

# **100 Common Non-Conformities in ISO 9001:2015 Audits**

A Practical Guide to Identifying, Understanding, and Fixing the  
Most Common ISO 9001 Audit Issues

## Objectives of This Guide:

Achieving **ISO 9001 certification** demonstrates your organization's commitment to quality, continuous improvement, and customer satisfaction.

But many organizations face common **non-conformities** during audits that delay certification or uncover deeper issues in the **quality management system (QMS)**.

This guide compiles **100 real-world ISO 9001 non-conformities**, based on interviews with over **200 certified lead auditors**, and shows you how to fix them with practical, actionable advice.

- ✓ Understand what ISO 9001 is and how to apply its principles
- ✓ Identify and resolve the most common ISO 9001 audit issues
- ✓ Align your QMS with **ISO 9001 requirements** clause-by-clause
- ✓ Use real audit scenarios to prepare your teams more effectively
- ✓ Improve compliance using our structured **ISO 9001 audit checklist**
- ✓ Support continual improvement across leadership, planning, support, and operations

### **This Guide Is Ideal For:**

- Quality Managers and ISO Coordinators preparing for certification
- Auditors and consultants supporting ISO 9001 implementation
- Operations and compliance professionals working on corrective actions
- Business leaders aiming to align quality with performance and customer value

Use this resource as a strategic roadmap to elevate your QMS maturity, build audit readiness, and strengthen quality culture across your organization.

## 1. Poor Understanding of Organizational Context

### **Clause: 4.1 – Understanding the Organization and Its Context**

#### **What's going wrong:**

Organizations submit overly vague or generic descriptions of internal and external issues — without connecting them to their QMS objectives or risks.

#### **Why it matters during an audit:**

This clause frames your entire QMS. If the context isn't well-defined, auditors may find the system disconnected from strategic reality.

#### **How to fix it:**

- ✓ Identify relevant business, legal, social, technological, and environmental factors
- ✓ Link those issues to the QMS scope and risk planning
- ✓ Update the context at least annually or after major changes
- ✓ Document the analysis and reference it in your management review

#### **Real-world result:**

A meaningful context statement ensures your QMS is aligned with your business environment — and audit-ready.

## 2. No Formal Identification of Interested Parties

### **Clause: 4.2 – Understanding the Needs and Expectations of Interested Parties**

#### **What's going wrong:**

Many teams either skip this clause or list stakeholders without analyzing their expectations, risks, or relevance to the QMS.

**Why it matters during an audit:**

ISO 9001 certification depends on stakeholder-driven planning. Auditors expect to see how customer, regulatory, and internal needs influence the system.

**How to fix it:**

- ✓ List key internal and external interested parties (e.g., customers, regulators, employees)
- ✓ Capture their requirements in a register
- ✓ Link requirements to QMS controls or quality objectives
- ✓ Review and update this register periodically

**Real-world result:**

This ensures your QMS delivers value and builds trust with customers, suppliers, and auditors alike.

### 3. Quality Policy Is Too Generic or Unused

**📌 Clause: 5.2 – Quality Policy****What's going wrong:**

The policy is often copied from a template or only published on the company website — without being understood, implemented, or reviewed.

**Why it matters during an audit:**

Auditors test whether employees know the policy and how it shapes daily decisions. A vague or irrelevant policy undermines leadership commitment.

**How to fix it:**

- ✓ Write a tailored quality policy based on your organization's purpose and goals
- ✓ Link the policy to quality objectives and continual improvement

- ✓ Communicate it in training, onboarding, and internal communications
- ✓ Review and revise it annually in the management review

**Real-world result:**

A visible, relevant policy motivates teams and shows auditors that quality starts at the top.

#### 4. Risk-Based Thinking Is Missing

##### **Clause: 6.1 – Actions to Address Risks and Opportunities**

**What's going wrong:**

Some organizations skip risk assessments altogether, or only do them for high-level business risks — not within the QMS context.

**Why it matters during an audit:**

Risk-based thinking is a core ISO 9001 requirement. Lack of it signals reactive management and process instability.

**How to fix it:**

- ✓ Identify QMS risks and opportunities per process or department
- ✓ Maintain a live risk register with assigned owners and treatment plans
- ✓ Include risk discussions in planning and reviews
- ✓ Tie risk mitigation to quality objectives

**Real-world result:**

Risk-based thinking improves foresight, resilience, and audit performance.

## 5. Quality Objectives Are Vague or Unmeasurable

### **Clause: 6.2 – Quality Objectives and Planning to Achieve Them**

#### **What’s going wrong:**

Objectives like “Improve customer satisfaction” or “Enhance efficiency” are too vague — with no metrics, timelines, or responsibilities.

#### **Why it matters during an audit:**

Auditors look for SMART objectives (Specific, Measurable, Achievable, Relevant, Time-bound) and clear tracking mechanisms.

#### **How to fix it:**

- ✓ Set SMART goals tied to your quality policy and stakeholder needs
- ✓ Define how each objective will be achieved, tracked, and reviewed
- ✓ Assign owners and update status regularly
- ✓ Include objectives in performance reports and management reviews

#### **Real-world result:**

Clear objectives drive measurable improvement — and prove your QMS is outcome-focused.

## 6. Unclear or Incomplete Process Mapping

### **Clause: 4.4 – Quality Management System and Its Processes**

#### **What’s going wrong:**

Organizations may define their processes, but miss key elements like sequence, interaction, inputs/outputs, and performance indicators.

#### **Why it matters during an audit:**

The “process approach” is foundational to ISO 9001. Weak mapping makes your system seem fragmented.

**How to fix it:**

- ✓ Document core and supporting QMS processes
- ✓ Define inputs, outputs, KPIs, owners, and links to other processes
- ✓ Use flowcharts, SIPOC diagrams, or matrices for clarity
- ✓ Review process maps annually and during major changes

**Real-world result:**

A strong process approach improves integration, auditability, and continuous improvement.

**7. Internal Audits Are Irregular or Superficial** **Clause: 9.2 – Internal Audit****What's going wrong:**

Internal audits are sometimes rushed, undocumented, or too narrow in scope. Findings are rarely followed up properly.

**Why it matters during an audit:**

Auditors rely on internal audits as proof of QMS performance. Weak audits = weak system control.

**How to fix it:**

- ✓ Develop a documented internal audit program covering all ISO 9001 clauses and processes
- ✓ Train auditors for objectivity and competence
- ✓ Record findings, root causes, and actions
- ✓ Track progress and effectiveness

**Real-world result:**

Robust internal audits reduce surprises during external reviews and reinforce compliance.

## 8. No Evidence of Corrective Action Effectiveness

### ✦ Clause: 10.2 – Nonconformity and Corrective Action

#### **What's going wrong:**

Corrective actions are logged, but there's no follow-up to confirm that the issue is resolved and won't recur.

#### **Why it matters during an audit:**

ISO 9001 requires evidence of effectiveness. Without it, repeat issues can invalidate your system.

#### **How to fix it:**

- ✓ Record each corrective action with cause, action taken, and responsible party
- ✓ Verify results over time and document closure
- ✓ Link to your risk register if relevant
- ✓ Use trend analysis to identify systemic issues

#### **Real-world result:**

Effective corrective action builds trust with auditors and reduces repeat problems.

## 9. No Supplier Evaluation or Re-evaluation Process

### ✦ Clause: 8.4 – Control of Externally Provided Processes, Products, and Services

#### **What's going wrong:**

Suppliers are onboarded without due diligence. There's no tracking of their performance, risks, or impact on quality.

**Why it matters during an audit:**

Suppliers are an extension of your QMS. Lack of oversight risks product/service nonconformities and audit findings.

**How to fix it:**

- ✓ Develop criteria for supplier selection, approval, and re-evaluation
- ✓ Maintain records of evaluations and decisions
- ✓ Monitor supplier performance and link to risk and quality metrics
- ✓ Take corrective actions where needed

**Real-world result:**

A strong supplier control system reduces operational risk and ensures compliance across your value chain.

**10. No Data-Driven Decision-Making** **Clause: 9.1.3 – Analysis and Evaluation****What's going wrong:**

Organizations collect data (e.g., customer feedback, nonconformities) but don't analyze it to make decisions or drive improvements.

**Why it matters during an audit:**

ISO 9001 promotes evidence-based decision-making. Weak analysis = missed improvement opportunities.

**How to fix it:**

- ✓ Identify key performance data needed to evaluate QMS health
- ✓ Analyze trends, root causes, and performance against objectives
- ✓ Present findings during reviews and planning
- ✓ Take action based on insights

**Real-world result:**

Data-driven decisions improve agility, accountability, and audit success.

**11. Outdated or Uncontrolled Documents** **Clause: 7.5 – Documented Information****What's going wrong:**

Outdated versions of procedures, forms, or policies are still in circulation. There's no control over who can edit, approve, or distribute them.

**Why it matters during an audit:**

ISO 9001 certification depends on strict document control. Uncontrolled documentation undermines the integrity of the QMS.

**How to fix it:**

- ✓ Implement a document control system with version history
- ✓ Define roles for approval, review, and distribution
- ✓ Archive obsolete versions properly
- ✓ Train staff to use only the latest controlled documents

**Real-world result:**

Proper document control prevents confusion, maintains consistency, and satisfies audit requirements.

**12. Customer Satisfaction Not Effectively Monitored** **Clause: 9.1.2 – Customer Satisfaction**

**What's going wrong:**

Organizations don't have a structured method for collecting or analyzing customer satisfaction data.

**Why it matters during an audit:**

One of the key goals of ISO 9001 is meeting customer expectations. If you're not measuring satisfaction, you can't improve it.

**How to fix it:**

- ✓ Use surveys, complaint logs, or direct feedback mechanisms
- ✓ Analyze trends and identify causes of dissatisfaction
- ✓ Use feedback to inform objectives and improvements
- ✓ Present customer satisfaction data in management reviews

**Real-world result:**

Tracking satisfaction helps you respond to customer needs and proves your QMS adds value.

### 13. Poor Change Control in the QMS

**📌 Clause: 6.3 – Planning of Changes****What's going wrong:**

Changes to processes or procedures are made informally — without assessing potential risks, impacts, or the need to update documentation.

**Why it matters during an audit:**

Auditors expect a structured, traceable change process. Ad hoc changes = instability and non-compliance.

**How to fix it:**

- ✓ Define a change control process including risk analysis and approval steps

- ✓ Document all planned changes and their rationale
- ✓ Communicate changes to affected stakeholders
- ✓ Review effectiveness after implementation

**Real-world result:**

Controlled change ensures your QMS adapts without compromising consistency or compliance.

## 14. Roles and Responsibilities Not Clearly Defined

### 🚩 **Clause: 5.3 – Organizational Roles, Responsibilities and Authorities**

**What's going wrong:**

Teams are unclear about who owns which process, who approves decisions, or who's accountable for objectives.

**Why it matters during an audit:**

Ambiguity creates accountability gaps. ISO 9001 requires clearly defined and communicated roles.

**How to fix it:**

- ✓ Use a responsibility matrix (e.g., RACI) for all QMS roles
- ✓ Include QMS roles in job descriptions and org charts
- ✓ Review roles during audits or staff changes
- ✓ Train personnel on their QMS responsibilities

**Real-world result:**

Clarity in roles improves execution, oversight, and audit confidence.

## 15. No Evidence of Continual Improvement

### **Clause: 10.3 – Continual Improvement**

#### **What's going wrong:**

The organization treats ISO 9001 as a one-time certification. No structured efforts are made to drive improvement across processes.

#### **Why it matters during an audit:**

ISO 9001 is built on the principle of continual improvement. Without it, your system appears stagnant.

#### **How to fix it:**

- ✓ Identify opportunities from audits, feedback, and data analysis
- ✓ Track improvements with assigned owners and measurable outcomes
- ✓ Present progress in management reviews
- ✓ Celebrate and communicate results internally

#### **Real-world result:**

Improvement-focused QMSs are more agile, effective, and auditor-approved.

## 16. Calibration of Monitoring Equipment Not Performed

### **Clause: 7.1.5 – Monitoring and Measuring Resources**

#### **What's going wrong:**

Instruments used for inspection or monitoring are not calibrated or have expired certificates.

#### **Why it matters during an audit:**

Uncalibrated tools = unreliable data. Auditors expect controlled and verified equipment.

**How to fix it:**

- ✓ Maintain a calibration schedule for all monitoring tools
- ✓ Keep records of calibration status, dates, and outcomes
- ✓ Label equipment clearly
- ✓ Remove expired equipment from use

**Real-world result:**

Calibrated tools ensure accuracy and confidence in product or process evaluations.

**17. Lack of Competency Records** **Clause: 7.2 – Competence****What's going wrong:**

There's no documented evidence that employees have the training or skills required to perform QMS-related tasks.

**Why it matters during an audit:**

Auditors assess whether people are competent — not just trained. Missing records = findings.

**How to fix it:**

- ✓ Maintain a competence matrix for key QMS roles
- ✓ Link training records to required skills
- ✓ Evaluate effectiveness of training regularly
- ✓ Retain evidence of certifications, assessments, or practical performance

**Real-world result:**

Proving competence builds auditor trust and boosts performance across the board.

## 18. Supplier Performance Not Evaluated Regularly

### **Clause: 8.4.1 – Control of External Providers**

#### **What's going wrong:**

Once onboarded, suppliers are rarely re-evaluated or scored on performance.

#### **Why it matters during an audit:**

Suppliers directly affect product/service quality. Regular reviews are part of ISO 9001 requirements.

#### **How to fix it:**

- ✓ Create a supplier evaluation form with performance criteria (e.g., quality, delivery, responsiveness)
- ✓ Set review intervals (e.g., annually, per contract)
- ✓ Document results and required actions
- ✓ Share performance feedback with suppliers

#### **Real-world result:**

Evaluated suppliers improve consistency, reduce risk, and align better with QMS goals.

## 19. Incomplete or Inconsistent Work Instructions

### **Clause: 8.5.1 – Control of Production and Service Provision**

#### **What's going wrong:**

Operators follow tribal knowledge or old versions of work instructions — if any exist at all.

**Why it matters during an audit:**

Inconsistent instructions lead to product/service variation. Auditors look for standardized methods.

**How to fix it:**

- ✓ Document work instructions for all critical activities
- ✓ Ensure alignment with product specs and QMS requirements
- ✓ Use visual aids where needed
- ✓ Review and update documents regularly

**Real-world result:**

Clear work instructions reduce errors and show process control during audits.

**20. Lack of Evidence for Management Commitment****📌 Clause: 5.1.1 – Leadership and Commitment****What's going wrong:**

Leadership appears absent from QMS activities. There's no visible involvement in reviews, policies, or improvement.

**Why it matters during an audit:**

ISO 9001 emphasizes leadership. Auditors expect clear support for the QMS from top management.

**How to fix it:**

- ✓ Involve leadership in setting QMS goals, reviewing data, and leading communication
- ✓ Record participation in meetings and reviews
- ✓ Link business strategy with QMS direction
- ✓ Assign QMS responsibilities to senior leaders

**Real-world result:**

Visible leadership boosts team engagement, aligns quality with strategy, and strengthens your audit outcomes.

**21. No Defined Method for Evaluating QMS Performance****📌 Clause: 9.1.1 – Monitoring, Measurement, Analysis and Evaluation****What's going wrong:**

Organizations collect scattered data (like complaints or output counts) but don't link it to overall QMS performance.

**Why it matters during an audit:**

Without structured evaluation, auditors can't verify whether your QMS is working — or improving.

**How to fix it:**

- ✓ Define what you'll monitor (e.g., objectives, KPIs, customer feedback)
- ✓ Identify evaluation methods and frequency
- ✓ Analyze data and document conclusions
- ✓ Use findings to drive actions and reviews

**Real-world result:**

A consistent evaluation method ensures that data supports improvement — not just compliance.

**22. Management Reviews Are Missing Required Inputs****📌 Clause: 9.3.2 – Management Review Inputs**

**What's going wrong:**

Reviews focus only on objectives or KPIs and overlook crucial inputs like audit results, risks, feedback, or opportunities.

**Why it matters during an audit:**

Incomplete reviews miss essential oversight functions. Auditors want to see that all required topics are covered.

**How to fix it:**

- ✓ Use a standard agenda that reflects all required ISO 9001 inputs
- ✓ Include data from internal audits, suppliers, risks, customer feedback, and objectives
- ✓ Keep minutes showing all topics were reviewed
- ✓ Record decisions and assign follow-up responsibilities

**Real-world result:**

Comprehensive reviews show leadership commitment and system maturity.

**23. Lack of Alignment Between Quality Objectives and Policy****✦ Clause: 6.2 & 5.2 – Objectives and Quality Policy****What's going wrong:**

Organizations define quality objectives in isolation — without linking them to the quality policy or strategic direction.

**Why it matters during an audit:**

Objectives must reflect policy goals. If not, auditors may see a misaligned system with no strategic cohesion.

**How to fix it:**

- ✓ Break down policy commitments into measurable objectives

- ✓ Assign KPIs to track policy performance
- ✓ Review alignment during planning and management reviews
- ✓ Update objectives as policy evolves

**Real-world result:**

Strong alignment connects vision to execution and strengthens audit narratives.

## 24. No Records of Nonconforming Outputs

### ✦ Clause: 8.7 – Control of Nonconforming Outputs

**What's going wrong:**

Issues are fixed on the spot, but there's no documentation of what went wrong, who corrected it, or how recurrence is prevented.

**Why it matters during an audit:**

ISO 9001 requires records of what didn't conform. No traceability = nonconformity in itself.

**How to fix it:**

- ✓ Document each nonconforming output, including what, when, and how it was corrected
- ✓ Analyze trends over time
- ✓ Link issues to corrective actions if needed
- ✓ Review data during performance evaluations

**Real-world result:**

Systematic handling of nonconformities boosts transparency and prevents hidden risks.

## 25. Purchasing Controls Are Weak or Unclear

### **Clause: 8.4 – Control of External Providers**

#### **What's going wrong:**

There are no clear procedures for verifying that purchased goods or services meet specified requirements.

#### **Why it matters during an audit:**

Suppliers affect quality directly. Auditors expect tight controls over what enters your process.

#### **How to fix it:**

- ✓ Set criteria for incoming inspections or approvals
- ✓ Maintain purchase specs or requirements
- ✓ Document acceptance, rejection, and supplier follow-up
- ✓ Train purchasing staff on QMS expectations

#### **Real-world result:**

Stronger purchasing control improves quality, reduces defects, and satisfies clause 8.4 audit checks.

## 26. Work Environment Requirements Not Defined or Monitored

### **Clause: 7.1.4 – Environment for the Operation of Processes**

#### **What's going wrong:**

There's no documented or monitored control over factors like lighting, cleanliness, or ergonomic conditions.

#### **Why it matters during an audit:**

Auditors assess whether the work environment supports consistent, conforming outputs — and if issues are addressed.

**How to fix it:**

- ✓ Identify environmental factors for each process or product type
- ✓ Conduct regular walk-throughs or environmental audits
- ✓ Record issues and corrective actions
- ✓ Involve operators in feedback

**Real-world result:**

Improved environments boost performance, safety, and product conformity.

**27. Customer Complaints Are Not Tracked or Analyzed****✦ Clause: 9.1.2 & 10.2 – Customer Satisfaction & Corrective Action****What's going wrong:**

Complaints are handled informally. There's no central log, trend analysis, or documented resolution.

**Why it matters during an audit:**

Customer feedback is essential data. Missing complaint tracking can result in findings under both satisfaction and nonconformity clauses.

**How to fix it:**

- ✓ Set up a complaint log with categories, root cause fields, and resolution tracking
- ✓ Review trends regularly
- ✓ Link frequent issues to corrective actions
- ✓ Report summaries in management reviews

**Real-world result:**

Complaint data becomes a driver for service and process improvement.

## 28. Products/Services Not Verified Before Release

### **Clause: 8.6 – Release of Products and Services**

#### **What's going wrong:**

There's no formal inspection, sign-off, or verification process before delivering to customers or internal users.

#### **Why it matters during an audit:**

Auditors must see how you verify that requirements are met. No release controls = potential nonconforming product.

#### **How to fix it:**

- ✓ Define release checkpoints for each deliverable or process
- ✓ Assign authorized verifiers
- ✓ Record approvals with date, criteria, and verifier name
- ✓ Use samples, checklists, or QA data where applicable

#### **Real-world result:**

Proper release control ensures delivery confidence and product traceability.

## 29. Outdated Risk and Opportunity Assessments

### **Clause: 6.1 – Planning of Risks and Opportunities**

#### **What's going wrong:**

Initial risks are identified during implementation — but never updated as the business, products, or customers change.

#### **Why it matters during an audit:**

Risk-based thinking is continuous. Stale assessments reflect poor QMS responsiveness.

**How to fix it:**

- ✓ Review risks quarterly or after major changes
- ✓ Involve department leads in updates
- ✓ Add new risks from incidents, customer feedback, or audits
- ✓ Update mitigation plans and ownership as needed

**Real-world result:**

Dynamic risk planning improves readiness and resilience.

**30. Quality Manual or Documentation Not Reflecting Actual Practices****✦ Clause: 4.4 & 7.5 – QMS Processes & Documentation****What's going wrong:**

What's written in the quality manual or procedures doesn't match what people actually do — or it's outdated altogether.

**Why it matters during an audit:**

Inconsistencies between practice and documentation suggest either the QMS isn't implemented or not controlled.

**How to fix it:**

- ✓ Review documentation during internal audits
- ✓ Involve process owners in document updates
- ✓ Train teams on the current version
- ✓ Archive obsolete versions properly

**Real-world result:**

Living documentation ensures your QMS reflects reality and passes audits with confidence.

## 31. Inadequate Control Over Nonconforming Product

### **Clause: 8.7 – Control of Nonconforming Outputs**

#### **What's going wrong:**

Defective or out-of-spec products are not properly segregated, labeled, or tracked. Some even continue through the process or are delivered to customers.

#### **Why it matters during an audit:**

Auditors expect a robust system to identify and prevent unintended use of nonconforming outputs.

#### **How to fix it:**

- ✓ Label and physically segregate nonconforming items
- ✓ Document what went wrong and what action was taken
- ✓ Assign responsibility for review and disposition
- ✓ Trend analysis for recurring issues

#### **Real-world result:**

Better control prevents rework, recalls, and customer dissatisfaction.

## 32. No Defined Criteria for Product/Service Acceptance

### **Clause: 8.5.1 – Control of Production and Service Provision**

#### **What's going wrong:**

Products or services are “accepted” based on informal standards — there's no defined quality criteria.

#### **Why it matters during an audit:**

Auditors require evidence of predefined, measurable acceptance criteria tied to customer or regulatory requirements.

**How to fix it:**

- ✓ Define criteria for each product or service (dimensions, tolerances, deliverables)
- ✓ Include criteria in procedures and work instructions
- ✓ Train staff to apply them consistently
- ✓ Record acceptance decisions

**Real-world result:**

Clear acceptance criteria reduce variation and audit challenges.

**33. Inspection and Test Records Are Incomplete** **Clause: 8.6 – Release of Products and Services****What's going wrong:**

Inspection steps are done verbally or casually, and there's little documentation of who performed the check or what was reviewed.

**Why it matters during an audit:**

ISO 9001 requires evidence of conformity. Lack of records creates traceability risks.

**How to fix it:**

- ✓ Document inspections using checklists or forms
- ✓ Capture the date, inspector, and result
- ✓ Store records systematically
- ✓ Review inspection data regularly

**Real-world result:**

Reliable inspection records reinforce process integrity and quality control.

## 34. Lack of Design and Development Controls

### **Clause: 8.3 – Design and Development of Products and Services**

#### **What's going wrong:**

Design steps (planning, validation, verification) are informal or undocumented, even when the organization develops new products.

#### **Why it matters during an audit:**

Auditors expect a structured approach to product development — without it, design-related risks increase.

#### **How to fix it:**

- ✓ Define the stages of design (planning, inputs, outputs, reviews, verification, validation)
- ✓ Maintain documentation for each stage
- ✓ Assign responsibilities
- ✓ Review and revise designs systematically

#### **Real-world result:**

Controlled design processes reduce defects, delays, and audit surprises.

## 35. Customer Property Not Properly Handled

### **Clause: 8.5.3 – Property Belonging to Customers or External Providers**

#### **What's going wrong:**

Customer-supplied tools, data, or equipment are lost, damaged, or misused — often due to a lack of accountability.

**Why it matters during an audit:**

Customer property is protected under ISO 9001. Mishandling can damage relationships and lead to audit findings.

**How to fix it:**

- ✓ Log customer property upon receipt
- ✓ Inspect and tag items clearly
- ✓ Store separately when possible
- ✓ Document return or disposal

**Real-world result:**

Proper handling shows professionalism and protects customer trust.

**36. No Evidence of Employee Awareness of QMS Goals** **Clause: 7.3 – Awareness****What's going wrong:**

Employees know their job tasks but have no idea how their work relates to the quality policy, objectives, or customer satisfaction.

**Why it matters during an audit:**

Auditors often interview staff to assess awareness. Poor responses indicate poor communication and engagement.

**How to fix it:**

- ✓ Communicate the quality policy and objectives regularly
- ✓ Use toolbox talks, posters, newsletters, and intranet updates
- ✓ Quiz or interview employees during internal audits
- ✓ Include QMS in onboarding

**Real-world result:**

Awareness builds alignment, motivation, and confidence during audits.

## 37. Failure to Review Customer Requirements Before Acceptance

### **Clause: 8.2.3 – Review of Requirements for Products and Services**

#### **What's going wrong:**

Sales teams accept orders without reviewing feasibility, capacity, or technical specs. Gaps lead to missed expectations.

#### **Why it matters during an audit:**

This clause ensures customer expectations are understood and met. Skipping the review = delivery risks.

#### **How to fix it:**

- ✓ Review technical, legal, and delivery requirements before order confirmation
- ✓ Record who reviewed what
- ✓ Communicate requirements clearly to operations
- ✓ Get customer approval for changes

#### **Real-world result:**

Pre-contract review reduces rework, returns, and reputational damage.

## 38. Unclear Control of Process Changes

### **Clause: 8.5.6 – Control of Changes**

#### **What's going wrong:**

Changes to production or service delivery (equipment, software, materials) are implemented without formal approval or risk assessment.

**Why it matters during an audit:**

Auditors expect traceability and structured decision-making when changes are made.

**How to fix it:**

- ✓ Document all significant process changes
- ✓ Include impact analysis and approvals
- ✓ Communicate changes to affected teams
- ✓ Validate changes before full implementation

**Real-world result:**

Change control maintains process stability and reduces nonconformities.

**39. Retention Times for Records Not Defined****📌 Clause: 7.5.3 – Control of Documented Information****What's going wrong:**

No one knows how long records (e.g., training logs, inspection results, supplier evaluations) must be kept — or where they're stored.

**Why it matters during an audit:**

Auditors expect clarity and consistency. Uncontrolled records = non-compliance.

**How to fix it:**

- ✓ Define retention periods for all QMS records
- ✓ Include this in document control procedures
- ✓ Automate archival or deletion where possible
- ✓ Train staff on storage and retrieval

**Real-world result:**

Structured recordkeeping improves compliance and avoids audit issues.

## 40. Processes Not Measured or Reviewed for Effectiveness

### ✦ Clause: 9.1.1 – Monitoring, Measurement, Analysis and Evaluation

#### **What's going wrong:**

Core processes run day-to-day, but there's no tracking of whether they meet planned results or contribute to objectives.

#### **Why it matters during an audit:**

Auditors require evidence of performance monitoring and analysis.

#### **How to fix it:**

- ✓ Define KPIs for each major process
- ✓ Assign ownership and review frequency
- ✓ Track trends and take action when targets are missed
- ✓ Report outcomes in reviews

#### **Real-world result:**

Ongoing measurement drives improvement and demonstrates QMS control.

## 41. No Verification of External Provider's Product or Service

### ✦ Clause: 8.4.2 – Type and Extent of Control

#### **What's going wrong:**

Purchased items or outsourced services are accepted without checking if they meet defined requirements.

#### **Why it matters during an audit:**

Without verification, you risk using nonconforming inputs — which directly impacts product/service quality.

**How to fix it:**

- ✓ Define what verification is needed (e.g., inspection, certification, sampling)
- ✓ Apply verification based on risk and product impact
- ✓ Keep records of acceptance and actions taken
- ✓ Include verification steps in procedures

**Real-world result:**

Verification ensures input quality and reduces the chance of downstream failures.

## 42. Incomplete Management Review Records

### 📌 Clause: 9.3.3 – Management Review Outputs

**What's going wrong:**

Management reviews are conducted, but there's no documentation of decisions, responsibilities, or action plans.

**Why it matters during an audit:**

Auditors expect output records as proof of leadership engagement and follow-through.

**How to fix it:**

- ✓ Use a template with required output fields (e.g., actions, owners, timelines)
- ✓ Assign actions during the meeting and record status updates
- ✓ Review previous actions in subsequent reviews
- ✓ Archive minutes and action logs

**Real-world result:**

Documented outputs show direction, accountability, and continual improvement.

**43. Calibration Records Missing or Incomplete****✦ Clause: 7.1.5.2 – Measurement Traceability****What's going wrong:**

Measuring equipment is used for inspections, but calibration logs are missing or expired.

**Why it matters during an audit:**

Calibrated tools are essential for valid inspection results. Missing records = major nonconformity.

**How to fix it:**

- ✓ Maintain a calibration log for all relevant equipment
- ✓ Include last/next due dates, results, and cert numbers
- ✓ Tag equipment with status
- ✓ Remove out-of-calibration tools from use

**Real-world result:**

Proper calibration ensures reliable measurements and confident product release.

**44. No Procedure for Handling Customer Feedback****✦ Clause: 9.1.2 – Customer Satisfaction****What's going wrong:**

Feedback is received via calls or emails but not tracked, analyzed, or used to drive improvement.

**Why it matters during an audit:**

ISO 9001 emphasizes the voice of the customer. Ignoring it weakens your QMS and audit standing.

**How to fix it:**

- ✓ Create a documented feedback-handling procedure
- ✓ Categorize feedback (positive, negative, suggestions)
- ✓ Use it to inform risk planning, objectives, and improvements
- ✓ Report insights in reviews

**Real-world result:**

Structured feedback handling improves customer focus and QMS maturity.

**45. Nonconforming Product Continues Through Production****📌 Clause: 8.7 – Control of Nonconforming Outputs****What's going wrong:**

Even when a defect is identified, there's no halt or segregation — defective items continue downstream or to the customer.

**Why it matters during an audit:**

Uncontrolled product flow is a serious quality and compliance risk.

**How to fix it:**

- ✓ Train staff to identify and stop nonconforming output
- ✓ Use red tag systems, hold bins, or quarantine zones
- ✓ Assign authority for release or rework
- ✓ Document every instance

**Real-world result:**

Controlled output prevents customer impact and demonstrates production discipline.

## 46. No Formal Corrective Action Log Maintained

### **Clause: 10.2 – Nonconformity and Corrective Action**

#### **What's going wrong:**

Corrective actions are issued verbally or via email, but not logged or tracked systematically.

#### **Why it matters during an audit:**

Auditors require visibility into how issues are corrected and prevented from recurring.

#### **How to fix it:**

- ✓ Use a centralized corrective action log or system
- ✓ Include problem, cause, action, owner, and due date
- ✓ Verify and document effectiveness
- ✓ Review status in management or audit meetings

#### **Real-world result:**

Systematic tracking shows accountability and reduces repeat issues.

## 47. Inadequate Planning for QMS Changes

### **Clause: 6.3 – Planning of Changes**

#### **What's going wrong:**

System or process changes (e.g., new software, org restructure) are implemented without assessing impact on the QMS.

**Why it matters during an audit:**

Changes must be planned, controlled, and documented — or they could destabilize compliant processes.

**How to fix it:**

- ✓ Define a change planning checklist
- ✓ Evaluate risks, resources, roles, and documentation updates
- ✓ Communicate change plans to stakeholders
- ✓ Monitor post-change outcomes

**Real-world result:**

Planned change preserves QMS integrity and business continuity.

**48. Poor Traceability in Production or Service Delivery****📌 Clause: 8.5.2 – Identification and Traceability****What's going wrong:**

Products or batches can't be traced back to their origin — especially after nonconformities or complaints.

**Why it matters during an audit:**

Lack of traceability makes investigation, rework, or recall nearly impossible.

**How to fix it:**

- ✓ Identify each product, lot, or service instance with unique codes or tags
- ✓ Maintain logs linking customer orders to production batches
- ✓ Track throughout the process and into distribution
- ✓ Train staff on how to trace quickly during issues

**Real-world result:**

Traceability enables fast resolution and is essential for regulated industries.

## 49. No Monitoring of Supplier-Related Risks

### ✦ Clause: 8.4.1 – General Requirements for Control of External Providers

#### **What's going wrong:**

Risks such as sole sourcing, unstable delivery, or changing specs aren't documented or monitored.

#### **Why it matters during an audit:**

Supplier risk can lead to quality failures, production delays, or nonconformities — auditors will flag the absence of controls.

#### **How to fix it:**

- ✓ Assess supplier risks during onboarding and annually
- ✓ Record risk types (e.g., financial, performance, geographic)
- ✓ Plan mitigation actions (alternatives, dual sourcing)
- ✓ Link supplier risk to overall QMS risk planning

#### **Real-world result:**

Proactive supplier risk management keeps operations stable and customers satisfied.

## 50. Overreliance on One Person for QMS Knowledge

### ✦ Clause: 7.1.6 – Organizational Knowledge

#### **What's going wrong:**

QMS knowledge (e.g., audit history, document control, training records) resides with one person — and is undocumented or inaccessible.

**Why it matters during an audit:**

If that person is unavailable, it exposes the QMS to breakdown and noncompliance.

**How to fix it:**

- ✓ Document processes and key knowledge areas in procedures or handbooks
- ✓ Cross-train staff
- ✓ Store QMS documents and records in a shared, accessible location
- ✓ Review knowledge transfer in audits and reviews

**Real-world result:**

Distributed knowledge ensures QMS continuity and team resilience.

**51. No Periodic Review of Documented Information** **Clause: 7.5.2 – Creating and Updating****What's going wrong:**

Documents such as procedures, work instructions, and forms are created once and never reviewed, even after changes to processes.

**Why it matters during an audit:**

Outdated documentation increases the risk of process errors and nonconforming outputs — a red flag for auditors.

**How to fix it:**

- ✓ Set review intervals (e.g., annually or after process changes)
- ✓ Assign document owners responsible for updates
- ✓ Log revisions with dates and approval signatures
- ✓ Archive obsolete versions appropriately

**Real-world result:**

Reviewed and current documents keep your QMS aligned with reality and reduce audit risks.

**52. No Monitoring of Process Outputs Against Planned Results****✦ Clause: 9.1.1 – Monitoring and Measurement****What's going wrong:**

Key processes are executed without tracking their effectiveness or comparing them against targets or KPIs.

**Why it matters during an audit:**

Auditors expect proof that your QMS is delivering results — not just operating in a vacuum.

**How to fix it:**

- ✓ Define output indicators for each core process
- ✓ Measure regularly and compare to expected results
- ✓ Investigate deviations and take corrective actions
- ✓ Include results in management reviews

**Real-world result:**

Monitoring confirms process effectiveness and enables data-driven improvements.

**53. Incomplete or Informal Training Records****✦ Clause: 7.2 – Competence**

**What's going wrong:**

Employees are trained but there's no formal record — or records lack dates, trainer names, or assessment results.

**Why it matters during an audit:**

Auditors need evidence that training happened and was effective. Missing records = gaps in competence proof.

**How to fix it:**

- ✓ Use standardized training record templates
- ✓ Capture date, topic, trainer, attendees, and evaluation
- ✓ Store records centrally and securely
- ✓ Periodically audit training records for completeness

**Real-world result:**

Complete records ensure you can prove readiness and compliance at any time.

**54. No Process for Evaluating the Effectiveness of Training** **Clause: 7.2 – Competence****What's going wrong:**

Training is provided, but there's no way to confirm if it actually improved knowledge, skill, or performance.

**Why it matters during an audit:**

Competence = training + verification. Without evaluating effectiveness, training becomes a formality.

**How to fix it:**

- ✓ Include quizzes, assessments, or on-the-job observations post-training
- ✓ Collect supervisor feedback on employee performance

- ✓ Update training content if outcomes fall short
- ✓ Use effectiveness data to plan future training

**Real-world result:**

Effective training programs improve capability, quality, and audit readiness.

**55. Management Review Frequency Not Justified****📌 Clause: 9.3.1 – Management Review Frequency****What's going wrong:**

Management reviews are held infrequently or irregularly — with no rationale documented for the chosen schedule.

**Why it matters during an audit:**

Auditors want assurance that reviews happen often enough to address QMS performance and changes.

**How to fix it:**

- ✓ Define review frequency in your QMS documentation (e.g., semi-annually, quarterly)
- ✓ Justify frequency based on complexity, risk, and previous findings
- ✓ Ensure timely reviews after major events or changes
- ✓ Maintain a calendar and meeting log

**Real-world result:**

Consistent reviews improve responsiveness and demonstrate leadership oversight.

## 56. Lack of Risk Consideration in Process Design

### **Clause: 6.1 – Planning for Risk and Opportunity**

#### **What's going wrong:**

When new processes are introduced or changed, risks are not formally assessed or documented.

#### **Why it matters during an audit:**

ISO 9001 requires risk-based thinking. If risk is absent from process design, it implies weak foresight.

#### **How to fix it:**

- ✓ Conduct a simple risk assessment for each new or changed process
- ✓ Identify potential failures, their impact, and mitigation steps
- ✓ Document the evaluation and retain as evidence
- ✓ Link to your overall QMS risk register

#### **Real-world result:**

Risk-informed design prevents surprises and strengthens audit defense.

## 57. Customer Requirements Not Communicated Internally

### **Clause: 8.2.4 – Changes to Requirements for Products and Services**

#### **What's going wrong:**

Changes in orders, delivery terms, or product specs aren't clearly relayed from sales to production or fulfillment.

#### **Why it matters during an audit:**

Miscommunication results in nonconforming products or missed expectations — and auditors take notice.

**How to fix it:**

- ✓ Create a documented handoff process between sales and ops
- ✓ Use change logs and acknowledgments
- ✓ Confirm changes are understood by affected departments
- ✓ Maintain version control on order specs and delivery terms

**Real-world result:**

Effective communication improves consistency and reduces customer complaints.

**58. Supplier-Related Nonconformities Not Tracked** **Clause: 8.4.2 – Control of External Providers****What's going wrong:**

Suppliers cause issues, but there's no centralized tracking system or feedback loop for their improvement.

**Why it matters during an audit:**

Auditors want evidence that poor supplier performance is monitored and corrected.

**How to fix it:**

- ✓ Track supplier-related defects or delays
- ✓ Review trends and recurring issues
- ✓ Communicate findings and expectations to the supplier
- ✓ Use this data during re-evaluation or selection

**Real-world result:**

Accountability improves supplier relationships and incoming quality.

## 59. No Communication of the Quality Policy to New Employees

### **Clause: 7.3 – Awareness**

#### **What's going wrong:**

New hires aren't informed of the quality policy or their role in the QMS — leaving them disconnected from strategic quality goals.

#### **Why it matters during an audit:**

Auditors may interview staff. If they don't know the policy, it suggests poor onboarding or disengagement.

#### **How to fix it:**

- ✓ Include the policy in onboarding programs
- ✓ Display the policy where teams work (e.g., breakrooms, dashboards)
- ✓ Have team leads explain how it connects to their roles
- ✓ Quiz or verify understanding during internal audits

#### **Real-world result:**

Well-informed staff improve ownership, engagement, and audit response quality.

## 60. Complaints Are Not Categorized for Trend Analysis

### **Clause: 9.1.2 – Customer Satisfaction**

#### **What's going wrong:**

Complaints are logged, but there's no system to categorize them (e.g., product, service, delivery) or analyze trends.

#### **Why it matters during an audit:**

Without categorization, it's hard to identify systemic issues — which prevents effective corrective action.

**How to fix it:**

- ✓ Categorize complaints by source, type, severity, or location
- ✓ Analyze trends monthly or quarterly
- ✓ Link frequent complaint types to root causes and actions
- ✓ Report findings in management reviews

**Real-world result:**

Trend analysis turns complaints into strategic insight and system improvement.

**61. Products Released Without Proper Authorization** **Clause: 8.6 – Release of Products and Services****What's going wrong:**

Products or services are delivered to customers without documented approval or verification of conformance to requirements.

**Why it matters during an audit:**

ISO 9001 requires documented evidence of release and conformity. Skipping this exposes the organization to compliance and customer satisfaction risks.

**How to fix it:**

- ✓ Define who is authorized to release each product or service
- ✓ Maintain records of inspections, tests, and approvals
- ✓ Use sign-offs, stamps, or digital systems to track release points
- ✓ Train employees on release protocols

**Real-world result:**

Controlled release processes protect quality and accountability across the value chain.

## 62. No Integration of QMS with Business Strategy

### **Clause: 5.1.1 – Leadership and Commitment**

#### **What’s going wrong:**

The QMS is treated as an isolated system instead of being integrated into organizational goals and planning.

#### **Why it matters during an audit:**

Auditors want to see that the QMS is driving — not following — the business. A disconnected system signals weak leadership involvement.

#### **How to fix it:**

- ✓ Link QMS objectives with strategic goals
- ✓ Involve leadership in QMS reviews and audits
- ✓ Include quality metrics in business performance dashboards
- ✓ Reflect QMS priorities in operational planning

#### **Real-world result:**

Strategic integration strengthens the QMS, creates leadership ownership, and earns auditor praise.

## 63. No Procedure for Handling Internal Communication

### **Clause: 7.4 – Communication**

#### **What’s going wrong:**

Departments operate in silos, with no structured way to communicate QMS updates, changes, or performance data.

**Why it matters during an audit:**

ISO 9001 emphasizes effective communication. Poor internal flow creates gaps in understanding and execution.

**How to fix it:**

- ✓ Define internal communication channels (emails, meetings, platforms)
- ✓ Schedule regular quality meetings or bulletins
- ✓ Log and review key QMS-related communications
- ✓ Include communication strategy in the QMS manual

**Real-world result:**

Effective communication improves alignment, reduces errors, and drives cross-functional consistency.

**64. No Actions Taken Based on Audit Findings** **Clause: 9.2.2 – Internal Audit****What's going wrong:**

Internal audits identify issues, but corrective actions are not assigned, followed up, or verified for effectiveness.

**Why it matters during an audit:**

Unresolved findings suggest a broken internal control system and weak commitment to improvement.

**How to fix it:**

- ✓ Log all findings in a corrective action tracking system
- ✓ Assign owners, deadlines, and verification criteria
- ✓ Review action status in QMS meetings
- ✓ Link repeat issues to risk planning

**Real-world result:**

Timely follow-up on audit findings builds a responsive, reliable quality culture.

**65. No Defined Criteria for Selecting Suppliers****✦ Clause: 8.4.1 – Control of External Providers****What's going wrong:**

Suppliers are chosen informally without standardized evaluation based on quality, risk, or performance.

**Why it matters during an audit:**

Auditors require documented criteria to ensure suppliers are competent and aligned with QMS requirements.

**How to fix it:**

- ✓ Create a supplier qualification checklist or scorecard
- ✓ Define criteria: cost, delivery, certifications, history, compliance
- ✓ Retain evaluation records for all approved suppliers
- ✓ Re-evaluate suppliers annually or based on performance

**Real-world result:**

Objective supplier selection ensures better outcomes and transparency during audits.

## 66. Process Performance Not Reviewed Against Objectives

### **Clause: 9.1.1 – Monitoring and Evaluation**

#### **What's going wrong:**

Performance metrics are collected, but they're not compared against goals or reviewed for trends and deviations.

#### **Why it matters during an audit:**

ISO 9001 requires evaluation — not just data collection. Lack of analysis means missed improvement opportunities.

#### **How to fix it:**

- ✓ Compare performance to established objectives monthly/quarterly
- ✓ Use visual tools like trend charts and dashboards
- ✓ Review underperforming metrics in management meetings
- ✓ Take corrective or preventive action as needed

#### **Real-world result:**

Regular evaluation creates accountability, focus, and faster corrective action.

## 67. No Planning for Emergency Situations or Business Disruption

### **Clause: 8.5.1 – Control of Production and Service Provision**

#### **What's going wrong:**

Organizations lack contingency plans for operational disruptions (e.g., supplier failure, IT outages, equipment breakdowns).

#### **Why it matters during an audit:**

Auditors may test how resilient your QMS is under abnormal conditions. No planning = high risk.

**How to fix it:**

- ✓ Identify potential disruptions to key QMS processes
- ✓ Document response procedures or contingency plans
- ✓ Assign roles for emergency response and recovery
- ✓ Test plans through tabletop or live drills

**Real-world result:**

Preparedness reduces downtime and demonstrates maturity in service continuity.

**68. Unclear Product Identification During Production** **Clause: 8.5.2 – Identification and Traceability****What's going wrong:**

Products in production stages are unlabeled, making it unclear what they are, what status they hold, or where they belong.

**Why it matters during an audit:**

Lack of identification can lead to mix-ups, contamination, or nonconforming product reaching the customer.

**How to fix it:**

- ✓ Use clear labels, color codes, or barcodes for in-process items
- ✓ Mark inspection or production status (e.g., pending, in-process, approved, rejected)
- ✓ Train teams on identification protocol
- ✓ Include in audit checklists and process audits

**Real-world result:**

Strong identification supports traceability, product control, and audit confidence.

## 69. Records Not Legible or Protected from Damage

### 🚩 Clause: 7.5.3.2 – Protection of Documented Information

#### **What's going wrong:**

Forms, logs, or handwritten inspection records are faded, damaged, or stored in poor conditions.

#### **Why it matters during an audit:**

Auditors require readable, accessible, and protected records to verify compliance.

#### **How to fix it:**

- ✓ Switch to digital records where feasible
- ✓ Use secure storage for paper records (fire-safe cabinets, weatherproof folders)
- ✓ Set retention and preservation guidelines
- ✓ Train teams to check for record legibility before submission

#### **Real-world result:**

Protected records ensure continuity, data integrity, and peace of mind in audits.

## 70. Customer Requirements Not Reviewed After Order Changes

### 🚩 Clause: 8.2.4 – Changes to Requirements for Products and Services

#### **What's going wrong:**

When customers revise an order, spec, or deadline, the change is not formally reviewed or communicated across teams.

**Why it matters during an audit:**

Failure to review revised requirements can lead to nonconformity, missed delivery, or legal exposure.

**How to fix it:**

- ✓ Define a review process for customer-requested changes
- ✓ Update order records and confirm feasibility
- ✓ Notify all relevant departments
- ✓ Retain evidence of approval and communication

**Real-world result:**

Thorough change review ensures alignment, customer satisfaction, and legal protection.

**71. Inadequate Records of Design and Development Reviews****✦ Clause: 8.3.2 – Design and Development Planning****What's going wrong:**

Design stages may be followed, but review records (inputs, outputs, participants, decisions) are missing or incomplete.

**Why it matters during an audit:**

Auditors need documented evidence of planned reviews to ensure that designs meet requirements and risks are addressed.

**How to fix it:**

- ✓ Schedule design reviews at key stages
- ✓ Record attendees, outcomes, risks identified, and decisions made
- ✓ Retain meeting minutes or review checklists
- ✓ Link reviews to validation and verification steps

**Real-world result:**

Detailed reviews improve design integrity and traceability from concept to launch.

**72. No Action Taken on Performance Evaluation Results****📌 Clause: 9.1.1 – Evaluation of QMS Performance****What's going wrong:**

Organizations collect KPIs but don't use the insights to make decisions or drive changes in the QMS.

**Why it matters during an audit:**

Data without action suggests stagnation and weak management engagement.

**How to fix it:**

- ✓ Highlight underperforming KPIs in dashboards
- ✓ Set thresholds for action triggers
- ✓ Assign root cause analysis and corrective action
- ✓ Review impact in management meetings

**Real-world result:**

Action-oriented evaluation improves accountability and continuous improvement.

**73. Process Interactions Not Documented or Understood****📌 Clause: 4.4.1 – QMS and Its Processes**

**What's going wrong:**

Departments operate in silos with no clear understanding of how their work interacts with others.

**Why it matters during an audit:**

Auditors evaluate how well your processes function together as a system — not independently.

**How to fix it:**

- ✓ Map process inputs, outputs, and interfaces
- ✓ Use flowcharts or SIPOC diagrams
- ✓ Include process interaction awareness in QMS training
- ✓ Review interdependencies annually

**Real-world result:**

Better process visibility improves collaboration and overall QMS performance.

**74. No Plan or Method for Continual Improvement** **Clause: 10.3 – Continual Improvement****What's going wrong:**

Improvement is treated as reactive — only triggered by problems. There's no structured approach to proactive improvement.

**Why it matters during an audit:**

Continual improvement is a core ISO 9001 principle. A lack of planning suggests minimal maturity.

**How to fix it:**

- ✓ Create a continual improvement log
- ✓ Capture opportunities from audits, feedback, and KPI reviews

- ✓ Assign actions and monitor results
- ✓ Highlight improvements in reviews and communications

**Real-world result:**

Proactive improvement strengthens culture, compliance, and competitiveness.

## 75. No Defined Method for Retaining Organizational Knowledge

### **Clause: 7.1.6 – Organizational Knowledge**

**What's going wrong:**

Critical knowledge resides with individuals, with no system for capture, sharing, or succession planning.

**Why it matters during an audit:**

Auditors assess knowledge preservation, especially during staff turnover or rapid growth.

**How to fix it:**

- ✓ Identify critical knowledge areas (e.g., customer specs, technical know-how)
- ✓ Document procedures, tips, FAQs, and lessons learned
- ✓ Use a shared knowledge base or document management system
- ✓ Include in onboarding and training

**Real-world result:**

Knowledge retention ensures business continuity and quality consistency.

## 76. No Documentation of Product/Service Requirements

### **Clause: 8.2.2 – Determining Requirements for Products and Services**

#### **What's going wrong:**

Customer needs or regulatory requirements are understood informally — not written down or validated.

#### **Why it matters during an audit:**

ISO 9001 requires documented understanding of what's being provided. Assumptions = audit findings.

#### **How to fix it:**

- ✓ Use checklists or forms during order acceptance
- ✓ Document technical specs, service SLAs, and legal obligations
- ✓ Get customer confirmation where needed
- ✓ Store records with order or contract files

#### **Real-world result:**

Documented requirements improve delivery accuracy and customer satisfaction.

## 77. No Regular Update of the Quality Objectives

### **Clause: 6.2 – Quality Objectives and Planning**

#### **What's going wrong:**

Objectives are set once during implementation but are no longer reviewed or updated as business needs evolve.

**Why it matters during an audit:**

Auditors expect SMART, relevant objectives that are reviewed and refreshed regularly.

**How to fix it:**

- ✓ Review objectives annually (or when strategies change)
- ✓ Involve department heads in setting targets
- ✓ Track status with metrics and owners
- ✓ Report progress in management reviews

**Real-world result:**

Active objectives drive relevance, performance, and credibility in audits.

**78. Failure to Verify Design Outputs Before Release****📌 Clause: 8.3.4 – Design and Development Outputs****What's going wrong:**

Design outputs are passed to production or clients without formal verification against input requirements.

**Why it matters during an audit:**

ISO 9001 requires a verification step before release to ensure outputs meet expectations.

**How to fix it:**

- ✓ Compare design outputs to approved inputs (specs, requirements)
- ✓ Use checklists, simulations, or peer review
- ✓ Document verification results and decisions
- ✓ Include sign-off before transitioning to production

**Real-world result:**

Output verification reduces costly redesigns and improves customer satisfaction.

**79. No Visual Controls in Work Areas****📌 Clause: 8.5.1 – Control of Production and Service Provision****What's going wrong:**

Work areas lack visual aids (e.g., process flows, work instructions, checklists) leading to inconsistent practices.

**Why it matters during an audit:**

Visual controls reinforce standardization and help auditors confirm that procedures are followed.

**How to fix it:**

- ✓ Post process visuals, safety rules, and quality standards at workstations
- ✓ Use color coding, charts, or production boards
- ✓ Update visuals with changes
- ✓ Involve teams in design and feedback

**Real-world result:**

Visual cues improve compliance, speed, and consistency on the shop floor or in service delivery.

**80. Legal and Regulatory Requirements Not Identified or Reviewed****📌 Clause: 8.2.2 & 6.1 – Requirements and Risk Planning**

**What's going wrong:**

There's no documented list of legal, industry, or customer compliance obligations — or if one exists, it hasn't been updated in years.

**Why it matters during an audit:**

ISO 9001 requires identification and review of applicable compliance obligations.

**How to fix it:**

- ✓ Create a compliance register with laws, codes, and standards
- ✓ Assign responsibility for monitoring updates
- ✓ Review at least annually or when regulations change
- ✓ Link compliance risks to QMS controls and objectives

**Real-world result:**

Staying current on compliance avoids legal issues and builds trust with clients and regulators.

**81. No Verification of Outsourced Process Control** **Clause: 8.4.2 – Control of External Providers****What's going wrong:**

Critical outsourced processes (e.g., machining, testing, logistics) are not verified for conformity or quality impact.

**Why it matters during an audit:**

Outsourced work must meet the same standards as internal processes. No verification = no control.

**How to fix it:**

- ✓ Identify outsourced processes that impact product or service quality
- ✓ Define and apply monitoring methods (e.g., audits, inspection reports)

- ✓ Retain records of evaluations
- ✓ Include suppliers in internal audit planning if critical

**Real-world result:**

Outsourcing oversight improves reliability and keeps you compliant and audit-ready.

**82. No Formal Review of Quality Policy Effectiveness****📌 Clause: 5.2.2 – Communicating the Quality Policy****What's going wrong:**

The quality policy exists but isn't revisited or evaluated to ensure it remains relevant and effective.

**Why it matters during an audit:**

The policy must reflect current goals and be known and understood throughout the organization.

**How to fix it:**

- ✓ Review the quality policy at least annually
- ✓ Check alignment with strategic direction and QMS performance
- ✓ Communicate changes across teams
- ✓ Document review outcomes in management review records

**Real-world result:**

A living quality policy drives engagement and aligns the team with evolving business goals.

## 83. No Criteria for Evaluating the Effectiveness of Corrective Actions

### **Clause: 10.2.1 – Corrective Action**

#### **What's going wrong:**

Corrective actions are marked as “closed” without verifying if the problem was truly resolved.

#### **Why it matters during an audit:**

Without follow-up, issues may recur — and auditors will question the strength of your QMS.

#### **How to fix it:**

- ✓ Define success criteria for each corrective action
- ✓ Monitor affected areas for recurrence over time
- ✓ Validate changes with data, observations, or re-testing
- ✓ Document verification steps and results

#### **Real-world result:**

Verified actions build confidence in system reliability and reduce repeat findings.

## 84. No Awareness of Quality Objectives at the Operational Level

### **Clause: 7.3 – Awareness**

#### **What's going wrong:**

Frontline staff aren't aware of the company's quality goals — and don't know how their work impacts them.

#### **Why it matters during an audit:**

Employee awareness is essential for ISO 9001. Auditors may interview team members to check for this.

**How to fix it:**

- ✓ Break down quality objectives into department-level goals
- ✓ Share goals in team meetings, dashboards, and SOPs
- ✓ Review progress regularly and communicate updates
- ✓ Include objectives in onboarding and training

**Real-world result:**

Engaged employees drive performance and strengthen audit responses.

**85. No Record of Customer Requirement Changes****📌 Clause: 8.2.4 – Changes to Requirements for Products and Services****What's going wrong:**

Customer requests (e.g., delivery dates, specs) are handled informally and not logged — causing misunderstandings and missed targets.

**Why it matters during an audit:**

Auditors look for traceable evidence of requirement changes and how they're handled.

**How to fix it:**

- ✓ Use a change log or CRM system to document updates
- ✓ Record customer communication and internal approvals
- ✓ Notify affected teams immediately
- ✓ Archive changes with the original order record

**Real-world result:**

Change tracking reduces disputes, improves planning, and supports audit trail quality.

## 86. Unclear or Missing Definitions in Process Documentation

### **Clause: 7.5 – Documented Information**

#### **What's going wrong:**

Process documents use unclear terms or acronyms that aren't defined — leading to misinterpretation.

#### **Why it matters during an audit:**

ISO 9001 emphasizes clarity. Confusing language leads to inconsistent understanding and execution.

#### **How to fix it:**

- ✓ Add glossaries or definitions to SOPs and quality manuals
- ✓ Standardize terms across departments
- ✓ Avoid jargon or legacy acronyms unless explained
- ✓ Review documents during audits for readability

#### **Real-world result:**

Clear documentation improves training, consistency, and audit comprehension.

## 87. Production Planning Does Not Reflect Customer Requirements

### **Clause: 8.5.1 – Control of Production and Service Provision**

#### **What's going wrong:**

Production schedules are built around capacity — not aligned with customer deadlines, specs, or contract terms.

#### **Why it matters during an audit:**

ISO 9001 expects delivery and production planning to be driven by customer needs.

**How to fix it:**

- ✓ Integrate customer order data into planning systems
- ✓ Define capacity thresholds and rush procedures
- ✓ Monitor delivery performance and adjust plans accordingly
- ✓ Include planners in customer communication channels

**Real-world result:**

Customer-aligned planning improves satisfaction, trust, and on-time delivery metrics.

**88. Insufficient Retention of Internal Audit Records** **Clause: 9.2.2 – Internal Audit Records****What's going wrong:**

Audit results are discussed but not formally retained — or key records like checklists, findings, and evidence are missing.

**Why it matters during an audit:**

Auditors need proof that audits occurred, were thorough, and led to meaningful action.

**How to fix it:**

- ✓ Store audit checklists, notes, evidence, and reports in a secure, organized location
- ✓ Assign retention responsibilities
- ✓ Use audit software or document control systems
- ✓ Review records during internal and external audits

**Real-world result:**

Complete records protect your audit history and demonstrate consistent compliance.

## **89. No Metrics for Measuring Supplier Delivery or Quality Performance**

### **Clause: 8.4.1 – Control of External Providers**

#### **What's going wrong:**

Suppliers are evaluated subjectively — without metrics like defect rate, on-time delivery, or responsiveness.

#### **Why it matters during an audit:**

Objective metrics support transparent supplier control and contract decisions.

#### **How to fix it:**

- ✓ Define KPIs for suppliers (e.g., % on-time, % conforming)
- ✓ Track and trend performance quarterly
- ✓ Share results with suppliers for continuous improvement
- ✓ Use metrics during annual re-evaluation

#### **Real-world result:**

Data-driven evaluations improve supplier accountability and strengthen compliance.

## **90. Inconsistent Use of QMS Templates and Forms**

### **Clause: 7.5 – Documented Information**

#### **What's going wrong:**

Teams use outdated or modified versions of forms, bypassing standard QMS templates and controls.

**Why it matters during an audit:**

Lack of standardization introduces risk, confusion, and documentation inconsistencies.

**How to fix it:**

- ✓ Centralize and version-control all official QMS forms
- ✓ Restrict editing or duplication of templates
- ✓ Train teams on proper use and access points
- ✓ Review form use during internal audits

**Real-world result:**

Consistent documentation builds confidence and protects the integrity of your records.

**91. No Defined Escalation Process for Quality Issues****📌 Clause: 10.2.1 – Nonconformity and Corrective Action****What's going wrong:**

When issues occur, there's no clear path for escalation — resulting in delays or unresolved problems.

**Why it matters during an audit:**

Auditors expect a process that ensures quality concerns are addressed promptly and at the right level.

**How to fix it:**

- ✓ Define escalation thresholds (e.g., risk level, customer impact)
- ✓ Document escalation steps and responsible roles
- ✓ Train teams on when and how to escalate
- ✓ Track escalated issues separately with closure status

**Real-world result:**

Faster, structured escalation ensures problems are handled before they spread.

**92. Preventive Actions Not Documented or Tracked****📌 Clause: 6.1 – Actions to Address Risks and Opportunities****What's going wrong:**

Opportunities for improvement or risk reduction are discussed — but no actions are assigned or documented.

**Why it matters during an audit:**

ISO 9001 requires action on opportunities, not just problems. Lack of preventive action shows reactive thinking.

**How to fix it:**

- ✓ Maintain a preventive action register
- ✓ Log opportunities with assigned owners and due dates
- ✓ Monitor implementation and impact
- ✓ Review progress in management reviews

**Real-world result:**

Preventive action supports proactive QMS development and risk reduction.

**93. No Cross-Training for Key QMS Roles****📌 Clause: 7.1.6 – Organizational Knowledge**

**What's going wrong:**

If one key person is absent, critical QMS processes stop — because no one else knows what to do.

**Why it matters during an audit:**

Auditors assess knowledge resilience. Over-reliance on individuals increases risk.

**How to fix it:**

- ✓ Identify critical QMS tasks and backup personnel
- ✓ Create simple training or SOPs for cross-training
- ✓ Rotate responsibilities where feasible
- ✓ Maintain a QMS continuity plan

**Real-world result:**

Cross-trained teams reduce disruptions and build QMS flexibility.

**94. Customer Feedback Not Integrated into Risk Planning****📌 Clause: 6.1 & 9.1.2 – Risks and Customer Satisfaction****What's going wrong:**

Feedback is collected but not evaluated as part of your QMS risks and opportunities.

**Why it matters during an audit:**

Auditors expect customer input to drive improvements and mitigation planning.

**How to fix it:**

- ✓ Analyze feedback trends for patterns
- ✓ Include high-risk feedback in risk registers

- ✓ Use insights to update controls or objectives
- ✓ Reference customer data in reviews and decisions

**Real-world result:**

Feedback-driven risk planning improves relevance and stakeholder trust.

**95. Unclear Criteria for Measuring Service Effectiveness****📌 Clause: 8.5.1 & 9.1.1 – Service Control and Evaluation****What's going wrong:**

Service-based organizations fail to define what “good” service looks like or how to measure it.

**Why it matters during an audit:**

ISO 9001 applies to both products and services — service metrics are essential.

**How to fix it:**

- ✓ Define KPIs for service areas (e.g., response time, resolution rate, satisfaction scores)
- ✓ Monitor performance against targets
- ✓ Involve service leads in QMS planning
- ✓ Review and adjust metrics as customer needs change

**Real-world result:**

Service measurement improves consistency and audit defensibility for service providers.

**96. Poor Integration of Corrective Actions Across Departments****📌 Clause: 10.2 – Corrective Action**

**What's going wrong:**

Actions taken in one department don't inform or benefit others — allowing repeat issues across teams.

**Why it matters during an audit:**

A siloed QMS limits improvement and may signal poor systemic thinking.

**How to fix it:**

- ✓ Share lessons learned across departments
- ✓ Include cross-functional team reviews in major actions
- ✓ Document shared improvements and effectiveness
- ✓ Build a centralized improvement dashboard

**Real-world result:**

Integrated action multiplies impact and drives company-wide improvement.

**97. Failure to Link Nonconformities to Quality Objectives****📌 Clause: 6.2 & 10.2 – Objectives and Corrective Action****What's going wrong:**

Even after issues arise, related objectives are not updated or adjusted — creating a disconnect.

**Why it matters during an audit:**

Quality objectives must evolve based on real-world issues. Lack of alignment shows stagnation.

**How to fix it:**

- ✓ Review nonconformities when updating objectives
- ✓ Set new targets for recurring weak areas

- ✓ Include relevant actions in planning
- ✓ Report changes in reviews

**Real-world result:**

Linked objectives support targeted improvement and responsive planning.

**98. Poor Version Control on Quality Records**** Clause: 7.5.3 – Control of Documented Information****What's going wrong:**

Multiple versions of logs, forms, or policies are in circulation — causing errors or confusion.

**Why it matters during an audit:**

Uncontrolled records risk compliance and traceability issues.

**How to fix it:**

- ✓ Store records in a centralized digital repository
- ✓ Apply naming/versioning conventions
- ✓ Train teams on accessing only approved versions
- ✓ Conduct internal audits for version control

**Real-world result:**

Clean, current records support consistency, accuracy, and audit clarity.

**99. No Structured Evaluation of Risk Treatment Plans**** Clause: 6.1 – Actions to Address Risks and Opportunities**

**What's going wrong:**

Risks are documented but mitigation efforts are not followed up or evaluated for success.

**Why it matters during an audit:**

Auditors expect active management of risk — not just identification.

**How to fix it:**

- ✓ Define desired outcomes for each risk treatment
- ✓ Assign deadlines and responsibilities
- ✓ Monitor effectiveness with data
- ✓ Report in reviews and take further action if needed

**Real-world result:**

Evaluated risk plans demonstrate maturity, control, and strategic foresight.

**100. No Use of a Quality Management Roadmap or Improvement Plan****✦ Clause: 10.3 – Continual Improvement****What's going wrong:**

Improvements happen ad hoc — there's no structured roadmap or long-term QMS development plan.

**Why it matters during an audit:**

ISO 9001 expects structured, documented improvement over time — a sign of system maturity.

**How to fix it:**

- ✓ Create a QMS roadmap aligned with business goals
- ✓ Include process enhancements, tool upgrades, training goals
- ✓ Review quarterly and adjust based on data and audits
- ✓ Communicate roadmap updates across departments

**Real-world result:**

A documented roadmap elevates your QMS from reactive to strategic — and auditors notice.

## Strengthening Your ISO 9001 Compliance Journey

Achieving and maintaining ISO 9001:2015 certification is more than just passing an audit — it's about building a high-performance quality management system that empowers your teams, earns customer trust, and drives real business value.

By addressing these 100 common non-conformities, you move beyond checkbox compliance and into the realm of proactive improvement, strategic alignment, and sustainable results.

### **Continual Improvement Is the Goal**

Regular internal audits, employee engagement, and performance reviews ensure your QMS adapts to change and remains resilient.

### **Documentation and Accountability Matter**

Maintain clear records of decisions, changes, actions, and reviews — not just for audits, but for business clarity and continuity.

### **Turn ISO 9001 Into a Competitive Advantage**

A mature, audit-ready QMS doesn't just keep you compliant — it helps you innovate, grow, and outperform your competitors.

Use this guide as your roadmap to smarter quality management. Stay audit-ready, stay customer-focused, and let ISO 9001 power your next stage of growth.

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ISO 9001 Lead Auditor Certification is based on Quality Management Systems.



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