QUALITY GURUS INC.

ISO 9001:2026

Transition Gap Analysis Checklist

For organizations certified to ISO 9001:2015

What this checklist does

ISO 9001:2026 keeps the same ten clauses, the same process approach and the same intent as the 2015 edition. Most of your management system is unaffected. This checklist isolates the clauses where a 2015 certified organization genuinely has something to do, states what changed, and gives you a line to record your finding and your evidence.

Work through Section A clause by clause. Use Section B to re-baseline your documented information against the new wording. Use Section C to sequence the work into a transition plan.

Document control

Organization	
Scope or site assessed	
Assessed by	
Date of assessment	
Certification body	
Revision	

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Upcoming course
learn.qualitygurus.com/courses/iso-9001-2026

How to use this checklist

Read this page once before you start.

Working method

1. Get the 2026 edition and read Annex A next to the requirements. Annex A is now the clearest statement of intent available and settles most interpretation arguments.
2. Take one clause row at a time. Read what changed, then look at what your system does today.
3. Tick **Conforms** only when you can point at the evidence. Tick **Gap** when something has to change. Tick **N/A** when the clause does not apply to your scope and you have a written justification.
4. Record the evidence or the action in the right hand column, with an owner and a target date.
5. Roll every Gap into the transition plan in Section C.

Effort key

LOW Wording, renaming or cross-reference work. Usually a document edit.

MED A new field, a new agenda item or a new piece of evidence.

HIGH New process or new records. Plan it properly.

A note on scale

The 2026 edition changes wording in many places but changes substance in only about twenty. The single largest piece of work is the separation of opportunities from risks in Clause 6.1.

What has not changed

The ten clause structure, the process approach, PDCA, risk-based thinking, the seven quality management principles, the scope and applicability rules, and the underlying documented information requirements. A 2015 system that works will still work. Nothing in this checklist asks you to rebuild it.

Transition timing

Transition periods are set by IAF resolution and by your own certification body, not by the standard itself. Confirm your deadline and your audit slot with your certification body early. Audit calendars fill quickly in the final year of any transition.

At a glance

Forty one action items. Two of them carry most of the work.

HIGH	6.1.2 Actions to address risks, and 6.1.3 Actions to address opportunities.
MED	4.2, 5.1.1, 6.3, 7.1.4, 7.1.6, 7.3, 8.1, 8.2.1, 8.3.5, 8.4.2, 8.4.3, 8.5.1, 8.5.6, 9.1.3, 9.3.2, and the documented information wording change that runs through the whole standard.
LOW	0.3.1, 0.3.3, 0.4, Clause 2, 4.1, 4.3, 4.4.1, 4.4.2, 5.2.1, 5.2.2, 5.3, 7.1.3, 7.1.5.2, 7.5.2, 8.2.3.2, 8.2.4, 8.4.1, 9.2.2, 9.3.3, 10.1, Annex A and Annex B.

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Section A. Clause by clause gap analysis

Only the clauses where a 2015 certified organization has something to do. Clauses not listed here are unchanged in substance.

Clause	What changed in 2026, and what to do	Status	Evidence, owner, date
Introduction and Clause 2			Framing and references
0.3.1 Process approach	Risk-based thinking and opportunity-based thinking are named as two separate concepts. Opportunity is no longer a sub-idea inside risk-based thinking. **Action.** Update any training material or manual text that defines risk-based thinking as covering opportunity. Teach two concepts, not one. LOW	☐ Conforms ☐ Gap ☐ N/A	
0.3.3 Risk-based thinking	The 2015 sub-clause 0.3.3 no longer exists. Its content moved into Annex A.6.1.2 and A.6.1.3. **Action.** Repoint any cross-reference to 0.3.3 in your manual, procedures or training notes. LOW	☐ Conforms ☐ Gap ☐ N/A	
0.4 Relationship with other standards	The term Annex SL is no longer used. Clause 0.4 refers to the harmonized approach published in the ISO/IEC Directives. **Action.** Replace the phrase Annex SL with harmonized approach or harmonized structure in your documentation and training. LOW	☐ Conforms ☐ Gap ☐ N/A	
2 Normative references	ISO 9000 is cited without a year, so the current edition applies automatically. **Action.** Check that the copy of ISO 9000 you rely on is the current edition. LOW	☐ Conforms ☐ Gap ☐ N/A	
Clause 4			Context of the organization
4.1 Understanding the organization and its context	You shall determine whether climate change is a relevant issue. Introduced by Amendment 1:2024 and now permanent base text. **Action.** Record the conclusion, typically a line in your context review or an entry in the issues register. Deciding it is not relevant is valid if you can show it was considered. Nothing to do if you already implemented Amd 1:2024. LOW	☐ Conforms ☐ Gap ☐ N/A	
4.2 Needs and expectations of interested parties	New requirement to determine which interested party requirements are addressed through the QMS. A note confirms that interested parties can have climate related requirements. **Action.** Add a column to your interested party table showing which requirements you address through the QMS and which you do not. This also gives you a documented basis for setting some expectations aside. MED	☐ Conforms ☐ Gap ☐ N/A	

Clause	What changed in 2026, and what to do	Status	Evidence, owner, date
4.3 Determining the scope of the QMS	Wording changed to shall be available as documented information. **Action.** Update the wording where your manual quotes the clause. The scope statement itself does not change. LOW	☐ Conforms ☐ Gap ☐ N/A	
4.4.1 QMS and its processes	The list of requirements runs a) to i) instead of a) to h). **Action.** Renumber any internal audit checklist or manual section that cites 4.4.1 a) to h). LOW	☐ Conforms ☐ Gap ☐ N/A	
4.4.2 QMS and its processes	Maintain and retain replaced by documented information shall be available, and shall be available as evidence. **Action.** Update quoted wording only. The documents and records themselves do not change. LOW	☐ Conforms ☐ Gap ☐ N/A	
Clause 5			Leadership
5.1.1 Leadership and commitment	Twelve commitment items instead of ten. New item i) promoting quality culture and ethical behaviour. Promoting the process approach and promoting risk-based and opportunity-based thinking are now separate items. **Action.** Add the new items to leadership briefings and to the management review agenda. Expect auditors to interview top management on culture. The evidence is behavioural: how people who report problems are treated, what your measures reward, what happens at month end. MED	☐ Conforms ☐ Gap ☐ N/A	
5.2.1 Quality policy	The policy requirements are restated and reorganized. **Action.** Check your policy against the current item list. Most 2015 policies already comply without amendment. LOW	☐ Conforms ☐ Gap ☐ N/A	
5.2.2 Communicating the quality policy	Be available and be maintained becomes be available as documented information. **Action.** Update quoted wording. Put your evidence effort into understanding of the policy rather than proof of distribution. Ask people what the policy means for their own job. LOW	☐ Conforms ☐ Gap ☐ N/A	
5.3 Roles, responsibilities and authorities	Clause renamed. The word Organizational is dropped from the title. **Action.** Rename the clause in your documentation. Confirm someone is named for reporting improvement opportunities, separately from reporting QMS performance. LOW	☐ Conforms ☐ Gap ☐ N/A	

Clause	What changed in 2026, and what to do	Status	Evidence, owner, date
Clause 6			Planning
6.1.2 Actions to address risks	Risks and opportunities are handled in separate sub-clauses. 6.1.2 covers risks only, and requires them to be analysed and evaluated, not simply listed. **Action.** Separate risks from opportunities in your register. Show the analysis and the evaluation step. Check that your proportionality logic refers to potential impact on QMS results. HIGH	☐ Conforms ☐ Gap ☐ N/A	
6.1.3 Actions to address opportunities	New sub-clause. Opportunities get their own determine, analyse, evaluate, act and review cycle. **Action.** The largest single piece of work in the transition. Create an opportunity register or a clearly separate section, with owners, actions and effectiveness review, and feed it into management review under its own heading. HIGH	☐ Conforms ☐ Gap ☐ N/A	
6.3 Planning of changes	Change planning adds communication of the change, monitoring and evaluating its effectiveness, and reviewing the result. **Action.** Extend your change request or change control form with three fields: communication plan, how effectiveness will be monitored, and a review date. Annex A.6.3 points to ISO/TS 10020 for guidance. MED	☐ Conforms ☐ Gap ☐ N/A	
Clause 7			Support
7.1.3 Infrastructure	Infrastructure examples reflect remote and hybrid working. **Action.** If you have remote or hybrid roles, bring home working equipment, connectivity and software inside your infrastructure and maintenance thinking. LOW	☐ Conforms ☐ Gap ☐ N/A	
7.1.4 Environment for the operation of processes	Quality culture and ethical behaviour are recognised as factors that influence the environment for the operation of processes. **Action.** Be ready for questions about workload, shift patterns and how pressure is managed, and answer them with facts. The link between working environment and error rate is now explicit. MED	☐ Conforms ☐ Gap ☐ N/A	
7.1.5.2 Traceability of measurement results	Clause renamed from Measurement traceability. The basis used for calibration or verification where no standard exists moves from the record form to the document form of documented information. **Action.** Rename the clause in your calibration procedure and reclassify that basis as a document rather than a record. LOW	☐ Conforms ☐ Gap ☐ N/A	

Clause	What changed in 2026, and what to do	Status	Evidence, owner, date
7.1.6 Organizational knowledge	Knowledge shall be retained, applied and shared to the extent necessary. **Action.** Look at single points of failure. Where one person holds knowledge nobody else has, that is a gap against this clause as well as a risk under 6.1. MED	☐ Conforms ☐ Gap ☐ N/A	
7.3 Awareness	New awareness item covering the organizational quality culture and ethical behaviour. **Action.** Add quality culture and ethical behaviour to induction and refresher awareness training. Auditors will test it by asking people how things really work. MED	☐ Conforms ☐ Gap ☐ N/A	
7.5.2 Creating and updating documented information	Clause renamed from Creating and updating. **Action.** Rename the clause in your document control procedure and any audit checklist that quotes the title. LOW	☐ Conforms ☐ Gap ☐ N/A	
Clause 8			Operation
8.1 Operational planning and control	Acceptance criteria and process criteria are separate requirements. Outsourced processes becomes externally provided processes, products or services that are relevant to the QMS. **Action.** Check that your control plans define process criteria and not only product acceptance criteria. A moulding shop needs the barrel temperature window as well as the dimensional spec. MED	☐ Conforms ☐ Gap ☐ N/A	
8.2.1 Customer communica-tion	Item on contingency actions broadened from establishing specific requirements to providing information related to contingency actions. **Action.** Define the route and the trigger for telling customers about supply disruption, and name an owner for it. MED	☐ Conforms ☐ Gap ☐ N/A	
8.2.3.2 Review of requirements	Documented information shall be available as evidence of the results of the review and of any new or changed requirements. **Action.** Keep order amendment records with the same discipline as new order records. The word changed is explicit in the 2026 text. LOW	☐ Conforms ☐ Gap ☐ N/A	
8.2.4 Changes to requirements	Changes to product and service requirements now explicitly reach external providers as well as internal functions. **Action.** When a customer changes a specification, check whether your suppliers also need to be told, and build that step into the amendment route. LOW	☐ Conforms ☐ Gap ☐ N/A	

Clause	What changed in 2026, and what to do	Status	Evidence, owner, date
8.3.5 Design and development outputs	Design outputs shall specify the characteristics of the products and services **and the information on the products and services** essential for their intended purpose, including safe and proper provision. **Action.** Treat user instructions, warnings, labelling and safety information as design outputs subject to the same review, verification and change control as the product itself. MED	☐ Conforms ☐ Gap ☐ N/A	
8.4.1 External provision, general	The external provision wording is clarified and broadened. **Action.** Check whether any process is provided by a sister company or a group function that sits outside your certified scope. It is an external provider. LOW	☐ Conforms ☐ Gap ☐ N/A	
8.4.2 Type and extent of control	Determining controls shall take into account the potential impact of the externally provided processes, products and services, and the effectiveness of the provider's own controls. **Action.** When you justify the level of supplier control, show that impact and provider effectiveness were actually factored in, not merely considered. MED	☐ Conforms ☐ Gap ☐ N/A	
8.4.3 Information for external providers	The item on provider interactions now covers interactions with the organization and, as applicable, with its customers. **Action.** If any supplier contacts your customers directly, set expectations for that contact and communicate them to the supplier. MED	☐ Conforms ☐ Gap ☐ N/A	
8.5.1 Control of production and service provision	The availability of documented information becomes the availability **and use** of documented information that defines characteristics, activities and results. **Action.** Check that documented information is genuinely in use at the point of work, not merely available somewhere on the site. Expect this to be tested on the floor. MED	☐ Conforms ☐ Gap ☐ N/A	
8.5.6 Control of changes	The requirement itself is unchanged word for word. Only the documented information wording moved from retain to shall be available as evidence. **Action.** No action beyond the wording. The reinforced change requirements the Foreword refers to are in Clause 6.3, so build one change process that serves both. LOW	☐ Conforms ☐ Gap ☐ N/A	

Clause	What changed in 2026, and what to do	Status	Evidence, owner, date
Clause 9			Performance evaluation
9.1.3 Analysis and evaluation	The effectiveness of actions taken to address risks, and the effectiveness of actions taken to address opportunities, are separate analysis items. **Action.** Add two separate lines to your analysis and to your management review pack, one for risk action effectiveness and one for opportunity action effectiveness. MED	☐ Conforms ☐ Gap ☐ N/A	
9.2.2 Internal audit programme	The audit programme shall define audit objectives as well as criteria and scope for each audit. **Action.** Add an objective line to your audit plan template, separate from criteria and scope. LOW	☐ Conforms ☐ Gap ☐ N/A	
9.3.2 Management review inputs	New input covering changes in interested parties. The risk and opportunity effectiveness input splits into two separate items. **Action.** Update your management review agenda template: add interested party changes, and split the risk and opportunity effectiveness item in two. MED	☐ Conforms ☐ Gap ☐ N/A	
9.3.3 Management review results	Clause renamed from Management review outputs. **Action.** Rename the clause in your management review procedure and in your minutes template. LOW	☐ Conforms ☐ Gap ☐ N/A	
Clause 10			Improvement
10.1 Continual improvement	The 2015 Clause 10.1 General and Clause 10.3 Continual improvement merge into a single Clause 10.1 Continual improvement. There is no Clause 10.3 in the 2026 edition. **Action.** Search your manual, procedures, audit checklists and training material for references to Clause 10.3 and repoint them to 10.1. One of the easiest updates to miss and one of the easiest for an auditor to spot. LOW	☐ Conforms ☐ Gap ☐ N/A	
Throughout			Documented information
All Documented information wording	Maintain and retain are gone. A document is now expressed as shall be available as documented information. A record is expressed as documented information shall be available as evidence of. Annex A.2 e) explains the distinction. The underlying requirements are unchanged. **Action.** Update the wording in your manual and document control procedure. Use Section B of this checklist to re-baseline every mandatory item, and note that 7.1.5.2 a) moves from the record form to the document form. MED	☐ Conforms ☐ Gap ☐ N/A	

Clause	What changed in 2026, and what to do	Status	Evidence, owner, date
Annexes			Annex A and Annex B
A.1 to A.10 Clause by clause clarification	Annex A is expanded and now follows the clause structure, clarifying structure, terminology and intent for every clause. It is informative and adds no requirements. **Action.** Read Annex A alongside the requirements. Use A.6.1.2 to settle the recurring argument about whether a formal risk register is mandatory. It is not. LOW	☐ Conforms ☐ Gap ☐ N/A	
A.3 Applicability	Annex A.3 covers applicability and the justification of clauses determined not to be applicable. **Action.** Check that every exclusion in your scope statement carries a written justification. LOW	☐ Conforms ☐ Gap ☐ N/A	
B Annex B removed	Annex B, the list of other ISO/TC 176 standards, is deleted. Those pointers now sit inside Annex A at the relevant clauses and on the ISO/TC 176 website. **Action.** Remove or repoint any reference to Annex B in your documentation and training material. LOW	☐ Conforms ☐ Gap ☐ N/A	

Section B. Documented information re-baseline

Every mandatory item in ISO 9001:2026. The requirements are the same as 2015, only the wording changed. A **document** reads *shall be available as documented information*; a **record** reads *documented information shall be available as evidence of*. One item changes form: 7.1.5.2 a) was a record in 2015 and is a document in 2026.

Clause	What it covers	Form	In place	Where it lives
4.3	Scope of the quality management system	Document	☐ Yes ☐ No	
4.4.2 a)	Information needed to support the operation of processes	Document	☐ Yes ☐ No	
4.4.2 b)	Evidence that processes are carried out as planned	Record	☐ Yes ☐ No	
5.2.2	Quality policy	Document	☐ Yes ☐ No	
6.2.1	Quality objectives	Document	☐ Yes ☐ No	
7.1.5.1	Fitness for purpose of monitoring and measuring resources	Record	☐ Yes ☐ No	
7.1.5.2 a)	Basis used for calibration or verification where no standard exists	Document	☐ Yes ☐ No	
7.2	Competence	Record	☐ Yes ☐ No	
8.1	Confidence that processes were carried out as planned	Document	☐ Yes ☐ No	
8.1	Conformity of products and services to requirements	Record	☐ Yes ☐ No	
8.2.3.2	Results of requirements review, and new or changed requirements	Record	☐ Yes ☐ No	
8.3.3	Design and development inputs	Record	☐ Yes ☐ No	
8.3.4 f)	Design and development reviews, verification and validation	Record	☐ Yes ☐ No	
8.3.5	Design and development outputs	Record	☐ Yes ☐ No	
8.3.6	Design and development changes, reviews, authorizations and actions	Record	☐ Yes ☐ No	
8.4.1	Evaluation, selection, monitoring and re-evaluation of external providers	Record	☐ Yes ☐ No	
8.5.1 a)	Characteristics, activities and results in production and service provision	Document	☐ Yes ☐ No	
8.5.2	Information necessary to enable traceability	Record	☐ Yes ☐ No	
8.5.3	Customer or external provider property lost, damaged or unsuitable	Record	☐ Yes ☐ No	
8.5.6	Review of production or service changes, authorization and actions	Record	☐ Yes ☐ No	
8.6	Release of products and services, and the authorizing person	Record	☐ Yes ☐ No	
8.7.2	Nonconformity, actions, concessions and the deciding authority	Record	☐ Yes ☐ No	
9.1.1	Results of monitoring, measurement, analysis and evaluation	Record	☐ Yes ☐ No	
9.2.2	Implementation of the audit programme and the audit results	Record	☐ Yes ☐ No	
9.3.3	Results of management reviews	Record	☐ Yes ☐ No	
10.2.2	Nonconformities, actions taken and results of corrective action	Record	☐ Yes ☐ No	

Section C. Transition plan

A sequence that works. Steps 1 to 4 are preparation, 5 to 12 are the work, 13 to 15 close it out.

#	Action	Owner	Target date	Done
1	Obtain the 2026 edition and read Annex A alongside the requirements.			☐
2	Confirm the transition deadline and the audit slot with your certification body.			☐
3	Complete Section A of this checklist and list every Gap.			☐
4	Brief top management on the outcome, including the new quality culture and ethical behaviour requirements.			☐
5	Split risks and opportunities into separate registers or clearly separate sections. Largest single piece of work.			☐
6	Build the opportunity cycle: determine, analyse, evaluate, act, review effectiveness.			☐
7	Add opportunity effectiveness as a separate item in analysis (9.1.3) and in management review (9.3.2).			☐
8	Add changes in interested parties to the management review agenda.			☐
9	Extend the change control form with communication, effectiveness monitoring and review of results.			☐
10	Add quality culture and ethical behaviour to leadership briefings and awareness training.			☐
11	Record a conclusion on whether climate change is a relevant issue, and add the interested party filter to your 4.2 table.			☐
12	Update documented information wording throughout, using Section B to re-baseline. Repoint every reference to Clause 10.3 and rename 5.3, 7.1.5.2, 7.5.2 and 9.3.3.			☐
13	Add an objective line to the internal audit plan template.			☐
14	Run one internal audit against the 2026 edition while you still control the timetable.			☐
15	Hold a management review against the updated inputs and close out the findings.			☐

Sign off

Gap analysis completed by	Reviewed by	Date
_____	_____	_____

Notes

Going further

This checklist is a summary tool. It does not reproduce the text of either edition, and it is not a substitute for reading the standard. For a full clause by clause walkthrough of the 2026 edition, including the reasoning behind each change, see the Quality Gurus course:

learn.qualitygurus.com/courses/iso-9001-2026

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