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UNDERSTANDING
THE TRANSITION TO

ISO 9001:2026

What Has Changed from ISO 9001:2015?

A Practical Guide for Certified Organizations

Clause-by-clause changes, implementation implications and audit-readiness guidance



PRACTICAL GUIDANCE

KEY CHANGES

IMPLEMENTATION IMPLICATIONS

AUDIT-READINESS SUPPORT

PREPARED BY WECERT

A client-focused white paper designed to explain the transition from ISO 9001:2015 to ISO 9001:2026 in practical management-system terms.

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Purpose of This Guidance

A reader-friendly transition paper for management, quality professionals, internal auditors and consultants.

This guidance explains the key changes introduced in ISO 9001:2026 compared with ISO 9001:2015, from Clause 4.1 through Clause 10. It focuses on what changed, why the change matters, how organizations can respond, and what evidence auditors are likely to examine.

HOW TO USE THIS GUIDE

Each clause section follows the same reading path: Overview of the Change → What Changes → Practical Application → Common Challenges → Audit Implication → Key Takeaway.

Headline Changes

01 Climate change is explicitly considered within organizational context.

02 Relevant interested-party requirements must be filtered to determine which will be addressed through the QMS.

03 Quality culture and ethical behaviour become explicit leadership and awareness themes.

04 Risks and opportunities are treated through clearer and more distinct pathways.

05 Planning of changes is strengthened with communication, monitoring, evaluation and review.

06 Organizational knowledge is expected to be retained, applied and shared.

07 Management review is more explicitly connected to interested parties, risks and opportunities.

08 Clause 10 is restructured around continual improvement and corrective action.

General Changes and Terminology Updates

ISO 9001:2026 retains the familiar management-system architecture. The revision is best understood as a targeted modernization nather than a complete redesign. Several clauses are editorially refined, while selected areas are made more explicit, auditable and operationally useful.

Three types of change used in this guide

NEW / STRENGTHENED REQUIREMENT

Likely to require new evidence, a revised process or a more explicit management-system practice.

CLARIFICATION / MODERNIZATION

Makes the intended meaning clearer or updates the requirement for contemporary ways of working.

EDITORIAL / STRUCTURAL

Changes wording, arrangement or numbering without materially changing the obligation.

IMPORTANT

A mature ISO 9001:2015 system may already satisfy some 2026 expectations in practice. Transition planning should therefore begin with evidence-based gap analysis, not automatic document rewriting.

Context and Why the Change?

ISO 9001:2026 is not a complete redesign, but a targeted modernization of ISO 9001:2015 to reflect current and future business realities.

The changes aim to strengthen clarity, address emerging needs, and improve the standard's usability while maintaining the well-established management-system structure and core requirements.

01 | **Evolving Business Environment**
Digitalization, sustainability, changing expectations and increasing complexity require clearer guidance.

02 | **Greater Clarity and Usability**
Refinements make the requirements easier to understand and apply across different types and sizes of organizations.

03 | **Continuity with ISO 9001:2015**
The familiar 10-clause structure is retained, ensuring a manageable transition for certified organizations.

> *The revision builds on what works in ISO 9001:2015, while introducing focused updates to keep the standard relevant, clear and fit for the future.*



Scope of Changes in ISO 9001:2026

The changes in ISO 9001:2026 are targeted and focused. Most clauses retain their familiar intent, with revisions introduced to enhance clarity, address current needs and improve practical application.

01 | **Refined Requirements**
Several clauses have been updated to provide clearer wording, more explicit expectations and better alignment with current management practices.

02 | **New and Strengthened Considerations**
Additional guidance and expectations are introduced in areas such as organizational context, interested parties, risk and opportunity, knowledge management, and leadership and culture.

03 | **Improved Terminology and Definitions**
Key terms have been clarified or updated to reduce ambiguity and support consistent interpretation across different sectors and regions.

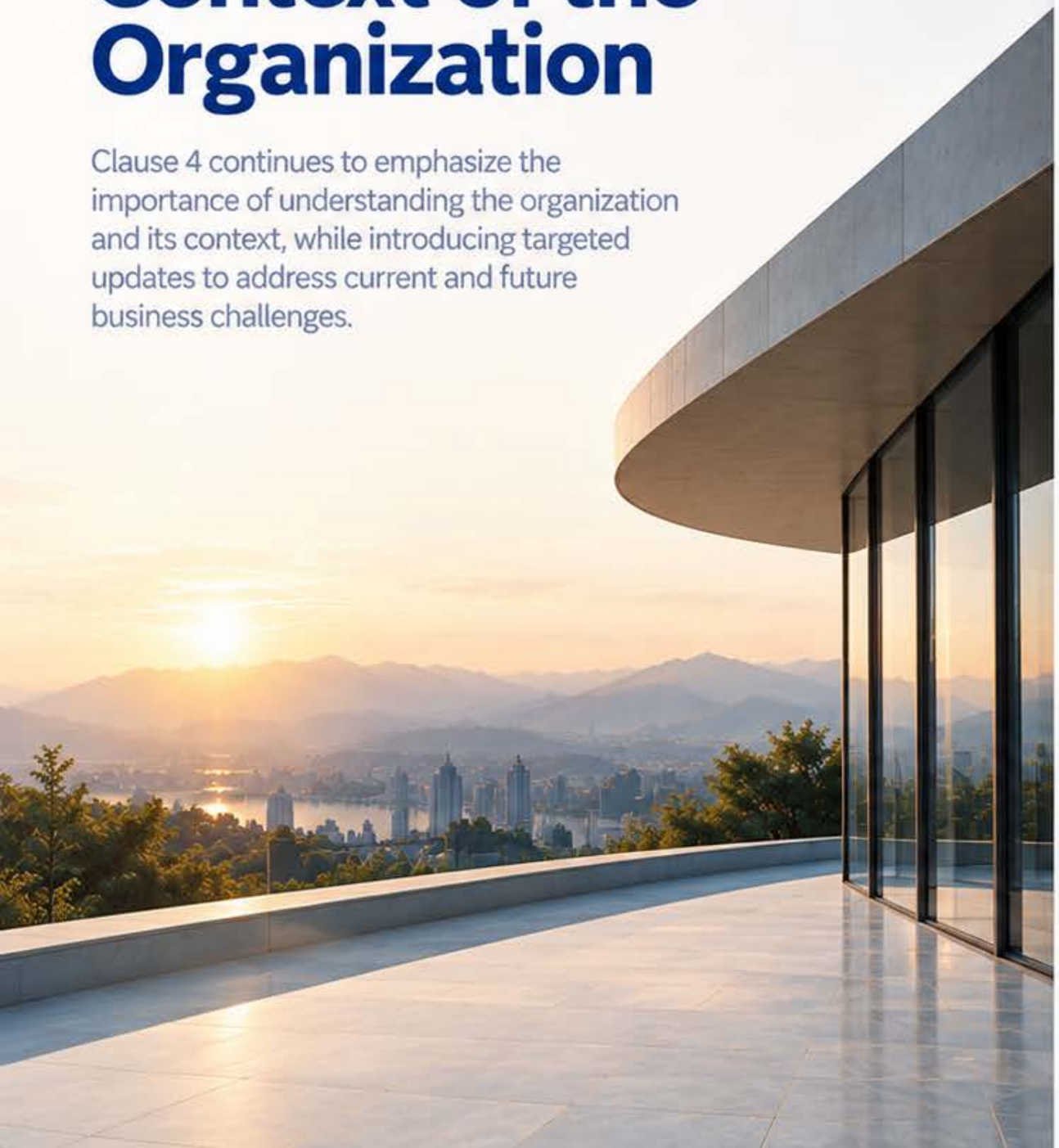
04 | **Enhanced Practical Guidance**
Selected requirements are expanded with more explicit guidance to help organizations implement and maintain effective quality management systems.

05 | **Alignment with Broader Trends**
Greater consideration is given to topics such as digitalization, sustainability, resilience, organizational knowledge and responsible business practices.

Clause 4

Context of the Organization

Clause 4 continues to emphasize the importance of understanding the organization and its context, while introducing targeted updates to address current and future business challenges.



Key changes in Clause 4
and their practical implications

4.1 Understanding the organization and its context

The 2026 edition places stronger emphasis on considering a wider range of internal and external factors, including climate change, technological developments and market changes.

Practical implications

- Consider new factors such as climate change and emerging technologies.
- Use structured tools to review and update the analysis more regularly.

4.2 Needs and expectations of interested parties

More explicit expectations to identify and monitor the needs and expectations of a broader range of interested parties, with increased focus on sustainability-related requirements where relevant.

Practical implications

- Identify a broader range of interested parties (e.g. regulators, communities, supply chain partners).
- Determine which requirements are relevant and how they are monitored over time.

4.3 Determining the scope of the QMS

Clearer guidance on how to determine and maintain the scope, taking into account internal and external issues, interested parties and the organization's strategic direction.

Practical implications

- Ensure the scope reflects current and future business plans.
- Provide clear justification for any exclusions, supported by objective evidence.

4.4 Quality management system and its processes

Minor updates to align terminology and clarify expectations for establishing, implementing, maintaining and continually improving processes.

Practical implications

- Ensure process interactions are defined and aligned with the organization's context and risks.
- Use a process-based approach that supports flexibility and modern ways of working.

Clause 5

Leadership

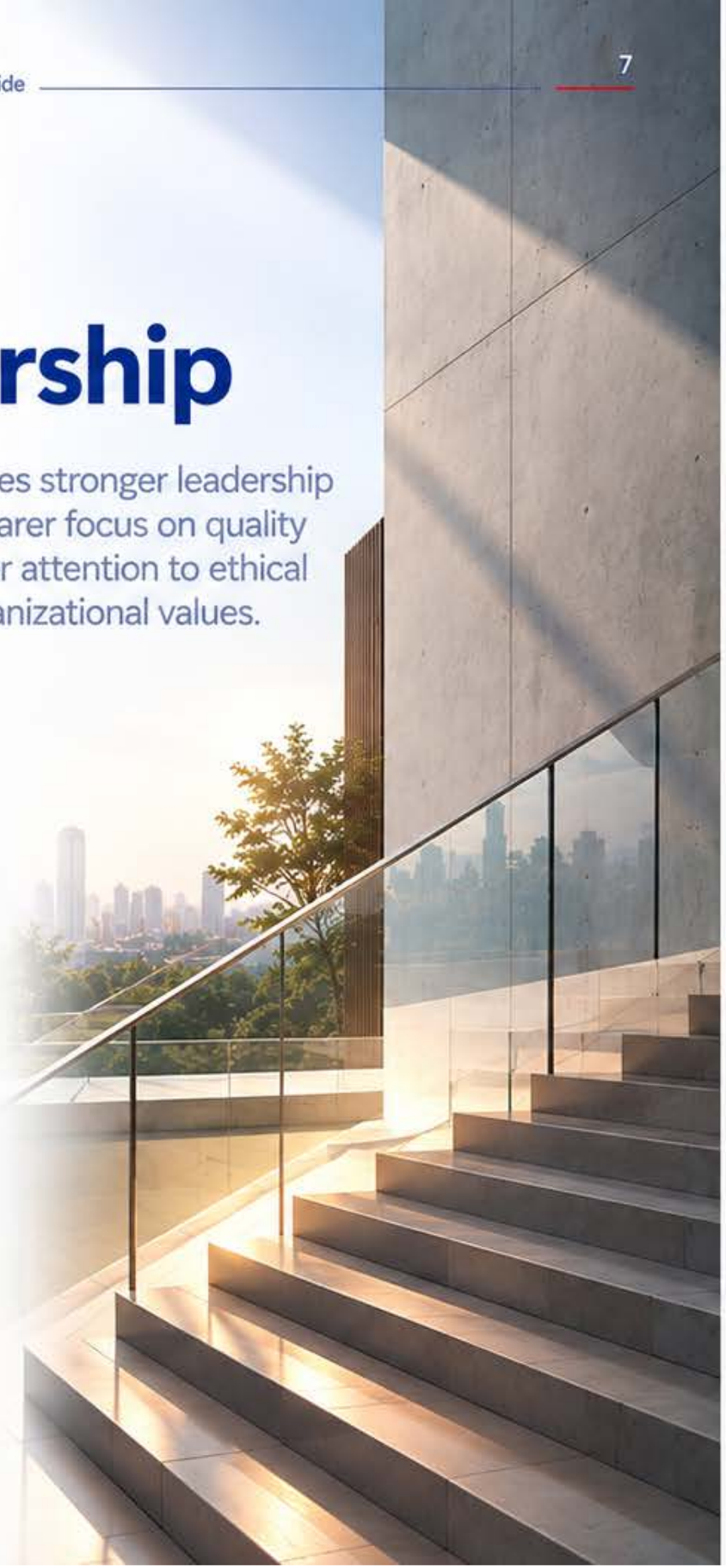
Clause 5 emphasizes stronger leadership commitment, a clearer focus on quality culture, and greater attention to ethical behaviour and organizational values.

5.1
Leadership and commitment

5.2
Policy

5.3
Organizational roles, responsibilities and authorities

5.4
Quality culture and ethical behaviour



Key changes in Clause 5
and their practical implications

5.1 Leadership and commitment

What has changed?
Stronger emphasis on visible and consistent leadership commitment, integration with the strategic direction, and a clearer link to quality culture and ethical behaviour.

Practical implications
- Demonstrate leadership through actions, not only statements.
- Integrate quality into strategy, culture and values.

5.2 Policy

What has changed?
More explicit requirements for the quality policy, including alignment with the organization's context, strategic direction and relevant stakeholder expectations.

Practical implications
- Ensure the policy reflects purpose and strategic direction.
- Communicate, understand and apply the policy at all relevant levels.

5.3 Organizational roles, responsibilities and authorities

What has changed?
Clarifications to ensure clear accountability, appropriate authority and effective communication of roles and responsibilities across the organization.

Practical implications
- Review and update roles and responsibilities.
- Ensure authorities are aligned with decision-making and risk management needs.

5.4 Quality culture and ethical behaviour

What has changed?
Greater emphasis on building a positive quality culture, promoting ethical behaviour and demonstrating integrity, trust and accountability in decision-making.

Practical implications
- Promote a culture that supports quality, transparency and ethical behaviour.
- Address behaviours that could undermine trust, integrity or conformity.



Key takeaway

Clause 5 in ISO 9001:2026 strengthens the role of leadership in shaping quality culture and ensuring that quality management is embedded in the organization's strategy, values and daily operations.

Clause 6

Planning

Clause 6 strengthens the focus on a risk-based and opportunity-based approach, with greater consideration of change, long-term resilience and alignment with strategic objectives.

6.1
Actions to address risks and opportunities

6.2
Quality objectives and planning to achieve them

6.3
Planning of changes

6.4
Control of changes

Key changes in Clause 6
and their practical implications

6.1 Actions to address risks and opportunities



What has changed?

Stronger emphasis on a broader range of risks and opportunities, including long-term factors such as climate change, technological developments and market disruptions, and clearer links with strategic direction.

Practical implications

- Consider a wider range of internal and external risks and opportunities, including long-term and emerging factors.
- Ensure that actions are proportionate, effective and integrated into business planning.

6.2 Quality objectives and planning to achieve them



What has changed?

Greater clarity on setting measurable quality objectives that are aligned with the organization's context, strategic direction and relevant interested party requirements.

Practical implications

- Ensure objectives are timebound, measurable and aligned with strategic priorities.
- Monitor progress regularly and take action where deviations occur.

6.3 Planning of changes



What has changed?

More explicit requirements for planning changes, including consideration of risks and opportunities, resource needs, and the potential impact on the quality management system and its objectives.

Practical implications

- Use a structured approach for planning and implementing changes.
- Assess potential impacts on processes, resources, objectives and interested parties.

6.4 Control of changes



What has changed?

Clearer guidance on controlling changes to ensure intended outcomes, minimize unwanted effects and maintain the integrity of the quality management system.

Practical implications

- Define and implement controls for changes.
- Review and verify that changes have achieved the intended outcomes without negative impacts.

Key takeaway

Clause 6 in ISO 9001:2026 provides clearer and more explicit requirements for managing risks, opportunities and changes, helping organizations to be more proactive, resilient and aligned with their strategic direction.



Clause 7

Support

Clause 7 places greater emphasis on the resources, competence, awareness, communication and organizational knowledge needed to support an effective quality management system.

Key changes in Clause 7
and their practical implications

7.1 Resources

What has changed?

Broader and clearer requirements for determining and providing the resources needed for the QMS, including people, infrastructure, process environment, monitoring and measurement resources, and organizational knowledge.

Practical implications

- Review and confirm adequacy of all resources against current and future needs.
- Ensure alignment between resource provision and strategic direction and customer requirements.

7.2 Competence

What has changed?

Greater emphasis on ensuring that people are competent on the basis of education, training, experience or other appropriate actions, and that competence is evaluated and maintained.

Practical implications

- Define competence requirements for relevant roles.
- Plan and implement training and other actions, and evaluate effectiveness.

7.3 Awareness

What has changed?

Clearer requirements for awareness of the quality policy, relevant objectives, individual contribution to the effectiveness of the QMS, and the implications of not conforming to requirements.

Practical implications

- Ensure people understand their roles and how their work contributes to quality.
- Communicate the implications of nonconformity in a practical and relevant way.

7.4 Communication

What has changed?

More explicit requirements for internal and external communication, including what to communicate, when, with whom and how.

Practical implications

- Define a structured communication process for internal and external interested parties.
- Ensure communication is timely, relevant, accurate and effective.

7.5 Documented information

What has changed?

Maintains the concept of documented information with greater flexibility, focusing on what is necessary for the effectiveness of the QMS and for demonstrated conformity.

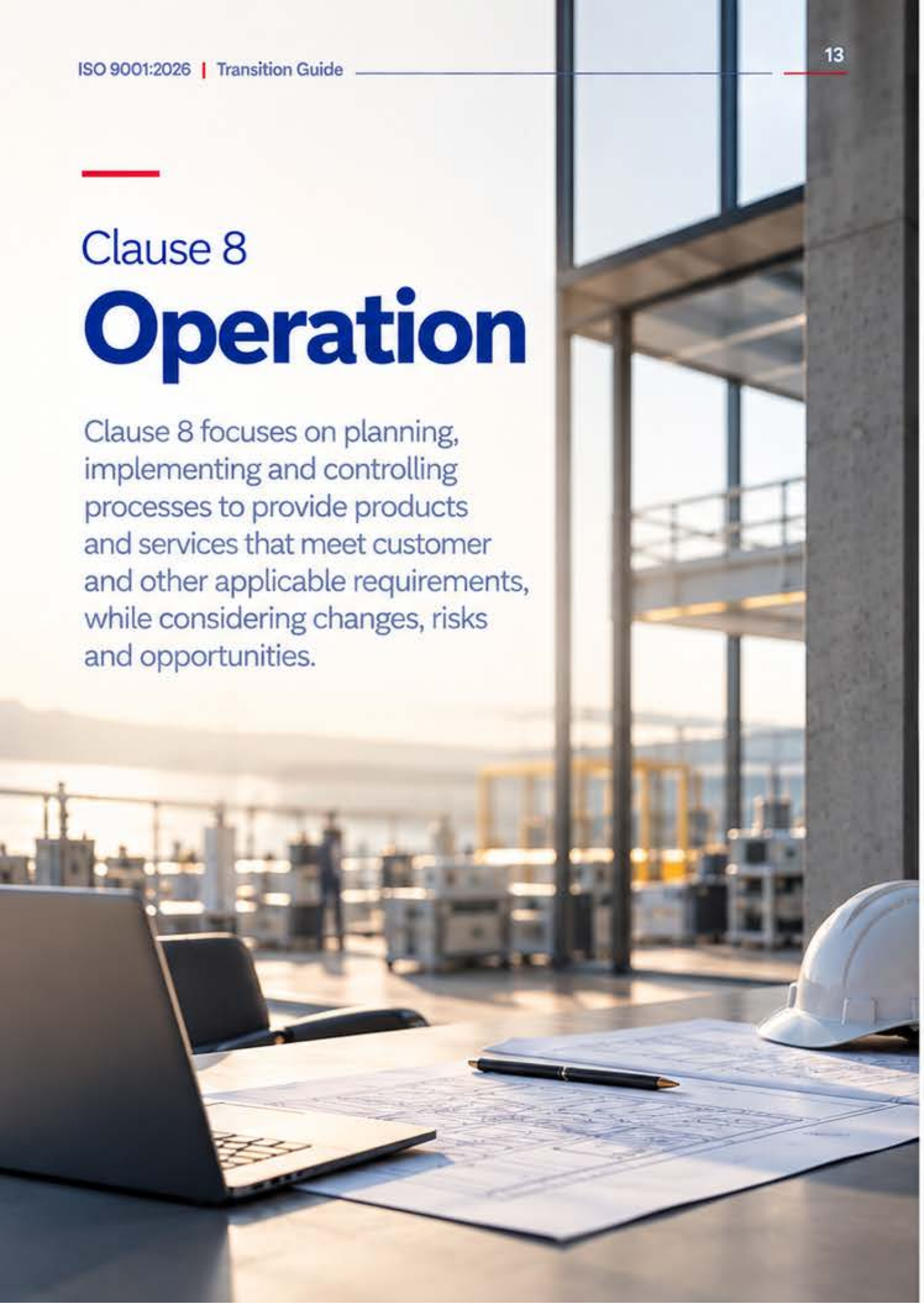
Practical implications

- Determine and maintain only the documented information needed for the QMS.
- Ensure information is controlled, accessible and protected appropriately.

Clause 8

Operation

Clause 8 focuses on planning, implementing and controlling processes to provide products and services that meet customer and other applicable requirements, while considering changes, risks and opportunities.



Key changes in Clause 8 (1/2) and their practical implications

8.1 Operational planning and control

What has changed?

Stronger emphasis on a planned and structured approach for operating processes, with clearer consideration of risks, opportunities, changes and the need to achieve intended outcomes more consistently.

Practical implications

- Ensure operational controls are risk-based and aligned with the organization's context and strategic direction.
- Define and maintain clear criteria for operation, monitoring, measurement and acceptance.
- Address changes and unintended consequences in operational planning.

8.2 Requirements for products and services

What has changed?

More explicit requirements for understanding and determining customer and other relevant requirements, with a stronger focus on product and service requirements before commitment and clearer links with customer communication.

Practical implications

- Review and confirm customer, statutory and regulatory, and internal requirements before acceptance.
- Ensure changes to requirements are identified and managed.
- Maintain clear records of reviews, confirmation and customer communication.



Clause 8
Operation

Clause 8 focuses on planning, implementing and controlling processes to provide products and services that meet customer and other applicable requirements, while considering changes, risks and opportunities.

8.3
Design and development of products and services

What has changed?

Greater clarity on planning, controlling and reviewing design and development activities, including stronger emphasis on inputs, verification, validation and control of changes.

Practical implications

- Ensure design and development processes are planned and controlled effectively.
- Define and review inputs, outputs, verification and validation criteria.
- Manage changes to design and development and retain appropriate records.

8.4
Control of externally provided processes, products and services

What has changed?

Clearer requirements for the selection, evaluation, monitoring and re-evaluation of external providers, with stronger consideration of their impact on conformity and customer satisfaction.

Practical implications

- Define and apply criteria for the selection, evaluation and re-evaluation of external providers.
- Monitor the performance of external providers.
- Ensure externally provided processes, products and services meet defined requirements.

8.5
Production and service provision

What has changed?

More explicit requirements for the control of production and service provision, including identification and traceability where necessary, control of property, preservation, post-delivery activities, and consideration of unintended changes.

Practical implications

- Ensure production and service provision are controlled under defined conditions.
- Apply identification and traceability where necessary.
- Manage customer or external property, preservation and delivery activities.
- Address post-delivery activities and prevent unintended changes.

8.6
Release of products and services

What has changed?

Stronger emphasis on ensuring that products and services are released only when they meet defined requirements, with clearer evidence of conformity and links to monitoring and measurement.

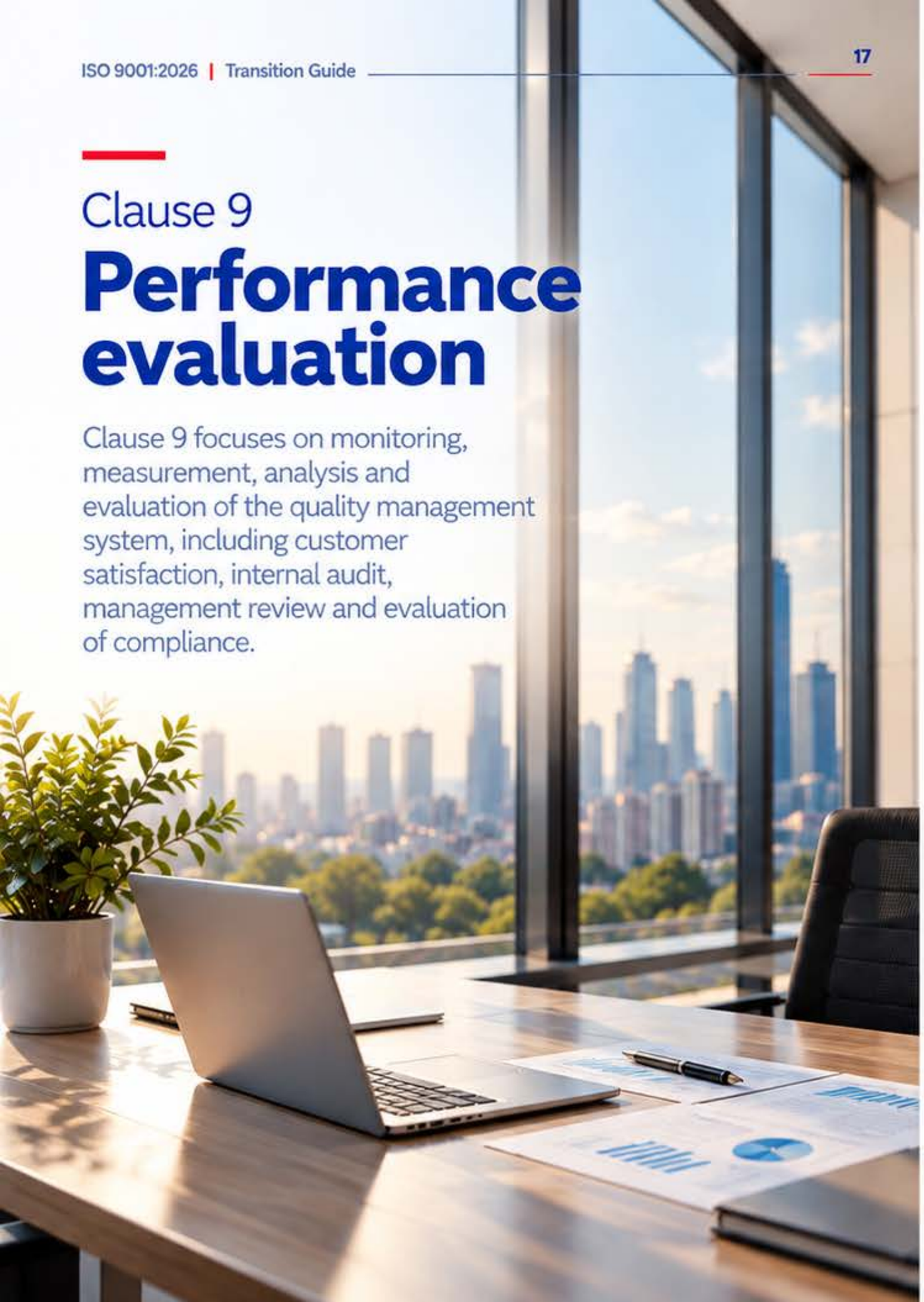
Practical implications

- Define and apply criteria for release based on requirements.
- Ensure appropriate records demonstrate conformity.
- Prevent the unintended release of nonconforming products and services.

Clause 9

Performance evaluation

Clause 9 focuses on monitoring, measurement, analysis and evaluation of the quality management system, including customer satisfaction, internal audit, management review and evaluation of compliance.



Key changes in Clause 9
and their practical implications

9.1 Monitoring, measurement, analysis and evaluation

What has changed?

More explicit requirements for determining what needs to be monitored and measured, how data is analyzed and evaluated, and greater emphasis on using this information for decision-making and continual improvement.

Practical implications

- Define and implement clear monitoring and measurement methods.
- Analyze and evaluate data to identify trends, opportunities and risks.
- Use performance information for decision-making and improvement.

9.2 Internal audit

What has changed?

Clearer focus on planning and conducting internal audits, considering the importance of processes, changes and results of previous audits, and ensuring auditor competence and objectivity.

Practical implications

- Plan internal audits based on the importance of processes and changes.
- Ensure auditor competence and independence.
- Take appropriate actions on audit findings and monitor their effectiveness.

9.3 Management review

What has changed?

More emphasis on reviewing the effectiveness of the quality management system, considering changes in context, risks and opportunities, and ensuring that decisions and actions are documented and followed up.

Practical implications

- Review the performance, adequacy and effectiveness of the QMS.
- Consider changes in internal and external issues, risks and opportunities.
- Ensure management review decisions and actions are recorded and tracked to completion.

Clause 10

Improvement

Clause 10 focuses on continual improvement of the quality management system, including management of nonconformities and corrective action, and the use of analysis and evaluation results to identify opportunities and drive enhancement.



Key changes in Clause 10
and their practical implications

10.1 General

What has changed?

Stronger emphasis on using analysis and evaluation results from across the QMS, including customer feedback, audits, process performance and risk inputs, to drive continual improvement in a more integrated and systematic way.

Practical implications

- Establish a more integrated approach to identifying and prioritizing improvement opportunities.
- Use a broader range of data sources, including customer feedback, audit results, process performance and risks.
- Ensure improvement actions are linked to measurable benefits.

10.2 Nonconformity and corrective action

What has changed?

Clearer and more structured requirements for managing nonconformities and taking corrective action, with greater emphasis on root cause analysis, effectiveness evaluation and preventing recurrence.

Practical implications

- Ensure nonconformities are controlled, documented and evaluated for subsequent action.
- Determine and address root causes, not only immediate symptoms.
- Evaluate the effectiveness of corrective actions.
- Prevent recurrence through systematic follow-up and knowledge sharing.

10.3 Continual improvement

What has changed?

Greater emphasis on continual improvement as an ongoing and proactive activity, using opportunities identified from analysis and evaluation, risk management, customer feedback and innovation, and considering the broader context and interested parties' needs.

Practical implications

- Actively identify and manage opportunities for improvement across the QMS.
- Use data and risk/opportunity analysis to drive improvement initiatives.
- Promote innovation and sharing of good practices.
- Ensure continual improvement is embedded in relevant processes and reviewed for effectiveness.

Transition **Roadmap**

A structured and phased approach to help organizations plan, implement and successfully transition from ISO 9001:2015 to ISO 9001:2026, ensuring continuous improvement and business value throughout the transition journey.



01 | Preparation (2025)

- Understand the key changes in ISO 9001:2026
- Assess the impact on your organization
- Determine transition approach and resources
- Raise awareness and build initial competence

02 | Implementation (2026)

- Update processes, documented information and records
- Implement changes and integrate them into the QMS
- Provide training and build competence
- Monitor implementation progress

03 | Evaluation (2027)

- Evaluate the effectiveness of implemented changes
- Conduct internal audits against ISO 9001:2026 requirements
- Address identified gaps and opportunities for improvement
- Prepare for certification audit

04 | Completion (2028)

- Complete all transition activities
- Ensure full compliance with ISO 9001:2026
- Undergo certification audit against ISO 9001:2026
- Leverage the new standard for continued improvement and business value

Q1–Q2 2025
Gap analysis and transition plan

Q3–Q4 2025
Awareness and initial training

Q1–Q2 2026
Implement changes and update documentation

Q3–Q4 2026
Internal audits and management review

Q1–Q2 2027
Address gaps and finalize implementation

Q3–Q4 2027
Certification audit (preparation and execution)

2028
Transition complete and continued improvement

Implementation Guidance and Audit Readiness

A practical approach to support organizations in planning and implementing the transition to ISO 9001:2026, and preparing for a successful certification audit.



Key success factors

- Top management commitment
- Integration with existing processes
- Clear documentation and evidence
- Competent and engaged people

Practical implementation steps

A structured approach to implement the key changes and prepare for audit.

01 Understand the changes

- Review the requirements of ISO 9001:2026.
- Identify the key changes relevant to your organization.
- Assess the impact on processes, documentation and resources.

02 Plan implementation

- Define the transition scope, responsibilities and timeline.
- Develop a detailed implementation plan.
- Identify training needs and allocate resources.

03 Implement and document

- Update processes, procedures and documented information.
- Implement necessary changes across the QMS.
- Maintain records of implementation activities.

04 Evaluate and prepare for audit

- Conduct internal audits against ISO 9001:2026 requirements.
- Review management review inputs and outputs.
- Address any identified gaps or nonconformities.
- Ensure audit readiness and confirm effectiveness of implemented changes.

Audit preparation focus areas

Ensure that the following areas are ready for certification audit.

Updated documentation
Procedures, records and evidence aligned with ISO 9001:2026

Implemented processes
Changes effectively implemented and operating

Competence and awareness
People trained and aware of new requirements

Internal audit and management review
Completed and demonstrating effectiveness

Executive Transition Checklist

A concise checklist for top management to monitor progress, ensure effective implementation of ISO 9001:2026 requirements, and prepare for a successful transition and certification audit.



Executive Transition Checklist

Key actions for management to ensure a smooth transition to ISO 9001:2026.

01 Context and planning

- [ ] Understand the key changes in ISO 9001:2026 and their impact.
- [ ] Review and update the context analysis and interested parties.
- [ ] Define responsibilities, timeline and required resources.

02 QMS alignment

- [ ] Review and update the QMS scope and documented information.
- [ ] Align processes with the new or revised requirements.
- [ ] Ensure integration with other management systems.

03 People and competence

- [ ] Identify training needs based on the changes in ISO 9001:2026.
- [ ] Provide training and awareness to relevant personnel.
- [ ] Ensure competence and assign responsibilities.

04 Performance evaluation

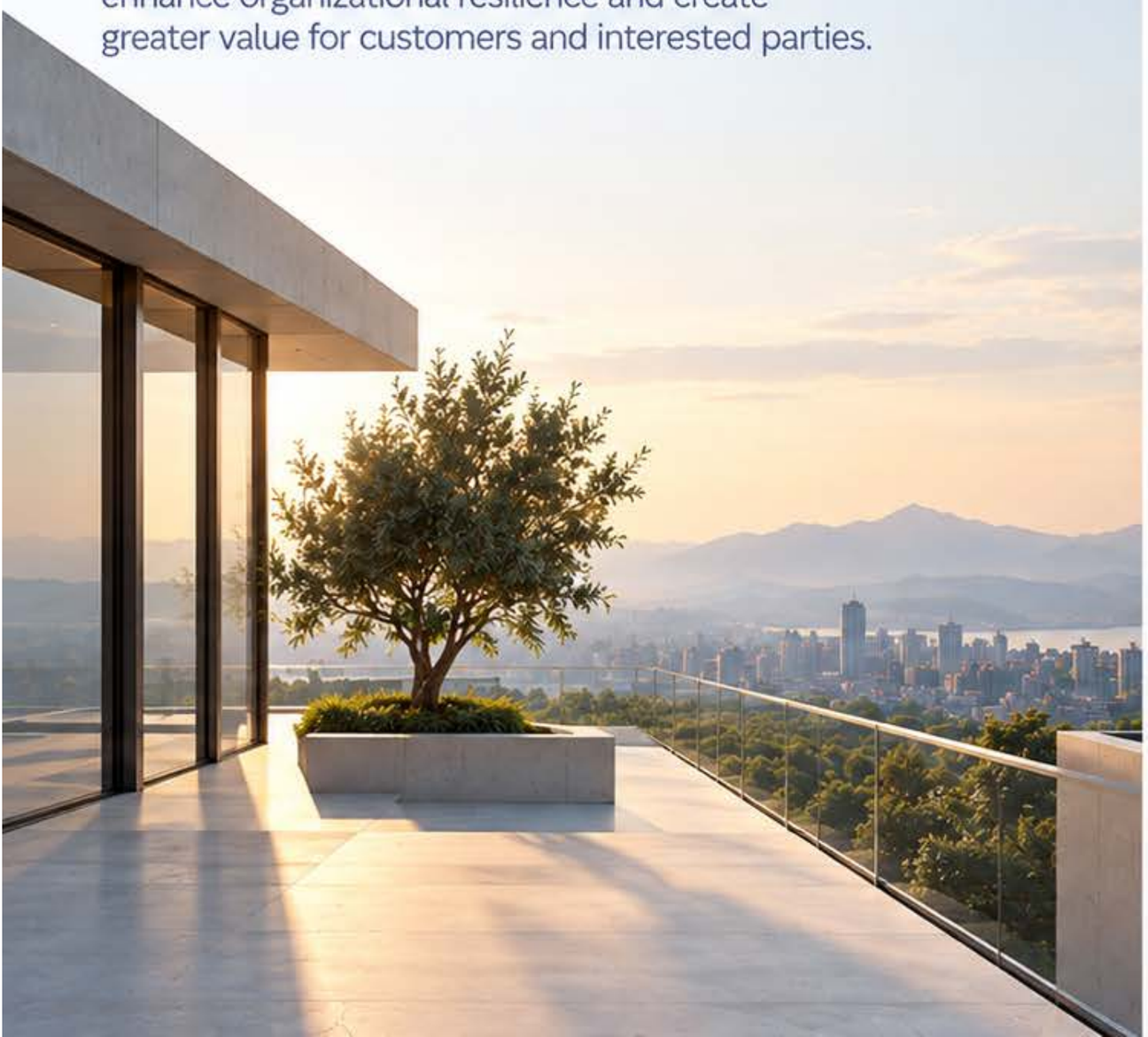
- [ ] Review and update monitoring and measurement methods.
- [ ] Ensure effective internal audit planning and execution.
- [ ] Evaluate management review inputs and process effectiveness.

05 Improvement and readiness

- [ ] Address identified gaps and nonconformities.
- [ ] Implement corrective actions and verify their effectiveness.
- [ ] Confirm the completion of all transition activities.
- [ ] Conduct a pre-audit or gap assessment to ensure readiness.

Final Conclusions and Recommendations

The transition to ISO 9001:2026 is an opportunity to strengthen your quality management system, enhance organizational resilience and create greater value for customers and interested parties.



Key recommendations

for successful transition and continued improvement

01

Adopt a strategic approach

Integrate the transition with your business strategy to drive long-term value and improve organizational performance.

02

Strengthen leadership and engagement

Ensure top management commitment and involve relevant personnel across the organization.

03

Update and align your QMS

Review and revise processes, documented information and interfaces to ensure alignment with ISO 9001:2026 requirements.

04

Focus on performance and improvement

Use data and evaluation to identify opportunities for improvement and to enhance customer satisfaction and organizational resilience.

05

Prepare for certification audit

Conduct internal audits, address any gaps, and ensure that your organization is ready to demonstrate effective implementation and compliance with ISO 9001:2026.

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