

1. Introduction

The process of laboratory accreditation requires laboratories to have quality control procedures for monitoring the quality of tests and calibrations performed by them. Requirements of ISO/IEC 17025 also states that statistical techniques should be applied for monitoring and reviewing of the results, and may include, inter-alia, internal quality control using reference materials, retesting or recalibration of retained items, participation in inter-laboratory comparison or proficiency-testing programs. This process of assuring the quality of test and calibration is the heart of the laboratory accreditation process in accordance with ISO/IEC 17025, which reposes reliability on the results.

According to ISO 15189, the laboratory shall design quality control procedures that verify the attainment of the intended quality of results. When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results shall be rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified. ISO 15189 also states that whenever an inter-laboratory comparison is not available; the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination results.

Internal Quality Control is a continuous and immediate monitoring of quality of test result by laboratory personnel. Some of the common and effective IQC techniques are:

- Calculation and monitoring of Coefficient of Variation (% CV) with Controls
- Estimation of 'Z' score
- Plotting of Levey-Jennings Charts and monitoring the same using Westgard Rules
- Estimation of Within Lab 'Z' score
- Estimation of Between Lab 'Z' score
- Estimation of Zeta score & "E_N" Number

All laboratories can and should perform these IQC activities in order to generate reliable results. The above would, however, be possible only when the members of the test and calibration laboratories are adequately trained in the use of simple statistical techniques, which are essential for performing these activities.

2. Course Objectives

The aim of the course is to provide a concerted and comprehensive training for members of test and calibration laboratories in the use of statistical techniques to perform and generate reliable test results.

3. You should attend this course if,

- ✓ You want to understand compliance with requirements of ISO/IEC 17025 and ISO 15189 for laboratory accreditation
- ✓ You want to get hands-on experience on the application of simple statistical techniques including control charts
- ✓ You want to understand how to control quality of measurement and examination processes so that quality of test and examination result is assured
- ✓ You want to understand robust statistics and learning its application to overcome the shortcomings of classical statistics in data analysis involving outliers
- ✓ You want to learn early detection of quality problems in measurement processes for timely correction and need-based corrective actions

4. Course Material

Course kit comprising detailed course material with several worked-out examples which will help participants to understand subject matter, 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 2nd day of the course will be issued a certificate by FICCI.

6. Course Schedule & Registration Procedure

The course is of non-residential nature. It is of 2 days duration and is conducted from 0900 hrs to 1730 hrs daily. On the second 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 8,000/- per participant plus 12.36% Service Tax (Total Rs. 8,989/-).

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.

7. About our Lead Faculty

Our Lead faculty of this course Mr. Basudev Bhattacharya has rich experience of 45 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; the 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 185 in-house workshops and training programmes on LMS and other quality & measurement related topics in India, Bangladesh, Mauritius, Dubai, Abu Dhabi & Kuwait, and has trained more than 2300 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.

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 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.

9. Course Dates

May 27 – 28, 2014

10. Course Venue

**Hotel Suba International
Plot 211, Chakala Sahar Road
Opp. Cigarette Factory, Andheri (E)
Mumbai – 400 099
Maharashtra, India**

For further details & to reserve your seat, please contact:

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11. Course Content

1. Introduction

- 1.1. Requirements of ISO/IEC 17025 and ISO 15189

2. Introduction to Basic Statistics

- 2.1 Sample and Population
- 2.2 Different data summarization methods viz. Graphical, Tubular & Numerical
- 2.3 Important Measures of Central Tendency – Mean, Median, Mode
- 2.4 Range, Deviation, Variance
- 2.5 Standard Deviation
- 2.6 Quartile
- 2.7 Inter-quartile range & Normal inter-quartile range

3. Syndicated Exercises on estimation of CV, 'Z' Score and 'E_N' value by both classical and robust statistics

4. Quality parameters using statistics

- 4.1 Coefficient of Variation (CV)
- 4.2 "Z" Score
- 4.3 Classical and Robust Statistics
- 4.4 "ζ" (Zeta) Score
- 4.5 "E_N" Number

5. Use of Levey – Jennings Chart in analytical measurement process

- 5.1 1 level QC & 2 Level QC
- 5.2 Construction a L&J Chart

6. Syndicate Exercises on construction of Levey – Jennings Chart

7. With Laboratory and Between Laboratory 'Z' Scores

8. Syndicated exercises on estimation of within and between laboratory 'Z' scores

Some Comments from participants of LMS 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.
- Overall arrangements, ambience and faculty were excellent and I would like to further participate in such other Quality training programmes
- I have really gained a lot of understanding on the concept of LMS & I really am thankful to FICCI for conducting such courses
- The structured methodology and experience and expertise level of the faculty.
- Training material was very clear and sequential methodology was conducive to learning.
- The deliberations by Faculty were the best thing. His pace & pitch during the entire course was constant which led to good learning.
- The trainer has vast knowledge and the skill of imparting training is unmatched. His valuable inputs will definitely help our ability to do well in future course.
- Getting training from such a great experience trainer is really a great experience. Thank you very much, sir for such a wonderful training!!!
- Trainer given very good presentation and transform and described each and every point related to training. Please continue it for next time. It will be very helpful for laboratory.