NABL 210

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ASSESSOR GUIDE

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PREFACE

This Guide is to provide assistance to NABL Assessors. It describes the role of an Assessor in conducting the Assessment-related activities for NABL. The methodologies being described are basically to help an Assessor to be able to discharge his/ her responsibilities very effectively. Since an Assessor would be representing NABL during the assessment of an applicant laboratory, he should understand NABL and its accreditation process, its objectives, mission as well as the on-site assessment methodology.

An Assessor must ensure that he carries with him ISO/IEC 17025:2005 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189:2007 'Medical laboratories - Particular requirements for quality and competence', whichever is applicable and other relevant NABL documents during his visit to Laboratory on account of Laboratory Assessment assignment.

NABL 215: Assessment Forms and Checklist (based on ISO/IEC 17025:2005) and NABL 217: Assessment Forms and Checklist (Based on ISO 15189:2007) are supplementary documents to this document. The document includes various forms, which are to be used at the time of on-site assessment.

AMENDMENT SHEET

Sl	Page No.	Clause No.	Date of Amendment	Amendment made	Reasons	Signature QO	Signature Director
1.	5/21	2.2	16.10.2012	The team members shall ensure….. before proceeding with the assessment	APLAC Finding		
	10/21	6.1.(d)	16.10.2012	Note: The assessment team should spend …..scope of the assessment			
	12/21	6.2.(j)	16.10.2012	If the laboratory is functioning in shifts….. and report the details in NAF 2			
2.							
3.							
4.							
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7.							
8.							

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1. INTRODUCTION

The National Accreditation Board for Testing and Calibration Laboratories (NABL) provides third-party accreditation of testing and calibration laboratories according to international standards. The liberalisation (of trade and industry) policy of the Government of India provides greater thrust for exports. This makes it imperative for the laboratories, 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 laboratories are in line with international norms and practices.

NABL assures itself of the competence of the laboratories it accredits through a system of assessment in accordance with ISO/IEC 17025: 2005 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189: 2007 'Medical laboratories - Particular requirements for quality and competence', 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 laboratory's management system. The objective evidence so collected forms the basis:

- for arriving at a judgement for recommendation of the team
- to specify the competence of laboratory in terms of its capability to perform the test(s)/ calibration(s) 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.

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. provide the guidance to the Assessors during the assessment of a laboratory;
b. ensure uniformity of assessment and reporting; and
c. eliminate ambiguities or doubts about the interpretation of requirements(s).

2. ASSESSOR'S ROLE

2.1 The objective of any on-site assessment is to obtain evidence on compliance with respect to ISO/ IEC 17025: 2005 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189: 2007 'Medical laboratories - Particular requirements for quality and competence', whichever is applicable. Basically, the NABL Assessor's role is to conduct on-site assessment of laboratory to adjudge the compliance.

2.2 The Assessor shall also check that the laboratory meets other requirements of NABL including the NABL's Specific Criteria for the relevant field of testing/ calibration or medical testing and has competence to perform the specific test(s)/ calibration(s) or specific type of tests/ calibrations. The team members shall ensure that they are using the latest documents which are available on the web-site for each assessment. Also pay their attention to the specific announcements on web-site pertaining to policy decisions and its transition period (if any) etc before proceeding with the assessment.

2.3 Since laboratory accreditation requires formal recognition of competence to carry out specific tests/ calibrations or types of tests/ calibrations by a laboratory, 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 laboratory.

2.5 Notwithstanding the strength of the NABL system, the success of the accreditation scheme depends on the Assessors who perform on-site 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 Secretariat for abandoning the assessment process.

2.7 The role of Lead Assessor, Technical Assessor, Technical Expert and Technical Observer during assessment of testing and calibration laboratories is addressed in NABL 215, chapter 1 and for medical laboratories is addressed in NABL 217, chapter 1.

3. ASSESSOR ASSIGNMENT PROCEDURE

3.1 If the application form and/ or associated documents received from laboratory are acceptable to NABL, it shall appoint Assessment Team and inform the laboratory. NABL Secretariat, in consultation with Lead Assessor, will constitute the composition of team. Laboratories have the right to object to the appointment of a particular Lead Assessor/ Assessor, and in such cases, NABL may offer an alternative to the extent possible, if the reasons given by the laboratory 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 laboratory's requested scope of accreditation. The number of Assessors in the team shall depend on the range and volume of calibration or testing involved. For multi-disciplinary laboratory, Assessors shall be selected in such a manner so as to cover each discipline and its range/ scope of operation.

3.3 Lead Assessor/ Assessor(s) are informed subsequently after the laboratory has agreed on the membership of the team.

4. PROCEDURE FOR ASSESSMENT OF NEW APPLICANT LABORATORIES

4.1 NABL shall first appoint the Lead Assessor and send laboratory's Quality Manual and application to the Lead Assessor.

4.2 The Lead Assessor shall examine the Quality Manual and shall submit Adequacy Report to NABL within 30 days.

Once the laboratory satisfactorily address the inadequacies of the Quality manual; NABL shall plan the pre-assessment in consultation with the lead assessor and laboratory. However, if the adequacy report reveals only minor non-conformities in the quality manual, a Pre-Assessment visit may be planned without delay. The identification, classification and expression of non-conformity are given below:

A non-conformity can be identified and can be one or more of the following:

- related to the management system
- related to technical activities
- failure to fulfill the required objectives
- difference between work practices and documented instructions

A non-conformity can be classified as Major or Minor. A major non-conformity is:

- absence of a procedure required by standard
- significant failure to implement a procedure
- direct-effect on quality of results

All other non-conformities are minor.

The statement of non-conformity must be expressed as atleast one of the following:

- non-blaming statements of fact
- based on recorded objective evidence
- directly related to specific documented requirement

4.3 NABL shall then inform the Lead Assessor to undertake Pre-Assessment visit to laboratory to assess the Management System and the quantum of work, and take the following action:

(i) If the Management System is acceptable, the Lead Assessor shall inform NABL, recommending on-site assessment.

(ii) The Lead Assessor shall handover to the laboratory a copy of the complete report covering areas of inadequacies and actions to be taken by the laboratory in the forms given in NABL 209 and send the original report to NABL. On receipt of this report, NABL shall take up the matter with the laboratory for necessary action.

(iii) In case of no or minor inadequacies, the Lead Assessor may advise NABL on constitution of Assessment Team and date of assessment.

4.4 NABL shall inform Assessors and decide the dates of assessment consulting all concerned.

4.5 NABL shall send a copy of the application to each Assessor; a copy of Quality Manual, if available, (otherwise NABL instructs the laboratory to send the copy of quality manual). The Assessor may also seek any further information like test procedures etc. from the laboratory, in order to better prepare for their assigned areas of responsibility.

4.6 To the extent possible, the assessment shall be completed in one phase, even for multi-disciplinary laboratories. There shall be only one Lead Assessor for entire assessment. For large and multi-disciplinary laboratories, it may not be possible to conduct the assessment in one phase and may be completed in two or more phases.

5. PRE-ASSESSMENT VISIT

5.1 Objective

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

- to have a better understanding of the documentation;
- to familiarize with the facilities, sites/ location, circumstances and to have better knowledge of operations;
- to make the methodology to be adopted for the assessment;
- to check the preparedness of the laboratory to undergo assessment;
- 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

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

- explaining the purpose of the assessment, the tasks of Assessors and making clear to the laboratory the methodology to be adopted;
- explaining the obligations on the part of the laboratory to confirm by demonstration that the management of the laboratory understands the procedures;
- reviewing the management system documents including the availability of standard operating procedures to cover the tests/ measurements that it is carrying out, Internal Audit & Management Review reports;
- reviewing the scope of the accreditation;
- giving an overview of the accreditation process.
- obtain signatures on NABL 131 (Terms and Conditions for maintaining Accreditation) if not submitted by laboratory earlier.

6. ON-SITE ASSESSMENT

One day before the day of assessment, the Assessment Team shall meet and plan assessment program. This shall include the distribution of work amongst the Assessors. The format of the assessment plan to be finalised is given at NAF-1. The time schedules in the assessment plan shall be realistic so that each activity can be completed as scheduled. Lead assessor shall ensues proper time management of the team members during assessment.

6.1 Opening Meeting:

(a) To begin with the Lead Assessor and the team shall have an opening meeting with laboratory representatives where the team and the laboratory personnel will introduce each other.

(b) The Assessment team should get acquainted with the laboratory, the departments/ sections and their locations.

(c) The Lead Assessor should make it clear in his opening remarks that the object of the assessment is to assess the work of laboratory according to the ISO/ IEC 17025: 2005 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189: 2007 'Medical laboratories - Particular requirements for quality and competence', whichever is applicable.

(d) The Lead Assessor shall ensure that he / she explains the objective and scope of assessment and what is expected from the laboratory during the assessment.

(e) The Lead Assessor shall present the assessment plan (NAF 1) to laboratory representatives. The laboratory will be requested to assign guide/ co-coordinator to accompany each Assessor.

(f) The Lead Assessor shall assure the laboratory that all findings will be treated in strict confidence.

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

(h) lead assessor shall obtain signatures of all participants of opening meeting in NAF-1A

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

6.2 On-site Assessment Procedure:

(a) The Assessment Team shall proceed to various sections of the laboratory as planned earlier. Assessors must be objective and should not convey the impression of having superior knowledge and judgement.

(b) Assessor(s) should thoroughly examine the technical competence of the laboratory in terms of manpower, qualification, experience, upto date knowledge, equipment and other related elements.

(c) While interviewing the laboratory personnel, the assessors should create a comfortable environment to gather all information needed to accurately evaluate the competence of the laboratory.

(d) The technical competence of the laboratory personnel could be verified by examining their qualification, experience, training relevant to the job/ responsibilities assigned and observations during the tests/ calibrations.

(d) Assessors shall track the status of the laboratory's authorised signatories, which are detailed in the laboratory's application form and its Quality Manual/ Procedure Manual/ Work instructions.

Assessors shall check the authorised signatories of the laboratory based on the following criteria and recommend to NABL for approval:

- Qualification and experience as detailed in relevant specific criteria.
- Position in overall staff structure.
- Familiarity with the calibration or test procedures and awareness of any limitations of these procedures.
- Knowledge of the procedures for recording, reporting and checking results.
- Awareness of the needs for periodic re-calibration of equipment, where applicable.
- Awareness of the requirements and conditions for NABL accreditation, particularly those related to calibration/ test reports.

(e) Test methods used by the laboratory should be in accordance to those prescribed by organizations such as BIS, BSI, ASTM, etc. Other test/ calibration methods could be accepted, provided they are properly documented, controlled and appropriately validated.

(f) Assessors should ascertain that the measuring capability of the instrument/ equipment used by the laboratory is commensurate to the ranges in which the laboratory claims to

operate its system. This shall be an element in determining the scope of accreditation of laboratory.

(g) During assessment of calibration laboratories, the Assessor will review the capability of the laboratories to make measurements within the uncertainty claimed for each parameter for which accreditation is being sought. NABL may authorise the assessors to examine the result obtained by the laboratories in measurement audits.

(h) During their investigation, 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: 2005 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189: 2007 'Medical laboratories - Particular requirements for quality and competence', whichever is applicable, this should be recorded and included in the Assessment Report.

(i) For site testing/ site calibration 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.

(j) If the laboratory is functioning in shifts; the assessor shall ensure the competence of staff working in shift operations and report the details in NAF 2.

(k) Although the assessment must be thorough, the Assessors should avoid giving the impression that they are trying to score points or trap the laboratory staff in order to find reasons for rejecting its application. Assessors need to show a positive attitude during the process of assessment.

(l) The object of assessment is to ascertain by observations of the activities whether the work of the laboratory is being carried out in accordance with ISO/ IEC 17025: 2005 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189: 2007 'Medical laboratories - Particular requirements for quality and competence', whichever is applicable and any other requirements specified by NABL. 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 4. Each non-conformity shall be countersigned by the accompanying laboratory representative or the section incharge.

(m) At the time of assessment of the laboratory, Assessors will discuss with the Quality Manager of the laboratory whether the laboratory is participating in any National/ International Proficiency Testing/ Inter-Laboratory Comparison Program, their performance and the action taken by the laboratories if the performance was unsatisfactory.

(n) Checklists provided should be verified and completed during the course of assessment of the laboratory, Checklist(s) are like aid memoir to Assessors so that all aspect of laboratory management system and technical criteria are taken care of. However, NAF 2 should be used to record the observations.

(o) Lead Assessor shall, during the course of on-the-spot assessment, verify the effectiveness of management system and related documents using the audit techniques and shall raise the relevant non-conformity. The Lead Assessor shall use NAF 4 to record the findings. This form shall be an annexure to the final report.

(p) Since it is not possible to assess every procedure in operation, Assessors should use his own judgement to select one or more calibration/ test procedure(s) for their demonstration. The selection of the calibration/ test would have to be such that it can help assess the laboratory's competence, in terms of equipment and capabilities of experts with equal emphasis on site test/ site calibration for such laboratories. In doing so, the Assessors shall select items of work in progress, witness measurement and verify documents and record for calibration(s)/ test (s).

(q) The Assessors are required to conduct some replicate tests, where applicable, using old samples whose reported results are available to study repeatability and reproducibility of measurements.

(r) In some cases, Assessors may trace back results from previously issued certificates or reports to the original entries in the laboratory's registers/ notebooks/ worksheets. Aspects, which require evidence from some other area of laboratory before they can be settled, may be perused for further investigation. The Assessors shall use NAF 3 or NAF 3A to record the findings.

(s) Using the checklist, the Assessors shall conduct the technical assessment and examine the management system. They shall raise the non-conformity as may be relevant. The

Assessors shall use NAF 4 to record the findings. This form shall be an annexure to the final report.

(t) At the end of each assessment day, the Lead Assessor shall consolidate their findings. The Lead Assessor shall brief the laboratory about the non-conformity(s) noticed by the team. The above would facilitate laboratory take corrective actions on the non-conformity observed.

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

(t) The Lead Assessor and Assessors shall individually complete assessment report (NAF-4), which shall be countersigned by the accompanying laboratory representative. This report will indicate whether the non-conformity is major or minor.

(u) After the Assessors have completed their individual assessment, a preliminary meeting of Assessment Team is held to summarise their conclusions.

6.3 Compilation Report:

(a) Each Assessor, based on his verification, shall prepare as part of his recommendations the details of calibration and the test for which the laboratory is to be accredited.

(b) The Lead Assessor shall consolidate the findings in (NAF-5) based on individual Assessor's report(s) (NAF-4).

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

6.4 Closing Meeting:

(a) The Lead Assessor shall summarise the findings of the Assessment Team and present it to the laboratory representatives. The Lead Assessor shall invite each Assessor to summarise his/ her findings.

(b) During the closing meeting, the management representative present shall be asked to suggest a date for completion of corrective action of all non-conformity and to acknowledge this by signing NAF 6. A copy of this form along with NAF 4 & NAF 5, Form 71 and Form

72/73 (not the original) are to be given to the representative of the laboratory. For details, please refer to procedures for conducting closing meeting (Section 7).

(c) The closing meeting is to end with thanks giving for the co-operation and assistance given by laboratory.

6.5 Post Assessment:

(a) Lead Assessor shall send the assessment report along with recommendation to NABL secretariat at the earliest (within ten days of assessment) and in confidence by speed post or by courier service mail.

(b) Assessor shall close the NC(s) raised once laboratory have taken satisfactory corrective actions and submit satisfactory documentary evidence.

(c) When a further visit is required / clarifications required, the Assessors shall be contacted by NABL secretariat.

7. GUIDE TO FORMULATE RECOMMENDATIONS FOR NABL

a. The Lead Assessor shall take into account the number and type of non-conformities found during assessment.

b. Where no non-conformities are found, the Lead Assessor shall recommend accreditation of the laboratory.

c. When non-conformities are found, the Lead Assessor cannot recommend accreditation. In such cases, the recommendation shall be such that accreditation may be granted subject to the satisfactory discharge of all non-conformities. Lead Assessor should also recommend if the evidence of the corrective actions received from laboratory would suffice or a further visit by NABL official or Assessor would be required.

d. Where in one area of testing or calibration, major non-conformities have been identified/ recorded, but overall there are no major system failures, the Lead Assessor may recommend accreditation for all areas except for the non-complying area.

e. The laboratory management shall be asked to specify the period required to complete the corrective action for non-conformities. This period should not be more than 2 months. Normally, a period of one month should be regarded as reasonable.

f. Where the number and seriousness of non-conformities found is such that the whole of the laboratory's management system and organisation is demonstrably inadequate, the Lead Assessor's recommendations shall be such that accreditation is refused. In such cases, the Lead Assessor shall advise the laboratory to discuss action with NABL.

8. PROCEDURE FOR CONDUCTING CLOSING MEETING

The purpose of the closing meeting is to enable the team to present the laboratory management with a summary of the findings of the assessment and to inform the management of the recommendations that the team will make to the NABL secretariat:

(a) The concluding report (NAF-6) shall be based on the summary report including (NAF- 4 and NAF-5) prepared by Assessment Team.

(b) Final meeting shall be chaired by the Lead Assessor, who should:

- ♦ Thank the laboratory for its assistance and cooperation. He shall also refer to individuals as may be appropriate.
- ♦ Explain the significance of the type of non-conformities.
- ♦ Ask for questions to be deferred until the findings have been presented, although points of clarification should not be refused.
- ♦ Invite each Assessor to summarise his or her findings based on the report, but it should not be discussed in detail. He should present his/ her findings as individual Assessor.
- ♦ Invite the laboratory to specify the date by which any required corrective actions will be implemented.
- ♦ Provide the laboratory with an opportunity to discuss the assessment and answer any questions.

(c) 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 laboratory is still unwilling to implement the recommendations, the Lead Assessor should advise them to take up the matter with NABL.

(d) Lead assessor shall obtain signature of those who attend the closing meeting in NAF -1A.

9. SCOPE OF ACCREDITATION

It is NABL's policy to define the scope of a laboratory's accreditation as precisely as possible. To ensure that users of the laboratories are provided an accurate and unambiguous description of the range of calibration(s)/ test(s) covered by the laboratory's accreditation. Laboratories are, therefore, asked to specify in detail the types of test(s)/ calibration(s) for which accreditation is sought. Laboratories are required to list the standard specifications or other methods relevant to test(s)/ calibration(s) and the major items of equipments used to conduct those tests and calibrations.

(a) Assessor(s) should ensure by discussing with laboratory for capability and competence of the laboratory to determine and define its scope of accreditation.

(b) Every effort will have to be made to reach agreement with the laboratory 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.

(c) In some cases, as the assessment proceeds, it may become clear that the laboratory is not really in a position to achieve accreditation in certain areas within the originally conceived 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 72 / 73.

(d) The list submitted as scope of accreditation by the laboratory may be used for this purpose. It should ensure for the elements of accreditation as detailed in Form 72 and Form 73 of NABL 215: Assessment Forms and Checklists – based on ISO/ IEC 17025: 2005, are covered. For recommending the scope of accreditation for medical laboratories, Form 72 of NABL 217: Assessment Forms and Checklists – based on ISO 15189:2007, be used.

(e) The recommended scope of accreditation shall clearly specify the parameters for which the laboratory is performing site test(s)/ calibration (s).

(f) When laboratory refers to handbook type publications like IP, BP, NCCLS, etc. in its scope of accreditation, the assessor(s) shall ensure that relevant clause/ chapter/ page number of the procedure is mentioned.

10. PROCEDURE FOR HANDLING THE QUALITY MANUAL AND OTHER DOCUMENTS AFTER ASSESSMENT

For reasons of ensuring confidentiality of documents of the laboratory, the following rules are to be observed:

a. On completion of the assessment visit, Assessors shall return the Quality Manual, Application and other documents to the laboratory.
b. The Lead Assessor shall return the Quality Manual and application along with assessment report to NABL in original.

11. SURVEILLANCE AND RE-ASSESSMENT

a. Accreditation is granted for the period of two years. Surveillance of accredited laboratory is to be completed on yearly basis, and should be conducted each year. The first surveillance is on-site and subsequent surveillances are desktop.

b. Surveillance is to ensure that accredited laboratory continues to comply with ISO/ IEC 17025: 2005 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189: 2007 'Medical laboratories - Particular requirements for quality and competence', whichever is applicable.

c. The on-site surveillance or re-assessment team shall be headed by a Lead Assessor.

d. The on-site surveillance visit shall take place within 12 months of the grant of accreditation and cover selected aspects of the laboratory, such that the entire scope is covered including those of site testing/ site calibration.

e. NABL shall provide the on-site surveillance / re-assessment audit team a copy of relevant parts of the previous assessment report as a background information

f. Assessors to concentrate particularly on any areas of calibration/ testing 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.

g. Members of the on-site surveillance / re-assessment team can obtain a copy of the Quality Manual at the time of audit or prior to it from the laboratory.

h. If during an on-site surveillance or Reassessment visit, it is found that there have been significant changes, e.g., of 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 laboratory's capabilities, particularly as described in the scope of accreditation and that they have already been fully notified to NABL.

i. A Re-assessment visit will involve a comprehensive re-examination of the laboratory's management system and calibration/ testing activities and will be similar in format and detail to the initial assessment.

j. The Re-assessment visit shall normally take place four months prior to expiry of accreditation. Laboratories have been requested to apply for renewal of accreditation, six months prior to expiry of accreditation.

k. At the time of on-site surveillance/ re-assessment, Assessors are required to find out whether the laboratories have participated in National/ International recognised Proficiency Testing/ Inter-Laboratory Comparison program as specified in their 4 year Pt participation plan. Also, whether they have taken the necessary corrective action in those situations, where their performance was not found to be satisfactory.

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