

AMENDMENT SHEET

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1. INTRODUCTION

The document provides guidance to Conformity Assessment Bodies (CABs) {Testing Laboratories, Calibration Laboratories, Medical Testing Laboratories, Proficiency Testing Providers (PTPs) and Reference Material Producers (RMPs)} for planning, preparation and execution of remote assessment by NABL.

2. DEFINITIONS

2.1. Remote Assessment

Assessment of the physical location of a CAB, using electronic means.

Note: Assessments done remotely may include a combination of the following assessment techniques:

- File/records review.
- Documents review.
- Review of performance in proficiency testing and other inter-laboratory comparisons.
- Review of existing internal quality control activities.
- Interviewing.
- Remote witnessing.

2.2. Information and Communication Technology (ICT)

Use of technology for gathering, storing, retrieving, processing, analyzing, and transmitting the information. It includes software and hardware such as smartphones, handheld devices, laptop computers, desktop computers, video cameras, wearable technology etc.

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3. SCOPE

This document provides guidance on remote assessment, including use of Information and Communication Technology (ICT) tools for remote assessments.

4. CONSIDERATIONS FOR REMOTE ASSESSMENT

- 4.1. A CAB will be required to undergo remote assessment only under conditions decided by NABL. The need for conducting remote assessment may arise due to extraordinary circumstances, policy decisions, fulfilment of objectives of Accreditation Body etc.
- 4.2. NABL will check the feasibility of such an assessment for the scope applied and the risk associated with it before taking the consent of the CAB for scheduling the assessment remotely.
- 4.3. NABL will determine the extent of assessment to be done remotely (i.e. partial or full).
- 4.4. Remote Assessments cannot be insisted upon by any CAB as a matter of right in lieu of physical visit of the assessment team to the location of CAB.
- 4.5. The size of the assessment team and duration of assessment may also vary from that of the assessments done through visit to the CAB premises physically.

5. SECURITY AND CONFIDENTIALITY

- 5.1. The security and confidentiality of electronic or electronically transmitted information are particularly important when facing assessment using ICT. This includes data in storage, data in transit, and data in use.
- 5.2. The data protection and privacy issues of the CAB will be duly considered by NABL.
- 5.3. Assessment recording by CAB is not permitted.
- 5.4. Any privacy issue must be brought to the notice of NABL before start of assessment when the feasibility checks are being done by NABL.

6. PREPARATION FOR REMOTE ASSESSMENT

- 6.1.** The CAB will be informed by the concerned officer about making the necessary arrangement of virtual platform for each assessor who will assess the CAB remotely.
- 6.2.** The CAB is responsible for providing a secure platform. Facility for remote assessment and Video presenting skills of the CAB will be verified before the assessment.
- 6.3.** The CAB may need to set up a fixed camera location for demonstration of test / calibration/ PTP/ RMP activities. The requirement will be informed to the CAB in advance.
- 6.4.** Effective audio and video facilities shall be made available by the CAB at all times during assessment to ensure proper witness and interaction.
- 6.5.** The CAB shall keep soft copies of all its documents, records for online sharing with the assessment team members. The CAB may provide 'view only' versions of all soft copies during the assessment. However, in case any document or record is required by the assessment team for scrutiny / analysis before the conduct of assessment or during the assessment, copy shall be provided to the assessment team through document sharing platforms as per the CAB policy. The CAB has to enable security and profile access to the assessors and concerned NABL officer involved in the assessment.
- 6.6.** A preparatory meeting on the virtual platform that the CAB would utilize for the assessment is to be done along with the concerned officer from NABL. Any further arrangement that needs to be done by the CAB to make the demonstration better, shall be communicated by the concerned NABL officer.
- 6.7.** For each member of the assessment team, one person from the CAB shall be associated during the entire duration of the assessment. Any preparation on sample, that is required to be done for the purpose of test/calibration witness to be done will be communicated by the assessor to the CAB in advance.
- 6.8.** The CAB is required to ensure that the proceedings of the assessment does not get slowed down due to multiple connections needed during the assessment.
- 6.9.** In the opening meeting, the address at which the CAB is operating is to be shared with the assessment team.
- 6.10.** Assessor request for a walk through of the CAB before the commencement of the assessment, should be carried out without delay.
- 6.11.** Before start of each session, the CAB representative shall scan everyone who is present in the room.
- 6.12.** The information obtained by the assessors during the course of the assessment will be kept confidential. Facility for scanning and sharing any record or document during the assessment is to be ensured by the CAB.

- 6.13. Any photograph that is to be taken for the assessment, the same will be done by the assessor after informing the CAB.
- 6.14. The internet connectivity along with the availability of CAB persons on the virtual platform shall be ensured throughout the assessment. In case of poor connectivity and difficulty in carrying out the assessment, the assessment team may abandon the assessment under intimation to the concerned NABL officer. The assessment charges will have to be borne by the CAB even in such a case.
- 6.15. Any pre-recorded video will not be accepted by the assessment team. The demonstration of CAB test / calibration / PTP / RMP activity is required to be done during the assessment.
- 6.16. In case any part of the scope is not possible to be witnessed due to limitation of the virtual means, the assessor will place it on record and the same will be taken up for on-site assessment at a later date by NABL.
- 6.17. In case time specified in the schedule is required to be extended, the consent of the CAB will be obtained by the assessment team under intimation to the concerned NABL officer. In case there is a disagreement then assessment team may contact NABL for resolution.
- 6.18. The CAB has to acknowledge the assessment findings shared by the assessment team.
- 6.19. The CAB should confirm the deletion of any confidential documents, records, photographs, recording etc. (if taken by means other than through the app) from the assessors before or during the closing meeting.
- 6.20. CAB will be held responsible for any breach of confidential data and information of the assessment obtained through ICT.
- 6.21. The requirements of NABL 131 are required to be followed at all times by the CAB.

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