GUIDE 2025/2026

ISO 9001 guide for mid-sized companies

Quality management to ISO 9001:2026, explained plainly

notivia GmbH

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1 What is ISO 9001?

1.1 The standard in plain words

ISO 9001 is the most widely used standard for quality management systems in the world. The current edition **ISO 9001:2026** appeared on 16 September 2026 **and replaces the 2015 edition**; the German issue, DIN EN ISO 9001:2026, is available from DIN Media.

Around a million organisations worldwide are certified to it — across **every sector** and **every size** . From a two-person business to a corporation the standard text is the same; what differs is how much of it you have to build.

> **The core idea:** ISO 9001 does not ask “are you good?”, it asks “can you show that you deliver reliably — and that you notice when you do not?” The standard describes no product, only the way an organisation plans, controls and improves its processes.

For many companies the certificate is in practice a **condition of taking part**. Tenders, supplier questionnaires and framework contracts regularly assume it — often during pre-qualification, long before the first order.

1.2 The ISO 9000 family

Four standards belong together; only one of them can be certified:

1. **ISO 9000** — fundamentals and vocabulary. Sets out the seven quality management principles and fixes the language. Not certifiable.
2. **ISO 9001** — the requirements. The only standard of the family your management system is audited and certified against.
3. **ISO 9004** — guidance for sustained success. Reaches beyond the certification requirements; useful for maturity and development.
4. **ISO 19011** — guidance for auditing management systems: planning, conduct, auditor competence, reporting.

> **A way to remember it:** if you want to *understand* it, read 9000. If you want to *certify* , you need 9001. If you want to *go further* , use 9004. And if you want to audit, look in 19011.

1.3 What is new in the 2026 edition

The basic structure with clauses 4 to 10 stays. What is new are mostly points that used to be implied and are now asked for explicitly:

clauses 4–10	61	30 Sept 2029
structure unchanged	auditable requirements	until then 2015 certificates hold

- **Quality culture and ethical behaviour** — cl. 5.1.1 and 7.3: a culture in which deviations are reported rather than hidden.
- **Risks and opportunities kept apart** — cl. 6.1: risks are treated, opportunities assessed and then deliberately taken or dropped.

- **Planning of changes** — cl. 6.3: purpose, consequences, resources and responsibilities, instead of letting changes happen on the side.
- **Organisational knowledge** — cl. 7.1.6: what knowledge you need in order to deliver, and how you keep it when someone leaves.
- **Climate change as a context factor** — cl. 4.1 and 4.2: consider whether it is relevant to you. A reasoned no is enough, but it has to be made.
- **Objectives for each internal audit** — cl. 9.2: every audit needs objectives of its own, not just an annual programme.
- **A sharper management review** — cl. 9.3.2: the required inputs are named more clearly than before.

1.4 Certification and accreditation

Only bodies that are **accredited** for it may certify — in Germany through DAkkS, the national accreditation body. A certificate without an accreditation mark is formally worthless, and many purchasing departments check.

The audit runs in two stages: stage 1 reviews documentation and readiness, stage 2 the **lived implementation** on site. Surveillance audits follow each year, with recertification after three.

> **Worth knowing:** before you appoint a body, check that it is accredited for your sector (NACE code). A body without the matching scope may not certify you — otherwise that only surfaces at the audit.

2 Who needs ISO 9001?

ISO 9001 is sector-neutral. It applies to manufacturing as much as to services, and to a business with five people as much as to one with five hundred — only the extent differs.

A. Manufacturing and suppliers

- machining, turning, assembly
- plastics, metal and electronics production
- plant and special machinery construction
- contract manufacturing and extended workbench
- system suppliers with their own design

B. Services and IT

Agencies, engineering offices and IT service providers use ISO 9001 to show that delivery is **repeatable**and does not hang on individuals. When people change, that is an argument that holds up in a sales conversation.

C. Public sector buyers

Procurement offices often require ISO 9001 as **proof of suitability**. Without the certificate a bid fails on formal grounds — however good it is on the merits.

> **A special case:** if you supply aerospace, you need EN 9100. That contains ISO 9001 in full — build ISO 9001 first and most of it is already in place.

D. When do you not need it yet?

If neither customers nor tenders ask for it and you are not planning to certify, a described and lived process without a certificate is enough. The effort pays off as soon as the first large customer asks for proof — and by then there is usually no time.

> **A real example:** an engineering office with 22 people worked for years without a certificate. When an energy utility put it into pre-qualification, the deadline was nine months. Because the processes were lived but written down nowhere, most of the work was in writing them down — not in changing them.

3 The path to the certificate — 7 phases

With a management system of the same basic structure already in place the path is considerably shorter. This order has proved itself:

Phase 1 — Record the processes

Record what actually happens, not what should. The result is a process map with interactions, responsibilities and measures (cl. 4.4). *Three to five weeks.*

Phase 2 — Context and scope

Determine interested parties and their requirements, consider climate change as a context factor, bound the scope and give reasons for anything not applicable (cl. 4.1–4.3). *One to two weeks.*

Phase 3 — Leadership, policy and objectives

The quality policy, measurable objectives per process, roles and authorities — and newly: anchoring quality culture and ethical behaviour (cl. 5). *Two to four weeks.*

Phase 4 — Risks, opportunities and changes

Treat risks, assess opportunities separately and decide on them, make changes to the system plannable (cl. 6.1 and 6.3). *Three to five weeks.*

Phase 5 — Operation and supply chain

Customer requirements, design, supplier assessment, production, measuring equipment and the handling of nonconforming output (cl. 7 and 8). *Four to eight weeks.*

Phase 6 — Metrics and customer satisfaction

Set measures per process, evaluate customer satisfaction and complaints, secure organisational knowledge (cl. 7.1.6 and 9.1). *Three to five weeks.*

Phase 7 — Internal audit and certification

An internal audit programme with objectives of its own per audit, the management review under 9.3.2, then stages 1 and 2 with the certification body. *Two to four months.*

> **Tip:** four to eight weeks usually sit between stage 1 and stage 2. Book both stages when you appoint the body — otherwise you lose at the end the weeks you saved at the start.

4 What does ISO 9001 cost?

The decisive factor is how far your processes are already written down. An existing system of the same basic structure — ISO 27001, say — roughly halves the effort:

Starting point	Our part*	Timeframe	Internal effort
Up to 5 staff	**€5,000**	3–5 months	8–15 person-days
6–50 staff	**€10,000**	4–8 months	15–30 person-days
51–100 staff	**€16,600**	6–10 months	30–50 person-days
Several sites	**on request**	8–14 months	50–80 person-days
Moving from 2015 to 2026	**from €2,400**	2–4 months	5–12 person-days

* A fixed price for one site or a bounded scope: recording the processes, closing the gaps, the documents, the internal audit and audit preparation. Excluding the certification audit, which the certification body charges separately. All prices exclude VAT.

What drives the cost?

- **How far the processes are written down:** lived but undocumented routines are the most common case — and the largest single block.
- **An existing management system:** ISO 27001, ISO 42001 or EN 9100 share clauses 4 to 7 and 9 to 10 with ISO 9001.
- **The number of sites:** every site with processes of its own means its own evidence and audit time.
- **Design within the scope:** if you design yourself, clause 8.3 has to be covered in full — a noticeable extra block.

Running cost after certification

Plan for **15–25 % of the set-up cost per year**. The certificate runs for three years, with a surveillance audit each year. On top of that:

- an internal audit programme with objectives per audit
- the management review under cl. 9.3.2
- supplier assessment and control of measuring equipment
- evaluating customer satisfaction and complaints
- keeping the process map current as things change

> **On transparency:** only compare quotes for an identical scope. A quote for “ISO 9001” that does not name the sites, the headcount and whether design is included cannot be compared with any other.

5 The 10 most common mistakes

From guiding a good many certification projects, we know the usual stumbling blocks:

1. **Drawing the process map as an org chart**
   What is asked for are processes with interactions, inputs and outputs — not the departmental structure. This is one of the most frequent audit findings of all.

2. **Leaving out opportunities**
   Since the 2026 edition risks and opportunities stand apart. Keep only risks and you have met half the requirement — and it shows immediately.

3. **Objectives without a measure**
   “Increase customer satisfaction” is not an objective. Without a measure, a baseline and a date it cannot be audited.

4. **Skipping climate change**
   The requirement is new and looks like a side issue. A reasoned statement is enough — but it has to be made and written down.

5. **An internal audit without objectives of its own**
   An annual programme is no longer enough since 2026. Every audit needs a question it is meant to answer.

6. **The management review as a formality**
   Minutes without decisions are not a review. What is asked for are decisions on resources, objectives and improvements.

7. **Exclusions without a reason**
   Exclusions are allowed (cl. 4.3) — but only with a reason stated in the scope. Leaving something out silently is a nonconformity.

8. **Documents written for the audit, not for the work**
   A manual nobody knows surfaces in stage 2. Auditors ask the people, not the document.

9. **Supplier assessment as a list only**
   What is asked for are criteria, an assessment interval and a consequence. A list without assessment does not meet cl. 8.4.

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Appointing the certification body too late

Four to eight weeks sit between stage 1 and stage 2, and booking needs lead time. Ask only after your internal preparation and you lose two to three months.

6 Readiness check: are you ready?

Answer the following ten questions honestly with yes or no. The result shows your ISO 9001 maturity.

1. **Is there a process map showing interactions?**
   Cl. 4.4 — processes, their sequence and how they work together, not the org chart.
2. **Are interested parties and their requirements determined?**
   Cl. 4.1–4.2 — including whether climate change is relevant to you.
3. **Is the scope set out and justified?**
   Cl. 4.3 — anything not applicable explicitly reasoned.
4. **Do you keep risks and opportunities apart?**
   Cl. 6.1 — opportunities assessed and deliberately taken or dropped.
5. **Do your quality objectives have measures and dates?**
   Cl. 6.2 — per process, with a baseline and an owner.
6. **Is it settled what knowledge the organisation needs?**
   Cl. 7.1.6 — and how it is kept when someone leaves.
7. **Do you assess suppliers against fixed criteria?**
   Cl. 8.4 — criteria, assessment interval and consequence set out in writing.
8. **Do you measure customer satisfaction in a way that holds up?**
   Cl. 9.1.2 — not only counting complaints but asking actively.
9. **Does every internal audit have objectives of its own?**
   Cl. 9.2 — explicitly required since the 2026 edition.
10. **Does the management review lead to decisions?**
    Cl. 9.3 — decisions on resources, objectives and improvements, not just minutes.

Your yes answers	Where you stand	What to do
0–3 × yes	**At the beginning**	First record and write down the processes. That is the largest block. 8–14 months.
4–6 × yes	**Halfway there**	Usually what is missing is opportunities, knowledge or measurable objectives. 4–8 months.
7–10 × yes	**Close to certification**	Complete the audit programme and book the certification body. 2–4 months.

> ISO 9001 is straightforward to plan once the processes are lived — most of the work is in writing them down, not in changing them. If you have questions about the scope or the move to the 2026 edition, we are glad to help.

7 Glossary

The key terms around ISO 9001, explained plainly:

ISO 9001

The standard for quality management systems. The only certifiable standard of the ISO 9000 family; current edition ISO 9001:2026.

ISO 9000 / 9004 / 19011

Fundamentals and vocabulary, guidance for sustained success, guidance for auditing — none of them certifiable.

DAkkS

The German national accreditation body — it accredits the certification bodies. Without accreditation a certificate is formally worthless.

Process map

A picture of the processes with their sequence and interactions, inputs, outputs and responsibilities (cl. 4.4).

Interested parties

Everyone whose requirements matter to the management system: customers, authorities, owners, employees, suppliers (cl. 4.2).

Risks and opportunities

Kept apart since the 2026 edition: risks are treated, opportunities assessed and then deliberately taken or dropped (cl. 6.1).

Organisational knowledge

The knowledge needed to deliver, and the way it is kept and passed on (cl. 7.1.6).

Management review

The regular review of the management system by leadership, with defined inputs and decisions that follow from them (cl. 9.3).

Nonconforming output

An output that does not meet requirements. What has to be controlled is identification, the decision on what happens next, and the record (cl. 8.7).

Quality culture

New in 2026: a culture in which deviations are reported rather than hidden, and ethical conduct as part of the system (cl. 5.1.1, 7.3).

Not applicable

Requirements may be excluded where they do not apply — but only with a reason stated in the scope (cl. 4.3).

Measuring equipment

Equipment whose results demonstrate conformity. It needs calibration, identification and traceability (cl. 7.1.5).

Surveillance audit

The yearly audit between recertifications; it checks that the system is still applied effectively.

Stage 1 / Stage 2

The two steps of the certification audit: the document review and readiness assessment, then the check of the lived implementation on site.

8 Your next step

You have read this guide — that is the first step already. Implementing ISO 9001 in a structured way gives you the proof customers and procurement offices want to see — and, along the way, processes that hold even without an audit.

A free first conversation

In a 30-minute call, with no obligation, we work out together:

- ✓ How far are your processes already written down?
- ✓ How large is the delta to the 2026 edition?
- ✓ Does design belong in your scope?
- ✓ What timeframe and what budget are realistic?

No sales pitch, no pressure — just an honest assessment.

The ISO 9001 quick check

On **iso-easy.de** you can test your maturity in 3 minutes and get a first assessment — without leaving any contact details.

Contact

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iso-easy is part of notivia GmbH.

With more than 30 years in process and quality consulting we support mid-sized companies in implementing ISO 9001, ISO 27001, EN 9100 and neighbouring standards — practical, transparent and as equals.

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