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| **NABL 218A** | |
|  | **National Accreditation Board for Testing**  **and Calibration Laboratories (NABL)** |

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| **Checklist for Annual Surveillance** |

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| **Issue No.: 01**  **Issue Date: 06-08-2025** | **Amendment No.: --**  **Amendment Date: --** |

**AMENDMENT SHEET**

|  |  |  |  |  |  |  |  |  |
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| **S. No.** | **Amendment No.** | **Page No.** | **Clause No.** | **Date of Amendment** | **Amendment** | **Reasons** | **Signature**  **QA Team** | **Signature**  **of Competent Authority** |
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### **CONTENTS**

|  |  |  |
| --- | --- | --- |
| **SI.** | **Title** | **Page No.** |
|  | Amendment Sheet | 1 |
|  | Contents | 2 |
|  | Checklist for Annual Surveillance | 3 |
|  | NAF 4A - Assessor’s Summary on Non-Conformity | 7 |
|  | NAF 6A – Summary of Assessment | 8 |

**CHECKLIST FOR ANNUAL SURVEILLANCE**

|  |  |
| --- | --- |
| **Name of the CAB** |  |
| **Address** |  |
| **Field:** | Testing/ Calibration/Medical/PTP/RMP/Biobank |
| **Discipline (s)/ Category(s)** |  |
| **Accreditation validity period:** |  |
| **Period of the report**  **(since last assessment to till date):** |  |
| **CAB ID** |  |

1. **Status of implementation and monitoring the effectiveness of corrective actions(s) taken on non-conformities raised during last on-site assessment:**

|  |  |  |
| --- | --- | --- |
| **S.I.** | **Description** | **Assessor Remark** |
|  | No. of non-conformity(ies) raised during last assessment and subsequent supplementary assessment (if applicable) |  |
|  | Comment on corrective action(s) taken by CAB |  |
|  | Comment on continued compliance of corrective actions (as on date) |  |

1. **Internal Audit**

|  |  |  |
| --- | --- | --- |
| **S.I.** | **Description** | **Assessor Remark** |
|  | Availability of audit scope and plan/schedule |  |
|  | Frequency of internal audit as per procedure for internal audit |  |
|  | Dates of last two internal audit conducted |  |
|  | Particulars of persons who have conducted last internal audit i.e.   * Name of the Internal Auditor * Affiliation (Internal/ External) * Training status (whether trained as per ISO/IEC 17025 or ISO 15189 or ISO/IEC 17043 or ISO 17034 or ISO 20387) |  |
|  | Retain records as evidence of the implementation of the audit programme and the audit results. |  |
|  | Independence of activities audited was maintained |  |
|  | Whether all the activities (as required by standard) were covered in the audit |  |
|  | Whether site testing / calibration, mobile, collection centres etc) were covered in the audit |  |
|  | No. of non-conformity(ies) raised in last internal audit |  |
|  | Whether non-conformity(ies) are monitored for its closure as agreed time frame |  |

1. **Summary of last Management Review**

Date of last Management Review \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |
| --- | --- | --- |
| **S.I.** | **Description** | **Assessor Remark** |
|  | Whether all the agenda points as required by ISO/IEC 17025 or ISO 15189 or ISO/IEC 17043 or ISO 17034 or ISO 20387 were discussed including quality policy and objectives |  |
|  | Whether the inputs to management review recorded and it included information related to the points mentioned in the standard |  |
|  | Whether the outputs from the management review record all decisions and actions |  |
|  | Whether the actions completed as per recorded target |  |

1. **Complaints**

|  |  |  |
| --- | --- | --- |
| **S.I.** | **Description** | **Assessor Remark** |
|  | Total number of complaints received |  |
|  | Description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it; |  |
|  | Tracking and recording complaints, including actions undertaken to resolve them; |  |
|  | Ensuring that any appropriate action is taken. |  |

1. **Implementation of internal quality control (IQC) checks practiced by the CAB (wherever applicable)**

|  |  |  |
| --- | --- | --- |
| **S.I.** | **Description** | **Assessor Remark** |
|  | IQC plan, IQC data in each discipline/category of the CAB as per accredited scope mentioning frequency of IQC checks and acceptance criteria |  |
|  | Whether the acceptance criterion defined is met and corrective actions taken if required |  |

1. **Details of participation in EQA/ PT/ ILC and initiation of ILC by the CAB (wherever applicable)**

|  |  |  |
| --- | --- | --- |
| **S.I.** | **Description** | **Assessor Remark** |
|  | Compliance to the PT/ILC plan (Form 18) submitted by the CAB during last re-assessment as per requirements of NABL163 |  |
|  | Comment on performance EQA/ PT/ ILC |  |
|  | Details of root cause analysis in case of unsatisfactory performance, if any |  |
|  | To upload PT report/ summary of participation in PT/ ILC/ EQA |  |
|  |  |  |

**Assessor to upload PT report/ summary of participation in PT/ ILC/ EQA**

1. **Reference standards, CRM, equipment, held by the CAB** 
   1. **List of equipment**

*(To be uploaded by assessor in the format given below)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **SI.** | **Name of equipment**  **(Indicate if owned or on long term lease)** | **Model/ type/ year of make and Serial number** | **Range and accuracy** | **Date of last calibration** | **Calibration due on** | **Calibrated by** |
|  |  |  |  |  |  |  |

**Assessor Remark on metrological traceability as per NABL 142:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* 1. **List of Reference Material/ Reference Standards**

*(To be uploaded by assessor in the format given below)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SI.** | **Name of Reference Material/ Standard/ Strain/ Culture** | **Source** | **Date of Expiry/ Validity** | **Traceability** |
|  |  |  |  |  |

**Assessor Remark on metrological traceability as per NABL 142:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Details of Training provided to CAB personnel since last assessment**

|  |  |  |
| --- | --- | --- |
| **S.I.** | **Description** | **Assessor Remark** |
|  | Does the CAB identify training needs of its employees and prepare an annual training plan |  |
|  | Whether the training plan is implemented |  |
|  | Whether the effectiveness of training is evaluated and records are maintained |  |

1. **Test reports/ certificates, medical test reports / certificate, calibration certificate / report, PT report, RM document and Biobank Report.**

|  |  |
| --- | --- |
| **Description** | **Assessor Remark**  **(Assessor to mention particulars of test reports / certificates, medical test reports / certificate, calibration certificate / report, PT report, RM document and Biobank Report verified)** |
| Compliance of test reports / certificates, medical test reports / certificate, calibration certificate / report, PT report, RM document and Material Certificate Report w.r.t ISO/IEC 17025: 2017; ISO 15189: 2022, ISO/IEC 17043: 2023; ISO 17043: 2016; ISO 20387: 2018. |  |

**Assessor to upload test reports / certificates, medical test reports / certificate, calibration certificate / report, PT report, RM document and Biobank Report wherein non-compliance is observed.**

1. **Has there been a change in the following aspects of the CAB operations since last assessment?**

|  |  |  |
| --- | --- | --- |
| **S.I.** | **Description** | **Assessor Remark** |
|  | Legal Status |  |
|  | Ownership |  |
|  | Top Management |  |
|  | Key CAB Personnel |  |
|  | Policies |  |
|  | Resources |  |
|  | CAB Premises / address |  |
|  | Major Test/ Calibration equipment |  |
|  | Personnel declared by CAB to report, review and authorize the results/ PT Report/ RM Document/ Biobank Report |  |
|  | Any change in organization, personnel, facilities, scope of services, or any other significant factors that may impact its accreditation status. |  |

***Comments of Assessor on compliance against: -***

|  |  |
| --- | --- |
| NABL 131 | * Exact copy of test report / certificate, medical test report / certificate, calibration certificate / report, PT report, RM document and Biobank Report should be retained by the CAB. * The test report / certificate, medical test report / certificate, calibration certificate / report, PT report, RM document and Biobank Report shall promptly inform NABL of any changes in its organization, personnel, facilities, scope of services, or any other significant factors that may impact its accreditation status. |
| NABL 133 | * Assessor to comment on compliance of NABL 133 by verifying few test report / certificate, medical test report / certificate, calibration certificate / report, PT report, RM document and Biobank Report * Assessor to also verify if any test report / certificate, medical test report / certificate, calibration certificate / report, PT report and RM document has been issued by the laboratory during the non-accredited period (i.e break in accreditation cycle, if any) * If CAB uses NABL Accredited CAB Combined ILAC MRA Mark, assessor to verify its agreement with NABL. * If any NC raised during previous onsite assessment for misuse of NABL symbol / Claim of Accreditation and/ or any complaint registered by NABL related to misuse of NABL symbol, Assessor to give a comment regarding the same. * Check the website and promotional materials of the CAB to check compliance to NABL 133. * During non-accredited period assessor to check whether any misuse of NABL symbol or misclaim of NABL accreditation is there |
| NABL 142 |  |
| NABL 143 |  |
| NABL 163 |  |
| Specific Criteria | (Wherever applicable) |

*NAF 4A*

###### **ASSESSOR’S SUMMARY ON NON-CONFORMITY**

(Please use separate sheet for raising each Non-Conformity)

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of the CAB** |  | | |
| **Name of the Assessor** |  | | |
| **Date(s) of Assessment** |  | | |
| **Non-Conformity Statement:** | | | |
| **Cl. No. of ISO/IEC 17025:2017 or ISO 15189: 2022 or ISO/IEC 17043: 2023 or ISO 17034: 2016 or ISO 20387 & NABL 133 Clause No. / NABL Specific criteria:** | | |  |
|  Acceptance /  Non-acceptance  (Signature of CAB’s representative) | | Signature & Name of Assessor | |
| **CORRECTION AND/OR CORRECTIVE ACTIONS PROPOSED BY THE CAB (In case of acceptance)**  **REASON FOR NON-ACCEPTANCE ALONG WITH THE SUPPORTING DOCUMENTS (In case of non-acceptance)** | | | |
|  | | | |
| Signature & Name Authorized Representative of CAB | | | |
| **ASSESSOR’S COMMENTS ON CORRECTION AND/OR CORRECTIVE ACTIONS PROPOSED BY THE CAB (Root cause analysis to be submitted along with the evidences of correction and/or corrective actions)** | | | |
| Acceptance/Signature of Assessor | | | |

*NAF 6A*

## SUMMARY OF ASSESSMENT

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **SI.** | **Item** | **Details** | | | |
|  | **Name of the CAB** |  | | | |
|  | **Date(s) of Assessment** |  | | | |
|  | **Field** |  | | | |
|  | **Discipline(s)** |  | | | |
|  | **Facility** | Permanent/ Site/ Mobile/Permanent Site | | | |
|  | **Type of Assessment** | Annual Surveillance | | | |
|  | **Assessment Team/ Capacity** |  | | | |
|  | **Date of earlier visit:** | *Non-Conformities during earlier visit have/ have not been discharged. (Yes or No)* | | | |
|  | **Total no. of Non-conformities** |  | **Number of NC(s)** | | |
| **Clause 4** |  | | |
| **Clause 5** |  | | |
| **Clause 6** |  | | |
| **Clause 7** |  | | |
| **Clause 8** |  | | |
| **Total** |  | | |
|  | **Comment(s) of Assessment Team on compliance of CAB to:** | | | | |
| **NABL 133** |  | | | |
| **NABL 142** |  | | | |
| **NABL 143** |  | | | |
| **NABL 163** |  | | | |
| **Specific Criteria**  ***(wherever applicable)*** |  | | | |
|  | **Assessment Summary** |  | | | |
|  | **Recommendation of Assessment team as per ISO/IEC 17025:2017 or ISO 15189: 2022 or ISO/IEC 17043: 2023 or ISO 17034: 2016 or ISO 20387** | | | |  |
|  | Only if accreditation is recommended, date by which the Corrective Action to be submitted by the CAB for the above Non-conformities (Max. 30 days): | | | | |
|  | The requirements of NABL 133 have been explained by the Lead Assessor and understood by the CAB | | | |  |
| Acknowledgement by Authorised Representative of CAB’s & Date | | | | Signature of Assessor & Date | |

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

J200, World Trade Centre,

Nauroji Nagar, New Delhi-110029

Website: www.nabl-india.org

Tel. No.: +91-11-40032400 (30 lines)