የኢትዮጵያ እክሬዲቴሽን አገልግሎት ETHIOPIAN ACCREDITATION SERVICE **Policy on the Traceability of Measurement Results**	**Copy No.** **Page 1 of 16** **Document No. PM10 /01** **Revision no. 2.0** **Effective Date. 2023-02-07**

Reviewed by: Zewdu Ayele	**Approved by: Meseret Tessema**
Position: Quality Manager	**Position: Director General**
Signature:	**Signature:**

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1. Purpose

This policy document details the traceability requirements set by EAS and acceptable traceability terms for CABs in terms of the “ILAC Policy on the Traceability of Measurement Results”, ILAC-P10:07/2020.

2. Scope

It is applicable for all conformity assessment bodies (CABs) accredited through the EAS Accreditation Program, which are carried out under the ILAC Arrangements on Calibration and Testing. This policy also applies to other conformity assessment activities where measurement is involved i.e. involved medical Laboratories, Inspection bodies, product certification, Bio banks, Proficiency Testing providers and reference material producers. “ILAC Arrangement on Calibration” is applicable to the EAS accreditation of calibration laboratories,

Note: This document also provides guidance on the accreditation process of NMIs for the measurement services in order for the NMI to optimize the benefits from being accredited when it is, or is in the process of becoming, a signatory to the CIPM MRA, and to generally facilitate the process for Accreditation Bodies when accrediting the measurement services of NMIs. In case of an ambiguity or conflict with the wording in the last document cited in the next section, the text in that reference shall be substituted for an NMI instead of the text in this document

3. References

- ILAC P10:07/2020 ILAC Policy on Metrological Traceability of Measurement Results
- ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories.
- ISO 15189:2012 – Medical laboratories – Requirements for quality and competence
- JCGM 200:2012, International vocabulary of metrology – Basic and general concepts and associated terms (VIM).
- ILAC P14:09/2020 ILAC Policy for Measurement Uncertainty in Calibration
- Joint ILAC – BIPM partnership regarding the Accreditation of Calibration and Measurement Services of National Metrology Institutes, 21 January 2021

4. Responsibility

It is the responsibility of assessment team and the CAB that implement this policy.

5. Terms and abbreviations

5.1. Terms

Metrological traceability: - is the 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 (VIM: 2010).

Reference Standard: - The standard used to calibrate the working standard (e.g., reference thermometers, masses). These shall be calibrated externally, except in the case of NMIs or DIs, which have in-house access to primary standards.

Working Standard: - Routinely used to verify measuring instruments or measuring systems (e.g., working thermometers).

Reference Material (RM):- Material or substance whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to the materials. ISO34:2016

Certified Reference Material (CRM):- A Reference Material accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceability using valid procedures.

Critical equipment: equipment used for direct measurement of measure and reported or measure and to be directly/indirectly used in calculation of result to be included in a report / certificate.

Appropriate NMIs/Calibration laboratories:-those NMIs defined in option 1 or Calibration labs as in option 2 otherwise proven to be competent sources of traceability for cases of options 3A/3B (see page 5 of this document).

International Committee for Weight and Measures Mutual Recognition Arrangement (CIPM MRA):-is an arrangement between National Metrology Institutes which provides the technical framework to assure and for recognition of the validity National Metrology Institutes.

Joint Committee for Traceability in Laboratory Medicine (JCTLM) :- formed by the BIPM, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and ILAC, provides a worldwide platform to promote and give guidance on internationally recognized and accepted equivalence of measurements in Laboratory Medicine and traceability to appropriate measurement standards.

Key Comparison Database (KCDB):- is a publicly available, free web resource related to the CIPM MRA. It contains information on participants of the CIPM MRA, results of key and supplementary comparisons and peer reviewed Calibration and Measurement Capabilities (CMCs) (https://www.bipm.org/kcdb).

Metrological traceability chain (VIM 3 clause 2.42)

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

Metrological traceability to a measurement unit (VIM 3 clause 2.43):- 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’

Reference Material Producer (RMP) :- Body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference materials it produces (ISO 17034:2016).

5.2. Abbreviations

BIPM: International Bureau for Weights and Measures

BMC: Best Measurement Capability

CABs: Conformity Assessment Bodies

CIPM: International Committee for Weights and Measures

CMC: Calibration and Measurement Capability

CRM: Certified Reference Material

DI: Designated Institute

ILC: Inter-laboratory Comparison

KCDB: Key Comparison Data Base

MRA: Mutual Recognition Arrangement

NMI: National Metrology Institute

RM: Reference Material

RMPs: Reference Material Producer

6. Traceability Policy

6.1 Calibration and testing laboratories

According to ISO/IEC 17025:2017, clause 6.5.1

The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:

a) calibration provided by a competent laboratory; or

NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent.

b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or

NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or

international standards.

NOTE 3 Details of practical realization of the definitions of some important units are given in the SI brochure.

6.5.3 When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.:

a) certified values of certified reference materials provided by a competent producer;

b) 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.

Calibration services shall be obtained from the following four alternative sources of traceability:

I) An NMI, whose service is suitable for the intended calibration and is covered by the CIPM MRA, which can be found and viewed on the Internet in Appendix C of the BIPM KCDBhttp://kcdb.bipm.org/AppendixC/default.aspor

II) An accredited calibration laboratory, NMI or DI whose service is suitable for the intended use (i.e., the scope of accreditation specifically covers the appropriate calibration range and CMC) and the Accreditation Body is covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC, which can be found and viewed on the Internet athttp://ilac.org/signatory-search/

IIIa) An NMI, whose service is suitable for the intended use but not covered by the CIPM MRA, with demonstrated competence as described, in this case, a particular measuring device shall be calibrated by ILAC MRA signatory accreditation body.

IIIb) A calibration laboratory, whose service is suitable for the intended use but not covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC, with demonstrated competence as described.

In cases where traceability is established through IIIb), EAS shall ensure that the following

evidence of technical competence is verified and documented

- Records of calibration method validation
- estimation of uncertainty
- Documentation for traceability of measurements
- Documentation for assuring the quality of calibration results
- Documentation for competence of staff
- Documentation for suited accommodation and environmental conditions
- Audits of the calibration laboratory
- Participation in ILCs

Accreditation of NMI/CABs according to IIIa) or IIIb) by an ILAC -MRA member is a sufficient proof of competence. EAS will have the capacity to do so when accepted as ILAC-MRA member.

The choice of route IIIa) or IIIb) is a last resort if other routes are unavailable, as the first two alternatives are the best alternatives for traceability.

There are numerous fields in testing that calibrations cannot be strictly made in SI units. In these cases, traceability can be provided by:

- the use of certified reference materials provided by a competent supplier
- The use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

Participation in a suitable program of inter laboratory comparisons is also a way of providing traceability (consensus value) and is required where possible.

It is the responsibility of the laboratory to choose, justify and document its way to achieve traceability. The documentation shall be assessed by the accreditation body whether the selected way and its justification is satisfying.

6.2. Traceability for medical laboratories

In ISO 15189:2012, the requirements are:

The laboratory shall have a documented procedure for the calibration of equipment that directly or indirectly affects the results. This procedure includes:

a) taking into account conditions of use and the manufacturer's instructions;

b) recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment;

c) verifying the required measurement accuracy and the functioning of the measuring system at defined intervals;

d) recording the calibration status and date of recalibration;

e) ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated;

f) Safeguards to prevent adjustments or tampering that might invalidate results.

Metrological traceability shall be to a reference material or reference procedure of the higher metrological order available.

NOTE Documentation of calibration traceability to a higher order reference material or reference procedure maybe provided by an examination system manufacturer. Such documentation is acceptable as long as the manufacturer's Examination system and calibration procedures are used without modification.

Where this is not possible or relevant, other means for providing confidence in the results shall be applied, including but not limited to the following:

— Use of certified reference materials;

— Examination or calibration by another procedure;

— Mutual consensus standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned.

EAS accepts traceability through the following Certified Reference Materials if direct traceability to SI-units is not possible:

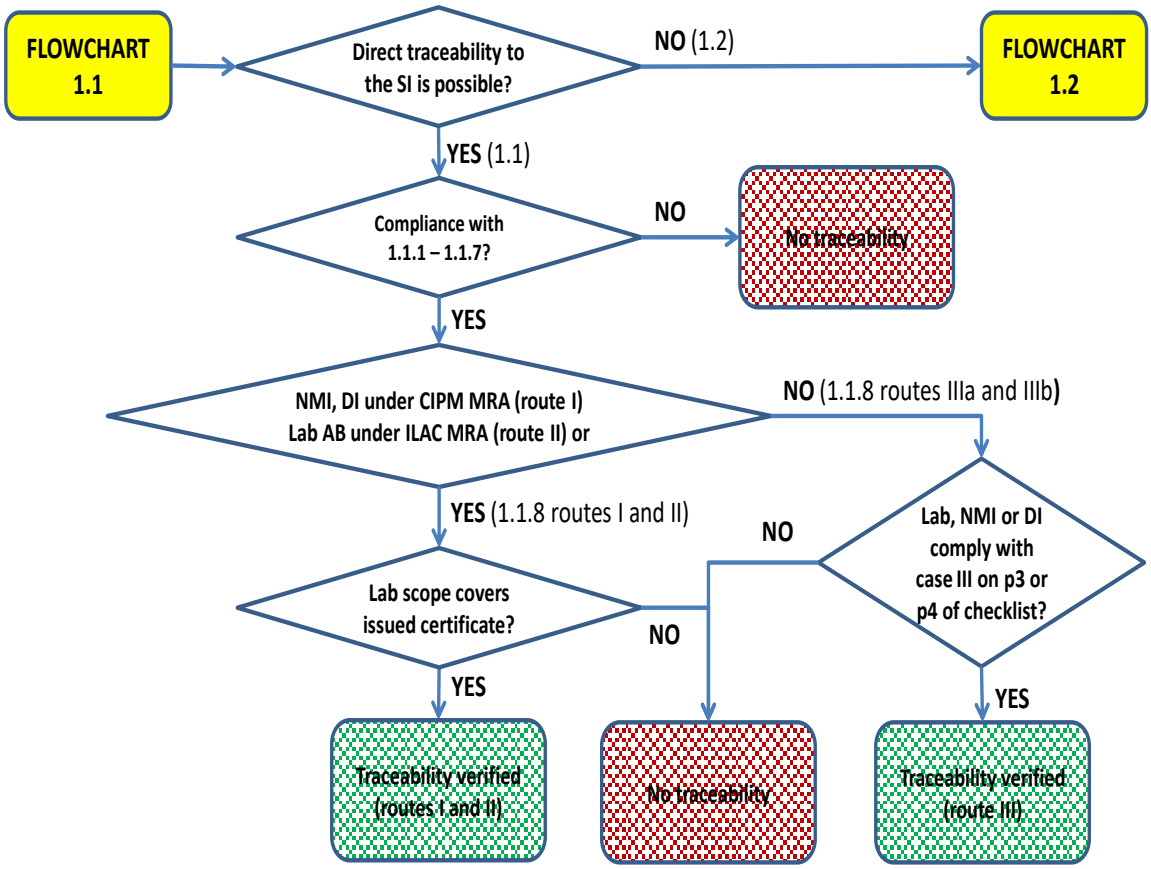
- if the Certified Reference Materials (CRMs) are included in the BIPM KCDB http://kcdb.bipm.org/AppendixC/default.asp;
- if the CRMs are included in the BIPM database created by the Joint Committee for Traceability

in Laboratory Medicine (JCTLM) http://www.bipm.org/jctlm/

The majority of available RMs and CRMs are produced by other (non-accredited) RMPs. Where CRMs and RMs do not meet the above criteria, they can be considered as critical consumables and the laboratory shall demonstrate that they are suitable for their intended use.

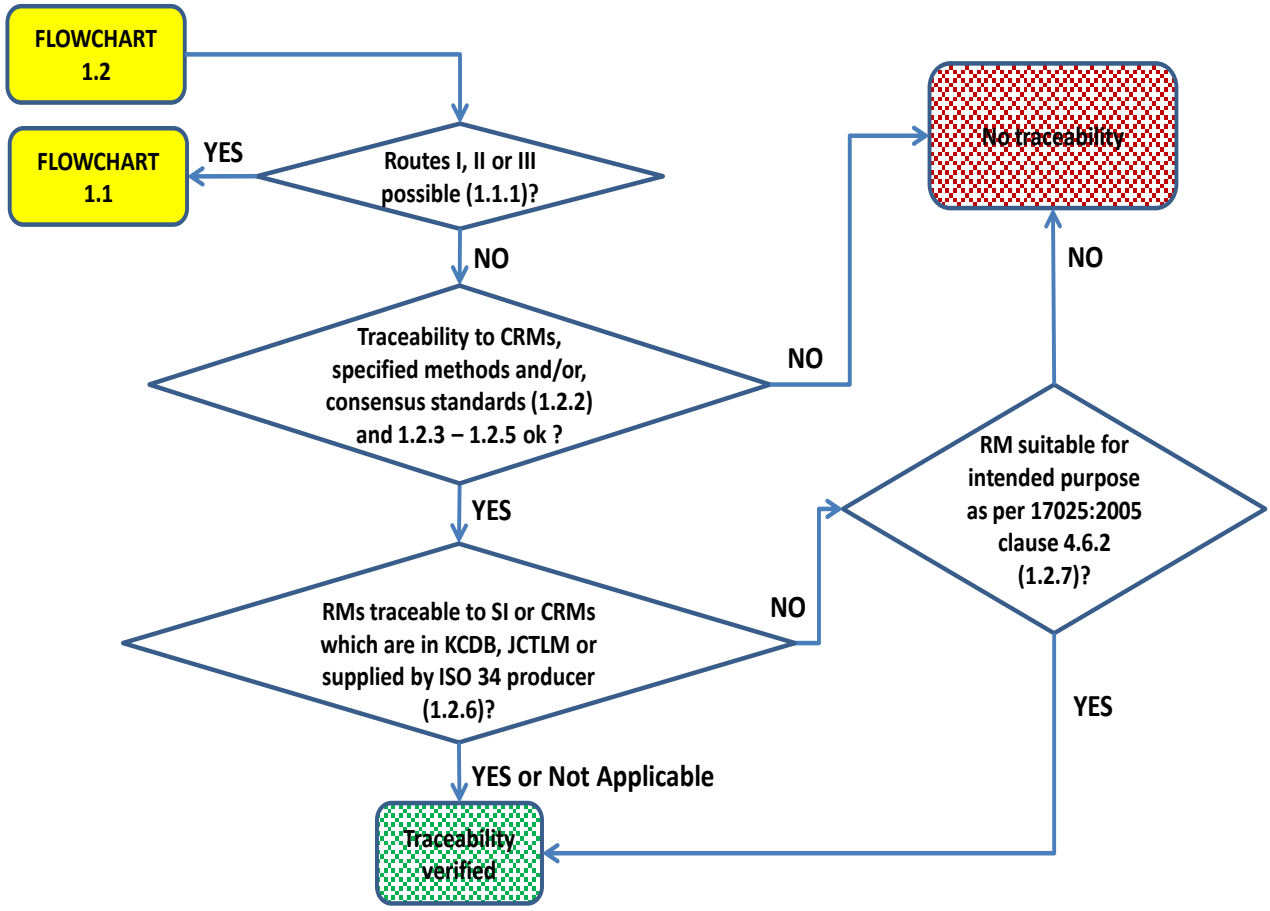
Annex A

TRACEABILITY FLOWCHART FOR CALIBRATION LABS, INCLUDING NMIs AND DIs, UNDER THE ILAC ARRANGEMENT ON CALIBRATION



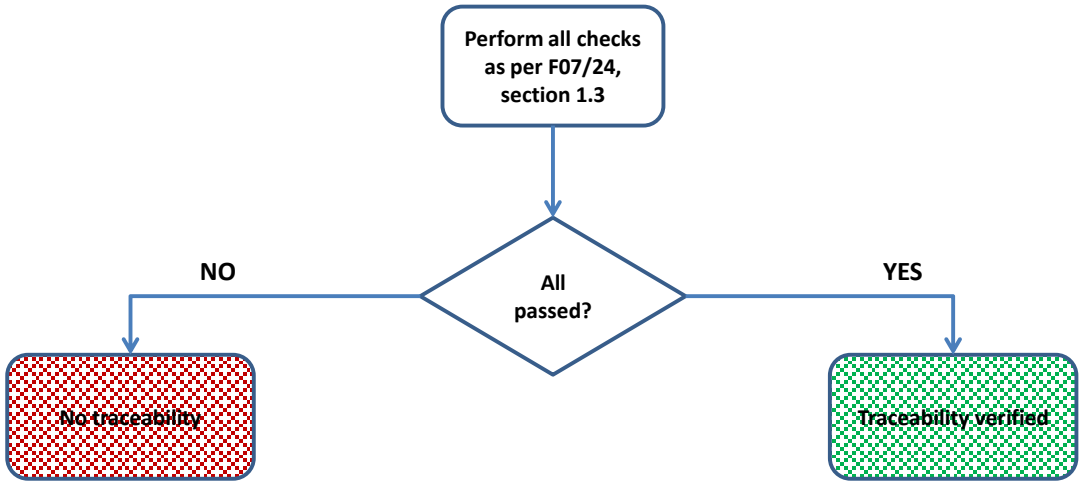
Numbers like 1.1 or 1.1.8 indicate section in checklist

TRACEABILITY FLOWCHART FOR CALIBRATION LABS, INCLUDING NMIs AND DIs, UNDER THE ILAC ARRANGEMENT ON CALIBRATION

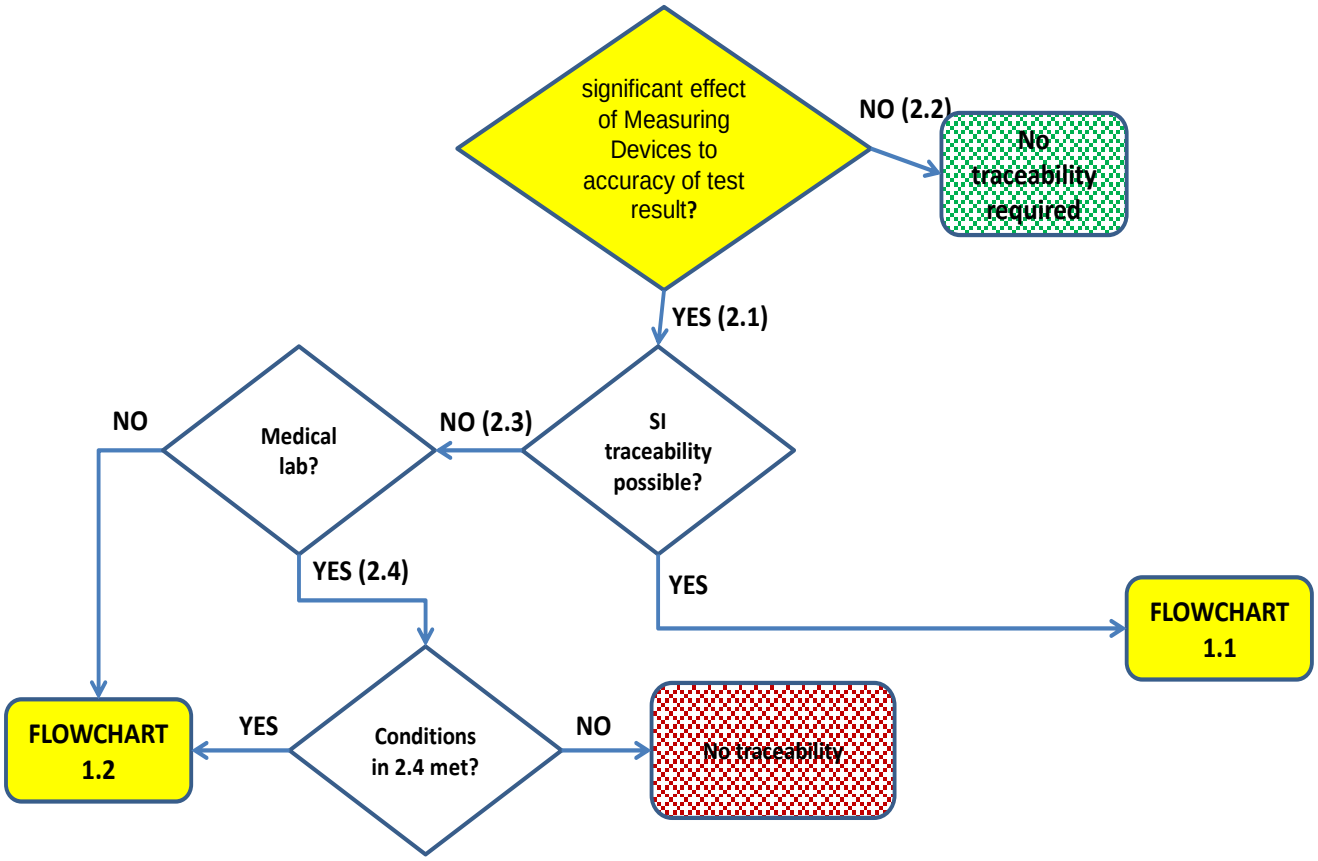


Numbers like 1.1 or 1.1.8 indicate section in checklist

TRACEABILITY FLOWCHART FOR IN-HOUSE CALIBRATION UNDER THE ILAC ARRANGEMENT ON CALIBRATION



This Chart is used as a guidance for assessors to assess traceability for testing and medical Laboratory



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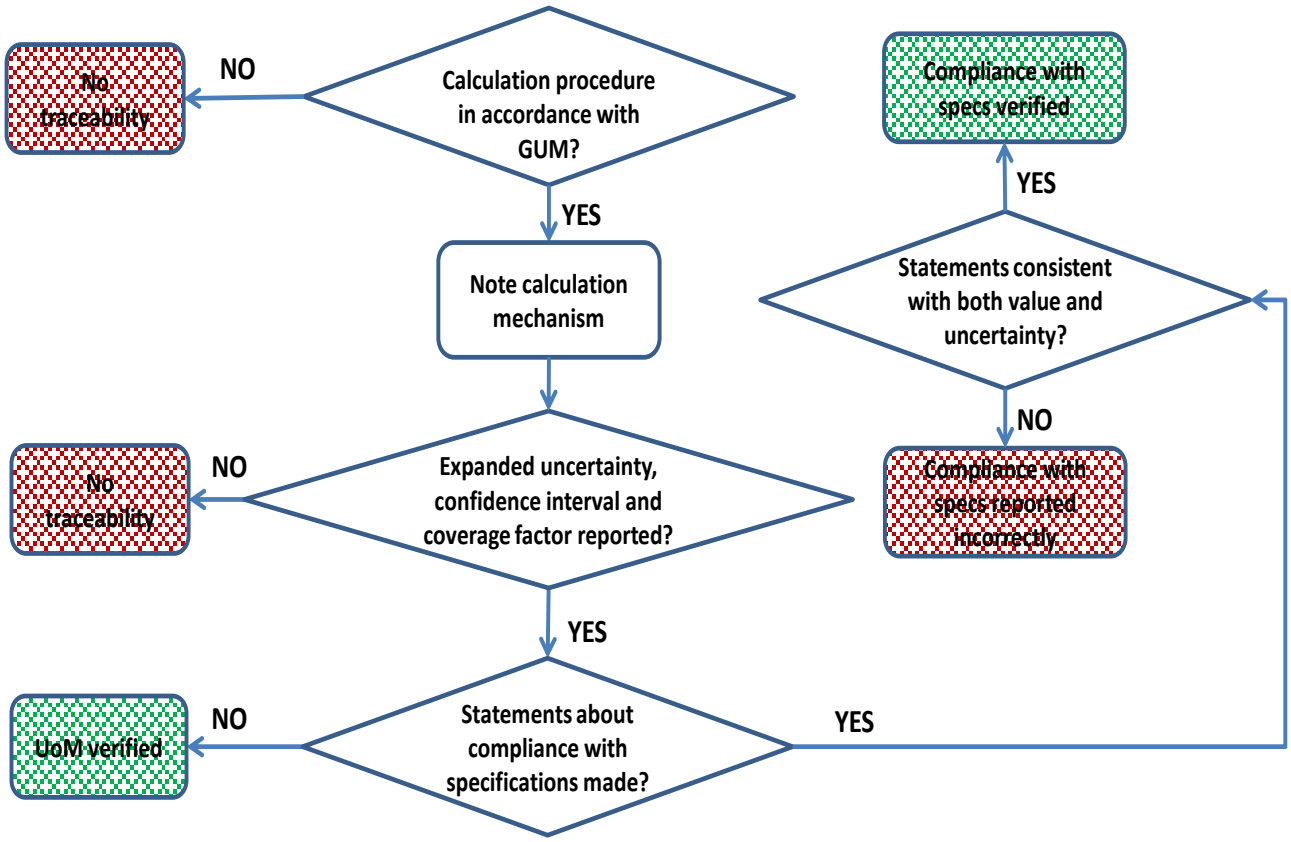
FLOWCHART FOR UNCERTAINTY OF MEASUREMENT (UoM)



Revision No.	Date approved	Revision History
1	2015-05-20	The title of the document was changed to Policy on the Traceability of Measurement Results Clause 3 was revised to include responsibility for the implementation of this document. Clause 4.8 was revised to make more clear how EAShandle the options to accept metrological traceability from accredited labs which are not covered by ILAC MRA or from NMIs which are not covered by CIPM MRA. Clause 4.8 was removed to make more clear how EAShandle the options to accept metrological traceability from accredited labs which are not covered by ILAC MRA or from NMIs which are not covered by CIPM MRA with conditions of similar to annex A on ILAC P10.
2	2015-10-29	Clause 4.2 was revised to describe routes of metrological traceability specially how it can be verified for non-accredited CAL labs and non MRA signatory NMIs
3	2016-03-01	Acronyms and definition of terminologies added to clarify and make document self-explanatory. Additional clause 5.7 was added to include Traceability through Reference Materials / Consensus Standards on page 7 of 8.
4	2016-05-25	Policy was re-written in response to AFRAC comments of 29 April 2016. Flow chart was added as Annex A on page 9 of 16
5	2016-08-30	Policy was re-written in response to AFRAC comments
6	2016-11-09	Under Clause 5.2 reference to ISO15189:2012 clause 5.6.3 was changed to clause 5.3.1.4 and ILAC GA resolution 8.12 was

		deleted.
1.7	2018-10-17	The document was revised according to the new ISO/IEC 17025:2017
1.8	2022-05-09	Added Term and definition CIPM, JCTLM, KCBD, Metrological Traceability Chain, Reference material producer, Removed >5% of total on the overall uncertainty and If an instrument is not being calibrated, evidence must be given that it contributes <5% of the total uncertainty from sub clause 5.1 Added particular measuring device shall be calibrated by ILAC MRA signatory accreditation body on part IIIa Remove the whole part of clause 5.3. Traceability of in-house calibrations
1.9	2021/05/11	The document is revised due to the name Ethiopian National Accreditation Office (ENAO) change to Ethiopian Accreditation Service (EAS) and new logo developed (ISO/IEC Guide 43-1 replaced by) ISO34:2016 under reference material definition
2.0	2023-02-07	• Correction done on page 1 that, this document was prepared by Meseret Tessema replaced by Zewdu Ayele (new quality manager). • Former director general was resigned and replaced by Mrs. Meseret Tessema.