

Understanding ISO 15189:2012 – a laboratory management course for Medical and Medical Imaging Laboratories

The ISO *15189: Medical Laboratories - Particular requirements for quality and competence* standard was written specifically for Medical and Medical Imaging laboratories. This standard has recently been revised to the third edition in November 2012. It is important for accredited Medical Testing laboratories and Medical Imaging Facilities to understand the differences between the two versions and implement its existing quality management system to meet the new requirements. It is also important for applicant laboratories to understand the requirements of ISO 15189 and develop a quality management system to improve the laboratory operations.

Course Objectives

- Understand and Implement the requirements of ISO 15189 as applied in Medical testing laboratories and Medical Imaging Facilities;
- Develop a quality system which can improve the laboratory operations to meet the needs of their customers

Course Duration

2 Days

Who Should Attend

This course is designed for:

- Laboratory managers and quality managers responsible for bringing their systems into compliance with ISO 15189
- Laboratory personnel who will be implementing and operating the quality system in Medical Testing laboratories and Medical Imaging facilities.

Course Outline

- Overview of ISO 15189 : Then and Now
- The Elements of ISO 15189
- Quality manual and procedures
- The Development, Documentation and Implementation of Quality Systems
- Management of records
- Improvement elements
- Internal audits and management review
- Staff issues and managing change
- Pre-examination procedures
- Laboratory facilities, equipment management and calibration
- Examination Procedures Quality control
- Overview on Estimation of Measurement Uncertainty
- Test Records and Reports
- Laboratory Information Management