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

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| **Desktop Surveillance** |

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| **ISSUE NO.: 03****ISSUE DATE: 19-Apr-2016** | **AMENDMENT NO.: 06****AMENDMENT DATE: 21-Feb-2024** |

**AMENDMENT SHEET**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Sl. No** | **Amendment No.** | **Page No.** | **Clause No.** | **Date of Amendment** | **Amendment**  | **Reasons** | **Signature QA Team** | **Signature Competent Authority** |
| 1 | 01 | -- | - | 15.10.2019 | -Inclusion of latest version of ISO/IEC 17025:2017.-ISO Guide 34:2009 replaced by ISO 17034:2016. | Publication of ISO/IEC 17025:2017 & ISO 17034:2016 version  | -Sd- | -Sd- |
| 2 | 3 | 1 | Text-‘last reassessment’ replaced by ‘on-site assessment’ as highlighted. | Procedural requirements |
| 3 | 02 | 2, 3, 4, 6 | - | 16.12.2019 | Inclusion of ISO/IEC 17025:2005 | To process the desktop documents (as per ISO/IEC 17025: 2005 version)  | -Sd- | -Sd- |
| 4 | 5, 6 | - | 16.12.2019 | Removal of term authorized signatory | NABL policy decision |
| 5 | 03 | 2 | - | 17.12.2019 | Preface revised as highlighted | NABL policy decision | -Sd- | -Sd- |
| 6 | 04 | 4 | 5.b | 17.06.2020 | Sentence revised as follow:“IQC plan, sample IQC data in each discipline of the CAB as per accredited scope mentioning frequency of IQC checks and acceptance criteria”. | Internal Review (Feedback received from ACM) | -Sd- | -Sd- |
| 7 | 4 | 5.c | Sentence revised as follow:“Whether the acceptance criterion defined is met and corrective actions taken if required”. |
| 8 | 5 | 9.g | “Address” word added. |
| 9 | 05 | 2,3,4,6 | 2h3.1b12.2 | 01.06.2021 | Reference to ISO/IEC 17025: 2005 deleted. | ISO/IEC 17025:2005 is transitioned to ISO/IEC 17025: 2017 | -Sd- | -Sd- |
| 10 | 06 | 3 | Preface | 21.02.2024 | As highlighted | Release of ISO 15189: 2022 & ISO/IEC 17043: 2023 | -Sd- | -Sd- |
| 4 | 2.g, h | 1. Internal review
2. Release of ISO 15189: 2022 & ISO/IEC 17043: 2023
 | -Sd- | -Sd- |
| 5 | 3.1 b | Release of ISO 15189: 2022 & ISO/IEC 17043: 2023 | -Sd- | -Sd- |
| 7 | 12.2 | Release of ISO 15189: 2022 & ISO/IEC 17043: 2023 | -Sd- | -Sd- |

**PREFACE**

For an accredited Conformity Assessment Body (CAB) to maintain its accreditation status, it is mandatory that the CAB continues to comply with the requirements of ISO/IEC 17025: 2017 or ISO: 15189: 2012 or ISO 15189: 2022 or ISO/IEC 17043:2010 or ISO/IEC 17043: 2023 or ISO 17034:2016 (whichever is relevant) and NABL policies, for which NABL conducts annual surveillance. Once a CAB has been accredited, NABL may conduct onsite surveillance visit to verify the continued compliance.

For the purpose of desktop surveillance, the CAB should provide the information as per this document and the same will be considered to verify the continued compliance for maintaining accreditation. The information provided by the CAB is evaluated at NABL secretariat and if the information is conforming to the requirements; the CAB is allowed to continue its accreditation status based on desktop surveillance. However; if the information provided is insufficient to establish the continued compliance; an onsite assessment may be conducted.

The CABs are therefore advised to provide the desired information accurately as per the format. The information provided is subject to verification at onsite surveillance (if conducted) or in subsequent reassessment visit. Any wrong information provided may lead to adverse decision by NABL.

**INFORMATION TO BE FURNISHED BY CAB FOR DESKTOP SURVEILLANCE**

|  |  |
| --- | --- |
| CAB 's name, address & ID:  |  |
| Field:  | Testing/ Calibration/ Medical / PTP / RMP |
| Discipline(s): |  |
| Accreditation validity period:  |  |
| Period of the report:  |  |

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

|  |  |  |
| --- | --- | --- |
| Non-conformities raised during last on-site assessment | Brief Summary of corrective actions taken | Evidence of continued compliance of corrective actions (as on date) |
|  |  |  |

1. Summary of last internal audit findings and corrective actions taken on non-conformities raised during the audit

a) Availability of audit scope and plan/schedule Yes/No

b) Frequency of internal audit as per procedure for internal audit.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

c) Dates of last two internal audit conducted \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

d) Particulars of persons who have conducted last internal audit

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name(s) of auditors(s) & designation | Qualification | Affiliation(Internal/ External) | Training status(whether trained as per ISO/IEC 17025 / ISO 15189 / ISO /IEC 17043 / ISO 17034) | Details of training organization & duration of training  |
|  |  |  |  |  |

1. Comment on independence of activities audited\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Whether all the activities (as required by standard) were covered in the audit Yes / No
3. Whether site testing / site calibration, mobile facility, collection centres (if applicable) were covered in the audit Yes / No
4. Whether the all the requirements of ISO/IEC 17025: 2017or ISO 15189: 2012 or ISO 15189: 2022 or ISO/IEC 17043:2010 or ISO/IEC 17043: 2023 or ISO 17034:2016 were covered in audit Yes/ No
5. Number of NCs raised...........
6. Whether NCs are monitored for its closure as agreed time frame Yes / No

k)

|  |  |  |  |
| --- | --- | --- | --- |
| Sl. No. | Non-conformities raised during last Internal audit | Brief Summary of corrective actions taken | Status (Closed/Open) |
|  |  |  |  |

**3.** Management Review Meeting

3.1 Summary of last Management Review

a)Date of last Management Review\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

b) Whether all the agenda points as required by the relevant standard (ISO/IEC 17025: 2017or ISO 15189: 2012 or ISO 15189: 2022 or ISO/IEC 17043: 2010 or ISO/IEC 17043: 2023 or ISO 17034:2016 were discussed including quality policy and objectives Yes/ No

c) Whether minutes of the meeting and with actions points thereon were recorded Yes/No

d) Whether the action plan implemented as targeted Yes/ No

3.2 Minutes of last Management Review Meeting (Annexure......)

**4.** Summary of complaints received and status of their resolutions

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| S. No. | Complaint No. & date | Complaint details | Investigation findings | Corrective action taken | Status settled/unsettled |
|  |  |  |  |  |  |

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

a) Which of the following quality control measures are used by the CAB, please tick appropriate column(s).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Use of Certified reference material/reference material. |  |  |  |
|  | Use of internal quality control material |  |  |  |
|  | Replicate testing using same or different method. |  |  |  |
|  | Retesting of retained item |  |  |  |
|  | Replicate calibration using same or different method |  |  |  |
|  | Recalibration of retained items. |  |  |  |
|  | Use of control charts using control samples |  |  |  |
|  | Use of control charts using check standards |  |  |  |
|  | Correlation of results for different characteristics of an item |  |  |  |
|  | Any other technique(s); Please specify...... |  |  |  |

1. IQC plan, sample IQC data in each discipline of the CAB as per accredited scope mentioning frequency of IQC checks and acceptance criteria (Annexure: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)
2. Whether the acceptance criterion defined is met and corrective actions taken if required Yes/ No

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

a) Availability of EQAS/ PT/ ILC plan as per requirements of NABL163 Yes/ No

b) Whether the ILC/PT activities complied as per the plan submitted Yes/ No

c) Please provide clarifications of lapses in implementation (if any) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Results of EQAS/ PT/ ILC participation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| EQAS/ PT providers (or) ILC/ coordinating CAB | PT programme No. | Parameter | *Z* Score/ En Value / SDI | Details of root cause analysis in case of unsatisfactory performance |
|  |  |  |  |  |

**7**. Please furnish detail of the reference standards, CRM, equipment, held by the CAB

|  |  |  |  |
| --- | --- | --- | --- |
| S. No. | Reference standard/ CRM/ equipment (Make &Model No. if applicable) | Date of calibration (reference standard/ equipment)/ Date of validity (CRM) | Metrological traceability/ calibration agency |
|  |  |  |  |

*Note: Equipment, CRM, Reference standards details shall be given separately wherever applicable*

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

a) Does the CAB identify training needs of its employees and prepare an annual training plan Yes/No

b) Whether the training plan implemented Yes/ No

c) Please provide clarifications of lapses in implementation (if any) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

d) Whether the effectiveness of training is evaluated and records are maintained Yes/ No

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

a) Legal Status : Yes/No (If yes, give details thereof)

b) Ownership : Yes/No (If yes, give details thereof)

c) Top Management : Yes/No (If yes, give details thereof)

d) Key CAB Personnel : Yes/No (If yes, give details thereof)

e) Policies : Yes/No (If yes, give details thereof)

f) Resources : Yes/No (If yes, give details thereof)

g) CAB Premises / address : Yes/No (If yes, give details thereof)

h) Major Test/ Calibration equipment : Yes/ No (If yes, give details thereof)

i) Personnel declared for report, review and : Yes/ No (If yes, give details thereof)

 authorize the results

*Note: For any of above stated changes; CAB should have informed NABL within 15 days of its change as defined in NABL 131. The above declarations cannot be considered as an application for change*

**10.** Does the CAB want a change/ addition in personnel declared for report, review and authorize the results? If yes please furnish the details of proposed personnel for report, review and authorize the results along with specimen signature.

**11.** Desktop surveillance fee details: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Note: Provide the transaction details along with the amount paid.*

**12.**Self declarations

12.1 (a) Please give a self-declaration confirming the valid calibration status of various equipment and reference standards held by the CAB. The declaration should also focus on compliance to metrological traceability policy as given in NABL 142.*Annexure….*

(b) In case the CAB has enhanced the periodicity of calibration of any equipment(s), please give detailed technical justification for the same. *Annexure*....

*Note: The self-declaration to be given by a competent authority on CAB’s letter head*

12.2 Please furnish a self-declaration by the head of the CAB / CAB director for continued compliance of the CAB to ISO/IEC 17025: 2017 or ISO15189: 2012 or ISO 15189: 2022 or ISO/IEC17043:2010 or ISO/IEC 17043: 2023 or ISO17034:2016(whichever is applicable) and relevant NABL specific criteria (s) (wherever applicable) since last on-site assessment. Annexure….

*Note: The self-declaration to be given on CAB’s letter head*

**13.** All information provided above is true and I am aware that any wrong information / declaration given therein may lead to adverse actions by NABL

 Signature of CAB Head/CAB Director\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name & Designation\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date & Place \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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