GUIDANCE ON THE APPLICATION OF THE LABORATORY ACCREDITATION CRITERIA

TRACEABILITY OF MEASUREMENT

ESYD GA 2

Issue: 02
Revision: 00
Issue Date: 14-03-1997
Revision Date: 03-02-2023
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1. INTRODUCTION

1.1 A basic requirement of calibration and testing laboratories is the calibration of the working **measuring** instruments with **measuring** instruments **or standards** of better accuracy which are calibrated again in one or more calibration procedures to national standards, such as those maintained by a National Institute of Metrology. This ability to relate measurements to appropriate measurement standards, following an unbroken chain of calibrations, is referred to as measurement traceability.

1.2 The official requirements of the National Accreditation System for traceability of measurements are defined in accordance with the standards ELOT EN ISO/IEC 17025:2017, ELOT EN ISO 15189:2012 (only for medical laboratories) and the ILAC-P10:07/2020 guideline. This Guideline provides additional clarifications and instructions on how to achieve traceability. Calibration and testing laboratories applying for accreditation to ESYD, must meet all these requirements before being granted accreditation by ESYD.

1.3 ESYD requires that all measurements which are necessary for the correct performance of a calibration or test are traceable, where the concept of traceability is applicable in practice, to the units of the SI (Systeme international d'unites) system, to the realization of a physical constant, to another recognized standard, or to reference material, certified or not. The way in which this policy is to be applied is specified in section 2. This traceability requirement applies to any measurements that may significantly affect the result of the calibration or test or its validity.

1.4 In some areas of testing, such as chemical, microbiological and forensic testing, reference materials are used as reference measurement standards. ESYD requires, where possible, that these reference materials are traceable to national measurement standards or national or international reference material standards and have been produced in a technically valid manner. The specificity of this policy is provided in paragraph 2.**4.**

2. PROVISION OF OFFICIAL TRACEABILITY ASSURANCE

2.1 Calibration laboratories

2.1.1 Appropriate external calibration laboratories for providing traceability are the following:

1) A National Institute of Metrology, which provides calibration services appropriate for the intended use, covered by the CIPM MRA mutual recognition agreement. These services are listed in the BIPM KCDB database, which also provides (CMCs - **Calibration Measurement Capabilities**) information of the range and the uncertainty for each service provided **by the relevant National Metrology Institute**; or
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 ILAC Agreement or by Regional Arrangements recognized by ILAC **such as the EA-MLA** *(ILAC P10_07/2020 sect.2 par. 2)* or

3a) A National Institute of Metrology whose suitable for the intended use but not covered by the CIPM MRA (**i.e. does not have published CMCs for those services in the BIPM-KCDB database). In such a case, according to ILAC-P10:07/2020, the Accreditation Body shall establish a policy to ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025. -see relevant Annex I on the policy of ESYD.**

3b) A calibration laboratory whose calibration services is suitable for the intended use, but not covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC. **In this case, the Accreditation Body shall establish a policy to ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025. -see relevant Annex II on the policy of ESYD.**

2.1.2. Options 3a) and 3b) shall be selected only if options 1) and 2) **are not possible for documented reasons and in specific calibration cases**. Also, in the case of options 3a) and 3b), the laboratory under evaluation shall document the technical competence of the laboratory providing the calibration services.

NOTE

Where metrological traceability in the SI is not technically feasible, it is the responsibility of the accredited body to:

(a) Choose a way to satisfy metrological traceability requirements by using certified values or certified reference materials (CRMs) provided by a competent producer, or

(b) Document the results of a suitable comparison to reference measurement procedures, specified methods, or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use.

(c) Participation in inter-laboratory comparisons, for example in the case of empirical methods.

NOTE: When metrological traceability to solely SI units is not appropriate or applicable to the 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 the conditions of measurement (such as environmental conditions) are under sufficient control to provide a reliable result.

2.2 Testing laboratories

(For accreditation according to ISO 17025:2017 and ISO 15189)

2.2.1 For calibrations that, based on the measurement uncertainty budget, contribute significantly to the **combined** measurement uncertainty, the criteria and the requirements for establishing traceability for calibration laboratories shall be applied.

2.2.2 If the laboratory wishes to exclude the calibration of a part of the equipment, it shall document that the contribution of the corresponding uncertainty to the final measurement uncertainty is negligible (non-critical calibration).

2.2.3 In the case of accreditation of medical laboratories according to ELOT EN ISO 15189:2012, the requirements of par. 5.3.1.4 of ELOT EN ISO 15189:2012 shall be applied.

2.3. Calibration, testing and medical laboratories

(For accreditation according to ISO 17025:2017 and ISO 15189)

2.3.1 Calibration Laboratories shall apply the metrological traceability requirements of paragraph 2.1 for all calibrations that are considered into the uncertainty budgets of their measurements. In addition, as part of the dissemination of traceability, Calibration Laboratories shall make the necessary corrections based on the errors/deviations in the calibrations of their reference standards used for the calibration of other metrological standards and measuring instruments.

2.3.2. Testing Laboratories

1) **For calibrations that, based on the measurement uncertainty budget, contribute significantly to the combined uncertainty of the measurement, the criteria and traceability assurance requirements mentioned above for calibration laboratories shall be applied.**
2) **If they wish to exclude the calibration of a piece of equipment, they shall document that the contribution of the corresponding uncertainty to the final uncertainty of the measurement is negligible ("non-critical" calibration), as well as take into account the results of a relevant risk analysis, i.e. what would be the impact of measurement errors using the measuring equipment in question on the trueness of the measurement results of the method.**

2.3.3 In the case of accreditation of medical laboratories according to ELOT EN ISO 15189:2012, the requirements of par. 5.3.1.4 of ELOT EN ISO 15189:2012 shall be applied.

2.4 Use of Reference Materials (RM) and Certified Reference Materials (CRM)
(For accreditation according to ISO 17025:2017 and ISO 15189)

2.4.1 The reference value of an RM is not considered, by default, traceable, however the use of a CRM ensures (by definition) traceability to the corresponding SI system units.

2.4.2 ESYD's policy on the traceability of materials provided by Reference Material Producers (RMPs) is reflected in the following:

- The reference value of a CRM, which is produced by a National Metrological Institute and included in the BIPM KCDB database, or produced by an accredited (**RMP as part of its accredited scope and the relevant Accreditation Body complies with the ILAC-MRA or regional agreements recognized by ILAC e.g. EA-MLA)** according to ISO 17034:2016, as part of its scope of Accreditation, is considered to be metrologically traceable.
- CRM reference values, which are covered by corresponding entries in the JCTLM database, are also considered metrologically traceable.
- RMs and CRMs produced by other RMPs that do not fall into the above two categories may be considered as critical consumables for the quality of the tests performed and the laboratory shall document that each RM and CRM used is suitable for the intended use (clause 6.6.1 of ISO **17025:2017).**

Surplus test materials are often available from proficiency testing (PT) providers. It should be checked whether the PT provider can provide additional stability information to demonstrate the ongoing stability of the property value 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.

2.4.3 Further information, either on the bodies providing traceable calibrations or on the suitability of reference materials, can be obtained by ESYD.

3. Internal calibrations of test equipment

Calibration and testing laboratories may calibrate in house their measuring equipment. This activity shall be subject to all the relevant specifications and requirements of ESYD for calibration laboratories and shall be assessed by ESYD as if the laboratory were accredited as a provider of the relevant services.

NOTE: An internal calibration normally leads to the determination of appropriate metrological properties of the instrument under calibration, such as measurement uncertainty and errors/deviations from actual values. Internal controls in which a laboratory makes comparisons between the measurement indications of an appropriately calibrated measuring instrument and another instrument under test, do not constitute calibration, but only an indicative means of control.

4. IF IT IS DIFFICULT TO PROVE TRACEABILITY

4.1 It is recognized that for some types of measurement, traceability to national and international measurements standards cannot be easily established or demonstrated. An example is the measurement of complex material properties such as textural and physico-chemical characteristics of papers, fabrics and yarns. Even in the case of complex physical properties or complex equipment, where it is not possible to achieve traceability, it is often possible to distinguish either individual measurement parameters or parts of the equipment where traceability is important and can be established. ESYD usually provides guidance on what is appropriate for any given situation.

4.2 In cases where measurements that significantly affect the outcome of calibration or testing, traceability to national or international standards is not possible, laboratories shall be prepared to provide alternative evidence to correlate their results. This may be done, for example, by participating in an appropriate proficiency testing program, inter-process comparisons or by performing calibration/inspection tests on inspection samples or on materials provided by reliable external bodies.

REFERENCES

[1] ΕΛΟΤ EN ISO/IEC 17025:2017 «General Requirements for the competence of testing and calibration laboratories»

[2] a) EN ISO 15189:2012 «Medical laboratories - Requirements for Quality and Competence»
b) EN ISO 15189:2022 «Medical laboratories - Requirements for Quality and Competence»

[3] ILAC P10:7/2020 «ILAC Policy on the Traceability of Measurement Results»

[4] EA-4/02 M:2022 «Evaluation of the Uncertainty of Measurement in Calibration»,

[5] JCGM 100 «Evaluation of Measurement data - Guide to the expression of Uncertainty in Measurement», BIPM (2008) – πρώην GUM 1995 with minor modifications

ANNEX I

ESYD's Policy for calibration services provided by National Metrology Institutes, which are not covered by CIPM-MRA (paragraph 3a in paragraph 2.1.1. of GA 2)

Calibration services provided by National Institutes of Metrology, which are not covered by the CIPM-MRA agreement, i.e. do not correspond to specific lines of published CMCs (Calibration Measurement Capabilities) of the specific National Institutes of Metrology are accepted, according to paragraph 3a of par.2.1.1. of the GA2 of E.SY.D., under the following conditions.

In cases where there are no other calibration services covered by CIPM-MRA, i.e. covered by published CMCs, in the specific metrological field (measurement quantities), the following conditions apply:

1. **These services must be covered by an implemented Management System (MS), in accordance with the requirements of ISO 17025:2017. Indicatively, written procedures for calibration methods, internal audits, issuing certificates, calculation of measurement uncertainty, etc., shall be implemented, therefore it is necessary to be audited and reviewed. The National Metrology Institutes should be able to provide, on request, relevant documentation, such as a list of applicable documents of MS.**
2. **These calibrations shall be covered by successful participation in internationally recognized interlaboratory schemes over a 10-year period, such as those organised under EURAMET. National Metrology Institutes should be able, on request, to provide relevant documentation, such as an appropriate register of their interlaboratory participations, reflecting the criteria for successful participation.**
3. **These calibrations shall be traceable to the SI system using appropriately calibrated reference standards. National Institutes of Metrology should be able to provide, on request, relevant documentation with reference to the numbers of the relevant calibration certificates of the reference standards.**
4. **If requested by ESYD, the National Metrology Institute should be able to provide documentation on the equipment used, the suitability of the facilities and conditions used and data from inspections.**
5. **The staff of the National Metrology Institutes directly involved and carrying out these calibrations and applying the relevant procedures above, has the necessary technical competence. National Metrology Institutes should be able, upon request, to document the technical competence of their staff employed in these services by providing summary information regarding: a) qualifications, b) experience in the relevant field of metrology/verification and other related fields, c) participation in international technical committees in the relevant field and related fields, d) other relevant qualities (such as accreditation assessor, EURAMET peer reviewer, etc.).**

   In cases where in the specific metrological field (measurement quantities), there are other provided calibration services covered by CIPM-MRA, i.e. covered by published CMCs, the following shall apply:

   A special case of acceptable calibration services provided by National Metrology Institutes is one in which: a) these services are part of a service scope that includes other similar services, for the same or related quantities, covered by CIPM-MRA, i.e., by CMCs and also b) are at a higher metrological level (lower measurement uncertainty) than the provided calibration services or even c) are perfectly relevant.

Note - Features and illustrative examples are given:
Example for (a) and (b) above relates to calibration services for calibration of calipers, micrometers, rules, etc. (not included in CIPM-MRA), which belong to the same field of measurement (length), in which also calibration services of standard length plates covered by CIPM-MRA is included, i.e. they have published CMCs.
Example for (a) and (b) above refers to calibration services for standard length calibrations of standard plates with comparison of more than 100 mm, where the Institute has published CMCs for calibrations of plates up to 100 mm in length with comparison.
Example for (a) and (c) above refers to temperature chamber calibration services (not included in CIPM-MRA), which belong to the same measurement field (temperature), in which also temperature sensor calibration services covered by CIPM-MRA is included, i.e. they have published CMCs.

ANNEX II ESYD 's Policy for calibration services provided by calibration laboratories, which are not covered by the ILAC-MRA calibration (paragraph 3b in par. 2.1.1. of GA2)

Appropriate evidence of the technical competence of the non-accredited ILAC mutual recognition agreement calibration service provider and the claimed metrological traceability may include, but are not limited to the following (numbers in parentheses refer to par. and subparagraphs of ISO 17025:2017):

- **Records and documentation for metrological traceability of measurement results (6.5)**
- **Records and documentation for ensuring the validity of results (7.7)**
- **Records for equipment that may affect laboratory activities (6.4)**
- **Records and documentation for facilities and environmental conditions (6.3)**
- **Records of calibration method validation (7.2.2.4)**
- **Procedures for the assessment of measurement uncertainty (7.6)**
- **Records and documentation for technical competence of personnel (6.2)**
- **Audits of the calibration laboratory (6.6 and 8.8)**

In order to verify the above, it may be necessary for the laboratory providing the calibration services to perform an assessment of the laboratory under assessment (second-party assessment), similar to that which an accreditation body would perform to assess its technical competence.