



Green Tqm Group

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ISO 9001:2026 WHITE PAPER

**Quality Management Systems: Technical
Interpretation and Transition Implications
of the Sixth Edition.**

A technical briefing for quality leaders, QMS
implementers, auditors & quality professionals

Edition: 1.0 | 1 October 2026.

1. Executive Summary

ISO 9001:2026 is the sixth edition of the world’s most widely used quality management system (QMS) standard. It arrives more than a decade after the 2015 edition and has been developed as an **evolutionary revision rather than a rewrite**. The structure, core principles and overall intent will be recognisable to anyone familiar with ISO 9001:2015. Most amendments clarify, restructure or refine existing requirements; a smaller number genuinely strengthen expectations.

For top management, the revision is notable because it places two new expectations on leadership: to **promote quality culture and ethical behaviour** (clause 5.1.1 i)) and to promote **opportunity-based thinking alongside risk-based thinking**. For planners and process owners, risks and opportunities now sit in separate subclauses, and organisations must **analyse and evaluate** them rather than merely determine them. For change owners, clause 6.3 now requires consideration of how changes are communicated, how their effectiveness is monitored and evaluated, and how their results are reviewed. For internal auditors, each audit must have a defined **objective** in addition to criteria and scope.

1.1 Headline findings

Theme	Summary of the change
Overall nature	Evolutionary, not transformational. Existing QMS structures, documentation and audit methods remain valid where effective.
Quality culture and ethics	New top-management responsibility (5.1.1 i)), mirrored by a new awareness requirement (7.3 e)); a note to 7.1.4 recognises their influence on the process environment.
Risks and opportunities	Clause 6.1 split into 6.1.1 Determining, 6.1.2 Actions to address risks and the new 6.1.3 Actions to address opportunities; “analyse and evaluate” introduced; risk-based thinking text moves from clause 0.3.3 to Annex A.
Management of change	Clause 6.3 adds communication, monitoring and evaluation of effectiveness, and review of results; management review inputs (9.3.2) are made explicit.
Climate	Climate-related changes from Amendment 1:2024 are absorbed into clauses 4.1 and 4.2.
Terminology	Core Harmonized Structure terms are included in clause 3; “retain/maintain documented information” is replaced by “documented information shall be available (as evidence of)”.
Annex A	Completely restructured, now addresses every clause 4–10; remains informative. Annex B is deleted.
Audit and improvement	Internal audit objectives required (9.2.2); customer satisfaction (not perception of needs being met) is monitored (9.1.2); clause 10 reordered with continual improvement first.

1.2 What organisations should do

- **Do not redesign the QMS.** Review how current processes, controls and evidence demonstrate alignment with the revised requirements.
- **Start early.** A three-year transition period is planned for organisations certified to ISO 9001:2015; early gap analysis supports an orderly move with the chosen certification body.
- **Engage top management first.** The changes with the highest consequence – quality culture, ethical behaviour, opportunity-based thinking and change governance – are leadership matters that cannot be delegated away.
- **Focus on effectiveness, not artefacts.** Analysis, proportionality, integration into processes and evaluation of results are the evidential themes of the revision.
- **Prepare people for audit.** Expect more probing questions from certification bodies on the new and strengthened areas.

Key message

The 2026 revision does not tell organisations to build something new. It asks them to demonstrate – with fit-for-purpose, available evidence – that what they already do is analysed, proportionate, integrated, communicated and effective.

2. Introduction, Scope and Approach

2.1 Background

ISO 9001 specifies requirements for a QMS where an organisation needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements and aims to enhance customer satisfaction through effective application of the system (ISO 9001, clause 1). The 2026 edition published more than ten years after ISO 9001:2015, will affect those who implement the standard, those who audit QMSs and those who provide ISO 9001-based training.

Meeting the new requirements is expected to improve quality performance, but it will not be without challenges. In particular, evidence expectations are shifting from the mere existence of records towards demonstrable effectiveness, and leadership behaviours are brought closer to the auditable core of the standard.

2.2 Purpose of this white paper

This paper consolidates and re-presents the content of the ISO 9001:2026 training material in a structured technical form. It aims to:

- explain the nature and rationale of the revision;
- interpret each affected clause and distinguish genuine new requirements from clarification and rewording;
- set out implications separately for QMS implementers and auditors; and
- provide practical tools – a change register, a transition roadmap and a gap-analysis framework – that readers can adapt.

2.3 Analytical framework

The source material applies a consistent four-part “thematic approach” to every topic, and this paper retains that logic so that findings remain traceable:

Element	Question answered
Focus of the change	What has been updated, and why does it matter?
Affected clauses	Where do the changes appear in ISO 9001:2026?
Interpretation	What does the requirement mean in practice and how should it be understood?
Implications	What follows for (1) QMS auditors and (2) QMS implementers?

2.4 Classification of changes

Throughout this paper each change is classified using the four categories applied in the revision commentary:



Category	Meaning
Clarification	Improves understanding of an existing requirement, often supported by expanded guidance in Annex A.
Rewording	Reflects alignment with the Harmonized Structure (HS) and improved readability, without changing intent.
Strengthened	Adds obligations to an existing requirement or places greater emphasis on a specific area.
Alignment	Brings terminology into line with the HS, for example “this document” in place of “this International Standard”.

2.5 Limitations

The paper relies on the supplied training content and is not a verbatim reproduction of the standard. Clause numbering follows the references used in that content. Readers should verify precise wording, notes and examples against the published ISO 9001:2026 and ISO 9000:2026 before using them as audit criteria.

3. Nature of the Revision

3.1 An evolutionary revision

ISO 9001:2026 continues to adopt the Harmonized Structure (HS) – the standardized ten-clause framework with identical core text, common terms and definitions used by all ISO management system standards – with ISO 9001-specific content added. At first reading the 2026 edition appears similar to its predecessor. A detailed comparison confirms that there has been a deliberate effort to revise wording so that requirements are **clearer, easier to interpret and easier to translate**.

Many changes concern clarification and rewording rather than new obligations. Where obligations have been added they are concentrated in a handful of areas: quality culture and ethical behavior, the treatment of risks and opportunities, climate considerations, and planning and management of change.

3.2 Terminology standardization

Two terminology shifts recur throughout the standard:

- **“This document”** replaces “this International Standard”, consistent with HS drafting conventions.
- **Documented information.** The phrases “maintain documented information” and “retain documented information” are withdrawn. They are replaced by “documented information shall be available” (for information that describes or directs) and “documented information shall be available as evidence of” (for evidential information).

Annex A, subclause A.2, clarifies the meaning of several key words and phrases used in the standard – for example “consider”, “continual”, “applicable”, “appropriate”, “ensure”, “take into account” and “strategic direction” – and confirms that no order of precedence is implied by the sequence of items in bullet lists.

Practitioner insight: “consider” versus “determine”

The expert panel noted a recurring subtle shift from “consider” (give it some thought) to “determine” (assess seriously, examining permutations and options). Seemingly minor wording changes of this kind can raise the evidential bar and should be read closely during gap analysis.

3.3 What does not change

QMS auditors need to be familiar with the updates, but there is **no impact on audit processes**: audit methodology remains unchanged, implementation approaches remain valid and existing QMS structures remain acceptable. A frequent misunderstanding is that wholesale restructuring or new tools are required. In most cases they are not.

Common assumption	Position under ISO 9001:2026
Remove	Organisations need not remove a management representative role. The dedicated-representative requirement was deleted in 2015, but organisations may keep the role.
Eliminate	Existing manuals and documented procedures need not be withdrawn. Neither is required, but if effective and necessary they may remain, provided they align with the revised requirements.
Renumber or rename	Existing QMS documentation need not be renumbered or renamed to match revised clause references. The choice rests with the organisation.
Restructure	The management system need not follow the sequence of the standard, provided all requirements are met.
Refresh	Documented information need not be rewritten to use new terms. Terms such as “records” or “supplier” (rather than “documented information” or “external provider”) remain acceptable.
Adopt	No specific tools are mandated – for example PESTLE for context or SWOT for risks and opportunities. The organisation chooses appropriate methods.

Table 3.1 – Changes not required for existing QMSs (source: training content, Module 2).

3.4 Interpretation and implications

The changes introduced in the foundational clauses relate primarily to structure, wording and terminology. They improve clarity, support consistent interpretation and reduce reliance on external sources by embedding core terms in the standard itself. Importantly, they do **not alter the intent** of existing requirements.

Implications for QMS implementers	Implications for auditors
Avoid unnecessary restructuring of existing arrangements. Recognise that most changes are clarification, alignment and usability improvements. Understand that systems need not be redesigned, and terminology updates do not require operational change. Prioritise understanding the revised requirements, guided by Annex A.	Align audit expectations with the interpretive nature of the revision. No new auditing methods are required; existing approaches remain valid. Do not raise findings based on misinterpretation of requirements. Use Annex A to guide interpretation, not as audit criteria.

4. Clauses 0–3: Introduction, Scope, References and Terms

Clauses 0 to 3 establish the foundation of the standard. They are not requirements to be implemented, but they frame how requirements should be interpreted.

4.1 Clause 0 – Introduction

The Introduction continues to describe the benefits of a QMS, the seven quality management principles, the process approach, the Plan-Do-Check-Act (PDCA) cycle, risk-based thinking and the relationship with other management system standards.

Subclause	What changed	What it means
0.1 General	Figure 1 (single-process schematic) updated; references to risk-based thinking removed; explanatory text on “shall, should, may, can” removed.	Concepts relocated rather than lost; content streamlined to reduce duplication.
0.2 Quality management principles	“This international standard” becomes “this document”; “typical actions” simplified to “actions”.	No change to the seven principles or their application.
0.3.1 Process approach	Bullet b) now reads “processes in terms of risk, opportunity and added value”; “any process” becomes “any single process”; Figure 1 inputs box expanded to include “decisions”.	Approach unchanged in principle; wording refined. Risk and opportunity are now explicit in the process approach.
0.3.2 PDCA cycle	Explanation of PDCA stages now precedes Figure 2; circles replaced with hexagons; PDCA labels moved into the hexagons; stronger visual link between clauses and QMS scope.	No change to the concept; improved logical flow.
0.3.3 Risk-based thinking	Subclause deleted. Guidance relocated to Annex A (A.6.1.2); new opportunity-based thinking guidance in A.6.1.3.	Risk-based thinking still applies; its treatment is restructured, not removed.
0.4 Other management system standards	Framework now explicitly named as the HS; relationship extended to ISO/TS 9002 (to be replaced by ISO 9002, under development); Annex B deleted and references moved to Annex A.	Improved alignment and integration; no change to how the standard is applied.

4.2 Clause 1 – Scope

The substantive content is unchanged. ISO 9001:2026 remains applicable to any organisation that needs to demonstrate its ability to consistently provide products and services conforming to customer and applicable statutory and regulatory requirements, and that seeks to enhance customer

satisfaction through application of the system. The only amendment is the HS-driven replacement of “this international standard” by “this document”.

4.3 Clause 2 – Normative references

A normative reference is a document indispensable for the correct application of a standard. Clause 2 now cites **ISO 9000:2026, Quality management – Fundamentals and vocabulary**. ISO 9001:2026 must not be used in conjunction with ISO 9000:2015. Auditors and quality professionals should obtain a legitimate copy of ISO 9000:2026 and ensure it is the reference used in assessing conformity and maintaining the QMS.

4.4 Clause 3 – Terms and definitions

In 2015 the standard simply directed readers to ISO 9000. The 2026 edition instead **embeds** a combination of core management-system terms drawn from the HS and quality-specific terms from ISO 9000:2026, supplemented with notes or examples. This improves accessibility and consistency of interpretation.

Source of definition	Terms (clause 3 numbering as listed in the source)
Harmonized Structure (core terms)	3.1 organization; 3.3 top management; 3.5 policy; 3.6 objective; 3.9 competence; 3.10 documented information; 3.11 performance; 3.12 continual improvement; 3.13 effectiveness
HS / ISO 9000:2026 (with quality-specific notes)	3.2 interested party; 3.4 management system; 3.7 risk; 3.8 process; 3.14 requirement; 3.15 conformity; 3.16 nonconformity; 3.17 corrective action; 3.18 audit; 3.19 measurement; 3.20 monitoring
ISO 9000:2026 (quality management)	3.4.1 quality management system; 3.5.1 quality policy; 3.6.1 quality objective

Table 4.1 – Terms included directly in ISO 9001:2026 clause 3.

Further definitions can be searched through the ISO Online Browsing Platform (www.iso.org/obp) and IEC Electropedia (www.electropedia.org), which the standard references.

4.5 Key takeaways

- The revision is evolutionary: purpose and structure are unchanged.
- Changes in clauses 0–3 are clarification, alignment and usability improvements.
- Organisations should not over-interpret these clauses or redesign their QMS in response.

5. Annex A: Purpose, Status and Appropriate Use

5.1 A substantially expanded informative annex

Alongside the ten main clauses, ISO 9001 contains Annex A, which supports understanding of the requirements and helps prevent misinterpretation. In the 2015 edition the annex addressed only a handful of topics considered to need further clarification. The 2026 annex is **completely restructured** and now provides guidance for every clause from 4 to 10.

Annex A is intended for interpretation. It does not provide implementation guidance; for that, users should refer to **ISO/TS 9002, Guidelines for the application of ISO 9001**.

5.2 Principal updates

Annex A area	Update in ISO 9001:2026
A.2 Structure and terminology	Substantially revised; the 2015 comparison table with ISO 9001:2008 is removed.
A.3 Applicability	Wording clarified to focus on achieving intended QMS results. The requirement to justify and document requirements deemed outside QMS scope is unchanged (cf. clause 4.3).
A.4.2 Interested parties	Guidance refined to clarify identification of relevant interested parties, their needs and expectations, including ongoing consideration of changing requirements.
A.6.1.2 Risk-based thinking	Aligned more closely to the requirements of clause 6.1.2; receives the content relocated from 0.3.3.
A.6.1.3 Opportunity-based thinking	New guidance accompanying the new requirements for actions to address opportunities.
A.7.5 Documented information	Expanded: extent, format, evidential use and control, including external and obsolete information and protection of evidence.
A.8.4 Outsourcing	Confirms that organisations retain responsibility for conformity when processes are outsourced.
A.5.1 Leadership and commitment	Guidance on understanding, evaluating and improving quality culture; the seven quality management principles are described as an integral part of quality culture.

5.3 Structure: 2015 versus 2026

ISO 9001:2015 Annex A	ISO 9001:2026 Annex A
A.1 Structure and terminology A.2 Products and services (deleted) A.3 Interested parties A.4 Risk-based thinking A.5 Applicability A.6 Documented information A.7 Organizational knowledge A.8 Control of externally provided products and services	A.1 General; A.2 Structure and terminology; A.3 Applicability A.4 Context (A.4.1–A.4.4, incl. interested parties) A.5 Leadership (A.5.1–A.5.3) A.6 Planning (A.6.1.1 General, A.6.1.2 Risk-based thinking, A.6.1.3 Opportunity-based thinking, A.6.2 Planning of changes) A.7 Support (A.7.1.1–A.7.1.6, A.7.2–A.7.5) A.8 Operation (A.8.1–A.8.7) A.9 Performance evaluation (A.9.1–A.9.3) A.10 Improvement (A.10.1–A.10.2)

Table 5.1 – Annex A structure (summarised from the source comparison; relocated items noted in the source with “previously” references).

5.4 Removal of Annex B

The previous Annex B listed other ISO/TC 176 standards of interest, including ISO 9000, ISO 9004, the ISO 10000-series guidance documents and ISO 19011 (guidelines for auditing management systems). In 2026 the annex is removed and the relevant standards are referenced in the notes to each section of Annex A, with a reminder that the full list of TC 176 standards is available on the ISO/TC 176 website. This is a shift from a stand-alone reference list to guidance in context.

5.5 Interpretation and implications

Because Annex A is informative, organisations are **not required** to demonstrate conformity with its interpretations, and auditors must not treat it as requirements.

QMS implementers	Auditors
Use Annex A as a practical reference to interpret requirements in context. Map existing processes against the updated guidance and identify where intent is already met. Justify existing approaches rather than redesigning systems unnecessarily. Use it in transition planning – e.g. refining scope justification, reviewing interested parties, strengthening documented information controls.	Use Annex A to inform professional judgement: shape lines of enquiry and assess the organisation’s reasoning. Evaluate how concepts such as interested parties and risk-based thinking are understood and applied. Never treat Annex A as auditable criteria; assess conformity against the requirements, allowing flexibility in how they are met, while confirming approaches are logical, justified and effective.

6. Context and Leadership: Quality Culture and Ethical Behaviour

6.1 Focus of the change

The revision expands leadership responsibilities within the QMS. Leadership has always been central to ISO 9001, but the 2026 edition introduces an additional focus: top management must **promote quality culture and ethical behaviour**, and must promote opportunity-based thinking alongside risk-based thinking. Leadership is the most critical success factor in a QMS; without genuine commitment at every leadership level, the system will not realise its potential.

6.2 Clause 5.1.1 – Leadership and commitment

Clause 5.1.1 sets out the demonstrations expected of the individual or group directing and controlling the organisation at the highest level. The revision reorders and rewords the list and introduces four notable changes:

1. **New item i)** requires top management to promote quality culture and ethical behaviour. This responsibility cannot be delegated.
2. The 2015 item d) (“promoting the use of the process approach and risk-based thinking”) is split into **j)** promoting the process approach and **k)** promoting risk-based thinking and opportunity-based thinking.
3. The 2015 item i) “promoting improvement” becomes **g)** “promoting continual improvement”.
4. A **new NOTE 2** states that an organisation’s quality culture and ethical behaviour are reflected in its shared values, attitudes, practices and actions.

6.3 Definitions and the limits of evidence

ISO 9001 and the HS contain no definition of quality culture. ISO 9000:2026, a normative reference, defines it as a culture supporting the achievement of the quality policy and objectives and the delivery of products and services that meet the needs and expectations of customers and other interested parties. ISO 10010 uses an equivalent definition, and ISO 26000 defines ethical behaviour as behaviour in accordance with accepted principles of right or good conduct in the context of a particular situation and consistent with international norms of behaviour. Because ISO 10010 and ISO 26000 are **not** normative references, auditors should not apply their definitions unless the organisation has incorporated them into its QMS.

The wording of 5.1.1 i) is open to interpretation, so auditors should focus only on whether there is **evidence that top management actively promotes** quality culture and ethical behaviour. If so, the requirement is met. Weak culture or unethical conduct is more likely to surface as nonconformities elsewhere in the QMS than to be assessed directly against this clause. As the expert panel observed, the standard does not require a particular or even a “positive” culture – only that quality culture and ethical behaviour be promoted – and auditors should not prescribe a culture or judge whether they like it.

Expert perspective

Richard Green (CQP FCQI, CQI representative on ISO/TC 176) anticipated that few nonconformities will be raised directly against 5.1.1, “a bit like context” in 2015, but that a poor culture will generate poor results evident “further down the food chain”. Samantha Roberts (Global Accreditation Director, NQA) cautioned that certification bodies cannot pre-define what good looks like because every business differs.

6.4 Organisational context (clauses 4.1 and 4.2)

Clause 4 is not fundamentally changed, but it now more explicitly requires evolving external conditions – such as climate change – to be taken into account when understanding the organisation’s environment.

Clause	Update
4.1 Understanding the organization	The organisation must be aware of environmental issues, such as climate change, that may relate to its purpose. Internal and external issues remain those relevant to the QMS and strategic direction that could affect intended results. NOTE 2 adds the political environment as a potential external consideration; NOTE 3 adds strategic identifiers, resources and knowledge to internal context.
4.2 Interested parties	Minor rewording and a new item c). The organisation determines relevant interested-party requirements and which of them are to be addressed through the QMS (these become the relevant requirements), and must monitor and review information about interested parties and their requirements. A new note reminds users that relevant requirements may relate to climate change.
7.1.4 Environment for the operation of processes	The 2015 note (“a combination of human and physical factors”) is rewritten: a suitable environment can include a combination of factors that differ by the products and services provided, and some factors can be influenced by quality culture and ethical behaviour. The note is not a requirement.

6.5 Interpretation

The revision does not raise the overall level of leadership responsibility but adds a focus area. Expectations are deliberately **non-prescriptive**: the standard does not define what a quality culture should look like. Leadership effectiveness is demonstrated through visible engagement, consistent messaging and alignment between stated intent and actual practice, so that the QMS is integrated into how the organisation operates rather than existing as a stand-alone system.

6.6 Implications

QMS implementers	Auditors
• Leadership support: show that top management promotes opportunity-based alongside risk-based thinking, with support extended to all roles relevant to QMS effectiveness – through communications, decisions and visible backing. • Expectations: establish and consistently communicate quality culture, ethics and both modes of thinking via policy, objectives, leadership messages and daily management. • Interested parties: determine which requirements the QMS will address. Not new in substance – the 2026 text consolidates what 2015 spread over several subclauses. • Climate: evidence consideration in context analysis, risk and opportunity assessment and planning. • Culture and ethics: no model or framework is mandated; demonstrate promotion through behaviours, reinforcement of values and alignment of words and practice.	• Culture: seek evidence that leaders drive quality, using the ISO 9000:2026 definition; ethical strategies consistent with the seven principles (clause 0.2) are a reasonable lens, recognising that cultures differ. • Interested parties: confirm that the organisation has determined which requirements it addresses through the QMS and that they are reflected in processes; climate-related requirements only where relevant. • Climate: in most cases climate change will be a relevant issue; expect evidence in planning, particularly 6.1.1. • 7.1.4: the note is explanatory; assess conformity against the clause, not the note. • Method: sample leadership communications, observe behaviour in interviews, test consistency between statements and practice.

7. Awareness and Competence

7.1 Focus of the change

Clause 7 (Support) ensures the resources needed for an effective QMS are in place. The revision reinforces leadership intent by making sure expectations set at the top are **understood and applied across the organisation**. It does so by adding quality culture and ethical behaviour to the awareness requirements and by clarifying how evidence of competence is expressed.

7.2 Clause-level changes

Clause	ISO 9001:2015	ISO 9001:2026
7.1.3 Infrastructure	Note: “infrastructure can include:”	Note applies “for all types of work (e.g. on site, remote or a combination thereof)”, clarifying applicability to differing working locations.
7.2 Competence – item a)	“that affects the performance and effectiveness of the QMS”	“that affects its QMS performance”.
7.2 Competence – item d)	“retain appropriate documented information as evidence of competence” (a bullet)	Appropriate documented information “shall be available as evidence of competence”, now a separate paragraph rather than a bullet.
7.3 Awareness	Four items a)–d)	New item e) : the organisational quality culture and ethical behaviour. Links directly to 5.1.1 i).

7.3 Interpretation

The new awareness item ensures leadership’s promotion of quality culture and ethical behaviour is not left at the top: people doing work under the organisation’s control must be aware of the expectations established by leadership. Awareness of the quality policy, relevant objectives, individual contribution to QMS effectiveness (including the benefits of improved performance) and the implications of non-conformance continue to apply, with emphasis on **meaningful understanding rather than formal acknowledgement**.

In clause 7.2 the simplified wording stresses accessibility and usability of evidence and aligns with HS text. The mindset shifts as follows:

Old mindset	Reinforced mindset
“Do we have records?”	“Can we demonstrate competence?”
“Have we retained documented information?”	“Is it available and fit for purpose?”
“Is this documented?”	“Is there appropriate evidence?”



7.4 Implications

QMS implementers	Auditors
• Evidence of competence: keep appropriate evidence in a form accessible and suited to the role so that it can be produced when required. • Awareness: communicate culture and ethics expectations through leadership messaging and daily activities until individuals can describe them in the context of their own role.	• Awareness (7.3 e): seek objective evidence through discussion and observation that individuals can explain expectations relevant to their role; focus on how effectively top management's promotion reaches the organisation. • Competence evidence: verify that relevant evidence exists and can be accessed, not just that it has been "retained". • Raising findings: nonconformities can no longer be raised against 7.2 d) because the item no longer exists; lack of competence evidence is raised against 7.2.

8. Risk and Opportunity Planning

8.1 Focus of the change

Clause 6 is the “Plan” stage of PDCA. It draws on the determinations of clauses 4.1 and 4.2 to establish risks and opportunities, requires action to address them, and covers quality objectives and the planning of changes. It does not address planning of the processes that deliver conforming products and services; that remains in clause 8.1. The 2026 revision **separates determination from action** and **risk from opportunity**.

8.2 Restructured clause 6.1

Level	ISO 9001:2015	ISO 9001:2026
6.1.1	Untitled. Use outputs of 4.1 and 4.2 to determine risks and opportunities.	Determining risks and opportunities. Retains the 2015 text plus a list of items; a) and c) become a) and b); “desired effects” becomes “desirable effects”; “achieving continual improvement” becomes “achieving improvement”.
6.1.2	Untitled. Plan actions for risks and opportunities, integrate and evaluate effectiveness.	Actions to address risks. Substantially rewritten to focus solely on risk (see below).
6.1.3	Did not exist.	Actions to address opportunities. Entirely new (see below).

Clause 6.1.2 – Actions to address risks

- Organisations must **determine, analyse and evaluate** risks that can affect the QMS’s intended results.
- Actions must be **proportionate to the potential impact on the intended results of the QMS** – no longer limited to impact on conformity of products and services.
- A new Note 1 confirms that risks can include the ability to provide conforming products and services **during and after a disruption**; the 2015 note becomes Note 2.

Clause 6.1.3 – Actions to address opportunities

- Organisations must determine, analyse and evaluate opportunities that may better position them to achieve intended results.
- Actions must be planned, **integrated into the QMS** and evaluated for effectiveness.
- Actions must be **appropriate to the organisation’s context** and support achievement of intended results; a note gives examples.

The split is carried through to clause 9.3.2, where the 2015 input on effectiveness of actions to address risks and opportunities is divided into one item for risks and one for opportunities (and mirrored in 9.1.3 e) and f)).



8.3 Continuity of risk-based thinking

Deletion of clause 0.3.3 does not weaken risk-based thinking. Its explanatory content now lives in A.6.1.2, with parallel opportunity-based thinking guidance in A.6.1.3. The main body now concentrates on requirements; explanation sits in the annex. Moving this content has no implication for implementing or auditing a QMS.

8.4 Evidence expectations

Actions to address risks and opportunities should be demonstrably:

Attribute	What good evidence looks like
Determined	Risks and opportunities are identified from context (4.1) and interested-party requirements (4.2), then analysed and evaluated – not merely listed.
Proportionate	Level of action varies with significance rather than applying one uniform response. Risk actions are tied to impact on intended QMS results.
Integrated	Actions are embedded in operational workflows and QMS processes, not managed as a separate register.
Evaluated	The effectiveness of risk actions and of opportunity actions is evaluated separately and fed into data analysis (9.1.3) and management review (9.3.2).

8.5 Implications

QMS implementers	Auditors
• Show the chain from identified risk/opportunity through analysis and evaluation to planned action. • Vary the response by significance; document the rationale for proportionality. • Embed actions in process planning and operational workflows. • Treat the two separately even if addressed in the same process; demonstrate that opportunities are not an afterthought. • Update references: 0.3.3 is now Annex A; no implementation consequence.	• Judge the logic, not the tool: is there a clear relationship between risks, opportunities and actions? • Test proportionality by reviewing how risks were evaluated and why actions were chosen. • Confirm balance: planning evidence must cover opportunities as well as risk mitigation. • Do not penalise the relocation of risk-based thinking text.

Practitioner advice

The certification perspective is that risk analysis must not become a tick-box exercise. Link risks and opportunities to internal audit, management review and change planning, and use data the organisation already holds to support the analysis.

9. Planning and Managing Change

9.1 Focus of the change

Clause 6.3 ensures the QMS continues to function effectively while it changes. It remains in the “Plan” stage but now adds expectations on **communication, monitoring, evaluation and review** of change, linking planning with performance evaluation (clause 9) and management review.

9.2 Strengthened clause 6.3

Changes must be carried out in a controlled manner “to ensure they are implemented effectively and to achieve intended results”. The wording of existing items is supplemented and three items are added.

Item	ISO 9001:2015	ISO 9001:2026
b) integrity of the QMS	“the integrity of the QMS”	“the potential impact on the integrity of the QMS”
c) resources	“the availability of resources”	“the availability of resources and information ”
e) (new)	–	Communicating the changes
f) (new)	–	How effectiveness of the changes will be monitored and evaluated
g) (new)	–	How the results of making the changes will be reviewed

9.3 Related changes in clause 9

- **9.1.1 b)** now reads that methods for monitoring, measurement, analysis and evaluation are determined “as applicable, to ensure valid results”.
- **9.3.2** now states that management review “shall include” specified inputs (replacing “taking into consideration”), and a new input c) – **changes in the needs and expectations of interested parties relevant to the QMS** – precedes the trends list, which becomes item d).
- **7.4 Communication** is unchanged but is now explicitly engaged by change management.

9.4 Interpretation

Theme	Reading
Selectivity and appropriateness	“As applicable” confirms organisations choose monitoring and evaluation methods relevant to processes and context, not uniform coverage.
Validity	Methods must be capable of producing valid, reliable results – fit for purpose in showing whether changes achieved intended results.



Theme	Reading
Communication	Change communication is a deliberate, defined element of change control, not something assumed to occur.
Link between implementation and evaluation	Evaluation activities are directly tied to assessing effectiveness of planned change.
Management review	“Shall include” makes inputs mandatory in content; review is one mechanism for assessing change outcomes.

9.5 Implications

QMS implementers	Auditors
• Review existing monitoring methods for relevance to change effectiveness; do not add methods for their own sake. • Confirm that methods can yield valid results. • Apply existing communication processes to changes and make triggers explicit. • Check management review agendas include change outcomes and changes in interested-party expectations.	• Do not expect monitoring of every aspect of production or service provision. • Consider whether methods can produce valid results – a change of emphasis, not of audit practice. • Confirm communication of change was considered, using existing processes. • Check how change outcomes are monitored, evaluated and reviewed; be aware of the “shall include” management-review wording.

10. Operational Control, Documented Information and Outsourcing

10.1 Focus of the change

Clause 8 is the operational core of the QMS. The 2026 revision makes existing control arrangements **more explicit** – particularly communication, responsibilities and oversight of external providers – while leaving the underlying requirements essentially unchanged. Throughout the clause, “retain documented information” is replaced by “documented information shall be available as evidence of”.

10.2 Clause-by-clause analysis

Clause	Change	Nature
8.1 Operational planning and control	Items reordered (2015 b)2) becomes b); b)1) becomes c); c) becomes e)); e)1) and e)2) merged into generic text. No substantive change.	Rewording / structural
8.2.1 Customer communication	Item e) extended to providing information on contingency actions, including related disruptions to provision ; new note lists example channels.	Strengthened
8.2.3 Review of requirements	“specified” becomes “defined”; “as applicable” added to post-delivery activities; internet-sales note refers to “product or service information” and “websites and catalogues”; 8.2.3.2 evidence covers “new or changed requirements”.	Clarification
8.3.1 General	New note: design and development can include cycles of review, verification, validation and feedback.	Clarification
8.3.2–8.3.3 Planning, inputs	“customers and users” becomes “customers and other relevant interested parties ”; inputs “complete, unambiguous and adequate”.	Clarification
8.3.4 Controls	Minor rewording (“actions to address problems”); evidence “available”.	Rewording
8.3.5 Outputs	Now includes information on products and services essential for intended purpose and safe and proper use, in addition to characteristics.	Clarification / strengthened
8.3.6 Changes	“identify” becomes “ determine the impact of ” changes.	Strengthened
8.4.1 General	Minor wording; last paragraph split – criteria for evaluation, selection, monitoring and re-evaluation; and evidence of control.	Rewording

Clause	Change	Nature
8.4.3 Information for external providers	Providers must be told of requirements for communication with the organisation, its customers and other relevant interested parties; verification or validation may occur at the provider's premises or another location ; accountability remains with the organisation.	Clarification
8.5.1–8.5.6	Re-numbering of sub-items (8.5.1 a)); 8.5.2 restructured into items a)–d) with traceability evidence “available”; 8.5.3 and 8.5.6 evidence wording aligned.	Rewording
8.6 Release	Evidence wording aligned.	Alignment
8.7 Nonconforming outputs	8.7.2 reworked with items a)–d); intent unchanged.	Rewording

Table 10.1 – Summary of clause 8 changes (derived from the source change tables).

10.3 Interpretation

- **8.1** – restructuring only; no implementation change.
- **8.2** – clarified communication: where disruption to provision is likely, tell the customer; evidence must exist for changed requirements as well as new ones.
- **8.3** – the interested-party scope widens design inputs; outputs must include usage information; design changes are assessed for impact rather than merely logged.
- **8.4** – expectations on communication with external providers are explicit, verification location is flexible and accountability for conformity stays with the organisation.
- **8.5–8.7** – substantively unchanged; terminology and structure aligned.

10.4 Implications

QMS implementers	Auditors
• 8.2: add disruption-update triggers to customer communication processes; keep accessible records of requirements and subsequent changes. • 8.3: consider relevant interested parties in planning; define outputs to include technical characteristics and use information; document how design changes are evaluated before approval. • 8.4: specify communication expectations in supplier agreements; define where and how verification or validation will occur. • Documented information: review control of evidence in line with the expanded A.7.5 guidance.	• 8.2: confirm disruption communication is addressed and sample records for new and changed requirements (8.2.3.2). • 8.3: review inputs and outputs for interested-party consideration and for use information; check evidence of design change impact decisions. • 8.4: review supplier arrangements; do not insist on verification at the provider's premises; confirm accountability remains with the organisation. • 8.1, 8.5–8.7: no change in audit approach.

11. Performance Evaluation and Improvement

11.1 Focus of the change

Clause 9 is the “Check” stage and clause 10 the “Act” stage of PDCA. The revision strengthens performance oversight by clarifying the purpose of monitoring, making audit objectives explicit, and reordering improvement so that **continual improvement** leads and corrective action follows.

11.2 Clause 9.1 – Monitoring, measurement, analysis and evaluation

Clause	ISO 9001:2015	ISO 9001:2026
9.1.1 b)	Methods determined to ensure valid results	Methods determined “ as applicable ” to ensure valid results
9.1.2	Monitor customers’ perceptions of the degree to which needs and expectations have been fulfilled	Monitor customer satisfaction – distinct from needs being met, since a customer’s needs can be met while satisfaction is low
9.1.3 opening	“appropriate data and information”	“ relevant data and information”
9.1.3 b)	“the degree of customer satisfaction”	“customer satisfaction”: insight, not just a score
9.1.3 d)	“if planning has been effectively implemented”	“the effectiveness of planning implementation”
9.1.3 e)–f)	One item on effectiveness of actions on risks and opportunities	Split: e) risks; f) opportunities; later items renumbered g) and h)

Expert perspective on customer satisfaction

The CQI representative explained that the committee had argued for “customer experience” rather than satisfaction, without success. The 2026 emphasis is on analysis: a score such as a Net Promoter Score of 7 is meaningless until compared with the past, with targets and with drivers. Understand what drives satisfaction and feed that into planning.

11.3 Clause 9.2 – Internal audit

Subclauses are now titled: **9.2.1 General** and **9.2.2 Internal audit programme**. Beyond HS-aligned wording, the key change is that the organisation must **define audit objectives for each audit**, in addition to criteria and scope. Results must be reported to “relevant managers”. Evidence of the audit programme and results becomes “documented information shall be available as evidence of ...”, as a separate paragraph instead of the former item f).



11.4 Clause 9.3 – Management review

9.3.2 now states that the review “shall include” the listed inputs, adds changes in interested-party needs and expectations as an input, and splits the effectiveness of actions on risks and opportunities (see Sections 8 and 9).

11.5 Clause 10 – Improvement

Clause	ISO 9001:2015	ISO 9001:2026
10.1 Continual improvement	Was 10.3; second paragraph omitted monitoring and measurement and referred to “needs or opportunities”	Merges former 10.3 and parts of 10.1. The organisation considers results of monitoring, measurement, analysis and evaluation of data and information, and management review output, to determine opportunities . The 2015 opening sentence about customer requirements and satisfaction is deleted.
10.2 Nonconformity and corrective action	10.2.1 referred to complaints; item b) “reviewing and analysing”; 10.2.2 “retain documented information”	Complaints moved to a note (complaints can be a source of nonconformity); item b) “reviewing the nonconformity”; evidence “shall be available”.

11.6 Interpretation

- **Improvement before correction.** Placing continual improvement first reinforces improvement as ongoing rather than reactive.
- **Data-informed.** References to monitoring, measurement and data make explicit that improvement follows evaluated information.
- **Connected clause 9 and 10.** Satisfaction evaluation, audit objectives and review inputs combine to give improvement a defined evidential basis.

11.7 Implications

QMS implementers	Auditors
• No new improvement or corrective-action process is required; link existing improvement activities to monitoring, analysis, evaluation and management-review outputs. • Revisit satisfaction methods to understand drivers, not only levels. • Add audit objectives to each audit plan alongside criteria and scope. • Report audit results to relevant managers.	• Continue to expect improvement across the full PDCA cycle. • Verify that improvement actions are supported by performance-evaluation information, including satisfaction and audit results. • Confirm that each internal audit has defined objectives and that satisfaction is evaluated. • Interpret consistently with Annex A; support findings with objective evidence.

12. Consolidated Clause Change Register

The register below consolidates changes discussed in this paper. “Strengthened” changes are those most likely to require action. Use it as the master reference for transition planning.

Clause	Change (2015 → 2026)	Category	Priority
0.1–0.4	Figures updated; 0.3.3 deleted and relocated to Annex A; HS named; ISO/TS 9002 referenced	Clarification / alignment	Awareness
1–2	“this document”; normative reference ISO 9000:2026	Alignment	Awareness
3	Core HS and quality terms embedded	Clarification	Awareness
4.1	Climate change awareness; political environment (Note 2); strategic identifiers, resources, knowledge (Note 3)	Strengthened	Action
4.2	Determine requirements to be addressed through QMS; monitor and review; climate note	Clarification / strengthened	Action
5.1.1	New i): promote quality culture and ethical behaviour (non-delegable); j)/k) process approach and risk/opportunity thinking; g) continual improvement; new Note 2	Strengthened	High
6.1.1	Determining risks and opportunities (retitled)	Rewording	Action
6.1.2	Risks: determine, analyse, evaluate; proportionate to impact on intended results; disruption note	Strengthened	High
6.1.3	New: opportunities determined, analysed, evaluated, actioned, integrated, evaluated	New	High
6.3	Added communication, monitoring/evaluation and review of change; resources and information	Strengthened	High
7.1.3 / 7.1.4	Remote and on-site work; environment note linked to culture	Clarification	Awareness
7.2	Evidence “available”; item d) removed; wording simplified	Rewording	Action
7.3	New e): awareness of quality culture and ethical behaviour	Strengthened	High
8.1–8.7	Evidence terminology; 8.2.1 disruption information; 8.3 interested parties, outputs info, impact of change; 8.4 communication to providers, verification location, accountability	Clarification / strengthened	Action
9.1	“as applicable”; customer satisfaction; relevant data; e)/f) split	Clarification / strengthened	Action



Clause	Change (2015 → 2026)	Category	Priority
9.2	Titled subclauses; audit objectives; report to relevant managers	Strengthened	High
9.3.2	“shall include”; new input on interested-party needs; risk/opportunity split	Clarification	Action
10.1–10.2	Continual improvement leads; complaints to note; evidence “available”	Clarification	Awareness
Annex A / B	Annex A fully restructured; Annex B deleted	Clarification	Awareness

Table 12.1 – Consolidated register. Priority is a practitioner suggestion based on the evidential weight of each change, not an official classification.

13. Transition Strategy and Roadmap

13.1 Transition period and responsibilities

A **three-year transition period** is planned for organisations certified to ISO 9001:2015 that wish to gain certification to ISO 9001:2026. During this period organisations are responsible for becoming aware of the changes, reviewing their existing QMS, identifying gaps, examining options to close them, and verifying that the 2026 requirements are met and the system remains effective. Organisations should confirm final transition rules and dates with their certification body and accreditation body.

13.2 Five-phase roadmap

Phase	Key activities	Typical outputs	Owner
1. Awareness	Obtain ISO 9001:2026 and ISO 9000:2026; brief top management and process owners; confirm certification body arrangements	Briefing pack; transition plan	Quality manager; top management
2. Gap analysis	Compare QMS against Section 12 register; use Annex A to confirm where intent is already met	Gap register; impact assessment	Quality manager; auditors
3. Solution design	Prioritise strengthened areas: culture/ethics promotion, opportunity planning, change control, audit objectives, satisfaction analysis	Action plan; revised procedures where needed	Process owners
4. Implementation and verification	Implement actions; train; run internal audit against 2026 requirements; hold management review including new inputs	Internal audit report; management review minutes	All; top management
5. Certification	Prepare audit participants; schedule transition audit; sustain effectiveness	Transition certificate; improvement plan	Quality manager

13.3 Advice from the certification perspective

- **Start early.** Do not defer to the last week of the transition window.
- **Engage leadership** so that responsibility is shared across the business and not left to one function.



- **Focus on effectiveness.** Do not treat risk and opportunity analysis as a one-off tick-box; connect it to internal audit and management review.
- **Use existing data** to support risk, opportunity and change evaluation.
- **Prepare audit participants.** Certification body auditors will ask more questions about the new and strengthened areas.

13.4 Illustrative timeline

Period	Focus	Evidence milestone
Months 0–3	Awareness, leadership briefing, standards acquired	Approved transition plan
Months 3–9	Gap analysis, prioritisation	Signed-off gap register
Months 9–18	Implementation, training, culture communications	Updated processes; awareness evidence
Months 18–24	Internal audit and management review against 2026	Closed internal findings
Months 24–36	Certification transition audit (earlier is acceptable)	Certificate to ISO 9001:2026

Table 13.2 – Illustrative planning guide only; actual dates depend on the certification body and final transition rules.

14. Gap-Analysis Framework and Evidence Guide

The following framework helps organisations test readiness. It is organised by the strengthened themes and identifies the type of evidence an auditor is likely to seek. Evidence examples are illustrative; organisations choose their own methods.

Area (clause)	Self-assessment question	Example evidence
Quality culture and ethics (5.1.1 i)	Can top management show how it promotes quality culture and ethical behaviour?	Leadership communications, ethics statements, decisions that reinforce values, meeting minutes
Awareness (7.3 e)	Can people describe expectations in terms of their own role?	Interview responses, induction content, toolbox talks, observed behaviour
Climate (4.1, 4.2)	Has climate change been considered where relevant?	Context analysis, risk and opportunity register entries, interested-party analysis
Risks (6.1.2)	Are risks analysed, evaluated and addressed in proportion to impact on intended results?	Risk evaluation criteria, selected actions with rationale, disruption considerations
Opportunities (6.1.3)	Are opportunities analysed, evaluated and actioned separately?	Opportunity log, approved actions, effectiveness reviews
Change (6.3)	Are communication, monitoring/evaluation and review planned for each QMS change?	Change plans, communication records, post-implementation reviews
Competence (7.2)	Is competence evidence available, accessible and fit for purpose?	Competence matrices, training evidence retrievable on request
Design (8.3)	Are interested parties considered, outputs inclusive of use information, change impact determined?	Design inputs, output specifications, impact assessments
External providers (8.4)	Are communication and verification expectations defined and accountability retained?	Supplier agreements, verification plans
Customer satisfaction (9.1.2–9.1.3)	Do we understand drivers of satisfaction, not only scores?	Trend analysis, feedback themes, actions linked to findings
Internal audit (9.2.2)	Does every audit have objectives, criteria and scope?	Audit programme and plans
Management review (9.3.2)	Do inputs include interested-party changes and separate risk/opportunity effectiveness?	Review agendas and minutes



Area (clause)	Self-assessment question	Example evidence
Improvement (10.1)	Are improvement decisions based on analysed data and management-review outputs?	Improvement register linked to analysis

14.1 Applying a simple maturity scale

Level	Description
0 – Not addressed	No evidence the requirement is understood.
1 – Partial	Practices exist informally; evidence is inconsistent or not accessible.
2 – Defined	Requirement is met within processes; evidence is available.
3 – Effective	Outcomes are evaluated, results reviewed and improvements demonstrably follow.

Aim for at least level 2 on all requirements at transition audit, and level 3 for the strengthened areas of leadership, risk and opportunity, change and internal audit.

15. Audit Judgement and Common Misconceptions

15.1 Principles for reliable audit conclusions

The revision stresses consistency and defensibility in audit findings. Documented information “available as evidence” is a recurring expectation across clauses, so findings must rest on **objective audit evidence**, an accurate understanding of the requirement and a consistent interpretation of the standard.

- Changes must be correctly interpreted.
- No requirements may be imposed beyond those in the new edition or agreed by the organisation.
- Findings must be proportionate and justified; conclusions must remain defensible during transition.
- Annex A informs professional judgement but is never audit criteria.

15.2 Frequently encountered misconceptions

Misconception	Clarification
The QMS must be restructured to follow the new clause order.	No. Providing all requirements are met, structure is the organisation’s choice.
Records must be renamed “documented information”.	No. Existing terminology remains acceptable.
SWOT or PESTLE is now required.	No. No specific tool is mandated.
Annex A statements are requirements.	No. Annex A is informative and cannot be audited against.
Auditors must judge whether culture is “good”.	No. 5.1.1 i) requires evidence of promotion, not a prescribed culture.
Risk-based thinking has been removed.	No. Text moved to Annex A; requirements are in clause 6.1.2.
A nonconformity can still be raised against 7.2 d).	No. The item no longer exists; raise against 7.2.
Customer satisfaction and meeting needs are the same.	No. 9.1.2 requires monitoring satisfaction itself.
Outsourcing a process transfers responsibility.	No. Accountability for conformity remains with the organisation.

15.3 Illustrative review scenario

Consider an organisation preparing for transition. Its risk register lists risks only, its internal audit plans state criteria and scope, and its management review agenda carries “risks and opportunities” as one input. A reviewer would conclude that: (i) a separate opportunity analysis, evaluation and action trail is needed (6.1.3); (ii) audit plans need objectives (9.2.2); (iii) the management review agenda should split the effectiveness of actions on risks and on opportunities and add changes in interested-party needs (9.3.2); and (iv) the change procedure should address communication, monitoring and review (6.3). None of these requires a redesign of the QMS – each is an incremental amendment to existing documented processes.

16. Conclusions

ISO 9001:2026 is best characterised as a **limited technical revision**. It preserves the HS structure, the process approach and PDCA, and it sharpens the language through which requirements are expressed. The additions are targeted:

5. Top management must promote quality culture and ethical behaviour, and people must be aware of them.
6. Risks and opportunities are separated and must be analysed and evaluated; risk actions are proportionate and opportunity actions appropriate to context.
7. Management of change requires communication, evaluation of effectiveness and review of results.
8. Climate considerations are embedded in context and interested-party requirements.
9. Internal audits have objectives; customer satisfaction is monitored as such; improvement is data-informed.
10. Evidence terminology shifts to “available as evidence of”; Annex A becomes a comprehensive interpretive aid but not audit criteria.

For organisations, the most valuable response is neither alarm nor complacency. A structured gap analysis, early leadership engagement and a focus on effectiveness will let most mature QMSs transition with modest adjustment, and will convert the revision into real improvement in quality performance.

Closing perspective

The standard now asks not only whether the system exists, but whether leaders shape the culture it operates in, whether risk and opportunity are genuinely weighed, and whether change achieves what it intended.

References

- [1] ISO 9001:2026, Quality management systems – Requirements (sixth edition). International Organization for Standardization.
- [2] ISO 9000:2026, Quality management – Fundamentals and vocabulary. International Organization for Standardization.
- [3] ISO 9001:2015/Amd 1:2024, Quality management systems – Requirements – Amendment 1: Climate action changes.
- [4] ISO/TS 9002, Quality management systems – Guidelines for the application of ISO 9001 (to be replaced by ISO 9002, under development, per source material).
- [5] ISO 9004, Quality management – Quality of an organization – Guidance to achieve sustained success.
- [6] ISO 10010, Quality management – Guidance for quality culture (definition of quality culture cited in the source material).
- [7] ISO 19011, Guidelines for auditing management systems.
- [8] ISO 26000, Guidance on social responsibility (definition of ethical behaviour cited in the source material).
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- [10] ISO/TC 176 (Quality management and quality assurance) committee page:
<https://www.iso.org/committee/53882.html>.
- [11] ISO Online Browsing Platform: www.iso.org/obp; IEC Electropedia: www.electropedia.org.
- [12] Quality Live 2026 panel discussion on the ISO 9001:2026 revision (R. Green, CQP FCQI; S. Roberts, NQA; N. O'Doherty), as reproduced in the supplied training content.
- [13] Supplied training content, "IRCA New Version Training Content", Modules 1–10 (uploaded file).

Appendix A – Glossary of Key Terms

Term	Meaning as used in this paper
Annex A	Informative annex of ISO 9001:2026 providing interpretive guidance for clauses 4–10; not auditable criteria.
Documented information “available as evidence of”	HS phrase replacing “retain documented information”; emphasises accessibility and fitness for purpose of evidence.
Ethical behaviour	Behaviour consistent with accepted principles of right or good conduct in context and with international norms (ISO 26000 definition; not normative for ISO 9001).
Harmonized Structure (HS)	Standardised ten-clause framework, core text and terms for all ISO management system standards.
Opportunity-based thinking	Determining, analysing and evaluating opportunities to better position the organisation to achieve intended results (6.1.3, A.6.1.3).
PDCA	Plan-Do-Check-Act cycle: clause 6 (Plan), 7–8 (Do), 9 (Check), 10 (Act) with 4–5 as context and leadership.
Quality culture	Culture supporting achievement of the quality policy and objectives and delivery of products and services that meet customer and other interested-party needs (ISO 9000:2026).
Risk-based thinking	Applying risk awareness in determining, analysing, evaluating and addressing risks to intended QMS results (6.1.2, A.6.1.2).
Top management	Person or group who directs and controls the organisation at the highest level.

end