

NABL 208



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Pre-Assessment Guidelines and Forms (based on ISO 15189:2012)

ISSUE NO. : 02
ISSUE DATE : 19-Apr-2016

AMENDMENT NO. : 02
AMENDMENT DATE : 02-May-2018

AMENDMENT SHEET

SI	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QM	Signature CEO
1	12/12	Form7 4	13-May-2016	Form 74 includes QM Adequacy	IQA	-Sd-	-Sd-
2	11/12	NPF 3	02-May-2018	Change in timeline for CA of pre-assessment to Max. 15 days	Internal	Sd/-	Sd/-
3							
4							
5							
6							
7							
8							
9							
10							

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No: NABL 208	Pre-Assessment Guidelines and Forms (based on ISO 15189:2012)			
Issue No: 02	Issue Date: 19-Apr-2016	Amend No: 02	Amend Date: 02-May-2018	Page No: 1/12

CONTENTS

S. No.	Title	Page Nos.
1.	Amendment Sheet	1
2.	Contents	2
3.	Guide to use Pre-Assessment Forms & Checklist	3
4.	Pre Assessment Checklist – NPF 1	5
5.	Non Conformities Observed during Pre-Assessment – NPF 2	10
6.	Pre Assessment Report – NPF 3	11
7.	Declaration of Impartiality & Confidentiality – Form 74	12

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No: NABL 208	Pre-Assessment Guidelines and Forms (based on ISO 15189:2012)			
Issue No: 02	Issue Date: 19-Apr-2016	Amend No: 02	Amend Date: 02-May-2018	Page No: 2/12

GUIDE TO USE PRE-ASSESSMENT FORMS & CHECKLIST

1. INTRODUCTION

It is presumed that the Lead Assessor, who has been nominated by the NABL Secretariat, is fully aware of the NABL Accreditation process, its objectives and the on-site Assessment procedure. The Lead Assessor shall have the overall responsibility of conducting the assessment and shall be responsible for pre-assessment of the laboratory and for conducting the on-site assessment of the concerned laboratory. Towards the task of on-site assessment, the lead assessor shall be assisted by a team of assessors commensurate with the scope of accreditation.

This document contains Pre-assessment forms and Checklist, which shall be used to report the pre-assessment findings. The document shall guide the Lead Assessor in completing various forms & checklists and compiling the report.

2. PRE ASSESSMENT

After the laboratory has taken the corrective action on the concerns expressed in the Quality Manual Adequacy Report and has submitted a report to the satisfaction of the NABL, NABL Secretariat shall fix up a date for Pre-assessment in consultation with the laboratory and the Lead Assessor.

While the Lead Assessor proceeds to the laboratory for Pre-assessment, he should be in possession of the laboratory's Applications Forms, Quality Manual, Corrective action report on the adequacy of the Quality Manual (if any) and any other information supplied by NABL Secretariat.

The Lead Assessor, during Pre-assessment shall:

- i. check the overall implementation of the management system as per the documented Quality Manual
- ii. study the scope of accreditation so that the time frame, number of assessors required in various disciplines and visits to collection centres, if applicable, 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 laboratory or the number of disciplines, departments and collection facilities.
- iii. check whether the laboratory has conducted a comprehensive Internal Audit in accordance with ISO 15189:2012.
- iv. assess the degree of preparedness of the laboratory for the Assessment in terms of compliance to NPF 1.

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No: NABL 208	Pre-Assessment Guidelines and Forms (based on ISO 15189:2012)			
Issue No: 02	Issue Date: 19-Apr-2016	Amend No: 02	Amend Date: 02-May-2018	Page No: 3/12

- v. obtain signatures on NABL 131 – Terms and Conditions for Obtaining and Maintaining Accreditation, from the laboratory, if not submitted by laboratory earlier
- vi. explain to the laboratory regarding the methodology to be adopted for Assessment and the obligations of the laboratory
- vii. submit a report to NABL Secretariat

3. COMPILATION OF PREASSESSMENT FORMS & CHECKLIST

The Lead Assessor must review the Laboratory's documented management system to verify compliance with the requirements of ISO 15189:2012. He should complete the Checklist NPF 1 by recording his observation – 'Yes' or 'No' (by marking a ✓ in the appropriate box), related to the requirements of respective clause number of the checklist and offering brief comments. If the Lead Assessor has a doubt in other area(s), even though not listed in the checklist, he is free to assess or go into details where he feels and annex his findings, to the report.

All Non-Conformity(ies) must be identified and to be reported in NPF 2. Additional sheets may be added, if required. The Lead Assessor should finally summarise the conduct of Pre-Assessment and record the recommendations in NPF 3. The Lead Assessor must carefully fill the forms and check list and sign all pages of the Pre-Assessment Report. He should also obtain signature of the authorised person of the laboratory on NPF 2 & 3. The report should be compiled in the order NPF 3, 2, 1 & Form 74 and any other additional pages or annexure thereafter.

The Lead Assessor shall submit the Pre-Assessment Report to NABL Secretariat within 10 days of completion of Pre-Assessment.

Instructions:

- i. Verify the information provided by the lab in application form NABL 153 (S.No. 1a).
- ii. Check all the columns as per format i.e. appropriate material to be tested, Test methodology (delete obsolete and redundant tests), acceptable range of testing, actual %CV / ±MU upto one decimal (S.No. 1b).
- iii. Check availability of Procedures and records as per the standard requirements i.e. mandatory procedures as required in ISO 15189:2012 (wherever written as "...shall have documented procedure....") (S.No. 2c).

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No: NABL 208	Pre-Assessment Guidelines and Forms (based on ISO 15189:2012)			
Issue No: 02	Issue Date: 19-Apr-2016	Amend No: 02	Amend Date: 02-May-2018	Page No: 4/12