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|  | **NABL 208(A)** |
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| **Pre-Assessment Guidelines and Forms (based on ISO 15189:2022)** |

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| **ISSUE NO.: 01****ISSUE DATE: 03-Aug-2023** | **AMENDMENT NO.: --****AMENDMENT DATE: --** |

**AMENDMENT SHEET**

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| **Sl.** | **Amendment No.**  | **Page No.** | **Clause No.** | **Date of Amendment** | **Amendment**  | **Reasons** | **Signature Quality Team** | **Signature** **Competent Authority**  |
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**GUIDE TO USE PRE-ASSESSMENT FORMS & CHECKLIST**

1. **INTRODUCTION**

The Lead Assessor shall have the overall responsibility of conducting the pre-assessment of the laboratory. During Initial Assessment Lead Assessor will be accompanied by team of Technical 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**

Once the Document Review process is completed, a pre-assessment of the laboratory is conducted (if opted by the laboratory or if NABL decides to conduct the same based on the outcome of document review as pre-assessment is optional) by lead assessor appointed by NABL. The date for pre-assessment finalized 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, Management System Document, Corrective action report on the adequacy of the Management System Document (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 Management System Document
2. Study the scope of accreditation so that the time frame, number of assessors required in various disciplines and visits to collection centres/mobile facility/site facility, if applicable, for the assessment can be determined. The Lead Assessor shall also assess the risks associated with the scope and personnel, if any which need to be taken into consideration while planning, scheduling and/or conducting assessment.
3. Check whether the laboratory has conducted a comprehensive Internal Audit in accordance with ISO 15189: 2022.
4. Assess the degree of preparedness of the laboratory for the Assessment in terms of compliance to NPF 1.
5. explain to the laboratory regarding the methodology to be adopted for assessment and the obligations of the laboratory
6. submit a report to NABL.
7. **COMPILATION OF PREASSESSMENT FORMS & CHECKLIST**

The Lead Assessor must review the Laboratory’s management system documents to verify compliance with the requirements of ISO 15189:2022. 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 (for cross-frontier CABs). 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.

**NPF 1**

**PRE-ASSESSMENT CHECKLIST**

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

| **SI.** | **Requirement** | **Observation**(Mark √ in the appropriate box) |
| --- | --- | --- |
| **Yes** | **No** |
|  | **Review of Application Form/s (NABL 153)** |
|  | correctness of contents |  |  |
|  | scope of accreditation |  |  |
| **Remarks:**  |
|  | **General Requirements:** |
| Whether laboratory has mechanism for the following: |
| a) | To maintain the Impartiality |  |  |
| b) | To maintain the Confidentiality |  |  |
| c) | Requirements regarding patients’ well-being, safety and rights |  |  |
| **Remarks:** |
|  | **Structural and Governance Requirements:** |
| a) | Whether laboratory director is available |  |  |
| b) | Whether laboratory director have the necessary competence, authority and resources to fulfil the standard requirements. |  |  |
| c) | Whether duties and responsibilities of laboratory director were documented  |  |  |
| d) | Whether laboratory director delegated the responsibilities to qualified persons. |  |  |
| e) | Description and documentation of scope / range of laboratory activities including POCT/Sample Collection |  |  |
| f) | Whether laboratory management ensure the appropriate laboratory advice and interpretation are available and meet the needs of patients and users |  |  |
| g) | Whether laboratory has defined its Organization and Management structure. |  |  |
| h) | Whether laboratory has specified responsibility, authority and interrelationships of all personnel. |  |  |
| i) | Whether laboratory has assigned personnel for implementation, maintenance and improvement of management system. |  |  |
| j) | Availability of Objectives and policies in the laboratory |  |  |
| k) | Whether laboratory management has established, implemented and maintained processes for identifying risks. |  |  |
| **Remarks:** |
|  | **Personnel:** |
| a) | Whether the laboratory has sufficient no. of competent personnel to perform its activities |  |  |
| b) | Whether laboratory has specified and documented the competence requirements for each function influencing the results of laboratory activities |  |  |
| c) | Whether laboratory has authorized personnel to perform specific laboratory activities |  |  |
| d) | Whether continuing education program is available to personnel  |  |  |
| e) | Whether laboratory has procedures and retained records for the personnel. |  |  |
| **Remarks:** |
|  | **Facilities and Environmental conditions** |
| a) | Does the laboratory have suitable facilities for the laboratory activities |  |  |
| b) | Whether laboratory is maintaining the environmental conditions for laboratory activities  |  |  |
| c) | Whether the laboratory has adequate storage facilities |  |  |
| d) | Whether the laboratory has adequate personnel facilities |  |  |
| e) | Whether the laboratory has adequate patient sample collection facilities |  |  |
| **Remarks:** |
|  | **Equipment** |  |  |
| a) | Availability of processes for selection, purchasing, installation, acceptance testing, handling, transport, storage, use, maintenance and decommissioning of equipment. |  |  |
| b) | Whether major equipments are available as per list submitted along-with application form NABL 153.  |  |  |
| c) | Availability of Maintenance plan of Equipment  |  |  |
| d) | Availability of Equipment records. |  |  |
| **Remarks:** |
|  | **Equipment calibration and metrological traceability** |  |  |
| a) | Whether laboratory has specified the requirements for calibration and traceability |  |  |
| b) | Whether procedures for calibration of equipment are available  |  |  |
| c) | Whether documented unbroken chain of calibrations are available for maintaining metrological traceability of its measurement results |  |  |
| **Remarks:** |
|  | **Reagent and consumables** |  |  |
| a) | Availability of processes for the selection, procurement, reception, storage, acceptance testing and inventory management of reagents and consumables. |  |  |
| b) | Availability of Storage facilities |  |  |
| c) | Whether performance of reagents and consumables were verified before placing into use  |  |  |
| d) | Availability of inventory management system for reagents and consumables.  |  |  |
| e) | Availability of instructions for use of reagents and consumables |  |  |
| f) | Availability of records for reagent and consumables |  |  |
| **Remarks:** |
|  | **Service Agreements** |  |  |
| a) | Availability of procedure to establish and review agreement for providing laboratory activities |  |  |
| b) | Availability of agreements with POCT operators |  |  |
| **Remarks:** |
|  | **Pre-examination processes:** |  |  |
| a) | Availability of procedure for pre-examination processes. |  |  |
| b) | Availability of information about laboratory services to patients and users  |  |  |
| c) | Whether request form examination request is as per standard guidelines.  |  |  |
| d) | Availability of procedure for Oral requests for examinations, if applicable |  |  |
| e) | Availability of procedure for primary sample collection and handling |  |  |
| f) | Availability of instructions for Pre-collection activities. |  |  |
| g) | Availability of patient consent for all procedure carried out on the patients |  |  |
| h) | Availability of instructions for collection activities. |  |  |
| i) | Availability of instructions for Sample transportation |  |  |
| j) | Availability of procedure for sample receipt |  |  |
| k) | Availability of procedure for pre-examination handling, preparation and storage of samples |  |  |
| **Remarks** |
| 1.
 | **Examination Processes** |  |  |
| Selection, Verification and Validation of examination processes |  |  |
| a) | Whether test procedures were verified before introducing into the routine use. |  |  |
| b) | Whether laboratory have selected validated test procedures |  |  |
| c) | Whether laboratory is evaluating and documenting measurement uncertainty (+MU) for Quantitative, Semi-quantitative and Qualitative tests. |  |  |
| d) | Whether biological reference intervals or clinical decision limits defined by the laboratory. |  |  |
| e) | Availability of examination procedures as per the standard requirements |  |  |
| **Remarks** |
|  | **Internal Quality Control (IQC)** |
| a) | Availability of quality control procedures. |  |  |
| b) | Availability of appropriate quality control materials |  |  |
| c) | Availability of use of other methods for IQC if appropriate IQC material is not available |  |  |
| d) | Availability of defined acceptability criteria to prevent the release of patient results in theevent of quality control failures |  |  |
| **Remarks:** |
|  | **External Quality Assessment (EQA)** |  |  |
| a) | Availability of procedure for participation in the external quality assessment programmes |  |  |
| b) | Whether lab performing alternate approaches where a formal EQA not available. |  |  |
| c) | Whether results of EQA were reviewed and appropriate corrective actions taken in case outliers |  |  |
| **Remarks** |
|  | **Comparability of examination results** |  |  |
| a) | Availability of procedures for the comparability of examination results |  |  |
| b) | Availability of records for results of comparability performed and its acceptability |  |  |
| **Remarks** |
|  | **Post Examination processes** |  |  |
| a) | Availability of procedures and authorised personnel for the review of examinations results before release |  |  |
| b) | Availability of records of all results which are provided orally |  |  |
| c) | Availability of procedure for implementation of system for automated selection, review, release and reporting of results |  |  |
| d) | Availability of information in the report as per the standard requirements |  |  |
| e) | Availability of procedure for issue of amended or revised results. |  |  |
| f) | Whether the laboratory has specified the retention period for samples |  |  |
| g) | Whether safe disposal is as per the standard, local or national regulations wherever applicable.  |  |  |
| **Remarks:** |
|  | **Nonconforming work** |  |  |
| a) | Availability of process for nonconforming work |  |  |
| **Remarks** |
|  | **Control of data and information management** |  |  |
| a) | Whether the laboratory has specified the authorities and responsibilities for information management |  |  |
| b) | Whether the laboratory has documented and validated information system management before implementation |  |  |
| c) | Whether the laboratory has planned processes to maintain operations in the event of failure or down time. |  |  |
| d) | Whether the laboratory has ensured that the provider/operator of the system complies with the requirements of the standard, if applicable |  |  |
| **Remarks** |
|  | **Complaints** |  |  |
| a) | Availability of process for handling complaints |  |  |
| **Remarks** |
|  | **Continuity and Emergency preparedness planning** |  |  |
| a) | Whether the laboratory has plan, procedure and technical measures to enable continuedOperations |  |  |
| b) | Whether the laboratory has periodically tested and planned response capabilityexercised |  |  |
| **Remarks** |
|  | **Management System Requirements** |  |  |
| a) | Availability of Objectives and policies in the laboratory |  |  |
| b) | Availability of Management system documents |  |  |
| c) | Availability of Procedures and records as per the standard requirements.  |  |  |
| d) | Availability of Procedures and records to ensure the effective planning, operation and control of its processes.  |  |  |
| e) | Availability of copies of regulations, standards and other normative reference documents. |  |  |
| f) | Availability of relevant NABL documents (NABL 131, 133, 112, 216, 142 etc.).  |  |  |
| g) | Whether following points are covered in the Management System documents: |  |  |
| i) | Quality policy and Quality objectives or its reference |  |  |
| ii) | Description of scope / range of laboratory activities including POCT/Sample Collection |  |  |
| iii) | Presentation of the Organization and Management structure of the laboratory. |  |  |
| iv | Description of the roles and responsibilities of Laboratory management |  |  |
| v) | Documented polices established for the Management system documents 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 Management system documents and the referenced documents |  |  |
| i) | Whether the laboratory has ensured control of documents as per the requirement of the standard. |  |  |
| k) | Whether the laboratory has established and retained legible records to demonstrate fulfilment of the requirements of the standard. |  |  |
| **Remarks:** |
|  | **Management System Implementation**  |
| a) | Whether laboratory has established processes needed for consistent fulfilment of the requirements of Management System |  |  |
| b) | Whether sequence of interaction of the processes determined |  |  |
| c) | Whether criteria is determined to ensure the effective implementation and maintaining a quality management system. |  |  |
| d) | Whether lab has identified, selected opportunities for improvement |  |  |
| **Remarks:** |
|  | **Actions to address risks and opportunities for improvement:** |
| a)  | Whether laboratory has identified risks and opportunities for improvement associated with the laboratory activities as per the requirements of the standard |  |  |
| b) | Whether the laboratory has recorded decisions made and actions taken on risks and opportunities |  |  |
| **Remarks:** |
|  | **Improvement** |
| a) | Whether laboratory has identified and selected opportunities for improvement |  |  |
| b) | Whether laboratory has evaluated effectiveness of actions taken |  |  |
| c) | Whether laboratory has records of feedbacks from laboratory patients, user and personnel |  |  |
| **Remarks:** |
|  | **Non-conformities and corrective actions:** |
| a) | Whether the laboratory has retained records of nonconformities and corrective actions taken |  |  |
| b) | Whether laboratory has evaluated the effectiveness of corrective actions  |  |  |
| **Remarks:** |
|  | **Evaluations** |
| a) | Availability of audit criteria  |  |  |
| b) | Availability of audit scope  |  |  |
| c) | Availability of audit frequency |  |  |
| d) | Availability of audit method |  |  |
| e) | Availability of Audit Plan |  |  |
| f) | All requirements of ISO 15189:2022, 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  |  |  |
| h) | Timely corrective action on non-conformities  |  |  |
| i) | Audit conducted by qualified, trained and Independent personnel |  |  |
| **Remarks:** |
|  | **Management reviews** |
| a) | Availability of Management review plan |  |  |
| b) | All requirements of clause 8.9 of ISO 15189:2022, are incorporated in the agenda of review in the last one year |  |  |
| c) | Availability of minutes of last Management review meeting |  |  |
| **Remarks:** |
|  | ***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 100A, 100B, 153, 131) |  |  |
| **Remarks:****Signature/ Name of the Lead Assessor** |  |  |

\* Mark  in the appropriate box

**NPF 2**

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

|  |  |
| --- | --- |
| **Laboratory:** | **Date(s) of Visit:** |
| **Sl.** | **Non-conformity*****(to be filled by Lead Assessor)*** |  **Corrective Action proposed by the laboratory** ***(to be filled by laboratory)*** |
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|  |  |  |
| **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:** |
| **Person responsible to implement management system:** | **Date(s) of Visit:** |
| **Field:** Medical | **Discipline(s):** | **Facility** *(Permanent/ POCT/ Mobile/ Site facility):* |
| **Applicable Standard: ISO 15189: 2022****NABL Specific Criteria – NABL 112** |
| **Persons Contacted:** |
| **Corrective action taken on the adequacy report implemented:** | Yes / No |
| **Latest version of** Management System documents- 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** | *Document Review/ Pre-Assessment / Initial Assessment / Onsite 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)**

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