that these persons are competent on the basis of education, training or experience?• Taken actions to acquire the necessary competence?• Retained appropriate documented information as evidence of competence?		

7.3 AWARENESS

ISO 9001 introduces a specific requirement that an organisation makes personnel under its control aware both of the organisation's quality objectives as well as the consequences of nonconformance with its QMS requirements.

Everyone (internal or external) doing work for the organisation shall have been made aware of:

- the organisation's quality policy and quality objectives;
- their contribution to the effectiveness of the QMS, including the benefits of improved quality performance;
- the implications of not conforming with QMS requirements.

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This table summarises the requirements of clause 7.3.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Are persons aware of: <ul style="list-style-type: none">• The quality policy?• Relevant quality objectives?• Their contribution to the effectiveness of the QMS?• The implications of not conforming with the QMS requirements?		

7.4 COMMUNICATION

There is now a specific requirement relating to communication with persons outside the organisation. There are specific requirements relating to this communication process and organisations will have had to identify both the internal and external communications that need to take place, including:

- what needs to be communicated;
- when this communication should take place;
- how the information will be communicated; and
- who should receive such communications.

This table summarises the requirements of clause 7.4.

PLANNING OF PRODUCT REALISATION	✓ OR X	COMMENT/PLAN
Has the organisation determined the internal and external communications relevant to the QMS: <ul style="list-style-type: none">• On what it will communicate?• When to communicate?• With whom to communicate?• How to communicate?• Who communicates?		

7.5 DOCUMENTED INFORMATION

The terms 'documented procedure' and 'record' used in ISO 9001:2008 have both been replaced throughout ISO 9001:2015 by the term 'documented information', which is defined as information required to be controlled and maintained by an organisation, as well as the medium on which it is contained. Where reference previously was to documented procedures (e.g. to define, control or support

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a process) this is now expressed as a requirement to 'maintain' documented information; where reference previously was to records this is now expressed as a requirement to 'retain' documented information.

Documented information can be in any format and media and from any source. The term 'documented information' itself can refer to:

- the quality management system, including related processes;
- information created in order for the organisation to operate (documentation);
- evidence of results achieved (records).

The extent of documented information required for a QMS can differ from one organisation to another.

This can be due to:

- the size of organisation and its type of activities, processes, products and services;
- the complexity of processes and their interactions;
- the competence of organisational personnel.

The organisation needs to determine the level of documented information necessary to control its own QMS.

The requirements relating to the creation and updating of documented information are essentially the same. However, whilst there is no longer any requirement for a document control procedure, the organisation will need to demonstrate that the documented information itself is being controlled. This control now needs to include adequate protection "...e.g. from loss of confidentiality, improper use, or loss of integrity".

Control of 'access' to documented information is now a specific requirement. 'Access' can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information. Where documented information is held electronically, there shall be adequate passwords or other access systems in place. Similarly, there will be a need to verify that there are satisfactory systems in place to permit access to documented information where electronic systems crash or are otherwise unavailable.

An organisation's existing operational procedures, work instructions, flow charts, process maps, etc. are all examples of documented information and it does not now have to remove their current

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quality manual or documented procedures. If an organisation wishes to retain these then they can do so. Nor do organisations have to restructure, rename or renumber their existing manuals or procedures just to bring them in line with the clause structure in ISO 9001.

This table summarises the requirements of clause 7.5

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Does the organisation's QMS include: <ul style="list-style-type: none"> • Documented information required by ISO 9001? • Documented information determined by the organisation as being necessary? 		
When creating or updating documented information does it have: <ul style="list-style-type: none"> • Identification and description? • Format and media? • Review and approval for suitability and adequacy? 		
Is documented information controlled to ensure: <ul style="list-style-type: none"> • It is available and suitable for use, where and when it is needed? • Is adequately protected? 		
The organisation has to address the following for control of documented information: <ul style="list-style-type: none"> • Distribution, access, retrieval and use? • Storage and preservation? • Control of changes? • Retention and disposition? 		
Is documented information of external origin identified as appropriate and controlled?		
Is documented information retained as evidence of conformity protected from unintended alterations?		

8.1 OPERATIONAL PLANNING AND CONTROL

ISO 9001 introduces a requirement to establish the 'criteria for the processes' and to implement controls 'in accordance with the criteria'. The emphasis is on controlling the processes and organisations need to demonstrate that they have planned and implemented the appropriate process criteria:

- inputs, outputs, resources, controls, criteria, process measurement indicators, etc.; plus
- any actions required to address identified risks and opportunities.

The processes involved will not only be those necessary to meet requirements for conforming products and services, but also those required to implement any actions needed to address identified risks and opportunities.

Organisations are also required to control not only planned changes to processes (and to process controls), but also to unintended, unplanned changes. Where unintended changes are made, the organisation has to demonstrate that it identifies any actual or potential adverse effects and takes action to mitigate them.

An organisation is required to retain the documented information necessary to demonstrate both that its processes have been carried out as planned and that products and services conform to requirements. This will include information on unplanned changes, adverse effects and actions taken to address them.

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This table summarises the requirements of clause 8.1.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Does the organisation plan, implement and control the processes by: <ul style="list-style-type: none"> • Determining requirements for the product or service? • Establishing criteria for the processes and the acceptance of products and services? • Determining the resources needed to achieve conformity to product or service requirements? • Implementing control of the processes in accordance with the criteria? • Determining, maintaining and retaining documented information to have confidence that the processes have been carried out and to demonstrate conformity of products and services to their requirements? 		
Is the output of the planning suitable for the operations?		
Control planned changes and review the consequence of unintended changes, taking action to mitigate any adverse effects?		
Ensure that outsourced processes are controlled?		

8.2 REQUIREMENTS FOR PRODUCTS AND SERVICES

There is now a requirement that organisations must demonstrate that they have specific processes in place for establishing the requirements for the products and services it intends to offer to customers. There is also now a requirement that these processes must include, where relevant, communicating with customers in relation to:

- the handling or treatment of customer property;
- specific requirements for contingency actions.

Additionally, organisations must also now have in place processes for obtaining ‘customer views and perceptions’, including customer complaints.

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None of these processes are required to be documented although organisations will need to establish a controlled methodology for communicating with clients and demonstrating whether these processes are systematically and consistently carried out.

Determination of requirements related to products and services – ISO 9001 now requires the organisation to demonstrate that it has a specific process for establishing the requirements for the products and services it intends to offer to customers. In addition, there is now a requirement that organisations must also be able to substantiate any claims it makes for the products and services it offers.

The process for establishing customer requirements does not need to be documented although organisations will need to establish a controlled methodology for communicating with clients and demonstrating whether these processes are systematically and consistently carried out.

Any claims that an organisation makes about its products and services have to be proved or demonstrated by the organisation. This may include claims made in direct communication with clients, technical product information, marketing materials, etc.

Review of requirements related to products and services – there is a note in ISO 9001 that makes it clear that ‘requirements’ can now also include those arising from relevant interested parties.

Organisations are required to retain documented information that describes the results of the review(s), including those relating to any new or changed requirements for the products and services.

This table summarises the requirements of clause 8.2.

PROVISION OF RESOURCES	✓ OR X	COMMENT/PLAN
Does customer communication include: <ul style="list-style-type: none"> • Providing information relating to products and services? • Handling enquiries, contracts or order handling? • Obtaining customer feedback? • Handling customer property? • Establishing specific requirements for contingency actions. 		

<p>Does the organisation ensure that:</p> <ul style="list-style-type: none"> • The requirements for products and services are defined? • It can meet claims for the products and services it offers? 		
<p>Does the organisation have the ability to meet the requirements for products and services to be offered to the customer?</p>		
<p>Does the organisation conduct a review before committing to supply including:</p> <ul style="list-style-type: none"> • Requirements specified by the customer for delivery and post-delivery activities? • Requirements not stated by the customer? • Requirements specified by the organisation? • Statutory and regulatory requirements? • Contract or order requirements? 		
<p>Contract or order requirements differing from those previously defined are resolved?</p>		
<p>Customer requirements confirmed by the organisation before acceptance?</p>		
<p>Documented information retained:</p> <ul style="list-style-type: none"> • On the results of the review? • On any new requirements for the products and services? 		
<p>When requirements for products and services are changed the relevant documented information is amended?</p>		

8.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES

ISO 9001 now makes clear those circumstances when ‘design and development’ is required:

- where the organisation has not established detailed requirements for products or services, or
- where these have not been defined by the customer or other interested parties.

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In such circumstances, an organisation must have a design and development process in place. Where requirements for products and services have not been established or defined, to the extent that enables product/service provision to take place, then a design process has to be implemented. The design and development process does not need to be documented although the organisation will need to establish that a controlled methodology is in place for establishing/defining requirements.

8.3.2 Design and development planning – ISO 9001 now requires an organisation, when determining the necessary stages and controls for design and development, to also consider:

- the nature, duration and complexity of the design and development activities; and
- whether customer and user groups need to be involved in the design and development process.

The organisation shall retain all documented information as necessary to confirm that that design and development requirements have been met.

8.3.3 Design and development inputs – there is no longer any requirement to include ‘information derived from previous similar designs’ as design inputs. However, ISO 9001 introduces the requirements that an organisation must include the following additional design inputs:

- internal and external resources needed for the design and development of products and services; and
- the potential consequences of failure due to the nature of the products and services.

There is no requirement that the required design and development inputs are available as documented information. The organisation shall have a controlled methodology in place for identifying the necessary inputs.

8.3.4 Design and development controls – although this is a new clause it combines the requirements relating to design review, verification and validation. There are no significant changes in requirements, but current requirement in ISO 9001:2008 that, where practicable, validation should be completed prior to the delivery or implementation of the product/service has been removed. Nor is there any specific requirement as to who should participate in design reviews.

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8.3.5 Design and development outputs – there is no longer any reference for design and development outputs having to be ‘in a form suitable for verification against the design and development input’ or that they must be ‘approved prior to release’. There is, however, now a requirement that the outputs include or make reference to any monitoring and measuring requirements. Organisations are required to retain the documented information resulting from the design and development process.

8.3.6 Design and development changes – there is no longer any reference for design and development changes having to be ‘verified’, ‘validated and approved before implementation’. Organisations are required to retain the documented information relating to design and development changes.

This table summarises the requirements of clause 8.3.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Has the organisation established, implemented and maintained a design and development process?		
Does the organisation consider: <ul style="list-style-type: none"> • The nature, duration and complexity? • The required process stages including design and development reviews? • Required verification and validation activities? • The responsibilities and authorities involved? • Internal and external resource needs? • The need to control interfaces between persons? • The need for involvement of customers and users? • Requirements for subsequent provision of products and services? • The level of control expected by customers and other relevant interested parties? • Documented information needed to demonstrate requirements have been met? 		

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<p>Does the organisation determine the requirements essential for the specific types of products and services?</p>		
<p>Does the organisation consider:</p> <ul style="list-style-type: none"> • Functional and performance requirements? • Information derived from previous similar design and development activities? • Statutory and regulatory requirements? • Codes of practice or standards that they are committed to implement? • Potential consequences of failure? 		
<p>Are inputs adequate, complete and unambiguous?</p>		
<p>Are conflicting inputs resolved?</p>		
<p>Is documented information on inputs retained?</p>		
<p>Does the organisation apply controls to the process to ensure that:</p> <ul style="list-style-type: none"> • Results to be achieved are defined? • Reviews are conducted? • Verification activities are conducted? • Validation activities are conducted? • Any necessary actions are taken during the reviews or verification and validation activities? • Documented information of these activities is retained? 		
<p>Does the organisation ensure that outputs:</p> <ul style="list-style-type: none"> • Meet the input requirements? • Are adequate? • Include or reference monitoring and measuring requirements? • Specify the characteristics that are essential for the intended purpose and their safe and proper provision? 		

Is documented information retained on the design and development process?		
Does the organisation identify, review and control changes made during or subsequent to the design and development of products and services?		
Is documented information retained on: <ul style="list-style-type: none"> • Design and development changes? • The results of reviews? • The authorisation of the changes? • The actions taken to prevent adverse impacts? 		

8.4 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES

‘Control of externally provided products and services’ covers 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.

ISO 9001 requires organisations to also establish specific criteria for monitoring the performance of external providers and to retain documented information on the results of performance evaluation and re-evaluation monitoring.

The organisation shall have:

- established criteria against which it will evaluate, monitor and re-evaluate the performance of external suppliers; and
- retained documented information relating to the results of this evaluation, monitoring and re-evaluation.

Type and extent of control of external provision – the requirements of ISO 9001 now incorporate elements that were previously only ‘Notes’ to clause 4.1 in ISO 9001:2008.

The requirement that inspection activities should be in place to verify that “purchased product meets specified purchase requirements” has been changed to “do not adversely affect the organisation's ability to consistently deliver conforming products and services to its customers”.

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As part of the process for defining the controls to be applied to external providers themselves and to the products and services they supply, organisations are now required to take into account:

- the potential impact of the externally provided processes, products and services on the organisation’s ability to consistently meet customer and applicable statutory and regulatory requirements; and
- the perceived effectiveness of the controls applied by these external providers themselves.

This means that an organisation is now required to take a risk-based approach when determining the type and extent of controls to apply to external providers of processes, products and services. There is no requirement that this has to be documented, but given that the criteria for selection, evaluation, monitoring and re-evaluation of external providers has to be documented the organisation should be able to demonstrate whether it has adopted the risk based approach that is required.

Information for external providers – organisations are now also required to give external providers information about:

- how they will interact with the organisation’s QMS; and
- how their performance will be monitored and controlled by the organisation.

There is also an additional requirement that organisations must communicate to external providers any ‘competence’ requirements that apply to their personnel. Organisations will have to demonstrate that the information identified is communicated to external providers and that the organisation ensures the information is adequate before it is communicated to them.

This table summarises the requirements of clause 8.4.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Does the organisation ensure externally provided processes, products and services conform to requirements?		
Are the controls applied determined when: <ul style="list-style-type: none"> • Products and services from external providers are intended for incorporation into the organisation’s own products and services? 		

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<ul style="list-style-type: none"> • Products and services provided directly to the customer by external providers on behalf of the organisation? • A process or part of a process is provided by the external provider? 		
<p>Has the organisation determined and applied criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers?</p>		
<p>Is documented information retained on these activities?</p>		
<p>Does the organisation ensure externally provided processes, products and services do not adversely affect the organisation's ability to consistently deliver conforming products and services?</p>		
<p>Does the organisation:</p> <ul style="list-style-type: none"> • Ensure externally provided processes remain within their control? • Define both the controls applied to an external provider and to the resulting output? • Take into consideration the potential impact of the externally provided processes, products and services to meet requirements (customer, statutory, regulatory); the effectiveness of the controls applied by the external provider? • Determine the verification necessary to ensure that the externally provided processes, products and services meet requirements? 		

<p>Does the organisation communicate to external providers its requirement for:</p> <ul style="list-style-type: none">• The processes, products and services to be provided? The approval of products and services, methods, processes and equipment, the release of products and services?• Competence?• External providers' interactions with the organisation?• Control and monitoring of the external providers' performance?• Verification and validation activities that it intends to perform at the external providers' premises?		
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8.5 PRODUCTION AND SERVICE PROVISION

Control of production and service provision – organisations will now have to demonstrate that controls have been implemented in relation to:

- the availability of documented product/service/process information;
- defined process criteria;
- personnel competence;
- the suitability of infrastructure, environment and resources.

A key addition is that ISO 9001 now specifically requires documented information that defines

- the processes to be carried out and/or activities to be performed;
- the monitoring and measurement required to be carried out at specific stages; and
- the results to be achieved.

Identification and traceability – the emphasis in ISO 9001 is now on 'process outputs' rather than products. 'Process outputs' are the results of any activities that are ready for delivery to the organisation's customer or to an internal customer (e.g. receiver of the inputs to the next process). They can include products, services, intermediate parts, components, etc.

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Property belonging to customers or external providers – these requirements now also cover property belonging to any external providers used by an organisation. This would include any external provider's property that was to be used by the organisation in its own products and services. A note in ISO 9001 makes it clear that the definition of customer property has been widened to specify that it can include material, components, tools and equipment, customer premises, intellectual property and personal data.

Preservation – again the emphasis now is on 'process outputs' rather than product. A note in ISO 9001 indicates that 'preservation' can include identification, handling, packaging, storage, transmission or transportation as well as protection.

The inclusion of 'transmission' may be an issue where an organisation produces and circulates data or other information electronically as part of a product or service. In such cases the data transmission protection systems adopted by the organisation shall reflect the risk of loss or security breach identified by the organisation.

Post-delivery activities – these are new requirements that post-delivery activities are carried out under 'controlled conditions'. Organisations are now required to consider specific issues when determining what post-delivery activities are required:

- any risks associated with a product or service;
- the nature of the product or service, how it will be used and what its intended lifetime is;
- any account customer feedback; and
- any applicable statutory or legal requirements.

A note in ISO 9001 indicates that 'post-delivery activities' can include actions under warranty provisions, contractual obligations such as maintenance services and supplementary services such as recycling or final disposal.

When deciding what post-delivery activities are required, an organisation shall have considered the issues identified in clause 8.5.5 a) – d). Organisations will need to demonstrate that they have taken all these considerations into account, as appropriate. Particular attention will need to be given to this process where there is a high level of potential risk associated with the products and services (e.g. safety-critical components) or where there is a long product lifespan.

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Control of changes – these are new specific requirements. Organisations need to demonstrate that where they are to make unplanned changes to its processes in order to ensure its products or services conform to specified requirements, these changes must be reviewed and made in a controlled manner. Where unplanned changes are made, organisations must retain documented information identifying:

- the results of the review of changes;
- the personnel who authorised the changes; and
- any necessary actions.

This may be from meeting minutes, correspondence with customers or external providers, nonconformance reports, concession requests, etc. They will then have to verify that the documentation deals with the issues identified above.

This table summarises the requirements of clause 8.5.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Has the organisation implemented production and service provision under controlled conditions?		
Controlled conditions include: <ul style="list-style-type: none"> • Documented information that defines the characteristics of the products, the services or the activities? • The results to be achieved? • Use of suitable monitoring and measuring resources; monitoring and measurement activities at appropriate stages; suitable infrastructure and environment; appointment of competent persons; validation and periodic revalidation; implementations of actions to prevent human error; release, delivery and post-delivery activities? 		
Does the organisation use suitable means to identify outputs?		
Does the organisation identify the status of process outputs?		
Is any documented information retained that is necessary to ensure traceability?		

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Does the organisation exercise care with property belonging to customers or external providers?		
Does the organisation identify, verify, protect and safeguard the customers or external providers' property?		
Is documented information retained in the event that the property of the customer or external provider is lost, damaged or unsuitable for use?		
Does the organisation preserve the outputs during production and service provision?		
<p>Does the organisation consider the following when determining the extent of post-delivery activities required:</p> <ul style="list-style-type: none"> • Statutory and regulatory requirements? • Potential undesired consequences associated with the products or services? • The nature, use and intended lifetime of the products and services? • Customer requirements? • Customer feedback? 		
Does the organisation review and control changes for production and service provision?		
Is documented information retained describing results of the review of changes, the person authorising the change and actions arising from the review?		

8.6 RELEASE OF PRODUCTS AND SERVICES

Apart from some changes in terminology, the requirements are the same as those in ISO 9001:2008 clauses 7.4.3 and 8.2.4.

This table summarises the requirements of clause 8.6.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Are planned arrangements implemented at appropriate stages?		
Release of products and services does not proceed until the planned arrangements have been completed, unless otherwise approved by a relevant authority and, as applicable, by the customer?		
Is documented information retained on the release of products and services?		
Does the documented information contain: <ul style="list-style-type: none"> • Evidence of conformity with the acceptance criteria? • Traceability to the persons authorising release? 		

8.7 CONTROL OF NONCONFORMING OUTPUTS

‘Process outputs’ are now the key focus of the requirements. The options available to an organisation when nonconformities are identified are now more explicitly detailed. Additionally, the details of the person or authority that makes the decision on how to deal with a nonconformity has now to be identified.

Although there is no longer a requirement for a procedure, documented information still has to be retained that gives information on the actions taken to deal with nonconformances.

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This table summarises the requirements of clause 8.7.

REQUIREMENTS OF PRODUCT REALISATION	✓ OR X	COMMENT/PLAN
Are outputs that do not conform to their requirements identified and controlled to prevent unintended use or delivery?		
Does the organisation take appropriate corrective action based on the nature of the nonconformity even when detected after delivery of the products or during and after the provision of services?		
Does the organisation deal with nonconforming outputs in one of the following: <ul style="list-style-type: none"> • Correction? • Segregation, containment, return or suspension of provision of products and services? • Informing the customer? • Obtaining authorisation for acceptance under concession? 		
Is documented information retained of actions taken on nonconforming process outputs, products and services?		
Is documented information retained that: <ul style="list-style-type: none"> • Describes the nonconformity? • Describes the action taken? • Describes any concessions obtained? • Identifies the authority deciding the action in respect of the nonconformity? 		

9.1 MONITORING, MEASUREMENT, ANALYSIS AND EVALUATION

The previous requirement that an organisation had to plan and implement the necessary “monitoring, measurement, analysis and improvement processes” has been replaced by the requirement that the organisation identify the ‘what’, ‘how’ and ‘when’ of the monitoring and measurement:

- what needs to be monitored and measured;

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- the methods for monitoring, measurement, analysis and evaluation, as applicable, that are necessary to ensure valid results;
- when the monitoring and measuring shall be performed; and
- when the results from monitoring and measurement shall be analysed and evaluated.

Organisations need to be able to demonstrate that they have considered what has to be measured/monitored, as well as how and when they are going to do so. They then need to demonstrate that this is what they have done and that they have both analysed and evaluated the measuring/monitoring results.

Organisations are required to retain documented information as evidence of the results of monitoring and measurement activities.

Customer satisfaction – organisations now need to demonstrate that they have sought out information relating to how customers view the organisation itself as well as its products and services. They also must have a defined methodology identifying both how they will obtain this information and what they will use it for.

A note in ISO 9001 makes it clear that information related to customer views or perceptions can include customer satisfaction or opinion surveys, customer data on delivered products or services quality, market-share analysis, compliments, warranty claims, etc.

There is no specific requirement that this information has to be documented, but an organisation will have to demonstrate that it is actively seeking out information on customer perception of not just about its products and services, but also about the organisation itself. An organisation will also have to show how it does this and what it does with the information that it collects.

Analysis and evaluation – there are now explicit requirements relating to how the analysis and evaluation data must be used. Organisations now need to demonstrate 'evaluation' as well as analysis of data (from measurement, monitoring or other sources); there has to be evidence of interpretation of the data analysis they carry out.

Although there are no specific requirements that this analysis and evaluation has to be documented, there is now an explicit requirement that the outputs, or results of the analysis and evaluation, must be used to provide inputs to management reviews. Evidence of what the organisation is doing in terms of data analysis and evaluation should, therefore, be available.

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This table summarises the requirements of clause 9.1.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Has the organisation determined: <ul style="list-style-type: none"> • What needs to be monitored or measured? • Methods for monitoring, measurement, analysis and evaluation to ensure valid results? • When the monitoring and measuring shall be performed? When the results shall be analysed and evaluated? 		
Does the organisation evaluate the performance and the effectiveness of the QMS?		
Does the organisation retain documented information as evidence of the results?		
Does the organisation monitor customer perceptions of the degree to which their needs and expectations have been fulfilled?		
Has the organisation determined the methods for obtaining, monitoring and reviewing this information?		
Are the results of analysis used to evaluate: Conformity of products and services? The degree of customer satisfaction? The performance and effectiveness of the QMS? If planning has been implemented effectively? The effectiveness of actions taken to address risks and opportunities? The performance of external providers? The need for improvements within the QMS?		

9.2 INTERNAL AUDIT

An organisation now also needs to demonstrate that when planning its audit programme, it has taken into consideration:

- its quality objectives;
- customer feedback;
- any changes that have taken place that impact on the organisation.

Additionally, there is now a specific requirement that the 'results of audits' are reported to the relevant management within an organisation; this mirrors the same input requirement for management review.

Although a documented procedure is no longer required, organisations must retain documented information as evidence of the implementation of the audit programme and the audit results.

This table summarises the requirements of clause 9.2.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Are internal audits conducted at planned intervals to provide information that the QMS: <ul style="list-style-type: none">• Conforms to the organisation's own requirements for its QMS; the requirements of ISO 9001?• Is effectively implemented and maintained?		

<p>Does the organisation:</p> <ul style="list-style-type: none"> • Plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, taking account of the importance of the processes concerned, customer feedback, changes affecting the organisation, results of previous audits? • Define the audit criteria and scope for each audit? • Select auditors to ensure objectivity and impartiality? • Ensure the results are reported to the relevant management? • Take appropriate correction and corrective action without undue delay? • Retain documented information of the audit programme and audit results? 		
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9.3 MANAGEMENT REVIEW

The key requirements of the management review process remain as before but organisations will need to demonstrate that the ‘inputs’ to its’ management review now also includes:

- changes in external and internal issues relevant to both the organisation’s QMS and to its strategic direction;
- external provider issues;
- interested party issues;
- adequacy of QMS resources;
- effectiveness of actions taken to address any risks and/or opportunities.

The new ISO 9001 requirements relating to organisational context and actions to address risks and opportunities are reflected in these additions to the management review inputs. An organisation will need to demonstrate that its management review deals with how its overall QMS performance is relevant to its strategic direction and organisational environment.

Organisations are required to retain documented information as evidence of the results of management reviews, but given the broader organisational issues that now have to be considered as part of the review process it is likely that interviews of the senior management in relation to the organisation’s strategic direction,

internal and external issues, etc., will take place.

This table summarises the requirements of clause 9.3.

CUSTOMER COMMUNICATION	✓ OR X	COMMENT/PLAN
Top management shall review the organisation's QMS at planned intervals to ensure it continuing suitability, adequacy, effectiveness and alignment with the strategic direction?		
Management review planned and carried out considering: <ul style="list-style-type: none"> • The status of actions from previous management reviews? • Changes in external and internal issues relevant to the QMS? • Information on performance and effectiveness of the QMS including: customer satisfaction and feedback from interested parties; the extent to which quality objectives have been met; process performance and conformity of products and services; nonconformities and corrective actions; monitoring and measurement results; audit results; performance of external providers? • The adequacy of resources? • Effectiveness of actions taken to address risks and opportunities? • Opportunities for improvement? 		
Management review outputs: <ul style="list-style-type: none"> • Opportunities for improvement? • Any need for changes to the QMS? • Resource needs? 		
Is documented information retained as evidence of the results of management reviews?		

10.1 GENERAL (IMPROVEMENT)

This is a new section that emphasises the general need to improve processes, products and services, as well as QMS results, in order to meet customer requirements and enhance customer satisfaction. Organisations will need to demonstrate that they actively look for opportunities to improve their processes, products and services, as

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well as the performance of their quality management system.

The organisation will need to demonstrate that it is seeking to make improvements to its processes, products and services, as well as to its QMS.

This table summarises the requirements of clause 10.1.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Are opportunities for improvement determined and selected to meet customer requirements and enhance customer satisfaction?		
Does this include: <ul style="list-style-type: none">• Improving products and services, to address future needs and expectations?• Correcting, preventing or reducing undesired effects?• Improving the performance and effectiveness of the QMS?		

10.2 NONCONFORMITY AND CORRECTIVE ACTION

There is no longer any reference to 'preventive action'. There is now an additional requirement in ISO 9001 for organisations to address the 'consequences' of nonconformities, which is a recognition that not all of its processes and/or activities will represent the same level of risk in terms of the organisation's ability to meet its objectives. For that reason, the consequences of failures or nonconformities in relation to processes, systems, products and/or services will not be the same for all organisations. When deciding how to deal with the consequences of non-conformities, therefore, including its component processes and activities, an organisation needs to demonstrate that it considers both the type and level of risk associated with them.

There is also a new requirement to determine whether any identified nonconformity could also exist elsewhere within the organisation's processes, products, services and or systems, or whether they could potentially happen elsewhere. This covers some of the requirements previously included under preventive action.

It may be impossible to eliminate the cause of a nonconformity, in which case the corrective action taken may only be able to reduce the likelihood of recurrence to an acceptable level.

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Although a documented procedure is no longer required, organisations are required to retain documented information that identifies the nature of any nonconformity, the subsequent action(s) taken and the results of any corrective action.

This table summarises the requirements of clause 10.2.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
When a nonconformity occurs does the organisation: <ul style="list-style-type: none"> • React to the nonconformity and take action to control and correct it; deal with the consequences? • Evaluate the need for action to eliminate the causes of the non-conformity so that it does not recur or occur elsewhere by: reviewing and analysing the nonconformity; determining the causes of the nonconformity; determining if similar nonconformities exist or could potentially occur? • Implement any action needed? • Review the effectiveness of corrective action taken? • Update risks and opportunities determined during planning? • Make changes to the QMS? 		
Are corrective actions appropriate to the effects of the nonconformities encountered?		
Is documented information retained as evidence of: <ul style="list-style-type: none"> • The nature of the nonconformities and any subsequent actions taken? • The results of any corrective action 		

10.3 CONTINUAL IMPROVEMENT

Organisations now need to demonstrate that they are using the outputs from their analysis, evaluation and review processes to identify areas of unsatisfactory performance and opportunities for improvement.

There is no specific requirement that evidence of these activities has to be available as documented information.

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This table shows the requirements of clause 10.3.

REQUIREMENTS	✓ OR X	COMMENT/PLAN
Does the organisation continually improve the suitability, adequacy and effectiveness of the QMS?		
Does the organisation consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement?		

THE CERTIFICATION PROCESS

The certification process is broken down into four stages:

- A review of the documented system against the standard and according to the scope of certification and to ascertain the organisation's preparedness for the certification audit (also called the stage 1 audit)
- The certification audit (also called the stage 2 audit)
- Certification
- Ongoing surveillance visits

REVIEW OF DOCUMENTED SYSTEM (STAGE 1)

This is a full review of the documented system to make sure that it meets the requirements of ISO 9001, the scope of certification and the needs of the organisation. It is also used to evaluate the organisation's location and to determine the preparedness for the stage 2 audit. At this time it should also be made apparent to the organisation that they should have identified the processes, objectives and operation of the QMS and that they should have planned and started to perform internal audits and management reviews. To achieve this at least part of the stage 1 audit will be carried out 'on-site' at the organisation's premises. Any shortcomings are reported to the organisation for consideration prior to the certification audit taking place.

THE CERTIFICATION AUDIT (STAGE 2)

This builds upon the preceding stage and checks compliance with all the requirements of ISO 9001 as well as the organisation's own documented procedures. The audit starts with an opening meeting to set the scene for this process. It then reviews any findings from the stage 1 audit before proceeding to a site tour and

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the full audit. The requirements of ISO 9001 are then checked in detail by sampling and by interviewing the relevant organisation's personnel. The audit usually concludes with audits of the audit process and management review and closes with a private meeting of the auditors (there could be one auditor or a team involved) to review and agree their findings followed by a presentation of the outcome of the audit to the organisation's top management. It will of course be a presentation of good news if you have established, implemented and audited your QMS with due diligence.

CERTIFICATION

This process is carried out by SGS where the decision is made to grant the issue of an ISO 9001 certificate, to the organisation's scope, based on the recommendation from the stage 2 audit.

ONGOING SURVEILLANCE VISITS

These are conducted at defined intervals to ensure that the organisation is continuing to maintain their QMS against the requirements of the standard and to continually improve it.

And finally, some pointers on what helps an organisation to achieve certification on their first attempt:

- Make sure the QMS is fully implemented
- Carry out at least one full sweep of internal audits and carry out any resulting corrective and preventive actions
- Ensure that all personnel understand the system, quality policy and objectives Have evidence available to show that the process of continuous improvement is actually happening
- Contact SGS as early in the process as possible
- Do not ask for the certification audit until you are sure you are ready

SGS TRAINING

SGS training solutions help customers get the most from their training budget, and with our sector-experienced tutors we can meet specific training objectives of any organisation.

In the UK we have over 50 training courses available in a number of management systems, complemented by a wide range of specialised training courses.

Through the use of our accelerated learning techniques and blended learning experiences we can achieve learning objectives for individuals or workforces. These courses are delivered publicly in a network around the UK, or they can be delivered in-company if you prefer.

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QUALITY MANAGEMENT SYSTEMS COURSES:

- ISO 9001:2015 introduction and awareness
- ISO 9001:2015 internal auditor
- ISO 9001:2015 lead auditor

SGS IN THE UK

SGS is an accredited certification body to standards such as ISO 14001 (Environmental Management Systems), OHSAS 18001 (Occupational Health and Safety) in addition to ISO 9001 (Quality Management Systems). Each can be assessed individually or as part of an integrated management system.

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- Industrial, engineering and manufacturing
- Consumer products and retail
- Travel, tourism and leisure
- Government and institutions

SGS ACADEMY

TRANSFORMING PEOPLE
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The services which are available to help you achieve your business objectives, for both the service and manufacturing industries, include:

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Founded in 1878, SGS is recognised as the global benchmark for the highest standards of expertise and integrity.

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WHEN YOU NEED TO BE SURE

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