Document Title

Registration Scheme

for

Laboratory Management Systems (LMS)

ISO 17025:2017/ISO 15189:2012

Consultant

Document Number: QCI/NBQP/LMS/CON/Ver2.0

A number of consultants are helping organizations in various sectors in the process of Laboratory Management Systems (LMS) realization. The selection of a capable LMS Consultant by a laboratory is important in ensuring that their LMS is capable of meeting the planned objectives of the laboratory/CAB in the most efficient and cost-effective manner.

The scheme for registration of LMS Consultants will help to certify the credentials of competent consultants who have knowledge about ISO/IEC 17025:2017 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189:2012 'Medical laboratories - Particular requirements for quality and competence', whichever is applicable, and also help the laboratories in selecting a competent consultant through the list of registered/empaneled consultants maintained by NBQP.

Individual Consultants – They may be individuals having requisite educational background and experience/ expertise in their respective areas. NBQP offers three grades of registration: Consultant, Senior Consultant and Principal Consultant.

Assessment Procedure

* Desktop review of documents pertaining to education, experience, LMS documentation provided during consultancy etc.
* Interview with the NBQP panel of Consultant Examiners

Registration under this scheme is available without restriction to all applicants who satisfy the NBQP registration requirements.

All information provided by the applicants can be verified and shared with the stakeholders at any stage during or after the assessment process. NBQP reserves the right to utilize the information provided by the applicants for legal, research, for sharing with other IPC members or for any other purpose as may be deemed fit by NBQP. In case an applicant wants the information to be kept confidential, a communication must be sent to NBQP citing reasons for the same. NBQP has the right to take decision in this regard as it may deem fit.

NBQP reserves all rights to amend its registration criteria, procedures and fees etc. as it may deem fit. Applicants are requested to refer to NBQP website https://acr.qci.org.in/ for the updated criteria before applying for registration.

Section 1: REQUIREMENTS FOR REGISTRATION

1.1 Personal Attributes

Applicants for Registration should be able to demonstrate the personal attributes needed for the effective and efficient performance of the consulting services. Desirable personal attributes for consultants are described in ISO 10019 Clause 4.2.2.

A Consultant should demonstrate to be:

a) Ethical - fair, truthful, sincere, honest and discreet;
b) Observant - actively observing physical surroundings and activities;
c) Perceptive - aware of and able to understand situations;
d) Versatile - able to readily adapt to different situations;
e) Tenacious - persistent and focused on achieving objectives;
f) Decisive - able to reach timely conclusions based on logical reasoning and analysis;
g) Self-reliant - able to act and function independently whilst interacting effectively with others;
h) Communicative – able to listen to & effectively interact with all levels of organization.

1.2 Skills and Knowledge

Applicants should through education, training, work experience and consulting experience be able to demonstrate a satisfactory level of competence in all of the following areas:

1.2.1 Management Systems specific knowledge and skills

Applicants shall also have basic knowledge of the ISO and other guidance documents stated in the bibliographies at the end of ISO 17025:2017 and ISO 15189:2012.

Applicants shall have general knowledge of:

a) The standardization and accreditation systems at national and international level.
b) ILAC (International Laboratory Accreditation Cooperation) / APLAC (Asia Pacific Laboratory Accreditation Cooperation).

1.2.2 Standard specific knowledge and skills

For ISO 17025:

The applicant should have knowledge on the following requirements:

- The management of documents through the document life cycle for review, update, authorization etc.
- Competence of subcontracted party for Tests and Calibrations activities of a laboratory.
- Quality of Purchasing Services and Supplies and its evaluation against predefined specifications.
- Mechanism for taking feedback from Customer and other services.
- Complaint handling system and its effective resolution including the documentation and investigations.
- Policies and process for the control of Nonconforming Testing and/or Calibration and other operations of a laboratory with respect to the previously defined specifications including the knowledge on the corrective actions and its evaluation.
- Ways for improvement of effectiveness of the laboratory's management system through complaints, suggestions, identification of risk, and management reviews.
- Selection, implementation, documentation, and monitoring of corrective actions for elimination of deviations/non-conformity from laboratory and management procedures.
- Preventive Action to reduce the likelihood of the occurrence of the potential non-conformities and how to monitor and evaluate the same.
- Control of Records for unique identification, availability when needed, and protection against unauthorized access for viewing or changing.
- Internal technical and quality procedures for verifying that the laboratory complies with ISO/IEC 17025, including its management, findings, follow-up and actions.
- Continued suitability and effectiveness of the quality system, policies, and testing and calibration procedures.

For ISO 15189:

In addition to the knowledge requirements stated above for ISO 17025, in respect of ISO 15189, the applicant should have knowledge on the following requirements:

- Understanding of point of care testing, post examination processes, pre-examination process, safe sample collection mechanism, turnaround time between two specified points through pre-examination, examination and post examination processes, safe procedures for primary sample collection and handling, sample transportation.
- Understanding of legal requirements.
- Understanding of safe laboratory practices and their implementation.
- Understanding of ways and means for defining, implementing and monitoring performance and quality improvement standards.
- Understanding of quality policy, quality objectives, interrelationship between responsibility and authority.
- Understanding of relationship between referring and referral laboratories.
- Ability for resolution of complaints.
- Appreciation of the importance of risks and the quality indicators.
- Ability to assess the competency of each person in the laboratory through reviews and effecting continuing education and professional development of those.
- Understanding of the effect of available accommodation and environmental conditions.
- Understanding of equipment calibration and metrological traceability of equipment.
- Understanding of management of reagents and consumables in respect of their quality and availability.
- Ability of the effect of measurement uncertainty of measured quantity values.
- Understanding of the importance of storage, retention and disposal of clinical samples.
- Ability to appreciate the importance of report attributes, report content, release of results, automated selection and reporting of results, revising report in case-to-case basis, all in harmony with laboratory information management system.

.

1.3 Education

The applicant should have completed Post Graduation/Graduation with specified work experience as mentioned in this document. Documentary evidence of the claims on the above should be submitted along with the Application form.

1.4 Work/Consultancy Experience

The applicant shall have relevant experience in managerial, professional and technical aspects of the consultancy services to be provided. This may involve the exercise of judgment, problem solving and communication with all interested parties, enabling the consultant to assist the organization in making effective decisions.

For Testing & Calibration Laboratory:

Sr. No.	Grade	Total Work Experience for Engineering Graduate	Total Work Experience for Non-Engineering Graduate	Training (Mandatory)	Minimum No. of ISO 17025:2017 Realization/ Implementation
1	Consultant	5 years	7 years	Completed 5 days NABL Assessor Training Course (ISO 17025:2017)	4
2	Senior Consultant	10 years	12 years		8
3	Principal Consultant	15 years	17 years		12

For Medical Laboratory:

Sr. No.	Grade	Total Work Experience for Medical Post-Graduate*	Total Work Experience for Medical Graduate*	Training (Mandatory)	Minimum No. of 15189:2012 Realization/ Implementation
1	Consultant	5 years	7 years	Completed 5 days NABL Assessor Training Course (ISO 15189:2012)	4
2	Senior Consultant	10 years	12 years		8
3	Principal Consultant	15 years	17 years		12

* Degree in laboratory medicine/ Clinical Pathology/ Hematology/ Clinical Bio Chemistry/ Clinical Microbiology/ Molecular Biology/ Genetics/ Cytogenetic/ Serology/ Histopathology/Cytology.

1.5 Application Reference

For initial Registration each applicant should be referred by either the current employer or by one alternative person who has a professional relationship with the applicant. Referrals should have direct experience and/or personal knowledge of the applicant relating to those elements of the application for which they have attested.

1.6 Personal Declaration

All applicants for initial Registration and re-Registration should sign a declaration whereby they agree to observe and to abide by the NBQP Code of Conduct (Section-6) and that all complaints regarding their performance will be formally logged and dealt with in a manner to prevent recurrence, by NBQP.

1.7 Re-Registration (maintaining Registration)

All registered consultants should be periodically re-registered. The period between initial Registration and re-Registration should not exceed three years. Each applicant for re-Registration should maintain a written declaration from the client of each consultancy regarding the realization undertaken and the details of the professional development undertaken during this period.

For each year of the re-Registration period, NBQP registered consultants should submit documentary evidence either of having performed a minimum of complete 1 project realization or of having acquired equivalent consultancy experience.

1.8 Professional Development

The NBQP registered consultant should, in each year of the Registration period, undertake at least 15 hours of appropriate continuing professional development (Section 7). Evidence of that professional development, verified by the provider, or the applicant's employer should be submitted as part of the application for re-Registration.

The professional development records should show the duration and type of activity undertaken and details of the provider. In the selection of appropriate professional development, consultants should consider their personal strengths and weaknesses and identify areas for personal improvement.

1.9 Code of conduct

All consultants are obliged to improve the standing of the consulting profession by rigorously observing the Code of Conduct. Failure to do so may result in suspension or withdrawal of Registration.

Kindly refer to Section 6 for more details.

Section 2: EVALUATION FEES

2.1 The Complete application form with the requisite fee must be submitted online on the NBQP Auditor Consultant Registration Portal.

2.2 All credentials should be submitted to NBQP though online portal. All applications must be supported by documentary evidence, e.g. legible self-attested photocopies of original certificates etc. Original documentary evidence should be made available only when asked for.

2.3 An incomplete application or not adequately supported by required documents would result in delay in processing or rejection of application.

2.4 NBQP will carry out evaluation of applicant's competencies in following steps:

a) **Adequacy Review –** To check the adequacy of documents submitted by the applicant in support of the application.

b) **Desk-Top Review –** To determine whether the contents of the application form and the supporting documents provided by the applicant are conforming to the Consultant Registration Scheme requirements.

c) **Interview -** A verification of the applicant's consultancy competence related to the documents provided by him and the requirements mentioned in this document through a face-to-face/AV interview on case-to-case basis. The applicant will have to appear at own cost for the interview.

An applicant who is rejected during the interview, will have an option to reapply only after 6 months.

Section 3: REGISTRATION FEES

The fee structure is determined annually and is applicable for 1 year. The validity of the Registration is also for 1 year. The current Fee Structure is as follows:

a) Application Fee

An application should be accompanied with the application fee, without which the application will not be processed. This fee covers the administrative costs for processing the applications.

b) Annual Registration fee

Successful applicants will be intimated for the remittance of Registration Fee through automated emails. The applicants will be required to submit the fee as per the fee structure within the specified time frame. The Certificate will be generated online after completion of registration.

c) Re-Registration fee

An applicant has to pay the Re-Registration Fees only if he does not renew his application within 3 months of the expiry of his registration.

d) Regrade Fee

This fee covers the administrative cost required for each regrade consideration. This fee is due with the re-grade submission. This fee needs to be paid while renewal of application in case the applicant wants to upgrade his category and has submitted relevant documents as per the eligibility criteria.

FEE STRUCTURE

I) Application Fee

First time	**Rs. 3,000/-**
Re-Registration	**Rs. 1,500/-**

II) Annual Registration Fee

Consultant	Rs. 10,000/- for 1 year
Senior Consultant	Rs. 12,500/- for 1 year
Principal Consultant	Rs. 15,000/- for 1 year

Applicants can apply for 3 years Registration and avail 15% discount on the total fee

III) Regrade Fee **Rs. 2,000/-**

Note:

1. 18% GST will be charged extra, as applicable w.e.f. 1st July 2017
2. All fees are to be paid through the Portal only & are non-refundable.

Section 4: REGISTRATION CERTIFICATE AND REGISTER

4.1 All successful applicants will be issued a Registration Certificate online.

4.2 The validity of the Certificate will be for the period for which the fee has been paid by the applicant (maximum three years)

4.3 The Register of Consultants will be uploaded on the NBQP website.

Section 5: COMPLAINTS, APPEALS & DISCIPLINARY PROCEEDINGS

5.1 Any complaint by the applicant should be made directly to Deputy Director (NBQP) and escalated (if required) to CEO-NBQP.

5.2 In case of non-acceptance of the decision of CEO-NBQP, the applicant can appeal to the Secretary General-QCI who will then appoint an independent appeal committee for the purpose.

5.3 Similarly complaints will be considered according to the procedures of NBQP, which are made by following:

a) Registered Consultant against a fellow registered Consultant or
b) An organization, certification body or other body against a registered Consultant

5.4 NBQP retains the right to undertake disciplinary proceedings against registered Consultants who are found to have acted contrary to the Code of Conduct. Options available include suspension of registration and in instances of serious or sustained breach, withdrawal of registration.

5.5 NBQP may suspend or cancel the NBQP registration because of the following but not limited to:

a) providing insufficient or incorrect information to NBQP at the time of registration.
b) illegal use of NBQP registration or logo
c) failure to report any major complaint against the applicant
d) any other condition deemed appropriate by NBQP
e) at own request

Section 6: CODE OF CONDUCT

All consultants are obliged to improve the standing of the consulting profession by rigorously observing the Code of Conduct. Failure to do so may result in suspension or withdrawal of Registration.

Consultants undertake:

a) to act professionally, accurately and in an unbiased manner
b) to strive to increase the competence and prestige of the consultancy profession
c) to assist those in their employment or under their supervision in developing their management, professional and consultancy skills
d) to maintain the confidentiality of information provided by or acquired from the organization
e) to avoid and/or declare any conflict of interest that may affect the work to be carried out
f) to maintain independence from certification or Registration bodies
g) to maintain impartiality in an organization's selection of certification bodies/ registrars
h) not to act in any way that would prejudice the reputation of the NBQP or the Consultant Registration process and to co-operate fully with an inquiry in the event of any alleged breach of this code

Section 7: Continuing Professional Development (CPD) Log

Name Registration No

Date (DD/MM/YY)	Duration of CPD in hours	Type of Activity Formal / Informal	Details of Activity (Title & Duration)	Name / Designation / Contact Details incl. tel. /fax nos.	Description of Activity require

Annexure A: Consultancy Log (for each project implemented)

Consultant Name _____

Role in the Project Observer Team Member Team Leader

Names of other Team Members I _____ II _____

III _____ IV _____

Consultancy Date From_____ To _____

The applicant	* carried out autonomously the tasks assigned by the project/team leader. * participated in all the periodical & final meetings of the consultancy team to verify the progress and the consistency of the work in relation with the client agreed objectives * carried out the training of company personnel involved in the project. * carried out the work ethically and satisfactorily met the objectives.

(to be authenticated by the company where LMS consultancy provided)

Company Name _____

Company Address _____

Product/Service _____

Standard Implemented _____

No. of Employees _____

Is the Company Certified (ISO 17025:2017/ISO 15189:2012)? _____

If yes, then date of Certification _____

Name of Certification Agency _____

Signing Authority _____

Designation _____

Signature / Date _____

(To be authenticated by the employer on whose behalf consultancy provided)

Name & Address of Consultancy Company _____

Tel/Fax/Email _____

Contact Person (with designation) _____

Signature _____

Signature (Applicant) _____Stamp_____