

ISO 9001:2026 Transition Gap Analysis Checklist

For organizations transitioning from ISO 9001:2015 to ISO 9001:2026

Purpose: Use this checklist for an initial review of an existing ISO 9001:2015 QMS against the key new, changed and enhanced requirements of ISO 9001:2026. It is a transition tool and is not intended to replace a complete conformity audit against ISO 9001:2026.

Status: C = Conform | P = Partial | G = Gap | N/A = Not Applicable

Change Type: New/Changed | Enhanced/Clarified | Guidance/Note

Clause	Change Type	2026 Change / Enhancement	Gap Analysis Question	Suggested Evidence to Review	Status	Action Required
4.1	New/Changed	Climate change explicitly considered as a context issue	Has the organization determined whether climate change is a relevant issue affecting its QMS and intended results?	Context analysis; SWOT/PESTLE; risk register; management review	☐ C ☐ P ☐ G	
4.2	New/Changed	Determine which relevant interested-party requirements will be addressed through the QMS	Have relevant interested parties and their requirements been identified, and has the organization determined which requirements will be addressed through the QMS?	Interested-party register; customer/regulatory requirements; context review	☐ C ☐ P ☐ G	
4.2	Guidance/Note	Relevant interested parties can have requirements related to climate change	Has the organization considered whether relevant interested parties have requirements related to climate change?	Interested-party analysis; customer requirements; regulatory requirements	☐ C ☐ P ☐ G ☐ N/A	
5.1.1	New/Changed	Quality culture and ethical behaviour explicitly introduced	Does top management actively promote a quality culture and ethical behaviour within the organization?	Leadership communication; meeting records; interviews; escalation practices; management actions	☐ C ☐ P ☐ G	
5.2	Enhanced/Clarified	Quality policy strengthened in relation to strategic direction and application	Does the quality policy appropriately take account of the organization's strategic direction, and is it implemented, understood and applied?	Quality policy; business/strategic plan; objectives; employee interviews	☐ C ☐ P ☐ G	
5.3	Enhanced/Clarified	Responsibilities include opportunities for improvement and QMS integrity during change	Are responsibilities and authorities clear for reporting opportunities for improvement and maintaining QMS integrity when changes are planned and implemented?	Organization chart; job descriptions; QMS responsibilities; change records	☐ C ☐ P ☐ G	
6.1.1	New/Changed	Risks and opportunities more clearly distinguished	Does the organization's planning process appropriately determine both risks and opportunities that could affect QMS results?	Risk/opportunity register; business planning; process reviews	☐ C ☐ P ☐ G	
6.1.2	New/Changed	Separate actions to address risks	Are risks determined, analysed and evaluated, with proportionate actions planned and integrated into QMS processes?	Risk assessments; process risks; action plans; operational controls	☐ C ☐ P ☐ G	
6.1.2	New/Changed	Effectiveness of risk actions	Does the organization evaluate whether actions taken to address risks are effective?	Risk reviews; KPI results; management review; follow-up records	☐ C ☐ P ☐ G	
6.1.3	New/Changed	Separate actions to address opportunities	Are opportunities determined, analysed and evaluated, rather than simply being treated as the opposite of risks?	Opportunity register; improvement plans; strategic/process planning	☐ C ☐ P ☐ G	
6.1.3	New/Changed	Effectiveness of opportunity actions	Are actions addressing opportunities integrated and implemented through relevant QMS processes, and is their effectiveness evaluated?	Improvement projects; KPI results; project reviews; management review	☐ C ☐ P ☐ G	
6.2	Enhanced/Clarified	Evaluation of quality-objective results clarified	When planning quality objectives, has the organization determined how the results will be evaluated?	Quality objectives; KPI dashboard; objective/action plans	☐ C ☐ P ☐ G	
6.3	New/Changed	Communication added to planning of changes	Does the organization determine what needs to be communicated, to whom and how when QMS changes are planned?	Change-management procedure/form; project/change records	☐ C ☐ P ☐ G	
6.3	New/Changed	Effectiveness and review of changes strengthened	Does change planning define how effectiveness will be monitored and evaluated and how results will be reviewed?	Change plans; validation/review records; KPI data; post-implementation reviews	☐ C ☐ P ☐ G	
7.1.3	Guidance/Note	Infrastructure note recognizes on-site, remote and combined working	Where relevant, has the organization considered whether infrastructure adequately supports on-site, remote or combined working arrangements?	Infrastructure planning; ICT arrangements; remote-working controls	☐ C ☐ P ☐ G ☐ N/A	
7.1.6	Enhanced/Clarified	Updated notes clarify the different forms organizational knowledge can take: experience-based knowledge held by people; knowledge acquired through education, training and learning from others; knowledge embedded in methods, processes and products; and knowledge represented in documented	Has the organization considered the different forms of knowledge needed for its processes, and are appropriate arrangements in place to capture, retain, apply and share important human and digitally stored knowledge?	Knowledge matrix; competency/training records; lessons learned; work methods; procedures; technical databases; digital systems; knowledge-transfer or succession arrangements	☐ C ☐ P ☐ G	

Clause	Change Type	2026 Change / Enhancement	Gap Analysis Question	Suggested Evidence to Review	Status	Action Required
		information, digital systems and other media.				
7.3	New/Changed	Awareness of quality culture and ethical behaviour	Are relevant personnel aware of the organization's quality culture and expected ethical behaviour and what these mean in their work?	Interviews; induction/training; communications; awareness activities	☐ C ☐ P ☐ G	
8.2.1	Enhanced/Clarified	Contingency-related customer communication strengthened	Where relevant, are arrangements established for communicating with customers regarding contingency actions and disruptions affecting products/services?	Contingency plans; customer communication process; disruption records	☐ C ☐ P ☐ G ☐ N/A	
8.2.4	Enhanced/Clarified	Changes communicated to relevant interested parties	When product/service requirements change, are relevant documents updated and are the changes communicated to relevant interested parties?	Contract/order changes; specifications; change notices; communication records	☐ C ☐ P ☐ G	
8.3	Enhanced/Clarified	Design and development requirements clarified	Where design applies, do existing controls adequately address evolving design inputs and appropriate involvement of customers/relevant interested parties?	Design plans; design inputs; review records; customer involvement	☐ C ☐ P ☐ G ☐ N/A	
9.1.3	New/Changed	Separate evaluation of actions addressing opportunities	Does analysis and evaluation include the effectiveness of actions taken to address opportunities, as well as risks?	KPI analysis; opportunity reviews; improvement results; management review	☐ C ☐ P ☐ G	
9.2	Enhanced/Clarified	Audit objectives explicitly addressed	Are audit objectives determined for individual internal audits together with scope and criteria?	Audit programme; audit plans; audit reports	☐ C ☐ P ☐ G	
9.3.2	New/Changed	Management review inputs explicitly include changes in the needs and expectations of interested parties that are relevant to the QMS. The effectiveness of actions addressing risks and opportunities is also considered separately.	Does management review explicitly consider changes in the needs and expectations of relevant interested parties? Does it separately review the effectiveness of actions taken to address risks and opportunities?	Management review agenda/minutes; interested-party register; changes in customer, statutory/regulatory or other relevant requirements; risk and opportunity reviews; effectiveness results	☐ C ☐ P ☐ G	
10.1	Enhanced/Clarified	Continual improvement restructured	Have QMS documents and practices been reviewed against the revised 10.1 Continual improvement structure, including improvement of processes, products/services and addressing future needs?	Improvement programme; KPI trends; management review; improvement records	☐ C ☐ P ☐ G	

Overall Gap Analysis Summary

Assessment	Number Identified
Conform - Existing QMS already addresses requirement	
Partial - Existing arrangements need enhancement	
Gap - New action required	
N/A - Not applicable	

Priority Actions Identified

1. _____
2. _____
3. _____
4. _____
5. _____

Important note: This checklist focuses on transition-related changes and enhancements. Notes and Annex A provide useful clarification but do not, by themselves, create additional requirements. Organizations should use the official ISO 9001:2026 standard as the definitive source when determining conformity.