Training Content

1. Introduction 1.1. Certification and Accreditation 1.2. The Global scenario and APLAC, ILAC MRA	**2. Overview of concept of Laboratory Management System (LMS) & structure of ISO 15189**
3. Comparison between ISO 15189:2007 and ISO 15189:2012	**4. Summary of changes in ISO 15189:2012**
5. Understanding Management Requirements of ISO 15189:2012 with detailed examination of important management system elements 5.1. Organization and management responsibility 5.2. Document control 5.3. Identification and control of non-conformities 5.4. Corrective action 5.5. Preventive action 5.6. Management review	**6. Understanding Technical Requirement of ISO 15189:2012 Standard with detailed examination of important technical operations** 6.1. Personnel 6.2. Laboratory equipment, reagents and consumables 6.3. Pre-examination processes 6.4. Ensuring quality of examination results 6.5. Laboratory information management
7. Auditing Practice 7.1. Contents of clause 4.14 of ISO 15189 - Evaluation and audit 7.2. Introduction to audit 7.3. Types and methods of Audit 7.4. Checklist preparation, audit planning and audit schedule 7.5. The audit process 7.6. Identification of non-conformities 7.7. Preparation of Audit Report 7.8. The internal audit process	**8. Implementation of laboratory management system with evidence leading to accreditation**
9. Understanding the specific criteria of NABL accreditation on Clinical Laboratories	**10. The accreditation process of NABL** 10.1. Adequacy audit on receipt of application compliant to NABL requirement 10.2. Pre-assessment by Lead Assessor 10.3. Final assessment after closure of NC if any on pre-assessment 10.4. Examination of assessment report by Accreditation Committee after closure of NC if any raised during final assessment 10.5. Issue of accreditation certificate after recommendation by Accreditation Committee
11. Syndicated exercise on: 11.1. Management requirement 11.2. Developing documented procedure 11.3. Technical requirements 11.4. Developing standard operating procedure 11.5. Preparation of checklist for Audit 11.6. Identification and writing of NCs	