ISO 17025 Laboratory Compliance Guide

This guide provides laboratories with a structured approach to achieving and maintaining compliance with ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories. The guide covers documentation, procedures, quality management, technical requirements, and continuous improvement practices.

1. Scope and Purpose

ISO 17025 applies to all laboratories performing testing and calibration. The purpose is to ensure competence, impartiality, and consistent operation.

2. Management Requirements

Laboratories must implement a Quality Management System (QMS). Key elements include: organizational structure, impartiality, confidentiality, document control, and continual improvement.

3. Resource Requirements

Compliance requires adequate facilities, calibrated equipment, competent personnel, and controlled environmental conditions to ensure validity of results.

4. Process Requirements

Processes should cover sampling, method validation, measurement traceability, handling test items, and reporting results. Records of all activities must be maintained.

5. Technical Competence

Staff must be trained and competent. Competence must be demonstrated through regular assessments, proficiency testing, and documented training programs.

6. Documentation Requirements

Laboratories must establish and maintain policies, standard operating procedures (SOPs), work instructions, and records in line with ISO 17025.

7. Internal Audits and Management Review

Regular internal audits should be conducted to verify compliance. Management must review audit findings, risks, and opportunities for improvement.

8. Risk-Based Thinking

Risk management must be applied across laboratory operations to ensure reliability and minimize errors in testing and calibration.

9. Continuous Improvement

A culture of continuous improvement should be maintained by analyzing audit outcomes, customer feedback, corrective actions, and performance metrics.

ISO 17025 Compliance Checklist

Requirement	Compliant (Yes/No)	Notes
Quality Manual in place		
Organizational structure defined		
Documented procedures for testing/calibration		
Equipment calibration records maintained		
Personnel competence records available		
Proficiency testing conducted regularly		
Internal audits conducted		
Management reviews documented		
Risk assessment performed		
Corrective and preventive actions tracked		