KENYA ACCREDITATION SERVICE

Document Title: CRITERIA FOR THE ACCREDITATION OF CALIBRATION LABORATORIES - GENERAL

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Approval and Authorization

Completion of the following signature blocks signifies the review and approval of this Document.

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1 OVERVIEW CONTENT

1.1 Process Overview

This document serves to amplify and interpret the requirements of ISO/IEC 17025:2005 for the accreditation of Testing and Calibration laboratories. The calibration laboratories covered under this criterion includes:

1.1.1 Electrical

1.1.2 Heat and temperature

1.1.3 Optical and radiometry

1.1.4 Mass, volume and density

1.1.5 Pressure and flow

1.1.6 Revolution

1.1.7 Torque

1.1.8 Time and frequency

1.1.9 Dimensional

This Criteria document should be read in conjunction with ISO/IEC 17025:2005, KENAS General Assessment criteria for Testing and Calibration Laboratories, KENAS Terms and Conditions documents and the applicable government regulations.

1.2 Purpose

This criteria document covers Calibration performed using standard methods, non-standard methods and laboratory-developed methods. This document is applicable to all type of calibration laboratories including those which form part of inspection and/or certification organization. It is also applicable to all calibration laboratories regardless of the number of personnel or extent of the calibration activities.

1.3 Scope

This criteria document set out the general requirements to be met by the calibration laboratory. However, it does not detail how such requirements shall be met. It is the responsibility of the laboratory management to determine the best approach to meet such requirements, the overall quality of the laboratory and its resource allocations. KENAS assessment team may require the

laboratory to demonstrate to them the method selected to determine its adequacy in meeting the requirements of this criteria document.

Supplementary criteria documents for specific areas in metrology shall be available and may give useful and detailed information in specific areas of metrology.

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1.4 Role(s) and Responsibility

Role	Responsibility
Testing and Calibration Team	• Development of draft for Technical Committee Review. • Administration of Periodic review
Testing and Calibration Technical Committee	• Technical Draft Review and approval
Assessors and Technical Experts	• Ensure that Accredited labs comply with the requirements in this guidance document

2 DEFINITIONS / ABBREVIATIONS

The table below defines new or changed terms that are included in or associated with this process.

Term	Definition
KENAS	Kenya Accreditation Service
KEBS	Kenya Bureau of Standards
NMI	National Metrology Institute
NSB	National Standards Body
OIML:	International Organization of Legal Metrology.
ISO	International organization for standardization.
CMC:	Calibration and Measurement Capability
Calibration and Measurement Capability (CMC):	The smallest expanded uncertainty that a laboratory can claim within its scope of accreditation.
Calibration:	Specific types of measurement performed on measuring instruments to establish the relationship between the indicated values and known values of a measured quantity.

Proficiency Testing:	Determination of laboratory performance by means of comparing and evaluating calibrations or tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.
Traceability:	Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.
Uncertainty:	The amount by which a true value may differ from a measured value, at a given confidence level.

3 Process instructions

3.1 Personnel requirements:

3.1.1 The calibration laboratory shall engage staff possessing the technical and professional expertise necessary to perform the calibration. The staff may be full-time, part-time or contracted personnel. The personnel performing the calibration shall satisfy all the requirements defined in clause 5.2 of ISO/IEC 17025:2005.

3.1.2 KENAS accredited and applicant laboratories are required to provide training to their calibration technicians and to their authorized signatories to comply with the requirements of ISO/IEC 17025:2005. The calibration laboratory shall evaluate and appraise the calibration technicians to be competent before allowing them to perform calibration work independently.

3.2 Environmental and Accommodation Requirements:

3.2.1 To be deemed capable of making adequate measurements, calibration laboratories shall provide an environment with adequate environmental controls appropriate for the level of measurements to be made as required by clause 5.3 of ISO/IEC 17025:2005.

3.2.2 Temperature/Pressure: The calibration shall be performed at stable ambient conditions under ambient atmospheric pressure at temperatures close to room temperature. Typical recommended values are given specific criteria guideline documents.

3.2.3 Lighting within the laboratory shall be adequate to facilitate the correct performance of the calibration work undertaken. Cognizance shall be taken of the minimum levels of lighting as specified in clause 5.0 of the Occupational Safety and Health Act (OSHA Act 2007).

3.2.4 Housekeeping: Calibration laboratory shall have adequate space, be free from dust and fumes, free from vibration and acoustic noise and free from any contamination especially in locations where calibration items are calibrated.

3.2.5 The extent to which these environmental factors apply will vary according to the uncertainty to which calibrations are performed and to the specific area of metrology.

3.2.6 Where necessary the laboratory shall maintain appropriate records to demonstrate and confirm the environmental conditions within the laboratory.

3.3 Safety Requirements:

All Metrology and Calibration laboratories are expected to comply with the Occupational Safety and health Act 2007 and any other health and safety requirements which shall apply.

3.4 Assessment Focus:

In addition to the general assessment rules in the assessor guide, the following points shall be taken into consideration while assessing calibration laboratories.

3.5 **Calibration Methods**:

3.5.1 The calibration laboratory shall apply adequate methods, which render correct and credible results. The procedures for selecting a method, especially when the object of calibration can be calibrated according to several methods shall be assessed.

3.5.2 Each calibration procedure, the methodology and all the procedures for giving an estimation of measurement uncertainties and the related Calibration and Measurement Capabilities (CMCs) shall be assessed.

3.6 Resource availability and Method validation:

3.6.1 Resource Availability:

The availability of the appropriate resources for carrying out calibrations shall be checked, the facilities and the equipment of the laboratory shall be examined, and any other influence factors having an important impact on the assessed calibration procedures shall be estimated.

3.6.2 Method Validation

3.6.2.1 The validation procedures and validation records shall be assessed, which should, among other, confirm the correctness of the estimated measurement uncertainties.

3.6.2.2 The assessor shall check the records of implementing the standard methods into the laboratory, and in the case of modifications, the corresponding partial validations.

3.7 Traceability:

3.7.1 Traceability of a measurement result is ensured when the result can be related to a stated reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

3.7.2 The assessor shall find out how the traceability of the results of individual calibrations is assured (acceptable measurement traceability).

3.7.3 The concept of measurement traceability shall also include the competence of all the people involved, the fitness of each measurement environment, the suitability of the methods used and all other aspects of the quality and technical systems involved at each step in the chain of measurements.

3.7.4 The assessor shall include checking the equipment and any performance of internal calibrations (of the standards and/or reference materials used) used in traceability. The assessor shall assess the control of these equipment and any internal calibrations undertaken by the calibration laboratory.

3.8 **Witnessing the Calibration**:

3.8.1 Witnessing of the performance of individual calibration procedures – or at least the key parts of these procedures, when long-lasting procedures are concerned – shall be included.

3.8.2 The assessor shall assess the conformity of the procedures performed against the requirements for the given calibration procedure.

3.8.3 When practicable, the assessor shall witness the calibrations carried out according to the regular work plan of the laboratory. When, at the time of the assessment visit, the laboratory is not planning any calibrations that the assessor would like to witness, the particular calibration can be performed specially for this purpose on a corresponding (e.g. already calibrated) sample. This shall be agreed in the opening meeting.

3.8.4 If the assessor intends to witness calibrations which need special preparation, the laboratory shall be notified in advance to that effect.

3.9 Quality of results (participation in inter-laboratory comparisons):

3.9.1 The assessor shall examine the records of the laboratory's participation in inter-laboratory comparisons. The assessor shall determine whether the selected comparisons and the scope of participation are conforming (with reference to the accredited procedures) to the accredited procedures. The assessment shall include the results/performance of the laboratory.

3.9.2 Particular attention shall be paid to any possible negative results of participations, and the assessor shall examine the adequateness of the corrective actions implemented by the laboratory in this respect.

3.9.3 The assessor shall assess and report the importance and relation of these results to the scope of accreditation, and as an ultimate consequence, propose a change of the scope (suspension, withdrawal, changes, and the like) of accreditation.

3.10 Uncertainty of Measurement:

3.10.1 Metrology and Calibration laboratories shall document a policy / procedure on calculation of the uncertainty of measurement.

3.10.2 The assessor shall determine if all known components of uncertainty arising from type A and type B contributions have been considered while evaluating and estimating the uncertainty measurement of the particular calibration.

3.10.3 For accredited calibration laboratories, the scope of calibration shall include a CMC which shall be assigned to each of the calibration for which the calibration is accredited.

3.10.4 The assessor through examining of the calibration records of the measuring equipment and the conditions under which the calibration are performed, shall determine whether the smallest uncertainty of measurement for each calibration proposed by the laboratory is acceptable.

3.10.5 Conformity with the requirements of the documents ILAC-P14 (ILAC Policy for Uncertainty in Calibration) shall be mandatory.

3.11 Scope of accreditation:

3.11.1 Each Calibration laboratory accredited under KENAS shall have the specific scope and ranges for which it is accredited clearly given in its Accreditation Schedule. Each time the assessor shall check the validity of the Accreditation scope for compliance.

3.11.2 In the assessment report the assessor shall obligatorily give his/her comments regarding the scope, which may include the failures identified, estimates of expected incorrect values (e.g. within the scope of quantities or CMC or other restrictions in calibrations), or

estimates of intended demonstrated changes given by the laboratory, which shall finally be confirmed through considering the nonconformities found by the assessment**.**

3.11.3 Otherwise, when the assessor identifies no changes or corrections to the scope of accreditation, and also no impacts on the granted scope are to be expected from notified corrective action, the assessor shall clearly and concisely report on this as well.

3.11.4 In the initial assessment, and in surveillance assessments, the competence of the calibration laboratory against the complete scope of accreditation shall always be assessed.

3.12 On site Calibration:

3.12.1 Some metrological measurements for which formal laboratory accommodation is not essential, e.g. balance calibration, field pressure or temperature calibrations, meter calibration, tank calibration etc. may be performed in site and accreditation may be granted for these calibrations even though the laboratory has no calibration room set aside for this work. In these circumstances KENAS shall consider the staff, reference standards, measuring equipment, storage facilities, transport, and office facilities as to make a laboratory.

3.12.2 The assessor shall witness the calibration on site and check for competence of the calibration laboratory in undertaking its scope of work.

3.12.3 Where an accredited calibration laboratory offers site calibration from more than one branch, with all branches having the same scope and procedures, the accredited main branch(s) shall be fully assessed as usual. The assessment shall cover staff from all sites and their records and equipment details. In addition, each subsidiary branch operation shall, where possible, be assessed at least once between routine surveillance. Every branch shall be included in the accredited laboratory's internal audit schedule and the accredited laboratory's quality management system shall encompass all branch and site operations.

3.12.4 The accredited laboratory's scope of accreditation shall list all branches from which the site calibration services are offered. Site calibration capability shall be clearly identified in the scope of accreditation along with the least uncertainty (CMC) for each accredited measurement range.

3.13 Calibration Certificates:

3.13.1 The assessor shall examine sample of calibration certificates offered by the calibration laboratory to check for compliance of the Clauses 5.10.2 and 5.10.4 of ISO 17025: 2005.

3.13.2 For accredited laboratories, the assessor shall check for the correct use of KENAS logo in the certificates with respect to the scope accredited and the capability range as indicated in the schedule.

3.13.3 The assessor shall also check laboratory's accreditation number (for already accredited laboratory), results of the measurements with units, uncertainty of measurements, measurement traceability, etc.

3.13.4 The assessor shall ensure that the laboratories have not reported measurement uncertainties that are below their Least Uncertainty of Measurement, or Calibration and Measurement Capability (CMC).

4 REFERENCE AND RELATED DOCUMENTS

Ref	Document Identifier	Document Title
1.	ISO/IEC 17011	Conformity Assessment-General requirements for accreditation bodies accrediting conformity assessment bodies
2.	ISO/IEC 17025	Conformity Assessment – General requirements for Testing and Calibration Laboratories
3.	KENAS-TS-F-004	Confidentiality Form
4.	KENAS-POL-036-02	KENAS Policy on traceability of measurements
5.	ISO/IEC 17000	Conformity assessment - Vocabulary and general principles.
6.	ILAC –P14	ILAC Policy for uncertainty in calibration
7.	OSHA 2007	Occupational Health and Safety Act 2007
8.	KENAS-POL-038	KENAS Policy on Proficiency Testing and Inter-laboratory Comparisons
9.	KENAS-POL-041	KENAS Policy om measurement uncertainty in calibration laboratories
10.	KENAS-GUD-032	Guidance on use of Accreditation Marks and Reference to Accreditation Status.

5 TRAINING

Notification to CABs and awareness by Assessors.

6 REVISION HISTORY

Date	Ver	Revised By	Reason For Revision
16/03/2013	01	ADTC	• Initial
14/03/2017	02	ADTC	• Align guideline to the right template. • Incorporate references, and terms and definitions in the appropriate sections. • Addition of references KENAS-POL-038, KENAS-POL-041