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|  |  | **NABL 209** |
|  | **National Accreditation Board for Testing****and Calibration Laboratories (NABL)** |

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| **Pre-Assessment Guidelines and Forms****(based on ISO/IEC 17025)** |

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| **ISSUE NO.: 04****ISSUE DATE: 19-Apr-2016** | **AMENDMENT NO.: 04****AMENDMENT DATE: 09-Dec-2021** |

**AMENDMENT SHEET**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **S. No.** | **Page No.** | **Clause No.** | **Date of Amendment** | **Amendment**  | **Reasons** | **Signature QA Team** | **Signature Competent Authority** |
| 1 | 11 | Form 74 | 13.05.2016 | Form 74 includes QM Adequacy | IQA | -Sd- | -Sd- |
| 2 | 10 | NPF3 | 02.05.2018 | Change in time (Max 15 days) for corrective action | Internal | -Sd- | -Sd- |
| 3 | 2,3, 4 | 2 & 3 | 21.12.2018 | As highlighted | Policy decision | -Sd- | -Sd- |
| 5, 6, 7 | NPF-1 |
| 10 | NPF-3 |
| 4 | 3,3,4,11 | 1, 2,3,Form 74 | 09.12.2021 | As highlighted | Internal Review | -Sd- | -Sd- |
| 3 | 2. ii | Mobile facility included |
| 4 | 2. v | Word “submitted” is replaced with “acceptance”  |
| 6 | 4 | Qualified and trained word is replaced with “competent” | Aligned with standard |
| 6,7,7 | 6,7,9 | As highlighted |
| 8 | 10 | As highlighted | Aligned with NABL 163 |
| 10 | NPF3 |  | As highlighted | Internal review |
| 5 |  |  |  |  |  |  |  |
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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 Final 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. |
|  |  |
|  |  |
| **2.** | **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 Form, Quality Manual/ Management system document, Corrective action report on the adequacy of document review and any other information supplied by NABL.  |
|  |  |
|  | The Lead Assessor, during Pre-assessment shall: |
|  |  |
|  | i. | check the overall implementation of the management system as per the documented Quality Manual/ Management system document. |
|  | ii. | study the scope of accreditation so that the time frame, number of assessors required in various disciplines and visits to Site testing/ calibration facilities, mobile facility, if applicable, for the assessment can be determined. The Lead Assessor shall also assess the risks associated with the scope, location and personnel, if any which need to be taken into consideration while planning, scheduling and/or conducting assessment.  |
|  | iii. | check whether the laboratory has conducted a comprehensive Internal Audit in accordance with ISO/ IEC 17025: 2017.  |
|  | iv. | assess the degree of preparedness of the laboratory for the assessment and give observations in NPF 1. |
|  | v. | obtain acceptance of NABL 131 – Terms and Conditions for Obtaining and Maintaining NABL Accreditation, from the laboratory, if not accepted by laboratory earlier |
|  | vi. | explain to the laboratory regarding the methodology to be adopted for assessment and the obligations of the laboratory |
|  | vii. | submit a report to NABL  |
|  |  |  |
|  |  |  |
| **3.** | **COMPILATION OF PRE-ASSESSMENT FORMS & CHECKLIST**  |
|  |  |  |
|  | The Lead Assessor must review the laboratory’s documented management system to verify compliance with the requirements of ISO/ IEC 17025: 2017. The Lead Assessor 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 can assess and verify the details if felt necessary and annex his findings, to the report.  |
|  |  |
|  | All Non-Conformity (ies) must be identified and to be reported, in NPF 2. 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/acceptance 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 information or annexure thereafter.  |
|  |  |
|  | The Lead Assessor shall submit the Pre-Assessment Report to NABL within 10 days of completion of Pre-Assessment.  |

*NPF 1*

1 of 4

**PRE-ASSESSMENT CHECKLIST**

|  |  |
| --- | --- |
| **Laboratory:** | **Date(s) of Visit:** |
|  |
| **Sl.** | Requirement  | Observation\* |
| Yes | No |
| ***1.*** | *Review of Application Form(s)*  |
|  |  | for correctness of contents |  |  |
|  |  | for Scope of accreditation |  |  |
|  | *Comments on Application Form:* |
| **2.** | Management System Documentation |
|  |  | Document review – cross-reference to Procedures and other documents  |  |  |
|  |  | Availability of all required cross-referenced Procedures (list to be enclosed) (wherever applicable) |  |  |
|  |  | Availability of other documents like Standards, Codes, Calibration/ Test methods, Operating Instructions etc. (list to be enclosed) |  |  |
|  |  | Availability of NABL documents (list to be enclosed) |  |  |
|  | Comments on Management System Documentation: |
| ***3.*** | ***Management System Implementation (sample audit)*** |
|  |  | Availability of relevant documents at place of work |  |  |
|  |  | Are procedures being followed |  |  |
|  |  | Awareness of Management System and NABL requirements  |  |  |
|  | *Comments on Implementation and effectiveness of Management System:* |

\* Mark  in the appropriate box

*NPF 1*

2 of 4

|  |  |  |
| --- | --- | --- |
| **Sl.** | Requirement | Observation\* |
| Yes | No |
| ***4.*** | Internal Audit |
|  |  | Availability of Audit program |  |  |
|  |  | Availability of Audit Plan  |  |  |
|  |  | All requirements of ISO/ IEC 17025: 2017 as applicable, covering all activities of laboratory audited at least once in the last one year |  |  |
|  |  | Timely corrective action on non-conformities  |  |  |
|  |  | Audit conducted by competent and independent personnel |  |  |
|  | *Comments on effectiveness of Internal Audit:* |
| ***5.*** | *Management Review* |
|  |  | Availability of Management review schedule and records |  |  |
|  |  | All requirements of ISO/ IEC 17025: 2017 are incorporated in the agenda of review in the last one year |  |  |
|  |  | Evidence of at least one Management review |  |  |
|  | Comments on effectiveness of Management review: |
| ***6.*** | *Personnel* |
|  |  | Availability of competence requirements of laboratory personnel  |  |  |
|  |  | Training programme on ISO/ IEC 17025: 2017 for the laboratory personnel  |  |  |
|  |  | Plan/ Schedule for imparting training to laboratory personnel for the current year |  |  |
|  |  | Availability of competent personnel responsible for implementation, maintenance and improvement of management system of the laboratory and suitability of persons who report, review and authorize the results |  |  |
|  | *Comments on Personnel and Training:* |

\* Mark  in the appropriate box

*NPF 1*

3 of 4

|  |  |  |
| --- | --- | --- |
| **Sl.** | Requirement | Observation\* |
| Yes | No |
| ***7.*** | Facilities and Environmental conditions  |
|  |  | Does the laboratory have suitable facilities for the laboratory activities |  |  |
|  |  | Maintenance of necessary environmental conditions (sample audit) |  |  |
|  | *Comments on facilities and environmental conditions:* |
| ***8.*** | *Equipment/ Reference Standards* |
|  |  | Availability of equipment commensurate with the scope applied for |  |  |
|  |  | Availability of Calibration Schedule |  |  |
|  |  | Availability of CRMs with respect to scope applied for |  |  |
|  |  | Traceability established as per NABL policy |  |  |
|  |  | Intermediate Checks |  |  |
|  |  | Maintenance Schedule – maintenance check-list |  |  |
|  | *Comments on Equipment/ Reference Standards:* |
| ***9.*** | *Evidence* of evaluation of measurement *uncertainty* |
|  |  | Preliminary check whether the laboratory has taken any action regarding evaluation of measurement uncertainty |  |  |
|  |  | Ranges covered for all Products/ Parameter/ measured quantity for all disciplines  |  |  |
|  | *Comments on measurement uncertainty:* |

\* Mark  in the appropriate box

## *NPF 1*

4 of 4

|  |  |  |
| --- | --- | --- |
| **Sl.** | Requirement | Observation\* |
| Yes | No |
| ***10.*** | *Proficiency Testing and Internal Quality Control* |
|  |  | Participation in at least one Proficiency Testing programme for each discipline and corrective action taken, if any, on the PT results  |  |  |
|  |  | Availability of 2-year Proficiency Testing plan covering all groups under each discipline of Accreditation  |  |  |
|  |  | Is the Quality Control programme extensive and cover the product/ test range being tested/ calibrated |  |  |
|  |  | Does the laboratory retain samples for quality checks  |  |  |
|  |  | Has laboratory taken any alternate steps where formal PT Programs are not available/ scheduled or not appropriate (summary to be provided) |  |  |
|  | *Comments on Proficiency Testing and Internal Quality Control:* |
| ***11.*** | *Discussions with the Laboratory on Final Assessment* |
|  |  | Overview of the methodology to be adopted  |  |  |
|  |  | Task/ role of Lead Assessor, Technical Assessor(s) and Observers  |  |  |
|  |  | Obligations of the laboratory  |  |  |
|  | *Record any special discussion:* |

\* Mark  in the appropriate box

*NPF 2*

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

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

Note: Use additional sheets of this form, if required

*NPF 3*

## PRE-ASSESSMENT REPORT

|  |
| --- |
| **Laboratory:** |
| **Person responsible for the management system:** | **Date(s) of Visit:** |
| **Field:** *Testing/ Calibration* | **Discipline(s):** |
| **Applicable Standard: ISO/IEC 17025: 2017** **NABL Specific Criteria** (if applicable)- |
| **Persons Contacted:** |
| **Corrective action taken on the document review report** | *Yes / No* |
| Latest version of Quality Manual/ Management system document -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 |  |
|  | Specific recommendation for planning the assessment w.r.t. scope, location, department, no. of personnel in the laboratory.  | *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 and Name of Authorised representative of Lab. & Date** | Signature and 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 / Assessment / on-site 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/ Management system document, 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  |

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