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ISO 9001 Internal Audit Checklist

Clause-by-clause audit questions built around what certification auditors actually probe - for internal audits, surveillance prep, and pre-certification readiness.

ORGANIZATION	AUDIT SCOPE / PROCESS	AUDITOR(S)	DATE

How to Use This Checklist

An internal audit checklist is only as good as the questions on it. The checklists that don't work ask whether something exists rather than whether it works. "Is there a quality policy?" checks a box. "Can the machine operator on second shift tell you what the quality policy means for their work?" tells you something useful.

Don't try to cover every question in one session. ISO 9001 lets you split your internal audit program across multiple sessions through the year, covering different clauses or processes in each. A focused two-hour audit of operations will find more real issues than a rushed full-day audit trying to cover everything. For every question, look for objective evidence - ask to see records, watch a process, walk the floor. The best findings come from comparing what the procedure says against what actually happens. Mark each item **Complying**, **Finding**, or **N/A**, and note the evidence you reviewed.

Clause 4: Context of the Organization

AUDIT QUESTION	STATUS	EVIDENCE / NOTES
Has the organization identified internal and external issues relevant to its purpose and strategic direction? Are these documented and reviewed?	☐ Complying ☐ Finding ☐ N/A	
Are interested parties identified with their relevant requirements? Does the organization monitor changes in interested-party expectations?	☐ Complying ☐ Finding ☐ N/A	
Is the QMS scope defined and documented, with any exclusions justified? Does it reflect the actual products, services, and sites covered?	☐ Complying ☐ Finding ☐ N/A	

Are QMS processes identified with their sequence and interaction defined? Can anyone in the organization explain how their process connects to the overall system?	☐ Complying ☐ Finding ☐ N/A	

Clause 5: Leadership

AUDIT QUESTION	STATUS	EVIDENCE / NOTES
Can top management demonstrate active involvement in the QMS - participating in reviews, allocating resources, removing obstacles - not just signing policies? When did leadership last discuss quality performance outside the annual management review?	☐ Complying ☐ Finding ☐ N/A	
Is the quality policy appropriate to the organization's purpose, and is it communicated, understood, and available?	☐ Complying ☐ Finding ☐ N/A	
Are roles, responsibilities, and authorities defined and communicated? In a small shop, can people tell you who is responsible for document control, nonconformity management, and customer communication - even if one person covers multiple roles?	☐ Complying ☐ Finding ☐ N/A	
Is customer focus evident throughout operations - customer requirements determined and met, risks to conformity addressed, customer satisfaction monitored?	☐ Complying ☐ Finding ☐ N/A	

AUDITOR'S TIP

Ask three people at different levels what the quality policy means for their work. If nobody can paraphrase it, the communication isn't working.

Clause 6: Planning

AUDIT QUESTION	STATUS	EVIDENCE / NOTES
Has the organization determined risks and opportunities that need to be addressed? A formal risk register isn't required, but there should be evidence that risks were identified and actions planned. Check management review minutes for risk discussions.	☐ Complying ☐ Finding ☐ N/A	

Are quality objectives established at relevant functions, levels, and processes? Are they measurable, monitored, and updated? Ask to see current objectives and the data showing progress.	☐ Complying ☐ Finding ☐ N/A	
When QMS changes are planned, does the organization consider the purpose of the change, potential consequences, resource needs, and responsibility assignments? Look for recent examples - a new product, a process change, a supplier switch.	☐ Complying ☐ Finding ☐ N/A	

> **AUDITOR'S TIP**
> If the objectives haven't changed in three years and nobody tracks them between reviews, that's a finding.

Clause 7: Support

AUDIT QUESTION	STATUS	EVIDENCE / NOTES
Are adequate resources provided - people, infrastructure, work environment, monitoring equipment? Is monitoring and measuring equipment calibrated or verified at specified intervals?	☐ Complying ☐ Finding ☐ N/A	
Is organizational knowledge determined, maintained, and made available? What happens when your most experienced employee retires - is critical process knowledge documented or trapped in one person's head?	☐ Complying ☐ Finding ☐ N/A	
Are competence requirements defined for positions affecting quality, with evidence of competence evaluation beyond training records alone? If someone completed training but quality problems persist in their work, how is the gap addressed?	☐ Complying ☐ Finding ☐ N/A	
Beyond the policy, are people aware of the quality objectives relevant to their work, how they contribute to the effectiveness of the QMS, and what it means when requirements aren't followed? Ask an operator what a nonconformity in their area would mean downstream.	☐ Complying ☐ Finding ☐ N/A	
Are internal and external communication processes defined? Is documented information controlled - created, updated, version-managed, and retained appropriately?	☐ Complying ☐ Finding ☐ N/A	

AUDITOR'S TIP

Pull the calibration log. Check whether calibrations are current and whether out-of-tolerance conditions triggered a review of affected products.

Clause 8: Operation

AUDIT QUESTION	STATUS	EVIDENCE / NOTES
Are operational processes planned and controlled, with criteria established for processes and product acceptance? Do work instructions, job travelers, and inspection plans match the processes actually being performed?	☐ Complying ☐ Finding ☐ N/A	
Are customer requirements determined and reviewed before commitment? Check a sample of recent orders: was the print reviewed, were tolerances confirmed, were material requirements verified, and is there a record of that review?	☐ Complying ☐ Finding ☐ N/A	
When customer requirements change - an amended purchase order, a print revision, a quantity or delivery change - is the change communicated to affected people, and are documents and records updated? Trace a recent order amendment through the shop.	☐ Complying ☐ Finding ☐ N/A	
If design and development is in scope: are inputs, outputs, reviews, verification, validation, and change controls documented? If excluded: is the exclusion justified, and is the organization truly not performing design? Modifying a customer's design, selecting materials, or developing custom tooling may constitute design.	☐ Complying ☐ Finding ☐ N/A	
Are external providers evaluated, selected, and monitored? Is there an approved supplier list, and when was it last updated? Trace a recent purchase order from supplier evaluation through receiving inspection to production use.	☐ Complying ☐ Finding ☐ N/A	
Is product identification and traceability maintained under controlled conditions? Pick a finished part: can you trace it back to its raw material, the machine, the operator, and the inspection results?	☐ Complying ☐ Finding ☐ N/A	
Is property belonging to customers or external providers - material, tooling, fixtures, returnable packaging, drawings, and intellectual property - identified, verified, protected, and reported to the owner if lost, damaged, or found unsuitable?	☐ Complying ☐ Finding ☐ N/A	

Are outputs preserved through production and delivery - handling, packaging, storage conditions, contamination and damage control? Walk the storage areas: is anything unidentified, expired, or deteriorating?	☐ Complying ☐ Finding ☐ N/A	
Where post-delivery activities apply - warranty, maintenance, returns, service obligations - are they defined and controlled, considering customer requirements, product risk, and feedback?	☐ Complying ☐ Finding ☐ N/A	
Are changes to production or service provision - process changes, equipment moves, alternate methods or materials - reviewed and controlled, with records showing what was evaluated and who authorized the change?	☐ Complying ☐ Finding ☐ N/A	
Are products and services released against defined acceptance criteria, with records providing evidence of conformity and traceability to the person(s) authorizing release? Pull recent release records: can you identify who released the last shipment?	☐ Complying ☐ Finding ☐ N/A	
Are nonconforming outputs identified and controlled, with a documented disposition process (rework, scrap, customer concession)? Check the nonconformance log and verify recent entries were dispositioned and closed.	☐ Complying ☐ Finding ☐ N/A	

AUDITOR'S TIP

Contract review is the most commonly missed documentation step in small manufacturing. Sample recent orders first.

Clause 9: Performance Evaluation

AUDIT QUESTION	STATUS	EVIDENCE / NOTES
What is the organization monitoring and measuring? How is customer satisfaction tracked - delivery performance trends, complaint data, return rates, repeat business, not just surveys? Is the data analyzed and used to drive decisions?	☐ Complying ☐ Finding ☐ N/A	
Is the internal audit program planned to cover the full QMS scope, with auditors who are objective and impartial (not auditing their own work)? Review the schedule, recent reports, and corrective actions from findings.	☐ Complying ☐ Finding ☐ N/A	

Is monitoring data actually analyzed and evaluated - conformity of products and services, customer satisfaction, QMS performance, supplier performance, and effectiveness of actions taken on risks - with results feeding management review?	☐ Complying ☐ Finding ☐ N/A	
Has management review been conducted with the full set of required inputs - status of previous actions, changes in internal and external issues, customer satisfaction and feedback, objectives progress, process performance, nonconformities and corrective actions, audit results, supplier performance, resource adequacy, effectiveness of risk actions, and improvement opportunities? Are outputs documented with decisions and action items, and were action items from the previous review actually completed?	☐ Complying ☐ Finding ☐ N/A	

> **AUDITOR'S TIP**
> If every audit report says "no findings," that's a red flag. It usually means the audit wasn't thorough enough, not that the system is perfect.

Clause 10: Improvement

AUDIT QUESTION	STATUS	EVIDENCE / NOTES
Is there evidence of continual improvement activities - corrective action trends, process improvements, objective achievements, management review outputs? The standard expects an active improvement cycle, not a wish list.	☐ Complying ☐ Finding ☐ N/A	
Is there a documented corrective action process? Pull recent corrective actions: was the root cause identified (not just the symptom), was the action appropriate to the cause, was effectiveness verified, and are similar nonconformities recurring?	☐ Complying ☐ Finding ☐ N/A	
Are corrective actions closed in a timely manner? Open corrective actions older than 90 days without documented progress are a common audit finding.	☐ Complying ☐ Finding ☐ N/A	

Red Flags That Signal Deeper Issues

Individual findings matter, but patterns across findings often reveal systemic issues worth investigating:

PATTERN	SEEN?	NOTES
The same corrective action keeps getting raised at consecutive audits with different wording but the same underlying problem. Root cause analysis isn't going deep enough.	☐ Yes ☐ No	
Training records exist for everyone but nobody can explain what they learned. Training is a compliance exercise, not a competence-building tool.	☐ Yes ☐ No	
The quality manual was last revised years ago while product lines, suppliers, and departments have changed. System documentation has drifted from reality.	☐ Yes ☐ No	
Management review minutes show the same objectives being "continued" year after year with no progress discussion. Leadership engagement is superficial.	☐ Yes ☐ No	
Calibration records are current but nobody has evaluated what happens to products measured with out-of-tolerance equipment. The process is followed without understanding its purpose.	☐ Yes ☐ No	

Findings Summary

#	CLAUSE	FINDING DESCRIPTION	TYPE (NC / OFI)	OWNER	TARGET CLOSE DATE
1					
2					
3					
4					
5					
6					

Customize this checklist to your operation. Add questions specific to your industry, processes, and known risk areas; remove questions outside your scope. The best internal audit programs evolve - each cycle should refine the questions based on what you found (or didn't find) last time.

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