



KENYA ACCREDITATION SERVICE

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CIRCULAR No. 01/2021

TO ALL ACCREDITED BODIES AND APPLICANTS

INFORMATIVE CIRCULAR – NEW ACCREDITATION AGREEMENT TO THE NEW LEGAL STATUTE – THE KENYA ACCREDITATION SERVICE ACT, 2019

1. Introduction

The purpose of this Circular is to inform all accredited bodies, applicants and potential clients of the changes introduced in the alignment of the existing accreditation agreement to the Kenya Accreditation Service (“the Service”) new legal statute – the Kenya Accreditation Service Act 2019 (Act No. 17 of 2019).

All accredited bodies and applicants are required to take note of the highlighted changes contained in this Circular, which sets out changes in terms of agreement between the Service, the accredited bodies, and applicants with provisions of the Act.

2. Background

As set out in the International Standard *ISO/IEC 17011:2017 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*, KENAS is required to hold an Accreditation Agreement with each of its clients.

The current edition of the Agreement was developed in 2012 under the *Kenya Accreditation Service Order, 2009 (Legal Notice No. 55 of 2009)*. Since then, various supplementary amendments were made over the years to cover for additional policy changes and obligations introduced by the ISO/IEC 17011 standard, and/or mandatory provisions of the international accreditation cooperation bodies, namely International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC).

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Following the enactment of the *Kenya Accreditation Service Act 2019* (hereafter referred as the 'Act') on 14th August 2019, the Service has been undertaking transitional processes, which include, among others, alignment of the existing Accreditation Agreement established under the Kenya Accreditation Service Order 2009 (Legal Notice No. 55 of 2009) to comply with the Act and the requirements of ISO/IEC 17011:2017 Standard.

As highlighted during the second Client Dialogue Forum held on 10th December 2020, the transition process for the significant changes introduced by the Act is almost complete. In line with the provisions of Section 35 of the Act, the aligned (new) Accreditation Agreement, and the changes introduced, take effect immediately. All existing signed Agreements remain effective, until a new Agreement is signed in line with this Circular. Each accredited body and applicant will be notified in due course when the existing signed Agreements will be replaced.

3. Significant Changes to the Accreditation Agreement

The following are the highlights of changes have been introduced to the aligned Accreditation Agreement:

(a) Definition and Interpretation

Definition of the following terms have been added to the Accreditation Agreement as provided in the Act and the ISO/IEC 17011: 2017 Standard for purposes of clarity in interpretation, namely:

- **"Accreditation"** means, in relation to a Conformity Assessment Body, an attestation by the Service that the Conformity assessment body is competent to carry out specific conformity assessment tasks.
- **"Accreditation Advisory Committee"** means an Accreditation Advisory Committee established under section 9 of the Kenya Accreditation Service Act, 2019.
- **"Accredited body"** means an organization or a facility that has been accredited by the Service.
- **"Accreditation certificate"** means a document or set of documents that states that Accreditation has been granted to the conformity assessment body named in the documents, the conditions under which the Accreditation has been granted and the scope of the Accreditation.
- **"Accreditation mark"** means the mark issued by the Service to be used by an accredited body to indicate that body's accreditation status.
- **"Accreditation scheme"** means the rules, processes or any other requirements established by the Service relating to specific conformity assessment activities to which a similar accreditation standard applies.
- **"Assessment"** means the process undertaken by the Service to evaluate the competence of a conformity assessment body based on particular standards or other normative documents for a defined scope of Accreditation.
- **"Board"** means the Board of Directors of the Service established under section 7 of Kenya Accreditation Service Act, 2019.



- **"Conformity assessment"** means a demonstration that specified requirements relating to a product, process, system, person or body have been fulfilled.
- **"Conformity assessment body"** herein also referred to as **"CAB"**, means a body that carries out compliance assessment services including the activities of calibration, certification of management systems, persons, processes, products or services, inspection, medical testing, production of reference materials, proficiency testing, testing (general), validation and verification.
- **"Scope of accreditation"** means the specific conformity assessment services that may be offered by a conformity assessment body for which Accreditation has been granted by the Service.
- **"Service"** means the Kenya Accreditation Service established under section 4 of the Kenya Accreditation Service Act, 2019; herein also referred to as **"KENAS"**.
- **"Tribunal"** means the Accreditation Appeals Tribunal established under section 16 of the Act.

(b) Rights and Obligations of KENAS (Article 1)

Introduces surveillance as provided in ISO/IEC 17011:2017 standard and re-assessment as provided in the Act and makes further changes in 1.14 in compliance with the provisions of the Act.

(c) Rights and obligations of the CAB (Article 2)

This has been amended to ensure conformity with the Act, ISO/IEC 17011:2017 and the industry practices.

(d) Complaints (Article 3)

Amendment on Article 3.1 introduces the procedure for submitting complaints to KENAS. The guideline will be available on the KENAS website.

(e) Health and Safety (Article 4)

This Clause existed in the old agreement but following the COVID-19 pandemic the Ministry of Health and related Government guidelines have been added. Take note that requirement to provide Personal Protective Equipment (PPE) kits during site visit is mandatory.

(f) Confidentiality (Article 5)

The purpose of this Article is to protect the CAB's data. It has been amended to align with the Data Protection Act, 2019. Given that there is now a Data Commissioner, KENAS has appointed an Officer in charge of data protection for any document or information received from CABs.

(g) Fees (Article 6)

Article 6 has been amended to align the issues of fees with the Provisions of Section 15 of the Act and fees schedule. Non-payment is a non-conformity in accordance with Section 15 of the Act, consequences for which is suspension and withdrawal as provided under Article 11 and thereafter termination of Accreditation Agreement as provided under Article 13.

(h) Liability (Article 8)

Article 8.2-8.4 has been amended for Legal Compliance Purposes.

(i) Appeals (Article 10)

Previously, Appeals on Accreditation decisions were made through the Standards Tribunal; the Act has now established the Accreditation Appeals Tribunal which has now been set up to deal with Appeals relating to decisions by KENAS, thereby resulting to amendment of this Article.

(j) Suspension/ Withdrawal (Article 11)

This has been amended to align it with the guidelines for suspension and withdrawal of the Accreditation as provided under Section 15 the Act.

(k) Accreditation Certificate, Logo, Accreditation Mark and combined Mark(s) (Article 12)

This has been amended to include the ILAC MRA and IAF MLA combined marks. Guidelines on the use of marks are available on the KENAS website, and the misuse of the same will result in criminal and civil liabilities.

(l) Termination (Article 13)

This has been amended to conform with the guidelines and provisions of the Act on withdrawal of Accreditation which essentially translates to termination of the agreement.

(m) Severability (Article 16)

This Article has been introduced for legal compliance purposes.

4. Implementation of the new Accreditation Agreement

The new edition of the agreement is now available and can be downloaded on our website (www.kenas.go.ke). Accredited bodies and applicants are requested to familiarize themselves with the obligations of this new Agreement.

The transition from the existing agreement to the new edition will be communicated to individual clients and on the timing to retire the existing agreement.

Finally, clients should take note that the Service is not in a position to agree to customised versions through omission or alteration, given that the changes to the new Agreement are primarily required by the Act, ISO/IEC 17011 standard and related mandatory documents published by IAF or ILAC.

Please contact us for any clarifications.



Martin Chesire
CHIEF EXECUTIVE OFFICER