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ACC-CD-50-01

Criteria For the Accreditation of Gas Detectors and Breath Alcohol Analysers Calibration Laboratories

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1 Background Information

1.1 Introduction

This document provides guidance for the evaluation of technical competence of calibration laboratories calibrating gas detectors and breath alcohol analysers. These include instruments used to measure toxic gases, flammable gases (via % LEL sensors), and oxygen concentration for gas detectors. Breath alcohol analysers are used for detecting alcohol concentration. Gas detectors and breath alcohol analysers are widely used in safety-critical applications (confined spaces, industrial plants, utilities). Accurate calibration is essential because incorrect readings may lead to fatal incidents

1.2 Purpose

This guidance document serves to complement and align with the requirements of ISO/IEC 17025 for Calibration Laboratories for gas detection. It also integrates relevant KENAS policies, procedures, and guidance documents to ensure the comprehensive and consistent application of best practices in the calibration of the scope.

1.3 Scope

This document is applicable to calibration laboratories calibrating the following instruments:

- Calibration of gas detection instruments
- Calibration of breath alcohol analysers
- Breath alcohol analysers

The criteria outlined herein will be utilized alongside the Assessor Guide and Terms of Reference ACC-CD-02-01, the Procedure for Management and Reporting of Assessments ACC-PR-07-01, the Procedure for Sampling during Assessment and Internal Audits ACC-PR-03-01, the Policy for Management of Extraordinary Events PL-13-01, the Policy for Handling Objections to Assessors/Experts PL-30-01, and applicable International Laboratory Accreditation Cooperation (ILAC) policies and guidance documents. Accreditation shall be granted based on the Calibration Laboratory's demonstrated competence.

1.4 Role(s) and Responsibility

Role	Responsibility
Manager Calibration	Process owner
Principal Accreditation Officer Calibration	Reviewer

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Role	Responsibility
Chief Manager Laboratories	Recommender
Chief Executive Officer	Approval
Calibration Laboratories	Compliance

2 Terms and Definitions

For this guidance document, the following terms and definitions shall apply in addition to those given in ISO/IEC 17000 and the Kenya Accreditation Service Act 2019.

2.1 Definition of Terms

2.1.1 Accreditation

Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

2.1.2 Scope of accreditation

The specific conformity assessment services for which accreditation is sought or has been granted.

2.1.3 Measurement

The process of experimentally obtaining one or more values that can reasonably be attributed to a size.

2.1.4 Metrological traceability

Refers to the ownership of a measurement result referenced through an uninterrupted and documented calibration chain, each contributing to the measurement uncertainty.

2.1.5 Breath alcohol analysers

A breath alcohol analyser is a device that determines breath alcohol concentration (BrAC) by analysing a breath sample, typically expressed in units such as mg of alcohol per litre of breath (mg/L). The result is commonly used to infer blood alcohol concentration (BAC) using an accepted conversion ratio.

2.1.6 Gas detection instruments

Gas detection instruments are devices designed to detect, identify, and/or measure the concentration of specific gases in air or other environments, typically to ensure safety, environmental monitoring, or process control.

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3 Acronyms and Abbreviations

AB	Accreditation Body
CL	Calibration Laboratory
CEO	Chief Executive Officer
CML	Chief Manager, Laboratories
MCAL	Manager Calibration
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
KENAS	Kenya Accreditation Service
TS	Technical Specifications
NMI	National Metrology Institute

4 Criteria

4.1 Requirements of Accreditation

4.1.1 General requirements:

4.1.1.1 A Laboratory applying for accreditation in the scope of calibration of gas detectors and breath alcohol analysers shall provide:

a) A definition of the competency required related to the gas detectors and breath alcohol analyser methods being applied.
b) Information about the availability of this competency (competence evaluation of personnel undertaking calibration activities).
c) A potential client who has made an application for calibration for the scope under review.

4.1.2 Application Package:

4.1.2.1 The application package includes the following:

a) Duly filled application form
b) Corporate Profile
c) Copy of documents demonstrating legal status
d) Geographic activity details including specification of calibration activities carried out at each location.
e) Cross reference matrix identifying the Calibration Laboratory's Management System documentation where accreditation requirements are met.

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f) Management System Documents such as procedures and supporting documents that demonstrate conformity to accreditation requirements
g) Resume/CVs of proposed technical signatories

4.2 Determination of Accreditation Scope

The accreditation scope of calibration laboratory shall be the following:

4.2.1 Gas detection instruments

4.2.1.1 Single gas (Potable or fixed)

4.2.1.2 Multigas (Potable or fixed)

4.2.2 Breath alcohol analysers (based on legal admissibility)

4.2.2.1 Evidential Breath Tester (Fuel cell sensor) - Portable and fixed

4.2.2.2 Non-evidential Tester (Semi-conductor sensor) -Portable and fixed

4.3 Human Resource Requirements

4.3.1 The Calibration Laboratories shall establish competence criteria for personnel involved in the management and implementation of calibration methods. Personnel performing calibration activities shall possess, at a minimum, a Diploma in Chemistry, Engineering, Occupational Safety, Metrology, or a related field.

4.3.2 The Calibration Laboratory shall demonstrate that the personnel understand the chemistry and physics behind detector performance including but not limited to the following subject areas:

a) Sensor technologies (electrochemical, catalytic bead, infrared, PID)
b) Gas Dynamics (diffusion, pressure effects)
c) Cross-sensitivities and interferences
d) Safe handling of gas cylinders

4.3.3 The Calibration Laboratory shall retain records to demonstrate that the qualification of personnel involved in the calibration activity is appropriate to the calibration to be carried out and demonstrating competence in

a) Operating detectors from multiple manufacturers
b) Using calibration docks or automated systems
c) Handling reference gas mixtures
d) Estimating measurement uncertainty
e) Applying environmental corrections (T, RH, and pressure)

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4.3.4 The Calibration Laboratory shall periodically monitor the competence of the personnel involved in the calibration activities.

4.3.5 Personnel involved in calibration activities shall maintain and improve their knowledge and skills through continuous professional development (CPD) activities, such as training, seminars and conferences.

4.4 Equipment and calibration

4.4.1 Traceability and validity of certified reference materials is important. The Calibration Laboratory shall use CRMs traceable to NMIs. The certificates of traceability should contain concentration, uncertainty, stability/expiry and preparation method.

4.4.2 All reference gases shall have traceable certificates. Flowmeters and mass flow controllers must be calibrated by accredited laboratories.

4.4.3 Equipment may include but not limited to:

a) Traceable Calibration gas
b) Fixed Flow/Demand regulators and flowmeters with known uncertainty
c) Calibration chambers (if applicable)
d) Non-reactive tubing and fittings

4.5 Environmental conditions:

4.5.1 Calibration laboratories shall monitor and control the environmental conditions including but not limited to temperature, pressure, humidity and ventilation. These conditions influence gas density and sensor output. Poor ventilation is a safety hazard and may contaminate zero calibration.

4.6 Calibration Methods and procedures

4.6.1 The calibration procedures shall cover detector preparation, prechecks (battery, warm up, zeroing), span gas application, stabilization period, reading capture, adjustment process, post calibration verification. The procedures shall align with manufacturer guidance.

4.6.2 The laboratory shall use validated methods demonstrating repeatability and reproducibility, linearity (if multi-point calibration); recovery within ±10% (unless manufacturer differs) and response time (T90). The T90 checks ensure detector safety functionality.

4.6.3 To ensure safety controls the procedures shall address flammable gas handling, toxic gas exposure prevention, ventilation and purging, safe cylinder storage. The calibration shall document emergency plans.

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4.7 Measurement Uncertainty:

4.7.1 The Calibration Laboratory shall have written procedures for the determination of measurement uncertainties for calibration activities performed.

4.7.2 Measurement uncertainty components to be considered include CRM gas uncertainty, flow rate uncertainty, detector resolution, repeatability, cross sensitivity, sensor drift and environmental influences. A full GUM compliant budget shall be given for each measurand.

4.7.3 The expanded uncertainty shall be reported with k=2.

4.8 The Quality Assurance in Calibrations

4.8.1 A Calibration Laboratory shall have quality control activities to assess calibration competency. Quality assurance in calibrations shall be done in accordance with the requirements of ISO/IEC 17025.

4.8.2 Intermediate checks shall be conducted including but not limited to verification of flow devices, routine bump tests of reference detectors and zero air checks.

4.9 On-site Assessment

4.9.1 During the initial assessment, the implementation of policies and procedures shall be assessed at the office(s) of the Calibration Laboratory.

4.9.2 The initial on-site assessment comprises of two mandatory components to determine if the Calibration Laboratory should be granted accreditation:

a) Assessment of the applicant's implementation of its management system in an office assessment.
b) Assessment of the applicant's calibration services – witnessed assessment

4.9.3 During the office assessment, the team shall sample the records of clients and personnel, representative of the scope for which accreditation is sought.

4.9.4 In case the Calibration Laboratory has any engagement with a consultancy body, KENAS shall verify records of this consultancy body to confirm the effectiveness of measures taken to mitigate any identified risks to impartiality.

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4.10 Maintenance of accreditation

4.10.1 The implementation of the accredited calibration scope for gas detectors and alcohol breath analysers shall be verified during surveillance assessments by KENAS.

4.11 Appeals Handling

4.11.1 A calibration laboratory that is aggrieved by a decision of KENAS may, by notice in writing to the Chief Executive Officer and upon payment of the prescribed fees, appeal against the decision within twenty-one days of being notified of the decision as outlined in the third schedule of the Kenya Accreditation Service Act, Cap 496 A.

4.11.2 A notice of appeal under this section shall set out the grounds of the appeal.

4.11.3 The Chief Executive Officer shall, within seven days of receipt of the notice under sub-section (2), forward the notice to the Accreditation Appeals Tribunal.

4.11.4 The Accreditation Appeals Tribunal shall consider the notice of appeal and the response of KENAS before making an award.

4.11.5 An award of the Accreditation Appeals Tribunal may —

a) confirm the decision of KENAS.

b) vary the decision of KENAS.

c) direct KENAS to carry out a fresh evaluation of the application or undertake a fresh assessment of the conformity assessment body; or

d) issue other orders it may consider necessary.

4.12 General remarks on witnessing

4.12.1 In addition to the above-mentioned considerations for selection of calibration activities to be witnessed, the following will apply:

4.12.1.1 KENAS will not witness the same personnel more than once within the same scope.

4.12.1.2 KENAS will not witness calibrations at the same organization repeatedly.

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4.13 Quality Management system:

4.13.1 The quality system shall describe the general and specific arrangements for the conduct of all calibration activities under accreditation and should specifically incorporate:

4.13.1.1 the arrangements for managing calibration work including the organisational interface and controls between the permanent facilities and remote or site locations.

4.13.1.2 the control and authorisation of calibration specific procedures and methods.

4.13.1.3 the need to ensure that calibration procedures and methods are available at the point of calibration, whether in the laboratory or on site.

4.14 Accreditation Standards

A Calibration laboratory shall satisfy the following normative documents for accreditation of calibration of gas detectors.

4.15 Review of Criteria Document

4.15.1 This document shall be revised/amended after every four (4) years.

5 Associated Documents

Ref	Document Identifier	Document Title
1.	ISO/IEC 17025	Conformity assessment — General requirements for the competence of testing and calibration laboratories
2.	ISO 6142	Calibration of gas mixture preparation
3.	ISO 6145	Gas dilution and flow control
4.	ISO 10156	Gas flammability classification
5.	ILAC P10	ILAC Policy on Traceability of Measurement Results
6.	ILAC P14	ILAC Policy for Measurement Uncertainty in Calibration

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6 Revision/ Amendment Record

Date	Ver	Revised By	Reason for Revision
29/06/2026	01	SDE	New document

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