

# A practical guide to ISO 9001:2015



Management system standards are revised to keep them current, relevant to market changes, to introduce new methods and thinking and to maintain compatibility with other applicable standards.

ISO 9001:2015 follows the new ISO format defined in Annex SL that provides a framework for a generic management system standard with a high level structure, identical core text, common clause titles and common terms and definitions. In future, all management system standards will migrate at their next revision to have the same look and feel, ensuring integration, compatibility and consistency.

There are some significant new requirements in ISO 9001: 2015, together with amended definitions that need to be considered. “Shall” is used to indicate a requirement and there are more than 100 of them but many are carried over from ISO 9001:2008.

There are also around 35 requirements for documented information which can include manuals, policies, procedures and records.

[This document highlights the significant changes.](#)

## INTRODUCTION

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### Risk based thinking

You should utilise a process approach, the Plan-Do-Check-Act cycle and the concept of risk based thinking.

Risk is associated with the consequences of an event and the likelihood of occurrence and risk-based thinking has been implied in previous versions of ISO 9001 in the form of corrective and preventive action.

By introducing risk-based thinking, risks and opportunities should be identified and addressed at key stages of the business process activity and be considered as means of improving positive results and preventing negative ones.

There is no requirement for formal risk assessments but you should identify and control risks and threats to your organisation and take appropriate action, thereby giving top management a clearer understanding of the potential consequences if risks are not addressed.

## SCOPE

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Your quality management system should be used to provide products and services that meet customer, statutory and regulatory requirements and enhance customer satisfaction.

## TERMS AND DEFINITIONS

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There are a number of new terms and definitions in ISO 9001:2015 such as documented information that need to be considered.

## CONTEXT OF THE ORGANISATION

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### Understanding the organisation and its context

You need a high-level understanding of the important external and internal issues, the position of your business that can affect your intended outcomes and who your interested parties are.

External issues include legal, technological, competitive, market, cultural, social and economic requirements.

Internal issues include your own values, culture, knowledge and performance.

These issues can result in risks and opportunities that shape your ability to meet your desired quality outcomes.

### Understanding the needs and expectations of interested parties

You need to determine who your relevant interested parties are and what their needs and expectations might be.

It is up to you to decide if a requirement of an interested party is relevant or applicable.

Interested parties could be customers, employees, neighbours or regulators and their needs could be contractual, voluntary or regulatory requirements.

Interested parties can present risk if their needs are not met and you should take action to meet their expectations and reduce that risk.

### Determining the scope of the quality management system

You have the flexibility to define the boundaries and applicability of your quality management system, taking into consideration external and internal issues, requirements of relevant interested parties and your products and services.

The scope should state the types of products and services offered and justify the exclusion of any requirement of ISO 9001:2015.

Compliance with the standard can only be claimed if these exclusions do not affect your ability to ensure conformity of products and services and enhance customer satisfaction.

Documented information is required.

### Quality management system and its processes

The sequence and interaction of processes and systems should be defined and continually improved, taking into account risks and opportunities.

Documented information is required.

## LEADERSHIP

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### Leadership and commitment

There is greater emphasis on the role of top management who, in addition to managing the system are now required to demonstrate leadership by establishing policy and objectives and promoting continual improvement.

Responsibility can be delegated and key staff should be involved at appropriate levels but top management must remain accountable and a hands-on approach is necessary. Third party audits will require a significant input from top management which will form part of the audit plan. Expect top management to be interviewed on topics such as risks, policies, objectives, targets, planning, compliance obligations, protection of the environment and assignment of roles and responsibilities amongst others.

Your top management is required to take a forward thinking approach and demonstrate leadership by establishing policy and objectives, promoting continual improvement, a process approach and risk based thinking.

### Customer focus

Top management must demonstrate leadership and commitment by ensuring that customer, statutory and regulatory requirements are met, risks and opportunities are addressed and customer satisfaction is maintained.

### Policy

The policy must be established by top management, documented, understood within your own organisation and be available to interested parties if appropriate.

### Organisational roles, responsibilities and authorities

Top management should assign responsibility and authorities for various aspects of the quality management system. The term “management representative” is no longer used and the responsibilities and authorities can be assigned to an individual or a number of individuals.

## PLANNING

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### Actions to address risks and opportunities

You should plan how to address risks and opportunities, integrate actions into the system and evaluate the effectiveness of any actions.

Addressing risk can include avoiding risk, taking risk, eliminating the source of risk, sharing or retaining risk.

Opportunities can lead to the introduction of new practices, launching new products and services or using new technology.

Planning what is required, who is expected to carry it out and when it is required is preferable to having to carry out corrective action and an easier concept to understand than the need for preventive action required by previous versions of ISO 9001.

## SUPPORT

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### Organisational knowledge

Appropriate knowledge should be determined, maintained, made available and updated when necessary.

Knowledge can be specific, gained by experience, used and shared to achieve objectives and can be based on intellectual property, experience, lessons learned, standards, academia or conferences for example.

### Communication

You must determine what, when, with whom and how to communicate internally and externally and who communicates.

## PRACTICAL STEPS TO TRANSITION

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By going for early transition, you will gain the benefits of implementing the most up-to-date thinking on management system standards and demonstrating your commitment to your management system by maintaining it to the latest requirements.

If you have implemented other management system standards such as ISO 14001 that also follow the same high level structure, it will be relatively easy to integrate them with each other.

- ◆ Obtain a copy of ISO 9001:2015 - you can order this through the Alcumus ISOQAR website [www.alcumusgroup/isoqar](http://www.alcumusgroup/isoqar)
- ◆ Carry out a gap analysis of your current system against new requirements. Document and implement any changes to comply with the standard
- ◆ Train your employees
- ◆ Carry out an internal audit against requirements and implement any corrective action required
- ◆ Decide when you would like your transition audit and contact us to arrange dates
- ◆ If you are already certified to ISO 9001 you can go for transition on a scheduled surveillance audit, recertification audit or have a separate stand-alone transition audit
- ◆ If you are not yet certified to a management system standard, please contact our Technical Sales team on 0161 866 6186

## HOW CAN WE HELP?

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- ◆ You can attend a transition training course, Alcumus Academy offer a range of suitable courses to help with transition, you can contact them on 0161-866 6189
- ◆ Practical advice is available on the Alcumus ISOQAR website [www.alcumusgroup/isoqar](http://www.alcumusgroup/isoqar)
- ◆ There are checklists available on the website that you can download
- ◆ We can carry out a pre-assessment at a time to suit you
- ◆ Talk to your auditor, they will have the most up-to-date information
- ◆ You can contact our Technical Department on 0161 866 6188

## SUMMARY

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The Draft International Standard (DIS) was published in May 2014

The Final Draft International Standard (FDIS) was published on 09 July 2015

ISO 9001:2015 was published on 24 September 2015 and you will then have three years from date of publication to complete your transition.

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