KAN
Komite Akreditasi Nasional

POLICY ON TRACEABILITY OF MEASUREMENT RESULTS

KAN U-06

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF
ilac-MRA
APAC
ASIA PACIFIC ACCREDITATION COOPERATION

LIST OF AMENDMENT

No.	Date	Clause Number Revised	Brief Description of Changes
1	01 Oct 2020	5.2	Nomenclature change from KIM LIPI to SNSU

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Date of Issue: 1 October 2020

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1. INTRODUCTION

Acceptance of conformity assessment results in various activities around the world are largely determined by the reference of measurements used by the various stakeholders.

Metrological Traceability is an essential element that can facilitate acceptance of conformity assessment results.

Metrological Traceability of the measurement results to the SI is required by each country to participate actively in the global trade.

This document is intended for all calibration and testing laboratories, and inspection bodies, where testing and/or calibration is involved.

2. TERMS AND DEFINITIONS

The following definitions apply throughout this document :

Accredited Organization
Throughout this document, the term “Accredited Organization”, which includes CABs, is used to refer to organizations covered by the ILAC Arrangement. Whenever the term “Accredited Organization” is used in the text, it applies to both the applicant and the Accredited Organization, unless otherwise specified.

BIPM
Bureau International des Poids et Mesures
BIPM is the intergovernmental organization through which Member States act together on matters related to measurement science and measurement standards.

CAB
Conformity Assessment Body
Body that performs conformity assessment activities and that can be the object of accreditation.

CIPM MRA
International Committee for Weight and Measures Mutual Recognition Arrangement
The CIPM MRA – is an arrangement between National Metrology Institutes which provides the technical framework to assure the mutual recognition of national measurement standards and for recognition of the validity of calibration and measurement certificates issued by National Metrology Institutes.

CRM
Certified Reference Material
Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the

value of the specified property, its associated uncertainty, and a statement of metrological traceability

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

KCDB
Key Comparison Database
The 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 (VIM 3 clause 2.41)
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.

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.

Note1: The expression “traceability to the SI” means metrological traceability to a measurement unit of the International System of Units.

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.

RM
Reference Material
Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process

RMP
Reference Material Producer
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

3. POLICY ON TRACEABILITY IN CALIBRATION

The general requirements for traceability in ISO/IEC 17025 is described in Clauses 6.5.1. The further traceability requirement for laboratories is described in 6.5.2.

For equipment and reference standards that must be calibrated, KAN policy is that they shall be calibrated by:

3.1 The National Metrology Institute of Indonesia, Standar Nasional Satuan Ukuran (SNSU) – National Standardization Agency (BSN) or a national metrology institute of other countries whose service is suitable for the intended need and is covered by CIPM MRA,
or

3.2 A calibration laboratory accredited by KAN whose service is suitable for the intended need, bearing KAN accreditation symbols or reference to its accreditation status,

3.3 An accredited calibration laboratory whose service is suitable for the intended need and the accreditation body is covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC,

3.4 In case where it is not possible to obtain calibration for the required quantities from any of sources cited in 3.1 to 3.3, the sources of traceability as described in 3.5.1 or 3.5.2 is acceptable providing additional assurance is obtained as described in 3.5.3,

3.4.1 The National Metrology Institute of Indonesia or a national metrology institute of other countries whose service is suitable for the intended need but is not covered by the CIPM MRA;

3.4.2 A calibration laboratory whose service is suitable for the intended need but is not covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC;

3.4.3 A CAB using services of point 3.5.1 and 3.5.2 must therefore ensure that appropriate evidence for claimed traceability and measurement uncertainty is available. CAB need to have evidence of an assessment of calibration service provider similar to that which would be conducted by KAN. KAN will assess such evidence and the organisation 's ability to evaluate it. Consequently, this will add the duration of assessment;

Such evidence may include, but is not limited to the following:

a) Procedures and records of calibration method validation
b) Procedures for estimation of uncertainty and the associated
c) uncertainty budgets
d) Documentation for traceability of measurement results
e) Evidence of staff competence and authorization

f) Documentation for assuring the quality of calibration results
g) Documentation for accommodation and environmental conditions
h) On-site audit of the calibration laboratory

3.5 In-house calibration certificates and/or reports issued by the part of testing laboratories , inspection bodies and/or reference material producers . In-house calibration activities is not always necessary to be accredited separately as calibration laboratory. However to ensure the metrological traceability it should be assessed by the assessor and/calibration experts during the assessment of its parent organization. Organizations that perform calibrations in-house shall:

3.5.1 maintain documented procedures for in-house calibration and the in-house calibration shall be evidenced by the calibration report, certificate or sticker or other appropriate methods and calibration records shall be retained for an appropriate prescribed time;

3.5.2 maintain documented procedures for in-house calibration and the in-house calibration shall be evidenced by the calibration report, certificate or sticker or other appropriate methods and calibration records shall be retained for an appropriate prescribed time;

3.5.3 be able to demonstrate traceability to the SI system of unit by obtaining calibration services from accredited calibration laboratory or national metrology institute for its calibration reference standards;

3.5.4 have and apply the measurement uncertainty evaluation procedure. The uncertainty of measurement should be taken into account in the state conformance with specifications;

3.5.5 recalibrate its reference standards at appropriate intervals to ensure that the reference values are reliable. Policies and procedures for set and change the calibration interval should be based on historical behavior of the reference standard.

3.6 If the laboratory has demonstrated that the policy in Clause 3.1 to 3.6 of this document cannot be reasonably met, or the calibration cannot be strictly made in SI units, it is the responsibility of the laboratory to provide the appropriate evidence, e.g.

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

b. The use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

This evidence shall be documented and the documentation shall be assessed by KAN.

3.7 Special Circumstances

KAN recognizes that there are circumstances where a non-accredited laboratory can be used as follows:

3.7.1 Cases where the reference standard or M&TE warranty from the Original Equipment Manufacturer (OEM) will be deemed null and void should another calibration provider other than the OEM be used. Evidence of the warranty shall be maintained by the CAB. In this case Clause 3.5.2 applies.

3.7.2 Cases where the calibration must be performed by the OEM since proprietary software is needed to perform the calibration which is not made available by the OEM to the public through policy or pricing. Evidence that use of such software is required for the performance of the calibration shall be maintained by the CAB. In this case Clause 3.5.2 applies.

3.7.3 Cases where a piece of equipment is newly purchased with a non-accredited OEM calibration or where a piece of equipment is repaired and provided with a non-accredited OEM calibration. Where an accredited calibration is available from the OEM the laboratory shall obtain the accredited calibration.

4. OLICY ON TRACEABILITY IN TESTING, PROFICIENY TESTING PROVIDERS AND INSPECTION

4.1 The policy covers testing/measurernent by laboratories accredited to ISO/IEC 17025, ISO 15189, ISO/IEC 17043 and also by inspection body accredited to ISO/IEC 17020.

4.2 KAN policy on traceability in testing/measurement is as follows:

4.2.1 If the calibration of instrumerts used in testing contributes significantly to the overall uncertainty, the same policy for traceability in Clause 3 of this document applies.

4.2.2 If a calibration is not a dominant factor in the testing 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 me surement uncertainty of the test and therefore traceability does not need to be demonstrated.

4.2.3 In case where traceability to SI units is not applicable, inspection bodies must provide alternative evidence; of the correlation or accuracy of inspection results. This may be done, for example, by participating in a suitable proficiency testing program, or by using of certified reference materials provide by a competent supplier to give a reliable physical or chemical characterization of a material or by using specified methods or consensus standards that are clearly described and agreed by all parties concerned or by performing check calibrations/tests on audit samples or

materials provided by reputable outside bodies.

5. POLICY ON TRACEABILITY THROUGH REFERENCE MATERIALS (RMS) AND CERTIFIED REFERENCE MATERIALS (CRMS)

5.1 The traceability requirements for reference materials in ISO/IEC 17025 are described in Clause 6.5.2 and 6.5.3.

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

5.2 KAN policy on traceability provided by reference material producers is as follows:

a. The values assigned to CRMs produced by Standar Nasional Satuan Ukuran (SNSU) – National Standardization Agency (BSN) and other NMIs, which are listed in the BIPM KCDB, or produced by an accredited RMP under its accredited scope of accreditation to ISO 17034:2016, are considered to have established valid traceability. For values assigned to CRMs which are not covered by CIPM MRA, KAN shall review to accept the traceability based on other information such as international comparison (if available) and technical publication.
b. The values assigned to CRMs listed in the JCTLM database are considered to have established valid traceability.
c. RMs produced by other reference material producers are considered as critical consumables and the laboratory shall demonstrate that each RM is suitable for its intended use as required by ISO/IEC 17025 or ISO 15189 or ISO/IEC 17043.

6. REFERENCES

1. International Vocabulary of Metrology – Basic and General Concepts and Associated Terms VIM, 3rd edition, JCGM 200:2012 (JCGM 200:20008 with minor corrections) available from the BIPM homepage : *www.bipm.org* or ISO/IEC Guide 99:2007 available from ISO.
2. ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.
3. ISO/IEC 17043, General requirements for proficiency testing
4. ISO 15189, Medical laboratories – Particular requirements for quality and competence.
5. ISO 17034, General requirements for the competence of reference material producers.
6. ILAC-P10 – ILAC Policy on the Traceability of Measurement Results