Empowering & Inspiring Excellence

Company Registration No. 2014/063827/07

ONLINE Course

Implementation of Laboratory Systems based on ISO/IEC 17025:2017

Course Overview

The basic requirements for a management system for testing and calibration laboratories are based on the international standard ISO/IEC 17025. These international standard requirements are used globally for the assessment and accreditation of laboratories by Accreditation Bodies. Laboratory accreditation to ISO/IEC 17025 by a recognized accreditation body such as the South African National Accreditation System (SANAS) or SADCAS provides any laboratory with adequate evidence of technical competence to perform specific types of tests according to national and international standards. Laboratory accreditation also provides laboratory managers and customers with adequate assurance of the quality of results reported by the laboratory. Customers need to have confidence in the accuracy and reliability of the laboratory test results in order to make important decisions.

This course is aimed at equipping participants to be able to unpack and implement the requirements of ISO/IEC 17025:2017 standard. The course focuses on the detailed requirements for establishing, **practical implementing** and maintaining the ISO/IEC 17025 accredited laboratory quality management system and obtain or maintain SANAS accreditation as evidence of laboratory competence.

Course Objectives

To equip participants with the knowledge and skills required for practical implementation of a Laboratory Management System based on ISO/IEC 17025:2017.

On completion of the course participants will be able to:

- Know and implement the ISO 17025:2017 requirements
- Have a clear understanding of the new structure of ISO/IEC 17025 standard
- Know and understand the major and minor changes in the new ISO/IEC 17025:2017 standard
- Understand and explain new concepts in ISO17025:2017 such as:

    - PDCA process
    - Risk/Opportunities identification and mitigation;
    - Verification and Validation
    - Decision Rules
    - Principles of Impartiality.
- Know the required documents and records and be able to implement actionable clauses.
- Know implementation steps and laboratory accreditation requirements

Course Content

- Overview of quality
- Quality Assurance and Quality Control
- Overview of quality management system (why QMS? what are the benefits?)
- History and Current Status of ISO/IEC 17025 standard
- Why ISO/IEC 17025:2005 needed to be revised
- Relationship between ISO 17025 and ISO 9001
- Changes in the new ISO 9001:2015 and their impact on ISO/IEC 17025 standard
- Transition from ISO 17025:2005 to ISO 17025:2017 Standard
- Accreditation of Management System by accreditation bodies e.g. SANAS & SADCAS
- Registration vs. Accreditation vs. Certification
- Mutual Recognition Arrangements
- ISO/IEC 17025:2017 The new structure
- A comparison of the Elements of ISO/IEC 17025:2017 Standard and ISO17025:2005
- Key changes in ISO/IEC 17025:2017: Major and minor changes
- New Definitions and Concepts for ISO/IEC17025:2017 including PDCA process, Risk/Opportunities identification and mitigation, Risk Management Methods, Principles of Impartiality and Confidentiality
- Requirements from the ISO/IEC 17025:2017 Standard:
    - **General requirements and Structural Requirements** (Organizational and Management Structure)
    - **Resource requirements** :
        - Personnel (Awareness, Training and personnel competency evaluation)
        - Metrological Traceability
        - Equipment (suitability, verification and calibration)
        - Facilities & Environmental conditions
        - Management of Externally provided products and services.
    - **Process requirements** : Laboratory Processes using the PDCA model (customer work requests through to final report/certificate delivery including the following:

        - Review of requests, tenders and contracts
        - Selection, Verification & Validation of Methods
        - Sampling
        - Handling of test items
        - Handling of technical records
        - Overview on the evaluation of Measurement Uncertainty
        - Ensuring the validity of results (including inter-laboratory comparison and Proficiency Testing)
        - Reporting Results
        - Handling complaints
        - Handling and prevention of non-conforming work
        - Control of data & information management
    - **Management System requirements**
        - Management System Documentation
        - Control of management system documents
        - Control of records
        - Identifying and implementing actions to address risks & opportunities
        - Identifying and implementing improvement
        - Internal Audits
        - Management reviews
- Identifying and writing non-conformances, problem solving through root cause analysis and implementing of appropriate corrective action(s) and preventive action(s)
- Road map / implementation plan for ISO 17025 new requirements
- List of forms and SOPs required for accreditation (templates to be provided during and after the course if required)
- Quality Control Charts (QC charts)

Who should attend?

- Quality persons including Quality Assurance Managers, Quality Managers and Quality assistances and Quality team leaders
- Laboratory Managers, Middle management
- Laboratory personnel including supervisors, Scientists, Chemists, Microbiologists, Laboratory Analysts and anyone responsible for implementing or maintaining the Laboratory Quality System

Entry requirements

- Participants should have a good comprehension of English and be able to read, write and communicate in English
- Participants should be working in the laboratory environment or have knowledge of the laboratory environment

Assessment

- Formative assessment through quizzes, online discussions, case studies and student
- activities/exercises
- Examination at the end of the course may be given.
- Portfolio of Evidence
- Full attendance of all contact sessions is essential for a certificate to be issued

Course duration: 3 days

Cost R3 200 per person

For Further Information on our training courses, or to register for a course, please contact us on:

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