

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

**MEASUREMENT AND CALIBRATION SYSTEMS**

***Hellenic Accreditation System S.A.***

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**Prepared by: Quality Manager of ESYD**

**Approved by: Chairman of ESYD**

**Quality Manager of ESYD**

**Chairman of ESYD**

# ***Hellenic Accreditation System S.A.***

## **MEASUREMENT AND CALIBRATION SYSTEMS**

### **0 INTRODUCTION**

- 0.1 ESYD GA1 contains the ESYD requirements for measurement traceability and calibration. This Guideline has been prepared to ensure that laboratories comply with both the measurement and traceability requirements of ELOT EN ISO/IEC 17025 and the relevant requirements for calibration and testing equipment set out in ISO 10012: 2003.
- 0.2 The requirements of this Guideline shall be met by all ESYD accredited calibration laboratories and testing laboratories when providing an ESYD accredited calibration or testing service for a Client, or performing in-house calibrations in support of their accredited activities.
- 0.3 For the purposes of this Guideline, the terminology of ELOT EN ISO/IEC 17025 and the definitions of ISO 10012:2003 apply.

### **1 GENERAL**

- 1.1 The Laboratory shall have a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards and measuring/test equipment used in the performance of accredited calibrations and tests. Measurements performed by the Laboratory and by sub-contractors that it uses shall be covered by this system.
- 1.2 This system shall be designed to ensure that the Laboratory has the necessary procedures and resources to carry out calibrations, tests and supporting measurements within the required time-scales and designated limits. The Laboratory should set these limits and they shall be consistent with the Laboratory's schedule of accreditation, the relevant calibration or test specifications and/or the requirements of the Client. The system shall also ensure that any measuring and test equipment, and any reference material used, performs as intended.
- 1.3 The system shall include arrangements to prevent errors that are outside specified limits of permissible error, and to provide for rapid detection of deficiencies and immediate corrective action as required by ELOT EN ISO/IEC 17025.
- 1.4 The policies and the procedures for this system shall be documented in the Laboratory's quality manual and associated quality documentation. They shall clearly define the responsibilities and duties of each member of staff involved in the activities listed in paragraph 1.1 of this Guideline.

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- 1.5 The Quality Manager shall ensure that the measurement and calibration system used by the Laboratory is included in the program for quality system audits, and that the results of such audits are evaluated at the Laboratory's periodic review of the quality system.
- 1.6 Laboratory staff shall have the qualifications, training, experience and skill to perform the tasks referred to in this Guideline. Staff training shall be maintained up-to-date .
- 1.7 As required by ELOT EN ISO/IEC 17025, the Laboratory shall maintain records on training, competency and staff authorized to use equipment or/and reference materials or perform calibrations or/and tests in-house or in the Client's house.

**2 PLANNING AND SELECTION OF EQUIPMENT/REFERENCE MATERIALS**

- 2.1 The Laboratory shall review the requirements of the Client, and of any relevant technical specification, before commencing calibration or testing. If the work is within the capability of the Laboratory it shall, before commencing, establish a program to ensure that measurement standards/reference materials, measuring/test equipment and environmental conditions necessary for the performance of the work are available to achieve the accuracy, stability, range and resolution required. The Laboratory shall also ensure that it has the staff resources needed.
- 2.2 The Laboratory shall ensure that all the items of measuring equipment needed for the work, including reference measurement standards, meet the requirements of ESYD GA 1.
- 2.3 The Laboratory shall also ensure that, where required by ESYD, it uses reference materials as measurement standards to assist in the estimation of uncertainties of measurement, to calibrate measuring and test equipment, to monitor Laboratory performance and to validate methods. Where required, reference materials shall also be used as transfer standards to compare methods.
- 2.4 Wherever possible, the Laboratory should use both primary pure reference materials and reference materials that have matrices matching those of the calibration/test items to take account of matrix effects.
- 2.5 The Laboratory shall also, wherever possible, use reference materials that have been certified as having been produced and characterized in a technically valid manner. 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. The certificate shall, wherever possible, also provide evidence of traceability to national or international standards of measurement, or to national or international standard reference materials.
- 2.6 Where a certified reference material is not available, reference materials with suitable properties and stability shall be used. The properties required of these materials shall, wherever possible, be characterized by acceptable procedures such as those as recommended in ISO Guide 35:2006, "Certification of reference materials – General and statistical principles for certification". These

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procedures may include: analysis/testing by a definitive method; analysis/testing by a number of methods based on different physical or chemical principles, or analysis/testing by a number of laboratories using either the same or different methods.

- 2.7 Where the Laboratory prepares standards from materials of known properties, or purchases uncertified standards such as chemical standards, the Laboratory shall verify that the standards are of acceptable quality and suitable for the purpose. Standards should be purchased, where possible, from suppliers as detailed in 2.5 of this Guideline.

### **3 UNCERTAINTY OF MEASUREMENT**

- 3.1 The Laboratory is required to produce an estimate of the uncertainty of its measurements, to include the estimation of uncertainty in its methods and procedures for calibration and testing, and to report the uncertainty of measurement in calibration certificates and in test certificates and test reports, where relevant.
- 3.2 Estimates of uncertainty of measurement shall take into account all significant identified uncertainties in the measurement and testing processes, including those attributable to measuring equipment, reference measurement standards (including material used as a reference standard), staff using or operating equipment, measurement procedures, sampling and environmental conditions.
- 3.3 In estimating uncertainties of measurement, the Laboratory shall take into account the data obtained from internal quality control schemes and other relevant sources, (see ELOT EN ISO/IEC 17025). The Laboratory shall also ensure that any requirements for the estimation of uncertainty and for the determination of compliance with specified requirements shall be stated as in the relevant EA publications.
- 3.4 In setting the acceptance limits for the calibration of measuring and testing equipment, the Laboratory shall ensure that the limits chosen allow for the conditions under which the equipment or reference material is to be used. Such limits may be significantly different to those applicable during the calibration process.

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## **4 CALIBRATION PROCEDURES- CALIBRATION CERTIFICATES**

4.1 The Laboratory shall use methods and procedures for the calibration of measuring equipment, reference measurement standards (including reference materials) and test equipment used in calibration and testing laboratories that comply with the requirements of ELOT EN ISO/IEC 17025. The methods and procedures shall include, but not be limited to:

- (a) identification of the instrument, gauge or test equipment, or group of such items to which the procedure is applicable
- (b) identification of all measurement standards/reference materials and associated equipment used to perform the calibration
- (c) the procedures to be adopted for handling, transporting, storing and using measuring equipment and reference materials used for calibration, including details of lifetime and measures to prevent contamination or loss of determinant
- (d) the procedures to be adopted for handling, transporting, storing and preparing items for calibration
- (e) the environmental conditions that must be used, the limits applicable, the procedure for any corrections that may have to be made as a result of the environmental conditions and, where relevant, the minimum period of stabilization before calibration
- (f) the method or procedure for calibration in the form of written instructions and diagrams where appropriate
- (g) details of the measurement or calibration data to be recorded and the method for presentation and analysis of this data
- (h) the limits of acceptance for the calibration data for the item or type of item being calibrated
- (i) the estimation of the uncertainty of measurement of the calibration process (see paragraph 4.2 of this Guideline)
- (j) the procedures to be adopted for selecting calibration intervals when the equipment/reference material is being used by the Laboratory to perform calibration or tests
- (k) the procedures for checking equipment and reference materials between calibrations

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- (l) an identification number, number of pages, date of issue and name and person authorizing issue and use of the procedure.
- 4.2 In its procedures for estimating the uncertainty of the calibration process, the Laboratory shall take into account the cumulative effect of the uncertainties of measurement of each successive stage in the chain of calibrations for each measurement standard and item of equipment calibrated. The Laboratory shall take action when the total uncertainty of measurement is such that it significantly compromises its ability to make measurements within the limits of permissible error.
- 4.3 Where the Laboratory uses the services of an external organization to calibrate measuring and test equipment, the requirements of ELOT EN ISO/IEC 17025 shall be met. If the services of a ESYD accredited calibration laboratory are not available, the Laboratory shall ensure that the calibration certificate provided contains the information described in the following paragraph.
- 4.4 The Calibration certificate shall include at least the following information:
- (a) the title "Certificate of Calibration"
  - (b) the name and the address of the laboratory and the place where the measurements were taken, if it is different than that of the laboratory premises
  - (c) a unique identification of the calibration certificate (e.g. the issue number) and into each page an identification element, in order to ensure that the page is recognized as part of the calibration certificate, and also a clear identification of the end of the certificate.
  - (d) the name and the address of the client
  - (e) the identification of the method and the instrumentation used (type of instrument and serial number)
  - (f) the description, the status and the identity of the calibrated item
  - (g) the receipt date of the item when it is critical for the validity and the application of the results and the date of calibration
  - (h) information about the plan and sampling procedures used by the laboratory or other organizations
  - (i) the calibration results and where necessary the units
  - (j) the name, the position and the signature of the person(s) who are in charge to grant the calibration certificate
  - (k) where it is relevant, a statement that the results are related only with the calibrated items
  - (l) the conditions (eg environmental) under which the calibration was carried out
  - (m) the uncertainty of measurement (\*) or/and a statement of compliance with any relevant metrological specification
  - (n) a statement indicating how traceability to national standards has been achieved

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- (o) for calibration certificates which are within the Scope of Accreditation of the laboratory, the accreditation certificate issue number and the logo of the Accreditation Body
- (p) a statement that the certificate shall not be reproduced other than in full and after the written approval of the Lab
- (q) the seal of the Lab

(\*) the confidence levels should accompany the uncertainty of the measurement

An example of a Calibration Certificate is the following:



ΠΙΣΤΟΠΟΙΗΤΙΚΟ ΔΙΑΚΡΙΒΩΣΗΣ

Διακρίβωσης \*  
Αρ. Πιστ. XXX

(\* εφόσον το Πιστοποιητικό περιέχει διαπιστευμένες μετρήσεις)

Certificate of Calibration

Αριθμός πιστοποιητικού / Certificate number :D9-06-XXX  
Αριθμός σειράς οργάνου / Instrument serial No: XXXX

Θέση Λογότυπου Εργαστηρίου

Εκδόθηκε από / Issued by :

**Τίτλος Εργαστηρίου**

**Laboratory Name**

**Εργαστήριο Θερμοκρασίας**

**Laboratory of Temperature**

Διεύθυνση Εργαστηρίου,

Laboratory Address

Τηλ./Tel. +030 ..... , Fax +030 .....

e-mail: .....

Πελάτης / Customer:

**Κωδικός αντικειμένου / Item Code:** 18/03-06/6

Περιγραφή:

Θερμόμετρο Υδραργύρου, εύρος κλίμακας: 50 έως 100 °C,  
διαγράμμιση κλίμακας: 0,5°C, μερικής βύθισης: 3 inch

Description:

Mercury in glass thermometer, scale range: 50 to 100 °C  
scale division: 0,5 °C, partial immersion: 3 inch

Κατασκευαστής / Manufacturer:

BAIRD & TATLOCK British make N/F

Τύπος / Type:

ZECOL

Αριθμός Σειράς / Serial Number:

XXXXX

Ημερομηνία Παραλαβής / Date of receipt:

29/03/06

Δεν επιτρέπεται η αναπαραγωγή του πιστοποιητικού αυτού παρά μόνο καθ' ολοκληρία, εκτός αν δοθεί γραπτή έγκριση από "Τίτλος Εταιρείας" και "Τίτλος Εργαστηρίου" που το εκδίδει. Πιστοποιητικά Διακρίβωσης μη φέροντα σφραγίδα και υπογραφή δεν έχουν ισχύ. Αντίγραφο του παρόντος πιστοποιητικού θα διατηρηθεί στο εργαστήριο που το εκδίδει για μία περίοδο τουλάχιστο δέκα ετών.

Τα αποτελέσματα αφορούν μόνο τα αντικείμενα που έχουν διακριβωθεί.

This certificate may not be reproduced other than in full, except with the prior written approval of both the Laboratory Name and the issuing laboratory. Calibration Certificates without seal and signature are not valid. A copy of this certificate will be kept at the issuing laboratory for a period of at least ten years. The results concern only the calibrated items

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**ΠΙΣΤΟΠΟΙΗΤΙΚΟ ΔΙΑΚΡΙΒΩΣΗΣ**

Διακρίβώσεις \*  
Αρ. Πιστ. XXX

(\* εφόσον το Πιστοποιητικό περιέχει διαπιστευμένες μετρήσεις)

**Certificate of Calibration**

Αριθμός πιστοποιητικού / *Certificate number* :D9-06-XXX

Αριθμός σειράς οργάνου / *Instrument serial No*: XXXX

Ημερομηνία Διακρίβωσης:

14/04/06

*Date of Calibration*:

Σφραγίδα / *Seal* :

Ημερομηνία έκδοσης /  
*Date of issue*: 02/05/06

Υπογραφή / *Signature*:

Υπεύθυνος Εργαστηρίου / *Person in charge of the Laboratory*

**Διακρίβωση θερμομέτρου Υδραργύρου με τη μέθοδο της σύγκρισης /  
*Comparison calibration of Mercury in glass thermometer***

**1. Κατάσταση αντικειμένου προς διακρίβωση / *Condition of object to be calibrated***

Το θερμοόμετρο κατά την παραλαβή ήταν σε καλή κατάσταση / *the thermometer is in good condition*

**2. Συνθήκες εργαστηρίου διακρίβωσης / *Laboratory ambient conditions***

Θερμοκρασία / *Temperature*:  $23 \pm 2^\circ\text{C}$

Σχετική Υγρασία / *Relative Humidity*:  $45 \pm 10\% \text{ R.H.}$

**3. Διαδικασία Διακρίβωσης / *Calibration Procedure***

Το θερμοόμετρο διακρίβώθηκε μέσω σύγκρισης των ενδείξεών του με τις θερμοκρασιακές ενδείξεις από δύο θερμοόμετρα αναφοράς. Η σύγκριση έγινε μέσα σε συνεχώς αναδευόμενο λουτρό νερού. Το θερμοόμετρο διακρίβώθηκε σε συνθήκες μερικής βύθισης της στήλης του υδραργύρου στο υγρό του λουτρού βαθμονόμησης (3 inches, σύμφωνα με τις προδιαγραφές του). Ως θερμοόμετρα αναφοράς χρησιμοποιήθηκαν δύο θερμοόμετρα αντιστάσεως Λευκόχρυσου, ονομαστικής αντιστάσεως 100Ω, στους 0,01°C.

Δεν επιτρέπεται η αναπαραγωγή του πιστοποιητικού αυτού παρά μόνο καθ' ολοκληρία, εκτός αν δοθεί γραπτή έγκριση από "Τίτλος Εταιρείας" και "Τίτλος Εργαστηρίου" που το εκδίδει. Πιστοποιητικά Διακρίβωσης μη φέροντα σφραγίδα και υπογραφή δεν έχουν ισχύ. Αντίγραφο του παρόντος πιστοποιητικού θα διατηρηθεί στο εργαστήριο που το εκδίδει για μία περίοδο τουλάχιστο δέκα ετών.

Τα αποτελέσματα αφορούν μόνο τα αντικείμενα που έχουν διακριβωθεί.

*This certificate may not be reproduced other than in full, except with the prior written approval of both the Laboratory Name and the issuing laboratory. Calibration Certificates without seal and signature are not valid. A copy of this certificate will be kept at the issuing laboratory for a period of at least ten years. The results concern only the calibrated items*

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**ΠΙΣΤΟΠΟΙΗΤΙΚΟ ΔΙΑΚΡΙΒΩΣΗΣ**

Διακρίβωσης \*  
Αρ. Πιστ. XXX

(\* εφόσον το Πιστοποιητικό περιέχει διαπιστευμένες μετρήσεις)

**Certificate of Calibration**

Αριθμός πιστοποιητικού / *Certificate number* : D9-06-XXX  
Αριθμός σειράς οργάνου / *Instrument serial No*: XXXX

*The thermometer was calibrated by comparison using two standard Platinum resistance thermometers as a reference. The comparison was performed in a continuously stirred water bath. The thermometer was calibrated under conditions of partial immersion in the liquid bath (3inches, according to its specifications). The reference thermometers used have a nominal resistance value of 100 Ohms at 0,01 °C.*

**4. Ιχνηλασιμότητα / Traceability**

Τα πρότυπα θερμομέτρα αντιστάσεως Λευκόχρυσου που χρησιμοποιήθηκαν σαν αναφορά (Αρ. Σειράς: 24000/1 & 24000/2), έχουν πιστοποιητικά διακρίβωσης με ιχνηλασιμότητα στα Εθνικά πρότυπα της Ελλάδας.

*The reference standard Platinum resistance thermometers used (Serial No: 24000/1 & 24000/2) bear calibration certificates traceable to the national standards of Greece.*

**5. Αβεβαιότητα / Uncertainty**

Η διευρυμένη αβεβαιότητα που αναφέρεται είναι το γινόμενο της τυπικής αβεβαιότητας ( $u$ ) με τον συντελεστή κάλυψης  $k = 2$  και παρέχει επίπεδο εμπιστοσύνης 95%. Προσδιορίζεται σύμφωνα με το έντυπο «*Guide to the expression of uncertainty in measurement*» (ISO, Geneva, 1995).

Περιλαμβάνει την αβεβαιότητα της θερμοκρασίας αναφοράς και την αβεβαιότητα του οργάνου υπό διακρίβωση.

Αφορά τις μετρήσεις κατά την διάρκεια της διακρίβωσης και δεν περιέχει ενδεχόμενες μακροπρόθεσμες μεταβολές του οργάνου. Είναι ευθύνη του χρήστη να προσδιορίσει τις μεταβολές αυτές καθώς και την αβεβαιότητα μέτρησης του οργάνου στις εκάστοτε συνθήκες χρήσης του.

*The reported expanded uncertainty is based on a standard uncertainty ( $u$ ) multiplied by a coverage factor  $k = 2$ , providing a confidence level of 95%. It has been evaluated in accordance to the «*Guide to the expression of uncertainty in measurement*» (ISO, Geneva, 1995).*

*It includes the reference temperature uncertainty and the instrument under test uncertainty.*

*It applies at the time of the calibration only. It is the user's responsibility to determine the long term drift and the uncertainty under the actual conditions of use.*

**6. Αποτελέσματα Διακρίβωσης/ Calibration Results**

Δεν επιτρέπεται η αναπαραγωγή του πιστοποιητικού αυτού παρά μόνο καθ' ολοκληρία, εκτός αν δοθεί γραπτή έγκριση από "Τίτλος Εταιρείας" και "Τίτλος Εργαστηρίου" που το εκδίδει. Πιστοποιητικά Διακρίβωσης μη φέροντα σφραγίδα και υπογραφή δεν έχουν ισχύ. Αντίγραφο του παρόντος πιστοποιητικού θα διατηρηθεί στο εργαστήριο που το εκδίδει για μία περίοδο τουλάχιστο δέκα ετών.

Τα αποτελέσματα αφορούν μόνο τα αντικείμενα που έχουν διακριβωθεί.

*This certificate may not be reproduced other than in full, except with the prior written approval of both the Laboratory Name and the issuing laboratory. Calibration Certificates without seal and signature are not valid. A copy of this certificate will be kept at the issuing laboratory for a period of at least ten years. The results concern only the calibrated items*



## ΠΙΣΤΟΠΟΙΗΤΙΚΟ ΔΙΑΚΡΙΒΩΣΗΣ

Διακρίβωσης \*  
Αρ. Πιστ. XXX

(\* εφόσον το Πιστοποιητικό περιέχει διαπιστευμένες μετρήσεις)

### Certificate of Calibration

Αριθμός πιστοποιητικού / Certificate number : D9-06-XXX

Αριθμός σειράς οργάνου / Instrument serial No: XXXX

Ένδειξη του προς διακρίβωση θερμομέτρου(°C) <i>Temperature reading of the thermometer under calibration (°C)</i>	Διόρθωση ένδειξης (°C) <i>Indication correction(°C)</i>	Θερμοκρασία εξέχουσας στήλης υδραργύρου* (°C) <i>Emergent liquid column temperature *(°C)</i>	Αβεβαιότητα μέτρησης (2u) <i>Measurement uncertainty (2u)</i>
60,00	-0,15	42	±0,10°C
99,00	-0,25	65	±0,10°C

\*Σε περίπτωση που το όργανο χρησιμοποιηθεί σε διαφορετική θερμοκρασία εξέχουσας στήλης, από αυτή που αναφέρεται στο πιστοποιητικό διακρίβωσης, πρέπει να γίνει μία πρόσθετη διόρθωση στην ένδειξη του θερμομέτρου, με βάση την εξίσωση

$C = nk(T_{cert} - T_{user})$  όπου :

n = ο αριθμός των βαθμών της εξέχουσας στήλης

k = ο συντελεστής διαστολής του υδραργύρου σε γυαλί (=0,00016 °C<sup>-1</sup>)

T<sub>cert</sub> = η τιμή (θερμοκρασία εξέχουσας στήλης) από το πιστοποιητικό διακρίβωσης

T<sub>user</sub> = η θερμοκρασία εξέχουσας στήλης κατά τη χρήση

### Τέλος Πιστοποιητικού Διακρίβωσης / End of Calibration Certificate

Δεν επιτρέπεται η αναπαραγωγή του πιστοποιητικού αυτού παρά μόνο καθ' ολοκληρία, εκτός αν δοθεί γραπτή έγκριση από "Τίτλος Εταιρείας" και "Τίτλος Εργαστηρίου" που το εκδίδει. Πιστοποιητικά Διακρίβωσης μη φέροντα σφραγίδα και υπογραφή δεν έχουν ισχύ. Αντίγραφο του παρόντος πιστοποιητικού θα διατηρηθεί στο εργαστήριο που το εκδίδει για μία περίοδο τουλάχιστο δέκα ετών.

Τα αποτελέσματα αφορούν μόνο τα αντικείμενα που έχουν διακριβωθεί.

*This certificate may not be reproduced other than in full, except with the prior written approval of both the Laboratory Name and the issuing laboratory. Calibration Certificates without seal and signature are not valid. A copy of this certificate will be kept at the issuing laboratory for a period of at least ten years. The results concern only the calibrated items*

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## **5 RECORDS**

- 5.1 The Laboratory shall maintain records for each item of measuring equipment, including reference measurement standards and reference material standards and test equipment, used in the performance of calibration or tests. The records shall show, either through in-house documentation or calibration certificates from external organizations, that each calibration in the chain of traceability has been carried out.
- 5.2 The Laboratory shall ensure that the records contain detailed information of the equipment/reference material used for calibrations (see ELOT EN ISO/IEC 17025), and that there is also a full and up-to-date history of the calibration of this equipment/reference material (see ELOT EN ISO/IEC 17025).
- 5.3 The records shall provide sufficient information to demonstrate the measurement capability and traceability of each item of measuring equipment and the range of use of each reference material, its lifetime and required storage conditions.
- 5.4 Each record shall include or refer to:
- (a) the date on which each calibration was performed
  - (b) the calibration results obtained after and, where relevant, before any adjustment and repair
  - (c) the specified calibration interval
  - (d) reference to the calibration method or procedure used and any relevant standard or specification
  - (e) the specified limits of permissible error
  - (f) calibration certificates, bearing the ESYD logo, from ESYD accredited calibration laboratories of appropriate measurement capability or from the Laboratory holding the national standard for the measurement standards used, or from a laboratory meeting the requirements for traceability specified in ESYD GA2, Traceability of Measurement
  - (g) certificates or other documentation, for all reference materials used for calibration, providing evidence of characterization of the material, and evidence of traceability to national or international standards of measurement, or to national or international standard reference materials

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- (h) the environmental conditions at the time of calibration and the corrections made, where necessary, for such conditions
- (i) a statement of the uncertainties of measurement involved in the calibration and of their cumulative effect
- (j) any design or performance specifications met
- (k) name of persons performing the calibration and checking the results
- (l) any limitations in use resulting from the calibration data obtained
- (m) details of any maintenance carried out in accordance with the requirements of ELOT EN ISOIEC 17025 and of any servicing, adjustment, repair or modification, particularly at the time of calibration.

5.5 Similar records, as appropriate, shall be maintained for any checks carried out on equipment or reference materials between calibrations.

## **6 CALIBRATION INTERVALS**

6.1 The Laboratory shall have documented criteria for the selection of calibration intervals for all measuring and test equipment used.

6.2 Reference measurement standards shall be calibrated at intervals approved by ESYD. Reference materials shall be checked for deterioration and, if necessary, replaced.

6.3 All other measuring and test equipment shall be calibrated at intervals approved by ESYD and determined by the following factors:

- (a) the requirements of any relevant standard specifications for the measurements/tests involved
- (b) the recommendation of the equipment manufacturer
- (c) the type and stability of the equipment
- (d) the extent and severity of use
- (e) the influence of the environmental conditions (eg temperature, humidity, vibration and dust)

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- (f) the accuracy of measurement needed for the calibration or test concerned
- (g) trends determined by examination of records of previous calibrations
- (h) evidence obtained from service and maintenance records
- (i) any known or observed tendency for the equipment to exhibit wear or to drift in performance
- (j) the frequency of, and information from, in-house checks, using known standards.

6.4 When selecting intervals for the maintenance and calibration of measuring and test equipment, the Laboratory shall take into account all of the relevant factors in 6.3 of this Guideline. It shall do so in such a way as to minimize the risk that the results of any calibrations/tests performed between calibrations may be affected because some of the measuring or test equipment used has failed to perform to specified requirements. For certain types of measurement, such as chemical analysis using chromatographs or spectrometers, calibration is necessary as part of normal operations using appropriate chemicals or certified reference materials.

6.5 When selecting intervals for the maintenance and calibration of new measuring and test equipment, the Laboratory shall ensure that, where only limited information is available, the interval initially selected is shorter than the expected eventual interval. The interval may then be adjusted at a later date as a result of information obtained from further calibrations and checks.

6.6 The Laboratory shall have procedures for the periodic review of maintenance and calibration intervals to take into account the variation in the type, frequency and conditions of use of any measuring or test equipment. When the performance of measuring and test equipment deviates from the specified requirements, the requirements of ELOT EN ISO/IEC 17025 shall be met and the maintenance and calibration intervals shall be reviewed immediately and modified where necessary. The ISO 10012: 2003 provides guidance on methods for the determination and review of maintenance and calibration intervals. Such equipment shall not be returned to service until the reason for the deviation has been eliminated and the equipment has been re-calibrated.

6.7 The Laboratory shall shorten the intervals between calibrations (and maintenance where appropriate) when the results of preceding calibrations or intermediate checks indicate that the measuring and test equipment is no longer performing in accordance with the specified requirements.

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6.8 The Laboratory shall increase the interval between calibrations only when the results of preceding calibrations, and any intermediate checks or quality control data, indicate that the performance of the measuring and test equipment is likely to remain within the specified requirements throughout the new period between calibrations.

6.9 Due to the fact that there is not a general rule relevant to the calibration intervals each type of equipment shall be handled separately.

The Laboratory determines the calibration intervals taking into consideration the following:

- the standard equipment shall have at least 3 times better accuracy than the item under calibration, which means that the contribution from the standard equipment error's shall be lower than the 1/3, taking into consideration that during the uncertainty calculation a confidence level of 95% (k=2) shall be assured
- the history of the equipment. Generally the following principle exists: when the calibration results, under the predetermined calibration interval, for three consequent calibration intervals are within the predetermined limits of error, then the calibration interval may be increased, e.g. 50%. On the opposite, if they are out of the limits, then the calibration interval shall be reduced, e.g. to the half.
- methods of statistical analysis
- the way of handling and restoration of the equipment during it's usual operation
- the recommendation of the equipment manufacturer
- the consequences of the equipment measurement of its clients, when uses standard equipment which is out of the acceptable limits
- international Standards or bibliography

It is mentioned that in the cases where the primary and secondary equipment are used as working standards, the calibration intervals shall be determined as the same of working standards.

- The Calibration Laboratories may establish the calibration intervals up to the double of the time intervals set in Table A of Annex A which follows, only when the history of the equipment and it's use allow it
- For measurement equipment used in testing laboratories and in the industry the calibration intervals set in Table B of Annex A are proposed.
- In Part C of Annex A the minimum parameters which shall be checked/calibrated for equipment used in chemical, microbiological and clinical laboratories are included in order to be a guide for the ESYD assessors and the testing labs.

The proposed calibration and performance checking intervals are indicative for providing a tool for the assessors and the labs.

**7 SEALING OF CALIBRATED EQUIPMENT**

- 7.1 The Laboratory shall have procedures to prevent adjustable devices on measuring and test equipment (other than those intended for the user), whose setting affects the performance, being altered by unauthorized staff. Where seals (labels, solder, wire, paint etc) are used, they shall be designed to indicate clearly when unauthorized adjustment has been made. The procedures shall ensure that, where a seal has been damaged or broken, the requirements of ELOT EN ISO/IEC 17025 are met.

**8 LABELING OF CALIBRATED EQUIPMENT AND REFERENCE MATERIALS**

- 8.1 The requirements for labeling, codifying, or otherwise identifying the status of calibration of measuring and test equipment used by the Laboratory are given in ELOT EN ISO/IEC 17025.
- 8.2 When equipment has been calibrated, or reference materials certified by an external organization, the Laboratory shall ensure that the equipment/reference material is fit for use, is labeled and that it has a certificate (or notification, where a certificate might be delayed) to indicate the results of the calibration.
- 8.3 Labels, or other methods of codifying or identifying the equipment/reference material, shall, as well as indicating calibration status, clearly indicate to the staff using the equipment/reference material, any limitations of the calibration and/or any restrictions on the use of the equipment/reference material.
- 8.4 Any item of measuring or test equipment, or any reference material, that is not calibrated, shall not be used for accredited calibration/testing. If there is any possibility that staff might at any time use such equipment or material for accredited calibration/testing before it has been calibrated, it shall be appropriately labeled and, if possible, segregated.

**9 GUIDANCE FOR THE INTERNAL CALIBRATIONS ASSESSMENT**

- 9.1 The Labs that perform internal calibrations or checking of their test equipment must fulfill the requirements of EN ISO/IEC 17025:2005 Standard.
- 9.2 The Lab's that carry out tests in various fields perform, usually, internal calibrations or checking of their testing equipment in the following categories:
- Volumetric equipment: Calibration according to proper ISO Standard.
  - Ovens, furnaces, incubators: Temperature profile checking using calibrated standard thermometer.
  - Autoclaves: Temperature checking and profile using calibrated standard thermometer with proved traceability and chronometer checking.
  - Thermometers: Calibration using a calibrated standard thermometer with proved traceability.
  - Balances: Calibration using calibrated standard weights of proper class, with proved traceability  
(i.e : Class E1 for balances of 0.1mg resolution)
  - Spectrophotometers: Calibration using CRM's for specific wavelengths.
  - Instrumental analysis equipment, such as GC, HPLC, AAS, FT-IR etc.: Operation qualification, performance verification and gradation using proper CRM's.
  - Instrumental analysis equipment, such as calorimeters: Calibration using CRM's.
  - Micrometers, dimension measurement equipment etc: Calibration using Gauge Blocks.
  - Manometers: Calibration using standard pressure.
  - Other.
- 9.3 Where in the above list an internal calibration is performed, then this calibration must fulfill the requirements of this Guidance as well as the requirements of Guidance ESYD-GA2. More specifically:
- a. The Laboratory must have and apply standardized calibration methods.
  - b. The Laboratory must have and apply proper uncertainty of measurements procedures including the uncertainty budget, for each measurement.
  - c. The personnel that perform the internal calibrations must have the proper training to indicate the technical competence for these calibrations.
- 9.4 The assessment of the Laboratory's competence at internal calibrations is included in the plan of assessment, according to ESYD-PA.
- 9.5 The Laboratory must have informed ESYD with its Application Form, Part 7, that it performs internal calibrations in specific quantities.
- 9.6 The Laboratory that performs internal calibrations must submit the relevant Procedures (including the uncertainty budget calculation), accompanying the Quality Manual and the rest of its Procedures.
- 9.7 In the special case that the Laboratory 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.

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- 9.8 The assessment of the internal calibrations is mandatory in the Laboratory initial assessment and re-assessment.
- 9.9 The present chapter applies also to Internal Calibrations performed by Accredited Laboratories or Laboratories that are employed by Certification or Inspection Bodies and Inspection Bodies for Motor Vehicles.

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## ANNEX A

Table A. Proposed calibration intervals for standard equipment of the Calibration Laboratories  
(according to the proposals of OIML and NIST)

See the Greek version

Table B. Proposed calibration intervals of measurement equipment of testing laboratories and industry  
(according to the Hellas Lab technical document)

See the Greek version

Part C. Calibration intervals, calibrations and performance checks of testing laboratory's equipment

See the Greek version