Course Objectives

Laboratory Management Course

ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories"

Learning Objectives: This course will help the participants to:

- Understand the requirements of ISO/IEC 17025:2017 as applied to calibration/testing laboratories; and
- Develop a quality system which can improve the laboratory operations to meet the needs of their clients understand the SAC requirements for accreditation

Duration: Up to 3 days

PART A: ISO/IEC 17025:2017:

Description: This course is a comprehensive review of the philosophies and requirements of this international Standard. The participant will gain an understanding of conformity assessment using the risks and opportunities-based approach.

Outline & Outcomes: After successful completion of the course, the participant will be able to:

- 1. Describe the structure of the Standard as it relates to process flow
- 2. Understand the requirements as applied to laboratories as defined in the Standard
- 3. Apply the additional SAC requirements to pertinent clauses within the Standard
- 4. Describe and apply the process-based approach;
- 5. Explain new concepts such as: a. Continual Improvement (using PDCA, objectives and KPIs); b. Verification and Validation; c. Decision Rules; d. Principles of Impartiality; and e. Risk-Based Thinking
- 6. Analyze scenarios to identify non-conformities, risks, and opportunities related to the requirements in the standard;
- 7. Analyze sample calibration records to demonstrate metrological traceability; and 8. List the areas where Documents and Records are required

PART B: Understanding Your Quality Management System:

Description: During this course, the participant will gain an understanding of the basic concepts of management system documentation structure, content, and development using the process-based approach and risk-based thinking. The participant will also practice developing processes, Standard Operation Procedures (SOPs), and applying mechanisms to control, review, and update documents on an ongoing basis.

Outline & Outcomes: After successful completion of the course, the participant will be able to:

- 1. Identify terms used in conformity assessment Standards which refer to a "Document";
- 2. Define and differentiate document terms;
- 3. Identify requirements for documents;

- 4. Define the sources of input (clients) and input requirements for developing the documents
- 5. Identify and evaluate the risks associated with the process
- 6. Establish key objectives and monitoring tools to ensure success in implementation of the document
- 7. Employ document writing and control techniques; and
- 8. Describe different document design formats, including LIMS