



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Procedure for Quality Assurance Scheme for Basic Composite Medical Laboratories (Entry Level)

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1. Introduction

1.1 Scenario of Diagnostic Laboratories in India

The exact number of pathology and diagnostic labs is not known but it is estimated that there are about 1, 00,000 of them in India. Out of these, 80% are supposedly small, 18% are medium and only 2% of them are large sized. Most of the small laboratories are performing routine/basic testing and are situated in peripheral remote areas.

Access to healthcare is asymmetric between rural and urban areas. While urban residents have a choice between public and private laboratories, rural residents face far fewer choices.

So, the contribution of small laboratories performing basic testing to needs of population of rural and small towns is enormous.

1.2 Present Status of ISO 15189 accreditation

Accreditation is not mandatory for clinical laboratories in India.

Of the estimated 1, 00,000 pathology and diagnostic labs in India, only about 1000 are accredited by NABL. This is about 1% of the total number of diagnostics laboratories in the country. Looking at this small percentage of laboratories which could achieve accreditation, it seems that there are major gaps in majority of laboratories. Unless appropriate steps are taken to encourage these laboratories for adopting quality practices; it will take decades to fill these gaps. This is substantiated by the fact that in year 2009-2010, CGHS announced “NABL accreditation” as mandatory criteria for empanelment of laboratories. Following this announcement, NABL received as many as 225 applications under medical laboratory accreditation program as per ISO 15189. However, of these 225 applications, 80% got closed as the laboratories could not meet the requirements of NABL accreditation. This indicates that it is not feasible, especially for small laboratories performing basic testing to straightaway achieve ISO 15189 accreditation.

The simplest way to bring quality at grass root level of health system in India is by gradually sensitizing the majority category (i.e. laboratories performing basic testing) about doable basic quality practices whereby they get encouraged to achieve next set of quality approaches. Finally, majority of them would aspire to meet requirements of ISO 15189 in totality.

1.3 Quality Assurance Scheme for Basic Composite Medical Laboratories (Entry Level)

For sensitizing the laboratories performing basic testing, NABL has initiated a voluntary scheme named as Quality Assurance Scheme (QAS) for Basic Composite (BC) Medical Laboratories (Entry Level). In order to bring maximum number of laboratories under this scheme, the criterion is based on the

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requirements enlisted in Gazette notification dated 18th May, 2018 by MOHFW to amend Clinical Establishments (Central Government) Rules, 2012.

Components of assessment of technical competence have been added to the criteria checklist. This will ensure quality of test results given by the laboratory and facilitate achieving ISO 15189 accreditation over a period of time.

The scheme will not be covered under ILAC/APAC MRA. The laboratories can switch to accreditation as per ISO 15189 at any point of time. However, the other way around is not allowed and laboratories once accredited will not be covered under this scheme.

Note:

1. *The scheme is purely voluntary.*
2. *Laboratories performing only basic routine tests are eligible to apply*
(For the list of basic tests, refer scope given in NABL 155; Application Form & Checklist for Quality Assurance Scheme for Basic Composite Medical Laboratories (Entry level).
3. *The complete test menu of the laboratory has to be applied in the application.*
4. *State Health Departments can adopt this for public health labs*

2. Procedure for New Applications

Interested laboratory will be required to submit application in prescribed application form (NABL 155 “*Application Form and Checklist for Quality Assurance Scheme for Basic Composite Medical Laboratories (Entry Level)*”) with scope covering complete test menu of the laboratory. The application shall be accompanied by checklist filled-in by the laboratories themselves, results of participation in Proficiency Testing (PT) and application fee of Rs. 1,000 plus taxes.

The application filled in all respect is to be submitted to NABL and the decision on grant of certificate for QAS-BC will be taken by NABL based on the details submitted in NABL 155 “*Application Form and Checklist for Quality Assurance Scheme for Basic Composite Medical Laboratories (Entry Level)*” and satisfactory participation in Proficiency Testing (PT). In such cases, no initial assessment will be conducted by NABL. However, where the Proficiency Testing (PT) participation is not evidenced, NABL assessor shall assess the laboratory during initial assessment according to the same checklist. The Entry Level QAS-BC certificate will be issued to the laboratory with validity of three years. Upon approval of the lab by NABL, the lab shall submit the fees of Rs. 13,000 plus applicable taxes towards assessment charges and membership fees for the period of three years. For fee structure, please refer NABL 100 “*General Information Brochure*”.

(Refer Flow Chart 1)

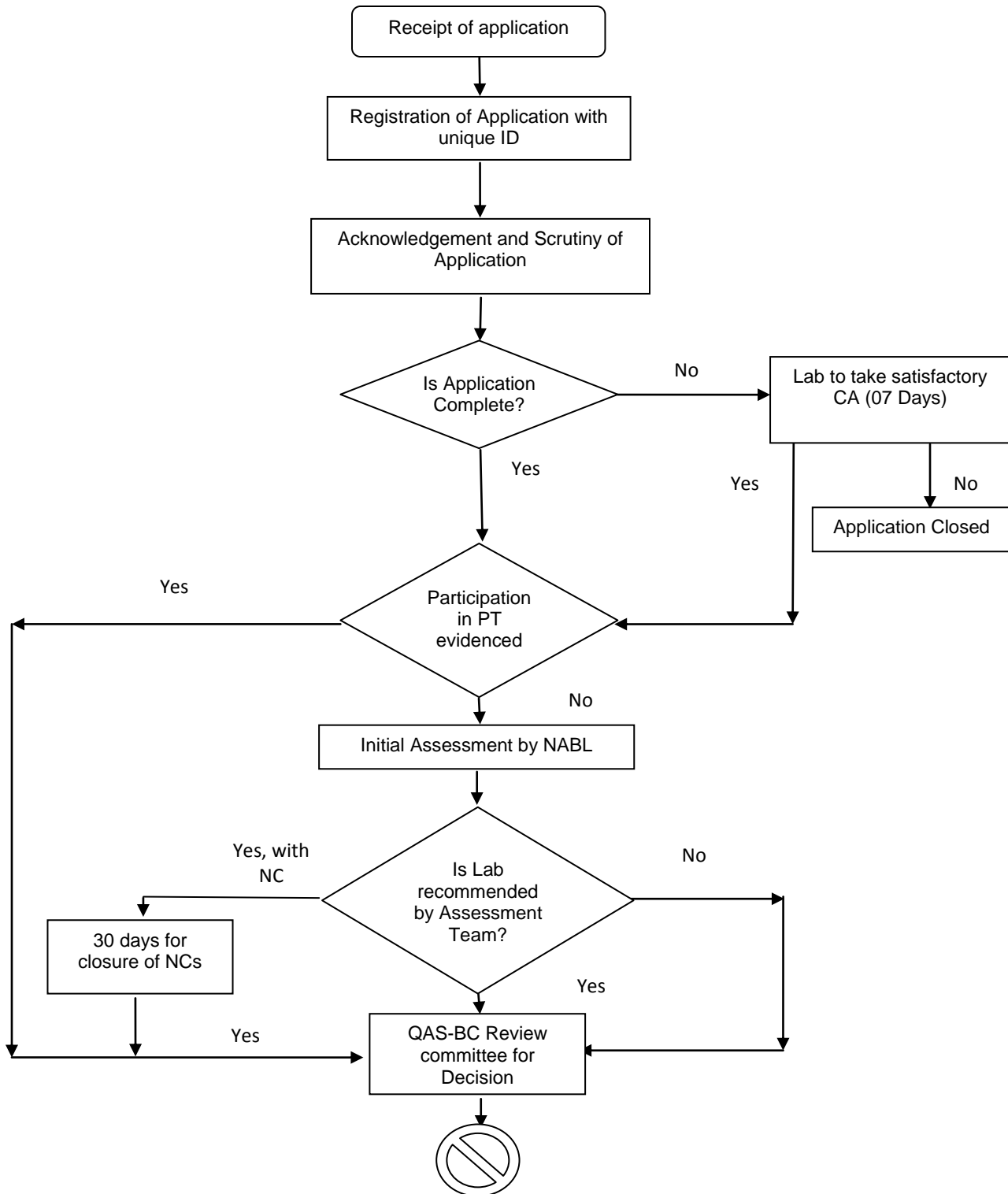
NABL will conduct an onsite assessment at least once during three years of cycle. Five to ten percent of the labs complying with QAS-BC scheme will undergo unannounced onsite assessment.

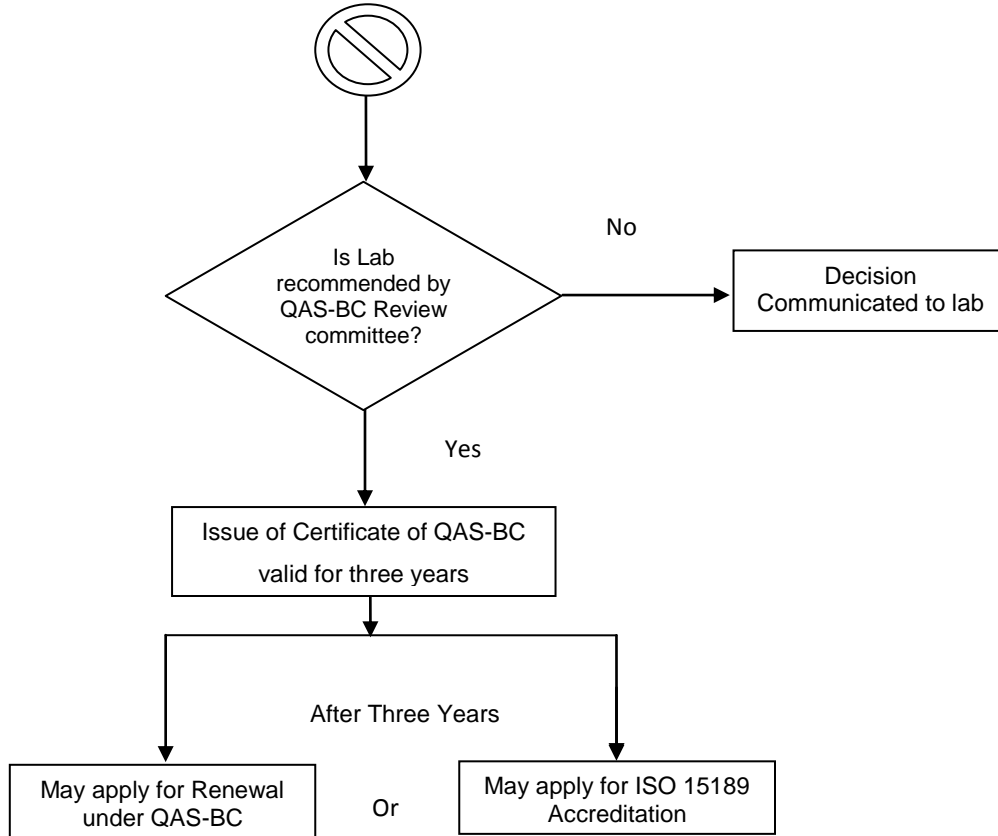
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(Refer Flow Chart 1)

The laboratories may continue under this scheme by applying for renewal after the cycle of three years. It is desired that the laboratories achieve accreditation as per ISO 15189 after two cycles i.e. six years.

Flow-Chart 1 (Applicant labs - Initial Assessment/Reassessment)

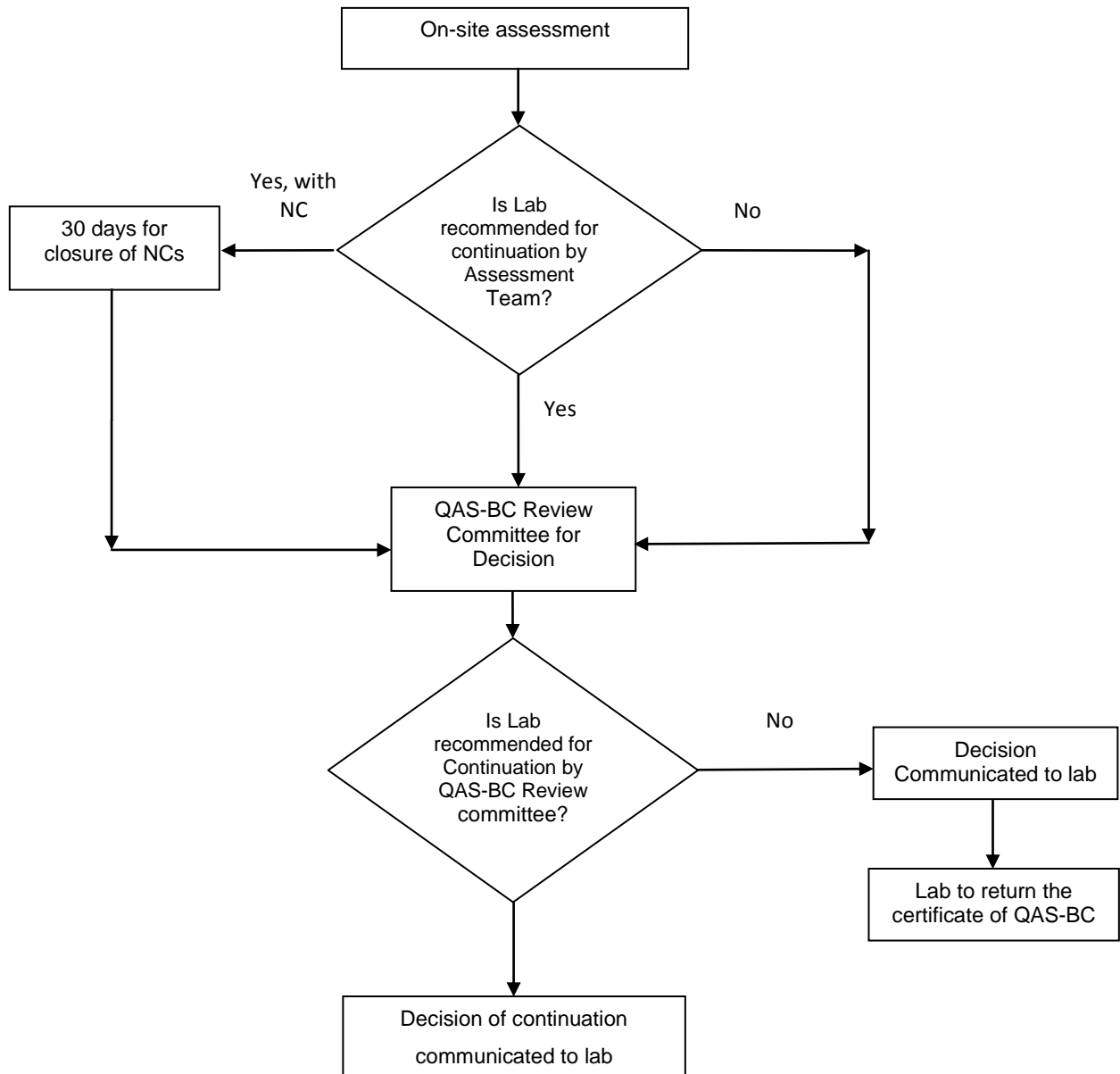




3. Procedure for On-Site Assessment

NABL will conduct an onsite assessment at least once during three years of cycle of the laboratories approved under this scheme. Five to ten percent of the labs complying with QAS-BC scheme will undergo unannounced onsite assessment.

Flow-Chart 2 (On-Site Assessment)



4. Privileges Extended to the Laboratory upon approval

Certificate of Compliance will be issued to the laboratories upon approval by NABL. The same will carry Certificate No. along with validity period.

Below is the representation of NABL claim to be made by the approved laboratory on its test reports:



QAS-BC-Entry Level-XX

5. Terms and Conditions for Applicant & Approved Laboratories for QAS-BC:

The applicant and approved laboratories under QAS-BC shall be required to fulfill the following terms & conditions:

1. The lab shall meet the requirements of regulators (local/regional/state /national regulations)
2. The scheme will not be covered under ILAC/APAC MRA. It is desired that the laboratories achieve accreditation as per ISO 15189 after two cycles (i.e. after six years). However, due to some reasons, if the laboratories wish to continue under this scheme, they have to apply for renewal one month before the expiry of the existing cycle.
3. The lab shall offer cooperation to NABL or its representative in undergoing assessments whenever NABL considered it as required:
 - a. Access to all lab areas of operations
 - b. Undertaking any check / inspection to verify the capability of the lab for the applied scope.
 - c. Witnessing the activities being performed relevant to this scheme.
 - d. Assessing the competence of the staff during assessment.
 - e. Access to all relevant information and documentation.
 - f. Access to those documents that provide insight into the level of independence and impartiality to the CAB from its related bodies, if applicable.
 - g. Access to all records pertaining to relevant personnel.
 - h. Providing names of all authorized signatory (s) who are responsible for authenticity and for review, evaluation & release of results (medical testing), as applicable.
 - i. Investigating any complaints against the lab.
4. The lab shall not involve in any kind of activity(ies) which may bring NABL to disrepute
5. The approved laboratories under QAS-BC, can relinquish through a written notice to NABL by surrendering the certificates of compliance with QAS-BC.

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6. The lab shall respond promptly to the changes initiated by NABL in its criteria (i.e. NABL 155), policies and procedures (i.e. NABL 128). The lab shall inform NABL when such alterations under the agreed time frame have been completed.
7. NABL absolves itself of any legal or financial liability arising out of activities of any of its lab covered under this scheme involving any accidental or consequential damages to personnel / equipment / products at any time.

Any violation of this terms and conditions shall result in denial of certificate under QAS-BC.

All disputes, if any, arising out of NABL decisions that remain unresolved through mechanism provided by NABL are subject to the exclusive jurisdiction of the Courts at New Delhi and none other.

6. Monitoring of Proficiency Testing (PT) participation

The approved labs shall submit the reports of Proficiency Testing (PT) participation annually from date of issue of certificate of QAS BC and the same will be reviewed by NABL

7. Procedure for Adverse Decision

7.1 Closure of Application

Conditions: -

1. When the lab's application is incomplete and it fails to complete the same within 7 days.
2. When the lab has neither submitted reports of Proficiency Testing (PT) participation nor is willing to undergo initial assessment (if applicable) within 15 days from the date of completion of application.
3. When the lab voluntarily withdraws application for QAS-BC.
4. When the lab relinquishes/withdraws by giving notice in writing to NABL by surrendering the certificates of QAS-BC.

Procedure for re-enrollment

The lab can apply afresh with relevant application form and applicable fee

7.2 Denial of Certificate to QAS-BC

Conditions: -

1. When the lab has not been recommended during the initial assessment (wherever applicable).
2. When the lab was recommended during initial assessment (wherever applicable) but failed to take corrective actions for the NCs raised within 30 days time.
3. When the lab has not been recommended for continuation during the on-site assessment.

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4. When the lab was recommended during assessment but failed to close the NCs raised within 30 days time.

Procedure for re-enrollment

The lab can apply afresh with relevant application form and applicable fee.

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