GUIDANCE FOR THE APPLICATION OF EQUIPMENT CALIBRATION AND TRACEABILITY OF MEASUREMENTS ON INSPECTION BODIES

ESYD G-DIAKRIB

Issue: 01
Revision: 01
Issue Date: 28-11-2007
Revision Date: 26-03-2015
Prepared by: The Quality Manager of ESYD
Approved by: The Head of ESYD

Quality Manager of ESYD **Head of ESYD**

An Inspection Body (IB), where appropriate, shall perform calibration of its measurement equipment, having a significant influence on the results of the inspections performed by the IB, before being put into service, and thereafter calibrate it according to an established programme (ELOT EN ISO/IEC 17020:2012, § 6.2.6). The calibration may be performed with one of the ways presented below:

A. Internal calibration (in house), thus the following must apply:

1. IBs that perform internal calibrations of their measurement equipment must fulfill the requirements listed below, according to the standards ELOT EN ISO/IEC 17025, ELOT EN ISO/IEC 17020, the guide ILAC P15:06/2014 (§ 6.2.7a) and the guidance ILAC-P10:01/2013, for the performance of these calibrations:

a) The IBs must have and apply documented procedures for the calibration or/and check of the equipment, as well as records of calibration method validation, in case of using non-standard calibration methods,

b) The IBs must have a proper procedure for the calculation of uncertainty of measurements, taking into account all components,

c) The personnel that perform the internal calibrations must have the proper training,

d) The IBs must have appropriate equipment and environmental conditions,

e) The IBs must have measurement reference standards calibrated by:

- National Metrology Laboratory, which provides services appropriate for intended use, covered by mutual recognition agreement CIPM MRA or
- Accredited calibration laboratory, having Scope of Accreditation (SoA) appropriate for intended use, by ESYD or other Accreditation Body, signatory to ILAC mutual recognition agreement or local agreements recognized by ILAC,

f) have internal and external (participation in programmes of interlaboratory comparisons) quality control results.

2. The IB must inform ESYD, either with its Application Form or relevant letter, that it performs internal calibrations of its equipment in specific quantities.

3. The IB that performs internal calibrations of its equipment must submit to ESYD the relevant procedures, including the procedures for the calculation of uncertainty of measurements.

4. The assessment of the IB's competence at performing internal calibrations is mandatory in the initial assessment, for the granting of accreditation.

5. During the initial assessment of an IB, there must be included in the assessment team either an ESYD Bodies Assessor, properly trained on the requirements of ELOT EN ISO/IEC 17025, or an ESYD Calibrations Assessor as a Technical Expert.

6. In the special case that the IB performs internal calibrations, which have not been previously stated and therefore the assessment team is not technically competent to assess them, the Lead Assessor informs ESYD to modify the assessment team by adding an appropriate Assessor, who performs a complementary assessment.
7. Any modifications in the calibration procedures must be communicated to ESYD and can be assessed on-site, in the frame of the next surveillance visit, on the basis of a relevant ESYD decision.
8. The assessment of the IB's competence at performing internal calibrations, in the frame of surveillance and reassessment visits, must be conducted either by ESYD Assessors for the standard ELOT EN ISO/IEC 17020, on condition that they have been previously trained on the requirements of ELOT EN ISO/IEC 17025, or by an ESYD Calibrations Assessor as a Technical Expert.
9. Regarding already accredited IBs performing internal calibrations, an assessment of their competence at performing internal calibrations must be conducted in the frame of the next surveillance visit, either by an ESYD Bodies Assessor, properly trained on the requirements of ELOT EN ISO/IEC 17025, or by an ESYD Calibrations Assessor as a Technical Expert.

B. External calibration, thus:
External suppliers providing calibration services are used. There are four (4) separate cases, according to the guide ILAC P15:06/2014 (§ 6.2.7b) and the guidance ILAC-P10:01/2013:

1. The supplier used is National Metrology Laboratory, which provides services appropriate for intended use, covered by mutual recognition agreement CIPM MRA.
2. The supplier used is accredited according to ELOT EN ISO/IEC 17025, in the specific technical field where the equipment calibration service is requested, by ESYD or other Accreditation Body, signatory to ILAC mutual recognition agreement or local agreements recognized by ILAC.
   Accreditation is a sufficient condition for co-operation between the IB and the provider of calibration services, which assures quality of services, provided that copies of the supplier's scope of accreditation are maintained in the IB's records.
3. The supplier used is National Metrology Laboratory, which provides services appropriate for intended use, but not covered by mutual recognition agreement CIPM MRA.

4. The supplier used is not accredited according to ELOT EN ISO/IEC 17025, by ESYD or other Accreditation Body, signatory to ILAC mutual recognition agreement or local agreements recognized by ILAC, in the specific technical field where the equipment calibration service is requested.

   The cases 3 and 4 are selected only if cases 1 and 2 are not available, either in Greece or abroad. Moreover, if selecting cases 3 and 4, the IB shall document the compliance of the supplier / calibration laboratory with ESYD traceability requirements. Appropriate evidence of compliance includes at least the following (numbers in the parentheses refer to clauses in ELOT EN ISO/IEC 17025:2005):

   - Calibration of the standards of the supplier / laboratory by (5.6.1):
     - National Metrology Laboratory, which provides services appropriate for intended use, covered by mutual recognition agreement CIPM MRA or
     - Accredited calibration laboratory, having SoA appropriate for intended use, by ESYD or other Accreditation Body, signatory to ILAC mutual recognition agreement or local agreements recognized by ILAC,
   - Results of participation in programmes of interlaboratory comparisons (5.9.1)
   - Appropriate equipment and environmental conditions (5.5.1 & 5.3)
   - Standard calibration methods or records of non-standard calibration methods validation (5.4.2 & 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)
   - Audits of the calibration laboratory (4.6.4 & 4.14)
   - The contents of the calibration certificate (5.10)

   For the documentation of all the previously mentioned, it may be necessary for the IB to perform a practical assessment of the supplier / laboratory providing calibration services (second party assessment), similar to that which would be undertaken by an Accreditation Body, to evaluate the technical competence of the supplier / calibration laboratory.

   Especially for aforementioned cases 3 and 4, an assessment of the competence of the IB to evaluate its supplier / calibration laboratory will take place, by an ESYD Bodies Assessor, properly trained on the requirements of ELOT EN ISO/IEC 17025, or an ESYD Calibrations Assessor.

Relevant findings must be assessed and, if necessary, the evaluation conducted by the IB to its supplier / calibration laboratory must be witnessed on-site.

For this reason, during the initial assessment of an IB, there must be included in the assessment team either an ESYD Bodies Assessor, properly trained on the requirements of ELOT EN ISO/IEC 17025, or an ESYD Calibrations Assessor as a Technical Expert.
In the frame of surveillance and reassessment visits of IBs, the evaluation by the IB of the provider of calibration services must be subject to assessment either by ESYD Bodies Assessors, on condition that they have been previously trained on the requirements of ELOT EN ISO/IEC 17025, or by an ESYD Calibrations Assessor as a Technical Expert.

Regarding already accredited IBs, an assessment of their competence at evaluating their suppliers of calibration services must be conducted in the frame of the next surveillance visit, either by an ESYD Bodies Assessor, properly trained on the requirements of ELOT EN ISO/IEC 17025, or by an ESYD Calibrations Assessor as a Technical Expert.