|  |  |
| --- | --- |
|  | **NABL 208** |
| **C:\Users\Sayal_2\AppData\Local\Microsoft\Windows\INetCache\Content.Outlook\MOPJ7GRD\NABL LOGO.jpg** | **National Accreditation Board for Testing**  **and Calibration Laboratories (NABL)** |

|  |
| --- |
| **Pre-Assessment Guidelines and Forms (based on ISO 15189:2012)** |

|  |  |
| --- | --- |
| **ISSUE NO. : 02**  **ISSUE DATE : 19-Apr-2016** | **AMENDMENT NO. : 02**  **AMENDMENT DATE : 02-May-2018** |

**AMENDMENT SHEET**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Sl** | **Page No.** | **Clause No.** | **Date of Amendment** | **Amendment** | **Reasons** | **Signature QM** | **Signature**  **CEO** |
| 1 | 12/12 | Form74 | 13-May-2016 | Form 74 includes QM Adequacy | IQA | -Sd- | -Sd- |
| 2 | 11/12 | NPF 3 | 02-May-2018 | Change in timeline for CA of pre-assessment to Max. 15 days | Internal | Sd/- | Sd/- |
| 3 |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |  |
| 7 |  |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |  |
| 9 |  |  |  |  |  |  |  |
| 10 |  |  |  |  |  |  |  |

### CONTENTS

|  |  |  |
| --- | --- | --- |
| **S. No.** | **Title** | **Page Nos.** |
|  |  |  |
|  | Amendment Sheet | 1 |
|  | Contents | 2 |
|  | Guide to use Pre-Assessment Forms & Checklist | 3 |
|  | Pre Assessment Checklist – NPF 1 | 5 |
|  | Non Conformities Observed during Pre-Assessment – NPF 2 | 10 |
|  | Pre Assessment Report – NPF 3 | 11 |
|  | Declaration of Impartiality & Confidentiality – Form 74 | 12 |

**GUIDE TO USE PRE-ASSESSMENT FORMS & CHECKLIST**

1. **INTRODUCTION**

It is presumed that the Lead Assessor, who has been nominated by the NABL Secretariat, is fully aware of the NABL Accreditation process, its objectives and the on-site Assessment procedure. The Lead Assessor shall have the overall responsibility of conducting the assessment and shall be responsible for pre-assessment of the laboratory and for conducting the on-site assessment of the concerned laboratory. Towards the task of on-site assessment, the lead assessor shall be assisted by a team of assessors commensurate with the scope of accreditation.

This document contains Pre-assessment forms and Checklist, which shall be used to report the pre-assessment findings. The document shall guide the Lead Assessor in completing various forms & checklists and compiling the report.

1. **PRE ASSESSMENT**

After the laboratory has taken the corrective action on the concerns expressed in the Quality Manual Adequacy Report and has submitted a report to the satisfaction of the NABL, NABL Secretariat shall fix up a date for Pre-assessment in consultation with the laboratory and the Lead Assessor.

While the Lead Assessor proceeds to the laboratory for Pre-assessment, he should be in possession of the laboratory’s Applications Forms, Quality Manual, Corrective action report on the adequacy of the Quality Manual (if any) and any other information supplied by NABL Secretariat.

The Lead Assessor, during Pre-assessment shall:

1. check the overall implementation of the management system as per the documented Quality Manual
2. study the scope of accreditation so that the time frame, number of assessors required in various disciplines and visits to collection centres, if applicable, for the assessment can be determined. The Lead Assessor shall also assess whether the Assessment is required to be split, based on the location of laboratory or the number of disciplines, departments and collection facilities.
3. check whether the laboratory has conducted a comprehensive Internal Audit in accordance with ISO 15189:2012.
4. assess the degree of preparedness of the laboratory for the Assessment in terms of compliance to NPF 1.
5. obtain signatures on NABL 131 – Terms and Conditions for Obtaining and Maintaining Accreditation, from the laboratory, if not submitted by laboratory earlier
6. explain to the laboratory regarding the methodology to be adopted for Assessment and the obligations of the laboratory
7. submit a report to NABL Secretariat
8. **COMPILATION OF PREASSESSMENT FORMS & CHECKLIST**

The Lead Assessor must review the Laboratory’s documented management system to verify compliance with the requirements of ISO 15189:2012. He should complete the Checklist NPF 1 by recording his observation – ‘Yes’ or ‘No’ (by marking a √ in the appropriate box), related to the requirements of respective clause number of the checklist and offering brief comments. If the Lead Assessor has a doubt in other area(s), even though not listed in the checklist, he is free to assess or go into details where he feels and annex his findings, to the report.

All Non-Conformity(ies) must be identified and to be reported in NPF 2. Additional sheets may be added, if required. The Lead Assessor should finally summarise the conduct of Pre-Assessment and record the recommendations in NPF 3. The Lead Assessor must carefully fill the forms and check list and sign all pages of the Pre-Assessment Report. He should also obtain signature of the authorised person of the laboratory on NPF 2 & 3. The report should be compiled in the order NPF 3, 2, 1 & Form 74 and any other additional pages or annexure thereafter.

The Lead Assessor shall submit the Pre-Assessment Report to NABL Secretariat within 10 days of completion of Pre-Assessment.

**Instructions:**

1. Verify the information provided by the lab in application form NABL 153 (S.No. 1a).
2. Check all the columns as per format i.e. appropriate material to be tested, Test methodology (delete obsolete and redundant tests), acceptable range of testing, actual %CV / ±MU upto one decimal (S.No. 1b).
3. Check availability of Procedures and records as per the standard requirements i.e. mandatory procedures as required in ISO 15189:2012 (wherever written as "...shall have documented procedure....") (S.No. 2c).

***NPF 1***

**PRE-ASSESSMENT CHECKLIST**

|  |  |
| --- | --- |
| **Laboratory:** | **Date(s) of Visit:** |

| **S.No.** | | **Requirement** | | **Observation**  (Mark √ in the appropriate box) | |
| --- | --- | --- | --- | --- | --- |
| **Yes** | **No** |
| 1. | **Review of Application Form/s (NABL 153)** | | | | |
| a) | correctness of contents | |  |  |
| b) | scope of accreditation | |  |  |
| **Remarks:** | | | | |
| **2.** | **Quality Management System Documentation** | | | | |
|  | Availability of Quality Policy and Quality objectives in the laboratory | |  |  |
|  | Availability of Quality Manual | |  |  |
|  | Availability of Procedures and records as per the standard requirements. | |  |  |
|  | Availability of Procedures and records to ensure the effective planning, operation and control of its processes. | |  |  |
|  | Availability of copies of regulations, standards and other normative documents. | |  |  |
|  | Availability of relevant NABL documents (NABL 131, 133, 112, 216, 142 etc.). | |  |  |
|  | Whether following points are covered in the Quality Manual: | |  |  |
| i. | Quality policy and Quality objectives or its reference |  |  |
| ii. | Description of scope of QMS |  |  |
| iii. | Presentation of the Organization and Management structure of the laboratory. |  |  |
| iv. | Description of the roles and responsibilities of Laboratory management (including the laboratory director and quality manager) |  |  |
| v. | Description of the structure and relationships of the documentation used in the QMS. |  |  |
| vi. | Documented polices established for the QMS and reference to the managerial and technical activities that support them. |  |  |
| h) | Whether all the staff has access to and is instructed on the use and application of the quality manual and the referenced documents. | |  |  |
| **Remarks:** | | | | |

***NPF 1***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **3.** | **Quality Management System Implementation (sample audit)** | | | |
| a) | Whether laboratory has established processes needed for QMS |  |  |
| b) | Whether sequence of interaction of the processes determined |  |  |
| c) | Whether criteria is determined to ensure the effective implementation of operation and control of these processes. |  |  |
| d) | Whether adequate resources are available to provide information necessary to support the operation and monitoring of these processes. |  |  |
| e) | Whether monitoring and evaluating these processes are done |  |  |
| f) | Whether lab has taken necessary actions to achieve planned results and continual improvement of these processes. |  |  |
| **Remarks:** | | | |
| 4. | **Internal Audit** | | | |
| a) | Availability of documented audit criteria |  |  |
| b) | Availability of documented audit scope |  |  |
| c) | Availability of documented audit frequency |  |  |
| d) | Availability of documented audit method |  |  |
| e) | Availability of Audit Plan |  |  |
| f) | All requirements of ISO 15189:2012, covering all activities of laboratory (including pre examination processes and sample collection facility) audited at least once in the last one year |  |  |
| g) | Timely corrective action on non-conformities |  |  |
| f) | Audit conducted by qualified, trained and Independent personnel |  |  |
| **Remarks:** | | | |
| **5.** | **Management Review** | | | |
| a) | Availability of Management review plan |  |  |
| b) | All requirements of clause 4.15 of ISO 15189:2012, are incorporated in the agenda of review in the last one year |  |  |
| c) | Availability of minutes of last Management review meeting |  |  |
| **Remarks:** | | | |

***NPF 1***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **6.** | **Personnel** | | | |
| a) | Whether laboratory director is available |  |  |
| b) | Whether laboratory director delegated the responsibilities to qualified persons. |  |  |
| c) | Whether duties and responsibilities of laboratory director were documented. |  |  |
| d) | Whether laboratory director have the necessary competence, authority and resources to fulfil the standard requirements. |  |  |
| e) | Competency/4 days training programme for designated Quality Manager on ISO 15189:2012. |  |  |
| f) | Whether quality manager is ensuring the processes in needed for the quality management system are established, implemented and maintained. |  |  |
| g) | Whether quality manager has the authority to discuss the matters related to QMS. |  |  |
| h) | Whether quality manager is ensuring the promotion of awareness of users needs and requirements throughout the laboratory organization. |  |  |
| i) | Whether the authorised signatories’ qualification is as per NABL 112 criteria. |  |  |
| **Remarks:** | | | |
| **7.** | **Accommodation and Environmental conditions** | | | |
| a) | Adequate laboratory and office facilities |  |  |
| b) | Adequate storage facilities |  |  |
| c) | Adequate staff facilities |  |  |
| d) | Adequate patient sample collection facilities |  |  |
| e) | Adequate facility maintenance and environmental conditions |  |  |
| **Remarks:** | | | |
| **8.** | **Laboratory Equipment, Reagents and Consumables** | | | |
| **Equipments** | | | |
| a) | Availability of documented procedure for selection, purchasing and management of equipments. |  |  |
| b) | Whether major equipments are available as per list submitted alongwith application form NABL 153. |  |  |
| c) | Maintenance plan of Equipment and calibration with metrological traceability. |  |  |
| d) | Availability of Equipment records. |  |  |
| **Reagents and Consumables** | | | |
| a) | Availability of documented procedure for the reception, storage, acceptance testing and inventory management of reagents and consumables. |  |  |
| b) | Availability Storage facilities |  |  |

***NPF 1***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | c) | Whether performance of reagents and consumables were verified before into use. | |  |  |
| d) | Availability of inventory control system for reagents and consumables. | |  |  |
| **Remarks:** | | | | |
| **9.** | **Pre-examination processes** | | | | |
| a) | Availability of documented procedure for pre-examination processes. | |  |  |
| b) | Availability of information about laboratory services to patients and users | |  |  |
| c) | Whether request form is as per standard guidelines. | |  |  |
| i. | Primary sample collection and handling |  |  |
| ii. | Availability of documented procedure of proper collection and handing primary samples. |  |  |
| iii. | Availability of instruction for Pre-collection activities. |  |  |
| iv. | Availability of instructions for collection activities. |  |  |
| **Remarks:** | | | | |
| **10.** | **Examination Processes** | | | | |
| Selection, Verification and Validation of examination processes | | |  |  |
| a) | Whether laboratory have selected validated procedures | |  |  |
| b) | Whether procedures were verified before introducing into the routine use. | |  |  |
| c) | Whether laboratory is calculating % CV / measurement uncertainty (+MU) for Quantitative, Semi-quantitative and Qualitative tests, as applicable. | |  |  |
| d) | Whether biological reference intervals or clinical decision values defined by the laboratory. | |  |  |
| e) | Availability of documented examination procedures as per the standard requirements. | |  |  |
| **Remarks:** | | | | |
| **11.** | **Ensuring Quality of Examination Results** | | | | |
| a) | Availability of quality control procedures. | |  |  |
| b) | Availability of appropriate quality control materials | |  |  |
| c) | Established procedure to prevent the release of patient results in the event of quality control failures. | |  |  |
| **Interlaboratory Comparisons** | | | | |
| a) | Participation in the external quality assessment programmes | |  |  |
| b) | Availability of procedure for Interlaboratory comparison participation | |  |  |
| c) | Whether lab performing alternate approaches where a formal EQA not available. | |  |  |
| d) | Whether Interlaboratory comparison sample analysed as a routine sample | |  |  |

***NPF 1***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | e) | Whether results of EQA were reviewed and discussed with relevant staff. | |  |  |
| f) | Availability of procedures for the comparability of examination results | |  |  |
| **Remarks:** | | | | |
| **12.** | **Post-examination Processes** | | | | |
| a) | Availability of procedures and authorised personnel for the review of examinations before release | |  |  |
| b) | Availability of procedure for storage, retention and disposal of clinical samples as per standard requirements. | |  |  |
| c) | Whether safe disposal is as per the standard local, national regulations wherever applicable. | |  |  |
| **Remarks:** | | | | |
| **13.** | **Reporting of Results** | | | | |
| a) | Whether report format is as per the standard requirements with all the contents | |  |  |
| **Remarks:** | | | | |
| **14.** | ***Discussions with the Laboratory on Final Assessment*** | | | | |
| a) | Overview of the methodology to be adopted | |  |  |
| i. | About team and number of the assessors |  |  |
| ii. | Procedure of Test(s) Witness |  |  |
| iii. | Process for competency evaluation |  |  |
| iv. | Assessment of collection centres, wherever applicable. |  |  |
| v. | Number of audit days required |  |  |
| b) | Obligations of the laboratory (as per NABL 100, 153, 131) | |  |  |
| **Remarks:**  **Signature/ Name of the Lead Assessor** | | | | |

***NPF 2***

**NON-CONFORMITIES OBSERVED DURING PRE-ASSESSMENT**

|  |  |  |
| --- | --- | --- |
| **Laboratory:** | | **Date(s) of Visit:** |
|  | | |
| **Sl.** | **Non-conformity**  ***(to be filled by LA)*** | **Corrective Action proposed by the laboratory**  ***(to be filled by lab)*** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| **Signature/ Name of Authorised representative of Lab. & Date** | | Signature/ Name of Lead Assessor & Date |

Note: Use additional sheets of this form, if required

***NPF 3***

**PRE-ASSESSMENT REPORT**

|  |  |  |
| --- | --- | --- |
| **Laboratory:** | | |
| **Quality Manager:** | | **Date(s) of Visit:** |
| **Field :** Medical | **Discipline(s):** | |
| **Applicable Standard: ISO 15189:2012**  **NABL Specific Criteria-** | | |
| **Persons Contacted:** | | |
| **Corrective action taken on the adequacy report implemented:** | | Yes / No |
| **Latest version of Quality Manual**   * issue no. & date * amend no. & date | |  |
| **Submission of NABL 131 (Terms & Conditions)** | | Submitted earlier/ Enclosed/ Not submitted |
| **No. of Non-conformities during Pre-assessment** | |  |
| **Summary of Pre-Assessment:** | | |
| **Recommendations of Time Estimation and Readiness of Laboratory):** | | |
| * Number of Assessors required, discipline wise, as per scope of accreditation | |  |
| * Number of audit days required | |  |
| * Whether the Assessment is required to be split based on locations of laboratory or number of disciplines/ collection facilities. If yes, elaborate | | Yes / No |
| * Is the Laboratory ready for Assessment If no, specify estimated time for taking corrective actions *(Max 15 days)* | | Yes / No |
| Any specific recommendations: | | |
| **Signature/ Name of Authorised representative of Lab. & Date** | | **Signature/ Name of Lead Assessor & Date** |

**FORM 74**

**DECLARATION OF IMPARTIALITY & CONFIDENTIALITY**

(to be filled in by each Assessor and enclosed with the Assessment report)

|  |  |  |
| --- | --- | --- |
| **Name** |  | Assessor ID:  (To be filled in by NABL Sect.) |
| **Designation** |  | |
| **Organisation** |  | |
| **Address** |  | |
| **Capacity** | Lead Assessor / Technical Assessor / Technical Expert / Observer | |
| **CAB\* Assessed** |  | |
| **Date of Assessment** |  | |
| **Type of Assessment** | *QM Adequacy / Pre-Assessment / Assessment / 1st Surveillance / Re-Assessment / Supplementary visit* | |

*\* CAB – Conformity Assessment Body (Testing / Medical / Calibration laboratory / Proficiency Testing Provider (PTP) / Reference Material Producer (RMP))*

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, hereby declare that

I have not offered any consultancy, guidance, supervision or other services to the CAB (e.g. internal audit), in any way.

I am / am not\* an ex-employee of the CAB and am/ am not\* related to any person of the management of the CAB.

I got an opportunity to go through various documents like Quality Manual, Procedural Manuals, Work instructions, Internal reports etc. of the above CAB and other related information that might have been given by NABL. I undertake to maintain strict confidentiality of the information acquired in course of discharge of my responsibility and shall not disclose to any person other than that required by NABL.

\* strike out which is not applicable

|  |  |
| --- | --- |
| Date:  Place : | Signature |

**National Accreditation Board for Testing and Calibration Laboratories (NABL)**

**NABL House**Plot No. 45, Sector 44,  
Gurgaon - 122002, Haryana  
Tel. no.: 91-124-4679700 (30 lines)  
Fax: 91-124-4679799  
Website: [www.nabl-india.org](http://www.nabl-india.org)