

# ISO 9001 HEALTHCARE CERTIFICATION CHECKLIST

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For hospitals, clinics, labs & healthcare organizations preparing for ISO 9001 audit in 2026

**How to use this checklist:** Work through each section before your external audit. Check off every item your team has completed. Any unchecked item is a gap that needs to be closed before you bring in a certification body. Share it with your quality management representative and department leads.

## 1. Leadership & Quality Policy

- ☐ Top management has formally committed to ISO 9001 and communicated it to all staff.  
*This must be documented, not verbal. Email announcements alone do not count.*
- ☐ A written quality policy exists that reflects your organization's patient care goals.  
*Generic templates will not pass. It must reference what your organization specifically does.*
- ☐ One person has been formally appointed as Quality Management Representative.  
*Not a committee. One named individual with documented authority and accountability.*
- ☐ Quality objectives are defined, measurable, and tied to patient care outcomes.  
*Examples: reduce patient complaint resolution time to 48 hrs; cut documentation errors by 20%.*
- ☐ Leadership conducts formal management reviews on a scheduled basis.  
*Ad hoc conversations do not count. Reviews must be documented with dates and attendees.*

## 2. Process Documentation & Document Control

- ☐ All core patient care processes are mapped and documented in writing.  
*Includes: patient intake, registration, treatment handoffs, discharge, and follow-up care.*
- ☐ A document control system is in place to manage versions and approvals.  
*Staff must always work from the current version. Outdated documents must be removed from circulation.*
- ☐ Documented procedures exist for how records are created, stored, and retrieved.  
*Paper and digital records both count. HIPAA alignment should be verified at this step.*
- ☐ Staff know where to find current procedures and how to flag outdated ones.  
*If your team is still emailing PDFs, this is likely a gap worth addressing before audit.*
- ☐ External documents such as regulatory guidelines are controlled and kept current.  
*Includes CDC guidelines, CMS requirements, and any accreditation standards your facility follows.*

## 3. Patient & Stakeholder Focus

- ☐ A formal process exists to capture patient feedback, complaints, and satisfaction data.  
*Surveys, comment cards, and portal feedback all qualify. Results must be tracked and actioned.*
- ☐ Patient complaints are logged, investigated, and resolved within a defined timeframe.  
*Auditors will look for evidence that complaints lead to action, not just acknowledgment.*
- ☐ Staff understand who your key stakeholders are beyond direct patients.  
*Include referring physicians, insurers, regulatory bodies, and community partners.*
- ☐ Stakeholder requirements are reviewed periodically and reflected in quality objectives.  
*What insurers require today may differ from 12 months ago. Schedule this as a recurring review.*

#### 4. Risk Management & Opportunity Planning

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- ☐ A risk register exists identifying operational risks specific to your healthcare setting.  
*Clinical risks belong in your patient safety framework. ISO 9001 focuses on process and operational risks.*
- ☐ Each identified risk has an owner, a likelihood rating, and a documented mitigation plan.  
*A list of risks without assigned owners is not a risk management system.*
- ☐ Opportunities for improvement are documented alongside risks.  
*ISO 9001 requires both. Examples: streamlining telehealth intake, reducing check-in wait time.*
- ☐ Risk review is built into your regular management review cycle.  
*Risks should be revisited at every management review, not just at the start of the year.*

#### 5. Staff Competency & Training Records

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- ☐ Job competency requirements are documented for every role that affects quality.  
*Includes front desk staff, billing teams, and coordinators, not just clinical personnel.*
- ☐ Training records are current, complete, and accessible for all staff members.  
*Auditors will ask to see these. If they live in a folder no one can find, that is a finding.*
- ☐ New staff follow a documented onboarding process tied to your quality management system.  
*This is what prevents the 'ask Sarah' problem. Every new hire should follow the same steps.*
- ☐ Staff understand how their individual role contributes to ISO 9001 compliance.  
*Awareness is a specific ISO 9001 requirement. General training sessions do not satisfy it.*
- ☐ Ongoing training needs are reviewed and scheduled at least annually.  
*Especially important when processes change, new technology is introduced, or incidents occur.*

#### 6. Internal Audits

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- ☐ An internal audit schedule covers all departments and processes without exception.  
*Audits cannot only happen in easy departments. All areas must be covered within the audit cycle.*
- ☐ Internal auditors are trained and are not auditing their own work.  
*Objectivity is a core requirement. A nurse cannot audit the nursing department they work in.*

- ☐ Internal audit findings are documented with corrective action owners and deadlines.  
*Finding a gap without assigning a deadline to fix it will become a non-conformance at external audit.*
- ☐ All findings from previous audit cycles have been reviewed and verified as closed.  
*Open findings from prior cycles will be the first thing an external auditor looks for.*

## 7. Corrective Actions & Continual Improvement (CAPA)

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- ☐ A formal process exists for logging non-conformances when processes fail or fall short.  
*This applies to near-misses too, not just fully documented failures.*
- ☐ Root cause analysis is performed for every significant non-conformance.  
*Correcting the symptom without identifying the root cause will result in repeat failures.*
- ☐ Corrective actions are assigned, tracked, and verified as effective after closure.  
*Effectiveness verification is often missed. Closing a CAPA does not automatically mean the problem is solved.*
- ☐ Trends in non-conformances are reviewed to identify systemic or recurring issues.  
*Three separate incidents in the same department are a pattern, not a coincidence.*
- ☐ Improvement initiatives are documented and tied back to measurable quality objectives.  
*Improvement must be intentional and measurable, not anecdotal or informal.*

## 8. Supplier & Vendor Management

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- ☐ A list of critical suppliers and external service providers is maintained and current.  
*Includes medical supply vendors, lab contractors, IT providers, and facility services.*
- ☐ Criteria for evaluating and selecting suppliers are documented before procurement.  
*Price alone is not a quality criterion. Documented evaluation processes are required.*
- ☐ Supplier performance is reviewed periodically against defined quality requirements.  
*At minimum, annual reviews should be documented with outcomes clearly recorded.*
- ☐ Non-performing suppliers have documented corrective actions or documented replacement decisions.  
*If a supplier consistently fails and nothing changes, auditors will flag this as a systemic gap.*

## 9. Pre-Audit Readiness

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- ☐ A mock internal audit has been completed within the last 90 days.  
*Self-assessments done too far in advance do not reflect current readiness.*
- ☐ All documentation is organized and retrievable within minutes, not hours.  
*Auditors work on a tight schedule. If you cannot produce a document quickly, that is a finding.*
- ☐ Staff have been briefed on what to expect during the external auditor's visit.  
*Staff who panic or give inconsistent answers during auditor interviews create unnecessary risk.*
- ☐ All open CAPAs, internal audit findings, and management review actions are closed or have escalation plans.  
*Going into your external audit with unresolved items from prior cycles is entirely avoidable.*

☐

Your certification body has been selected, contracted, and the audit date is confirmed.

*Allow adequate time between your last internal audit close-out and the external audit date.*

### Ready to manage all of this in one place?

P3 LogiQ centralizes your ISO 9001 documentation, internal audits, CAPA tracking, risk management, and training records so nothing falls through the cracks — before, during, or after your certification audit.

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