GUIDANCE ON THE APPLICATION OF THE LABORATORY ACCREDITATION CRITERIA

TRACEABILITY OF MEASUREMENT

ESYD GA 2

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TRACEABILITY OF MEASUREMENT

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. The national network of laboratories, with a NMI at the apex, enabling traceability of measurement to be achieved, constitutes the national measurement system in a country.

1.2 The formal ESYD requirements for traceability of measurement are set out in ELOT EN ISO/IEC 17025, and in the Guidance Publication GA1, Measurement and Calibration Systems. Calibration and testing laboratories applying for ESYD accreditation have to meet all of these requirements before ESYD accreditation can be granted.

1.3 In summary, ESYD requires that:

(a) All measurements necessary for the proper performance of a calibration or test whose accuracy may significantly affect the accuracy or validity of such calibrations or tests are traceable, where the concept is applicable in practice, through an unbroken chain of calibrations to national or international standards of measurement or to a certified reference material, as described in paragraph 2.1 and Section 5 of this publication.

(b) Each calibration in the traceability chain is carried out to appropriate technical requirements, which may be more or less stringent according to the situation concerned (see paragraph 2.2).

(c) Laboratories provide formal documented assurance that the requirements (a) and (b) above have been met - normally by having their measuring and testing equipment, including measurement standards, calibrated by a laboratory of the Greek national measurement system, or-of the national measurement system of a country which is a signatory to the European Accreditation-EA Multilateral Agreement, except the cases of paragraph 6, by using

certified reference materials and by holding official certificates from the laboratories they use (see sub-Section 3.1).

(d) All calibration certificates issued by an accredited laboratory contain a statement about traceability of measurement, uncertainty and confidence levels. Details of how to satisfy ESYD requirements for estimating and reporting uncertainty of measurement in calibration certificates are given in EA Document EA-4/02.

1.4 In some fields of testing, such as chemical 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.

1.5 This publication provides only general guidance for laboratories and assessors on the application of ESYD requirements for traceability. Details of HAS traceability requirements in specific fields of measurement and testing, and how these may be satisfied, are given in other relevant ESYD or EA publications.

2. CALIBRATION AND TRACEABILITY OF MEASUREMENT

2.1 Traceability of measurement is essential if the results of various measurements are to be comparable and if uncertainty of measurement is to be meaningfully assigned. ESYD requires that all measurements necessary for the proper performance of a calibration or test be traceable, where the concept is applicable, to national or international standards of measurement or, when using reference materials, to national or international reference materials. This requirement for traceability applies to any measurements that may significantly affect the result of the calibration or test or its validity, including subsidiary measurements, Thus, in the measurement of the emf of standard cells, both the measurement of the internal resistance of the cell and the measurement of the temperature of the oil bath used must be traceable to national standards. Likewise, in the testing of concrete cubes to BS 1881, not only should the load calibration of the compression testing machine be traceable to national standards, but measurements to establish cube weight should also be traceable to national standards.

2.2 If the ESYD requirement for traceability is to achieve its purpose, not only must an unbroken chain of calibrations exist, but every calibration in the traceability chain must be carried out in a technically sound manner; the staff, equipment/reference materials, environment and procedures involved in the calibration must be adequate for the task involved and must be controlled. The precise technical requirements that are appropriate for any given calibration depend on a number of features, including the accuracy sought in the calibration, the nature of the equipment/reference materials involved and the use to which the calibrated equipment is to be put.

2.3 For most types of calibration or test, it is necessary for the calibrations to be carried out in accordance with quite stringent technical requirements at all stages of the calibration chain; thus the calibration of a materials testing machine against a proving ring or load cell has to be carried out according to an established procedure by suitably trained and experienced operators.

2.4 For more straightforward types of measurement (or for subsidiary measurements whose accuracy does not significantly affect the result or its validity), the technical requirements at the lower end of the traceability chain may well be less stringent; thus in spread-of-flame tests, the stopwatch used to measure time interval (which is the principal measurement involved in this case) may reasonably be calibrated by staff testing it against broadcast time signals.

2.5 Specific guidance on what is appropriate in individual situations will be provided by ESYD wherever necessary.

3. PROVIDING FORMAL ASSURANCE OF TRACEABILITY

3.1 External calibrations

3.1.1 If confidence is to be placed in calibration and test results, there must exist formal assurance that the conditions of paragraphs 2.1 and 2.2 of this publication are met. Thus the measurements must be traceable back to national standards or national/international reference materials through an unbroken chain of calibrations, normally by using a laboratory of the national measurement system. The appropriate technical requirements for each calibration in the traceability chain must have been met.

3.1.2 For many measurements, ESYD normally requires calibration laboratories to provide the necessary assurance of traceability by having their calibration equipment calibrated by a laboratory holding the relevant national standard, or by a laboratory designated for the purpose by ESYD. A designated laboratory may be a ESYD accredited laboratory considered capable of providing traceable calibrations with appropriate levels of uncertainty, or a laboratory recognized for the purpose through the EA Multilateral Agreement (except the cases of par 6).

3.1.3 Testing laboratories are normally expected to provide the necessary assurance of traceability by having their test equipment calibrated by a laboratory that holds ESYD accreditation or accreditation from a laboratory accreditation body which is a signatory to the EA Multilateral Agreement. For certain specialized or particularly accurate types of calibration, it may be necessary for testing laboratories to use the services of laboratories holding the national standard as described in paragraph 3.1.2.

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

3.2 Calibration certificates for external calibrations

3.2.1 Where a laboratory requires traceability for its own test equipment or reference standards from external sources, the calibration certificate must be of a type that assures this traceability. A calibration certificate bearing the ESYD logo or the logo of the equivalent organization referred to in paragraphs 3.1.2 and 3.1.3 of this publication will give assurance of adequate traceability. In the case where a calibration certificate is not bearing the ESYD logo or the logo of an equivalent organization which is a signatory to the EA Multilateral Agreement, the laboratory shall provide to the ESYD Assessment team the Calibration Certificate of the standard equipment by which the calibration was carried out. This Certificate shall bearing the ESYD logo or the logo of an

equivalent organization which is a signatory to the EA Multilateral Agreement, or the calibration of the standard equipment shall have been carried out by a National Metrology Institute. If those evidences are not provided to the assessment team the calibration certificate is not acceptable. However, it will still be necessary for the laboratory receiving the calibration certificate to verify that the extent and accuracy of the calibration is sufficient for its needs. Normally this will be achieved by requiring a calibration to be performed that demonstrates compliance with a published specification for the equipment. In some cases specific instruction on the extent of calibration will need to be given to the calibration laboratory with the order for the calibration.
It is clarified that an ESYD accredited calibration laboratory shall only issue calibration certificates bearing ESYD logo for measurements that are in its Accreditation Scope. ESYD also accepts calibration certificates, issued by National Metrology Institute, being MRA member.

3.2.2 Testing laboratories must also ascertain whether an instrument is no longer performing within specified requirements by the time of calibration. They must record any such anomalies, and must take appropriate steps to notify any laboratory clients whose work has been affected.

3.3 In-house calibration of test equipment

3.3.1 Where the calibration of test equipment is technically straightforward, it is acceptable for testing laboratories to calibrate their own test equipment provided that they can demonstrate their competence and show that the calibration is done in accordance with the requirements of ELOT EN ISO/IEC 17025 and the Guidance Publication ESYD GA1. Suitable reference measurement standards that have been calibrated by laboratories of a national measurement system must be used and the procedure must be documented. Where the laboratory has to use a reference material as the measurement standard, it must ensure that the material has been certified as having been produced and characterized in a technically valid manner. The certificate must, wherever possible, provide evidence of traceability to national or international standards of measurement, or to national or international standard reference materials. The use of organizations, operating to the ISO 9000 series of standards for the production of reference materials, which also perform their analysis or testing activities in accordance with ELOT EN ISO/IEC 17025, would provide assurance of the quality of reference materials.

3.3.2 Where in-house calibrations are performed, ESYD assessors will seek assurance of the laboratory's internal traceability by examining the laboratory's calibration system and the laboratory's competence to carry out the appropriate measurements. The assessors will be concerned with the suitability of any measurement standards/materials the laboratory may hold, and with the laboratory's capability to calibrate its working instruments against such measurement standards/materials. The assessors will consider, among

other things, the adequacy of the laboratory's re-calibration schedule, taking into account the previous calibration record of the measuring instruments concerned, as well as any existing authoritative recommendations, such as those laid down in standard specifications or given by expert bodies or manufacturers of the equipment.

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.

4.3 For some tests, failure to achieve traceability at some stage of the measurement or testing process is likely to have a less significant effect upon the accuracy or validity of the calibration or test result than, for example, operator performance. In such cases ESYD may require that all laboratories accredited for such tests participate in a proficiency testing program.

5. TRACEABILITY TO MEASUREMENT STANDARDS OUTSIDE GREECE

5.1 ESYD requires laboratories to demonstrate traceability of their measurements to national measurement standards and to national measurement standards of other countries.

5.2 For a number of calibrations, traceability may have to be to a measurement standard outside Greece. In these circumstances ESYD will advise on standards that can be recognized. Normally these will be standards held by other national standards laboratories or provided by laboratories accredited by the signatories to the EA Multilateral Agreement.

5.3 Traceability to national measurement standards of other countries is also accepted for certain test measurements. Such traceability is permitted, for example, where particular tests or types of test are carried out to a technical specification that requires traceability to the national measurement standards of the country in which the specification has been published.

5.4 Where, in the circumstances described above, a testing laboratory chooses to establish the traceability of its measurements to a national measurement standard maintained outside Greece, calibration laboratories of the country concerned will probably be involved in the traceability chain. Adequate assurance must be available regarding the calibrations that such laboratories perform. Calibration certificates issued by a calibration laboratory outside Greece may be regarded as providing the necessary assurance if an agreement for the recognition of such certificates has been reached by ESYD. For example, participants in a EUROMET Agreement or the EA Multilateral Agreement for calibration laboratories all operate calibration services that issue certificates that would normally be acceptable to ESYD.

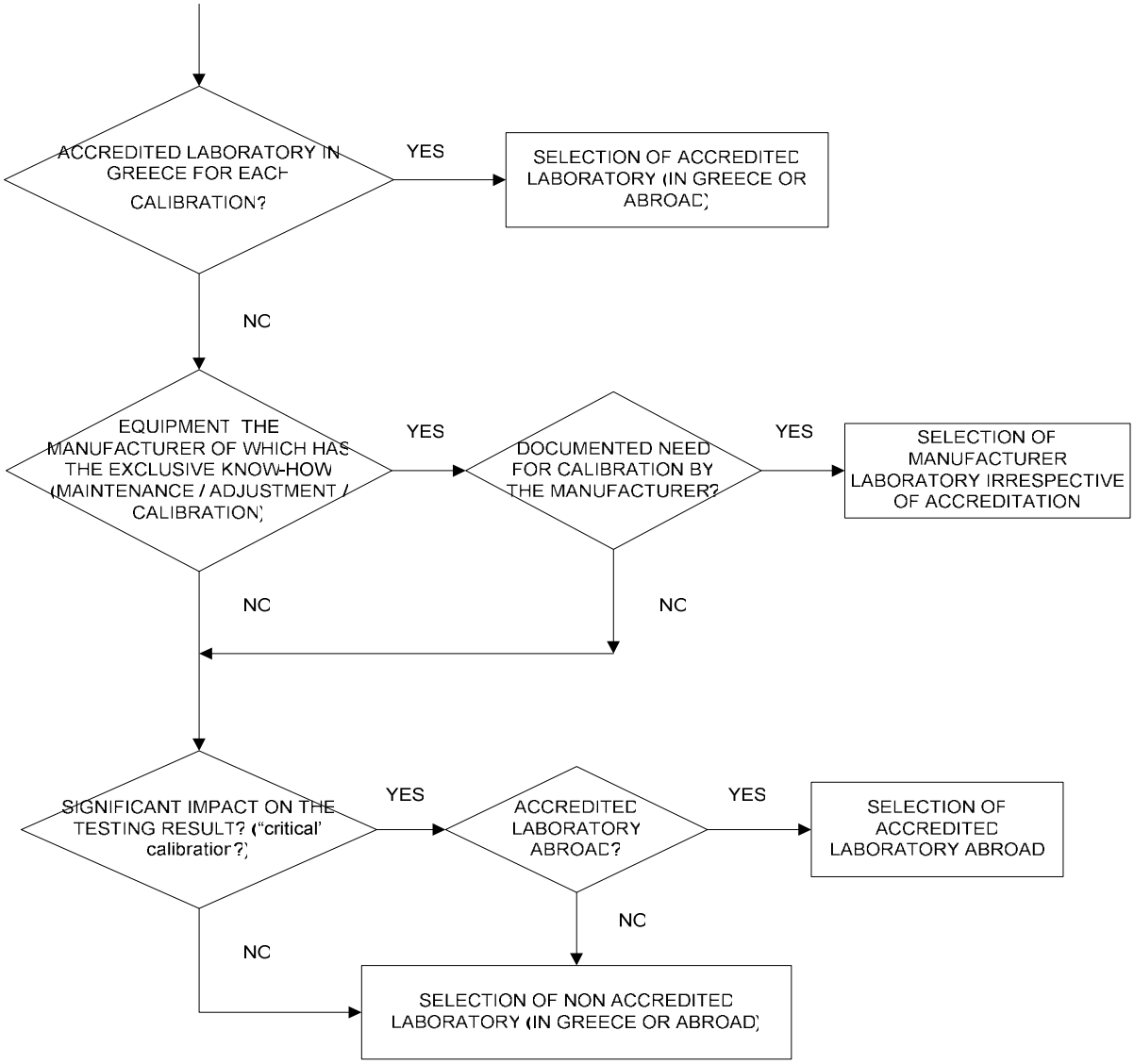
6. TRACEABILITY TO MEASUREMENT FOR NON ACCREDITED LABORATORIES

6.1 Calibration laboratories shall use only accredited calibration services no matter the measurand, the kind and type of the equipment to be calibrated.

6.2 Testing laboratories should use accredited calibration services in Greece or abroad for the calibration of their measuring equipment. The use of non accredited services could be acceptable under conditions.

6.3 Diagram 1 describes the decision making process in the case referred in paragr. 6.2

DIAGRAM 1: DECISION MAKING PROCESS FOR THE SELECTION OF ACCREDITED OR NON-ACCREDITED CALIBRATION LABORATORY (TO BE USED BY ACCREDITED TESTING LABORATORIES)



6.4 In any case, the assessment and approval criteria of non accredited calibration services are at least the following:
i) conformity with a) all the requirements of the paragraphs 5.10.1-2, 5.10.4-6 & 5.10.8 of the chapter 5.10 of the standard ISO/IEC 17025, "Reporting the results", for the assurance of the completeness and validity of the issued accreditation certificates without logo and b) every other relative ESYD requirement.

Note: to fulfill the requirement of the paragraph 5.10.2e), for the identification of the method used, reference should be made to the standard method used with possible exceptions - reference to the in-house technical calibration procedure is not adequate. If a non standard method was used , a brief description of the method used shall be provided.
ii) Valid calibration certificates of the measuring equipment used for the calibration.

6.5 ESYD accepts calibration certificates bearing the ESYD logo or the logo of an equivalent organization which is a signatory to the relevant Multilateral Agreement. ESYD also accepts calibration certificates issued by a National Metrology Institute, signatory of the BIPM MRA.

6.6 In any case, ESYD assessors shall pay attention to the assessment of non accredited calibration services as they are responsible to interpret, assess and implement the above policy. In the case where the ESYD Assessors are not convinced by the above data, they can ask the cooperation of the National Metrology Institute (NMI), the ESYD TCs or other experts from the country and abroad.