KENAS
Delivering Trust

KENYA
ACCREDITATION
SERVICE

PL-36-01

Traceability of Measurements Policy

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1 Background Information

1.1 Purpose

Traceability is the property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or International standards, through an unbroken chain of comparisons all having stated uncertainties. This is required for testing and calibration results. Traceability is characterized by reference to the SI units.

1.2 Scope

This policy applies to the Laboratory accreditation schemes (Calibration, Testing and Medical) including those that inform inspection and certification results.

1.3 Legal Basis

KENAS shall implement this policy in accordance with the ILAC Policy on Traceability of Measurement Results.

2 Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the KENAS Act 2019 and the following apply.

2.1 Acronyms and Abbreviations

CEO	Chief Executive Officer
KENAS	Kenya Accreditation Service
BIPM	International Bureau of Weights and Measures
CGPM	General Conference of Weights and Measures.
CIPM	International Committee on Weights and Measures.
ILAC	International Laboratory Accreditation Cooperation
JCTLM	Joint Committee for Traceability in Laboratory Medicine (CIPM, IFCC, ILAC)
KCDB	Key Comparisons Data Base
MRA	Mutual Recognition Arrangement
NMI	National Metrology Institutes (NMI)
RM	Reference Material

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RMP	Reference Material Producer
SI Units	International System of Units

2.2 Definition of Terms

2.2.1 Traceability of measurements

Refers to the method of ensuring that measurement is taking into account all uncertainties and is an accurate representation of an object being measured as guided by ISO 17000 and ISO 17011.

3 Policy Statement

3.1 Accredited testing and calibration laboratories shall be able to demonstrate that measurement results obtained under their scopes of accreditation are traceable to the SI units. Where such traceability is not technically possible or reasonable, the laboratory and the client and other interested parties may agree to using Certified Reference Materials provided by a competent supplier or using specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

3.2 It is KENAS Policy to require that laboratories seeking accreditation or those that are accredited derive their traceability from direct reference to accredited laboratory (accredited by an ILAC MRA Signatory) or from a National Metrology Institute whose services are suitable for the intended need and are covered by the CIPM MRA as indicated in the BIPM KCDB.

3.3 Accredited testing and calibration laboratories shall ensure the traceability of their in-house calibration and/or test/calibration results to an external calibration provider that is accredited for suitably small uncertainties.

3.4 Where 3.2 and 3.3 is not feasibly demonstrated through a justification, and a laboratory seeks services of an NMI whose service is suitable for intended need but not covered by the CIPM MRA or a calibration Laboratory whose service is suitable for intended need but not covered under the ILAC arrangement or by regional arrangements recognized by ILAC, the laboratory must ensure that appropriate evidence for claimed traceability and measurement uncertainty exists.

3.5 KENAS shall assess this evidence for completeness and appropriateness prior to granting accreditation. The appropriate evidence shall include but not be limited to;

a) Records of calibration method validation
b) Procedures for estimation of uncertainty

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c) Documentation for traceability of measurements
d) Documentation for assuring quality of calibration results
e) Documentation for competence of staff
f) Documentation for accommodation of environmental conditions
g) Audit records of the calibration laboratory including the traceability on calibrations.
h) Calibration certificates and /or reports issued by non-accredited calibration service provider shall meet the requirements of ISO/IEC 17025.

3.6 There are certain calibrations that cannot be made in SI units. In these cases, calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as reference materials. In this case participation in a suitable inter-laboratory comparison is required.

3.7 Traceability can be obtained through use of certified reference materials produced by NMI's and included in the BIPM KCDB or produced by an accredited RMP. The values assigned to CRM's covered by entries in the JCTLM database are considered to have established valid traceability

4 Associated Documents

Ref	Document Identifier	Document Title
1.	ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
2.	ISO 15189	Medical laboratories – Requirements for quality and competence
3.	ILAC P10	ILAC Policy on Traceability of Measurement Results.
4.	VIM	International Vocabulary of basic and general terms in metrology.

5 Revision/Amendment Records

Date	Ver	Revised By	Reason for Revision
30/04/2022	01	RSQ	Newly developed/formatted document

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