ISO 9001:2026 Overview and Guidance

Introduction

ISO 9001 Quality Management Systems is the most recognised international quality standard in the world and is used by organisations of every size and sector. Many organisations use **ISO 9001** as a framework for consistently providing products and services that meet customer and legal requirements, and many go on to achieve certification to show customers and other interested parties that they meet the requirements of the standard.



The current version of the standard is **ISO 9001:2026**, published on 16 September 2026. The previous version is ISO 9001:2015.

ISO 9001:2026 follows the harmonised structure used by ISO management system standards (formerly the high level structure, set out in Annex SL of the ISO/IEC Directives), so its clauses align closely with ISO 14001, ISO 45001 and other management system standards, which makes it straightforward to run them together as an integrated management system.

The standard promotes the framework known as **Plan-Do-Check-Act**, applied together with risk-based thinking and opportunity-based thinking. Although this is not a specific clause within the standard, it guides the general way of thinking when operating an ISO-compliant management system.

The standard is based on seven quality management principles:

- **Customer Focus** - meeting customer requirements and working to enhance customer satisfaction
- **Leadership** - top management set the direction and create the conditions for people to achieve the quality objectives
- **Engagement of People** - competent, empowered and engaged people at all levels of the organisation
- **Process Approach** - understanding and managing activities as interrelated processes that work together as a system
- **Improvement** - an ongoing focus on improving performance, processes, products and services
- **Evidence-based Decision Making** - decisions are based on the analysis and evaluation of data and information
- **Relationship Management** - managing relationships with interested parties such as suppliers and partners

What has changed in ISO 9001:2026

Compared to ISO 9001:2015, the main clause structure is unchanged and there are no new mandatory documents or records. Clause 3 now carries a small set of core terms and definitions, Annex A has

been rewritten to explain the intent of each clause without adding requirements, and Annex B has been removed.

The main changes are in the following clauses;

- **4.1 Understanding the organisation and its context** - the organisation must determine whether climate change is a relevant issue, as introduced by the 2024 amendment
- **4.2 Understanding the needs and expectations of interested parties** - the organisation must now determine which requirements are addressed through the management system
- **5.1.1 Leadership and commitment** - top management must promote a quality culture, ethical behaviour and opportunity-based thinking
- **5.3 Organisational roles, responsibilities and authorities** - reporting on opportunities for improvement becomes a separate responsibility
- **6.1 Actions to address risks and opportunities** - split into 6.1.1 determining risks and opportunities, 6.1.2 actions on risks and 6.1.3 actions on opportunities
- **6.3 Planning of changes** - planning must now also cover the information needed, communication of the change, and how its effectiveness is monitored and reviewed
- **7.3 Awareness** - people doing work under the organisation's control must be aware of the organisation's quality culture and ethical behaviour
- **8.2.1 Customer communication** - customers must be informed of relevant contingency actions, including those related to disruption
- **9.1.3 Analysis and evaluation** - the effectiveness of actions taken on risks and the effectiveness of actions taken on opportunities are now evaluated separately
- **9.2.2 Internal audit programme** - the objectives of each audit must now be defined, as well as its criteria and scope
- **9.3.2 Management review inputs** - a new input on changes in interested party needs, and separate inputs on actions for risks and for opportunities
- **10.1 Continual improvement** - previously numbered 10.3, as part of a restructure of clause 10

Quality Management

ISO 9001:2026 places more emphasis on the culture of the organisation. Top management are expected to promote a **quality culture and ethical behaviour**, and people doing work for the organisation need to be aware of them. The note on the environment for the operation of processes covers social and psychological factors, such as stress reduction and burnout prevention, and recognises that some of them can be influenced by quality culture and ethical behaviour.

Risks and opportunities are treated separately. Organisations determine, analyse and evaluate the risks that could affect their ability to provide conforming products and services - the standard notes

these can include disruption - and plan actions in proportion to the potential impact. Opportunities, such as new products or services, partnerships or emerging technologies, are considered in their own right. The standard does not require a formal risk management method or a documented risk management process.

Organisations must also determine whether **climate change** is a relevant issue for their quality management system, and changes to the quality management system must be carried out in a planned way, including how they will be communicated and how their effectiveness will be reviewed.

There is no requirement to prepare documentation relating to every clause in the standard, and nothing in the standard requires a documented quality manual.

There are some documentation requirements, however. The scope, quality policy and quality objectives must be available as documented information, and records must be kept as evidence of things such as competence, customer requirement reviews, supplier evaluation, release of products and services, nonconformities, internal audits and management reviews. The full standard should be reviewed and a documentation checklist completed to make sure all documentation requirements have been met.

Although a management system manual is not required, it is still a good idea to prepare documentation that provides an overview of key processes relating to quality. This documentation helps everyone within the organisation to understand and follow the key processes, and will also help with the audit as it can be presented to the auditor.

ISO 9001:2026 Certification Audit

During an audit the auditor(s) will be looking for objective evidence that each clause in the standard has been met and complied with.

Clauses 4 to 10 of the standard will all be reviewed. A requirement, such as design and development or the calibration of measuring equipment, can be determined as not applicable, provided this does not affect the ability to provide conforming products and services and enhance customer satisfaction. The justification must be stated in the scope of the quality management system.

As well as reviewing all the relevant clauses, there are various things you can prepare and have in place prior to the audit;

- Completed and up-to-date management review, including changes in interested party needs and the effectiveness of actions taken on risks and on opportunities
- Completed internal audit(s), with defined objectives, criteria and scope for each audit
- Quality objectives that are measurable and monitored, with plans in place to achieve them
- Evidence of customer feedback and monitoring of customer satisfaction

- Some examples of continual improvement
- Key records such as competence and equipment calibration records
- Evidence of compliance with applicable legal requirements for products and services, including recent updates to laws and regulations which affect the business
- A system for logging and tracking nonconformities, complaints and corrective actions
- Closure of any nonconformities and findings from prior audits (as applicable)
- Evidence that climate change has been considered when determining external and internal issues (clause 4.1)
- Evidence that risks and opportunities have been determined and actioned (clause 6.1)
- Evidence of how changes to the quality management system are planned, communicated and reviewed (clause 6.3)
- Evidence of how top management promote a quality culture and ethical behaviour, and that people are aware of it (clauses 5.1.1 and 7.3)

Presenting evidence during the audit

For guidance on the audit process, how to prepare for the audit, the overall audit plan, and the certification audit process, please review the **Certification Audit Guidance** which is available online here.

In an audit involving a site visit, the auditor will typically view evidence in person while asking questions; a site tour may also be conducted. For remote audits it is common for photographs and videos to be submitted as supporting evidence.

Further support

- Management system documentation and resources: isomanaged.com/alphazdocuments
- ISO Consultancy: isoassured.co.uk/iso-consultancy

Knowledge Base

More on ISO 9001, clause by clause, in the isomanaged.com knowledge base:
isomanaged.com/knowledge-base/iso-standards/iso-9001