Contents

1. Purpose

1.1 This document describes the ENAS requirements on metrological traceability as a key parameter to ensure confidence in the results of calibrations, testing and inspections performed by conformity assessment bodies (CAB) accredited by ENAS.

1.2 By setting its requirements on this document, ENAS acknowledges metrological traceability is an important concept to guarantee comparability of measurement results both nationally and internationally.

1.3 The requirements in this document aim to ensure the accreditations granted by ENAS are accepted as proof to ensure the competence of calibration laboratories and to rely on their services to provide metrological traceability.

2. Scope

2.1 These requirements are applicable to all testing, medical and calibration laboratories seeking ENAS accreditation (applicants and accredited) as per the metrological traceability requirements from ISO/IEC 17025 and ISO 15189 Standards. These requirements may also be applied to other conformity assessment activities where testing and/or calibration is involved such as inspection (ISO/IEC 17020) and product certification (ISO/IEC 17065).

2.2 For calibrations performed by a laboratory in order to establish metrological traceability for its own activities, and which are not a part of the laboratory's scope of accreditation (known as internal calibrations or "In-house" calibrations), the ENAS requirements in sections 4 and 5 below are applicable.

3. Definitions

3.1 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.

ISO/IEC 17025 and ISO 15189 refer to the VIM´s term of "metrological traceability

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'.

BIPM (International Bureau of Weights and Measures)

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.

CIPM MRA (International Committee for Weights 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

JCTLM (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.

KCDB (BIPM 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).

NMI (National Metrology Institute)

National Metrology Institute (NMI) and Designated Institutes (DI) maintain measurement standards in countries (or regions) all over the world. Throughout this document, the term “NMI” is used to cover both a National Metrology Institute as well as a Designated Institute.

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 (ISO 17034:2016).

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 (ISO 17034:2016).

EXAMPLE Human serum with assigned quantity value for the concentration of cholesterol and associated measurement uncertainty stated in an accompanying certificate, used as a calibrator or measurement trueness control material.

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 (ISO 17034:2016).

4. ENAS General Requirements for Calibration and Metrological Traceability

4.1 Any measurement equipment used for testing and/or calibration activities shall be calibrated before being placed or returned into service when:

- the measurement accuracy or measurement uncertainty affects the validity and/or uncertainty of the reported results, and/or

- calibration of the equipment is required to establish the metrological traceability of the reported results.

4.2 The CAB 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, leading to an appropriate reference. The CAB shall guarantee the level of comparability and confidence in the results required by ensuring its measurement results are traceable to the International System of Units (SI) (Figure 1), or by reference to a natural constant or other stated reference.

4.3 The CAB shall request proper metrological traceability as one of the purchasing terms and conditions when approving externally calibration services providers and evidence of that shall be provided to ENAS assessment team.

4.4 The CAB shall establish, review and adjust a calibration programme to maintain confidence in the metrological traceability and status of calibration of its measurement equipment. It is an obligation of the CAB to justify the need (or no need) for calibration.

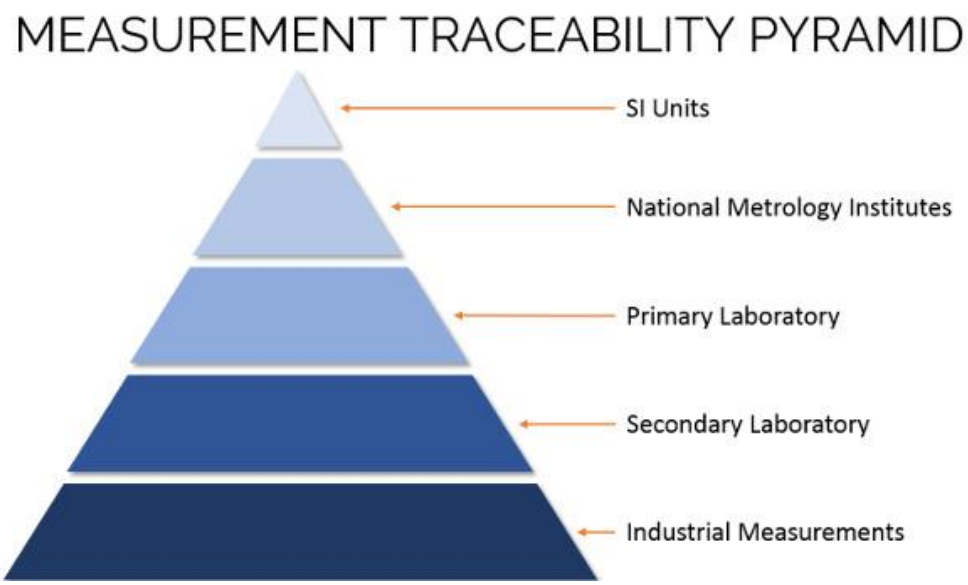

Figure 1 – Measurement Traceability Pyramid.

4.5 Maintenance of traceability in calibration programmes shall be supported by suitable calibration intervals of measuring instruments. Guidance can be found in ILAC relevant document (see section 8).

4.6 ENAS is aware that there may be situations in its accreditation activities where metrological traceability to the SI is not technically possible, measurement traceability options described in the section 5 next cannot be reasonably met, or even results may not be metrologically traceable. When that ensues, the CAB shall be responsible for providing the appropriate evidence and demonstrate metrological traceability to an appropriate reference by using:

a) certified values of certified reference materials or reference materials of the higher metrological order available, provided by a competent producer approved by ENAS (see section 7). It is considered that certified values of certified reference materials from reference materials producers conforming to ISO 17034 Standard provide metrological traceability.

b) results of reference measurement procedures, mutual consent methods or standards of the higher metrological order available that are clearly described, validated and accepted by all parties concerned as providing measurement results fit for the intended use.

Note: Documentation of calibration traceability to a higher order reference material or reference procedure may be provided by an examination system manufacturer. Such documentation shall be acceptable as long as the manufacturer's examination system and calibration procedures are used without modification.

In these situations, CAB's evidence of its metrological traceability shall be supported by conducting internal quality control activity and investigation such as:

- internal quality control activity based on systematic assessment of factors influencing the result (sources of error or magnitudes of influence);
- internal quality control activity based on systematic assessment of method robustness through variation of controlled measurement parameters or conditions;
- examination or calibration by another procedure/method, equipment;
- ratio or reciprocity-type measurements;
- documentation of statements regarding reagents, procedures or the examination system when traceability is provided by the supplier or manufacturer, as long the statements are applied without modification (medical laboratories);
- evaluation of measurement uncertainty of the results based on understanding of theoretical principles of the method and outcomes from the relevant internal quality control activity.

Additionally, the CAB shall carry out external quality control activity by participation in suitable proficiency testing and/or interlaboratory comparison programs as per ENAS requirements in the document ETR 02.

Note: In medical laboratories, Calibration Verification and Linearity (CVL) activity is considered suitable internal quality control technique when it is conducted by the laboratory. It shall be considered interlaboratory comparison suitable to demonstrate traceability when it is carried out by a group of peer laboratories with as high metrological level as possible, and meeting the requirements in ENAS document ETR 02. CVL is considered especially suitable in those cases where traceability is more difficult to establish due to lack of international reference materials (e.g. biological sample examination).

4.7 CAB shall provide evidence to justify its metrological traceability, calibration programme and proper implementation to ENAS assessment team.

5. ENAS Requirements for Traceability in Calibration Laboratories

5.1 Calibration laboratories shall establish metrological traceability of their measurement results by applying one or several of the following approved paths:

a) National Metrology Institutes (NMI) or Designated Institutes (DI) which calibration and measurement capabilities (CMC) are suitable for the intended need and are recognized under the CIPM MRA (International Committee of Weights and Measures Mutual Recognition Agreement). Services covered by the CIPM MRA can be viewed in the International Bureau of Weights and Measures Key Comparison Database (BIPM KCDB) which includes CMCs 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.

NMIs 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) Calibration laboratories whose calibration and measurement capabilities (CMC) are suitable for the intended use and are accredited by an accreditation body subject to the ILAC (International Laboratory Accreditation Cooperation) Arrangement or to Regional Arrangements recognized by ILAC for calibration. Scopes of accredited laboratories are publicly available from their respective accreditation bodies.

Note: Some calibration laboratories indicate that their services are 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 (APAC), may be included on the calibration certificate. Both of these options may be taken as evidence of traceability.

c1) National Metrology Institutes (NMI) or Designated Institutes (DI) which calibration and measurement capabilities (CMC) are suitable for the intended use but are not recognized under the CIPM MRA (International Committee of Weights and Measures Mutual Recognition Agreement).

c2) Calibration laboratories which calibration and measurement capabilities (CMC) are suitable for the intended use but are not accredited by an accreditation body subject to the ILAC (International Laboratory Accreditation Cooperation) Arrangement or to Regional Arrangements recognized by ILAC for calibration.

5.2 Routes a) or b) shall be the ones chosen by laboratories seeking ENAS accreditation because they mean metrological traceability of their measurements is demonstrated through the use of calibration services that have been subject to relevant peer review or accreditation.

5.3 Options c1) or c2) shall not be chosen based on purely economic considerations, and they shall be a last resort only when a) or b) are not technically possible for a particular calibration. The reason for that is that in routes c1) and c2) measurement traceability is not supported by objective peer review or accreditation process.

It should be noted that choosing one of these options, c1) or c2), will require significant effort by the CAB, i.e. it shall be required to demonstrate that there is appropriate evidence for claimed metrological traceability and measurement uncertainty of the calibration services to appropriate SI reference. Evidence shall include, but shall 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(s) to guarantee metrological traceability requirements are properly met. That assessment shall be aligned with ISO/IEC 17025 Standard relevant requirements and similar to that which would be conducted by an accreditation body which is signatory to the ILAC MRA, and aligned with. This evidence will be reviewed by ENAS at assessments of the CAB (which may add to the duration of assessments with associated additional fees reflective of the effort required).

5.4 Where traceability to SI units, or by reference to a natural constant or other stated reference, is not possible or relevant, ENAS requirements for traceability are as described in clause 4.6 above.

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

6. ENAS Requirements for Metrological Traceability in Testing and Medical Laboratories

6.1 Regarding traceability of tests and measurements, the following options shall be considered:

a) If the calibration of instruments used in testing contributes significantly to the overall uncertainty, the same requirements for metrological traceability applies as detailed in section 5 above.

b) If the result of a calibration is not a dominant factor/contribution in the testing result, the laboratory shall have quantitative evidence (analysis of magnitudes of influence and uncertainty budget) 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.

6.2 Where metrological traceability to SI units, or by reference to a natural constant or other stated reference, is not possible or relevant, ENAS requirements for metrological traceability are as described in clause 4.6 above.

7. ENAS Requirements for metrological traceability obtained through a reference material (RM) & certified reference material (CRM)

7.1 Measurement results shall, where possible, be traceable to SI units through certified reference materials (CRMs).

7.2 Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials (RMs). Metrological traceability based on use of RMs shall be to the reference material of the higher metrological order available.

7.3 Whenever values associated with RMs are not metrologically traceable (e.g. biological sample examination in medical laboratories), clause 4.6 of this document applies

Note: Values associated with CRMs are, by definition, metrologically traceable.

7.4 Metrological traceability shall be considered to have been established where:

a) The values assigned to CRMs are produced by NMIs and included in the BIPM KCDB.

b) The values assigned to CRMs are covered by entries in the JCTLM (Joint Committee for Traceability in Laboratory Medicine) database.

c) The values assigned to CRMs are produced by an accredited Reference Material Producer (RMP) under its accredited scope of accreditation to ISO 17034 Standard.

d) The values assigned to RMs are produced by a competent provider which shall be approved by ENAS after evaluation by assessment team by considering the materials as critical consumables according to relevant requirements by ISO/IEC 17025 or ISO 15189 standards.

Additionally, the laboratory shall demonstrate that each RM or CRM is suitable for its intended use through proper implementation of the internal and external quality control measures described in the clause 4.6 of this document.

8. Reference

- ILAC-P10: ILAC Policy on the Traceability of Measurement Results.
- ILAC G24: “Guidelines for the determination of calibration intervals of measuring instruments.
- ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
- ISO 15189 Medical laboratories - Requirements for quality and competence
- JCGM 200:2012: International vocabulary of metrology – Basic and general concepts and associated terms (VIM) - 3rd edition