

NABL 210



National Accreditation Board for Testing and Calibration Laboratories (NABL)

ASSESSOR GUIDE

ISSUE NO.: 07
ISSUE DATE: 22-Jan-2020

AMENDMENT NO.: 02
AMENDMENT DATE: 05-Jul-2021

AMENDMENT SHEET

S. No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature CEO
1.	5	2.2	18-Jul-2020	Inclusion of following text 'The compliance of all shall requirements are to be verified for compliance'	Internal review	-Sd-	-Sd-
2.	14	6.3.7i		Reference to NABL 165 removed and reference to application form included.	NABL 165 is withdrawn by NABL.		
3.	5	2.2	05-Jul-2021	The sentence "The compliance of all shall requirements are to be verified for compliance" is revised as "The compliance of all shall requirements are to be verified".	Repeated word deleted.	-Sd-	-Sd-
4.	8	2.14.1		Reference to NABL 215 'Assessment Forms & Checklists (based on ISO/ IEC 17025:2005) is deleted.	NABL 215 document is withdrawn in view of transition deadline.		
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1. INTRODUCTION

National Accreditation Board for Testing and Calibration Laboratories (NABL) provides third-party accreditation to Conformity Assessment Bodies {Testing Laboratories/ Calibration Laboratories / Medical Testing Laboratories / Proficiency Testing Provider (PTP) / Reference Material Producers (RMP)} according to international standards. The liberalization (of trade and industry) policy of Government of India provides greater thrust for exports. This makes it imperative for the Conformity Assessment Bodies (CABs), where the products are assessed, to be at international level of competence. NABL is, therefore, committed to ensure that the accreditation requirements and assessment system for CABs are in line with international norms and practices.

NABL assures itself of the competence of the CAB it accredits through a system of assessment in accordance with ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189 'Medical laboratories- Requirements for Quality and Competence or ISO/IEC 17043 'Conformity Assessment - General Requirements for Proficiency Testing' or ISO 17034 - General Requirements for the Competence of Reference Material Producers, whichever is applicable. The assessment is carried out by a team of Assessors, led by a Lead Assessor, empanelled by NABL.

The assessment is carried out systematically on all aspects of technical competence and of CAB's management system. The objective evidence so collected forms the basis:

- for arriving at a judgement for recommendation of the team on grant, continuation or renewal of accreditation,
- to specify the competence of CAB in terms of its capability to perform the activities for which it is seeking accreditation or holds accreditation

The objective of the assessment, however, is not to compile non-conformities as an evidence to justify denial of accreditation in case of negative recommendation.

This Guide has been published in order to provide assistance to NABL Assessor in conducting assessments for NABL. It describes the role of an Assessor in conducting the Assessment-related activities for NABL. The methodologies being described are basically

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to help an Assessor to be able to discharge his / her responsibilities effectively. Since an Assessor would be representing NABL during the assessment of a Conformity Assessment Bodies {Testing Laboratories/ Calibration Laboratories / Medical Testing Laboratories / Proficiency Testing Provider (PTP) / Reference Material Producers (RMP)}, (s)he should understand NABL and its accreditation process, its objectives, mission as well as the assessment methodology.

This guide has been prepared based on the general practices followed by international bodies and the experience of experts of the country. This document accordingly aims to:

- a. provides guidance to the Assessors for conducting assessment of a CAB;
- b. ensures uniformity of assessment and reporting; and

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2. ASSESSOR'S ROLE AND RESPONSIBILITY

- 2.1. The objective of any on-site assessment is to obtain evidence on compliance with respect to the ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189 'Medical laboratories - Requirements for Quality and Competence or ISO/IEC 17043 'Conformity Assessment - General Requirements for Proficiency Testing' or ISO 17034 - General Requirements for the Competence of Reference Material Producers, whichever is applicable. Basically, the NABL Assessor's role is to conduct assessment of CAB to adjudge the compliance to above Standards.
- 2.2. The Assessor shall also check that the CAB meets other requirements of NABL including the NABL's Specific Criteria for the relevant field and / or discipline (wherever applicable) and has competence to perform the specific test(s)/ calibration(s) / PT scheme or Production of RM/ CRM. **The compliance of all shall requirements are to be verified.** The Assessor shall ensure that (s)he is using the latest documents which are available on the NABL web-site for each assessment. The Assessor shall also pay attention to the specific announcements on web-site pertaining to policy decisions and its transition period (if any) before proceeding with the assessment.
- 2.3. Since CAB accreditation requires formal recognition of competence to carry out specific test(s)/ calibration(s) / PT scheme or Production of RM/CRM by a CAB, an Assessor has also to consider conformities against these aspects in the assessment. Thus, an Assessor would be required to exercise his scientific & technical judgement and form his opinion regarding extent of conformity with respect to accreditation criteria.
- 2.4. Assessors are required to maintain the confidentiality on the matters / subjects related to CAB.
- 2.5. Notwithstanding the strength of the NABL system, the success of the accreditation scheme depends on the Assessors who conduct assessment. Thus, the Assessors play a vital role in determining the credibility and value of the accreditation.
- 2.6. In case the assessment team members observe gross non-conformities in the documents and their implementation, the Lead Assessor shall consult with NABL for abandoning the assessment process.
- 2.7. The Lead Assessor is also required to monitor the performance of Technical Assessor(s), Expert(s) and the Observer(s). The lead assessor shall also recommend whether the Observer is capable to perform the role of a Technical Assessor in future, if asked by NABL, The Lead assessor's comments / rating for each Technical Assessor shall be enclosed with the report in Form 45(c).

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- 2.8. The Technical Assessor should clearly understand the areas / activities to be assessed by him. He must review the Laboratory's documented system to verify compliance with the requirements of ISO/IEC 17025/ ISO 15189 / ISO/IEC 17043 or ISO 17034, related NABL Specific Criteria and other policies/ guidelines of NABL. (S)he should assess to verify that the documented SOPs, test methods, records are indeed implemented & effective, and record observations. (S)he should also complete Checklist 2 related to the requirements of respective clauses and using NAF(XX) 3 and NAF(XX) 3A for witness done by him. The Technical Assessor must review and endorse the Measurement Uncertainty / % CV calculations for each test/ parameter witnessed. In case a Technical Expert is a member of the team, the Technical Assessor has to provide information to the Technical Expert regarding NABL forms and policies and guide him during the assessment. NC identified by the Technical Expert will however, be raised by the Lead Assessor.
- 2.9. The role of Technical Expert is same as that of Technical Assessor, except that he will seek guidance of Technical assessor in filling the relevant forms, checklist etc. Technical expert is not allowed to raise any NC. In case NC is identified during an assessment by TE, it has to be raised by the Lead Assessor (using his checklist in case of assessments conducted through portal).
- 2.10. The Observer (Potential Assessor) will be assigned to accompany the Lead Assessor and Technical Assessor(s) as per the schedule provided. (S)he shall be guided by the Lead Assessor and the Technical Assessor(s). (S)he is not required to submit any report however his/ her TA / DA form shall be submitted to the Lead Assessor. (S)he is not entitled for payment of any honorarium.
- 2.11. An Assessor must ensure that (s)he is well versed with:
- 2.11.1. Assessment principles including risk-based assessment principles, practices and techniques,
- 2.11.2. General management system principles and tools,
- 2.11.3. Applicable standard (ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189 'Medical laboratories - Requirements for Quality and Competence or ISO/IEC 17043 'Conformity Assessment - General Requirements for Proficiency Testing' or ISO 17034 'General Requirements for the Competence of Reference Material Producers'),
- 2.11.4. Other relevant Specific criteria documents, and
- 2.11.5. NABL policy documents prior to the visit to Conformity Assessment Bodies (CABs).

2.12. Considering improvement as a continuous process, the assessor is required to enhance following knowledge and skills on an on-going basis:

2.12.1. Understanding the knowledge of practices and processes of the Conformity Assessment Body business environment,

2.12.2. Communication skills,

2.12.3. Note-taking and report-writing skills,

2.12.4. Opening and closing meeting skills,

2.12.5. Interviewing skills,

2.12.6. Assessment management skills

2.13. The detailed requirements of knowledge and skills are mentioned below:

Knowledge and Skills	Accreditation Activities	
	Document Review	Assessment
Knowledge of Applicable Standard	√	√
Knowledge of relevant guidance and applicable documents	√	√
Knowledge of NABL Policies and Procedures	√	√
Knowledge of general regulatory requirements	√	√
Knowledge of assessment principles, practices and techniques	√	√
Knowledge of General management system principles and tools	√	√
Note-taking and report-writing skills	√	√
Knowledge of risk-based assessment principles		√
knowledge of practices and processes of the Conformity Assessment Body business environment		√
Communication skills		√
Interviewing skills		√
Opening and Closing meeting skills (including information to CAB about complaint and appeal mechanism of NABL in closing meeting)		√
Assessment Management Skills		√

2.14. The supplementary documents to this guide are as follows:

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- 2.14.1. For ISO/IEC 17025, NABL 209 'Pre-Assessment Guidelines and Forms (based on ISO/IEC 17025)' and NABL 219 'Assessment Forms and Checklist (based on ISO/IEC 17025: 2017),
- 2.14.2. For ISO 15189, NABL 208 'Pre-Assessment Guidelines and Forms (based on ISO 15189: 2012)' and NABL 217 'Assessment Forms and Checklist (based on ISO 15189)',
- 2.14.3. For ISO/IEC 17043, NABL 182 'Pre-assessment Guidelines and forms (based on ISO/IEC 17043: 2010)' and NABL 183 'Assessment Forms and Checklist (based on ISO/IEC 17043: 2010)',
- 2.14.4. For ISO 17034, NABL 192 'Pre-Assessment Guidelines & Forms (based on ISO 17034:2016)' and NABL 194 'Assessment Forms and Checklist (based on ISO 17034:2016)'.
- 2.14.5. NABL 213: Operational Manual for Online Assessment (For Assessors).

3. ASSESSOR ASSIGNMENT PROCEDURE

- 3.1. Whenever required, NABL shall constitute the assessment team and inform the CAB about the proposed assessment team. CABs have the right to object to the appointment of a particular Lead Assessor/ Technical Assessor, and in such cases, NABL may offer an alternative to the extent possible, if the reasons given by the CAB are acceptable to NABL.
- 3.2. Assessors are chosen to the extent possible from the empanelled list of Assessors maintained by NABL based on individual's technical expertise vis-à-vis a CAB's requested scope of accreditation. The number of Assessors in the team shall depend on the range and volume of scope involved. For multi-disciplinary CAB, Assessors shall be selected in such a manner so as to cover each discipline and its range/ scope of operation.
- 3.3. Lead Assessor/ Technical Assessor(s) are informed after the CAB has agreed to the members of the Assessment Team.

4. PROCEDURE FOR ASSESSMENT OF CAB

- 4.1. NABL appoints Lead Assessor and send CAB's Management System Document / Quality Manual and application(s) to the Lead Assessor.
- 4.2. The Lead Assessor shall examine the Management System Document / Quality Manual and application(s) and shall submit Document Review / Quality Manual Adequacy Report to NABL within 10 days along with Form 74.
- 4.3. Once the CAB satisfactorily addresses the inadequacies of the Document Review / Quality Manual Adequacy; NABL appoints another lead assessor and plan the pre-assessment (if opted by the CAB) in consultation with the Lead Assessor and CAB.
- 4.4. Appointed Lead Assessor has to undertake Pre-Assessment visit to CAB to assess the Management System and the quantum of work, and take the following actions:
 - 4.4.1. The lead assessor has to check the readiness of the CAB for final assessment.
 - 4.4.2. The Lead Assessor shall share a copy of the report to the CAB covering areas of inadequacies and actions to be taken by the CAB as mentioned in the forms given in NABL 209 or NABL 208 or NABL 182 or NABL 192 whichever is applicable and submit the report to NABL.
 - 4.4.3. The lead assessor has to provide comments on the corrective actions based on root cause analysis taken by the CAB on NCs raised (if any) at the earliest.
 - 4.4.4. In case there is no inadequacy or CAB has satisfactorily closed the NCs, the Lead Assessor has to recommend for final assessment.
- 4.5. NABL takes acceptance of the CAB on the members of the assessment team and dates of assessment. A CAB can raise objection to any member(s) of the assessment team with valid justification. After the dates and assessment team members are accepted by the CAB, communication is sent to the assessment team.
- 4.6. NABL provides a copy of the application, Management System Document / Quality Manual and previous assessment summary (wherever applicable) to each Assessor.
- 4.7. The Assessor may also seek any further information like test procedures etc. from the CAB, in order to better prepare for their assigned areas of responsibility.
- 4.8. The assessment team has to verify the continued compliance of corrective actions taken by the CAB against NC related to violation of NABL 131 & NABL 133, if raised during previous assessment and report to NABL.
- 4.9. To the extent possible, the assessment shall be completed in one phase, even for multi-disciplinary CABs. There shall be only one Lead Assessor for entire assessment. For

large and multi-disciplinary CABs, it may not be possible to conduct the assessment in one phase and may be completed in two or more phases (Split Assessment). In the app-based assessments, a Team Leader is appointed from the group of assessors who are not conducting the assessment on the same days as the Lead Assessor.

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5. PRE-ASSESSMENT

5.1. Objective

5.1.1. The objective of a Pre-Assessment visit carried out by NABL is:

- i. to have a better understanding of the documentation;
- ii. to familiarize with the facilities, sites / location, circumstances and to have better knowledge of operations;
- iii. to make the methodology to be adopted for the assessment;
- iv. to check the preparedness of the CAB to undergo assessment;
- v. to review the scope of accreditation and to ascertain the requirement of the number of assessors / experts and the duration of assessment. The Lead Assessor must take into consideration the travelling distance and time required for visit to different sites and also for witnessing site activities.

5.2. Visit

5.2.1. During the Pre-Assessment visit made by the Lead Assessor, the following actions should be carried out in every case:

- i. explaining the purpose of the assessment, the tasks of Assessors and making clear to the CAB the methodology to be adopted,
- ii. explaining the obligations on the part of the CAB to confirm by demonstration that the management of the CAB understands the procedures,
- iii. reviewing the management system documents including the availability of standard operating procedures to cover the tests / measurements / PT schemes / Production of RMs/CRMs that it is carrying out, Internal Audit & Management Review reports,
- iv. reviewing the scope of the accreditation,
- v. reviewing the traceability of equipment and reference standards,
- vi. Proficiency testing,
- vii. giving an overview of the accreditation process,
- viii. Informing CAB about non-conformances, if any and the number of days by which the corrective actions are to be submitted to NABL and share a copy of the report with the CAB.

6. ON-SITE ASSESSMENT

6.1. Before assessment, the Assessment Team shall interact and plan assessment program. This shall include the distribution of work amongst the Assessors. The format of the assessment plan to be finalized is given at NAF (XX)-1 of relevant checklist. The time schedules in the assessment plan shall be realistic so that each activity can be completed as scheduled. Lead assessor shall ensure proper time management of the team members during assessment.

6.2. Opening Meeting

6.2.1. To begin with the Lead Assessor and the team shall have an opening meeting with CAB representatives where the team and the CAB personnel will introduce each other and clarify their roles and responsibility.

6.2.2. The Assessment team should get acquainted with the CAB, the departments/ sections and their location(s).

6.2.3. The Lead Assessor should make it clear in his opening remarks that the object of the assessment is to assess the work of CAB according to ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189: 'Medical laboratories - Requirements for Quality and Competence or ISO/IEC 17043 'Conformity Assessment - General Requirements for Proficiency Testing' or ISO 17034 - General Requirements for the Competence of Reference Material Producers, whichever is applicable.

6.2.4. The Lead Assessor shall ensure that (s)he explains the purpose of assessment, accreditation criteria, assessment schedule/ plan, scope for the assessment, accreditation process, reporting etc. and what is expected from the CAB during the assessment.

6.2.5. The Lead Assessor shall confirm the changes / updates on scope, person proposed by CAB to review, report and authorize the results and express opinion and interpretation (wherever applicable), equipment etc.

6.2.6. The Lead Assessor shall present the assessment plan [NAF (XX)-1] to CAB representatives. The CAB is to be requested to assign co-coordinator to accompany each Assessor.

6.2.7. The Lead Assessor shall assure the CAB that all findings will be treated in strict confidence.

6.2.8. The Lead Assessor shall inform the CAB that the team members shall not be approached by the CAB for closure of NCs during the assessment and the response to the closure of NCs has to be sent by CAB after conducting root cause analysis.

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6.2.9. Lead assessor shall obtain signatures/ endorsement of all participants of opening meeting in NAF(XX)-1A.

Note: The assessment team should spend considerable time for the opening meeting specially to explain the objectives and scope of the assessment.

6.3. On-site Assessment Procedure

6.3.1. The Assessment Team shall proceed to various sections of the CAB as planned earlier.

6.3.2. Assessors must be objective and should not convey the impression of having superior knowledge and judgement.

6.3.3. Assessor(s) should thoroughly examine the technical competence of the CAB in terms of manpower, qualification, experience, up to date knowledge, equipment and other related elements. Assessor(s) shall also verify the confidentiality by CAB personnel including those on contract / outsourced.

6.3.4. While interviewing the CAB personnel, the assessors should create a comfortable environment to gather all information needed to accurately evaluate the competence of the CAB.

6.3.5. The technical competence of the CAB personnel could be verified by examining their qualification, experience, training relevant to the job/ responsibilities assigned and observations during the activities related to the scope of accreditation.

6.3.6. Assessor shall interview the person proposed by the CAB for opinion and interpretation of results in testing and calibration laboratories and report to NABL on the following criteria:

- i. Knowledge of relevant CAB accreditation standard,
- ii. Technical knowledge of the relevant scope

6.3.7. Assessors shall interview the personnel who are responsible to report, review and authorize the results of the CAB based on the following criteria and report to NABL for acceptance:

- i. Qualification and experience as detailed in relevant NABL specific criteria document/ application form.
- ii. Position in overall staff structure.
- iii. Familiarity with the calibration or test or PT Scheme or RM production procedure and awareness of any limitations of these procedures.
- iv. Knowledge of the procedures for recording, reporting and checking results.
- v. Awareness of the needs for periodic re-calibration of equipment, where applicable.
- vi. Awareness of the requirements and conditions for NABL accreditation.

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- 6.3.8. Test methods used by the CAB should be in accordance with those prescribed by National / International organizations. Other methods could be accepted, provided they are properly documented, controlled and appropriately validated.
- 6.3.9. Assessors should ascertain that the measuring capability of the instrument/ equipment used by the CAB is commensurate to the ranges in which it claims to operate its system. This shall be an element in determining the scope of accreditation of CAB.
- 6.3.10. During assessment of calibration laboratories, the Assessor shall review the capability of the laboratories to make measurements within the uncertainty claimed for each parameter for which accreditation is being sought.
- 6.3.11. During assessment, if the team finds that work is being sub-contracted, they should inquire into the circumstances and if the practice appears to contravene to ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189 'Medical laboratories - Requirements for Quality and Competence or ISO/IEC 17043 'Conformity Assessment - General Requirements for Proficiency Testing' or ISO 17034 - General Requirements for the Competence of Reference Material Producers, whichever is applicable, this should be recorded and included in the Assessment Report.
- 6.3.12. For site facilities the assessors shall do thorough examination of the operation of the management system at site, normally where testing / calibration for a customer is performed. The assessors shall also assess testing / calibration competency of the on-site staff, with particular emphasis on those tests / calibrations that can only be carried out at site. The same is to be done in case of temporary/ mobile facilities.
- 6.3.13. If the CAB is functioning in shifts; the assessor shall ensure the competence of staff working in shift operations and report the details.
- 6.3.14. Although the assessment must be thorough, the Assessors should avoid giving the impression that they are trying to score points or trap the CAB staff in order to find reasons for rejecting its application. Assessors need to show a positive attitude during the process of assessment. The object of assessment is to ascertain by observations of the activities whether the work of the CAB is being carried out in accordance with ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189 'Medical laboratories - Requirements for Quality and Competence or ISO/IEC 17043 'Conformity Assessment - General Requirements for Proficiency Testing' or ISO 17034 - General Requirements for the Competence of Reference Material Producers, whichever is applicable and any other requirements specified by NABL.

- 6.3.15. Favorable and adverse noting must be based on objective evidence and be recorded and verified before leaving the area under assessment. To secure agreement on the facts, and to avoid subsequent disputes, Assessors shall record detailed non-conformities as they occur in NAF (XX) 4. Each non-conformity shall be acknowledged / countersigned by the accompanying CAB representative or the section in charge.
- 6.3.16. At the time of assessment of the CAB, Assessors will discuss with the CAB staff whether the CAB is participating in any National / International Proficiency Testing, Interlaboratory Comparison Program, their performance and the action taken by the CAB based on root cause analysis, if the performance was unsatisfactory.
- 6.3.17. Checklists provided should be verified and completed during the course of assessment of the CAB, Checklist(s) are like aid memoir to Assessors so that all aspect of CAB management system and technical criteria are taken care of. NAF 2 is to be used to record the observations in case of integrated assessments of testing field only.
- 6.3.18. Assessor shall, during the course of assessment of the site/ mobile / temporary facility of the CAB, verify the effectiveness of management system and related documents using the audit techniques and shall raise the relevant non-conformity. The Assessor shall use NAF (XX) 4 to record the findings. This form shall be an annexure to the final report.
- 6.3.19. Since it is not possible to assess every procedure in operation, Assessors should use his/ her own judgement to select the calibration / test / PT Scheme / RMP activity for their demonstration. The selection of the calibration/ test / PT Scheme / RMP activity would have to be such that it can help assess the CAB's competence, in terms of equipment and capabilities of experts with equal emphasis on site activity / subcontracted activity for such CABs (in case of PTP and RMP). In doing so, the Assessors shall select items of work in progress, witness measurement and verify documents and record of calibrations / tests / PT Activities / RMP Activities. The emphasis shall be given to cover critical and important tests / parameters of all the applied / accredited groups/sub discipline / sub category in each discipline/ category based on risk analysis.
- 6.3.20. The Assessors are required to witness the conduct of some replicate tests, where applicable, using old samples whose reported results are available to study repeatability and reproducibility of measurements, Calibration witness, Review of PT scheme, production of reference materials, whichever is applicable.
- 6.3.21. In some cases, Assessors may trace back results from previously issued certificates or reports to the original entries in the CAB's registers/ notebooks/ worksheets. Aspects, which require evidence from some other area of CAB before they can be settled, may be

perused for further investigation. The Assessors shall use NAF (XX) 3 or NAF (XX) 3A to record the findings.

6.3.22. Using the checklist, the Assessors shall conduct the assessment and raise non-conformity as may be relevant using form NAF (XX) 4 to record the findings. This form shall be part of the final report.

6.3.23. At the end of each assessment day, the Lead Assessor shall consolidate their findings.

6.3.24. The Lead Assessor shall brief the CAB about the non-conformity(s) noticed by the team.

The above would facilitate CAB to take corrective actions on the non-conformity observed.

6.3.25. A formal meeting for de-briefing of each day's findings may not be necessary for small CABs (one with limited scope and resources), where the findings have been conveyed during the day's proceedings.

6.3.26. The Lead Assessor and Assessors shall individually complete "assessor's summary of Non-Conformity" [NAF (XX)-4], which shall be acknowledged / countersigned by the accompanying CAB representative. After the Assessors have completed their individual assessment, a preliminary meeting of Assessment Team is held to summarize their conclusions.

6.4. **Compilation of Report**

6.4.1. Each Assessor shall prepare his/ her recommendation on the scope to be recommended for accreditation. This has to be based on his/ her observations and verifications during the assessment.

6.4.2. The Lead Assessor shall consolidate the findings based on individual Assessor's report(s) including NAF (XX) -4.

6.4.3. The Lead Assessor shall, in his final report [NAF (XX) -6], give the reasons for limiting or partially recommending the scope of accreditation, for test(s)/ calibration(s) / PT(s) / RMP(s) against those applied. The Lead assessor/ Technical assessor must endorse / sign the documents related to scope of Testing or Calibration or PTP or RMP with the comment 'recommended'.

6.5. **Closing Meeting**

6.5.1. The Lead Assessor shall summarize the findings of the Assessment Team and present it to the CAB representative. The Lead Assessor shall invite each Assessor to summarize his/ her findings.

6.5.2. During the closing meeting, the management representative present shall be asked to suggest a date for completion of corrective action with root cause analysis of all non-

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conformity and to acknowledge /sign NAF (XX) 6. A copy of this form along with NAF (XX) 4 and Form (XX) 72/73 are to be shared with the representative of the CAB. For details, please refer to procedures for conducting closing meeting (Section 8).

6.5.3. The closing meeting is to end with thanks giving for the co-operation and assistance given by CAB.

6.6. **Post Assessment**

6.6.1. Lead Assessor shall send the assessment report along with recommendation to NABL at the earliest and in confidence by speed post or by courier service mail or through portal.

6.6.2. Assessor shall provide comments and recommend for closure of NC(s) raised once CAB have submitted satisfactory corrective actions including root cause analysis with documentary evidence.

6.6.3. In cases when assessor is not able to close the NC, then the assessor should give his/her opinion.

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7. GUIDE TO FORMULATE RECOMMENDATIONS

- 7.1. Where no non-conformities are found, the Lead Assessor shall recommend accreditation of the CAB.
- 7.2. The Lead Assessor shall take into account the nature of non-conformities found during assessment.
- 7.3. When non-conformities are found, the recommendation shall be such that accreditation is recommended subject to the satisfactory closure of all non-conformities.
- 7.4. When in one area of testing or calibration or RMP or PTP, competence is not established, but overall, there are no major system failures, the Lead Assessor may recommend accreditation for all areas except for the non-complying area.
- 7.5. The CAB management shall be asked to specify the period required to complete the corrective action for non-conformities in line with NABL norms.
- 7.6. Where the number and seriousness of non-conformities found is such that the whole of the CAB's management system and organization is demonstrably inadequate, the Lead Assessor's recommendations shall be such that accreditation is not recommended. In such cases, the CAB may write to NABL about the dissatisfaction / disagreement.

8. PROCEDURE FOR CONDUCTING CLOSING MEETING

- 8.1. The purpose of the closing meeting is to enable the team to present the CAB management with a summary of the findings of the assessment and to inform the management about the recommendations that the team will make to NABL. Thereafter the decision will be communicated to the CAB by NABL.
- 8.2. The concluding report [NAF (XX)-6] shall be based on the summary report including [NAF (XX)-4] prepared by Assessment Team.
- 8.3. Closing meeting shall be chaired by the Lead Assessor in presence of CAB senior management. The lead assessor has to:
 - 8.3.1. Thank the CAB for its assistance and co-operation. (S)he shall also refer to individuals as may be appropriate.
 - 8.3.2. Explain the significance of the non-conformities.
 - 8.3.3. Ask for questions to be deferred until the findings have been presented, although points of clarification should not be refused.
 - 8.3.4. Invite each Assessor to summarize his or her findings based on the report, but it should not be discussed in detail. (S)he should present his / her findings as individual Assessor.
 - 8.3.5. Invite the CAB to specify the date by which any required corrective actions will be implemented. It should be in line with NABL norms.
 - 8.3.6. Provide the CAB with an opportunity to discuss the assessment and answer any questions.
 - 8.3.7. Apprise CAB with the requirements of NABL 131 and NABL 133.
 - 8.3.8. During the closing meeting, the Assessment Team should not enter into debating the validity of their conclusions or recommendations. If these are questioned, the Assessor may, however, enumerate individual non-conformities, which justify the recommendations in question and point out the combined effect of the observations of the assessment. If the CAB is still unwilling to accept the recommendations, the Lead Assessor should advise them to take up the matter with NABL.
 - 8.3.9. Lead assessor shall obtain acknowledgement / signature of those who attend the closing meeting in NAF (XX)-1A.
 - 8.3.10. Lead Assessor shall inform the CAB about the complaint (NABL 132) and appeal (NABL 134) procedure of NABL.

9. SCOPE OF ACCREDITATION

- 9.1. It is NABL's policy to define the scope of a CAB's accreditation in line with ISO/IEC 17011. CABs are, therefore, asked to specify in detail the scope for which accreditation is sought in the desired format given in application forms (e.g. NABL 151 or NABL 152 or NABL 153 or NABL 154 or NABL 155 or NABL 180 or NABL 190).
- 9.2. Assessor(s) should ensure by discussing with CAB for capability and competence of the CAB to determine and define its scope of accreditation.
- 9.3. Every effort has to be made to reach agreement with the CAB on the content of their scope before the assessment. This is important, not only to avoid possible misunderstandings, but also to help the Assessors to operate effectively, concentrating their attention in those areas of activity appropriate to the scope of Accreditation.
- 9.4. In some cases, as the assessment proceeds, it may become clear that the CAB is not really in a position to achieve accreditation in certain areas within the originally applied scope. In such cases, the Lead Assessor may be able to recommend accreditation for a suitably reduced or redefined scope and it should reflect in Form (XX) 72 / 73.
- 9.5. The applied scope of accreditation by the CAB may be used for this purpose. It should ensure for the elements of accreditation as detailed in Form (XX) 72 / 73 are covered. The recommended scope of accreditation shall clearly specify the parameters for which the CAB is performing site activities.
- 9.6. When CAB refers to handbook type publications like IP, BP, NCCLS, USP, ASTM, AOAC etc. in its scope of accreditation, the assessor(s) shall ensure that relevant clause/ chapter/ page number of the procedure is mentioned.
- 9.7. The Assessors shall diligently verify the status of all test /calibration methods and their revision status while recommending the scope of accreditation. In case of withdrawn test methods, the same shall be clearly mentioned in the recommended scope of accreditation.

10. PROCEDURE FOR HANDLING THE MANAGEMENT SYSTEM DOCUMENT/ QUALITY MANUAL AND OTHER DOCUMENTS AFTER ASSESSMENT

10.1. For reasons of ensuring confidentiality of documents of the CAB, the following rule is to be observed:

10.1.1. On completion of the assessment visit, Assessors shall return the Management System Document/ Quality Manual, Application and other documents to the CAB wherever applicable.

11. ON-SITE SURVEILLANCE AND RE-ASSESSMENT

- 11.1. Accreditation is granted for a period of two years. Surveillance of accredited CAB is to be completed on yearly basis. On-site surveillance is conducted for integrated assessment CABs and in other cases as decided by NABL.
- 11.2. Surveillance is to ensure that accredited CAB continues to comply with ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189 'Medical laboratories - Requirements for Quality and Competence or ISO/IEC 17043 'Conformity Assessment - General Requirements for Proficiency Testing' or ISO 17034 - General Requirements for the Competence of Reference Material Producers, whichever is applicable.
- 11.3. The on-site surveillance or re-assessment team shall be headed by a Lead Assessor.
- 11.4. The on-site surveillance visit takes place within 12 months of the grant or renewal of accreditation and cover all aspects of the CAB accreditation, such that the entire scope is covered including those of site activities.
- 11.5. NABL provides on-site surveillance / re-assessment audit team a copy of relevant parts of the previous assessment report as a background information.
- 11.6. Assessors are required to concentrate particularly on areas where there is reason to believe standards have not been maintained, where non-conformities were observed during previous visits, or where there have been changes in staff. However, all elements of CAB accreditation standard are to be assessed.
- 11.7. Management System Document / Quality Manual will be made available to members of the assessment team by NABL prior to the assessment.
- 11.8. If during an on-site surveillance or re-assessment visit, it is found that there have been significant changes, e.g. staff, equipment or the range of services available, these matters shall be recorded. Assessors shall check that the changes are not such as to diminish the CABs capabilities, particularly as described in the scope of accreditation and that they have already been fully notified to NABL.

11.9. At the time of on-site surveillance/ re-assessment, Assessors are required to find out whether the CABs have participated in accredited Proficiency Testing program and Interlaboratory Comparison, wherever applicable, as specified in their 4-year PT participation plan. Also, whether they have taken the necessary corrective action based on root cause analysis in those situations, where their performance was not found to be satisfactory.

Note: As NABL has started to conduct the app-based assessment (Document Review or adequacy /Pre-assessment/ Final assessment/ re-assessment), the assessment team is essentially required to get acquainted with NABL 213: Operational Manual for Online Assessment (For Assessors). In app-based assessment, all required and relevant documents are available electronically.

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