



## KENYA ACCREDITATION SERVICE

Document Title: FORMULATION OF ACCREDITATION SCOPES

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-TS-OP-016	03	24/07/2015	24/08/2015	OP	1 of 8

### Approval and Authorization

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

Name	Job Title / Role	Signature	Date
Authored by	Assistant Director Inspection and verification	<i>Approved</i>	24/07/2015
Checked by	Deputy Director Technical Services	<i>Approved</i>	24/07/2015
Approved by	Chief Executive Officer	<i>Approved</i>	24/07/2015

### Periodic Review Approval and Authorization

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

Required by: (07/2018)

Name	Job Title / Role	Signature	Date
Checked by			
Approved by			

Required by: (07/2021)

Name	Job Title / Role	Signature	Date
Checked by			
Approved by			



# KENYA ACCREDITATION SERVICE

Document Title: FORMULATION OF ACCREDITATION SCOPES

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-TS-OP-016	03	24/07/2015	24/08/2015	OP	2 of 8

## 1 OVERVIEW CONTENT

### 1.1 Process Overview

The procedure provides for how the scopes for Calibration, Testing, Inspection and Certification are formulated in order to allow for clear statements that will avoid ambiguity and confusion to clients.

### 1.2 Purpose

The purpose of this procedure is to provide for scope definition of accreditation in order to allow for an effective and harmonised application among KENAS schemes in relation to the relevant international Standards

### 1.3 Scope

The procedure sets out how the scope of accreditation for the various schemes shall be defined.

### 1.4 Role(s) and Responsibility

Role	Responsibility
CEO	<ul style="list-style-type: none"><li>Approval.</li></ul>
Technical Services	<ul style="list-style-type: none"><li>Compliance and Implementation while providing guidance to clients whose scope may be insufficient.</li></ul>

## 2 DEFINITIONS/ABBREVIATIONS

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

Term	Definition
Scope	A formal and precise statement of the activities to which a Testing/Calibration facility, an Inspection or Certification Body is accredited for.
CAB	Conformity Assessment Body



# KENYA ACCREDITATION SERVICE

**Document Title: FORMULATION OF ACCREDITATION SCOPES**

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-TS-OP-016	03	24/07/2015	24/08/2015	OP	3 of 8

### 3 PROCESS INSTRUCTIONS

The scope of accreditation of a CAB is the official and detailed statement of the activities for which the CAB is accredited. In ISO/IEC 17011, it is required that the accreditation body shall provide an accreditation certificate to the accredited CAB which shall provide a brief indication of, or reference to, the scope of accreditation.

The formulation and assessment of the scope of accreditation represents the core of the accreditation process. The role of the KENAS is to ensure (to an adequate degree of confidence) that the CAB has the competence to offer the service defined in the scope.

KENAS shall accredit CAB's to a fixed scope.

### 4. THE DEFINITION OF THE SCOPE OF ACCREDITATION

#### 4.1 Testing and Calibration

The scope of accreditation can be clearly defined by parameters such as described in the table below:

Testing Laboratory	Calibration Laboratory	Medical / Veterinary Laboratory
<b>Testing field</b> (e.g. environmental testing or mechanical testing)	<b>Calibration field</b> (e.g. dimensional measurements; Force, Mass, Torque, Pressure, etc.)	<b>Medical field</b> (e.g. clinical chemistry, hematology)
<b>Type of test</b> (e.g. mass spectrometry or hardness testing). This may include the equipment or the equipment can be indicated independently.	-	<b>Examination technique</b> (e.g. IR spectrophotometry) This may include the equipment or the equipment can be indicated independently.
<b>Test object or product/Matrix</b> (e.g. automotive components); Matrices (e.g. tap water)	<b>Calibration objects</b> (e.g. gauge blocks, Balances, Resistance Thermometers, etc.)	<b>Specimen:</b> This is the biological sample (e.g. whole blood, serum, body fluid)
<b>Test parameter</b> (when appropriate) (e.g. hardness)	<b>Measurand</b> i.e. Quantity, property (e.g. length, Mass, Temperature, Pressure)	<b>Components / Analytes</b> (e.g. CO <sub>2</sub> ) or related groups of analytes (e.g. liver function)*
<b>Internal method with Reference to standardized method</b> (e.g. ISO 14577-1:2003)	<b>Internal Calibration procedure with Reference to standardized procedure</b> (when appropriate and applicable)	<b>Internal examination procedure with Reference to standardized procedure</b> (when appropriate and



# KENYA ACCREDITATION SERVICE

Document Title: FORMULATION OF ACCREDITATION SCOPES

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-TS-OP-016	03	24/07/2015	24/08/2015	OP	4 of 8

		applicable)
<b>Measurement range</b> where applicable	<b>Calibration and Measurement Capability (CMC)</b> – This implies the calibration measurement capability expressed as an expanded expressed as follows; Measurement Point / Range $\pm$ expanded uncertainty; (The expanded uncertainty is expressed as the standard uncertainty of measurement multiplied by a coverage factor $k=2$ , corresponding to a 95% confidence level. The unit of uncertainty shall be the same as that of the measurand, unless a range is used, in which case the uncertainty shall be expressed as a percentage which can further be calculated. In specialized fields like electrical additional parameters may be required and hence need to be specified e.g. frequency of applied voltage.	<b>Measurement range</b> where applicable
<b>Test Location</b>	<b>Calibration Site</b>	<b>Test Location</b>

The methods/calibration or examination procedures are usually an important reference to give in the scope and may be specific or generic and can be based on standard methods or laboratory-developed methods:

- Non-standard or laboratory-developed methods are developed by the laboratory itself or other parties, or adapted from standard methods and validated.
- Standard methods are developed by a standardization body or other well-established organizations whose methods are generally accepted by the technical sector in question.

In describing the scope of the laboratory it is relevant in some cases to give both a reference to a standardised method as well as an internal method reference (in the quality management system).

The scope of accreditation shall be described in the schedule that is annexed to the certificate of accreditation.



## KENYA ACCREDITATION SERVICE

**Document Title: FORMULATION OF ACCREDITATION SCOPES**

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-TS-OP-016	03	24/07/2015	24/08/2015	OP	5 of 8

### 4.2 Scoping for inspection bodies.

The scope of accreditation of inspection bodies shall be clearly defined by parameters such as described below:

<p><b>Field of Inspection</b></p> <p>(e.g. Product Design, Products (materials or equipment), Installation, Plant, Premises, Processes, Services and Surveys). Where the field is general like physical inspection; further information will be need for the product or service to which the inspection activity is being carried out.</p>
<p><b>Type and Range of inspection</b></p> <p>(e.g. In-service Inspection or Inspection of new products).</p>
<p><b>Codes / Regulations /Methods</b></p> <p>(e.g. Directives, local Regulations, Standard Specs, Internal procedures).</p>
<p>Inspection Location being the location where the inspection activity is carried out.</p>

### 4.3 Scoping for Certification bodies.

The scope of accreditation of certification bodies shall be clearly defined by parameters such as described below whose details are further provided in additional Criteria documents for the various management systems i.e. QMS, EMS, OHSAS, FSMS.

Management System	Product	Person
<p><b>Management System sub-scope</b> (e.g. QMS, EMS, FSMS, OHSAS, etc.)</p>	<p><b>Scheme</b> <i>This is the scheme to which the product certification rides (e.g. Global Gap, Kenya Gap, etc.)</i></p>	<p><b>Scheme</b> <i>This is the scheme to which the product certification rides(e.g. Kenya Registered Nurse)</i></p>
<p><b>IAF Codes</b> (These are the codes as defined in the listing as per the</p>	<p><b>Product</b> <i>Indicates the product(s) / process (es) that are</i></p>	-



## KENYA ACCREDITATION SERVICE

**Document Title: FORMULATION OF ACCREDITATION SCOPES**

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-TS-OP-016	03	24/07/2015	24/08/2015	OP	6 of 8

<i>KENAS guidance documents and IAF ID 1</i>	<i>certified under that scheme. (e.g. Green peas, Tea, Fish, etc.)</i>	
<b>NACE Codes</b> <i>The codes are as defined in the KENAS guidance documents or in NACE coding system version 2</i>	<b>Code / regulations/std.</b> <i>(applies to the particular industry, national, regional or international requirements to which the scheme is developed)</i>	<b>Code / regulations/std.</b> <i>(applies to the particular profession, industry, national, regional or international requirements to which the scheme is developed)</i>
<b>Number of Certifications</b> <i>This refers to the number of certifications that the CB has issued under the particular sub-scope and code</i>	-	-
<b>Number of auditors</b> <i>This refers to the number of auditors that the CB has issued under the particular sub-scope and code</i>	-	-

#### 4.4 Scoping for Proficiency Testing.

The scope of accreditation for PT providers shall be clearly defined by parameters such as described below:

<b>Field</b> <i>(e.g. Environmental , Mechanical Clinical)</i>
<b>Protocol</b> <i>(provide the detail to which the PT is based and if in-house the reference)</i>
<b>Equipment / Artefact</b> <i>(For testing and inspection fields the equipment and/or matrix maybe specified, but for Calibration, the Artefact will be of more importance)</i>
<b>Standard</b> <i>(This is the standard applied in reference to the PT program, It may be a National requirements hence regulation, etc.)</i>
<b>Parameter</b> <i>The analyte or component(s) provided for</i>



## KENYA ACCREDITATION SERVICE

Document Title: FORMULATION OF ACCREDITATION SCOPES

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-TS-OP-016	03	24/07/2015	24/08/2015	OP	7 of 8

*evaluation by the program*

**Measurement Capability**

The Application form for accreditation has provided for fields in which the CAB can populate the required information in order to provide for a clear scope.

#### 4 REFERENCE AND RELATED DOCUMENTS

Ref	Document Identifier	Document Title
1.	ISO/IEC 17011	<i>General requirements for accreditation bodies accrediting conformity assessment bodies</i>
2.	KENAS-OP-TS-010	Management of assessment, surveillance, re-assessments and reporting
3.	KENAS-OP-TS-018	Sampling during assessments and internal audits
4.	ISO/IEC 17020	Conformity assessment; requirements for the operation of various types of bodies performing inspection.
5.	ISO 15189	<i>Medical laboratories - Particular requirements for quality and competence</i>
6.	ISO/IEC 17021-1	<i>Conformity assessment - Requirements for bodies providing audit and certification of management systems</i>
7.	ISO/IEC 17024	<i>Conformity assessment - Requirements for bodies providing certification of persons</i>
8.	ISO/IEC 17025	<i>General requirements for the competence of testing and calibration laboratories</i>
9.	ISO/IEC 17043	<i>Proficiency testing by inter-laboratory comparison - Development and operation of proficiency testing schemes</i>
10.	ISO/IEC 17065	<i>Conformity assessment – Requirements for bodies operating product certification systems</i>
11.	ILAC G 18	Formulation of scopes for use by accreditation bodies.
12.	IAF ID1	QMS scopes of Accreditation
13.	KENAS-TS-F-022	Application for Accreditation
14.	ILAC P14	ILAC Policy for Uncertainty in Calibration



## KENYA ACCREDITATION SERVICE

Document Title: FORMULATION OF ACCREDITATION SCOPES

Document Identifier	Ver	Issue Date	Effective date	Type	Page No
KENAS-TS-OP-016	03	24/07/2015	24/08/2015	OP	8 of 8

### 5 TRAINING

Staff performing one or more of the roles specified in this procedure shall be taken through training to ensure that they demonstrate the capabilities required to successfully perform the activities described. A period not more than one month shall be allocated between the issue date and effective date to facilitate such training.

### 6 REVISION HISTORY

Date	Ver	Revised By	Reason For Revision
10/2/2014	01	ADIV	Align to requirements of ILAC G18
06/11/2014	02	ADIV	Addition of Normative Standard references.
24/11/2015	03	ADIV	Addition of ILAC P14 reference Clarification of CMC provided for in table under 4.1 as provided for in ILAC P14, 5.2 & 5.3