

ISO 9001:2026 Quality management systems — Requirements

ISO 9001:2026 sets requirements for a quality management system that helps organizations consistently deliver products and services that meet customer and regulatory requirements.



What it is

ISO 9001:2026 is the international standard that specifies requirements for a quality management system (QMS). It gives organizations a structured way to demonstrate that they can consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and that they work to enhance customer satisfaction through continual improvement. It is the only standard in the ISO 9000 family to which an organization can be certified, and ISO reports more than one million certificates in 189 countries.

The standard is published by the International Organization for Standardization (ISO) and developed by technical committee ISO/TC 176/SC 2. It is voluntary and applies to any organization regardless of size, sector, or the products and services it provides; customers, regulators, and supply-chain partners frequently make certification a condition of doing business. ISO published the sixth edition on 16 September 2026, replacing ISO 9001:2015 and its 2024 climate change amendment, both of which ISO now lists as withdrawn.

At a glance

PUBLISHER International Organization for Standardization (ISO)	TYPE Standard	VERSION 2026
EFFECTIVE September 2026	DOMAIN Quality & Safety	FAMILY ISO Management Systems
REGION International	ADOPTION MODEL Certification	IMPLEMENTATION COMPLEXITY Medium

Source: <https://www.iso.org/standard/9001>

Why it matters

- Consistent customer satisfaction** Defined processes and requirements for monitoring customer perception help organizations deliver what they promise and act on feedback.
- Recognized proof of quality** Certification is accepted worldwide and is frequently required in tenders, supplier qualification, and regulated supply chains.
- Risk-based thinking** Planning separates risks from opportunities, so problems are prevented and beneficial outcomes are pursued deliberately rather than corrected after the fact.
- Process efficiency** The process approach and the plan-do-check-act cycle expose waste, rework, and bottlenecks and give management data for improvement.

How SmartSuite supports ISO 9001:2026

ISO 9001 Clause Library

Hold clauses 4 to 10 as structured requirements linked to the processes, documents, and controls that satisfy each one.

Process Owners and Review Cadence

Assign owners to QMS processes and schedule internal audits, management reviews, and objective reviews so nothing lapses.

Documented Information and Audit Trail

Control documents and records with versioning, approvals, and timestamps that show auditors who changed what and when.

Internal Audits and Corrective Action

Plan audits, record findings, and drive nonconformances through root cause analysis to verified closure.

Supplier Evaluation and Risk Planning

Evaluate external providers and track risks and opportunities against the quality objectives they affect.

Quality Performance Reporting

Report customer satisfaction, objective attainment, open findings, and certification readiness to leadership.

Common framework mappings

ISO 13485:2016

IATF 16949:2016

ISO/IEC 20000-1

ISO 22301

ISO 27001:2022

ISO 42001

ISO 31000:2018

CMMI v3.0

GAMP 5

ISO 14971:2019

Official resources

ISO 9001:2015 Quality management systems — Requirements (withdrawn)

ISO's catalog page for the withdrawn fifth edition, superseded by ISO 9001:2026 in September 2026, with edition history and the 2024 climate change amendment.

iso.org/standard/62085.html

ISO 9000 family — Quality management

ISO's overview of the ISO 9000 family, the seven quality management principles, and sector-specific applications of ISO 9001.

iso.org/standards/popular/iso-9000-family

ISO 9001:2026 Quality management systems — Requirements

ISO's catalog page for the sixth edition, published in September 2026, which replaces ISO 9001:2015.

iso.org/standard/9001

ISO 9001:2026: What businesses need to know

ISO's explanation of what changed between the 2015 and 2026 editions and what it means for certified organizations.

iso.org/quality-management/iso-9001-2026

Frequently asked questions

What is ISO 9001:2026 used for?

ISO 9001:2026 is used to establish, implement, maintain, and continually improve a quality management system (QMS). Organizations apply it to show customers and regulators that their processes consistently deliver conforming products and services, and to drive improvement through measurement, internal audit, and corrective action.

Is ISO 9001 certification mandatory?

No. ISO 9001 is a voluntary standard and certification is optional, although it is the only standard in the ISO 9000 family that an organization can be certified to. Many customers, tenders, and regulated supply chains require certification as a condition of doing business, which is why ISO reports more than one million certificates worldwide.

What are the main requirements of ISO 9001:2026?

The auditable requirements sit in clauses 4 to 10: context of the organization, leadership, planning, support, operation, performance evaluation, and improvement, with a new informative Annex A that explains their intent. They rest on seven quality management principles and on the process approach, the plan-do-check-act cycle, and risk-based thinking, and the 2026 edition adds explicit expectations for quality culture and ethical behavior.

Can organizations still use ISO 9001:2015 now that ISO 9001:2026 is published?

ISO published ISO 9001:2026 on 16 September 2026 and lists the 2015 edition as withdrawn. Certified organizations move to the new edition under the transition arrangements set by accreditation and certification bodies; during that period existing ISO 9001:2015 certificates remain in use and organizations should plan a gap assessment against the 2026 requirements.

How does ISO 9001 relate to ISO 13485 and IATF 16949?

ISO 13485 for medical devices and IATF 16949 for automotive are sector-specific quality management standards built on ISO 9001. They keep its structure and add regulatory or customer-specific requirements, so an organization with an ISO 9001 QMS already has most of the foundation those schemes expect.

How long does it take to implement ISO 9001?

Timelines depend on the organization's size and process maturity, but most organizations plan six to twelve months from gap assessment to certification audit. The work includes defining scope and processes, producing the required documented information, running at least one full cycle of internal audit and management review, and then completing the stage 1 and stage 2 certification audits.

How does SmartSuite help with ISO 9001?

SmartSuite holds the QMS requirements, processes, documents, nonconformances, audits, and management review records in one system with owners, due dates, and an audit trail. Teams use it to keep evidence current between audits and to report quality performance to leadership.

License included / downloadable: No ISO 9001:2026 is sold by ISO and national standards bodies through the ISO Store and is not included with the platform.

Full framework page and mappings: smartsuite.com/frameworks/iso-9001-2026-quality-management-systems-qms