

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



**Organized by
FICCI QUALITY FORUM
Nov 5 – 8, 2013
FICCI, New Delhi**



1. Introduction

The Quality Manager of any laboratory is the key person responsible for establishing and implementing the management system for effective operations of testing & calibration laboratories. So it is essential that the designated Quality Manager should be well versed with the requirements of ISO/IEC 17025 or ISO 15189 (whichever is applicable).

It is now the requirement of NABL that Quality Manager of the laboratories holding or seeking accreditation from NABL should undergo 4 days training on ISO/IEC 17025.

All the NABL accredited/applicant laboratories of NABL are to comply with above requirements latest by September 2014 and all laboratories applying (first time) for NABL accreditation after 1st November 2012 are required to comply with this requirement which will be verified during Pre/Final assessment by NABL.

Apart from being a mandatory requirement of NABL, this training course is also suitable for Technical Managers of testing/calibration laboratories.

2. Course Objectives

The aim of the course is to provide a concerted and comprehensive training on development & implementation of ISO/IEC 17025 Laboratory Management System (LMS) for building competence of Quality/Technical Manager and other personnel of testing and calibration laboratories.

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

- ✓ Interpret the requirements of ISO/IEC 17025 and how to apply these requirements correctly
- ✓ Implement ISO/IEC 17025 LMS effectively
- ✓ Conduct an effective gap analysis/internal audit/ third party audit of LMS
- ✓ Meet NABL criteria for training of Quality Managers

3. You should attend this course if,

- ✓ You want to comply with mandatory NABL requirements for training of Quality Managers in laboratories
- ✓ You want to understand the value of operating effective laboratory management system
- ✓ 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 or you are already a Quality/Technical Manager in NABL accredited laboratory
- ✓ You want to assess LMS of your supporting laboratories

4. Course Material

Course kit comprising detailed course material and International Standard ISO/IEC 17025 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 organisation, schedule & registration procedure

The course is of non-residential nature. It is of 4 days duration and is conducted from 0900 hrs to 1730 hrs daily for the first three days & on the fourth day the course finishes at 1700 hrs after the written examination. Tea/Coffee and working lunch is provided by the organizers.

The fee for the course is Rs 14,000/- per participant plus 12.36% Service Tax (Total Rs 15,730/-)

For joining the course, participants are required to send their full particulars (name, designation, email, postal address, and phone number) along with fee by RTGS or cheque payable at Delhi in favour of "FICCI QUALITY FORUM" at the address mentioned under Course Venue.

8. About our Lead Faculty

Our Lead faculty of this course Mr. Basudev Bhattacharya has rich experience of 43 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 International Trade Centre; a Geneva based UN Agency. 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 150 in-house workshops and training programmes on LMS in India, Bangladesh, Mauritius, Dubai, Abu Dhabi & Kuwait, and has trained more than 2000 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 13 laboratories in different disciplines (viz. Chemical, Clinical, Mechanical, Electrical testing etc and Calibration of Mass-Dimension-Thermal-Pressure which have successfully achieved NABL accreditation.

9. 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 Nigel Bauer and Associates, UK 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) and Occupational Health and Safety Management System (OHSAS) 18001 standards. A summary of feedback given by past participants of these courses is included in this brochure.

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

10. Course Dates

Nov 5 - 8, 2013

11. Course Venue

Federation of Indian Chambers of Commerce & Industry (FICCI),

Federation House,

1 Tansen Marg, Near Mandi House

New Delhi –110001, India

For further details & to reserve your seat,

please contact:

Mritunjay Kumar

T: +91-11-2348 7356

M: +91 - 99111 64501

E: fqf@ficci.com; mritunjay.kumar@ficci.com

12. Course Content

1. Introduction

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

2. Overview of LMS and structure of ISO 17025

3. Management Requirements of ISO/IEC 17025 with detailed examination of important management system elements

- 3.1 Document control
- 3.2 Control of non-conformities
- 3.3 Corrective action
- 3.4 Preventive action
- 3.5 Management Review

4. Technical Requirements of ISO 17025 with detailed examination of important technical operations

- 4.1 Personnel
- 4.2 Accommodation and Environmental conditions
- 4.3 Test & calibration methods and method validation
- 4.4 Overview of measurement uncertainty
- 4.5 Equipment
- 4.6 Measurement Traceability
- 4.7 Assuring Quality of Test & Calibration Results

5. Internal Audit

- 5.1 Introduction to Audit
- 5.2 Types and Methods of Audit
- 5.3 Checklist Preparation,
- 5.4 Audit Planning and Audit Schedule.
- 5.5 The Audit Process
- 5.6 Identification of Non Conformities
- 5.7 Preparation of Audit Report

6. Steps of Implementation of LMS leading to accreditation

7. Discipline-wise specific criteria of NABL accreditation viz. Chemical, Mechanical, Electrical, Clinical, Biological, Calibration etc.

8. The Accreditation process of NABL

- 8.1 Adequacy audit
- 8.2 Pre-assessment by Lead Assessor
- 8.3 Final assessment
- 8.4 Examination of assessment report by Accreditation Committee
- 8.5 Issue of accreditation certificate

Syndicate Exercises on above

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 trainers.
- Calmness of trainers 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 both faculties were extremely good having full knowledge about the concept.
- Through this course, I got more benefit. Before this course my knowledge on quality management and auditing were 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 every clause 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 Lead Faculty were 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 9001:2008 covered and understood so well in 5 days.

LIST OF PARTICIPANT OF LAST ISO/IEC 17025 LABORATORY MANAGEMENT COURSE

| | |
|--|---|
| <p>Mr. P.K. Mohapatra Section Officer (Admin.) National Institute of Biologicals (MOHFW), Noida M: 9871594430 E: pkmohapatra@nib.gov.in</p> | <p>Mr. Jaipal Meena Laboratory Technician National Institute of Biologicals (MOHFW), Noida M: 9871325604 E: jai2007m@rediffmail.com</p> |
| <p>Dr. Bhoopendra Kumar , Associate Scientist (Study Director) Institute for Industrial Research and Toxicology, (IIRT) Ghaziabad M: 8826484884 E: iirtdelhi@gmail.com; drbhoopender@gmail.com</p> | <p>Mr. Abhisek Mishra, Director, QCA Institute for Industrial Research and Toxicology, (IIRT) Ghaziabad M: 09654699017 E: info@toxicityindia.org; abhi1986virgo@gmail.com</p> |
| <p>Ms. Nitasha Khatri, Scientific Officer Gujarat Environment Management Institute (GEMI) M: 09408635040 E: nitashakhatri@rediffmail.com</p> | <p>Shri Paresh Chavda, Chemical Engineer, Gujarat Environment Management Institute (GEMI) M: 9909419199 E: paresh.gemi@gmail.com</p> |
| <p>Ms. Pooja Pathak, Jr. Scientist Gujarat Environment Management Institute (GEMI) M: 09978136306 E: poo86@gmail.com</p> | <p>Ms. Kamna Nanda Group Leader, Medicinal Chemistry Daiichi Sankyo India Pharma Private Limited, Gurgaon T:0124-2840000,Ext 8759, M: 09818688640 E: kamna.nanda.jv@dsin.co.in</p> |
| <p>Mr. J.P. Sinha FICCI Research and Analysis Centre Dwarka, New Delhi M:09650901025; E: ipsinha@fraclabs.org</p> | <p>Ms. Sudha Karsija FICCI Research and Analysis Centre Dwarka, New Delhi E: sudha.karsija@fraclabs.org</p> |
| <p>Mr. K.C. Varshney Deputy Director (FSL) Forensic Science Laboratory, Govt. of NCT of Delhi T: 011-27555811; 27555812; M: 09013440170 E: kcv_fsldelhi@rediffmail.com</p> | <p>Dr. D. C. Tandel Bilag Industries Private Limited, Vapi T: +91-260-2400443 M: 09909988518 E: dahyabha.tandel@bayer.com</p> |
| <p>Mr. Umesh Prajapati Bilag Industries Private Limited, Vapi T: 0260-2400443 M: 992534586 E: umesh.prajapati@bayer.com</p> | <p>Mr. Prafull Shah Bilag Industries Private Limited, Vapi T: +91-260-2400443/444 (Ext 467) M: 9825730921 E: prafull.shah@bayer.com</p> |
| <p>Mr. Nasir Shaikh Bilag Industries Private Limited, Vapi T: +91-260-2400443/444/055 (Ext:353) M: 9998183174 E: nasir.shaikh@bayer.com</p> | <p>Ms. Rashmi Gupta FICCI Research and Analysis Centre, Dwarka, New Delhi M: 9873568817 E: rashmi.gupta@fraclabs.org</p> |