ISO 9001:2026

What has changed — and what to check in your quality management system (QMS)

A leadership briefing prepared from direct comparison of BS EN ISO 9001:2015 and BS EN ISO 9001:2026 | QFactorial | Sept 2026

This briefing does not constitute certification advice.

ISO 9001:2026 was published on 16 September 2026, following ISO 14001:2026 on 15 April 2026. Both revisions are now in their transition periods. The deadlines are ISO 9001 by September 2029 and ISO 14001 by April 2029. If you use both standards, the most efficient approach may be to plan both transitions together, aligning them with your next scheduled certification audit and completing them as a single coordinated programme. The changes to ISO 9001 are in six targeted areas, so a full gap assessment won't be required if you already comply with ISO 9001:2015. The important consideration when planning how to implement the changes is that they all require you to build up a body of evidence over time. Creating or revising policies and procedures will not suffice.

What's changed

1 Risks and opportunities are now separated

ISO 9001:2015 treated 'risks and opportunities' as a single combined concept. ISO 9001:2026 splits Clause 6.1 into three: 6.1.1 (determining risks and opportunities), 6.1.2 (actions to address risks) and 6.1.3 (actions to address opportunities). The split carries through into performance evaluation (9.1.3) and management review (9.3.2).

What to check in your QMS

Ensure:

- Risks and opportunities are determined, analysed, evaluated and planned as distinct items.
- Your data analysis and management review inputs report on the effectiveness of actions addressing risks, and the effectiveness of actions addressing opportunities, separately.

2 Change management is strengthened

Clause 6.3 grows from four considerations to seven. Alongside the purpose of changes, their impact on QMS integrity, and the allocation of responsibilities, you must now also consider the availability of information (not just resources), how the changes will be communicated, how their effectiveness will be monitored and evaluated, and how the results will be reviewed.

Ensure:

- Your change record or process explicitly addresses communication of changes, how effectiveness will be monitored, and how results will be reviewed (not just planning and resourcing).
- Key triggers include new products or service lines, organisational changes, IT changes, and changes to QMS processes or scope.
- You don't get caught out trying to retrospectively document a change after the event.

3 Quality culture and ethical behaviour

This is new territory for ISO 9001. Top management must now promote quality culture and ethical behaviour as part of leadership commitment (5.1.1), staff must be aware of the organisation's quality culture and ethical behaviour (7.3), and the environment for the operation of processes may be shaped by it (7.1.4). None of this is defined narrowly or prescriptively. It's about evidenced attitudes and practices, not documentation.

Ensure:

- Leadership can evidence specific actions or communications that promote quality culture and ethical behaviour, not just a values statement.
- Quality can be shown to be a full and natural part of business discussions, meetings and decisions, not an afterthought and not limited to quality awareness sessions.
- Doing the right thing is viewed with the same importance, and recognised in the same way, as doing the thing right.
- Anyone can explain, in their own words, what quality and doing the right thing mean in their job.

4 Internal audits need an objective

Each internal audit in your programme must have its own documented objective in addition to its criteria and scope.

Ensure:

- Each internal audit has a specific, documented objective, in addition to its established criteria and scope.

5 Context analysis must consider climate change

A 2024 amendment to ISO 9001:2015 already made this a normative requirement in Clause 4.1; 2026 simply folds it into the base text rather than sitting as a separate amendment. If you're already certified, this should already be evidenced.

Ensure:

- Your context analysis (4.1) explicitly records whether (and how) climate change is a relevant issue for the organisation.
- You consider indirect as well as direct impacts, e.g. the impact on your business if your suppliers and customers are impacted by climate change.
- No new action needed if this was fully addressed when the 2024 amendment came out.

6 Organisational knowledge to be applied and shared

Clause 7.1.6 changes the verbs: knowledge must now be 'retained, applied and shared,' not merely 'maintained and made available.' It's a narrower wording shift than the other changes here, but a real one. A library of knowledge no longer satisfies the requirement.

Ensure:

- Where processes or events generate knowledge, it is not just stored away 'just in case' but actively shared and applied.
- Your lessons learned, lunch n learn, mentoring and similar activities are alive and kicking.
- Knowledge is curated rather than simply filed. Not just the QMS itself, but other internal and external knowledge that helps people do their jobs and deliver quality output.
- Critical knowledge isn't lost when key individuals leave the organisation or change roles.

Not sure how or when to get started with the changes? Talk to us.
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