**GUIDANCE ON THE APPLICATION OF THE LABORATORY ACCREDITATION CRITERIA**

# TRACEABILITY OF MEASUREMENT

**ESYD GA 2**

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## 1. INTRODUCTION

1.1 It is an established practice for laboratories in various fields of calibration and testing to have their working instruments calibrated against more accurate instruments or standards, and for those standards to be checked back in turn, in one or more calibration steps, against national standards such as those held by a National Metrology Institute (NMI). This ability to relate measurements back to appropriate measurement standards, through an unbroken chain of calibrations, is referred to as traceability of measurement.

1.2 The formal ESYD requirements for traceability of measurement are set out in ELOT EN ISO/IEC 17025:2005, ELOT EN ISO/IEC 15189:2012 (only for medical laboratories) and in the Guidance Publication ILAC P10:01/2013. This publication provides specifications and guidance for the ways of achieving traceability of measurement. Calibration and testing laboratories applying for ESYD accreditation have to meet all of these requirements before ESYD accreditation can be granted.

1.3 ESYD requires that all measurements necessary for the proper performance of a calibration or test are traceable, where the concept of traceability is applicable in practice, through the units of the International System of units SI (Systeme International d' unites), the realization of a fundamental physical constant, other recognized standard, or certified reference material, or reference material. The way of implementation of this policy is analyzed in paragraph 2. This requirement for traceability applies to any measurements that may significantly affect the result of the calibration or test or its validity.

1.4 In some fields of testing, such as chemical, microbiological and forensic analysis, much use is made of reference materials as reference measurement standards. ESYD requires that, wherever possible, such reference materials be traceable to national standards of measurement or to national or international standard reference materials and have been produced in a technically valid manner. The specific requirements for this policy are given in paragraph 2.3.

## 2. PROVIDING FORMAL ASSURANCE OF TRACEABILITY

2.1 **Calibration Laboratories**

2.1.1 Suitable external calibration laboratories providing traceability of measurement are:

1) An National Metrological Institute 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.

or

2) An accredited calibration laboratory whose scope of accreditation specifically covers the appropriate calibration, accredited by ESYD or other Accreditation Body which participate to the ILAC Arrangement or Regional Arrangements recognized by ILAC. or

3a) An National Metrological Institute NMI whose service is suitable for the intended need but not covered by the CIPM MRA..or

3b) A calibration laboratory whose service is suitable for the intended need but it is not accredited by ESYD or other Accreditation Body which participate in the ILAC Arrangement or Regional Arrangements recognized by ILAC.

2.1.2 The possibilities 3a) and 3b) should only be selected in case the routes 1) and 2) are not possible either in Greece either abroad. In case of selection of routes 3a) or 3b) the assessed laboratory must provide the appropriate evidence for the technical competence of the calibration laboratory for its metrological traceability. Some evidence for the technical competence of the laboratory and claimed metrological traceability is likely to include but not be restricted to the following:-(numbers refer to clauses in ISO/IEC17025:2005):

- Calibration of the standards of the laboratory according the cases 10 and 2) of the paragraph 2.1.1 (5.6.1)
- Results from participation in interlaboratories Comparison (5.9.1)
- Suitability of the equipment and environmental conditions (5.5.1 & 5.3)
- Records of calibration method validation (5.4.5)
- Procedures for estimation of uncertainty (5.4.6)
- Documentation for assuring the quality of calibration results (5.9)
- Documentation for competence of staff (5.2)
- External Audits of the calibration laboratory (4.6.4 and 4.14)
- Content of the calibration report (5.10)

For the documentation of the above, it should be noted that it may be necessary to perform a practical assessment of the laboratory used, similar to that which would be undertaken by an Accreditation Body (second party certification), to ensure that competent work is actually being performed.

2.1.3 In cases where traceability to national standards is not feasible to the units of the SI system, in order to achieve the required traceability of measurements, the laboratory shall use the techniques that are described in paragraph 5.6.2.1.2 of ISO 17025:2005 (use of certified reference materials, use of specified methods and consensus standards etc).This possibility can only be accepted in cases where routes 1) to 3) of the paragraph 2.1.1 are not feasible. Adequate assurance for the use of the above mentioned techniques must be available during the assessment by ESYD.

2.2 **Testing Laboratories**
(*Accreditation according ISO 17025:2005 and ISO 15189:2012)*

2.2.1. For calibrations that according the uncertainty budget of the measurement they have a significant affect on the result, the requirements for traceability are the same with the requirements mentioned above for the calibration laboratories..

2.2.2. If the testing laboratory wants to exclude the calibration of a part of equipment, must provide the appropriate documentation that the contribution of this uncertainty does not significantly affect the uncertainty budget of the measurement ( not a critical calibration ).

2.2.3. In case of accreditation of medical laboratories according standard ΕΛΟΤ EN ISO 15189:2012, requirements of paragraphs 5.3.1.4 of ΕΛΟΤ EN ISO 15189:2012 must be fulfilled.

**2.3 Use of Reference Materials – RM and Certified Reference Materials – CRM**
*(Accreditation according ISO 17025:2005 and ISO 15189:2012)*

2.3.1. Reference value of a Reference Material is not traceable without the required documentation, however the use of a Certified Reference Material ensures (by definition) the required traceability to the SI units.

2.3.2 ESYD's policy concerning the traceability of materials that are produced from Reference Material Producers (RMP), reflected in the following:

- The values assigned to CRMs produced by NMIs and included in the BIPM KCDB or produced by an accredited RMP under its accredited scope of accreditation to ISO Guide 34:2009, are considered to have established valid traceability.
- The values assigned to CRMs covered by entries in the JCTLM database are considered to have established valid traceability.
- 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 clause 4.6.2 in ISO 17025 :2005

2.3.3 Further information or advice on where to seek traceable calibrations and on the use of reference materials may be obtained from ESYD.

**3 In-house calibration of test equipment**

It is acceptable for testing laboratories to calibrate their own test equipment provided that they can demonstrate their competence. This activity must meet all the requirements of ESYD for the calibration laboratories and it is assessed by the Accreditation Body the same way with an accredited calibration laboratory.

**4. IF TRACEABILITY IS DIFFICULT TO ESTABLISH**

4.1 It is recognized that, for some types of measurement, traceability to national standards is not easily established. Examples are measurements of complex properties of materials such as textural and physic-chemical characteristics of papers, cloths and yarns. Even with complex physical properties or complicated equipment where comprehensive traceability is not feasible, it is often possible to distinguish individual parameters of the measurement or components of the equipment where traceability is practicable and essential. ESYD normally provides guidance on what is appropriate for any given situation.

4.2 In cases where traceability to national standards is not feasible for measurements that have a significant bearing on the calibration or test result, laboratories must be prepared to provide alternative evidence of the correlation of their results. This may be done, for example, by participating in a suitable proficiency testing program, interlaboratory comparisons, or by performing check calibrations/tests on audit samples or materials provided by reputable outside bodies.

**REFERENCES**

[1] ΕΛΟΤ EN ISO/IEC 17025 (2005)

[2] EN ISO 15189 «Medical laboratories - Requirements for quality and competence « (2012)

[3] ILAC P10 «ILAC Policy on the traceability of measurement results» (2013)

[4] EA-4/02 M «Evaluation of the uncertainty of measurement In calibration», EURAMET (2013)

[5] JCGM 100 «Evaluation of measurement data - Guide to the expression of uncertainty in measurement», BIPM (2008) – previous GUM 1995 with changes