ISO 9001

ISO 9001:2015 → ISO 9001:2026 Clause Changes

Issued 2026

ISO 9001:2026 was published on 16 September 2026 and replaces ISO 9001:2015. The revision is a targeted update rather than a complete restructuring of ISO9001.

Clauses 1–10 remain the core structure, with the most significant changes concentrated around leadership, quality culture, strategic alignment, risks and opportunities, awareness, and clarification of requirements.

Outlined below is clause by clause overview:

Clause	ISO 9001:2015	ISO 9001:2026 – Main Change	Impact
1 Scope	Scope of QMS requirements	Clarifications and updated terminology	Low
2 Normative references	ISO 9000 reference	Updated alignment with current ISO terminology	Low
3 Terms & definitions	Definitions from ISO 9000	Updated/clarified terminology	Low–Medium
4 Context of the organisation	Context, interested parties, QMS scope and processes	Greater emphasis on strategic context, organisational environment and changing business conditions	Medium
4.1 Understanding the organisation and its context	Determine external/internal issues	Greater clarity on issues affecting strategic direction and QMS effectiveness	Medium
4.2 Interested parties	Determine relevant interested parties and requirements	Continued, with clearer connection to organisational context	Medium
4.3 QMS scope	Determine boundaries and applicability	Clarification rather than fundamental change	Low
4.4 QMS and its processes	Establish, implement, maintain and improve processes	Process approach retained; greater focus on effectiveness and integration	Low–Medium
5 Leadership	Leadership and commitment	Stronger emphasis on leadership, accountability and quality culture	High
5.1.1 Leadership & commitment	Demonstrate leadership and commitment	Quality culture and ethical behaviour explicitly strengthened	High

Clause	ISO 9001:2015	ISO 9001:2026 – Main Change	Impact
5.1.2 Customer focus	Customer requirements, risks and opportunities, customer satisfaction	Customer focus retained and reinforced	Medium
5.2 Quality policy	Establish, implement and maintain quality policy	Stronger connection with context and strategic direction	High
5.3 Roles, responsibilities & authorities	Assign responsibilities and authorities	Greater emphasis on accountability	Medium
6 Planning	Risks/opportunities, objectives and change	Greater clarity around risk versus opportunity	High
6.1 Risks & opportunities	Determine risks/opportunities and actions	Clearer separation between risks and opportunities; revised structure	High
6.2 Quality objectives	Establish objectives and planning	Greater connection with organisational strategy and performance	Medium
6.3 Planning of changes	Plan QMS changes	Requirement retained with clarification	Low–Medium
7 Support	Resources, competence, awareness, communication, documented information	Greater emphasis on people, culture and modern working environment	Medium
7.1 Resources	People, infrastructure, environment, monitoring resources, knowledge	Updated considerations, including organisational environment and knowledge	Medium
7.1.4 Environment for operation of processes	Suitable environment	Quality culture and ethical behaviour are reinforced	Medium–High
7.1.6 Organisational knowledge	Determine and maintain knowledge	Continued, with greater relevance to organisational knowledge in changing/digital environments	Medium
7.2 Competence	Competence of people	Requirement retained and clarified	Low
7.3 Awareness	Policy, objectives, contribution, implications	Greater emphasis on quality culture and ethical behaviour	High
7.4 Communication	Internal/external communication	Clarifications	Low
7.5 Documented information	Create, update and control information	Modernisation/clarification; fundamental requirement retained	Low–Medium

Clause	ISO 9001:2015	ISO 9001:2026 – Main Change	Impact
8 Operation	Operational planning, customer requirements, design, suppliers, production/service	Mostly continuity, with targeted clarifications	Medium
8.1 Operational planning & control	Plan, implement and control processes	Greater emphasis on effective operational control	Medium
8.2 Customer requirements	Customer communication and requirements	Retained with clarification	Low
8.3 Design & development	Design controls	Core requirements retained	Low–Medium
8.4 External providers	Supplier/provider controls	Greater relevance to complex and interconnected supply chains	Medium
8.5 Production/service provision	Controlled production/service	Clarifications and modernisation	Low–Medium
8.6 Release	Verification before release	Retained	Low
8.7 Nonconforming outputs	Control of nonconforming outputs	Retained with clarification	Low
9 Performance evaluation	Monitoring, measurement, analysis, evaluation, audit, management review	Greater emphasis on meaningful performance information and strategic relevance	Medium
9.1 Monitoring & measurement	Determine what/how/when to monitor	Greater focus on useful performance information	Medium
9.2 Internal audit	Planned audit programme	Requirements retained; alignment and clarification	Low
9.3 Management review	Review QMS suitability, adequacy and effectiveness	Stronger relationship with strategic direction and organisational performance	Medium–High
10 Improvement	General, nonconformity/corrective action, continual improvement	Continual improvement remains fundamental; clarification of improvement activities	Medium

The Major Changes to an ISO9001 Management System include:

1. Clause 5.1 — Leadership & Quality Culture

This is one of the most important changes.

ISO 9001:2026 places greater emphasis on:

- Quality culture
- Leadership behaviour
- Accountability
- Ethical behaviour
- Creating an environment where people contribute to QMS effectiveness
- Leadership's active involvement in quality

This means an auditor is likely to look beyond whether a quality policy exists and ask how management demonstrates and promotes quality in practice.

Potential evidence:

- Leadership objectives
- Quality culture initiatives
- Management communications
- Ethical behaviour expectations
- Management meeting records
- Quality performance discussions
- Employee engagement
- Examples of management decisions supporting quality

2. Clause 5.2 — Quality Policy

The quality policy now has a stronger connection with:

Context → Strategic direction → Quality policy → Objectives → QMS performance

This reinforces the idea that the Management System should support the organisation's business strategy rather than operate as a separate compliance system.

Gap-analysis question:

Does our Quality Policy clearly support our organisation's strategic direction and current business context?

3. Clause 6.1 — Risks and Opportunities

This is another significant change.

The 2015 edition combines consideration of risks and opportunities. The 2026 edition provides greater clarity and separation between the two.

The revised approach distinguishes between:

Risk
→ Potential negative effect or uncertainty that needs to be managed.

Opportunity
→ A situation or possibility that can produce beneficial results.

ISO specifically states that the revision provides clearer distinction between managing risks and pursuing opportunities.

This could require organisations to review their:

- Risk registers
- Opportunity registers
- SWOT analysis
- Business planning
- Improvement programmes
- Risk treatment plans
- Strategic planning processes

4. Clause 7.3 — Awareness

Awareness is strengthened.

Employees should not simply know:

- The Quality Policy
- Relevant Quality Objectives
- Their contribution
- The implications of nonconformity

There is now greater emphasis on understanding quality culture and ethical behaviour

This has implications for:

- Induction
- Training
- Toolbox talks
- Awareness programmes
- Competence records
- Internal communications
- Employee engagement

5. New Annex A

ISO 9001:2026 introduces a new informative Annex A intended to provide additional clarification of concepts, terminology and the intent of requirements.

This should be particularly useful when:

- Interpreting requirements
- Conducting internal audits
- Performing gap assessments
- Developing procedures
- Training personnel
- Preparing for certification audits

What Has NOT Fundamentally Changed?

The revision retains the familiar ISO 9001 framework.

The following remain central:

Customer focus →

Process approach →

Risk-based thinking →

Evidence-based decision making →

Continual improvement

ISO specifically states that customer focus, the process approach, risk-based thinking and continual improvement remain at the heart of the standard.

Therefore, an organisation with a mature ISO 9001:2015 Management System does not need to start again.

Recommended 2015 → 2026 Gap Analysis Structure

For an organisation preparing for transition, I would use this structure:

Area	Gap-analysis question
4 Context	Has our QMS context been reviewed against current strategic/business conditions?
4.1	Are internal/external issues current and relevant?
4.2	Are interested parties and their requirements current?
4.3	Does the QMS scope remain appropriate?
4.4	Are QMS processes effective and integrated?

Area	Gap-analysis question
5.1	Can top management demonstrate a quality culture?
5.2	Does the Quality Policy support strategic direction?
5.3	Are accountability and responsibilities clear?
6.1	Are risks and opportunities separately and effectively considered?
6.2	Are quality objectives aligned with business priorities?
7.1	Are adequate resources and organisational knowledge available?
7.3	Do people understand quality culture and ethical expectations?
8.4	Are external providers and supply-chain risks effectively controlled?
9.3	Does management review address strategic and QMS performance?
10	Does continual improvement demonstrate measurable improvement?

Transition deadline

Existing ISO 9001:2015-certified organisations have until 30 September 2029 to complete transition to ISO 9001:2026.

From **31 March 2028**, new and initial certifications can only be issued to ISO 9001:2026.

In practical terms, the highest-priority transition work should be Clauses 5.1, 5.2, 6.1 and 7.3, followed by a systematic review of Clauses 4–10 and the organisation's documented Management System.