MEASUREMENT AND CALIBRATION SYSTEMS

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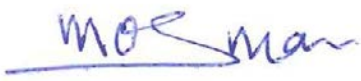

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Table of Modification

Mod. No./Date	Proposed by	Page No.	Modification in brief (old/new, added, cancelled)
5.1/Oct 2011	Quality Manager	2/9	Inclusion of measurment and calibration relevant clauses
5.2/Aug 2016	Quality Manager	All	No changes, just revision for all regulation

INDEX

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1. Introduction

1.1 EGAC requirements for the competence of calibration and testing laboratories, ISO/IEC 17025 Latest version clause 5.6 and ISO 15189 Latest version clause 5.3.1.4, contains requirements for measurement traceability and calibration. This requirements document has been prepared to ensure that laboratories comply with both the measurement and traceability requirements of ISO/IEC 17025 & ISO 15189 and also the relevant requirements for calibration and testing equipment not already covered by these standards that are set out in ISO 10012 Latest version. This document also applies to Inspection Bodies in regard of ISO/IEC 17020:2012 clauses 6.2.7 & 6.2.8. It also applies as a guide for the Certification Bodies in their audit against the relevant standard (e.g. ISO 9001:2015 cluse 7.1.5.2.a).

1.2 The requirements of this document shall be met by all EGAC accredited calibration laboratories and testing laboratories when calibrating their own equipment at an external laboratory, or performing in-house calibrations.

1.3 For the purposes of this Appendix, the terminology of ISO/IEC 17025:2005 & ISO 15189:2012 and the definitions of ISO 10012 apply.

2. General

2.1 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 any sub-contractors that it uses shall be covered by this system.

2.2 The system shall be designed to ensure that the Laboratory has the necessary procedures and resources to carry out calibrations and tests and supporting measurements within the required time-scales and designated limits. The Laboratory shall set these limits and they shall be consistent with the Laboratory's schedule of accreditation, the relevant calibration or test specification 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.

2.3 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 ISO/IEC 17025:2005 clauses 5.5.7 & 4.9 and ISO 15189:2012 clauses 5.3.1.5 & 4.10.

2.4 The policies and 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 one of this document.

2.5 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.

2.6 Laboratory staff shall have the qualifications, training, experience and skill to perform the tasks referred to in this document. Training shall be maintained up-to-date.

2.7 As required by ISO/IEC 17025 clause 5.2 (ISO 15189 clause 5.1) and ISO/IEC 17025 clause 4.12 (ISO 15189 clause 4.11), the Laboratory shall maintain records of training, competency, and staff authorized to use equipment and reference materials or to perform calibrations, tests, in-house calibrations and checks.

3. Planning and the selection of equipment/reference [ISO/IEC 17025 clauses 5.5, 5.6 & ISO 15189 clauses 5.3, 5.6]

3.1 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.

3.2 The Laboratory shall ensure that all items of measuring equipment needed for the work, including reference measurement standards, meet the requirements of ISO/IEC 17025 clauses 5.5, 5.6 & ISO 15189 clauses 5.3, 5.6.

3.3 The Laboratory shall also ensure that, where required by EGAC, 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.

3.4 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.

3.5 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 ISO/IEC 17025 or ISO 15189, 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.

3.6 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, Reference materials - General and statistical principles for certification. These 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.

3.7 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 3.5 of this document.

4. Uncertainty of measurement [ISO/IEC 17025 clauses 5.4.6, 5.6.2.1, 5.6.2.2, 5.10.3.1(c) & 5.10.4.1(b) and ISO 15189 clauses 5.5.1.4, 5.5.3(m)]

4.1 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.

4.2 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.

4.3 In estimating uncertainties of measurement, the Laboratory shall take account of data obtained from internal quality control schemes and other relevant sources, (see ISO/IEC 17025 clause 5.6.2.1.2). The Laboratory shall also ensure that any requirements for the estimation of uncertainty and for the determination of compliance with specified requirements as stated in the relevant EGAC publications, are complied with at all times.

4.4 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.

5. Calibration procedures [ISO/IEC 17025 clause 5.4]

5.1 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 ISO/IEC 17025 clause 5.4. 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 shelf life 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 5.2 of this Document);
(j) the procedures to be adopted for selecting calibration intervals when the equipment/reference material is being used by the Laboratory to perform calibrations or tests;
(k) the procedures for checking equipment and reference materials between calibrations;
(l) an identification number, number of pages, date of issue and name of person authorizing issue and use of the procedure.

5.2 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.

5.3 Where the Laboratory uses the services of an external organization to calibrate measuring and test equipment, the requirements of ISO/IEC 17025 cluse 5.6 shall be met. If the services of a EGAC accredited calibration laboratory are not available, and after considering EGAC's policy on traceabilty PB04L, the Laboratory shall ensure that the calibration certificate provided contains the following information:
(a) an unambiguous identification of the item calibrated;
(b) a description of the measurement standard(s) used and its calibration status;
(c) a statement indicating how traceability to national standards has been achieved;
(d) the method of calibration;
(e) a statement of compliance with any relevant specification;
(f) the calibration results;
(g) the uncertainty of measurement;
(h) the environmental conditions, where relevant;
(i) the date of calibration;
(j) the signature of the person under whose authority the certificate was issued;
(k) the name and address of the issuing organization and the date of the certificate.

6. Records [ISO/IEC 17025 cluses 4.12, 5.5 and 5.10]

6.1 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 calibrations 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.

6.2 The Laboratory shall ensure that the records contain detailed information of the equipment/reference material used for calibrations, and that there is also a full and up-

to-date history of the calibration of this equipment/reference material (see ISO/IEC 17025 clause 5.5).

6.3 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 shelf life and required storage conditions.

6.4 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 EGAC logo), from EGAC accredited calibration laboratories of appropriate measurement capability, from the Laboratory holding the national standard for the reference measurement standards used, or from a laboratory meeting the requirements for traceability specified in the EA document EA 5/01, 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;
(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 ISO/IEC 17025 clause 5.5 and of any servicing, adjustment, repair or modification, particularly at the time of calibration.

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

7. Calibration intervals [ISO/IEC 17025 clause 5.5.8, ILAC G24]

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

7.2 Reference measurement standards shall be calibrated at lab approved intervals. Reference materials shall be checked for deterioration and, if necessary, replaced.

7.3 All other measuring and test equipment should be calibrated see the following
(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);
(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.

7.4 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 7.3 of this document. 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.

7.5 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.

7.6 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 ISO/IEC 17025 shall be met and the maintenance and calibration intervals shall be reviewed immediately and modified where necessary. Such equipment shall not be returned to service until the reason for the deviation has been eliminated and the equipment has been re-calibrated.

7.7 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.

7.8 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.

8. Sealing of calibrated equipment

8.1 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 ISO/IEC 17025 are met.

9. Labelling of calibrated equipment and referen materials

9.1 The requirements for labeling, codifying, or otherwise identifying the status of calibration of measuring and test equipment used by the Laboratory are given in ISO/IEC 17025

9.2 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.

9.3 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.

9.4 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.