

ISO/IEC 17025 Laboratory Management System

Course Outline

Unit 1: Introduction to ISO/IEC 17025:2017 Standards

- Overview of ISO/IEC 17025:2017
- Importance of the standard for laboratory operations
- Key differences between ISO/IEC 17025:2005 and ISO/IEC 17025:2017
- Scope and applicability of the standard in laboratories
- Overview of key terms and definitions used in the standard
- Importance of maintaining international recognition and accreditation

Unit 2: Laboratory Management System Requirements

- Introduction to laboratory management systems (LMS)
- Documentation requirements and management
- Establishing roles and responsibilities within the laboratory
- Procedures for managing laboratory resources and infrastructure
- Risk-based thinking and its impact on management systems
- Continual improvement principles in laboratory environments

Unit 3: Competence of Personnel

- Defining competencies required for laboratory personnel
- Training and development plans for laboratory staff
- Evaluating competency through performance assessments
- Ensuring the availability of competent technical staff
- Documenting qualifications and certifications of personnel
- Addressing personnel shortages and skill gaps

Unit 4: Equipment and Calibration Management

- Overview of equipment management and maintenance
- Ensuring the calibration and verification of equipment
- Procedures for handling, storing, and maintaining equipment
- Selecting and managing external calibration services
- Ensuring the traceability of calibration standards
- Establishing calibration schedules and records

Unit 5: Testing and Calibration Methods

- Selection of appropriate testing and calibration methods
- Documenting and validating methods and procedures
- Ensuring the accuracy and precision of test results
- Implementing control and reference materials
- Method verification and validation processes
- Dealing with non-conforming results and corrective actions

Unit 6: Laboratory Environment and Safety

- Maintaining appropriate laboratory conditions
- Ensuring environmental control and monitoring

- Implementing health and safety protocols
- Managing potential risks in laboratory operations
- Providing personal protective equipment (PPE) for staff
- Emergency preparedness and response plans

Unit 7: Quality Control and Assurance

- Establishing quality control procedures for testing and calibration
- Performing proficiency testing and inter-laboratory comparisons
- Documenting quality assurance processes and outcomes
- Implementing corrective actions for non-conformities
- Internal audits and external reviews for quality assurance
- Creating and maintaining a quality manual

Unit 8: Document Control and Records Management

- Procedures for document control and versioning
- Ensuring traceability of laboratory records
- Establishing secure storage systems for laboratory documents
- Creating audit trails for laboratory processes
- Managing electronic records and data security
- Reviewing and revising documentation periodically

Unit 9: Risk Management in Laboratories

- Identifying and assessing risks in laboratory operations
- Developing risk mitigation strategies and plans
- Managing risk during laboratory testing and calibration
- Risk-based decision-making for laboratory operations
- Integrating risk management into the laboratory quality system
- Ensuring the safety of laboratory personnel and data integrity

Unit 10: Achieving and Maintaining Accreditation

- Understanding the accreditation process for ISO/IEC 17025:2017
- Steps to prepare for laboratory accreditation
- Engaging with accreditation bodies and external auditors
- Addressing findings from accreditation audits
- Maintaining ongoing compliance with ISO/IEC 17025:2017 standards
- Creating a sustainable approach to accreditation renewal