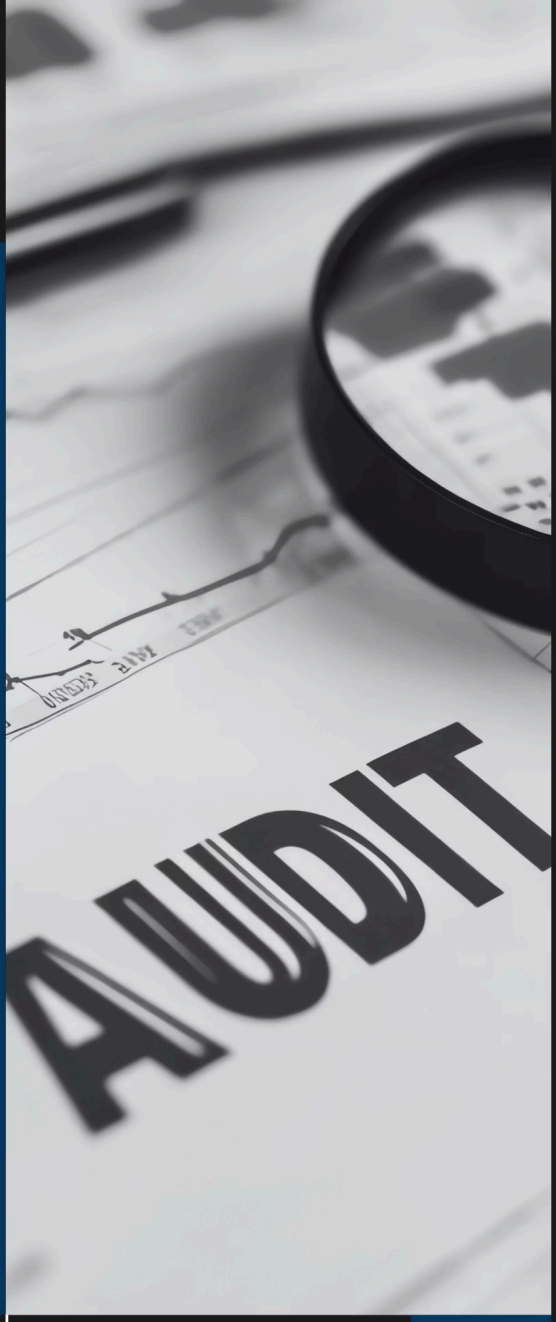
CERTIFIED ISO 9001: 2015 LEAD AUDITOR

CLAUSE-WISE AUDIT CHECKLIST



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Introduction to ISO 9001:2015 Auditing

This checklist serves as a systematic framework for evaluating Quality Management System (QMS) compliance against ISO 9001:2015 requirements. It ensures auditors conduct thorough, consistent assessments that drive organizational excellence and continuous improvement.

The modern audit approach emphasizes three critical pillars: risk-based thinking to anticipate and mitigate potential issues, a process approach that views the organization as interconnected activities, and continual improvement as an ongoing commitment rather than a one-time achievement.

Lead Auditors play a pivotal role in this ecosystem. They must balance technical expertise with interpersonal skills, ensuring audits are both rigorous and constructive. Their objective assessment provides organizations with valuable insights into QMS effectiveness while maintaining credibility and impartiality throughout the audit process.

Key Audit Principles

- Systematic evaluation methodology
- Risk-based thinking approach
- Process-oriented assessment
- Objective evidence collection
- Continual improvement focus

How to Use This Checklist

- Review each clause systematically during the audit
- Mark items as: Conforming ✓ / Non-conforming × / Not Applicable N/A
- Document objective evidence for each item reviewed
- Note observations, findings, and areas for improvement
- Reference specific documented information reviewed
- Record interviews conducted and processes observed
- Classify nonconformities as Major or Minor based on impact
- Ensure all findings are supported by verifiable evidence

Clause 4: Context of the Organization

Understanding organizational context forms the foundation of an effective QMS. This clause requires organizations to think strategically about internal and external factors that influence their ability to achieve intended outcomes.

4.1 Understanding the Organization and its Context

- Has the organization determined external and internal issues relevant to its purpose and strategic direction?
- Are these issues monitored and reviewed?
- Is there documented information about these issues?

4.2 Understanding the Needs and Expectations of Interested Parties

- Have relevant interested parties been identified?
- Are their requirements for the QMS determined?
- Is this information monitored and reviewed?

4.3 Determining the Scope of the QMS

- Is the QMS scope documented and available?
- Does it consider external/internal issues and interested party requirements?
- Are any non-applicable requirements justified?

4.4 Quality Management System and its Processes

- Are QMS processes identified and their interactions determined?
- Are process inputs, outputs, and resources defined?
- Are process risks and opportunities addressed?
- Are processes monitored and measured?
- Is continual improvement implemented?

Clause 5: Leadership

Leadership commitment is the engine that drives QMS success. This clause demands visible, active engagement from top management—not just delegation to quality departments. Auditors must verify that leaders take accountability for QMS effectiveness, establish clear quality policies aligned with strategic direction, and ensure these policies are communicated and understood at all organizational levels. The quality policy should not be a dusty document but a living guide that influences daily decisions.

5.1 Leadership and Commitment

- Does top management demonstrate leadership and commitment to the QMS?
- Is accountability for QMS effectiveness established?
- Are quality policy and objectives established and compatible with context?
- Is QMS integrated into business processes?
- Does management promote process approach and risk-based thinking?
- Are adequate resources made available?
- Is the importance of effective QMS communicated?
- Are people engaged, directed and supported?

5.2 Policy

- Is the quality policy appropriate to the organization's purpose and context?
- Does it provide framework for quality objectives?
- Includes commitment to satisfy requirements and continual improvement?
- Is it documented, communicated, and available to interested parties?

5.3 Organizational Roles, Responsibilities and Authorities

- Are roles, responsibilities and authorities assigned and communicated?
- Is responsibility for QMS conformity assigned?
- Are process outputs meeting requirements?
- Is customer focus promoted throughout the organization?
- Is QMS integrity maintained during changes?

Clause 6: Planning

Strategic planning transforms QMS from reactive to proactive. This clause emphasizes anticipating challenges and opportunities rather than simply responding to problems as they arise.

6.1 Actions to Address Risks and Opportunities

- Have risks and opportunities been determined considering context and interested parties?
- Are actions planned to address these risks and opportunities?
- Are these actions integrated into QMS processes?
- Is effectiveness of actions evaluated?

6.2 Quality Objectives and Planning to Achieve Them

- Are quality objectives established at relevant functions and levels?
- Are objectives consistent with quality policy?
- Are objectives measurable, monitored, communicated and updated?
- Is documented information on quality objectives maintained?
- Are plans established including: what will be done, resources required, who is responsible, when completed, how results evaluated?

6.3 Planning of Changes

- When changes to QMS are needed, are they carried out in planned manner?
- Is the purpose and potential consequences of changes considered?
- Is QMS integrity maintained during changes?
- Are resources available?
- Are responsibilities and authorities allocated?

Clause 7: Support

Even the best-designed QMS fails without adequate support. This clause addresses the critical resources, competencies, and infrastructure needed to operate effectively and achieve quality objectives.

7.1 Resources

- Are resources needed for QMS determined and provided?
- Are capabilities and constraints of existing internal resources considered?
- What needs to be obtained from external providers considered?
- **People:** Adequate persons available to operate QMS effectively?
- **Infrastructure:** Infrastructure determined, provided and maintained?
- **Environment:** Suitable environment for process operation determined and provided?
- **Monitoring and Measuring Resources:** Appropriate resources determined and provided? Are they suitable for monitoring/measurement activities? Maintained and verified?
- **Organizational Knowledge:** Knowledge needed determined and maintained? How is knowledge acquired and updated?

7.2 Competence

- Is required competence of persons determined?
- Are persons competent based on education, training or experience?
- Are actions taken to acquire competence where needed?
- Is effectiveness of actions evaluated?
- Is documented information retained as evidence of competence?

7.3 Awareness

- Are persons aware of quality policy, relevant quality objectives, their contribution to QMS effectiveness, and implications of not conforming?

7.4 Communication

- Are internal and external communications determined including what, when, with whom, how, and who communicates?

7.5 Documented Information

- Does QMS include documented information required by ISO 9001 and determined necessary by organization?
- Is documented information controlled (available, suitable, adequately protected)?
- Are creation, updating, and control of documented information addressed?

Clause 8: Operation

Operations is where quality is truly made. This comprehensive clause covers the entire realization process from customer requirements through product delivery, encompassing design, procurement, production, and release activities.

8.1 Operational Planning and Control

- Are processes needed to meet product/service requirements planned, implemented and controlled?
- Are requirements for products/services determined?
- Are criteria for processes and acceptance of products/services established?
- Are resources determined and made available?
- Is control of processes implemented according to criteria?
- Is documented information maintained to demonstrate conformity?

8.2 Requirements for Products and Services

8.2.1

- Customer requirements including delivery, post-delivery, statutory/regulatory determined?

8.2.2

- Are claims for products/services reviewed before commitment? Can requirements be met?

8.2.3

- Are changes to requirements reviewed and communicated?

8.3 Design and Development (if applicable)

- Is design/development process established, implemented and maintained?
- Are design stages, controls, responsibilities, and resources determined?
- Are design inputs, controls, outputs, and changes managed?

8.4 Control of Externally Provided Processes, Products and Services

- Are externally provided processes, products and services conforming to requirements?
- Are external providers evaluated, selected, monitored and re-evaluated?
- Are requirements for external providers determined and communicated?

8.5 Production and Service Provision

- Is production/service provision controlled under specified conditions?
- Are identification and traceability maintained where required?
- Is customer/external provider property protected?
- Are products preserved during processing and delivery?
- Are post-delivery activities addressed?
- Are changes controlled and reviewed?

8.6 Release of Products and Services

- Are planned arrangements implemented to verify requirements are met?
- Is evidence of conformity retained including authorization for release?

8.7 Control of Nonconforming Outputs

- Are nonconforming outputs identified and controlled?
- Are appropriate actions taken? Is documented information retained?

Clause 9: Performance Evaluation

You cannot manage what you do not measure. This clause demands organizations systematically monitor, measure, analyze, and evaluate QMS performance to drive informed decision-making and continual improvement.

9.1 Monitoring, Measurement, Analysis and Evaluation

- Has the organization determined what needs to be monitored and measured?
- Are methods for monitoring, measurement, analysis and evaluation determined?
- When is monitoring and measurement performed?
- When are results analyzed and evaluated?
- Is documented information retained as evidence of results?

9.1.2 Customer Satisfaction

- Is customer perception of degree to which their needs/expectations fulfilled monitored?
- Are methods for obtaining, monitoring and reviewing this information determined?

9.1.3 Analysis and Evaluation

- Are data and information from monitoring and measurement analyzed and evaluated?
- Does analysis demonstrate conformity of products/services, customer satisfaction, QMS performance, effectiveness of planning, risk/opportunity actions, external provider performance, and improvement needs?

9.2 Internal Audit

- Are internal audits conducted at planned intervals?
- Do audits provide information on whether QMS conforms to organization's requirements and ISO 9001 requirements?
- Is QMS effectively implemented and maintained?
- Is audit program planned considering importance of processes, changes, and previous audit results?

- Are audit criteria and scope defined?
- Are auditors selected ensuring objectivity and impartiality?
- Are audit results reported to relevant management?
- Are corrections and corrective actions taken without undue delay?
- Is documented information retained as evidence?

9.3 Management Review

- Does top management review QMS at planned intervals?
- Does review consider status of previous actions, changes in issues, performance information including trends, adequacy of resources, effectiveness of risk/opportunity actions, and improvement opportunities?
- Do outputs include decisions on improvement opportunities, change needs, and resource needs?
- Is documented information retained?

Clause 10: Improvement

Continual improvement is not optional—it's a fundamental requirement of ISO 9001:2015. This clause transforms the QMS from a static compliance tool into a dynamic engine for organizational excellence and competitive advantage.

10.1 General

- Has the organization determined and selected opportunities for improvement?
- Are actions implemented to meet customer requirements and enhance customer satisfaction?
- Do improvements include: improving products/services, correcting/preventing undesired effects, improving QMS performance and effectiveness?

10.2 Nonconformity and Corrective Action

- When nonconformity occurs, does the organization react to control and correct it?
- Are consequences dealt with?
- Is the need for action to eliminate root causes evaluated?
- Are similar nonconformities reviewed (potential or actual)?
- Are corrective actions appropriate to the effects of nonconformities?
- Is documented information retained as evidence of: nature of nonconformities, actions taken, results of corrective action?
- Are corrective actions reviewed for effectiveness?

10.3 Continual Improvement

- Does the organization continually improve suitability, adequacy and effectiveness of QMS?
- Are results of analysis and evaluation and management review outputs considered?
- Are improvement opportunities identified and necessary actions implemented?

Evidence to Review

- Nonconformity reports and corrective action records
- Root cause analysis documentation
- Effectiveness verification of corrective actions
- Improvement initiatives and their results
- Trend analysis of nonconformities
- Preventive action evidence
- Innovation and optimization projects

Audit Preparation and Planning

Effective audits begin long before the opening meeting. Thorough preparation ensures audits are focused, efficient, and deliver maximum value to the organization while maintaining professional standards and credibility.

Pre-Audit Preparation Checklist

- Review previous audit reports and corrective action status
- Understand organization's context, processes, and scope
- Review quality manual, procedures, and documented information
- Identify applicable statutory and regulatory requirements
- Determine audit objectives, scope, and criteria
- Prepare audit plan with schedule and resource allocation
- Select qualified audit team members
- Communicate audit plan to auditee in advance
- Prepare working documents and checklists
- Arrange logistics (access, facilities, safety requirements)

Audit Plan Components

- Audit objectives clearly stated
- Audit scope and boundaries defined
- Audit criteria (ISO 9001:2015 clauses, procedures, etc.)
- Audit schedule with time allocations per area/process
- Audit team members and their roles
- Auditee contacts and departments to be audited
- Language and logistics considerations
- Confidentiality and safety requirements

Opening Meeting Agenda

- Introductions of audit team and key auditee personnel
- Confirm audit objectives, scope, and criteria
- Review audit schedule and methodology
- Explain evidence collection and sampling approach
- Clarify roles, responsibilities, and communication protocols
- Address questions and concerns
- Confirm closing meeting arrangements

Evidence Collection Techniques

Objective evidence forms the foundation of credible audits. Lead auditors must master multiple evidence collection techniques to paint an accurate picture of QMS effectiveness and compliance.

Evidence Collection Methods Checklist:

Document Review

- Quality manual and policy documents
- Procedures and work instructions
- Records and forms (completed)
- Organizational charts and responsibility matrices
- Previous audit reports and corrective actions
- Management review minutes
- Training records and competency evidence
- Supplier evaluation records
- Customer feedback and complaints
- Monitoring and measurement data

Interviews

- Prepare open-ended questions in advance
- Interview personnel at various levels
- Ask about their understanding of processes and requirements
- Verify awareness of quality policy and objectives
- Confirm training and competence
- Understand how they handle nonconformities
- Assess knowledge of their role in QMS
- Cross-verify information from multiple sources

Observation

- Observe processes in actual operation
- Verify procedures are being followed
- Check workplace organization and conditions
- Observe use of equipment and monitoring devices
- Verify identification and traceability systems
- Check handling and storage of products
- Observe communication and coordination
- Note any unsafe conditions or practices

Sampling Strategy

- Select representative samples across time periods
- Include different shifts, products, or services
- Sample from various locations or departments
- Review both conforming and nonconforming examples
- Ensure sample size is adequate for conclusions
- Document sampling methodology and rationale

Evidence Documentation

- Record objective evidence clearly and factually
- Note document references (numbers, dates, revisions)
- Identify personnel interviewed (names, positions)
- Photograph or copy relevant evidence (with permission)
- Time-stamp observations
- Link evidence to specific audit criteria
- Maintain confidentiality and security of information

Nonconformity Identification and Reporting

Identifying and reporting nonconformities requires professional judgment, technical knowledge, and clear communication skills. The classification and documentation of findings directly impact the organization's improvement efforts.

Nonconformities must be stated objectively with clear evidence, avoiding ambiguous language or personal opinions. Each finding should be traceable to specific requirements and supported by verifiable evidence that withstands scrutiny.

1

Major Nonconformity

Absence or total breakdown of a system requirement, or situations that raise significant doubt about QMS capability to achieve intended outputs. May result in certification denial or suspension.

2

Minor Nonconformity

Isolated lapse in meeting a requirement that does not indicate system breakdown. Single occurrence or failure affecting limited scope that can be corrected quickly.

3

Observation or Opportunity

Potential improvement area or concern that doesn't constitute nonconformity but could develop into one if unaddressed. Best practices not yet implemented or trends requiring attention.

Nonconformity Documentation Requirements

Essential Elements:

- Clear statement of the nonconformity
- Reference to specific ISO 9001:2015 clause
- Objective evidence supporting the finding
- Extent and impact of the nonconformity
- Affected processes or areas
- Audit trail showing evidence source

Communication Guidelines:

- Use factual, non-judgmental language
- Discuss findings with auditees promptly
- Allow opportunity for clarification
- Provide examples and specific instances
- Document auditee responses
- Present findings in closing meeting clearly

Follow-up and Closure

The audit process doesn't end with the report. Effective follow-up ensures nonconformities are addressed, corrective actions are implemented, and improvements are sustained—transforming findings into lasting organizational benefits.

1

Corrective Action Plan

Organization develops plan addressing root causes, implementation timeline, and responsible parties within agreed timeframe (typically 30-90 days).

2

Plan Review

Lead auditor evaluates proposed actions for adequacy, ensuring they address root causes and prevent recurrence rather than just correcting immediate issue.

3

Implementation Verification

Evidence of implementation is submitted and reviewed. May include updated procedures, training records, or results from process changes.

4

Effectiveness Verification

Follow-up audit or review confirms corrective actions are effective. Verify through observation, records review, and interviews that changes are sustained.

5

Closure Documentation

Nonconformity is formally closed with documentation of verification activities and results. Audit records are updated and archived appropriately.

Verification Activities

- Review submitted evidence of corrective action
- Conduct follow-up interviews with relevant personnel
- Observe modified processes in operation
- Sample records to verify sustained implementation
- Assess whether root causes have been eliminated
- Confirm actions prevent recurrence not just correct

Closure Criteria

- Corrective action plan fully implemented
- Objective evidence demonstrates effectiveness
- Root causes have been addressed
- Process changes are documented and trained
- Sustainability mechanisms are in place
- No new nonconformities in corrected area

Important: Effectiveness verification should occur after sufficient time has passed for the corrective action to be tested under normal operating conditions. Premature closure risks recurrence of the same nonconformity.

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