Document Title **Course Registration Criteria** **For Training Program on**	
A. Laboratory Management Systems (LMS) and Internal Audit as per IS/ISO/IEC 17025:2017	**B.Laboratory Management Systems (LMS) and Internal Audit as per IS/ISO 15189:2012**
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1. ABBREVIATIONS

APAC	Asia Pacific Accreditation Cooperation
CRC	Course Registration Committee
CV	Curriculum vitae
DA	Desktop Assessment
EMP	Empaneled
IA	Initial Assessment
IH	In-house
ISO	International Organization for Standardization
ILAC	International Laboratory Accreditation Cooperation
LA	Lead Assessor
LMS	Laboratory Management System
MOU	Memorandum of Understanding
MRA	Mutual Recognition Arrangements
NABL	National Accreditation Board for Testing and Calibration Laboratories
NBQP	National Board for Quality Promotion
NGO	Non-Government Organization
NC	Non-conformity
OA	Office Assessment
Obs.	Observations
QCI	Quality Council of India
QMS	Quality Management System
RR	Re-registration
SA	Surveillance Assessment
TA	Technical Assessor
TC	Technical Committee
TO	Training Organization
TC	Technical Commitee
TOR	Terms of Reference
TQAS	Training Quality Assurance System
WA	Witness Assessment

2. GENERAL INFORMATION

2.1 BACKGROUND

Accreditation of Medical Laboratories in India is helping the Indian industry in all sectors in generating internationally accepted test results and in enhancing the quality and reliability of diagnostic information in the country and across the globe, thereby, contributing to the growth of Indian economy. Earlier, WTO had identified non-acceptance of test results and measurement data as Technical Barrier to Trade (TBT) and accreditation is considered to be the first essential step towards removal of such technical barriers.

Laboratory accreditation through third-party assessment is formally recognizing the technical competence of laboratories. Accreditation is granted by NABL to testing & calibration laboratories based on IS/ISO/IEC 17025 and medical laboratories based on ISO 15189. NABL is signatory to Asia Pacific Accreditation Cooperation (APAC) and International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangements (MRAs) for Testing, Calibration and Medical laboratories. The test and measurement data produced by accredited laboratories are acceptable amongst other MRA signatory economies in the world.

Laboratory accreditations are being provided in all major fields of Science, Engineering and Medical testing laboratories. There are many accredited laboratories in India and in neighboring countries and very large number of laboratories are in the process of getting accredited or in planning for accreditation in near future.

Laboratories personnel must have appropriate understanding of the requirements of Laboratory Management System (LMS) for accreditation purpose and thus will need to impart necessary training on the relevant conformity assessment standard to its personnel.

The shortage of trained personnel having adequate understanding on the relevant Laboratory Management System and conformity assessment standard is being highlighted in conferences or during discussions in different forums. Some of the institutes and individuals are conducting such training programmes for laboratory personnel. The capability and competence to design and deliver such programs needs to be ascertained. The quality of such training programs will have a direct bearing on the quality of laboratory personnel and the work they do to achieve or maintain laboratory accreditation. An attempt is made to prepare uniform structure for designing and conducting such training programmes.

Therefore, there is a need for a well-designed Course Registration Scheme which defines the requirements for Training Organization (TOs) on infrastructure, competence of human resources, course curriculum, trainee evaluation process, training quality assurance system, system-oriented approach etc. This will facilitate in providing competent and resourceful LMS Training Organization (TOs) for training the laboratory personnel. It will ultimately contribute towards improving and standardizing the quality of LMS trainings and thus the competence of laboratories.

2.2 LMS COURSE REGISTRATION SCHEME OUTLINE

NBQP has Course Registration Scheme for LMS training institutions for conducting "Training Program on Laboratory Management Systems (LMS) and Internal Audit as per IS/ISO/IEC 17025:2017" and "Training Program on Laboratory Management Systems (LMS) and Internal Audit as per IS/ISO 15189:2012".

The scheme is aimed to create an independent, transparent, and impartial Course Registration System for institutions engaged in imparting specialized trainings pertaining to laboratories. Qualified and experienced laboratory staff(s) desirous of enhancing their knowledge and skills of Laboratory Management Systems shall be the main beneficiary of such training programmes through training institutions registered with NBQP for LMS. Trained manpower/ quality manager/ technical manager is required by laboratories (testing/diagnostic), industry, NGOs, research bodies, administrators, government ministries/departments, Pollution Control Boards and all those concerned with testing/diagnostic labs.

The scheme is dynamic in nature. Modifications and changes may take place from time to time, as it ought to be continuously improving the delivery and effectiveness of the training.

3. COURSE OBJECTIVES

3.1 GENERAL

To provide Course Registration to Training Institutions capable of providing short term specialized LMS training programmes for persons involved in/wishing to make a career in the field of Testing, Calibration, Medical/diagnostic laboratories.

a) To encourage progressive improvement in LMS training course content, pedagogy, teaching methodology, experiential learning through case studies and other innovative mechanisms.
b) To ensure quality and effectiveness of LMS courses and training delivery system by the training Institutions.
c) A training participant who successfully completes the course shall be able to use his learning to conduct the following:

- Audit Process and responsibilities
- Planning the audit
- Performing the audit
- Reporting and following up the audit

3.2 CONTINUOS IMPROVEMENT

a. The training must reflect current and realistic LMS audit practices. It must reflect changes in the relevant LMS standards and specifications. Training must be designed and delivered to reflect current training practice and learning theory.
b. Training organization must have appropriate processes for gathering information and identifying ways to continuously improve NBQP certified training. Consider the following:

I. Including a course evaluation form, requesting participants to provide feedback on the course, including the effectiveness of the course in covering the Learning Objectives as well as their expectations; the knowledge, ability, and performance of the course faculty (s); the structure and design of the course, course materials and the course facilities.
II. Reviewing the suitability and effectiveness of Training Organization's quality management processes; the design and content of Training Organizations certified course(s); the delivery of certified courses, including faculty competence and improvement opportunities, and participant assessment methods. The training organization shall develop a set of metrics for evaluating and monitoring performance evaluation of various aspects of the course being run. Reviews may include:
    - Actions from the last review; any actions resulting from the instructions and recommendations of NBQP during audit or surveillance visits, or at other times as appropriate.
    - Results of monitoring and measurement activities.
    - Changes which might affect Training Organizations training course management, the content or delivery of Training Organizations courses, including changes in audit practice, standards, legislation and NBQP criteria.
    - Feedback and suggestions for improvement from course faculty, course participants, NBQP and others if appropriate.
    - Planning for improvement in the design and development of course(s), and for the amendment and updating of existing courses. Plans should make clear the actions required and associated responsibilities and authorities and include review milestones and measurement/monitoring points.

4. ADMINISTRATIVE PROCEDURE

4.1 ELIGIBILITY FOR TRAINING INSTITUTIONS

Any legally identifiable institution/organization engaged in the field of education/training/capacity building for Testing/Calibration/Medical laboratory personnel with requisite human resource and other facilities can apply for Course Registration Scheme for LMS with NBQP.

The training organization's Quality Management System shall be based on ISO 9001 standard. The training organization shall develop and maintain documented procedures for the effective administration of the course in line with ISO 9001. it is, however, not mandatory that organization should be ISO 9001:2015 certified. The QMS of the organization must address specific requirements of this Course registration process:

I. Procedure for Evaluating, Selecting, and appointing faculty members for the training
II. Procedure for Organizing and conducting training programme
III. Procedure for feedback collection, evaluation of feedback, Evaluating output/ improvements after Training
IV. Procedure for addressing complaints and suggestions.
V. Procedure for maintaining records and documents including training materials
VI. Procedure for periodic reviewing the curriculum and training materials
VII. Procedure for ensuring the implementation of all the above procedures

Some broad guidelines on issues to be addressed for each of the above items are given below:

I Procedure for evaluating, selecting, appointing faculty members:

a. Prescribing qualifications and experience requirements for faculty/resource persons (internal/ external)
b. Assessing performance of a candidate for faculty/resource person prior to appointment.
c. Assessing performance of a faculty/resource person after appointment
d. Identifying training areas of improvements for faculty/resource person
e. Fixing Terms of Reference for retention and guidelines for i) Imparting training ii) Code of conduct, and Conflict of Interest

II Procedure for organizing and conducting training programme:

a. Organizing a Training Programme including announcing the programme, defining minimum infrastructure requirements in terms of Conference space, seating, audio visual training aids, study material etc.
b. Defining roles and responsibilities of the Programme Coordinator and support to coordinator
c. Continuous evaluation of participants and test papers to be used at the end of the programme
d. Online portal giving information about i) Brief coverage of concerned training programme, ii) Faculty, iii) Dates of Course, iv) Facilities (Food/ residential/ non-residential etc.), v) Fees
e. Developing the Course Materials, it must include the relevant training programme.

III Procedure for Feedback collection, evaluation, and improvements:

a. Inviting feedback on Training imparted from participants in specific formats to assess faculty competence, mode of delivery, effectiveness etc.
b. Evaluating the feedback for identifying areas of strengths and improvements in respect of arrangements/facilities and quality of training
c. Corrective & preventive actions for gaps on arrangements/facilities
d. Action to be taken to close the gap on quality of training including replacing the concerned faculty, if required
e. Updating the test papers, as necessary

IV Procedure for addressing complaints, suggestions, and conflict of interest:

a. Informing the stakeholders about the availability of procedures for complaints, appeals, and conflict of interest.
b. Accepting complaints/ appeals
c. Handling and disposal (including authority and responsibility) of the same within reasonable time
d. Maintaining records of complaints/ appeals
e. Ensuring implementation of preventive/ corrective actions

V Procedure for maintaining records and documents including training material:
a. Approving documents prior to issue
b. Up-dation of documents, as required
c. Ensuring quick availability of relevant revision of the document.
d. Maintaining course specific records of venue, date, promotional literature, faculty/resource persons involved, identification of the test papers used, name, contact details & test results of each participant, unique number on certificates issued to the participants.
e. Storage, protection, retrieval, and disposal of documents

VI Procedure for periodic reviewing the curriculum and training materials:
a. Review of actions pending from last review
b. Action on feedback from stakeholders to update course curriculum
c. Updating of amendments in rules/laws, new case studies, latest scenario
d. Updating as per new environmental aspects and impacts
e. Administrative issues including future programmes.

VII Procedure for ensuring the implementation of above all procedures

5. COURSE MATERIAL

In the beginning of the course, training organization shall provide the course material to the training participants, description of the course format, training participant responsibilities, how the training participant will be evaluated, and the basis for each type of evaluation.

a. Each training participant shall have a copy of the current published version of ISO 17025/ISO 15189. Since these standards are licenced, the licenced version must be obtained by Training Organisation for the purpose of imparting training and copies given to participants with water mark or label “For Training Purpose Only”.
b. The course shall cover all aspects defined in the Objectives.
c. Training organization may provide participants with a copy of the specimen examination paper and the typical solutions.
d. The training course shall include both knowledge-based sessions (to facilitate understanding of concepts) and skill-based sessions (application of knowledge and skills in practical activities) and each training participant shall be subjected to realistic and current quality system audit practices and conditions.
    I. Knowledge based sessions may be faculty led but shall allow for some interaction with training participants enabling faculty to test learning of the training participants and training participants to clarify their understanding as required.
    II. Skills based sessions may be supported by faculty input to address the relevant requirements and techniques such as for managing meetings and interviews. This can be done through workshops, Group exercises case studies, auditor role-play including mock audits with the aim of developing auditing, interpersonal and leadership skills apart from developing a deeper understanding of the requirement of the standards.
e. Training aids such as videos that are directly relevant may be used to supplement the training by the faculty. No more than three hours of the total course time may be devoted to non-interactive, passive training aids.

6. CRITERIA FOR PARTICIPANTS

Training Organization should shortlist candidates for attending the course based on their qualification, experience, and exposure of LMS and related activities.

a. It is recommended that the training participants attending this course should have at least 1 years of lab/quality related experience, adequate knowledge of ISO 9000 series of standards and some basic knowledge of auditing will be an added advantage.

b. Successful completion of this course may not fully satisfy the requirements related to registration to "LMS Consultant" schemes being operated by NBQP.

7. COURSE STRUCTURE

The Training Course could be conducted in any of the following modes –

a) Regular Course - 4 consecutive days' classroom/online mode

b) Weekend Course - On separate weekend, provided the Course is completed within 28 days from the commencement of the course.

Note: Total duration of the course should not be less than 32 hours excluding breaks, out of which at least 50% time shall be allocated for skill-based activities and 2 hours for examination.

8. COURSE MANAGEMENT

8.1 CLASSROOM MANAGEMENT & FACILITIES

I. Classroom(s)/ lecture hall with comfortable and ergonomic seating capacity of 15 - 20% extra than the enrolled candidates and adequate space for conducting the training, sitting for faculty/observers.

II. Space/arrangements for doing group exercises by participants should be made available. When teamwork is involved, suitable rooms or areas should be arranged so that the activities and discussions of one team are not disturbed by those of other teams, or by anyone else.

III. Batch size should not be bigger than 20 and not less than 6 participants for effective delivery of the program. In case the number of participants is less than 6 on the scheduled date of the program, approval to be taken for the same from NBQP.

IV. Two faculty members must be available in the training area, including the lead faculty, if participants are more than 10 in classroom.

V. Training participants shall be required to be in attendance for the full duration of the course on all four days. Failure to do so shall be reflected in the training participant's continuous and final evaluations and the participants may not be awarded any certificate. In any case, if the participant is absent for more than half a day, the training organization must record the actions taken to make up for the absence and its justification in case a certificate is to be provided to the candidate.

VI. Contemporary training aids (as projectors, white board, markers, flipchart, audio, video facilities etc.) including requisite software should be made available.

VII. Suitable Training room environment should be ensured for effective delivery of the course.

VIII. The Dos & Don'ts should be explained to the participants (for e.g., keeping mobile on silent during conduct of the training, break timings, etc.)

IX. Adequate facilities should be ensured including provision of hygienic food/snacks and clean washrooms.

X. Other arrangements:

a. If the TO wants to conduct trainings at multi locations, these details should be mentioned in the online application form or before organizing the training with details of faculty, infrastructure etc. to NBQP.
b. Training Organizations using the infrastructure of other institute shall have a MOU with the 'other institute' for infrastructure and agreement for NBQP team to access these facilities

8.2 ONLINE TRAINING MANAGEMENT

Training Organization has to ensure/provide the following to NBQP:

a. Information on the virtual platform used (Zoom/ MS Teams/Webex or similar). Training Organization must ensure that the platform used has the following minimum options available:
   - Audio
   - Chat
   - Polling
   - Whiteboard/ Annotations
   - Emotions/ Response/ Emojis
   - Webcam
   - Break out rooms for group activities
   - Application share

- Desktop/ Screen share
- File Transfer
- Monitoring of candidates for exercises and exam by webcam and screen share.

b. Information on the availability of the applicable licenses for the product used above.

c. Information on the experience of the Training Organization as well as the Trainer(s) in conducting virtual trainings/webinars/workshops with the platform mentioned above.

d. Guidelines for trainers and Participants to ensure seamless operations and minimum requirements are needed at their end. These guidelines to be circulated to all trainers and Participants through email and explained before the start of each training program. Trainer & the Participants need to have good internet connectivity (speed >10MBPS).

e. Revised Course Schedule/Session Plan considering that there might be increase in the overall duration of the course as there will be technology involved, technological challenges encountered & added break times. Time allotted for role plays and workshops should also be considered for revision. Interactive time between trainer & Participants after each session should be clearly defined in the course schedule.

f. Continuous Evaluation of the Participants based on their punctuality; exercises & activities given to them & their physical & professional code of conduct.

g. Skill sets to be evaluated by video interaction and allowing Participants to share/display/ demonstrate their screen when required. Skill sets to include:
   - Generic skills - Can be evaluated based on leadership skills, time management, soft skills etc.
   - Auditing skills – Can be evaluated by role plays /workshops based on the sample manual.

h. Availability of a person with good knowledge of using the virtual platform at their end to encounter any software or internet issues occurring during the course & to resolve any issues experienced by the trainer or the Participants during the training.

i. Information on the procedure of the examination to be conducted after the end of the course. It is suggested that the examination is conducted in one of the following ways:
   - Through a pen and paper-based examination like conducted during a classroom training.
   - Through an online exam using a ProProfs or similar tool where the Participants can login using their credentials (username and password), exam duration is timer based, secure browser is used where candidates cannot leave the exam page else paper is auto submitted, audio and video is on for effective invigilation, feedback mechanism is available. Also, Training Organization's to consider providing additional time of 30 minutes considering the typing speed of some of the Participants may be slow. This is just to ensure that they do not lose out despite being knowledgeable.

j. Separate feedback to be designed for getting inputs on challenges faced by Participants and Trainers on technology infrastructure.

k. Process of updating the knowledge on new technologies to be available with Training Organization.

9. FACULTY

a. Requirements in respect of qualification and experience of Faculty with respect to conduct of the below mentioned training program are laid down below:

Faculty for Laboratory Management Systems (LMS) and Internal Audit as per IS/ISO/IEC 17025:2017	Faculty for Laboratory Management Systems (LMS) and Internal Audit as per IS/ISO 15189:2012
Qualification Master's degree in Engineering/Technology or master's degree in sciences.	**Qualification** Master's degree in laboratory medicine / Clinical Pathology/ Haematology/ Clinical Biochemistry/ Clinical Microbiology / Molecular Biology/ Genetics/ Cytogenetic/ Serology/ Histopathology/ Cytology
Experience a. Overall experience of 15 years out of which minimum 5 years in laboratory testing activities as well as minimum 1 year experience in conduct of training programs for LMS b. Conducted minimum 25 NABL assessments out of which at least 5 assessments as lead assessor. Or, c. Overall experience of 15 years out of which minimum 4 years' experience in development, documentation and implementation of accreditation scheme(s) as full-time staff with accreditation body as well as minimum 1 year experience in conduct of training/awareness programs.	**Experience** a. Overall experience of 15 years out of which minimum 5 years in medical testing activities as well as minimum 1 year experience in conduct of training programs for LMS b. Conducted minimum 25 NABL assessments out of which at least 5 assessments as lead assessor. Or, c. Overall experience of 15 years out of which minimum 4 years' experience in development, documentation, and implementation of accreditation scheme(s) as full-time staff with accreditation body as well as minimum 1 year experience in conduct of training/awareness programs.

b. Training organizer (coordinator & faculty in-house) shall be present during the complete training and shall be responsible for organizing, conducting, evaluating and for all other activities related to the training.

c. List of proposed faculties (with backup faculty if possible) with their identified competence & topics and schedule should be prepared and submitted along with the application form.

d. For empaneled/ visiting faculty, there should be a written agreement/MOU between the institution and empaneled/visiting faculty members including the key aspects mentioned below:
   - Name of the faculty & Training Organization
   - Name of Selected Training Program (ISO 17025/ISO 15189), disciplines, lecture
   - Scope of services covered and duration of the association
   - Specific roles & responsibilities and acceptance of visiting faculty (Not empaneled with more than two institutions)

e. Two faculty members must be available in the training programme, if participants are more than 10 in classroom or Online during any exercise/case study/ group discussion etc.

9.1) The faculty must have the following competence:

a) Shall be thoroughly experienced in the principles and practices of Laboratory and Auditing Management System relevant to the content of the course.
b) Ability to facilitate the learning of appropriate auditing knowledge and the development of auditing skills.
c) Familiarity with the current course materials and documentation.
d) Good communication skills to be able to impart necessary knowledge to training participants.
e) Have knowledge of current Lab Management and auditing practices and of relevant standards.
f) Familiarity with the applicable international and national regulations.
g) Skills in involving and engaging participants throughout the learning process.
h) Good knowledge of:
    - Different learning styles and the implications of these on training.
    - The effective use of training aids (slides, flip charts, video etc.)
    - Formal and informal methods to assess participant learning.
    - The difference between teaching knowledge and skills.

9.2) Assessment of trainers:

a) Training Organization must ensure that the competence of faculty is monitored. Assessment of lead faculty shall be done by NBQP during the course assessment.
b) However, the remaining faculty shall be assessed under the trainer qualification process established and maintained by the Training Organisation and the record should be retained. The list of qualified trainers should be maintained by the Training Organisation and shared with NBQP during the assessment along with the Course Material.
c) Feedback to be taken from participants, from other trainers, where available and include complaints and other customer feedback, results of previous trainer reviews as well as feedback from NBQP during assessment, wherever applicable.

10. SCOPE OF COURSE REGISTRATION AND EVALUATION CRITERIA

10.1 GENERAL

The Training Organization (TO) is expected to satisfy the requirement of faculty, course curriculum, training material, case studies, evaluations etc. in respect of the training programme for which Course Registration with NBQP is sought.

a) TO is required to choose training programme for Course Registration with NBQP depending on the resources and facilities available with them. TO may select any one and/or both programmes:

   a. Laboratory Management Systems (LMS) and Internal Audit as per IS/ISO/IEC 17025:2017

   b. Laboratory Management Systems (LMS) and Internal Audit as per IS/ISO 15189:2012

b) The TO shall prepare a detailed curriculum and submit it with the application. The programme should be a judicious mix of classroom training and case study exercises. These may comprise of group activities exercises, presentations by groups followed by discussions. videos, role play, and other modes may also be adopted. Course materials including case studies may preferably be sent to the Participants in advance or must be provided at the start of the training if not sent in advance.

10.2 CONTINUOS EVALUATION

While conducting a training programme care should be taken to ensure that each trainee is given due attention. Evaluation of the Participants should be based on marks obtained during continuous evaluation and assessment at the end of training programme.

The continuous evaluation shall be documented and shall evaluate each training participant's:

a) Achievement of the course objectives.
b) Attendance and punctuality during the course.
c) Interaction with the faculty.
d) The active participation during the training including for case studies.
e) Participants who fail the continuous assessment are required to retake another entire certified course in order to successfully complete the training.
f) Participants who fail the continuous assessment may take the written examination, but shall not receive a Certificate of Successful Completion, whatever their result in the written examination.
g) The continuous evaluation must be done daily at the end of the session for each participant.

Continuous evaluation	50%
Evaluation at the end of training (mix of subjective & objective)	50%

10.3 WRITTEN EXAMINATION

a) The written examination shall evaluate the training participants' comprehension of the audit process and the application of Lab Management System as per the applicable ISO standard.
b) Training Organization will be responsible for ensuring, through effective invigilation throughout the full duration of the examination, that participants are not provided with opportunities to copy, collude, or otherwise cheat during examinations. The invigilators must explain the rules and regulations for taking the

examination to the participants, allow participants time to read the rules and regulations and deal with any questions before the start of the examination.

c) Maximum marks shall be 100. The examination shall be designed in such a manner that a competent training participant (i.e., one who has demonstrated achievement of the learning objectives) can achieve a minimum mark of 60%.

d) The time allotted for taking the examination shall be two hours. Strict adherence to the time limit shall be maintained. However, the faculty may allow up to 30 minutes' additional time for taking the written examination, to a training participant with disability that adversely affects the training participant's capability to complete the examination in the allotted time as well as in cases where there is a limitation in understanding and interpreting English as a language. Any such allowance shall be indicated in the records of the course or of the examination with supporting reasons.

e) The question format in the examination shall be based on:
   - multiple choice or true/false.
   - short answer questions.
   - questions requiring long, descriptive answers.
   - analyzing audit evidence and preparing nonconformity report.

f) The % distribution of marks in each section shall be specified.

g) It should be specified clearly that candidates must restrict their answers in the space provided to them in the answer sheets.

h) The minimum passing grade shall be 60%.

i) The only reference material allowed during the examination is a copy of the ISO standard, Course material and self (participant's) notes.

j) Copies of the examination questions (other than those in a sample examination paper), examination papers, solutions or completed examination papers shall not be supplied to any training participant or any other party for any reason prior to the conduct of the exam.

k) Examination papers and solutions must be maintained, distributed, and retrieved in conditions of strictest security. Copies of examination papers, solutions or completed scripts must not be supplied to any participant or any other third party for any reason without written permission from NBQP.

l) Training Organization may provide participants with a copy of the specimen examination paper and the typical solutions.

m) Training Organization must select, at random, one of the examination papers for a particular presentation and ensure, where possible, that the faculty (s) for that presentation are not made aware of which examination paper is to be used.

n) The training organization should maintain at least three versions of the examination paper and ensure that two consecutive courses do not use the same version.

o) Training organization shall ensure that the faculty (s) for any given course are not aware of the examination questions.

10.4) GRADING: PASS/FAIL DECISIONS

a) Each examination paper shall be graded by the lead faculty. Another competent faculty shall check the addition of the score allotted in each section and re-grade all examination papers with scores between 50 and 60 percent.

b) The training organization shall have procedures to resolve any differences in grading by the two faculties and issue final grades.

c) Training Organization must ensure that marking and overall grading is consistent and calibrated.

10.5) RE-EXAMINATION

a) A training participant who fails the written examination for the course conducted by the training organization, shall be allowed one re- examination within twelve months of the last day of the course.
b) A different examination paper shall be used for the re-examination.
c) A training participant who fails the re-examination must take a full training course again before being eligible to take another examination.
d) Re-examination may be allowed at venue or at the training organization's premises in the presence of one of the faculty.
e) A participant failing in the continuous evaluation is not allowed to appear in re-examination and will not be awarded the 'successful completion certificate'.

11. CERTIFICATES

11.1) Two types of certificates may be issued to the participants attending the program:

a) A certificate of "successful completion" shall be provided to each training participant who has passed both the written examination and continuous evaluation.
b) A certificate of "Participation" may be provided to the participants who do not pass the written examination or continuous evaluation but who have satisfied the attendance requirement.
c) Certificates of Participation must be clearly distinguishable from the Certificates of Successful Completion.

11.2) The certificate shall:

- Clearly state that the course is registered with NBQP.
- Include the NBQP course registration mark.
- Include a unique identification number for each certificate.
- Clearly show the name of the training organization.
- Identify the course-by-course title, course number and dates of presentation of the course.
- Include the name of the training participant.
- State that the training participant named has participated /successfully completed the course.
- Include all information on a single side of the certificate.

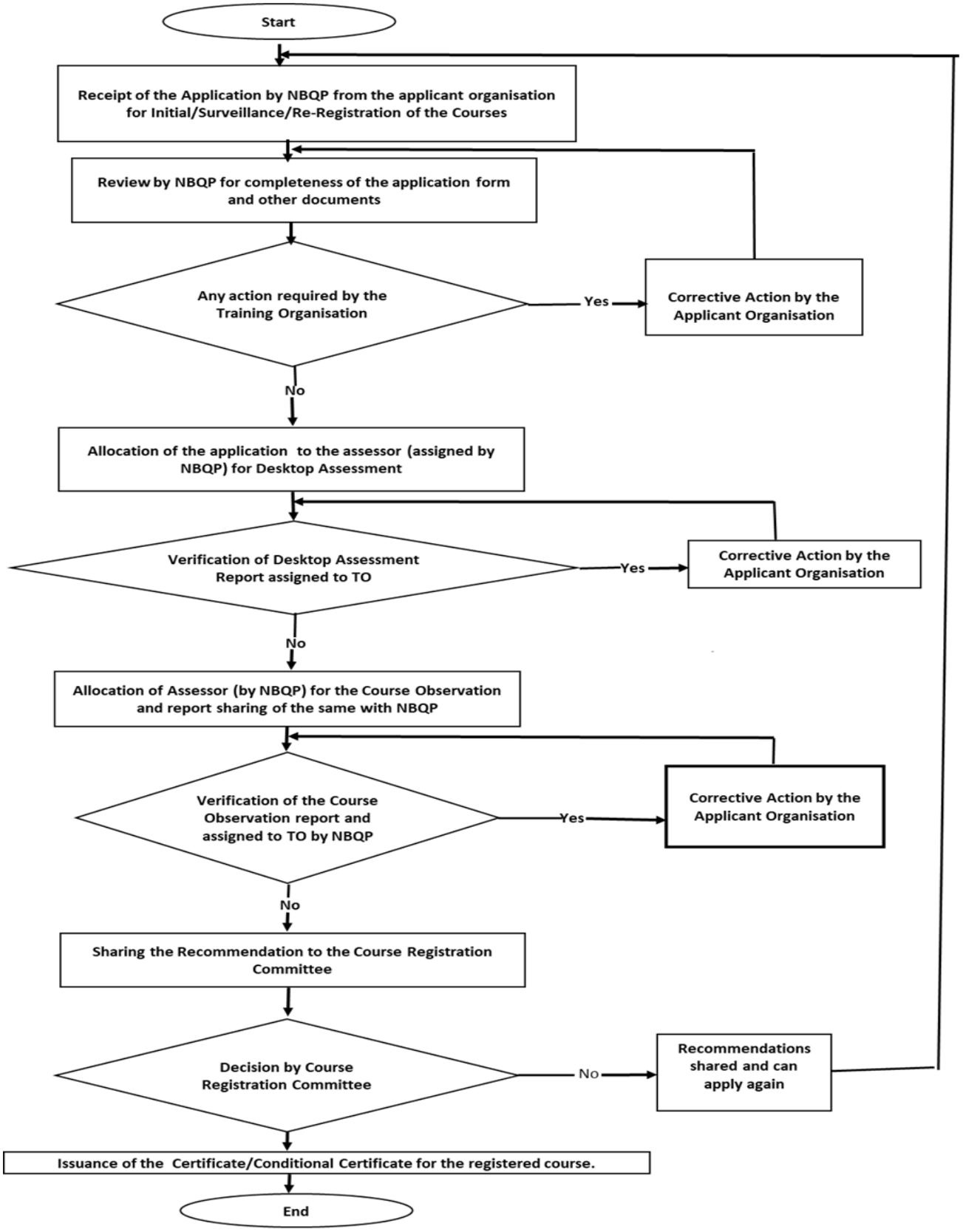
11.3) The sample and content of the certificates must be sent to NBQP for approval before the Training Organization issues them (during Initial registration) and as and when there are any changes made by the Training Organization.

12. RECORDS TO BE MAINTAINED BY THE TRAINING ORGANIZATION

The training organization shall maintain records to demonstrate conformance to the NBQP requirements. The records for each course presentation shall include:

a) Venue, dates, related advertisement, and promotional literature.
b) Names of faculty with their certification(s) at the time of that course presentation.
c) Identification of the sessions conducted by the support faculty.
d) Identification of the specific version/revision level of the course documentation used.
e) Identification of the examination paper version used.
f) Names of all training participants who attended the course, together with the continuous evaluation results and the examination results for each training participant.
g) All copies of marked examination papers, continuous evaluation forms and related summaries.
h) The percentage of training participants that successfully completed the course.
i) Unique identification number of each certificate of successful completion and the name of the training participant to whom it was issued.
j) A copy of completed examination papers (including re-sits) and the completed continuous assessment records for each participant.
k) Any complaints received. Training Organization must inform all participants of their right to make a complaint or an appeal and must provide them with written details of the process for doing so, on request. In the case of a complaint or appeal, Training Organization must notify each complainant or appellant in writing of the result of the complaint or appeal and of the right to appeal against the result to NBQP.
l) Record retention time: 5 Years.

13. COURSE REGISTRATION PROCESS



14. APPLICATION AND ASSESSMENT PROCESS

14.1) APPLICATION PROCESS

a) Details of the registration criteria and the Application Form are posted on the NBQP/QCI website. Any institution desiring the course registration under this scheme should carefully go through the requirements of the criteria, processes and assess their own adequacy and take care of shortfalls, if any, before applying.
b) Application form is to be filled on https://courseregistration.qci.org.in/
c) All the payments must be done through the online portal only.

14.2) ASSESSMENT PROCESS

Assessment Process comprises three parts:

14.2.1) Initial Assessment

a) ***Application Completeness:*** Submitted application shall be reviewed by NBQP secretariat for its completeness. Inadequacies in application (if any) shall be informed to Training Organization (TO). Training Organization should submit complete response within 30 days. Only completed applications will be further processed.

Note 1: If inadequacies are found in the response, the same will be communicated with an additional time of 30 days. If Training Organization fails to submit satisfactory response even after additional time, then the application will be made active only after the approval from competent authority.

Note 2: The inactive period will be for 45 days. The Training Organization may submit satisfactory response in the given time. If the response is not satisfactory then the application will be treated as closed and the Training Organization has to re-apply with full fees.

b) ***Desktop:*** NBQP assessor conducts adequacy assessment (application & technical assessments of documents submitted by Training Organization). Observation(s) and NCs (if any) would be communicated by NBQP secretariat. Training Organization should submit complete response within 30 days.

Note 3: Closure of NCs and observations submitted by Training Organization will be verified by NBQP assessor. Note 1 & 2 given under (a) will be followed for timelines.

c) ***Office Assessment:*** NBQP assessor conducts adequacy assessment (application & technical assessments of documents submitted by Training Organization), interaction with each faculty (in-house and empaneled), quality manager, concerned administrative staff etc., verification of infrastructure.

d) ***Witness Assessment:*** Witness assessment includes implementation of training organization's quality management system (Refer section 4), witness of course delivery and trainee's feedback. Assessment report [findings like observation(s) and NCs (if any)] would be reported by NBQP assessors to NBQP secretariat and in turn communicated to training organization. Corrective measures shall be submitted by Training Organization within 30 days. Decision regarding grant/denial of registration or provisional registration would be communicated.

Note 4: Closure of NCs and observations submitted by Training Organization will be verified by NBQP assessor.

14.2.2) Surveillance Assessment (SA)

a) If there is no change in faculty, course curriculum, quality manual, infrastructure, scope etc. then Training Organization shall pay surveillance fee and inform NBQP for due surveillance, Training Organization need not submit new application.
b) If there is any change in faculty, course curriculum, quality manual, infrastructure, modification of scope etc. then new application with updated details and applicable fee shall be submitted and same process as above will be followed.

c) SA will be conducted with particular emphasis on performance, quality of training delivery, implementation of training organization's quality management system, compliance to conditions of registration. One SA to be carried out between 10-12 months from the date of initial registration, 1st SA and 2nd SA.

14.2.3) Re-registration

a) Process will be similar as initial assessment, with particular emphasis on performance, feedback by Participants, continual improvement, training organization's quality management system etc. in three years from the date of initial registration. Re-registration application shall be submitted 2-3 months prior to Re-registration due date. Re-registration process shall be completed before the expiry of registration to avoid any discontinuation of registration.

14.3 TERMS & CONDITION FOR APPLICATION FOR COURSE REGISTRATION

a) The Training Organization shall inform NBQP the commencement date of the first Programme to enable NBQP to arrange the witness assessment by NBQP assessor(s).
b) The office and witness assessment of the first training Programme shall be conducted by the assessors deputed by NBQP.
c) Based on the office and witness assessment report, NCs and observation, if any shall be communicated by NBQP secretariat to the Training Organization for action & compliance. Training Organization shall submit evidence-based compliance of NCs and observations at the earliest but not later than 4 weeks. If required additional office and witness assessment may be required for verification of closures. The case then shall be placed now to CRC for granting full/conditional course registration.
d) Registration period of three years will be counted from the date of approval from CRC. However, this validity period is subject to satisfactory SA.

14.4 TERMS & CONDITIONS TO MAINTAIN COURSE REGISTRATION

a) Registration period of three years shall be counted from the date of initial registration; however, this validity period is subject to satisfactory Surveillance Assessment(s).
b) Training Organization shall submit complete SA/RA application 60 days prior to due date to maintain the registration continuity.
c) Registration shall expire at the end of its validity unless renewal is sought in time.
d) All payments shall be made in advance.
e) Franchising, licensing, subcontracting of NBQP registered Programme(s) is NOT permissible.
f) Training Organization shall inform NBQP with a copy of Programme just after the Programme announcement, name of the training Programme, dates, names of faculty, venue, expected number of participants, study material, presentations etc.
g) Training Organization shall submit to NBQP a soft copy of registered participants on the first day of the Programme start and a copy of successful candidates with certificate number after the result announcement.
h) Any change in faculty, employment status, curriculum etc. shall be informed to NBQP within 15 days with relevant documents.
i) Training Organization just after registration shall sign the 'Code of Conduct' and send it to NBQP Secretariat.
j) The Training Organization shall maintain relevant records of all trainings conducted including the following in hard or soft format –
   - Name of the training Programme, dates, names of faculty, venue, study material, presentations, training photos etc.
   - List of participants, singed attendance sheet, marks obtained in evaluation, feedback of participants and its analyses by Training Organization.

15. TERMS & CONDITIONS TO MAINTAIN COURSE REGISTRATION

15.1 SUSPENSION OR CANCELLATION OF COURSE REGISTRATION

NBQP shall suspend or cancel a registration on account of any or more grounds during registration process or after, but not limited, to the following:

a) Non-compliance, violation of the NBQP requirements, conditions of Registration.
b) Deviation from facts as stated in application and enclosures.
c) Submission of false or misleading information in the application or in subsequent submissions.
d) Improper use of NBQP Course Registration mark.
e) Carrying out changes in faculty members/ course content without approval from NBQP.
f) Failure to report any major legal (mandatory compliance) changes.
g) Using fraudulent practices by the training organization (Training Organization) in respect of its submission/ interaction with NBQP which would include, but not limited to, deliberate concealment and/or submission of false or misleading information, suppression of information, falsification of records or data, unauthorized use of course registration, and non-reporting of complaints against training institutions to NBQP.
h) Non- payment of applicable fees in time to NBQP.
i) Not submitting SA/RA application on time.
j) Franchising, licensing, or subcontracting of course/ Programs.
k) Any other condition deemed appropriate by NBQP.

15.2) CODE OF CONDUCT

All Training Organizations shall improve the standing of the profession by rigorously observing the Code of Conduct. Failure to do so may result in the suspension or cancellation of course registration. The Training Organization shall undertake:

a) To act professionally, accurately and in an unbiased manner.
b) To be truthful, accurate and fair to the assigned work, without any fear or favor.
c) To judiciously use the information provided by or acquired from the participant and to maintain the confidentiality of information received or acquired in connection with the assignment.
d) To avoid and / or declare any conflict of interest that may affect the work to be carried out.
e) Not to act in a manner detrimental to the reputation of any of the stakeholders including NBQP and the trainee.
f) To co-operate fully in any formal enquiry procedure of NBQP.
g) No sharing of the contact details of Participants with other laboratory/ organization/ company.

15.3) COMPLAINTS & APPEALS

a) The Training Organization shall establish documented procedures for handling and disposal of complaints and appeals within a reasonable time. The documented procedure shall include provision for:

- Providing information regarding complaint handling process / appeals to all interested parties.
- Acknowledgement of complaints/appeals.
- Complaint analysis/ investigation for redress of complaint/appeals.
- Communication with the complainant/appellate for satisfactory closure of the complaint/appeal.
- Involvement of NBQP in unresolved complaints or appeals, if any.

b) The Training Organization shall maintain records of all complaints and appeals and their resolutions including actions taken.
c) All complaints and appeal to be assessable to NBQP during the assessment.

15.4) GOVERNANCE

NBQP reserves the rights with respect to training modules development, implementation, coordination, management of these Training Programmes through Training Organizations. NBQP will have following functions (but not limited to):

a) Review of the Training Modules provided by Training Organizations.
b) Changing/ modifying the criteria/ guidelines/ fee structure.
c) Suspension/cancelling of registration in case of violation of any clause of the criteria.
d) Surprise visits/ extra witness assessments.

15.5) CONFIDENTIALITY

a) All information, documents submitted by the Training Organization to NBQP shall be used by NBQP (including NBQP Assessors and Members of Course Registration Committee) for the purpose of assessment & course registration only. However, the identity of the training organizations would be protected for sensitive information related to business whenever it is called for/ appropriate.
b) In case a Training Organization wants the information to be kept confidential, a communication shall be sent to NBQP citing reasons for the same. NBQP reserves the right to take decision in this regard.
c) The Training Organization shall have adequate arrangements consistent with applicable laws to safeguard confidentiality of all information provided by its stakeholders.
d) The Training Organization should maintain confidentiality of their participants related information like marks, evaluations, question paper, feedback form, answer sheets, personal details etc.

15.6) USE OF NBQP SYMBOL

a) NBQP Symbol (Which comprises of NBQP Logo, and the course Registration number issued by NBQP for a particular course) can be used by registered Training Organizations only at following places:
   - On promotional material and study material stating that the course is registered with NBQP, certificate for successful Participants, and mentioning course registration number.
   - On letter head and visiting cards mentioning that their Course has been registered with NBQP for the specific training.
   - On certificate issued to candidates clearly stating the course registration number.
b) Training Organization should ensure that NBQP symbol should not be used to the courses until registered completely with NBQP.
c) On suspension, withdrawal, after expiry of course registration validity, the training organization must not use NBQP symbol, else it will attract legal implications.

16. FEES STRUCTURE OF COURSE REGISTRATION SCHEME

Fees will be charged from the TO under the following heads:

(A) Laboratory Management Systems (LMS) and Internal Audit as per IS/ISO/IEC 17025				
For Conducting Training Programmes (→) Description (↓)	**Upto 3 Programmes~**	**4-5 Programmes~**	**6-10 Programmes~**	**>10 Programmes~**
Application fees for Registration	40000	60000	90000	120000
Office & Witness Assessment Fees	24000	24000	24000	24000
Annual Fees per year (3 fees in 3 years)	40000	60000	90000	120000
Surveillance Fees	40000	60000	90000	120000
Re-registration after 3 Years	40000	60000	90000	120000

(B) Laboratory Management Systems (LMS) and Internal Audit as per IS/ISO 15189				
For Conducting Training Programmes (→) Description (↓)	**Upto 3 Programmes~**	**4-5 Programmes~**	**6-10 Programmes~**	**>10 Programmes~**
Application fees for Registration	40000	60000	90000	120000
Office & Witness Assessment Fees	24000	24000	24000	24000
Annual Fees per year (3 fees in 3 years)	40000	60000	90000	120000
Surveillance Fees	40000	60000	90000	120000
Re-registration after 3 Years	40000	60000	90000	120000

For both courses (A) and (B) applied together by Training Organisation				
For Conducting Training Programmes (→) Description (↓)	**Upto 3 Programmes~**	**4-5 Programmes~**	**6-10 Programmes~**	**>10 Programmes~**
Application fees for Registration	70000	105000	150000	200000
Office & Witness Assessment Fees	48000	48000	48000	48000
Annual Fees per year (3 fees in 3 years)	70000	105000	150000	200000
Surveillance Fees	70000	105000	150000	200000
Re-registration after 3 Years	70000	105000	150000	200000

~ Figures mentioned in above tables are in Rs.

16.1) PAYMENT OF FEES

a) The applicable fees have to be paid through the Course Registration Portal.
b) Any pending fee payments must be made before finalizing the date of assessment.
c) Annual Registration fees shall be paid every year (from the date of initial registration).
d) No SA, re- registration, issuance of certificate etc. if dues are pending.
e) All fees are non-refundable.
f) Goods & Service Tax – extra as applicable.
g) Expenses on local travel, outstation travel, boarding and lodging etc. of NBQP Assessors will be charged on actuals in case of physical trainings.
    - Travel by air economy class or 2T AC if no air connection, boarding and lodging charges (to be borne by the TO at actual). If any deviation, then with the consent of TO.
    - If closure of NCs/Observations require extra office/ witness assessment or for any additional verification visit that will be charged extra Rs. 12000/ Per person day
    - Expansion of scope or modification of scope in SA, conducting more training then above fee will be applicable.
    - Any change in certificate with respect to scope, premises, faculty, address etc. will be charged Rs. 2000/- (Plus applicable GST)

For any further details contact:

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