Approval and Authorization

Completion of the following signature blocks signifies the review and approval of this Document.

Name	Job Title / Role	Signature	Date
Authored by	**ASSISTANT DIRECTOR TESTING AND CALIBRATION**	Approved	03/08/2015
Checked by	**DEPUTY DIRECTOR TECHNICAL SERVICES**	Approved	03/08/2015
Approved by	**CHIEF EXECUTIVE OFFICER**	Approved	03/08/2015

Periodic Review Approval and Authorization

Completion of the following signature blocks signifies the review and approval of this Document.

Required by: *(08/2018)*

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Required by: *(08/2021)*

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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 characterised by reference to the SI units.

2 SCOPE

This policy applies to the Laboratory accreditation schemes (Calibration, Testing and Medical), Laboratories included in inspection and certification bodies.

3 TERMS AND DEFINITIONS

The table below defines new or changed terms that are included in or associated with this process.

Term	Definition
NMI	National Metrology Institutes (NMI)
DI	Designated Institutes
JCTLM	Joint Committee for Traceability in Laboratory Medicine (CIPM, IFCC, ILAC)
RM	Reference Material
RMP	Reference Material Producer
ILAC	International Laboratory Accreditation Cooperation
CIPM	International Committee on Weights and Measures.
CGPM	General Conference of Weights and Measures.
KCDB	Key Comparisons Data Base
BIPM	International Bureau of Weights and Measures
SI Units	International System of Units

MRA	Mutual Recognition Arrangement
IFCC	International Federation of Clinical Chemistry

4 ROLE(S) AND RESPONSIBILITY

Role	Responsibility
CEO	• Approval
Technical Staff	• Compliance

5 POLICY

5.1 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.

5.2 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.

5.3 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.

5.4 Where 5.2 & 5.3 is not feasible 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 of a calibration Laboratory whose service is suitable for intended need but not covered under the ILAC arrangement of by regional arrangements recognized by ILAC, the laboratory must ensure that appropriate evidence for claimed traceability and measurement uncertainty exists. KENAS shall assess this evidence for completeness and appropriateness prior to granting accreditation. The appropriate evidence shall include but not be limited to:

5.4.1 Records of calibration method validation

5.4.2 Procedures for estimation of uncertainty

5.4.3 Documentation for traceability of measurements

5.4.4 Documentation for assuring quality of calibration results

5.4.5 Documentation for competence of staff

5.4.6 Documentation for accommodation of environmental conditions

5.4.7 Audit records of the calibration laboratory including the traceability on calibrations. Calibration certificates and /or reports issued by non-accredited calibration service provider shall meet the requirements of ISO/IEC 17025.

5.5 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.

5.6 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

6 REFERENCE AND RELATED DOCUMENTS

Ref	Document Identifier	Document Title
1.	ILAC G2	Traceability of measurements.
2.	ILAC P10	ILAC Policy on Traceability of Measurement Results.
3.	ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
4	ISO/15189	Medical laboratories – Requirements for quality and competence
5	VIM	International Vocabulary of basic and general terms in metrology.

7 TRAINING

Awareness sessions are required prior to implementation of this policy

8 REVISION HISTORY

Date	Ver	Revised By	Reason For Revision
15/11/2012	01	DDTS	• Initial
03/08/2015	02	ADTC	• Alignment to the Policy document template. • Incorporation of ILAC P10 requirements. • Inclusion of assessment requirements in clause 5.4 • Overall text reorganisation