

FREE RESOURCE

# Passing your ISO 9001 audit as an SME



The checklist that covers everything, without swallowing a full-time job.

Written for manufacturing SMEs: machine shops, mechanical subcontractors, fabrication.

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**Pierre Séré**

Founder — Asterion Solutions

[solutions-asterion.com](https://solutions-asterion.com)

## FREE RESOURCE

An ISO 9001 audit is not won during audit week. It is won all year, in the way evidence gets built as the work happens.

This checklist walks through, clause by clause, what your auditor will **actually** ask for — and what you need within reach to answer in minutes instead of digging through binders. Tick what is in place: whatever stays blank is your action plan.

### 1 The documentation base

§7.5 — Documented information

- ☐ A quality policy that is written, dated, signed by management, and **known** by the team (auditors often ask a random employee).
- ☐ A current manual or description of the quality system — even a light one: what matters is that it matches shop reality.
- ☐ Procedures for key processes available where the work happens, not only in a drawer.
- ☐ Version control: everyone knows which version is current, and older ones are withdrawn or clearly marked.
- ☐ Records retention and protection: you know **where** they are, **who** can change them, and how long you keep them.

### 2 Process mapping

§4.4 — Process approach

- ☐ Company processes are identified: sales, production, inspection, purchasing, shipping.
- ☐ Their **interactions** are described: who feeds whom, with what data.
- ☐ Every process has a named owner.
- ☐ Indicators exist for critical processes — and are actually monitored, not merely defined.

### 3 Management review

§9.3

- ☐ A management review took place within the **last 12 months**.
- ☐ The **inputs** (§9.3.2) are covered: status of previous actions, changes, quality performance, non-conformities, customer feedback, audits, risks, resources.
- ☐ The **outputs** (§9.3.3) are recorded: improvement decisions, resource needs, changes to the system.
- ☐ A **dated, retained record** exists — this is the direct evidence the auditor will check.

## 4

### Non-conformities and corrective actions

§8.7 and §10.2

- ☐ Non-conformities are **recorded** (non-conforming product, complaint, process deviation) and not quietly fixed.
- ☐ Each non-conformity is tied to the **process** that produced it.
- ☐ Where warranted, a **corrective action** is opened, linked to the non-conformity, with an owner and a due date.
- ☐ You verify the corrective action's **effectiveness**: not just "done", but "it has not come back".

**Classic trap.** Confusing correction (fixing the part) with corrective action (stopping it from happening again). Auditors know the difference, and this is where the finding usually lands.

## 5

### Risks and opportunities

§6.1

- ☐ Risks that could affect conformity are identified: single-source supplier, loss of a key skill, critical machine breakdown.
- ☐ Actions against those risks are planned and followed up.

## 6

### Metrology and measuring equipment

§7.1.5

- ☐ The list of instruments used for inspection is current.
- ☐ Every instrument has a known, **valid calibration status**.
- ☐ You can **prove** calibration: certificates are available quickly.
- ☐ You can link an instrument to the **parts it measured** — essential the day an instrument turns up out of tolerance.

## 7

### Release of products

§8.6

- ☐ Nothing ships until the **planned verifications** are complete **and documented**.
- ☐ There is a record of **who authorised release**: the inspection report is a deliverable, not a formality.

- ☐ An internal audit programme exists and is followed.
- ☐ Internal audits are carried out by **objective** people: nobody audits their own work.
- ☐ Findings from internal audits lead to actions.

#### THE COLD TEST

## The three questions auditors almost always ask

Answer all three in under five minutes each and your system is standing on its own.

### 1 "Show me the calibration certificate for the instrument that released this part, shipped eight months ago."

More than five minutes of searching means your traceability has a hole. What is being tested is not the certificate — it is the link between instrument and measurement.

### 2 "This non-conformity — what did you do so it would not come back?"

Correction is not enough. They expect the corrective action and its effectiveness check, with a date.

### 3 "Where is the record of your last management review?"

No dated record means clause §9.3.3 is not met. There is no arguing that one.

## The real subject: building evidence as the work happens

The difference between an audit that feels like an ordeal and one that goes smoothly has nothing to do with shop-floor skill. It comes down to one thing: does the evidence build itself at the moment of inspection, or must it be reconstructed in a panic the night before?

A report produced as the measurement is taken, a non-conformity recorded the moment it occurs: that is what turns an audit into a formality. **Everything else is paperwork played catch-up.**



We build trade software for Quebec manufacturing SMEs: inspection reports, quality management, instrument fleets. The goal is never to add paperwork — it is to make evidence the automatic by-product of work done properly.