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KENYA
ACCREDITATION
SERVICE

PL-43-02

Flexible Scope Accreditation Policy

Preamble

The Flexible Scope Accreditation Policy is one of the Client focused policies recommended by KENAS's Clients during the Client Dialogue Forum held on 9th June 2022. It is based on best practices drawn from normative standards and Accreditation Best Practices. It aligns with the Kenya Accreditation Service Act Cap 496 A laws of Kenya aspirations.

The Policy allows accredited bodies with demonstrated competence in fixed scopes and accredited under flexible scopes to manage all or part of a scope of accreditation without the necessity of a preliminary evaluation by KENAS for each new activity thereby avoiding application for extension of scope which is both time consuming and expensive. Its objective is to ensure that Clients accredited under flexible scopes are able to take immediate advantage of commercial opportunities.

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1 Background Information

1.1 Purpose

This policy establishes the overall requirements for accredited Conformity Assessment Bodies (CABs) to manage all or part of a scope of accreditation without the necessity of a preliminary evaluation by KENAS for each new activity. In addition, the policy provides guidance in fulfilment of the requirements of ISO/IEC 17025 and ISO 15189 on flexible scope accreditation.

The policy therefore sets out the framework within which KENAS accreditation for flexible scopes can be obtained by CABs, by allowing them to claim accreditation for changed methodologies or other parameters that fall within the competence of the CAB as confirmed by KENAS.

1.2 Scope

This policy applies to CABs seeking accreditation for flexible scopes and those accredited on flexible scopes.

1.3 Legal Basis

The Kenya Accreditation Service is a State Corporation established under the Kenya Accreditation Service Act Cap 496A Laws of Kenya mandated to accredit and exercise oversight over conformity assessment providers and maintain an internationally recognized accreditation system.

2 Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the Kenya Accreditation Service Act Cap 496A Laws of Kenya and the following further terms apply;

2.1 Acronyms and Abbreviations

AC	Ad-hoc Committee
CAB	Conformity Assessment Body
ILC	Inter Laboratory Comparison
KENAS	Kenya Accreditation Service
PT	Proficiency Testing

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2.2 Definition of Terms

2.2.1 Scope of Accreditation

Specific conformity assessment activities for which accreditation is sought or has been granted.

2.2.2 Flexible Scope

Scope of accreditation was established to allow CABs to make changes in methodology and other parameters which fall within the competence of the Conformity Assessment Body as confirmed by KENAS. It includes extending the scope of accreditation to introduce new locations. (Confirm the definition as provided in ISO 17000)

2.2.3 Fixed Scope

Clearly defined description of the specific conformity assessment activities for which the CAB holds accreditation. It recognises common competencies required to perform the conformity assessment activities relating to these items.

2.2.4 Object of Conformity Assessment

Any particular material, product, installation, process, system, person, claim or body to which conformity assessment is applied.

2.2.5 Conformity Assessment Activity

An activity that demonstrates that specific requirements are fulfilled. This can include testing, examination, inspection, certification and verification.

2.2.6 Conformity Assessment Standard

A normative standard that provides requirements for the operation of a specific type of conformity assessment body, and which is used by KENAS to assess and accredit a CAB.

2.2.7 Schedule of Accreditation

The document that KENAS issues, accompanying the certificate of accreditation, detailing the scope of accreditation awarded.

2.2.8 Validation

The process that is followed to demonstrate with the provision of objective evidence, that a specific method/procedure is suitable for the intended use.

2.2.9 Verification

This refers to the process where the applicability of the method to all products under test as well as staff competence in the method is established.

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2.2.10 Scheme Manager

KENAS personnel responsible for the scheme under which the flexible scope applies.

3 Policy Statement

3.1 Flexible scope eligibility criteria

3.1.1 The policy will only cover CABs that have previously demonstrated their competence through accreditation for fixed Scope of Accreditation for a specific technique/instrument, and who are able to demonstrate that accreditation of specific methods is related to an already accredited scope.

3.1.2 However, for CABs that are in their first accreditation cycle, a transition to the flexible scope can only be achieved, at the earliest, in connection with the first reassessment visit. CABs that have been accredited for more than one accreditation cycle, a transition to the flexible scope can only be achieved after having demonstrated their competence to manage fixed Scope of Accreditation in the defined fields.

3.1.3 The possibility of introducing new, modified or developed methods under flexible scope does not include introduction of new measurement principles of testing, calibration or examination not previously covered by the scope of accreditation.

3.1.4 However, in cases where there is a completely new technique and/or major changes due to equipment upgrades, the CAB shall be required to apply for extension of scope.

3.2 Preconditions for a flexible scope

3.2.1 The CAB shall analyse the need for flexible scope, identify and define the activities corresponding to the fixed scope.

3.2.2 The CAB shall introduce changes between assessment visits and comply with the principles presented in this document.

3.2.3 The flexible scope requires the CAB to have planned activities and a well-functioning management system. (PT, Validation of methods, ILC's)

3.3 Basic conditions for the introduction of a flexible scope

3.3.1 Demonstration that the CAB has effective and daily deployment procedures that are effective and transparent (validation/verification procedures).

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3.3.2 Comprehensive quality assurance procedures that are appropriate for the activities and take into account the factors of uncertainty. They are also monitored systematically for their efficiency.

3.3.3 A description of the principles of flexible scope and the activities that are encompassed by the flexible scope.

3.4 Requirements for management

3.4.1 Commitment and assurance of sufficient resources.

3.4.2 Definition of the personnel's responsibilities, authorizations and maintenance of their professional skills, also with respect to the flexible scope.

3.4.3 Appropriate procedures for identifying risk factors in activities.

a) Expertly conducted audits that also pay attention to activities covered by the flexible scope.
b) Active monitoring of customers' needs/feedback and co-operation with customers.

3.5 Requirements for those responsible of the flexible scope

3.5.1 Competence to modify activities in response to customers' needs

3.5.2 The ability to analyse the effects and risks of new or modified activities (such as resource needs).

3.5.3 Good management of documentation. Documentation shall be traceable, comprehensive and clearly show the operative changes.

3.6 The Application Process

3.6.1 The CAB shall make an application to KENAS through ACC-FM-06 with the proposed flexible scope of accreditation.

3.6.2 The application shall be accompanied by:

a) Clear and valid reason/s why accreditation of specific methods under fixed scope is not possible or not a viable solution.
b) List of Authorized Individuals or Technical Signatories responsible for the management of the flexible scope and their training and competence records. These records shall include evidence of training on the flexible scope applied for and competence to review the validation, verification data and risk assessment prior to authorizing the method before use.
c) Validation/qualification report/s for the applicable parameter;
d) Proficiency Testing (PT) and/or Inter Laboratory Comparison (ILC) plan and evidence of satisfactory performance of the latest PT and/or ILC results;
e) Procedure on training and competence evaluation;

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f) Quality control procedures to assure the validity of newly introduced methods;
g) Internal audit programme, which includes the development/review and accepting/authorizing of methods for flexible scope accreditation, Contract review procedure that addresses the requirements that fall within the flexible scope accreditation, including the review and authorization of methods;
h) Structure of reports for flexible scope accreditation.
i) A record of the new additions and/or modifications to the methods.

3.6.3 The responsible Scheme Manager shall clarify with the Applicant the flexible scope applied for, where necessary.

3.6.4 A Scheme Manager shall review the flexible scope applied for and, based on the information provided as per clause 3.6.2, recommend the decision for the accreditation to the CEO.

3.6.5 The AC may request the applicant and/or CAB for additional documentation , where necessary.

3.6.6 The decision of the AC shall be recorded in writing and include comments on the information provided for each point in clause 3.6.2. The AC decision shall be sent to the relevant Scheme Manager, who will advise the applicant CAB accordingly.

3.6.7 KENAS shall communicate the accreditation decision as defined in Rules for Granting, Maintaining, Renewing, Extending, Reducing, Suspending or Withdrawing Accreditation (ACC-RL-01).

3.7 Assessment

3.7.1 When assessing a Flexible Scope management system, the focus shall be on the operating principles and procedures defined. For technical operations, the emphasis shall be on the methods or activities proposed for the flexible scope.

3.7.2 The initial assessment shall take into consideration the necessary pre-requisites and well-functioning procedures as well as clear and comprehensive documentation.

3.7.3 During the subsequent visits, how the CAB has adhered to the principles of the flexible scope is assessed along with how it has applied the relevant procedures in its operations.

3.7.4 Risks shall be taken into consideration in all assessments.

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3.7.5 Where the CAB has not complied with the principles of the flexible scope and/or does not have sufficient competence to maintain a flexible scope, the assessors will assess the significance of the situation.

3.7.6 The evaluation of the situation or deviation might lead to the rejection of an application for flexible scope, suspension or withdrawal of the flexible scope accreditation where necessary.

3.7.7 The CAB may continue under its flexible scope if its activities are compliant with the requirements.

3.8 Responsibilities of the CAB

3.8.1 The CAB shall validate non-standard methods, CAB-developed methods and modifications of standard methods to confirm that methods are fit for the intended use. When a method is applied to a different matrix, it shall be revalidated for that matrix.

3.8.2 The CAB shall confirm through verification that it can properly operate the standard methods before introducing the activities/tests, record the results obtained and ensure that they fall within stipulated parameters, record the procedure used and a statement as to whether the method is fit for the intended use.

3.8.3 Technical signatories shall be experienced in the flexible scope and have excellent knowledge of the underlying principles and theory of the associated technique, including the sample preparation that is applied prior to the measurement.

3.8.4 Technical signatories shall have thorough knowledge of the statistical techniques that are used to validate, verify and transfer the method, assess the validation, verification data and calculate the uncertainty of measurement.

3.8.5 The CAB shall maintain a record of all methods used, modifications to methods and results reported on flexible scope accreditation. The records shall form part of the CAB's management system (have all the necessary control functions). The records shall be clear and comprehensive and include at least the following minimum information:

a) Method
b) Analyte
c) Matrix
d) Technique / Equipment
e) Description of change and date
f) Status of validation, verification and;
g) Personnel

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3.8.6 Where applicable, the CAB shall submit the records as per 5.1 above to KENAS six weeks before the next scheduled assessment and identify new additions and modifications to the methods in the records since the last assessment.

3.8.7 The CAB shall communicate any changes to KENAS as per KENAS-AG-01, Section 2.7 and 2.19, where there are aspects that may affect their flexible scope accreditation status, e.g. resignation of the individual responsible for the overall management of flexible scope and technical signatories.

3.8.8 The process of introducing new activities and locations (including development, review, approval and authorisation) shall be included within the internal audit program as should new and modified activities that become routine practice within the CAB or at new locations. Information on the application of the flexible scope process shall be included in management reviews.

3.8.9 The CABs contract review procedure shall detail how it processes a request which is within the boundaries of its flexible scope, but where the activity has not been undertaken before (i.e., not on the records), the CAB needs to ensure the following:

a) It has determined the most appropriate activities for meeting the client's requirements and whether the activity can be introduced within the bounds of the flexible scope
b) It informs the customer that it will not be able to issue a report under accreditation until the activities have been established and authorised within its system under its flexible scope process;
c) It has access to all necessary resources and other means required for the completion of the specific requested activity;
d) The necessary validation and/or verification has been carried out; and
e) Updating of the records is made only after appropriate technical activities have been properly performed and duly authorised.

3.9 Responsibility of KENAS

In order for KENAS to maintain confidence in the CAB's competence to operate flexible scope accreditation, KENAS shall:

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3.9.1 Conduct assessment as per applicable normative document. In reducing the number of man days needed to carry out a flexible scope assessment, reference shall be made to Estimation of Person Day Calculation Policy (PL-45).

3.9.2 Assess the adequacy of the criteria used by the CAB to deem the technical signatories competent and that of the monitoring program the CAB uses to maintain the competence of personnel (including succession planning).

3.9.3 Review CAB records that define and justify the basis upon which new/modified methods have been developed and implemented; (e.g.: competence of personnel, results of proficiency testing, method validation, measurement traceability, estimating uncertainties, equipment maintenance and calibration).

3.9.4 Sampling activities shall be as per Sampling during Asessment procedure (ACC-PR-03).

3.9.5 Maintain an up-to-date Schedule of Accreditation that clearly and unambiguously indicates the standard specification of a specific instrument, set of instruments or CAB apparatus, granted for flexible scope accreditation. This record shall also be updated on the KENAS website.

3.9.6 Should the CAB have issued any reports under accreditation that do not comply with the requirements of this document, KENAS shall take the necessary measures as referenced in the Accreditation Agreement (AG-01).

3.9.7 In the same way, depending upon the nature, implications and severity of the possible nonconformity identified in terms of the management of a flexible scope, and without prejudice to other actions (for example, suspension, reduction or withdrawal of accreditation as per ACC-RL-01-01, KENAS may decide to revise the scope such as to reduce or even withdraw the flexibility scope.

3.10 Pilot/Implementation Period

3.10.1 The CAB shall only use the KENAS symbol on certificates issued for work done under the flexible scope and not the Combined Mark.

3.10.2 This policy on flexible scopes shall be piloted for a period of one (1) year.

3.10.3 KENAS reserves the right to recall flexible scope as per the accreditation agreement.

3.10.4 KENAS shall maintain a register of CABs accredited for flexible scope under this policy.

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4 Associated Documents

Ref	Document Identifier	Document Title
1.	ISO/IEC 17011	Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies
2.	ILAC G18	Guideline for describing Scopes of Accreditation
3.	ACC-RL-01	Rules for Granting, Maintaining, Renewing, Extending, Reducing, Suspending or Withdrawing Accreditation
4.	AG-01	Accreditation Agreement
5.	ACC-PR-03	Sampling during Assessment procedure
6.	ACC-FM-06	Application for Accreditation Form

5 Revision/Amendment Records

Date	Ver	Revised By	Reason for Revision
13/10/2022	01	RSQ	Newly developed/formatted document
09/06/2025	02	QRM	Systematic review

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