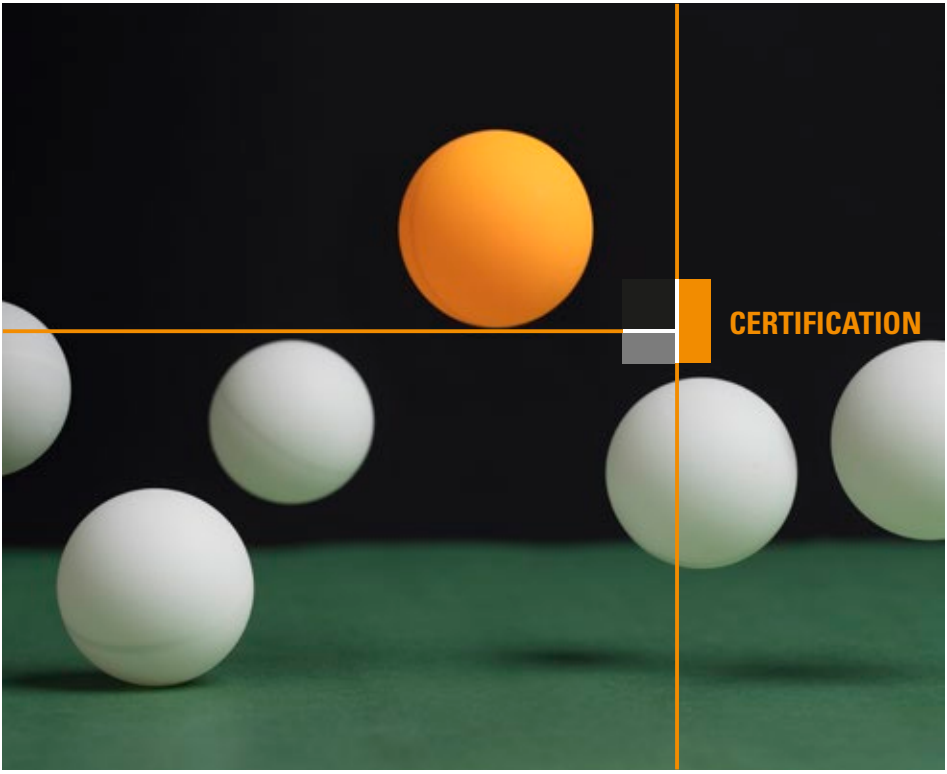


THE ROUTE TO ISO 9001:2015
IN A CHANGING WORLD

BE THE BENCHMARK

SGS

FOREWORD

The purpose of this booklet is to provide a simple introduction to ISO 9001 Quality Management Systems (QMS). 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 from the SGS Academy, and they can be contacted on +44 (0)1276 697 777 or ukacademy@sgs.com.

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.

CONTENTS

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 organization 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 organizations 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 organization.

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:

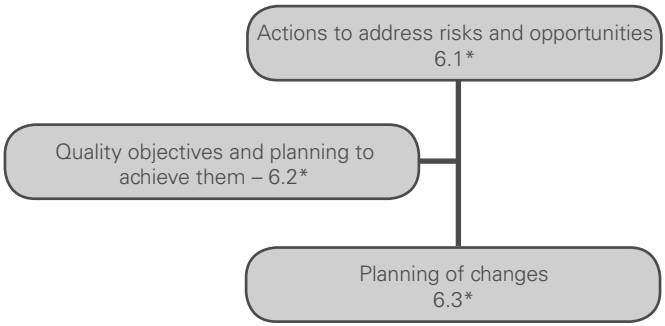
'shall' indicates a requirement

'should' indicates a recommendation

'may' indicates a permission

'can' indicates a possibility or a capability.

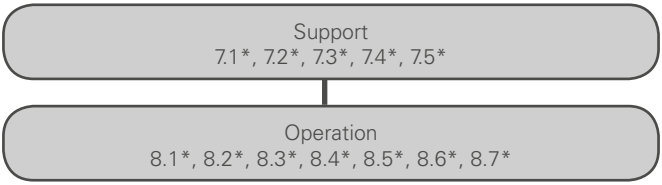
The '**PLAN**' part of the process starts by establishing the objectives, looking at risks and opportunities and any associated actions, and planning any changes necessary to deliver results in accordance with customer requirements and the organization's policies.



** clause of ISO 9001:2015*

The organization will also have to take into account the context of their organization, 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.

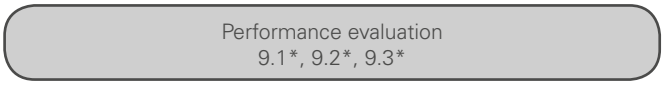
Now comes the '**DO**' part of the implementation cycle. The objectives and processes now established have to be implemented and managed.



** clause of ISO 9001:2015*

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.



** 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 organization to '**ACT**' against the findings and results, which may be through nonconformity and/or corrective action.

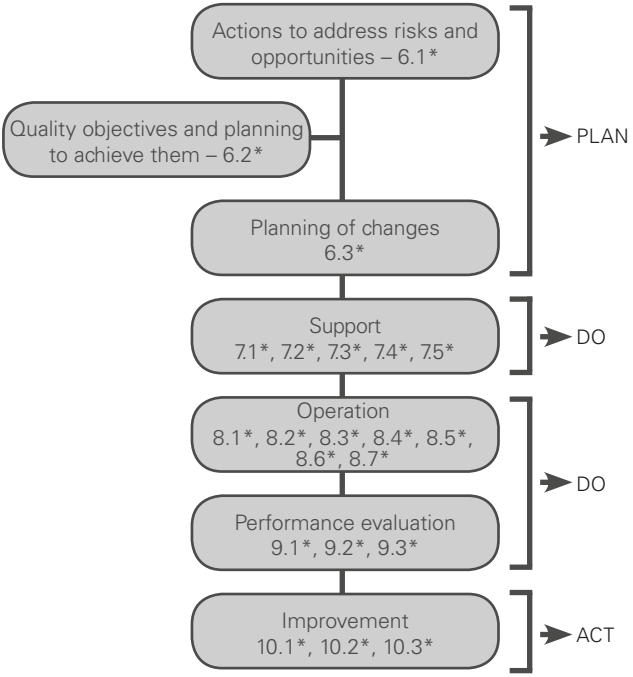
** clause of ISO 9001:2015*

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 organization 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". By adopting the Annex SL template, some of the requirements in ISO 9001:2015 are now located under different headings in some of the numbered clauses.

Although all of the requirements in ISO 9001:2015 are intended to be applicable to all types of organization, of whatever size, it is recognized that there may be circumstances where an organization cannot comply with a specific requirement because it simply does not undertake a certain type of activity as part of its business. In such a case the organization 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 organization 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 organization. It is only prescriptive in terms of **what** must happen, leaving the **how** to the organization to decide or devise for itself.

This approach means that ISO 9001 can be applied to any kind and scale of organization. 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 organization 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 ORGANIZATION AND ITS CONTEXT

The 'context' of the organization (sometimes called its business or organizational environment) refers to the combination of internal and external factors and conditions that can have an effect on an organization's approach to its products, services and investments. As a result, the design and implementation of an organization's quality management system will be influenced by its context (and any changes to it).

An organization's context will include, for example:

- the specific objectives of the organization;
- 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 organization uses and the way in which they interact;
- its size and organizational structure.

An organization 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 organization 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 organizations 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 organization. However, in many cases this information could be available from several different sources. It may form part of an organization's documented business plan or business strategy, for example, or be referenced on the organization'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 organization's context since the organization has to consider its 'strategic direction' when identifying internal and external issues. Depending on an organization's management structure, its management representative, for example, may not have sufficient knowledge of the issues relevant to the organization's context and be unable to provide the information necessary to verify compliance with the requirements of this clause.

This table summarizes the requirements of clause 4.1.

REQUIREMENTS	✓ OR ✗	COMMENT/PLAN
Has the organization determined: • Internal issues? • External issues? Relevant to its purpose and strategic direction		
Does the organization monitor and review: • Internal issues? • External issues?		

4.2 UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

An organization 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 organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements. The organization is also required to identify what requirements these interested parties themselves have, which are relevant to the organization'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 organization that can affect, be affected by, or perceive themselves to be affected by the decisions or activities of the organization implementing the QMS. These interested parties could include the organization'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 organization must consider whether or not they have an impact on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements or enhance customer satisfaction. Every organization 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 organization's QMS.

There will need to be some form of evidence that an organization 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 organization's QMS. There will also need to be evidence that the organization continues to review whether the relevance of these interested parties and/or their requirements change.

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

This table summarizes the requirements of clause 4.2.

REQUIREMENTS	✓ OR ✗	COMMENT/PLAN
Has the organization determined: • The interested parties? • The requirements of the interested parties?		
Does the organization: • Monitor and review information about the interested parties? • Monitor and review their relevant requirements?		

4.3 DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM

An organization must establish the scope of its quality management system, and there is a specific requirement that when doing so the organization 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;

c) the products and services of the organization.

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

The scope of an organization's QMS 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 summarizes the requirements of clause 4.3.

REQUIREMENTS	✔ OR ✘	COMMENT/PLAN
Has the organization determined the boundaries and applicability of the QMS to establish its scope?		
Has the organization considered: • 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 organization 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 includes specific requirements necessary for the adoption of a process approach.

This process approach requires an organization 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 organization. ISO 9001 requires an organization 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.

An organization 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 organizations may have different approaches to this. Similarly, an organization 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 summarizes the requirements of clause 4.4.

REQUIREMENTS	✔ OR ✘	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 organization: • 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 organization: • Maintain documented information? • Retain documented information?		

5.1 LEADERSHIP AND COMMITMENT

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

Top management must be able to demonstrate that they have taken responsibility for emphasizing 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 organization.

In those organizations where top management have effectively delegated responsibility for the QMS down to a management representative, then under ISO 9001 they will have to demonstrate much more direct involvement in the QMS. They can still delegate tasks to others, such as the management representative, 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 organization's QMS and to emphasize the importance of effective quality management and conformance with QMS requirements. They must also ensure that quality management system requirements are integral to the organization'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 organizational 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 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 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 also need to demonstrate that any risks and opportunities are being identified and addressed where they:

- could potentially have an impact on the organization'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.

This table summarizes the requirements of clause 5.1.

REQUIREMENTS	✔ OR ✘	COMMENT/PLAN
Has top management demonstrated leadership and commitment by: • 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: • 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

ISO 9001:2015 requires that an organization's quality policy is appropriate to both its purpose and its 'context'. This means that once the organization 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.

There is also a requirement that the quality policy includes a commitment to "...continual improvement" 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 organization's quality objectives are affected. There is no specific requirement that this ongoing review is documented.

There is also a requirement that the quality policy is made available to the organization'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 organization's website, for example, but other methods of ensuring that it is available can be used.

This table summarizes the requirements of clause 5.2.

REQUIREMENTS	✔ OR ✘	COMMENT/PLAN
Has top management established, implemented and maintained a quality policy that: • Is appropriate to the purpose and context of the organization 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: • Available and maintained as documented information? • Communicated, understood and applied? • Available to relevant interested parties?		

5.3 ORGANIZATIONAL ROLES, RESPONSIBILITIES AND AUTHORITIES

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

Top management must also 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 not a requirement to appoint a specific management representative, the tasks assigned to the management representative 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 summarizes the requirements of clause 5.3.

REQUIREMENTS	✔ OR ✘	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:
  • 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 organization is required to consider both its 'context' and 'interested parties' when planning and implementing its QMS.

This requirement obliges organizations 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 organization 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, organizations 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 organization'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 organizations. So when deciding how to plan and control its QMS, including its component processes and activities, the organization 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 organization 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.

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 organizations are free to choose the assessment and evaluation mechanism they consider is most appropriate for them. However, organizations 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 organization's risks and opportunities. Since these may have an influence on, or be influenced by, an organization's strategic direction or its context, it is likely that discussion of these issues will have to involve senior management. Depending on an organization's management structure, its management representative, for example, may not have sufficient knowledge of the all the risks and opportunities relevant to the organization and so be unable to provide the information necessary to verify compliance with the requirements of this clause.

This table summarizes the requirements of clause 6.1.

REQUIREMENTS	✓ OR ✗	COMMENT/PLAN
When planning the QMS has the organization considered the issues, risks and opportunities that need to be addressed to: • Give assurance the QMS can achieve its intended results? • Enhance desirable effects? • Prevent or reduce undesired effects? • Achieve improvement?		
Has the organization planned: • 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 of the product or service?		

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 organization's quality policy, there are requirements that must be established for 'relevant processes' and be relevant to the 'enhancement of customer satisfaction'. The implicit element of these changes is that an organization must demonstrate that their quality objectives actually 'add value' and not that they have been established in order to meet the bare minimum requirements.

An organization is required to maintain 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. Organizations are 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 be evaluated.

In some cases this will require organizations 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 organization has to maintain 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 summarizes the requirements of clause 6.2.

REQUIREMENTS	✓ OR ✗	COMMENT/PLAN
Has the organization established quality objectives at relevant functions, levels and processes?		
Are the quality objectives: • 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 organization determined: • 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 organization'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 organization'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.

Since ISO 9001 requires organizations 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 summarizes the requirements of clause 6.3.

REQUIREMENTS	✓ OR ✗	COMMENT/PLAN
Are changes carried out in a planned and systematic manner?		
Does the organization consider: • 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 organization 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 makes 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 a requirement for organizations 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 organization 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 organization 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 an emphasis on monitoring and measuring 'resources' rather than simply equipment; in this context, resources would include personnel, training, workplace environment, etc.

The organization 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.

Organizational knowledge – this is a new requirement that addresses the need for organizations to determine and maintain the knowledge obtained by the organization, including by its personnel, to ensure that it can achieve conformity of products and services. The primary requirement is that an organization 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 'organizational knowledge' that will need to be maintained will vary from one organization to another. It is likely to include knowledge held by competent personnel within the organization 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 organizational knowledge needed may be large or small, depending on an individual organization's activities, processes and circumstances, but the key question is whether the organization has identified the knowledge it needs to have in order to carry out its processes and activities.

This knowledge needs to be maintained and made available where and when necessary. It is up to the organization 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 organization is required to assess whether its existing organizational 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 summarizes the requirements of clause 7.1.

REQUIREMENTS	✓ OR ✗	COMMENT/PLAN
Have resources been determined and provided to establish, implement, maintain and continually improve the QMS?		
Has the organization considered: • The capabilities and constraints on existing internal resources? • What needs to be obtained from the external providers?		
Has the organization 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: • Suitable for the type of monitoring and measurement activities? • Maintained to ensure continued fitness for purpose? • Available with appropriate documented information retained?		
Is measuring equipment: • Calibrated? • Identified to determine its status? • Safeguarded from adjustment, damage or deterioration?		
Is validity of previous measurement results determined when measurement equipment is unfit for its intended use?		
Does the organization: • Determine the knowledge necessary for the operation of its processes? • Maintain the knowledge and make available to the extent necessary? • Address change by determining how to acquire necessary additional knowledge or required updates?		

7.2 COMPETENCE

ISO 9001 defines 'competence' as the ability to apply knowledge and skills to achieve intended results. An organization 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 organization 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.

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

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

This table summarizes the requirements of clause 7.2.

REQUIREMENTS	✓ OR ✗	COMMENT/PLAN
Has the organization: • 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 organization makes personnel under its control aware both of the organization's quality objectives as well as the consequences of nonconformance with its QMS requirements.

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

- the organization'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.

7.4 COMMUNICATION

There is a specific requirement relating to communication with persons outside the organization. There are specific requirements relating to this communication process and organizations 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 summarizes the requirements of clause 7.4.

PLANNING OF PRODUCT REALIZATION	✓ OR ✗	COMMENT/PLAN
Has the organization determined the internal and external communications relevant to the QMS: • On what it will communicate? • When to communicate? • With whom to communicate? • How to communicate? • Who communicates?		

7.5 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 organization to operate (documentation);
- evidence of results achieved (records).

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

This can be due to:

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

The organization 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. The organization must demonstrate that the documented information itself is being controlled. This control needs to include adequate protection "...e.g. from loss of confidentiality, improper use, or loss of integrity".

Control of 'access' to documented information is 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 organization's existing operational procedures, work instructions, flow charts, process maps, etc. are all examples of documented information and it does not have to remove their current quality manual or documented procedures. If an organization wishes to retain these then they can do so.

This table summarizes the requirements of clause 7.5.

REQUIREMENTS	✓ OR ✗	COMMENT/PLAN
Does the organization's QMS include: • Documented information required by ISO 9001? • Documented information determined by the organization as being necessary?		
When creating or updating documented information does it have: • Identification and description? • Format and media? • Review and approval for suitability and adequacy?		
Is documented information controlled to ensure: • It is available and suitable for use, where and when it is needed? • Is adequately protected?		
The organization has to address the following for control of documented information: • 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 has 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 organizations 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.

Organizations 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 organization has to demonstrate that it identifies any actual or potential adverse effects and takes action to mitigate them.

An organization 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.

This table summarizes the requirements of clause 8.1.

REQUIREMENTS	✓ OR ✗	COMMENT/PLAN
Does the organization plan, implement and control the processes by: • 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 a requirement that organizations 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 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, organizations must also have in place processes for obtaining 'customer views and perceptions', including customer complaints.

None of these processes are required to be documented although organizations 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 requires the organization 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 also a requirement that organizations 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 organizations 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 organization makes about its products and services have to be proven or demonstrated by the organization. This may include claims made in direct communication with clients, technical product information, marketing materials, etc.

Organizations 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 summarizes the requirements of clause 8.2.

PROVISION OF RESOURCES	✓ OR ✗	COMMENT/PLAN
Does customer communication include: • 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.		
Does the organization ensure that: • The requirements for products and services are defined? • It can meet claims for the products and services it offers?		

PROVISION OF RESOURCES	✓ OR ✗	COMMENT/PLAN
Does customer communication include: • 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.		
Does the organization ensure that: • The requirements for products and services are defined? • It can meet claims for the products and services it offers?		
Does the organization have the ability to meet the requirements for products and services to be offered to the customer?		
Does the organization conduct a review before committing to supply including: • Requirements specified by the customer for delivery and post-delivery activities? • Requirements not stated by the customer? • Requirements specified by the organization? • Statutory and regulatory requirements? • Contract or order requirements?		
Contract or order requirements differing from those previously defined are resolved?		
Customer requirements confirmed by the organization before acceptance?		
Documented information retained: • On the results of the review? • On any new requirements for the products and services?		
When requirements for products and services are changed the relevant documented information is amended?		

8.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES

ISO 9001 makes clear those circumstances when 'design and development' is required:

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

In such circumstances, an organization 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 organization will need to establish that a controlled methodology is in place for establishing/defining requirements.

8.3.2 Design and development planning – ISO 9001 requires an organization, 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 organization 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 – ISO 9001 introduces the requirements that an organization 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 a requirement that the required design and development inputs are retained as documented information. The organization 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 is not a specific requirement as to who should participate in design reviews.

8.3.5 Design and development outputs – there is not a 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, a requirement that the outputs include or make reference to any monitoring and measuring requirements. Organizations are required to retain the documented information resulting from the design and development outputs.

8.3.6 Design and development changes – there is no longer any reference for design and development changes having to be 'verified or validated' as this is now covered in clause 8.3.4. All changes have to be authorized. Organizations are required to retain documented information relating to design and development changes.

This table summarizes the requirements of clause 8.3.

PROVISION OF RESOURCES	✓ OR ✗	COMMENT/PLAN
Has the organization established, implemented and maintained a design and development process?		
Does the organization consider: • 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? • That documented information needed to demonstrate requirements have been met?		
Does the organization determine the requirements essential for the specific types of products and services?		
Does the organization consider: • 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?		
Are inputs adequate, complete and unambiguous?		
Are conflicting inputs resolved?		

This table summarizes the requirements of clause 8.3.

PROVISION OF RESOURCES	✓ OR ✗	COMMENT/PLAN
Is documented information on inputs retained?		
Does the organization apply controls to the process to ensure that: • 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?		
Does the organization ensure that outputs: • 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 organization identify, review and control changes made during or subsequent to the design and development of products and services?		
Is documented information retained on: • Design and development changes? • The results of reviews? • The authorization 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 organization or by any other means.

ISO 9001 requires organizations 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 organization 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.

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 organization's ability to consistently deliver conforming products and services to its customers".

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

- the potential impact of the externally provided processes, products and services on the organization'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 organization is 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 organization should be able to demonstrate whether it has adopted the risk based approach that is required.

Organizations are also required to give external providers information about:

- how they will interact with the organization; and
- how their performance will be controlled and monitored by the organization.

There is also an additional requirement that organizations must communicate to external providers any 'competence' requirements that apply to their personnel. Organizations will have to demonstrate that the information identified is communicated to external providers and that the organization ensures the information is adequate before it is communicated to them.

This table summarizes the requirements of clause 8.4.

PROVISION OF RESOURCES	✓ OR ✗	COMMENT/PLAN
Does the organization ensure externally provided processes, products and services conform to requirements?		
Are the controls applied determined when: • Products and services from external providers are intended for incorporation into the organization's own products and services? • Products and services provided directly to the customer by external providers on behalf of the organization? • A process or part of a process is provided by the external provider?		
Has the organization determined and applied criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers?		
Is documented information retained on these activities?		
Does the organization ensure externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services?		
Does the organization: • 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?		

PROVISION OF RESOURCES	✓ OR ✗	COMMENT/PLAN
Does the organization communicate to external providers its requirement for: • 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 organization? • Control and monitoring of the external providers' performance? • Verification and validation activities that it intends to perform at the external providers' premises?		

8.5 PRODUCTION AND SERVICE PROVISION

Controlled conditions of production and service provision – organizations will now have to demonstrate that controls have been implemented in relation to:

- the monitoring and measurement activities at appropriate stages
- actions to prevent human error
- personnel competence
- the suitability of infrastructure, environment and resources

A key addition is that ISO 9001 now specifically requires the availability of documented information which defines:

- the characteristics of products, services, or activities
- 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 organization'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.

Property belonging to customers or external providers – these requirements also cover property belonging to any external providers used by an organization. This would include any external provider's property that was to be used by the organization 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 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 organization 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 organization shall reflect the risk of loss or security breach identified by the organization.

Post-delivery activities – these are new requirements that post-delivery activities are carried out under 'controlled conditions'. Organizations are 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 organization shall have considered the issues identified in clause 8.5.5 a) – e). Organizations 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.

Control of changes – these are new specific requirements. Organizations need to demonstrate that if they 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, organizations must retain documented information identifying:

- the results of the review of changes;
- the personnel who authorized 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 summarizes the requirements of clause 8.5.

PROVISION OF RESOURCES	✓ OR ✗	COMMENT/PLAN
Has the organization implemented production and service provision under controlled conditions?		
Does the organization use suitable means to identify outputs?		
Does the organization identify the status of process outputs?		

PROVISION OF RESOURCES	✓ OR ✗	COMMENT/PLAN
Controlled conditions include: • 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?		
Is any documented information retained that is necessary to ensure traceability?		
Does the organization exercise care with property belonging to customers or external providers?		
Does the organization 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 organization preserve the outputs during production and service provision?		
Does the organization consider the following when determining the extent of post-delivery activities required: • 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 organization review and control changes for production and service provision?		
Is documented information retained describing results of the review of changes, the person authorizing the change and actions arising from the review?		

8.6 RELEASE OF PRODUCTS AND SERVICES

This table summarizes the requirements of clause 8.6.

REQUIREMENTS	✓ OR ✗	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: • Evidence of conformity with the acceptance criteria? • Traceability to the persons authorizing release?		

8.7 CONTROL OF NONCONFORMING OUTPUTS

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

This table summarizes the requirements of clause 8.7.

REQUIREMENTS OF PRODUCT REALIZATION	✓ OR ✗	COMMENT/PLAN
Are outputs that do not conform to their requirements identified and controlled to prevent unintended use or delivery?		
Does the organization 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?		

REQUIREMENTS OF PRODUCT REALIZATION	✓ OR ✗	COMMENT/PLAN
Does the organization deal with nonconforming outputs in one of the following: • Correction? • Segregation, containment, return or suspension of provision of products and services? • Informing the customer? • Obtaining authorization for acceptance under concession?		
Is documented information retained of actions taken on nonconforming process outputs, products and services?		
Is documented information retained that: • 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 organization had to plan and implement the necessary "monitoring, measurement, analysis and improvement processes" has been replaced by the requirement that the organization identify the 'what', 'how' and 'when' of the monitoring and measurement:

- what needs to be monitored and measured;
- 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 analyzed and evaluated.

Organizations 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 analyzed and evaluated the measuring/monitoring results.

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

Customer satisfaction – organizations must demonstrate that they have sought out information relating to how customers view the organization 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 organization 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 organization itself. An organization will also have to show how it does this and what it does with the information that it collects.

Analysis and evaluation – there are explicit requirements relating to how the analysis and evaluation data must be used. Organizations must 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 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 organization is doing in terms of data analysis and evaluation should, therefore, be available.

This table summarizes the requirements of clause 9.1.

REQUIREMENTS	✓ OR ✗	COMMENT/PLAN
Has the organization determined: • 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 analyzed and evaluated?		
Does the organization evaluate the performance and the effectiveness of the QMS?		
Does the organization retain documented information as evidence of the results?		
Does the organization monitor customer perceptions of the degree to which their needs and expectations have been fulfilled?		
Has the organization 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 organization must demonstrate that when planning its audit programme, it has taken into consideration:

- the importance of the processes concerned;
- the results of the previous audit;
- any changes that have taken place that impact on the organization.

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

Organizations must retain documented information as evidence of the implementation of the audit programme and the audit results.

This table summarizes the requirements of clause 9.2.

REQUIREMENTS	✓ OR ✗	COMMENT/PLAN
Are internal audits conducted at planned intervals to provide information that the QMS: • Conforms to the organization's own requirements for its QMS; the requirements of ISO 9001? • Is effectively implemented and maintained?		
Does the organization: • 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, changes affecting the organization, 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?		

9.3 MANAGEMENT REVIEW

Organizations will need to demonstrate that the 'inputs' to its' management review includes:

- changes in external and internal issues relevant to both the organization'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.

An organization will need to demonstrate that its management review deals with how its overall QMS performance is relevant to its strategic direction and organizational environment.

Organizations are required to retain documented information as evidence of the results of management reviews, but given the broader organizational 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 organization's strategic direction, internal and external issues, etc., will take place.

This table summarizes the requirements of clause 9.3.

CUSTOMER COMMUNICATION	✓ OR ✗	COMMENT/PLAN
Top management shall review the organization's QMS at planned intervals to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction.		
Management review planned and carried out considering: • 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?		

CUSTOMER COMMUNICATION	✓ OR ✗	COMMENT/PLAN
Management review outputs: • 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 section emphasizes the general need to improve processes, products and services, as well as QMS results, in order to meet customer requirements and enhance customer satisfaction. Organizations will need to demonstrate that they actively look for opportunities to improve their processes, products and services, as well as the performance of their quality management system.

The organization 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 summarizes the requirements of clause 10.1.

REQUIREMENTS	✓ OR ✗	COMMENT/PLAN
Are opportunities for improvement determined and selected to meet customer requirements and enhance customer satisfaction?		
Does this include: • 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 an additional requirement in ISO 9001 for organizations 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 organization'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 organizations. When deciding how to deal with the consequences of nonconformities, therefore, including its component processes and activities, an organization needs to demonstrate that it considers both the type and level of risk associated with them.

There is also a requirement to determine whether any identified nonconformity could also exist elsewhere within the organization'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.

Organizations 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 summarizes the requirements of clause 10.2.

REQUIREMENTS	✓ OR ✗	COMMENT/PLAN
When a nonconformity occurs does the organization: • 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 nonconformity 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: • The nature of the nonconformities and any subsequent actions taken? • The results of any corrective action		

10.3 CONTINUAL IMPROVEMENT

Organizations must 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.

This table shows the requirements of clause 10.3.

REQUIREMENTS	✓ OR ✗	COMMENT/PLAN
Does the organization continually improve the suitability, adequacy and effectiveness of the QMS?		
Does the organization 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 organization'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 organization. It is also used to evaluate the organization's location and to determine the preparedness for the stage 2 audit. At this time it should also be made apparent to the organization 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 organization's premises. Any shortcomings are reported to the organization 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 organization'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 the full audit. The requirements of ISO 9001 are then checked in detail by sampling and by interviewing the relevant organization's personnel. The audit usually concludes with checks 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 to the organization'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 organization's scope, based on the recommendation from the stage 2 audit.

ONGOING SURVEILLANCE VISITS

These are conducted at defined intervals to ensure that the organization 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 organization 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 ACADEMY

The greatest asset an organization has is its workforce. Unlocking the full potential of your employees is the key to creating a successful and dynamic business. To achieve this, employees must be provided with training that promotes continuous personal and professional development.

With help from the SGS Academy, you and your business can gain the knowledge you need to continually adapt the way you work, keeping ahead of market developments and enabling you to continuously develop all aspects of your career and organization. Whatever your level of knowledge, our experts will support you in progressing to the next level. SGS training solutions help customers get the most from their training budget, and with our sector-experienced tutors we can meet the specific training objectives of any organization.

In the UK we have over 80 training courses available across a number of management systems standards, complemented by a wide range of specialised training courses.

We make a promise to our clients that we will support you every step of the way, with a service that includes:

- A dedicated SGS Academy Training Specialist who ensures we understand and meet your current and future training needs
- An online learning management system where you can see your learning history, upcoming and recommended courses
- Interactive training where you can learn by doing, not by sitting through lectures and presentations
- Tutors who are not only practitioners in their field, but have a wealth of experience in training and mentoring
- Recommended customized options to address your organization's true business needs
- Certified training options allowing you to register with the Chartered Quality Institute and the International Register of Certificated Auditors (CQI|IRCA)

We use our values, traditions and network to support you throughout the training process and offer SGS' high standard of quality as a benchmark.

QUALITY MANAGEMENT SYSTEMS COURSES:

- ISO 9001:2015 Foundation eLearning
- ISO 9001:2015 Introduction and Awareness
- ISO 9001:2015 Internal Auditor
- ISO 9001:2015 Senior Management Briefing
- ISO 9001:2015 Lead Auditor
- Integrated Management Systems Auditor Training
- ISO 31000 Risk Management Awareness.

For more information contact the SGS Academy on +44 (0)1276 697 777 or email ukacademy@sgs.com.

SGS IN THE UK

SGS is an accredited certification body to standards such as ISO 14001 (Environmental Management Systems), ISO 45001 (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.

Other accredited standards are available on request. Visit www.sgs.co.uk to review our comprehensive solutions to your business requirements.

SGS provides a comprehensive range of technological and management services for the following key markets:

- Oil, gas, petrochemicals and minerals
- Agriculture and food sectors
- Industrial, engineering and manufacturing
- Consumer products and retail
- Travel, tourism and leisure
- Government and institutions

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

- Certification
- Inspection
- Testing and analysis
- Auditing
- Technical consultancy
- Measurement services
- Monitoring
- Training
- Valuation

SGS offers solutions to both the business-to-business and consumer markets.

THE SGS GROUP

The SGS Group is the clear global leader and innovator in inspection, verification, assessment and certification services. The Group comprises more than 300 affiliated companies, each separately organized and managed in accordance with the laws and local practices of the countries in which it does business.

Founded in 1878, SGS is recognized as the global benchmark for the highest standards of expertise and integrity. With more than 95,000 employees worldwide, we operate a network of more than 2,400 offices and laboratories around the world. Since it was established the SGS Group has remained dedicated to its independence as a guarantee of its total impartiality. SGS does not engage in any manufacturing, trading or financial activities which might compromise its independence and neutrality.

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WHEN YOU NEED TO BE SURE

SGS