



Quality Management System and
Laboratory Competence to ISO/IEC
17025:2017



Quality Management System and Laboratory Competence to ISO/IEC 17025:2017

Introduction

This Quality Management System and Laboratory Competence to ISO/IEC 17025:2017 course explores laboratory management systems. It is for senior laboratory technicians seeking to enhance their quality management expertise in laboratory environments. It defines the essential requirements to ensure competence and consistency in testing and calibration laboratories. It focuses on equipping participants with the knowledge needed to achieve accurate, reliable test results and to implement robust laboratory management practices aligned with international standards such as ISO 17025:2017.

Integrating the concept of LEC into laboratory training is crucial for understanding laboratory environmental conditions. This training is essential for maintaining laboratory standards, ensuring safety, and complying with international standards such as ISO 17025. Understanding the Laboratory Management System LMS significantly enhances laboratory operations. The effective implementation of an LMS, as the cornerstone of ISO 17025:2017 compliance, ensures efficient management of laboratory operations, resources, and personnel, leading to reliable results and increased customer satisfaction.

Targeted Groups

The Quality Management System and Laboratory Competence to ISO/IEC 17025:2017 course is for professionals seeking to acquire knowledge and skills, including:

- Senior laboratory technicians.
- Laboratory managers and supervisors.
- Quality assurance officers.
- Laboratory auditors.
- Laboratory process improvement specialists.
- Compliance officers in laboratory environments.
- Technical experts in testing and calibration laboratories.
- Professionals seeking ISO 17025 certification.

Course Objectives

By the end of this Quality Management System and Laboratory Competence to ISO/IEC 17025:2017 course, participants will be able to:

- Understand the fundamental principles of ISO 17025:2017 for laboratory management systems.
- Implement effective quality management systems tailored to laboratory environments.
- Conduct internal audits and assessments to ensure compliance with ISO laboratory management standards.
- Master documentation protocols and record-keeping requirements in accordance with ISO 17025.
- Ensure accuracy and reliability in calibration and testing processes.
- Manage and maintain laboratory equipment in line with ISO 17025 requirements.
- Apply comprehensive risk management strategies in laboratory operations.

- Strengthen continuous improvement strategies in laboratory practices.
- Achieve and maintain compliance with ISO 17025:2017 requirements.
- Support the development and competence of laboratory personnel.

Targeted Competencies

In this Quality Management System and Laboratory Competence to ISO/IEC 17025:2017 program, participants will gain the following competencies:

- Comprehensive understanding of ISO 17025:2017 requirements.
- Implementation of an effective Laboratory Management System LMS.
- Conducting internal audits for ISO 17025 accreditation compliance.
- Managing laboratory documentation and records securely and comprehensively.
- Ensuring testing and calibration accuracy according to ISO 17025:2017.
- Applying advanced laboratory risk management practices.
- Promoting continuous improvement in laboratory environments.
- Enhancing laboratory staff competence.
- Supervising laboratory equipment and required maintenance.

Studying Scenarios

In the Quality Management System and Laboratory Competence to ISO/IEC 17025:2017 training, participants will develop their capabilities by analyzing scenarios such as:

- Approaching an accreditation audit with incomplete calibration documentation.
- Discovery of test results that do not match reference values.
- Loss of an electronic record containing sensitive analytical results.
- Failure of a critical instrument during an essential test.
- Customer complaint regarding the accuracy of an issued inspection report.
- There is a discrepancy in the results between technicians analyzing the same sample.
- Delay in updating a standard operating procedure after an approved modification.
- Insufficient competence of a newly assigned technician for an accredited test.
- Failure in a proficiency testing program between accredited laboratories.

Course Content

Unit 1: Fundamentals of ISO/IEC 17025:2017 and Laboratory Management Systems

- Overview of ISO/IEC 17025:2017.
- Importance of the standard in laboratory operations.
- Key differences between ISO/IEC 17025:2005 and ISO/IEC 17025:2017.
- Scope and applicability of the standard in laboratories.
- Core terminology and definitions.
- Importance of maintaining international recognition and accreditation.
- Introduction to Laboratory Management Systems LMS.
- Documentation requirements and control.
- Defining laboratory roles and responsibilities.
- Management of laboratory resources and infrastructure.
- Risk-based thinking and its impact on management systems.
- Principles of continuous improvement in laboratory environments.

Unit 2: Personnel Competence, Equipment Management, and Calibration

- Identifying required laboratory staff competencies.
- Staff training and development plans.
- Competence evaluation through performance assessments.
- Ensuring the availability of qualified technical personnel.
- Documentation of qualifications and certifications.
- Addressing staffing shortages and skill gaps.
- Overview of equipment management and maintenance.
- Ensuring equipment calibration and verification.
- Equipment handling, storage, and maintenance procedures.
- Selection and management of external calibration services.
- Ensuring traceability of calibration standards.
- Preparing calibration schedules and records.

Unit 3: Testing and Calibration Methods and Quality Control

- Selection of appropriate testing and calibration methods.
- Documentation and validation of methods and procedures.
- Ensuring the accuracy and reliability of test results.
- Use of control materials and reference materials.
- Method validation and verification processes.
- Handling non-conforming results and corrective actions.
- Establishing quality control procedures for testing and calibration.
- Conducting proficiency testing and inter-laboratory comparisons.
- Documentation of quality assurance activities and results.
- Implementing corrective actions for non-conformities.
- Conducting internal audits and external reviews.
- Preparation and maintenance of the quality manual.

Unit 4: Laboratory Environment, Safety, and Document & Record Management

- Maintaining appropriate laboratory environmental conditions.
- Environmental monitoring and control.
- Implementation of health and safety protocols.
- Managing potential laboratory operational risks.
- Provision of personal protective equipment PPE.
- Emergency preparedness and response planning.
- Document control procedures and version management.
- Ensuring traceability of laboratory records.
- Secure storage systems for laboratory documentation.
- Establishing audit trails for laboratory processes.
- Electronic record management and data security.
- Periodic review and updating of documentation.

Unit 5: Risk Management, Accreditation, and Sustained Compliance

- Identifying and assessing risks in laboratory operations.
- Developing risk mitigation strategies and plans.
- Managing risks during testing and calibration processes.
- Risk-based decision-making in laboratory operations.

- Integrating risk management into the laboratory quality system.
- Ensuring personnel safety and data integrity.
- Understanding the ISO/IEC 17025:2017 accreditation process.
- Steps to prepare for laboratory accreditation.
- Communication with accreditation bodies and external auditors.
- Addressing findings from accreditation audits.
- Maintaining continuous compliance with ISO/IEC 17025:2017.
- Establishing a sustainable approach to accreditation renewal.

Final Insights & Key Takeaways

This course provides an understanding of the requirements of ISO/IEC 17025:2017 and enables participants to implement an effective quality management and laboratory competence system aligned with international best practices. Participants will learn to apply the concepts within the laboratory, while promoting internal auditing and continuous improvement initiatives to ensure sustainability and maintain accreditation status.