ISOQAR

GUIDE TO THE REQUIREMENTS OF ISO 9001:2015

A plain English guide to the ISO 9001:2015 Quality Management System

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WHAT ARE THE REQUIREMENTS OF ISO 9001?

Many people new to management systems are under the impression that an ISO standard is a set of rules that dictates how an organisation should go about its business. That's not correct.

With the introduction of BS 5750 in 1979, the British Standards Institution (BSI) founded the first true standard for a quality management system (QMS). BS 5750 is generally considered to be the precursor of the ISO 9000 series we know today.

The ISO 9000 standard series itself was internationally recognised in 1987. In this series of standards, ISO 9001 has become one of the most accepted standards in quality management. During the last two decades the standard has been updated three times to reflect the changing environment as well as the development of the quality management profession.

As the name suggests, ISO 9001:2015, the latest version of the standard, was published in 2015 and as of 15th September 2018 is the only certifiable version of ISO 9001.

The purpose of this guide

As you are probably aware, there is an entire global industry built on the back of ISO 9001. Helping to interpret, implement, maintain and audit Quality Management Systems is a profession in itself. It's unlikely that reading any one document will turn you into an expert overnight.

So, this document is an overview. It summarises the main requirements of ISO 9001, in as plain English as possible, to give you an idea of what's involved in implementing a Quality Management System in your organisation.

You should not be dismayed if you feel daunted by this. With some basic training and the support of an expert, you can join the other million or more business across the world who have achieved ISO 9001 certification.

Structure of this guide

In the sections below, we will guide you through the main elements, or 'clauses', of the standard.

The standard contains ten clauses – numbered 1 to 10 – with a range of subclauses.

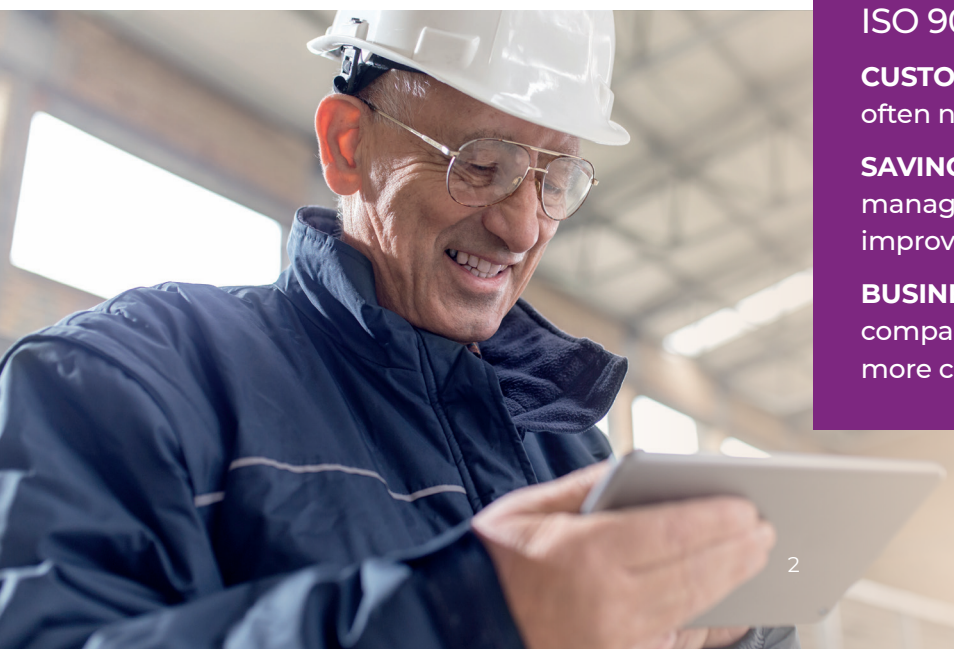
The first three clauses set out the Scope, Normative References, and Terms and Definitions for the standard. These sections focus on the standard itself and do not set out any requirements, so we will leave them aside for now as we turn our attention to the real essence of the standard.

Why do organisations get ISO 9001 Certified?

CUSTOMER DEMAND – it's often needed to win contracts

SAVING MONEY – quality management systems improve efficiency

BUSINESS GROWTH – certified companies retain and win more clients



CLAUSE 4 – CONTEXT OF THE ORGANISATION

This clause requires that you determine the relevant external and internal conditions that may affect your organisation's existence and strategy. The 'context' relates to the business environment in which you operate.

The purpose of this requirement is to get a good understanding of the relevant internal and external factors (the clause uses the word 'issues') that can affect your ability to achieve business goals – and by extension, your quality management system results – both positively and negatively.

You must look at your customers' requirements, the requirements of relevant stakeholders and relevant legal requirements. These requirements may exert influence, positively as well as negatively, on your quality management system.

Understanding the framework and terms is the basis for determining the important parts of your quality management system: scope, processes, policies, goals, and planning of the management system.

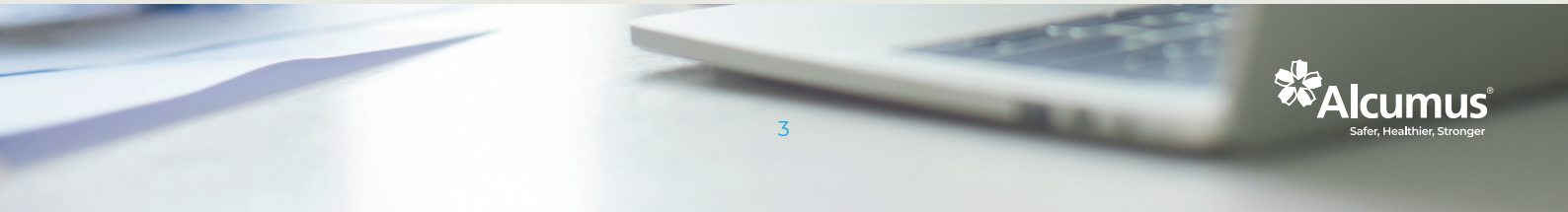
You can get information about the external and internal factors by, for example, following the general press and industry-specific journals.

Many organisations choose to analyse these issues by either a SWOT (Strengths, Weaknesses, Opportunities, Threats) or PESTLE (Political, Economic, Sociological, Technological, Legal, Environmental) analysis – or a combination of both.

Once you have a good understanding of the powers that act upon your organisation, you can determine the 'scope' of your quality management system – which parts of the organisation, and which products and services, are covered by the system.

EVOLUTION OF ISO 9001

ISO 9001 was first introduced in 1987, based on the UK Standard BS 5750.



CLAUSE 5 – LEADERSHIP AND COMMITMENT

Leadership

Management cannot 'outsource' responsibility for the QMS to junior colleagues somewhere in the structure of the organisation. The standard recognises that, when you as a leader point at someone, there are three fingers on the same hand pointing back at yourself!

So, this clause introduces the requirement for strong leadership and top management's commitment. ('Top Management' is a term that's used in the standard and refers to the person or group of people who directs and controls the organisation at the highest level.)

Top management has to be directly involved in the management system, as there are a number of specific requirements placed on them throughout the standard and a general requirement to take overall responsibility.

The 2015 version of the standard also uses the term 'Leadership', which is not to be confused with the general term 'Management'. In short, management is about *doing things right while leadership is about doing the right thing*.

Quality Policy

Top management must ensure that a Quality Policy is established. This is a written statement – normally no longer than one side of a piece of paper – that sets out the overall intention and direction of the organisation with regards to quality.

The policy must be appropriate to the organisation as well as establishing the framework for setting and reviewing goals. Furthermore, the organisation, through its Quality Policy, must state its commitment to comply with all and any applicable requirement as well as continual improvement of its QMS.

Organisational roles, responsibilities and authorities

This part of Clause 5 sets out the need for the organisation to determine what individuals in the organisation are expected to do and what they are allowed to do. Top management must ensure that responsibilities and authorities are determined, communicated and understood by all involved.

EVOLUTION OF ISO 9001

The 1994 version of the standard emphasized quality assurance through preventive actions rather than just checking at the end.

CLAUSE 6 – PLANNING

Risk-based thinking is one of the cornerstones of ISO 9001. This is all about ensuring that the expected results are achieved, and no unwanted incidents occur.

Processes must be established to prevent, reduce or eliminate the effect of unwanted events. The organisation must plan actions to handle the identified risks and possibilities depending on the effect and consequence of the incident.

Similarly, it must also establish processes that identify opportunities and plan actions to make the most of the identified opportunities.

There is actually no requirement for formal risk management and the establishment of a risk management system, but risk-based thinking must be introduced into the organisation depending on the products and services it produces or delivers.

This should help ensuring compliance with customer requirements, legislation, regulations and other requirements and ultimately result in customer satisfaction.

Planning for change

When the organisation decides that there is a need for change, it must be done within the scope of the QMS. Change should be planned and systematic, and the organisation must ensure that the change process has the resources needed to change the system as well as at the same time conforming to all the applicable requirements.

Quality objectives

Just as an organisation has objectives for operations, sales and functions such as HR, an ISO 9001 certified organisation must establish objectives for quality relating to relevant functions, levels, and processes. The established objectives must be followed up in (action) plans, specifically indicating:

- WHAT NEEDS TO BE DONE
- WHAT RESOURCES SHOULD BE USED
- WHO IS RESPONSIBLE
- WHEN TO DO IT
- HOW TO EVALUATE THE RESULT

EVOLUTION OF ISO 9001

The 2000 version put process management at the forefront.

CLAUSE 7 – SUPPORT

The organisation is required by this clause to establish and maintain the necessary infrastructure to ensure operation and compliance with product and performance.

The requirement is wide-ranging and looks at:

- **Process environment** (meaning the 'work environment') – The organisation should provide and manage a suitable environment to achieve and maintain the success of the organisation and competitiveness of its products.
- **Monitoring and measurement resources** – Where monitoring and measurement are used as proof of compliance with specified requirements, the organisation must ensure valid and reliable results.
- **Organisational knowledge** – This is knowledge that is generally gained by experience, which can be used to achieve the objectives of the organisation. The organisation must determine what knowledge is needed to operate processes and ensure conformance of products and services. Organisations must also consider how additional or updated knowledge will be gained, if necessary, for changing needs.
- **Competence** – This is the ability to use knowledge and skills to achieve intended results. The organisation must identify the competencies required, ensuring that employees are competent, or take action to address shortcomings.
- **Awareness** – This relates to employees' understanding of how the organisation's QMS relates to meeting customer and regulatory requirements. Employees must be aware of the quality policy and objectives as well as their contribution to ensuring compliance including benefits of improvement of performance and consequences of not being in conformity with the management system requirements.
- **Communication** – The organisation must decide how to communicate most effectively internally as well as externally. It must consider who to inform, what to inform about, how to do it and when to do it.
- **Documented information** – There is more flexibility than you might imagine in the way you choose to document the QMS. You need only cover what is necessary for your operations. These must then be managed in a way that ensures the efficiency of the management system.

EVOLUTION OF ISO 9001

The 2008 version added no new requirements but clarified some requirements and brought it into line with ISO 14001.

CLAUSE 8 – OPERATION

This is the 'Do' part of the Plan-Do-Check-Act (PDCA) cycle and is the day-to-day part of what your organisation does. This clause is at the very heart of the of the Quality Management System.

Processes

It sounds obvious, but processes needed to meet the requirements of the organisation. You need to ensure that what you do will result in the desired outcomes. So, processes need to be planned, implemented and controlled, as do the actions identified in earlier clauses about risks and opportunities. Furthermore, the organisation must introduce controls in relation to change and outsourced processes.

You are also expected to exercise care with property belonging to customers and suppliers whilst it is under your control. If their property suffers damage, is lost, or proves to be unsuitable for use, then you are expected to retain documented information on this.

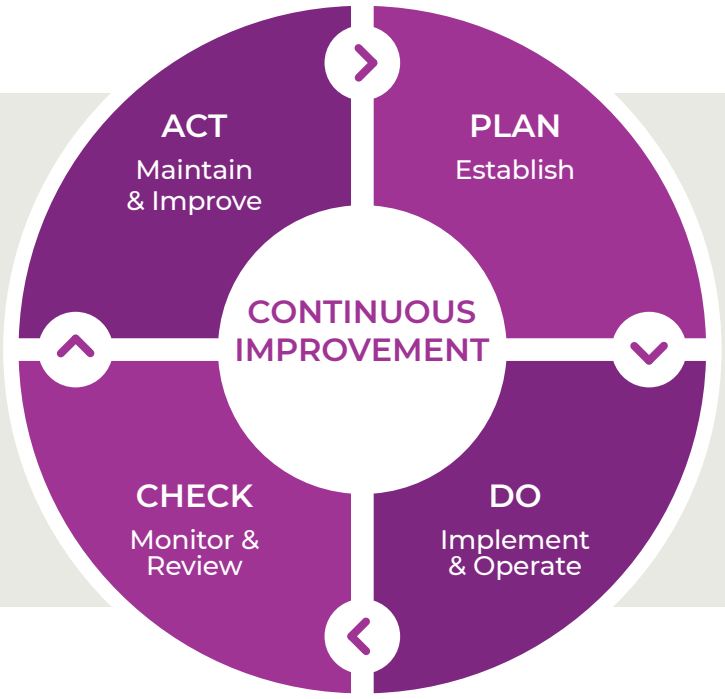
Communication

Clause 8 looks at the interface between your organisation and your customer. You should consider, for example:

- Product information such as brochures, samples, drawings and even your sales processes
- How you handle enquiries, contracts and orders
- Customer feedback and complaintYou are also required to manage communication with regards to contingency actions where required. For example, you should have back up plans to deal with unavoidable events and notify your customers when this may cause delays.

PDCA

The Plan-Do-Check-Act cycle is at the heart of ISO 9001 and ensures continuous improvement



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Design & Development

If you design and develop your products and services, then this is one of the more complex areas of your QMS. Many organisations are

not clear whether this clause applies to their organisation – if in doubt, you should take expert advice.

Even if it does apply, you do not necessarily require a procedure, but many aspects of the design and development process need to be documented in order to achieve ISO 9001 certification.

This section of ISO 9001:2015 is lengthy and quite complex and, if it is relevant to your organisation, requires more in-depth consideration.

Control

Externally provided processes, products and services, such as those provided by suppliers and sub-contractors, must be controlled. Even though these personnel are not within your own organisation, you need to ensure they are competent and have the necessary qualifications.

You must also decide how externally provided personnel interact with the QMS and how it controls the external provider's performance. There is a requirement in the clause to establish specific criteria for monitoring performance of, and communication with, external providers.

Outputs

Before your organisation releases the final product or service, you must verify that the product or service meets the customer requirements and you must retain documented information to demonstrate this.

Non-Conforming Outputs

Lastly, you are required to ensure that outputs that do not conform to their requirements are identified and controlled. There are no requirements for a procedure, but you are required to retain documented information that describes the nonconformity, the actions taken, and the concessions obtained.

EVOLUTION OF ISO 9001

ISO 9001:2015 is the latest version and is less prescriptive with more focus on performance than procedures.

CLAUSE 9 – PERFORMANCE EVALUATION

What does the organisation need to measure?

The organisation is required by this clause to determine what needs to be monitored, how to monitor and when to do it. The results must be measured, analysed and evaluated.

The following must be considered:

- Compliance with product requirements and performance
- Customer satisfaction – the extent to which customer expectations are met
- Performance and management system efficiency
- Effective implementation of planning, including actions to realise opportunities and manage risks
- Performance of external providers
- Need for management system improvements

There are no specific requirements for how to monitor, measure and evaluate but methods might, for example, include the use of statistical techniques.

Internal audit

Internal audits are used to assess conformity, evaluate effectiveness and identify opportunities for improvement. They also help you prepare for external audits.

They must be carried out at scheduled intervals to provide information about conformity to your own requirements for your organisation and the requirements of ISO 9001. The audit establishes whether these requirements are effectively implemented, and if the system is being properly maintained.

Management review

Top management must evaluate the quality management system at planned intervals to ensure that the system is suitable, effective, efficient and is aligned with the organisation's strategic direction.

85% of ISO 9001 certified organisations report that it is beneficial to business

(Alcumus ISOQAR, 2018)

CLAUSE 10 – IMPROVEMENT

Underpinning the concept of a QMS are the principles of corrective action and continual improvement.

In general, the organisation must identify opportunities for improvement as well as introduce necessary actions to meet customer demands and increase customer satisfaction.

These should, where appropriate, include improvements in products and performance to enhance customer satisfaction. You are also required to address future needs and expectations, prevent and reduce undesired effects and improve the performance and efficiency of the established management system itself.

Continual improvement

The organisation must continually improve the effectiveness and efficiency of its management system. Results from audits, analysis and evaluation of data and results from management review, should all be used to implement corrective and preventive action.

More than **1,100,000** organisations worldwide are certified to ISO 9001 and many more use the standard

SUMMARY

The decision to implement an ISO 9001 compliant Quality Management System is not one to take lightly. You need to dedicate time and resource to learning what's involved, the implementation of the system and its upkeep.

You'll undergo annual surveillance audits and a three-year certification cycle to review your management system and ensure continual improvement. So, you can't just install your QMS and forget about it.

But it doesn't need to be daunting. Hopefully this guide has removed some of the mystery from some of the clauses.

Much of what is required is common sense and simply good management. With a little reading, training and maybe the support of an external consultant, you can be well on your way to ISO 9001 Certification.

WHO IS UKAS?

The United Kingdom Accreditation Service (UKAS) is the only government recognised accreditation body for the UK. They ensure that Certification Bodies are auditing to the highest standards. Some certification bodies are not UKAS accredited and their certificates are not as widely accepted.

ABOUT ALCUMUS ISOQAR

We help organisations create better workplaces through a huge range of common and sector-specific standards and compliance assessments, allowing them to demonstrate to their customers, competitors, suppliers and staff, that they are committed to being the best that they can by minimising risk, delivering change, driving improvement and winning more work.

As one of the UK's largest UKAS accredited certification bodies we can audit, certify and train organisations across multiple sectors. We work worldwide, so we can help businesses gain a competitive edge anywhere they need us..

ABOUT ALCUMUS

Alcumus is a leading provider of software-led risk management solutions providing clients with advice, expertise and support to help them identify and mitigate risks, navigate compliance and keep people safe. It supports both UK and International clients – many of whom are on the FTSE 100 index - with a wide range of risk management services. This includes products across Supply Chain Management, EHSQ Software, UKAS Accredited Certification and HR and H&S support services. .

Our people are at the heart of our business, building strong relationships with our clients to understand their needs, minimise risks and navigate compliance through our in-depth knowledge of your sector, regulations and challenges.

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