Sri Lanka Accreditation Board for Conformity Assessment

Extensive Course on Laboratory Accreditation as per ISO/IEC 17025:2017 & ISO 15189:2012

September 2019

Course Content

1. **Introduction and overview of Accreditation, Conformity Assessment and Trade Agreements**
   Role of international bodies in relation to Standards, Accreditation & Metrology, TBT and SPS Agreements, Bi-lateral Agreements, Free Trade Agreements, World Trade Organization, role of National Focal point/inquiry points, role of competent authorities.

2. **Quality Management – Concepts and Applications**
   Quality, Quality control, Quality assurance, Quality Management, Quality Management concepts and applications, Conformity Assessment Concepts and Applications, Accreditation, Experiences in other countries, emerging accreditation schemes, ILAC and IAF and APAC.

3. **Introduction to ISO/IEC 17000 series of Standards, ISO 15189 & ISO 15190, Specific criteria & Accreditation Process**
   ISO/IEC 17001, ISO/IEC 17002, ISO/IEC 17003, ISO/IEC 17020, ISO/IEC 17021, ISO/IEC 17024, ISO/IEC 17025, ISO/IEC 17031, ISO/IEC 17043, ISO 15189, ISO 15190, Specific criteria, Accreditation process.

4. **Explanation of Clauses 1,2,3,4 & 5 of ISO/IEC 17025 and Clauses 1,2,3 , 4.1.1 of ISO15189**

   Organization identity & legal status, structural requirements including organization structure and tasks delegation, manager technician relationships, communication systems, impartiality and operational integrity, confidentiality, statutory and regulatory requirements applicable to medical and non-medical laboratory testing,

5. **Explanation of Clauses 6 of ISO/IEC 17025**

   Resources required to carry out testing activities (personnel, environmental conditions, equipment, metrological traceability, externally provided services, product/service requirements, purchasing, vender relations, vender evaluation, subcontracting, supply chain, e-business/commerce

6. **Explanation of Clauses relevant to resources- 4.1.1.4,4.1.2.7,4.5,4.6 & 4.7, 5.1, 5.2,5.3 of ISO 15189**

   Resources required to carry out testing activities (Personnel , environmental conditions, equipment, reagents and consumables, examination by referral laboratories, advisory services, external services and supplies), product/service requirements, purchasing, vender relations, vender evaluation, subcontracting, supply chain, e-business/commerce

7. Explanation of Clauses 7 of ISO/IEC 17025

Explain process requirements which covers review of request, tenders and contracts, selection, verification and validation of methods, sampling, handling of test/calibration items, evaluation of measurement uncertainty, ensuring validity of results, technical records, and reporting results.

8. Explanation of Clauses 4.4, 5.4, 5.5,5.6,5.7,5.8,5.9 of ISO 15189

Explain process requirements which covers service agreements, pre-examination process, examination process, ensuring quality of examination results, post-examination processes, reporting results, release of results

9. Explanation of Clauses 7.9,7.10, 7.10, 8.6, 8.7 & 8.8 of ISO/IEC 17025 and Clauses 4.8,4.9,4.10,4.11, 4.12, 4.13 ,4.14 & 4.15 of ISO 15189

Resolution of complaints, customer feedbacks, customer satisfaction surveys, handling of nonconforming situations, corrective and preventive actions, continual improvement, value chain, continuous improvement, incremental improvement, continual improvement, improvement models, action plan, service shop, process mapping, critical path analysis, Turnaround time, Management commitment, Leadership, management review and follow up.

10. Explanation of Clauses 8.2,8.3,8.4,7.11 of ISO/IEC 17025 and Clauses 4.1,4.2,4.3 & 5.10 of ISO 15189

Documentation of Management Systems, Level of Documentation, Development of Quality Manual, method manual, procedure manual, operational instructions, formats, Installation of management systems, Laboratory Information Management Systems, Control of data and management

11. Quality Management and Statistical Techniques

Statistical techniques and Quality management techniques required for laboratory testing

12. Method Validation & Verification and Measurement Uncertainty

Method Validation & verification and Measurement Uncertainty in Chemical Testing

13. Method Validation & Verification and Measurement Uncertainty

Method Validation & verification and Measurement Uncertainty in Biological Testing

14. Method Validation & Verification and Measurement Uncertainty

Method Validation & verification and Measurement Uncertainty in Physical Testing & Calibration

15. Method Validation and Verification, Measurement uncertainty & Specific requirements in relation to clauses 5.4,5.5,5.6 & 5.7

Method Validation and verification & Measurement Uncertainty in Biochemistry

16. **Method Validation and Verification, Measurement uncertainty & Specific requirements in relation to clauses 5.4,5.5,5.6 & 5.7**

Method Validation and verification in Hematology

17. **Method Validation and Verification, Measurement uncertainty & Specific requirements in relation to clauses 5.4,5.5,5.6 & 5.7**

Method Validation and verification in Microbiology

18. **Measurement Traceability, Measurement of Uncertainty and Decision Rules**

Measurement Traceability, primary, secondary, reference and work standards, Chain of traceability, Identification of uncertainty sources, Estimation of uncertainty, quantification of uncertainty components, reporting expanded and standard uncertainty, numerical expression of results, compliance against limits, decision rules, metrological traceability

19. **Intralaboratory Comparisons, Inter-laboratory Comparisons & Proficiency Testing as per ISO/IEC 17025**

Organizations, coordination, evaluation of results, reporting and performance evaluation and corrective actions for outliers

20. **Intralaboratory Comparisons, Inter-laboratory Comparisons & Proficiency Testing as per ISO 15189**

Organizations, coordination, evaluation of results, reporting and performance evaluation and corrective actions for outliers

21. **Similarities and Differences between ISO/IEC 17025 and ISO 15189**

Similarities and Differences between ISO/IEC 17025 and ISO 15189

22. **Risk based approach as per ISO/IEC 17025 and ISO 15189**

23. **Installation of ISO/IEC 17025 and ISO 15189**

Appointment of a Steering Committee, Appointment of a Management Representative, Deciding on Activities, Development of Vision, Mission, Quality policy, Goals and objectives, Changes in Organizational Structure, Developing action plans, execution of action plans, review of action plans, Management review

24. **Group Assignments on following areas**

Development of Policies (ISO/IEC 17025 and ISO 15189
Development of Quality Manual (ISO/IEC 17025 & ISO 15189)
Development of Procedures and Instructions (ISO/IEC 17025 and ISO 15189)
Development of Method Manual and Operational Instructions (ISO/IEC 17025 & ISO 15189)
Method Verification & Validation
Calculation of uncertainty of measurement (ISO /IEC 17025 and ISO 15189)

25. **Written Examination**

26. **Development of Quality manual** and related documentation (within 3 months after the programme)