STANDARDS ACT, 1974

Cap 496

THE STANDARDS (TESTING AND DESIGNATION OF LABORATORIES) REGULATIONS, 2026

ARRANGEMENT OF THE REGULATIONS

STANDARDS ACT, 1974

Cap 496

IN EXERCISE of the powers conferred by Section 20 of the Standards Act, Cap 496 the Cabinet Secretary for Investments, Trade and Industry makes the following Regulations—

THE STANDARDS (TESTING AND DESIGNATION OF LABORATORIES) REGULATIONS, 2026

PART I-PRELIMINARIES

Citation.

1. These Regulations may be cited as the Standards (Testing and Designation of Laboratories) Regulations, 2026.

Interpretation.

2. In these Regulations, unless the context otherwise requires—

"accreditation" means third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks;

"Act" means the Standards Act, Chapter 496 of the laws of Kenya;

"Certified Reference Material" means a material that is sufficiently homogeneous and stable characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability;

"Conformity assessment" means a demonstration that specified requirements are fulfilled and includes testing, calibration, inspection, validation, verification, certification, and reference material production;

"designation" means the recognition by the Bureau of a testing laboratory as competent to perform specific tests and measurement activities in accordance with the provisions of the Act;

"Proficiency testing" means the evaluation of laboratory performance against pre-established criteria through inter-laboratory comparisons; and

"Testing laboratory" means a laboratory that determines one or more characteristics of an object of conformity assessment according to a procedure;

Scope of the Regulations.

3. These Regulations shall apply to—

(a) designation of laboratories by the Bureau; and

(b) testing services offered by the Bureau and its designated laboratories under the Act.

Objects of the Regulations.

4. (1) The objects of these Regulations are to—

(a) establish a framework for the conduct of testing by the Bureau and its designated laboratories.

(b) provide for designation and oversight of testing laboratories by the Bureau to enhance conformity assessment; and

(c) promote the reliability, accuracy, and credibility of test results

PART II —TESTING LABORATORIES

Establishment of laboratories by the Bureau

5. (1) Pursuant to Section 12A (1) the Bureau shall establish laboratories.

(2) The laboratories of the Bureau shall —

(a) be the national reference testing laboratory for purposes of conformity assessment of products;
(b) provide testing, measurement and examination services;
(c) issue test certificates;
(c) produce certified reference materials;
(d) develop test methods;
(e) provide proficiency testing and inter-laboratory comparison services;
(f) Offer technical support on matters related to testing
(g) establish and maintain traceability of chemical and biological measurements; and
(h) oversight operations of designated laboratories.

Designation of laboratories

6. (1) The Bureau may designate an external laboratory to provide testing, measurement, examination services and issue test certificates in accordance with these Regulations.

(2) A laboratory shall be eligible for designation as a testing laboratory if it—

(a) is accredited to the applicable international standard on laboratory management systems within the relevant scope;

(b) possesses the necessary technical capacity, equipment and qualified personnel to perform the designated tests; and

(c) has participated in at least one proficiency testing scheme within the relevant scope in the last three years preceding the date of application.

Application for designation.

7. (1) A laboratory seeking designation shall submit an application in the form set out in the First schedule.

(2) The application shall be accompanied by—

(a) proof of meeting the conditions outlined under Regulation 6 (2); and

(b) payment of the applicable fee set out in the Second Schedule.

(3) The Bureau shall evaluate the application and may conduct an onsite assessment to verify compliance to the requirements for designation.

(4) The Bureau shall communicate its decision to approve or reject the application within 30 days from the date of receipt of a complete application.

(5) Where an application is rejected, the Bureau shall provide written reasons for the rejection.

Issuance of designation certificate

8. (1) Where a laboratory meets the designation requirements the Bureau shall issue a designation certificate specifying—

(a) name and address of the laboratory

(b) physical location of the laboratory

(c) validity period of the designation

(d) scope of tests

(e) any conditions attached to the designation

(2) The designation shall be valid for a period of three years.

(3) A designated laboratory may apply for renewal of its designation at least two months before expiry by submitting —

(a) proof of continued compliance with the conditions of designation; and

(b) payment of the renewal fee set out in the second schedule

Annual assessment

9. (1) The Bureau shall conduct an annual assessment of designated laboratories to verify continued compliance with these Regulations and the conditions for designation.

(2) The designated laboratory shall pay an annual assessment fee as set out in the second schedule.

Obligations of designated laboratories.

10. (1) A designated laboratory shall –

(a) conduct tests within the scope for which it has been granted designation;
(b) comply with the conditions for designation;
(c) issue correct, complete and reliable test results;
(d) submit test certificates and any other record to the Bureau as may be required;
(e) uphold confidentiality and ethical practices in the conduct of tests under these regulations;
(f) notify the Bureau of any changes that may significantly impact its capacity to provide designated tests or measurements.
(g) make use of certified reference material where applicable; and
(h) continue to participate in proficiency testing in the designated scopes.

Register of designated laboratories

11. The Bureau shall maintain a public register of designated testing laboratories which shall include—

(a) name, location and address of the laboratory;
(b) scope of tests for which the laboratory is designated; and
(c) status of designation.

Indemnity of the Bureau

12. (1) The Bureau shall not be liable for any errors, omissions or defects in testing conducted by a designated laboratory or any violations of the law by a designated laboratory.

(2) A designated laboratory shall indemnify and hold the Bureau harmless against any claims, damages or legal proceedings arising from—

(a) the conduct, outcome of tests; or
(b) any violations of the law by a designated laboratory.

Suspension and revocation of designation

13. (1) The Bureau may suspend the designation of a laboratory, in whole or in part, if the laboratory—

(a) fails to comply with any obligations or conditions of its designation; or
(b) misuses the designation beyond the authorised scope.

(2) The Bureau may revoke the designation of a laboratory if—

(a) the laboratory fails to remedy any conditions of a suspension within the specified timeline;
(b) the laboratory no longer holds a valid accreditation; or
(c) the designation was obtained through false, incorrect or misleading information provided by the laboratory.

PART III CONDUCT OF TESTS

Samples tested by the Bureau

14. (1) The Bureau may carry out tests in the normal conduct of its functions.

(2) The Bureau may carry out tests on samples submitted by any other person, including—

(a) private persons;
(b) public investigative agencies;
(c) other government agencies; or
(d) research institutions.

(3) A sample submitted under sub-regulation (2) shall meet the threshold and requirements determined by the Bureau.

(4) The Bureau may reject a sample which does not meet the criteria in sub-regulation (3).

(5) The results of a test conducted on a sample submitted under sub-regulation (2) shall only apply to the specific sample tested and shall not be interpreted as a general endorsement or condemnation of the product or process by the Bureau.

Handling of samples

15. (1) Every sample shall be registered upon receipt;

(2) Upon registration, the sample shall be assigned a unique identification and labelled accordingly.

(3) The condition of the sample, including any abnormalities, shall be recorded.

(4) A person submitting the sample shall be notified of any abnormalities to decide on whether to proceed with the test.

(5) To the greatest extent possible, the sample shall be forwarded to a testing laboratory in a manner that conceals the details of the product that may compromise impartiality in the testing process.

(6) Where applicable, the laboratory shall retain the sample for a period of at least 90 days after release of test results.

Test procedure

16. (1) Tests shall be conducted to ascertain conformity of the sample to the applicable standard or specification.

(2) The laboratory shall use the test methods developed by the Bureau in accordance with Section 12A(1)(c) of the Act or any other applicable method for which they are accredited.

(3) the laboratory shall retain records of the testing process including:

(a) dates of analysis;
(b) data generated;
(c) equipment used;
(d) computations;
(e) observations; and
(f) environmental conditions.

(4) The laboratory shall implement quality control measures to ensure the validity of the test results.

Issuance of a test certificate

17. (1) The laboratory shall issue a test certificate within 14 days of completing the tests.

(2) The certificate issued shall contain information including:

(a) description of the sample tested

(b) unique identification of sample tested
(c) applicable standard or specification
(d) date of issue of test certificate
(e) name and signature of the approving officer;
(f) the test method applied;
(g) the test results of each parameter tested;
(h) a statement indicating whether the results show compliance with the applicable standard or specification.

Review of test results

18. (1) A person who submitted a sample for testing may dispute the test results within seven days of issuance of a test certificate.

(2) The laboratory shall review the requests and may:
(a) request for additional information;
(b) affirm the results issued; and
(c) conduct a retest if necessary.

(3) where a retest is to be conducted, it shall be conducted on the sample retained by the laboratory in accordance with the specified conditions.

Precedence of test results by the Bureau

19. In case of conflict between a test certificate issued by the Bureau under these Regulations and any other test certificate, the test certificate of the Bureau shall take precedence.

PART IV MISCELLANEOUS PROVISIONS

Appeals

20. Any person aggrieved by any decision under these Regulations in relation to testing and designation may, within fourteen days, appeal to the Tribunal.

Revocation

21. The Standards (Evidence by Certificate) Regulations Legal Notice (Legal Notice No. 20 of 1984) is hereby revoked.

Made on the ……..……..……, 2026.

HON. LEE KINYANJUI
Cabinet Secretary for Investments, Trade and Industry

FIRST SCHEDULE

APPLICATION FORM FOR DESIGNATION

(Please type or write clearly in block letters)

1. APPLICANT DETAILS

Name of laboratory				
Address (Physical)				
Address (Postal)				
Telephone				
Email				
Website				
Name of contact person				
Designation of contact person				
Does your organization operate on several sites	Yes: ☐ No: ☐			
If yes, please provide details.				
Indicate the Legal Status of your Organization				
Total Number of Staff	Technical Staff		Non-Technical Staff	
Is your laboratory accredited	Yes ☐ No ☐			
(If yes, attach accreditation certificate and Schedule for Accreditation)				
Previous designation held (attach designation certificate)				

2. SCOPE OF DESIGNATION

Please indicate below the scope/field to which you are seeking designation for guidance if required

SCOPE/FIELD								
No.	**Testing Field**	**Examination technique**	**Equipment**	**Product/ Matrix**	**Components/ Parameter**	**Method**	**Measurement range**	**Test location**

3. **Which quality control tools do you apply in your laboratory (If any), for example Proficiency Testing, Inter-Laboratory Comparisons, Certified Reference Material and any other**

Please indicate below;

Quality Control Tool	Parameters	Frequency of participation/application

4. **SUBMISSION OF DOCUMENTS**

Accreditation certificate and schedule for accreditation	Yes: ☐ No: ☐
Previous Designation certificate	Yes: ☐ No: ☐
Certificate of registration/incorporation	Yes: ☐ No: ☐
Evidence of PT / ILC /Quality control	Yes: ☐ No: ☐
Application Fee paid (proof of payment)	Yes: ☐ No: ☐

5. **DECLARATION**

I/We hereby declare that the above information is correct. I/We agree to abide with the terms and conditions of designation and any other applicable regulations.

Name	
Designation	
Signature	
Date	

6. REVIEW BY THE BUREAU

Application form complete?	Yes: ☐	No: ☐
Application fee payment confirmed?	Yes: ☐	No: ☐
Applicable documents seen?	Yes: ☐	No: ☐
Applied Scope confirmed?	Yes: ☐	No: ☐
Adequacy of resources confirmed?	Yes: ☐	No: ☐

Explain any No response and Action	
Reviewed by;	
Designation	
Signature	
Date	

SECOND SCHEDULE

Assessment fees

Description	**Rate (KES)**
Application fees	30,000 (per product scope)
Designation fee	100,000 (per product scope)
Annual assessment fees	50,000 (per product scope)
Renewal fee	100,000 (per product scope)