Iso 17025 Internal Audit Checklist Example

Internal Audit Checklist for ISO/IEC 17025:2017

Internal Audit Checklist

Company Name			
Lab Address			
Auditor Name		Date	
Audit Type			

Instructions

isobudgets

ISO 17025 internal audit checklist example provides a structured approach for laboratories to evaluate their compliance with the international standard for testing and calibration laboratories. An internal audit is a crucial part of the quality management system, allowing organizations to assess their processes, identify areas for improvement, and ensure that they meet the standards required for accreditation. This article will detail an example checklist to guide laboratories through the internal audit process, focusing on the key elements of ISO 17025.

Understanding ISO 17025

ISO 17025 is the international standard that specifies the general requirements for the competence of testing and calibration laboratories. It covers various aspects, including:

- Management Requirements: These include organizational structure, management responsibility, and quality system.
- Technical Requirements: This involves the competence of personnel, testing methods, equipment, and validation of results.

The objective of an internal audit is to ensure that the laboratory adheres to these requirements and continually improves its processes.

Why Conduct an Internal Audit?

Conducting an internal audit is essential for several reasons:

1. Compliance Verification: Ensures that the laboratory complies with ISO 17025 requirements.
2. Continuous Improvement: Identifies areas for improvement and helps in enhancing the laboratory's processes.
3. Risk Management: Recognizes potential risks that could affect the quality of results.
4. Prepare for External Audits: Helps in preparing for accreditation body assessments by identifying non-conformities beforehand.
5. Employee Engagement: Involves staff in quality management, fostering a culture of quality.

ISO 17025 Internal Audit Checklist Example

An internal audit checklist is a practical tool that guides auditors in evaluating compliance with the ISO 17025 standard. Below is an example of a checklist that can be adapted based on specific laboratory needs.

1. Management Requirements

- 1.1 Quality Manual
- Is there a documented quality manual that complies with ISO 17025?
- Is the quality manual regularly reviewed and updated?

- 1.2 Management Responsibility
- Is there a defined organizational structure?
- Are responsibilities for quality management clearly defined?

- 1.3 Document Control
- Are documents controlled to ensure they are current and accessible?
- Is there a documented procedure for controlling documents?

- 1.4 Records Management
- Are records maintained as per the requirements of ISO 17025?
- Are retention times for records defined and adhered to?

- 1.5 Internal Audit Program
- Is there an internal audit program in place?
- Are audits conducted at planned intervals?

2. Technical Requirements

- 2.1 Personnel Competence
- Are personnel competent for their assigned tasks?
- Is there a training program in place to maintain and improve competence?

- 2.2 Testing and Calibration Methods
- Are testing and calibration methods documented?
- Are methods validated and periodically reviewed?

- 2.3 Equipment and Calibration
- Is equipment calibrated and maintained according to established procedures?
- Are calibration records maintained?

- 2.4 Test Reports and Records
- Are test reports formatted to include all necessary information?
- Are records of results retained for the specified duration?

3. Process Control

- 3.1 Planning of Processes
- Are processes planned and implemented to meet requirements?
- Are changes to processes documented and evaluated?

- 3.2 Measurement Uncertainty
- Is measurement uncertainty evaluated for all tests?
- Are the results of uncertainty calculations documented?

- 3.3 Handling of Test Items
- Are procedures in place for the identification and handling of test items?
- Are test items stored appropriately to prevent damage or contamination?

4. Non-Conformance and Corrective Actions

- 4.1 Non-Conformance Management
- Are procedures in place for identifying and managing non-conformances?
- Are corrective actions documented and followed up?

- 4.2 Preventive Actions
- Is there a system to identify potential non-conformances?
- Are preventive actions implemented and monitored?

5. Management Review

- 5.1 Review Process
- Is there a documented procedure for management reviews?
- Are reviews conducted at planned intervals?

- 5.2 Review Inputs
- Are inputs for management reviews documented, including audit results and feedback?
- Is there a record of decisions and actions from management reviews?

6. Continuous Improvement

- 6.1 Performance Metrics
- Are key performance indicators (KPIs) established and monitored?
- Is there a process for analyzing and reporting performance data?

- 6.2 Employee Feedback
- Is employee feedback on quality issues encouraged and documented?
- Are there forums or meetings to discuss quality improvements?

Implementing the Internal Audit Checklist

Once the checklist is completed, the next steps are crucial for ensuring its effectiveness:

1. Assign Responsibilities: Designate a lead auditor and team members responsible for conducting the audit.
2. Schedule the Audit: Plan the audit schedule, ensuring it aligns with laboratory operations.
3. Conduct the Audit: Use the checklist to assess compliance, document findings, and engage with relevant personnel.
4. Report Findings: Compile an audit report that highlights non-conformities, strengths, and opportunities for improvement.
5. Follow-Up: Create an action plan to address any identified non-conformities and monitor the implementation of corrective actions.

Conclusion

An ISO 17025 internal audit checklist example serves as a fundamental tool for laboratories seeking to maintain compliance with international standards. By systematically evaluating management and technical requirements, laboratories can enhance their processes, improve quality, and ensure that they are preparing effectively for external audits. Implementing regular internal audits not only meets regulatory demands but also fosters a culture of continuous improvement within the organization, ultimately leading to better service delivery and increased customer satisfaction.

Frequently Asked Questions

What is ISO 17025 and why is it important for laboratories?

ISO 17025 is an international standard that specifies the requirements for the competence of testing and calibration laboratories. It is important because it ensures laboratories produce valid and reliable results, enhancing their credibility and fostering customer confidence.

What are the key components of an ISO 17025 internal audit checklist?

Key components typically include sections on management responsibility, resource management, process control, quality assurance, and continual improvement. Each section should assess compliance with the standard's requirements.

How often should internal audits be conducted for ISO 17025 compliance?

Internal audits should be conducted at least once a year, but the frequency can be increased based on the size of the laboratory, the complexity of operations, or the results of previous audits.

What is the purpose of an internal audit in the context of ISO 17025?

The purpose of an internal audit is to evaluate the laboratory's compliance with ISO 17025 requirements, identify areas for improvement, ensure effective implementation of the quality management system, and prepare for external audits.

Can you provide an example of an item on an ISO 17025 internal audit checklist?

An example item could be: 'Are laboratory personnel adequately trained and qualified for their specific roles?'. This checks compliance with the requirement for personnel competence.

What steps should be taken after completing an internal audit for ISO 17025?

After completing an internal audit, the findings should be documented, communicated to relevant staff, corrective actions should be identified and implemented, and follow-up reviews should be scheduled to ensure issues are resolved.

How can laboratories prepare for an internal audit based on ISO 17025?

Laboratories can prepare by reviewing previous audit reports, ensuring all documentation is up to date, conducting pre-audit checks, and training staff on audit procedures and expectations.

What common non-conformities might be found during an ISO 17025 internal audit?

Common non-conformities include inadequate documentation of procedures, lack of training records, insufficient equipment calibration, and failure to follow established protocols.

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