Contents

1. Purpose ................................................................................................................................. 2
2. Scope ...................................................................................................................................... 2
3. Definitions ............................................................................................................................... 2
4. ENAS’s Policy on Traceability for Laboratories ................................................................. 3
5. Policy for traceability when performing tests and measurements ....................................... 5
6. Policy for traceability obtained through a reference material (RM) & certified reference material...... 6
7. Policy on Uncertainty of measurement .............................................................................. 7
8. In-house calibration by calibration and testing labs .............................................................. 8
9. Reference ................................................................................................................................. 10
1. Purpose
This document provides the ENAS policies on metrological traceability and uncertainty for calibration labs in accordance with ISO/IEC 17025 and ILAC P10 and P14.

2. Scope
These policies are applicable to all testing and calibration labs seeking ENAS accreditation.

3. Definitions
The following definitions apply throughout this document:

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.

In ISO/IEC 17025 and ISO 15189 the term “traceability” is equivalent to the VIM’s “Metrological traceability” and the term “traceability” is used throughout this document

BIPM (International Bureau of Weights and Measures)
The BIPM is an intergovernmental organization established by the Metre Convention, through which Member States act together on matters related to measurement science and measurement standards.

The key task of the Bureau is to ensure world-wide uniformity of measurements and their traceability to the International System of Units (SI).

CIPM MRA (International Committee for Weights and Measures Mutual Recognition Arrangement)
Signatories to the MRA include BIPM Member States, Associates of the BIPM General Conference on Weights and Measures, and other international organisations. The MRA provides a means of comparability of national metrology services including national measurement standards and calibration / measurement certificates issued by NMI’s.

JCTLM (Joint Committee for Traceability in Laboratory Medicine)
The joint committee includes the CIPM, IFCC (International Federation of Clinical Chemistry) and ILAC.

KCDB (BIPM Key Comparison Database)
The KCDB is a public website containing all information relating to the CIPM MRA, an arrangement establishing the equivalence of measurements made by, and certificates issued by, all the participating signatories.
The KCDB comprises two main sections, one containing information about the internationally recognised Calibration and Measurement Capabilities (CMCs) of the participating signatories and the other containing information about the comparisons supporting these CMCs.

**NMI (National Metrology Institute)**

NMIs 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. Australia’s national metrology institute is called the National Measurement Institute and is often referred by the same NMI acronym.

**4. ENAS’s Policy on Traceability for Laboratories**

4.1 This policy applies to:

   a. All ENAS applicant and accredited testing and calibration laboratories;
   b. All measurements, whether physical, chemical or biological;
   c. **Note:** It is acknowledged that the concept of metrological traceability of measurement results in fields such as the chemical, medical, and biological sciences is still under development.
   d. Calibrations performed by a facility for its own activities and which are not parts of its scope of accreditation (so called “in-house calibrations”).

4.2 Policy for Traceability when Performing Calibrations

For equipment and reference standards that have a significant effect on the reported result and associated uncertainty of measurement shall be calibrated by one of the following:

4.2.1 Services which are subject to peer review

   a) An NMI whose service is suitable for the intended need and is covered by the CIPM MRA. 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.

   **Notes:** Some NMIs may also indicate that their service is covered by the CIPM MRA by including the CIPM MRA logo on their calibration certificates, however, the fixing of the logo is not mandatory and the BIPM KCDB remains the authoritative source of verification.

   NMI from Member States participating in the Metre Convention may take traceability directly from measurements made at the BIPM. The KCDB provides an automatic link to the relevant BIPM calibration services (including the range and uncertainty). Individual calibration certificates issued by the BIPM are also listed.
b) An accredited calibration laboratory whose service is suitable for the intended need (i.e. the scope of accreditation specifically identifies the appropriate calibration) and accredited an accrediting body covered by the ILAC MRA for calibration.

Note: 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 recognised regional MRA e.g. Asia Pacific Laboratory Accreditation Cooperation (APLAC), may be included on the calibration certificate. Both of these options may be taken as evidence of traceability

4.3.1 Services which are not subject to peer review

The following two options should only be applicable when options a) and b) above are not possible for a particular calibration.

   c) An NMI whose service is suitable for the intended need but not covered by the CIPM MRA.

   d) A non-accredited calibration laboratory whose service is suitable for the intended need.

It is unlikely that a decision to choose option c) and d) will be made purely on economic grounds and is more likely to be a last resort. It should be noted that choosing one of these options will require significant effort by the facility i.e. it shall be required to demonstrate that there is evidence of claimed traceability and measurement uncertainty of the calibration services selected. This evidence will be reviewed by ENAS at assessments of the facility (which will add to the duration of assessments with associated additional fees reflective of the effort required).

The evidence the facility must maintain of the competence and claimed metrological traceability is likely to include but not be limited to the following:

- Audits of the calibration service provider
- Documentation for competence of staff
- Documentation for accommodation and environmental conditions
- Records of calibration method validation
- Procedures for estimation of uncertainty
- Documentation for traceability of measurements
- Documentation for assuring the quality of calibration results
In practical terms, the facility would need to have evidence of an assessment of the calibration service provider similar to that which would be conducted by an accreditation body which is signatory to the ILAC MRA.

Accreditations granted by ENAS are accepted as proof to ensure the competence of calibration laboratories and to rely on their services to establish an efficient metrological traceability.

4.3 When Calibrations cannot be strictly Traceable to SI Units

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:

- use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterisation of a material; and
- use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

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

This can only apply when the laboratory has demonstrated that options a) to d) cannot reasonably be met. It is the responsibility of the laboratory to choose a way to satisfy the clause and to provide the appropriate evidence which shall be reviewed by ENAS at assessments of the facility.

5. Policy for traceability when performing tests and measurements

For tests and measurements:

e) If the results of calibration of equipment used contributes significantly to the overall uncertainty, the same policy for traceability applies (as detailed above).

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

5.1 When traceability to SI units is not possible

Where traceability of measurements to SI units is not possible and/or relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories.
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 may be 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
- mutual consent standards or methods which are clearly established, specified, characterised and mutually agreed upon by all parties concerned

Accordingly, where traceability to SI units cannot be achieved, the same criteria as covered in 4.3 shall apply.

**6. Policy for traceability obtained through a reference material (RM) & certified reference material (CRM)**

Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Values associated with RMs may not be metrologically traceable. Values associated with CRMs are, by definition, metrologically traceable.

Traceability is considered to have been established where:

- **g)** The values assigned to CRMs are produced by NMLs and included in the BIPM KCDB or produced by an accredited Reference Material Producer (RMP) under its accredited scope of accreditation to ISO 17034.  
  Note: RMPs accredited by a signatory to a regional body e.g. Asia Pacific Laboratory Cooperation (APLAC), are considered to have established valid traceability.

- **h)** The values assigned to CRMs covered by entries in the JCTLM database are considered to have established valid traceability.

- **i)** 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 ISO/IEC 17025 or ISO 15189.
7. Policy on Uncertainty of measurement

This policy applies to both accredited and applicant laboratories that are seeking ENAS accreditation.

Calibration laboratories

1. Calibration laboratories shall have documented procedure for the estimation of measurement uncertainty.
2. Calibration laboratories shall report its calibration measurement capability (CMC) on its scope of accreditation in accordance with ILAC document P14.
3. Calibration laboratories shall report their measurement of uncertainty on all calibration certificates in accordance with ISO/IEC 17025.
4. Calibration laboratories shall maintain records of calibration personnel. These records shall demonstrate the technical competence of the personnel performing calibration, including the estimation of uncertainty of measurement.

Testing laboratories

1. The laboratory shall carry out a needs assessment for all tests in the scope (or proposed scope) of accreditation and define what actions are necessary with regards to determining and reporting the uncertainty. A policy/procedure covering this requirement shall be documented and records maintained for individual tests.
2. Testing laboratories shall have a documented procedure for the estimation of measurement of uncertainty.
3. The needs assessment matrix shall group the tests into the categories defined below:

   Category 1
   Qualitative or semi-qualitative tests that require no uncertainty budgets (tests that are exposure or environmental simulation only such as Salt Spray as per ASTM B117 etc., tests where the result is numerically rated by judgement, such as Tap Adhesion as per ASTM D3359 or tests where results are a comparison from a reference plaque such as Microstructure as per ASTM A247).

   Category 2
   A test performed to well recognized test methods that specify limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results as defined in ISO/IEC 17025. (e.g., Tensile Properties of Plastics as per ASTM D638, Compression Properties of metals as per ASTM E9, Tension Testing of Metals as per ASTM E8)

   Category 3
Physical, chemical, environmental or biological/microbiological test methods based on published regulatory or consensus methods: such as APHA, AOAC, ASTM, BS for which uncertainty is not defined in the method. Uncertainty may be estimated using the standard deviation of laboratory control samples for more than 50 points for these types of test.

**Category 4**

Laboratory-developed and non-standard methods. This will include standard methods that have been modified where the modification may affect the measurement uncertainty that needs identification of all components and detailed measurement uncertainty budgets. Budgets are to be calculated in accordance with published methods that are consistent with ISO “Guide to the Expression of Uncertainty of Measurements”.

4. Category 1 and 2 do not require estimation of uncertainty. Category 3 and 4 require varying degrees of rigor when estimating the measurement of uncertainty.

5. Testing laboratories shall report measurement uncertainty where applicable in accordance with ISO/IEC 17025.

**Implementation**

The calibration laboratories shall apply their procedures for estimating measurement of uncertainty and shall be able to show records of it being implemented for a period of at least 3 months prior to the assessment.

The testing laboratories shall apply their procedures for estimating uncertainty of measurement and be able to show records of it being implemented for a period of at least 3 months prior to the assessment. These records shall include the individual needs assessment for all tests.

8. **In-house calibration by calibration and testing labs**

In-house calibration systems aim to calibrate measuring equipment of the laboratory for its own standards. Traceability of measurement results in such a system needs to result in a suitable calibration measurement capability for the tests and calibrations involved.

The nature and scope of in-house calibration may differ depending on needs and capability of the laboratory in order to assure sufficient uncertainty of performed measurements. Accreditation of in-house calibrations is not always necessary. When assurance of traceability of the relevant measurement is necessary, the following conditions shall be fulfilled:

a. Calibration procedures shall be documented, calibration results shall be presented as certificates, reports etc. and measurement notes should be stored for the fixed period of time,
b. Competency of personnel involved in performing calibration should be documented; the documentation of trainings and evidence of competency (i.e. in the form of results of exams or results of audits in the scope of calibrations) shall be stored.

c. Traceability of calibration results to national or international standards shall be documented.

d. Uncertainty of measurement estimation procedures shall be consistent with the GUM and this uncertainty of measurement shall be taken into consideration when reporting compliance with specification.

e. Reference standards shall be calibrated at fixed intervals in order to assure their reliability; policy and procedures for establishing and changing these intervals shall be documented.

Where laboratories are undertaking calibrations of equipment using certified reference materials (CRMs) or reference materials (RMs), the onus will be on the laboratories to demonstrate to ENAS that:

i. Sufficient reference materials are held by the laboratory to calibrate the relevant items of equipment over their intended measurement ranges;

ii. Full records are kept of the identity and source of each certified reference material and/or reference material;

iii. In cases where certified reference materials are used, these materials are supplied by a recognized national institution. Full documentation of the certified values of these materials and the mode of validation of the certified values shall be held;

iv. In cases where it is necessary to use commercially prepared chemical standards as reference materials, that the claimed values of each batch of these chemicals are verified before use and records of verification are held;

v. Where necessary, all precautions have been taken to match the matrices of the reference materials to those encountered in the laboratory’s test samples or that the laboratory has determined and accounted for the effects of any non-matching of matrices.

Laboratories are asked to advise ENAS of any doubts about the assigned values of reference materials and laboratories are encouraged to refer all such doubts, together with supporting technical details, to the producers of the materials concerned.

The requirement for measurement traceability is not applicable to laboratories when the calibration contributes little to the total uncertainty of the examination result. In such cases, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed. This may be achieved by internal calibrations or verifications, or by
calibrations performed by a laboratory which need not satisfy the criteria but which should be competent.

Designated officers of the laboratory shall be assigned the responsibility for the calibration of equipment and management of reference materials.

Where an external calibration laboratory is used, the laboratory shall also be informed of the calibration requirements, including the ranges, the cardinal points, the required calibration uncertainties and the conditions under which calibrations are to be performed.

9. Reference

ILAC-P10: ILAC Policy on Metrological Traceability
ILAC P14: ILAC Policy on Uncertainty for Calibration Laboratories
VIM - International Vocabulary of Basic and General Terms — Basic and general concepts and associated terms
UKAS M3003 Expression of Uncertainty and Confidence in Measurement