

NABL 192



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Pre-Assessment Guidelines & Forms (based on ISO 17034:2016)

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AMENDMENT SHEET

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1. GUIDE TO CONDUCT PRE-ASSESSMENT

1.1. Introduction

The Lead Assessor, who has been nominated by the NABL, shall be fully aware of the NABL Accreditation process for Reference Material Producer (RMP) accreditation, its objectives and the on-site Assessment procedure. The Lead Assessor shall have the overall responsibility for conducting the onsite Pre-assessment of the RMP including review of all documents towards the task of Pre-assessment.

This document contains Pre-assessment forms and Checklist, which become part of the Pre-assessment Report, when filled by the assessment team. The document shall guide the Lead Assessor in completing various forms & checklists and compiling the report.

1.2. Pre-Assessment

1.2.1. After the RMP has submitted a report of satisfactory corrective action on the concerns expressed in the document review report, NABL shall fix up a date for Pre-assessment in consultation with the RMP and the Lead Assessor.

1.2.2. The Lead Assessor and/ or assessor shall proceed to the RMP site (and/ or Sub-contractor(s)'s Site) for Pre-assessment, with RM Producer's Applications Forms, System Management Document/ Quality Manual, Corrective action report on the document review and any other information provided by NABL.

1.2.3. The Assessment team, during Pre-assessment shall:

- i. Check the implementation of the Management System as documented in the System Management Document/ Quality Manual on a sample basis to provide confidence for proceeding with the final assessment.
- ii. Study the scope of accreditation and the activities of RMP/subcontractor(s), so that the time frame, number of assessors required in various Categories/ sub-categories/ sub-sub categories required for the assessment can be determined. The Lead Assessor shall also assess whether the Assessment is required to be split, based on the location of RMP and subcontractor or the number of Categories/ sub-categories/ sub-sub categories and the time required to visit different locations and the assessment thereof.
- iii. Check whether the Reference Material Producer has conducted a comprehensive internal audit in accordance with ISO 17034: 2016.
- iv. Assess the degree of preparedness of the RMP for the Assessment in terms of requirements specified in NPF RM1.
- v. Obtain signatures on NABL 131 – Terms and Conditions for Maintaining Accreditation, from the RMP, if not submitted earlier.
- vi. Explain to the RMP regarding the methodology to be adopted for assessment and their obligations.
- vii. Submit a Pre-assessment report to NABL.

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1.3. ASSESSMENT OF REFERENCE MATERIAL PRODUCER(S)

The RMP shall be assessed for the purpose of accreditation in accordance with ISO 17034:2016. There are many different approaches by which a RMP may produce and assign values to reference materials by different approaches. Hence the relevance of a requirement should be assessed in the context of the tasks performed. Tasks that may be critical for one RMP may not be as important or may even be insignificant for another. Reference materials (RMs) can range from the fairly simple e.g. calibration solution, to the very complex e.g. DNA sequence.

1.4. Compilation of Pre-Assessment Forms & Checklist

1.4.1. The Lead Assessor (LA) shall review the RMP's documented management system to verify availability and compliance with the requirements of ISO 17034: 2016 on a sample basis. LA should complete the checklist NPF RM1 by recording his/her observation – 'Yes' or 'No' (by marking a ✓ in the appropriate box), related to the requirements of respective clause number of the checklist and providing brief comments. In case there is a need for checking other details not listed in the checklist, the Lead Assessor is free to make detailed assessment and annex the findings, to the report.

1.4.2. All non-conformity (ies) must be identified and reported, separately in NPF RM2. Additional sheets may be added, if required. The Lead Assessor should finally summarise the conduct of pre-assessment and record the recommendations in NPF RM3. The Lead Assessor must carefully fill the forms and check list and sign all pages of the Pre-assessment report. Lead Assessor should also obtain signature of the authorised person of the RMP on NPF RM2 & RM3. The report should be compiled in the order NPF RM 3, 2 & 1 and any other additional pages or annexures thereafter.

1.4.3. The Lead Assessor shall submit the pre-assessment report to NABL after completion of Pre-assessment.

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