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|  |  | **NABL 156** |
| **NABL LOGO** | **National Accreditation Board for Testing****and Calibration Laboratories (NABL)** | **Image result for qci** |

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| **Application Form for Medical Imaging – Conformity Assessment Bodies (MI-CAB)** |

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| **ISSUE NO. :01****ISSUE DATE :09-May-2019** | **AMENDMENT NO. :****AMENDMENT DATE :** |

**AMENDMENT SHEET**

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| **Sl no** | **Page No.** | **Clause No.** | **Date of Amendment** | **Amendment**  | **Reasons** | **Signature****QM** | **Signature****CEO** |
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**Information & Instructions for completing an Application Form**

1. Application shall be made in the prescribed form NABL 156 only. Imaging procedures/ modalities that are intended to be covered under scope of accreditation should be covered in the same application form. The application shall consist of the following:
* Two copies of completed application form
* Two copies of MI-CAB Quality Manual
* Prescribed application fees
* Duly signed NABL-131

Incomplete application and insufficient number of copies submitted may lead to rejection of application. In case the space provided is insufficient, please use additional pages clearly indicating to which section they relate to.

2. The applicant MI- CAB shall undertake to carry out imaging procedures in such a way as to meet the requirement of ISO 15189:2012, NABL specific criteria, other relevant requirements of NABL and the regulatory authorities, as applicable at all times.

3. Applicant CAB(s) is advised to ensure that the latest versions of NABL documents are available with them.

1. The application fee and other necessary charges related to accreditation process are given in NABL document NABL 100 ‘General Information Brochure’ under NABL Finance and NABL Fee Structure’. NABL 100 is available on NABL website.
2. CABs are advised to familiarize themselves with NABL 100 ‘General Information Brochure’, NABL 201 ‘Procedure for dealing with Changes in Accredited Conformity Assessment Body’s Operations’, NABL 216 ‘Procedures for Dealing with Adverse Decisions’ and NABL 131 ‘Terms and Conditions for Obtaining and Maintaining Accreditation’ before filling up this form.
3. The applicant CAB shall provide photocopy of appropriate document(s) in support of the legal status claimed (e.g. Registration Certificate under Indian companies Act, Limited Liability Act, Partnership Act,Registration of Business as Sole Proprietor, Indian trust Act, Societies Registration Act, Any Government notification in support of establishment of institution/ CAB or any approval from local or regulatory bodies etc.) The name of the organization / CAB shall not be different from the name given in the proof of legal identity certificate. If it is different, valid reasons for the same shall be furnished. **Applicant CAB shall also provide photocopy of statutory requirements such as AERB Certificate, PC-PNDT Certificate.**
4. The applicant CAB shall intimate NABL about any change in the information provided in this application such as scope applied for accreditation, personnel, and location etc. within 15 days from the date of changes.
5. NABL expects applicant CAB(s) that are to be accredited to follow the imaging protocols/ procedures as mentioned in the current National or International standards and as stipulated by regulatory bodies. Where such procedures do not exist, other validated procedures are acceptable. In case CAB uses in-house validated methods, the validation data should be submitted along with the application.
6. The applicant CAB must participate satisfactorily in the available Proficiency Testing program/EQAS/ Peer Review conducted by APAC or NABL, any other national or international accredited/ recognized PT provider or in Internationally acceptable alternate approach for quality assurance. For participation in PT, refer NABL document NABL 163; *Policy for Proficiency Testing Activities*.
7. The CAB shall also inform NABL in advance about any reservation regarding appointment of Lead Assessor/ Assessor for the assessment.
8. The applicant CAB shall be given due notice of any intended changes relating to NABL accreditation criteria and will also be given such time, as in the opinion of NABL is reasonable to carry out the necessary adjustments to its procedure(s)**.** The CAB shall inform NABL when such adjustments have been completed.
9. The application must be filled up carefully to provide required information in such a manner that further correspondence for seeking clarifications are not required. Particularly the scope of accreditation (para 2.2) shall be complete to indicate unambiguously:
10. Imaging Modalities/Imaging Procedures
11. Categorization/ Protocol used
12. Type of Test- Qualitative or Quantitative with range for each test (as applicable)
13. % Tolerance/ Variance/CV (or) uncertainty of measurement (MU) for each test (wherever applicable) at a confidence probability of 95% wherever applicable.
14. The CAB locations, modalities, which the CAB intends to cover, vide NABL accreditation must be listed clearly. The tests those are performed at site should be clearly identified in the scope of accreditation (para 2.2).

***Multilocation MI-CAB****: - A MI-CAB with more than one location in the same district, with same legal identity. The details of each location shall be explicitly mentioned in 1.1 of application form. In events where the CAB operates from different district/ city/ state, each CAB shall apply separately for accreditation except those cases where safety or regulatory requirements are there for operation of the CAB. In such cases, the CAB shall provide the proper justification.*

1. The CAB shall submit NABL 131 duly signed by the Chief Executive or his/her Authorized Representative to NABL Secretariat along with this application form. By signing NABL 131 the CAB agrees to comply at all times with Terms and Conditions of NABL.
2. The CAB shall offer the NABL or its representative cooperation in:
3. undertaking any check to verify testing capability of the CAB.
4. the CAB shall unambiguously provide names of all authorized signatories who are responsible for authenticity and issue of Images and reports.
5. offering access to relevant areas of the MI- CAB including patient examination, preparation and imaging areas for witnessing the activity being performed.
6. examination of all relevant documentation and records.
7. interaction with all relevant personnel.
	1. The CAB shall discharge all non-conformities raised during the assessment within the stipulated time. The same shall be verified to the satisfaction of NABL. The final decision on accreditation shall rest with NABL.
	2. The application shall be kept confidential by NABL and information obtained during the processing of application, assessment visit and grant of accreditation shall be safeguarded and dealt with impartiality *until required by Law*. The procedure for processing of application for accreditation is given in NABL 100.

### Application Form for CAB Accreditation

We apply for NABL accreditation of our **Medical Imaging- Conformity Assessment Body (MI-CAB)** as per details given below:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | First Accreditation |  |  |  | Renewal of Accreditation |

|  |  |
| --- | --- |
|  | *Extension of Scope (Apart from the scheduled assessment)*  |

*(If accredited by NABL, please provide accreditation certificate no. & validity (if applicable) & CAB* ID:

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

1. **CAB Details**

|  |  |  |
| --- | --- | --- |
| **1.1** | **Name/ Identification of the CAB***(Permanent Facility)*  |  |
|  | **Location and Address(s)** |  |
|  | Telephone No. |  | Fax No. |  | E-mail |  |
|  |  |  |  |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **1.2** | **Does the CAB operate from different locations having same legal identity within the same district?** |  | **Yes** |  | **No** |
|  |  |
| a. | If yes, whether application for accreditation covers all locations |  | **Yes** |  | **No** |
| b. | If yes, whether complete details have been provided for each location with respect to 1.1, 2.1, 2.2, 3.1.2, 3.1.3, 3.3, 4, 6 of the application form. |  | **Yes** |  | **No** |

|  |  |  |
| --- | --- | --- |
| **1.3** | ***Name of Parent Organization***(if part of an organization) |  |
|  | Telephone No |  | Fax No. |  | E-mail |  |
|  |  |  |  |
| **1.4** | ***Legal identity of the CAB and date of establishment*** |  |
| (Please give Registration No. and name of authority who granted the registration. Copy of the certificate shall be enclosed) |
| **1.5** | ***Statutory Requirements*** |  |
|  | (Please submit the copy of Certificate/Licenses of statutory requirements) |  |
| **1.6** | ***Goods and Service Tax (GST) Number along with PAN/TAN Number***  |
|  |  |

|  |  |
| --- | --- |
| **1.7** | ***Type of CAB by service***(please tick in appropriate box) |
|  | open to others |  | partly open to others |  | an in-house activity |  |

|  |  |
| --- | --- |
| **1.8** | **Category of MI-CAB Operation** |
| Ionized radiation *(non-interventional)* |  |  | Sonography |  |
| Magnetic Resonance |  | Interventional radiology  |  |
|  | Nuclear medicine |  |  | Any Combination of above categories |  |

|  |  |  |
| --- | --- | --- |
| **1.9** | **Other accreditations­** |  |

|  |  |
| --- | --- |
| **1.10** | ***Indicate exactly how the name of the CAB are to appear on the certificate*** |
|  | In English |  |
|  |  |  |

1. **Accreditation Details**

|  |  |
| --- | --- |
| 2.1 | *Groups for which accreditation is sought*(please tick the appropriate box, separate annexures to be filled for each group, refer to Specific Criteria - MICAB for details on scope) |
|  | Projectional Radiography and Fluoroscopy  |  |
|  | CT  |  |
|  | MRI |  |
|  | Ultrasound and Color Doppler |  |
|  | Nuclear medicine |  |
|  | Interventional Radiology |  |

|  |  |
| --- | --- |
| **2.2** | ***Scope of Accreditation*** |
| **Sl No** | **Imaging Modality/** **Imaging Procedure** | **Protocol /Categorization used** | **Type of Test- Qualitative/ Quantitative (Range wherever applicable)** | **% Variance /Tolerance wherever applicable** |
|  |  |  |  |  |
|  |

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| --- | --- |
| **3** | **Organization** |
| **3.1** | ***Senior Management*** (Name, Designation, Telephone, Fax, E-mail) |
|  | 3.1.1. | Chief Executive of the MI-CAB |  |
|  | 3.1.2 | MI-CAB Director |  |
|  | 3.1.3 | Person responsible for the management system |  |
|  | 3.1.4 | Person responsible for technical operations |  |
|  | 3.1.5 | Contact person for NABL |  |

|  |  |
| --- | --- |
| **3.2** | ***Authorized Signatories*** |
|  | 3.2.1. | Authorized Signatories for approval of Imaging reports (Please refer to specific criteria**; NABL 135 for** MI-CAB for qualification and experience details) |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| S.No. | CAB/ Department/ Section | Name & Designation of Signatory | Qualification with Specialization | Experience in years related to present work | Relevant Training  | Authorised for specific procedure | Specimen Signature |
|  |  |  |  |  |  |  |  |

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| --- | --- |
| **3.3** | ***Organization Chart*** |
|  | 3.3.1. | Indicate in an organization chart the operating departments of the Medical Imaging CAB for which accreditation is being sought (please append) |
|  | 3.3.2 | Indicate how the MI-CAB is related to external organizations or to its own parent organization (where applicable) |

|  |  |
| --- | --- |
| **3.4** | ***Employees*** |
|  | **3.4.1.** | **Details of Staff** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **S.No.** | **Name** | **Designation+** | **Academic and Professional Qualifications\*** | **Experience related to present work (in years)** |
|  |  |  |  |  |
|  | \* Please clearly indicate the field of specialization + Quality Manager shall have 4 days training course on management system from a reputed institute Note: CAB operating in shifts shall clearly identify the staff working in shifts  |  |

|  |  |  |
| --- | --- | --- |
|  | **3.4.2.** | **\*Details of Radiological Safety Officer (wherever applicable)** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S.No.** | **Name** | **Academic and Professional Qualifications\*** | **Training Details regarding Radiological Safety** | **Experience in present organization (in years)** | **AERB Registration No.** |
|  |  |  |  |  |  |
| \*Attach copy of approval from AERB |

|  |  |
| --- | --- |
| **4** | **Equipment** |
| **4.1** | **List of major test equipment available for use**  |
| **S. No** | **Name of equipment** | **Model/ type/ year of make & Calibration frequency** | **Receipt date & date placed in service** | **Valid License/certificate no.** | **Date of last calibration/Quality Assurance** | **Calibration/Quality Assurance due on** | **Calibrated/QA by\*** |
|  |  |  |  |  |  |  |  |
| Note: Please attach the copy of valid License/certificate from statutory bodies such as AERB, PC-PNDT\* Please mention name of calibration agency In case the equipment is calibrated in-house, same needs to be clearly indicated under this column.Note- Please define Calibration frequency of equipments as given by OEMs |
| **4.2** | **List of Phantoms (Wherever applicable)** |
| **S. No** | **Phantom Type** | **Specifications** | **OEM/Supplier** | **Date of Placing in use** | **Traceability** |
|  |  |  |  |  |  |
|  |  |
| **4.3** | **#List of Radioisotopes (Applicable in Nuclear Medicine)** |
| **S. No** | **Name of Radioisotopes** | **Maximum activity Permitted by AERB**  | **Details of Supplier** | **Half Life** | **Energy (KeV)** |
|  |  |  |  |  |  |
| #Please attach copy of procurement/permission from AERB |

|  |  |
| --- | --- |
| **5.** | **Internal Audit and Management Review** |
| **5.1** | ***Date /schedule of last Internal Audit*** |
|  | 5.1.1 | Whether all requirements of ISO15189:2012 covering all activities of CAB have been audited at least once in last one year  | YES/NO |
|  | 5.1.2 | Whether various locations were covered in the audit | YES/NO |
|  | 5.1.3 | Whether pre and post examination activities were included in the audit schedule | YES/NO |
|  |  |  |  |
| 5.2 | ***Date of last Management Review*** |  |
|  |  |  |  |

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| **6.** | **Proficiency Testing** |
| **6.1** | Participation in PT / any other Inter CAB Comparison/Alternate approach.(for details and requirements please refer to ISO/ IEC 17043, & NABL 163, Specific Criteria for MI-CAB; NABL 135) |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Sl.no. | Image (Film, cassete or any acceptable form) | Imaging Procedure | Date of Testing/ examination | Organizing body  | Performance in terms of z score or any other criteria | Corrective action taken (if required) |
|  |  |  |  |  |  |  |

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| **7.**  | **Application Fees** |
| **7.1** | **Application fees (Rs.)** |  |
|  |  |
| **7.2** | DD / At par Cheque\* number |  |
|  |  |  |
|  | *\*All payments made through Cheques or Demand Draft shall be made in favor of* ***‘Quality Council of India'*** *payable at Gurugram.* *Note: Kindly make all kind of payments preferably through the ‘****Payment Gateway’*** *available on NABL website (www.nabl-ndia.org* |

**8. Declaration by the CAB**

##### **We declare that**

|  |  |
| --- | --- |
| 8.1 | We are familiar with the terms and conditions of maintaining accreditation (NABL 131), which is enclosed and will abide by them. |
| 8.2 | We have conducted internal audit at least once during the last one year. |
| 8.3 | We agree to comply fully with ISO15189:2012 and relevant specific criteria for the accreditation MI-CAB. |
| 8.5 | We agree to comply with accreditation procedures, pay all costs for pre-assessment, assessment, verification visit (if any), surveillance and reassessment irrespective of the result. |
| 8.6 | We agree to co-operate with the assessment team appointed by NABL for examination of all relevant documents by them and their visits to those parts of the CAB that are part of the scope of accreditation. |
| 8.7 | We satisfy all national, regional and local regulatory/statutory requirements for operating a CAB. |
| 8.8 | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ has provided consultancy for preparing towards NABL accreditation. (Information regarding any individual or organization who provided consultancy (if any) for NABL accreditation shall be declared) |
| 8.9 | No adverse action has been initiated / taken against the CAB in the past. (If yes, please provide the details with present status ……………………………………………………….) |
| 8.10 | Self-declaration shall be submitted by the CAB on the basis of the internal audit conducted by them, to confirm to NABL that their facility/ies are complying with NABL norms and relevant clauses of ISO 15189. |
| 8.11 | All information provided in this application is true. |

|  |  |
| --- | --- |
| Signature of CAB Head/ CAB Director |  |
| Name & Designation |  |
| Date & Place |  |
|  |  |

**9. Application Form - Check List**

|  |  |  |
| --- | --- | --- |
| **Sl.** | **Information / details provided as part of application** | **Availability** |
|  | Three copies of Application Forms |  |
|  | Two copies of Quality Manual (latest issue) according to ISO 15189 : 2012 |  |
|  | Application fees* Information on size of the CAB applied for accreditation
* Estimated applicable fees as per NABL 100
* Demand Draft / At Par Cheque in favor of Quality Council of India’ & details of payment made through Payment Gateway of NABL
 |  |
|  |
|  |
|  | Copy of Legal Identity (Registration Details of the CAB) |  |
|  | Copy of AERB,PC-PNDT Registration Certificate, RSO Certificate/ Radioactivity Permission |  |
|  | Calibration Certificate/ Quality Assurance Reports for Equipments listed. |  |
|  | *Goods and Service Tax (GST) Number along with PAN/TAN Number* |  |
|  | Scope of Accreditation with Imaging Procedure, Range of Testing and Variance/MU/ % CV (if applicable) |  |
|  | Details of Senior Management with Designation and Contact Details  |  |
|  | List of Staff and proposed Authorized Signatories |  |
|  | Organization Chart enclosed  |  |
|  | List of Equipments / Phantoms/ Radioisotopes used with details of Traceability |  |
|  | Details of participation in PT / ILC/ any other alternate approach |  |
|  | Dates of Internal Audit and Management Review |  |
|  | Self declaration to confirm that MI- CAB’s facilities are complying with NABL norms and relevant clauses of ISO 15189 on the basis of the internal audit conducted by CAB. |  |
|  | Declaration about the Consultant (if any) |  |
|  | Signed copy of NABL 131 (latest issue) |  |

Verified the above details and confirmed the availability of all required documents/ details as part of application form.

|  |  |
| --- | --- |
| Signature of CAB Head/ CAB Director |  |
| Name & Designation |  |
| Date & Place |  |

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