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NAB-MALTA

TECHNICAL GUIDE

ATG11 - Metrological Traceability of Measurement Results

Policy of the NAB-MALTA

Revision 10 June 2021

FOREWORD

Accreditation is the mechanism to assure customers of the competence of laboratories and other types of conformity assessment bodies.

The National Accreditation Board of Malta (NAB-MALTA) is the single national accreditation body appointed as per Article 4 of Regulation (EC) 765/2008 with responsibility for accreditation in accordance with the relevant normative documents. It operates a management system which complies with the requirements established in EN ISO/IEC 17011.

International trade relies on certificates and reports issued by competent bodies. Confidence in certificates and reports is achieved by accreditation. Confidence in accreditation is based on a series of confidence building steps between the accreditation bodies and accredited conformity assessment bodies and the assurance given by the accreditation body that the accredited conformity assessment body constantly implements the relevant criteria and maintains and continuously develops its competence as defined in the relevant standard. This assurance is achieved through accreditation which includes regular assessments and other types of accreditation activities.

The services of the NAB-MALTA are accessible to all applicants whose requests fall within the current activities as offered by the NAB-MALTA. Access is not conditional upon the size of the applicant laboratory or membership of any association or group.

For the scope of this guide, the masculine gender shall also refer to the feminine gender.

SCOPE OF PUBLICATION

This publication describes the policy of the NAB-MALTA with regards to the metrological traceability of measurement results as established in accreditation standards including EN ISO/IEC 17025, EN ISO 15189, EN ISO/IEC 17020 and EN ISO/IEC 17065. This policy shall be read together with **ILAC-P10**.

This is a mandatory document and comes into effect from 1st July 2021.

Contents

1. Terms and Definitions

1.1 **Metrological Traceability** (**International Vocabulary of Metrology, 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. Note 1: Clause 2.41 states that a "reference" can be a "definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard."

1.1.1 In EN ISO/IEC 17025, EN ISO 15189, EN ISO/IEC 17020, EN ISO/IEC 17065 and other standards used to assess Conformity Assessment Bodies (CABs), the term "traceability" is equivalent to the VIM's "Metrological Traceability" and the term "traceability" is used throughout this document.

1.2 **Metrological Traceability Chain (VIM 3 clause 2.42)** – Sequence of measurement standards and calibration that is used to relate a measurement result to a reference.

1.3 **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.

1.3.1 The expression "traceability to the SI" means metrological traceability to a measurement unit of the International System of Units.

1.4 **National metrology Institutes (NMI) and Designated Institutes (DI)** maintain measurement standards in countries (or regions) all over the world. The term NMI will be used throughout this document to cover both National Metrology Institutes and Designated Institutes.

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

1.6 **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. (EN ISO17034:2016)

1.7 **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. (EN ISO17034:2016)

1.8 **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 (EN ISO17034:2016)

1.9 **JCTLM** – The 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 recognised and accepted equivalence of measurements in Laboratory Medicine and traceability to appropriate measurement standards.

1.10 **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 Measurements Capabilities (CMCs) (https://www.bipm.org/kcdb).

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

1.12 **EA** – European Co-operation for Accreditation (http:///www.european-accreditation.org)

1.13 **MLA** – Multilateral Agreement

2. NAB-MALTA policy on metrological traceability in calibration

2.1 The general requirement for metrological traceability in EN ISO/IEC 17025 is:
"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."

2.2 Clause **6.5.2** in EN ISO/IEC 17025 states that *"The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through a) calibration provided by a competent laboratory""*. When metrological traceability is required, the measuring equipment shall be calibrated by:

2.2.1. An NMI whose service is suitable for the intended use and is covered by the CIPM MRA. Services covered by the CIPM MRA can be viewed in the BIPM KCDB, which includes the CMC's for each listed service.

Note 1: 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.

Note 2: NMIs from Member States participating in the Metre Convention may take metrological 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.

or

2.2.2 An accredited calibration laboratory whose service is suitable for the intended use (i.e., the scope of accreditation specifically covers the appropriate calibration) and the Accreditation Body is covered by the EA or ILAC Arrangement or by Regional Arrangements recognised by ILAC.

Note: In line with Regulations RAB02, only certificates bearing the accreditation symbol or a text reference to the accreditation of the calibration laboratory can benefit fully from the recognition that the EA MLA and, ILAC MRA and other recognised regional counterparts bring.

Calibration laboratories can indicate that their service is covered by the EA or ILAC Arrangement by including on the calibration certificate:

- The combined EA MLA /ILAC MRA mark, or
- The accreditation symbol of the Accreditation Body (that is a signatory to the EA/ILAC Arrangement) or the reference to its accredited status

Both of these options can be taken as evidence of metrological traceability.

or

2.2.3 An NMI whose service is suitable for the intended use but not covered by the CIPM MRA. In this case the CAB shall ensure that those services meet the relevant criteria for metrological traceability on ISO/IEC17025. The requirements of Clause 2.5 shall be followed.

or

2.2.4 A laboratory whose calibration service is suitable for the intended need but not covered by the EA/ILAC Arrangement or by Regional Arrangements recognised by EA. In this case the CAB shall ensure that those services meet the relevant criteria for metrological traceability on ISO/IEC17025. The requirements of Clause 2.5 shall be followed.

2.3 CABs that have demonstrated metrological traceability of their measurement results through the use of calibration services offered according to 2.2.1 or 2.2.2 above have made use of services that have been subject to relevant peer review or accreditation.

2.4 Options 2.2.3 and 2.2.4 should only be applicable when options 2.2.1 and 2.2.2 are not possible for a particular calibration. The choice of options 2.2.3 or 2.2.4 shall not be made on purely economic grounds and shall be the last resort if the other options are unavailable.

2.5 When using option 2.2.3. or 2.2.4. the CAB shall ensure that appropriate evidence for claimed metrological traceability and measurement uncertainty is available and such evidence shall be subject to an assessment by the NAB-MALTA. Appropriate evidence for the technical competence of the calibration service supplies and claimed metrological traceability shall include but not be limited to the following (numbers refer to clauses in EN ISO/IEC 17025):

- records of calibration method validation (7.2.2.4)
- procedures for evaluation of measurement uncertainty (7.6)
- documentation and records for metrological traceability of measurement results (6.5)
- documentation and records for ensuring the validity of calibration results (7.7)
- documentation and records for competence of personnel (6.2)
- records for equipment which can influence laboratory activities (6.4)
- documentation for facilities and environmental conditions (6.3)
- audits of the calibration laboratory (6.6 & 8.8)

2.6 For non-accredited calibration service suppliers it shall be noted that it may be necessary to perform a practical assessment of the calibration supplier used, similar to that which is carried out by the NAB-MALTA against the standard EN ISO/IEC 17025, to ensure that competent works is actually being

performed. The CAB shall have to demonstrate that it has the appropriate competence to carry out such a task.

2.7 There may be very exceptional cases where it might be very difficult for the laboratory to obtain the necessary records as per Clause 2.5 and carry out an assessment as per Clause 2.6. This may happen for a very specialised item of equipment and the manufacturer might be the only body capable of performing the calibration. Evidence will still be needed to ensure compliance with the applicable accreditation standard. The NAB-MALTA assessment team will review such a case to check whether it will be possible to accredit such a test/calibration or any related conformity assessment activity where such a calibration will have an influence on the conformity assessment results.

3. Policy for Metrological Traceability provided through Reference Material Producers (RMPs) through Certified Reference Materials (CRMs)

3.1 **EN ISO/IEC 17025** Clause 6.5.2 b traceability requirements in relation to reference materials include that when reference materials are used, traceability can be achieved from *"certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI".*

3.2 **EN ISO/IEC 17020** traceability requirements in relation to reference materials include:

"6.2.10 Reference materials shall, where possible, be traceable to national or international reference materials, where they exist."

3.3 The NAB-MALTA policy in regard to metrological traceability provided by Reference Material Producers (RMPs) through Certified Reference Materials (CRMs) is that the certified values assigned to CRMs are considered to have established valid metrological traceability when:

3.3.1 CRMs are produced by NMIs using a service that is included in the BIPM KCDB.

or

3.3.2 CRMs are produced by an accredited RMP under its scope of accreditation and the Accreditation Body is covered by the EA MLA , ILAC MRA or by other Regional Arrangements recognised by ILAC.

or

3.3.3 The certified values assigned to CRMs are covered by entries in the JCTLM database.

3.4 Where CRMs are produced by non-accredited RMPs, CABs shall demonstrate that CRMs have been provided by a competent RMP and that they are suitable for their intended use.

4. Policy when Metrological Traceability to the SI is not technically possible

4.1 When metrological traceability to the SI is not technically possible, the CAB shall ensure that it shall:

4.1.1 choose a way to satisfy metrological traceability requirements are satisfied by using certified values of certified reference materials provided by a competent producer.

or

4.1.2 documents the results of a suitable comparison to reference measurement producers, specified methods, or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use. Evidence of this comparison shall be assessed by the NAB-MALTA.

Note: When metrological traceability to solely SI unit is not appropriate or applicable to this application, a clearly defined measurand should be selected. Establishing metrological traceability therefore includes both the proof of identity of the property measured and the comparison of the results to an appropriate stated reference. The comparison is established by ensuring the measurement procedures are properly validated and/or verified, that measuring equipment is appropriately calibrated and that conditions of measurement (such as environmental conditions) are under sufficient control to provide a reliable result.

Note: Surplus test materials are often available from PT providers. It should be checked whether the PT provider can provide additional stability information to demonstrate the ongoing stability of the property values and matrix of the test material. If this cannot be provided, these test materials should not be considered as an alternative way to ensure the validity of results.

5. NAB-MALTA policy on metrological traceability in testing (including medical), inspection and certification of products, processes and services

5.1 In **EN ISO/IEC 17025** the requirements for traceability in testing laboratories are:

6.4.6 Measuring equipment shall be calibrated when:

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

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

5.2 In **EN ISO15189** the requirements for traceability in medical laboratories are:

"5.3.1.4 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."

5.3 In **EN ISO/IEC17020** the requirements for traceability in inspection bodies are:

"6.2.7 The overall programme of calibration of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the inspection body are traceable to national or international standards of measurement, where available. Where traceability to national or international standards of measurement is not applicable, the inspection body shall maintain evidence of correlation or accuracy of inspection results."

5.4 In **EN ISO/IEC17065** the requirements for traceability in certification bodies for products, process and services shall meet the applicable requirements of the relevant international standard and/or as specified by the various certification schemes (with requirements established by the scheme owners).

5.5 If the calibration of instruments used in testing, inspection and/or certification contributes significantly to the overall uncertainty, all the clauses under Sections 2 to 4 shall apply.

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

6. General requirements for calibration

6.1 The requirements of **EN ISO/IEC 17025** for calibration include:
"Measuring equipment shall be calibrated when the measurement accuracy or measurement uncertainty affects the validity of the reported results."

6.2 Calibrated equipment shall be used whenever values to be measured as specifically stated in standards and other similar documents.

6.3 Where the calibration of equipment is technically straightforward, it will be acceptable for CABs to calibrate their own equipment, in a competent manner, against suitable reference standards. In such cases, the CAB shall follow the requirements established in **ATG15 – NAB-MALTA Policy on the Performance of In-House Calibrations**.

6.4 Laboratories holding only management systems certification will be deemed to have not demonstrated the necessary technical competence.

6.5 Calibration certificates issued by equipment manufacturers or agents are generally not acceptable evidence of external traceability, unless these are clearly identified as having been issued by an acceptably accredited calibration laboratory, as defined in Section 2 of this policy.

6.5.1 In case of very specialised item of equipment with a single source of calibration refer to Clause 2.7.

6.6 Intervals between calibrations of measuring standards and measuring equipment shall be established by the CAB on the basis of stability, purpose and usage. Manufacturers and/or calibration laboratories may issue recommendations for the intervals between calibrations; however it is the CAB's responsibility to determine the adequate frequency between calibrations.

6.6.1 Intervals shall be established so that recalibration occurs prior to any probable change in accuracy that is of significance to the use of the equipment. Depending on the results of preceding calibrations, intervals of calibration shall be shortened, if necessary, to ensure continued accuracy.

6.6.2 Regular checks, normally referred to as **intermediate checks**, may be necessary between in between the calibration period. This depends upon use and the frequency of full calibration and shall be made according to the laboratories policies and procedures. Results of intermediate checks shall be recorded and maintained.

6.6.3 The selection of a conservatively short initial calibration interval and documented reviews of these intervals in the light of calibration results are features of a good calibration system. A guide to the selection of calibration intervals is given in **OIML (International Organisation of Legal Metrology) International Document No. 10 / ILAC G24:2007**.

7. REFERENCES

7.1 The following are important reference documents:

ATG15	Performance of In-House Calibrations – The Policy of the NAB-MALTA
RAB02	The Use of the Accreditation Symbol, Text Reference to Accreditation and Reference to EA MLA Signatory Status
VIM	International Vocabulary of Metrology – Basic and General Concepts and Associated Terms, 3rd edition, JCGM 200:2012
EN ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
EN ISO/IEC 17020	Requirements for the operation of various types of bodies performing inspections
EN ISO/IEC 17065	Conformity assessment – Requirements for bodies certifying products, processes and services
EN ISO 15189	Medical laboratories – Particular requirements for quality and competence
EN ISO 17034	General requirements for the competence of reference material producers.

7.2 Documents are available for download from the following websites:

NAB-MALTA: http://www.nabmalta.org.mt

EA: http://www.european-accreditation.org/documents.html

ILAC: http://www.ilac.org

BIPM: http://www.bipm.org

7.3 Standards are available for purchase from the Malta Competition and Consumer Affairs Authority (MCCAA).

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DO YOU NEED FURTHER INFORMATION?

This publication, application forms and other information about accreditation including this document, are available for download from the NAB-MALTA website at http://www.nabmalta.org.mt.

The EA (European Co-operation for Accreditation) publications referred to in this document are available for free download from http://www.european-accreditation.org.

Should you need any further information we advise you to contact us.

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