Effective Implementation and Internal Audit of ISO/IEC 17025:2017 Laboratory Management System (LMS) and NABL Criteria

Organized by
FICCI QUALITY FORUM
May 6 - 9, 2019
Mumbai

1. Introduction

Though the revised Standard, ISO/IEC 17025:2017 does not specify a position of Quality Manager, a laboratory holding or seeking accreditation is required to have personnel who, inter-alia, shall implement, maintain and improve the management system, and shall report to laboratory management on the performance of the management system and ensure the effectiveness of laboratory activities. So it is essential that the designated personnel, however named, should be well versed with all the requirements of ISO/IEC 17025:2017 version.

Since the Standard does not specify a Quality Manager, NABL's requirement of a 4-day course on ISO/IEC 17025 is construed to apply to all laboratory personnel who implement and maintain the laboratory management system

2. Course Objectives

The aim of the course is to provide a concerted and comprehensive training on development & implementation of ISO/IEC 17025:2017 Laboratory Management System (LMS) for building competence of all personnel who implement, maintain and improve laboratory activities in testing and calibration laboratories.

At the end of the course, participants will be able to:

- ✓ Interpret the requirements of ISO/IEC 17025:2017 and how to apply these requirements correctly
- ✓ Conduct an effective gap analysis / internal audit / third party audit of LMS
- ✓ Initiate and drive implementation of LMS in their laboratory in planned and effective manner

3. You should attend this course if,

- ✓ You want to comply with mandatory NABL criteria and requirements for training of personnel who implement,
maintain and improve laboratory activities
- ✓ You want to understand the value of operating effective LMS
- ✓ You are looking to expand your skills in the area of good laboratory practices
- ✓ You are involved in preparing your organisation for assessment/accreditation by NABL to the requirements of ISO/IEC 17025:2017
- ✓ You want to assess LMS of your supporting laboratories

4. Course Material

Course kit comprising detailed course material and International Standard ISO/IEC 17025:2017 is provided to each participant.

5. Methodology & Certification

A judicious mix of class room presentations, exercises, group discussion, case studies and hands-on practice will be used. Participants will be encouraged to relate the learning to live situations.

Participants who successfully complete the continuous assessment during the course and also the written examination conducted on 4th day of the course will be issued a certificate by FICCI.

6. Course Schedule & Registration Procedure

Date: May 6 - 9, 2019

Timing: 09:30 hrs – 17:30 hrs

Nature: Non residential

Venue: Mumbai

Participation Fee: Rs. 17,000 plus GST @ 18% i.e. total of Rs. 20,060/- (Includes cost of training, course kit, lunch, tea etc.)

Registration: Send registration form along with Cheque/DD in favour of "FICCI Quality Forum". The seats are limited to 20 and registration will be done on first come first serve basis

7. About our Lead Faculty

Our Lead faculty of this course Mr. Basudev Bhattacharya has rich experience of 47 years in the field of designing, functioning, & managing testing laboratories. He was one of the founder members of Pilot Test House of the Government of India, Ministry of Commerce, a premier test and calibration centre for testing export products from the country.

Mr Bhattacharya was trained on Laboratory Management in UK in 1988 under the Indo-EEC Co-operation. He has been an International consultant in the field of laboratory accreditation on behalf of the UN Agencies, ITC/UNCTAD/WTO, Geneva; and UNIDO, Vienna. He was Chairman of Technical Committee on Photometry of NABL and member of the NABL technical committees on Clinical & Food Testing Laboratories.

He has presented and published more than 30 papers on a variety of technical subjects in National and International Journals, seminars and conferences. He has conducted more than 270 in-house workshops and training programmes on LMS, Measurement Uncertainty, Quality Assurance, Calibration in India, Bangladesh, Mauritius, Dubai, Abu Dhabi, Kuwait, Rwanda, Maldives, Bhutan & Nepal and has trained more than 2800 persons. He has been providing auditing services to accredited laboratories and certified organizations as per ISO/IEC 17025, ISO 15189 & ISO 9001 Standards, and has conducted more than 75 such audits.

He has also provided LMS implementation support to 15 laboratories in different disciplines (viz. Chemical, Clinical, Mechanical, Electrical testing etc and Calibration of Mass-Dimension-Thermal-Pressure which have successfully achieved NABL accreditation.

8. About FICCI Quality Forum

FICCI Quality Forum (FQF) is a specialized division of Federation of Indian Chambers of Commerce and Industry (FICCI) set up with objective to sharpen the competitive edge of Indian Industry. FQF provides training, consultancy and research services focused on enhancing the quality quotient of clients and partner organization.

For the past 20 years, FQF is providing training on various ISO management systems and has a pool of highly competent & experienced trainers to conduct training courses.

FQF has collaboration arrangements with Intertek India for providing IRCA, UK approved Auditor/Lead Auditor training courses on ISO 9001 Quality Management System (QMS), ISO 14001 Environment Management System (EMS), ISO 22000 Food Safety Management System (FSMS), Occupational Health and Safety Management System (OHSAS) 18001, ISO 50001 Energy Management System (EnMS), ISO 27001 Information System Management System (ISMS) etc. A summary of feedback of past participants is also included in this brochure.

In addition, we also provide training on Six Sigma Green and Black belt certification, and Project Management, Risk Management etc. We also provide consultancy support on effective implementation of above management systems including Laboratory Management System (LMS) leading to certification/accreditation.

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9. Course Content

1. Introduction
  1.1. Certification and Accreditation
  1.2. The Global scenario and APLAC, ILAC MRA.

2. Overview of ISO/IEC 17025:2017

3. Nominal cross reference with 2005 version of the Standard

4. General Requirements
  4.1 Impartiality
  4.2 Confidentiality

5. Structural Requirements

6. Resource Requirements
  6.1 General
  6.2 Personnel
  6.3 Facilities and environmental conditions
  6.4 Equipment
  6.5 Metrological Traceability
  6.6 Externally provided products and services

7. Process Requirements
  7.1 Review of requests, tenders and contracts
  7.2 Selection, verification and validation of methods
  7.3 Sampling
  7.4 Handling of test or calibration items
  7.5 Technical records
  7.6 Evaluation of measurement uncertainty
  7.7 Ensuring the validity of results
  7.8 Reporting of results
  7.9 Complaints
  7.10 Nonconforming work
  7.11 Control of data and information management

8. Management Requirement
  8.1 Options
  8.2 Management system documentation
  8.3 Control of management system documents
  8.4 Control of records
  8.5 Actions to address risks and opportunities
  8.6 Improvement
  8.7 Corrective action
  8.8 Internal audits
  8.9 Management system reviews

Some Comments from participants of ISO Training Programs conducted by FICCI

- The course and the manner in which it was delivered certainly deserve high grades on the scale. It has gone beyond what I had actually expected before being part of it.
- The friendly and tension free environment created by the trainer.
- Calmness of trainer in answering all the queries.
- The learning that comes with each course is always good but the way it is given is really important. The Course material/learning were very well disseminated and the ease with which I could learn was good. I enjoyed learning.
- I had wonderful experience which is full of knowledge and information which will not only help in my professional life but also personal life.
- Programme was very good especially faculty was extremely good; having full knowledge about the concept.
- Through this course, I got more benefit. Before this course my knowledge on LMS was zero. But now I can say I am having more knowledge.
- The structured methodology and experience and expertise level of the faculty.
- Ample time being given to understand every aspect of the standard.
- Training material was very clear and sequential methodology was conducive to learning.
- The Role Play-Audit, Exercises in groups & individual assignments.
- The deliberations by the faculty was the best thing. His pace & pitch during the entire course was constant which led to good learning.
- Lively presentation, healthy interaction and professional approach.
- Teaching method was excellent. Still can't believe that whole ISO 17025 covered and understood so well in 4 days.

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9. Internal auditing
  9.1 Introduction to Audit
  9.2 Types and Methods of Audit
  9.3 Checklist Preparation,
  9.4 Audit Planning and Audit Schedule.
  9.5 The Audit Process
  9.6 Identification of Non-Conformities
  9.7 Preparation of Audit Report
10. Steps of Implementation of LMS leading to accreditation
11. Discipline-wise specific criteria of NABL accreditation viz. Chemical, Mechanical, Electrical, Clinical, Biological, Calibration etc.
12. The Accreditation process of NABL
  12.1 Adequacy audit
  12.2 Pre-assessment by Lead Assessor
  12.3 Final assessment
  12.4 Examination of assessment report by Accreditation Committee
  12.5 Issue of accreditation certificate
Syndicated Exercises on above	

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