

NABL 142



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Policy on Traceability of Measurement Results

ISSUE NO.: 06
ISSUE DATE: 06-Feb-2020

AMENDMENT NO.: --
AMENDMENT DATE: --

AMENDMENT SHEET

S. No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature CEO
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

CONTENTS

S. No.	Title	Page No.
	Amendment Sheet	1
	Contents	2
1.	Introduction	3
2.	Terms & Definitions	4
3.	Scope	5
4.	Policy	6

1. INTRODUCTION

To ensure confidence in the results of accredited CABs, NABL implement ILAC policies and use guidance documents to assist in the uniform and harmonised approach of accreditation criteria.

Metrological traceability of measurement results is a key to provide confidence in testing, calibrations, medical testing, proficiency testing and production of reference materials by accredited CABs covered by the ILAC Arrangement. A harmonised policy for Metrological traceability for accredited CAB is thus imperative.

Metrological traceability requires an unbroken chain of calibrations to stated references, all having stated uncertainties – refer ISO/IEC Guide 99:2007 - International vocabulary of metrology -- Basic and general concepts and associated terms (VIM).

All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service.

2. Terms and Definitions

The following definitions apply throughout this document:

2.1. Metrological traceability

Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

2.2. Metrological traceability chain

Sequence of measurement standards and calibrations that is used to relate a measurement result to a reference.

2.3. Metrological traceability to a measurement unit

Metrological traceability where the reference is the definition of a measurement unit through its practical realization

Note: The expression “traceability to the SI” means metrological traceability to a measurement unit of the International System of Units.

2.4. National Metrology Institutes (NMI)

National Metrology Institutes (NMI) and Designated Institutes (DI) maintain standards in countries (or regions) all over the world. Throughout this document, the term “NMI” is used to cover both National Metrology Institutes as well as Designated Institutes.

2.5. JCTLM

The CIPM, IFCC and ILAC Joint Committee for Traceability in Laboratory Medicine

3. SCOPE

This document describes the NABL policy with regard to the metrological traceability requirements from ISO/IEC 17025: 2017 and ISO 15189: 2012. This policy shall also be applied to other conformity assessment activities where testing and/ or calibration is involved (e.g., PTP and RMP). The traceability requirements are according to ILAC P10:01/2013 "ILAC policy on traceability of measurement results".

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 142	Policy on Traceability of Measurement results			
Issue No.: 06	Issue Date: 06-Feb-2020	Amend. No.: --	Amend. Date: --	Page No: 5 of 7

4. POLICY

4.1. For achieving traceability to the International System of Units (SI), NABL recognizes calibration of equipment and reference standards from

4.1.1. National Physical Laboratory (NPL, NMI of India) or any other NMI whose service is suitable for the intended need and is covered by the CIPM MRA.

Note: Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB which includes the range and uncertainty for each listed service.

Or

4.1.2. NABL accredited calibration laboratory or a calibration laboratory accredited by an Accreditation Body covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC e.g. by APAC, IAAC & EA whose service is suitable for the intended need (i.e. the scope of accreditation specifically covers the appropriate calibration through unbroken chain of calibration traceable back to primary standards, preferably to National standards i.e. NPL-India).

Note 1: Some calibration laboratories indicate that their service is covered by the ILAC Arrangement by including the ILAC Laboratory Combined MRA mark on the calibration certificate. Alternatively, the accreditation symbol of the accreditation body that is a signatory to the ILAC Arrangement and/or a recognized regional MLA may be included on the calibration certificate. Both of these options may be taken as evidence of traceability.

Note 2: when the above are not possible for a particular calibration, calibration laboratory whose service is suitable for the intended need but not covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC is also accepted. However, in these cases, NABL shall ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025: 2017.

or

4.1.3. Direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

4.2. There are certain calibrations that currently cannot be strictly made in SI units. In these cases, calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

4.2.1. The use of certified reference materials provided by a competent producer to give a reliable physical or chemical characterization of a material;

4.2.2. Results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

Participation in a suitable programme of inter laboratory comparisons is required where possible.

The situation 4.2 can only be applied in the case in which the laboratory has demonstrated that the policy 4.1 cannot reasonably be met. It is the responsibility of the laboratory to choose a way to satisfy 4.2 and to provide the appropriate evidence. This evidence shall be documented and the documentation shall be assessed by NABL.

4.3. If the calibration of instruments used contributes significantly to the overall uncertainty, the above policy for traceability applies.

However, if a calibration is not a dominant factor in the result, the laboratory shall have quantitative evidence to demonstrate that the associated contribution of a calibration contributes little (insignificantly) to the measurement result and the measurement uncertainty of the test and therefore traceability does not need to be demonstrated.

4.4. NABL policy in regard to traceability provided through Certified Reference Materials (CRMs)

4.4.1. The values assigned to CRMs produced by NMIs and included in the BIPM KCDB or produced by an accredited RMP under its accredited scope of accreditation to ISO/ IEC 17034 are considered to have established valid traceability.

4.4.2. The values assigned to CRMs covered by entries in the JCTLM database are considered to have established valid traceability.

4.4.3. The majority of RMs and CRMs are produced by other RMPs. These can be considered as critical consumables and the laboratory shall demonstrate that each RM or CRM is suitable for its intended use as required by applicable clause(s) of ISO/IEC 17025: 2017, ISO 15189: 2012, ISO/IEC 17043: 2010, ISO 17034: 2016.

Note: Values associated with RMs may not be metrologically traceable. Values associated with CRMs (by definition) are metrologically traceable.

National Accreditation Board for Testing and Calibration Laboratories				
Doc. No.: NABL 142	Policy on Traceability of Measurement results			
Issue No.: 06	Issue Date: 06-Feb-2020	Amend. No.: --	Amend. Date: --	Page No: 7 of 7

National Accreditation Board for Testing and Calibration Laboratories (NABL)

NABL House

Plot No. 45, Sector 44,
Gurugram - 122003, Haryana
Tel. no.: 91-124-4679700 (30 lines)
Fax: 91-124-4679799
Website: www.nabl-india.org