GOVERNMENT NOTICE No..... published on.....

THE ZANZIBAR STANDARDS ACT No 1 OF 2011

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THE ZANZIBAR BUREAU OF STANDARDS TESTING AND CALIBRATION LABORATORIES REGULATIONS, 2025

(Made under section 36(2)(h) of the Zanzibar Standards Act No. 1 of 2011)

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ARRANGEMENT OF REGULATIONS

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IN EXCERSICE of the powers conferred upon me under section 36(2)(h) of the Zanzibar Standards Act, No.1 of 2011, I, **ALI HAMAD ALI,** Minister for Trade and Industrial Development, do hereby make the following Regulations:

PART I PRELIMINARY PROVISIONS	
Citation	**1**.These Regulations may be cited as the, Zanzibar Bureau of Standards Testing and Calibration Laboratories Regulations, 2025
Application	2.These Regulations shall apply in the laboratory analysis of products and calibration of items, and shall come into operation immediately after being signed by Minister and published in the Gazette.
Interpretation	3. In these Regulations, unless the context otherwise requires-
	"accreditation" means the formal recognition of a laboratory by the Authority in relation to the competence of the laboratory to conform to specified standards;
	"Act" means the Zanzibar Standards Act No. 1 of 2011;
	"Agreement" means the arrangement undertaken by and legally binding on parties;
	"Analyst" means a qualified technical person designated as an analyst by the Director General on approval of the Board of Directors to perform tests, measurements, and analyses on samples according to established procedures;
	"Analyzed sample" sample submitted to the laboratory for analysis
	"Board" means the Board of Directors of the Zanzibar Bureau of Standards established under section 8 of the Act
	"Bureau" means the Zanzibar Bureau of Standards established under section 4 of the Act;
	"Calibration" means the set of operations that established under specified conditions, the relationship between values indicated by a measuring instrument or measuring system or values represented by a material measure, and the corresponding known values of measurand;
	"Calibration certificate" means document issued by the Bureau that report the result of calibration, provides measurement results (and their associated uncertainty) and confirms the traceability of measurement to recognize standards
	"Custodian" means a person responsible for proper receipt, identification, handling and storage of sample

	“Customer” means a person who receives laboratory services offered by the Bureau
	“Director General” has the meaning ascribed under the Act;
	“Disposal” means-controlled removal of analyzed sample or laboratory waste from the Bureau
	“Internal customer samples” means samples submitted to the laboratory by other departments, divisions, or units within the Bureau for internal quality control, verification, research, or routine testing purposes.
	“Item to be calibrated” means any measuring instrument, measurement standard, reference material, or device whose measurement performance needs to be verified and documented against a traceable reference.
	“Laboratory reference sample” is the portion of sample submitted to the laboratory which remain untested
	“Legal sample” means a sample that is officially taken, sealed, and documented in accordance with prescribed laws, regulations, or standards for the purpose of dispute resolution, or evidence in legal proceedings.
	“Method validation or verification” means an action of proving and documenting that any procedure, process, activity or system will, with a high degree of assurance, lead to the expected results;
	“Metrologist” means a qualified technical person designated as metrologist by the Director General on approval of the Board of Directors to ensures the accuracy, traceability, and reliability of measurements in accordance with recognized standards and regulations
	“Minister” means the Minister for the time being responsible for trade
	“Quality management system” means coordinated activities, processes and procedures focused on ensuring quality and consistently meeting customer requirements including enhancing their satisfaction;
	“Sample" means a portion of a material or product collected for testing according to a defined sampling procedure;
	“Specifications” means a list of tests, references to analytical procedures and appropriate acceptance criteria, which are numerical limits, ranges, or other criteria for the tests described;
	“Sub-contracting” means the process of entering a contractual agreement with a third-party laboratory to perform analysis of products or calibration of item on behalf of the Bureau
	“Standards inspector” means a person appointed, authorized or recognized as such under the Act;
	“Test report” means formal document that presents the results of testing or analysis performed on a sample, product, or material according to specified methods, standards, or requirements
	“Tested sample” means the portion of the sample to be analyzed
	“Type test sample” means Samples of products or materials that are submitted to the laboratory from outside sources of the Bureau for the purpose of testing, analysis, or verification.
	“Witness of test” means process by which person authorized by bureau observes and verifies that a test (or series of tests) has been performed in accordance with specified procedures and standards.

PART II POWERS OF THE BUREAU IN LABORATORY ANALYSIS AND CALIBRATION	
General powers	**4**.-(1) Subject to the provisions of the Act, The Bureau shall have the power to establish, manage, and operate laboratories necessary for carrying out testing, analytical and calibration activities to support standardization, certification, and quality assurance programs
	(2) Nothing in these Regulations shall be construed to limit or affect in any way the Bureau's power to take actions or any other measures under these Regulations, the Act or other applicable laws.
Powers of the Bureau to conduct test, analysis of Products and calibration of items	**5.**-(1) The Bureau shall have the Power to carry out scientific and technical test and analyses of products, materials, and commodities to determine their conformity with approved national or international standards, specifications, or regulatory requirements.
	(2) The Bureau shall have the Power to carry out calibration of items to confirms the traceability of measurement to recognize standards
	(3) For the purposes of analyzing products or calibration of items the bureau shall:
	(a) take or receive samples and items to be calibrated from different customers for testing and calibration respectively
	(b) sub-contract testing of samples or calibration of items when need arise;
	(c) develop and validate methods of analysis of products or calibration of items
	(d) offer training services on laboratory analytical and calibration techniques to industry experts, students, institutions and other stakeholders from within or outside of Zanzibar
	(**4**) The Bureau shall have the power to issue official test reports/calibration certificates or evidence of conformity or non-conformity to relevant standards.
PART III CATEGORIES OF SAMPLE AND ITEM TO BE CALIBRATED	
General categories of samples	**6. – (1)** There shall be the following categories of samples to be analyzed at ZBS laboratories-
	(a) Internal customer samples
	(b) Type Testing sample
Internal customer samples	7.Internal customer samples shall be submitted in accordance with the Bureau's procedure, including test request forms and proper labelling
Type Testing sample	8. – (1) All external customer samples shall be accepted only upon completion of the prescribed test request forms or official letter and payment of applicable fees as prescribed in ZBS's fee and charge regulations
	(2) Payment of fees shall be made prior to commencement of testing.
	(3) Additional fees may apply for urgent analysis, witness testing, re-testing, or issuance of duplicate test reports

ITEM TO BE CALIBRATED	9. (1) There shall be the following field of items to be calibrated at ZBS laboratories a) Mass related items b) Temperature and humidity measurement items c) Pressure related items d) Electrical measurement related items e) Dimensional measurement related items f) Force and torque related item g) Time and frequence measurement related items h) Volume and flow measurement related items i) Density measurement related items j) Chemical measurement related items k) Dosimetry measurement related items (2) Without prejudice to sub-regulation (1), the Bureau may extend the field of item to be calibrated if need arise
PART IV SAMPLE SUBMISSION, HANDLING AND TESTING	

Submission of samples	**10.** (1) All samples shall be submitted to sample custodian office for registration before directed to the respective laboratory
	(2) Samples submitted for testing to all Bureau's laboratories shall be accompanied by the following:
	(3) duly filled test request form or official letter as prescribed in the Bureau's laboratory procedures
	(4) Subject to sub-regulation (2), the minimum number of units to be submitted for testing depending on the nature of the product as specified by the Bureau
	(5) The submitted samples, that are not complying with sub regulation (3) and (4) of this regulation shall be rejected by the Bureau
Receipt of samples	11. (1) The Bureau shall receive samples in their original/modified package and which have not been tampered for packed products.
	(2) For samples from foreign countries, all shipping and clearance costs shall be borne by the customer.
	(3) Upon receipt of samples, custodian shall verify the physical appearance, completeness of test request forms or letter and proof of payment.
	(4) Samples submitted shall be recorded in the sample log book and shall be identified to ensure traceability throughout the testing process
	(5) Samples that are improperly sealed, inadequately labeled, or contaminated shall be rejected and returned to the applicant with written notification specifying the reason for rejection
Handling of samples	12. (1) Received samples shall be stored under conditions that maintain their integrity, such as controlled temperature, humidity, or light protection as applicable to the type of sample.
	(2) In handling of samples during analysis, preservation and storage conditions of samples at all stages shall be maintained by the respective laboratory.
Testing of samples	13. (1) Analysts shall ensure that assigned samples are tested as per agreed analytical methods.

	(2) Subject to sub-regulation (1), when testing samples all measures must be taken to ensure that all equipment have been calibrated or verified and methods have been validated and verified as appropriate, for the intended purpose.
	(3) Where a test method is not available or not applicable, upon the agreement with customer, the laboratory may develop or validate an alternative method, provided that the method ensures the reliability and reproducibility of results.
Issuance of Test Reports	14. (1) Upon completion of testing, the test reports shall be compiled, reviewed, and authorized in accordance with the Bureau's laboratory's quality management procedures. .
	(2) The Bureau shall issue a test report to authenticate that samples were tested and found to either comply or not comply with specifications
	(3) Without prejudice to sub-regulation (2), for specific issue the Bureau may issue a test report without authenticate that samples were tested and found to either comply or not comply with specifications
	(4) Subject to sub-regulation (1), the test report issued shall be in the format and content as specified by the Bureau
	(5) Test report shall only be released to the applicant or other authorized entities as determined by the Bureau.
	(6) Alteration, reproduction, or manipulation of a test report without written authorization is strictly prohibited and shall render the document invalid.
PART V SUBMISSION, HANDLING AND CALIBRATION OF ITEMS	
Request for calibration	15. (1) Any person or organization intending to obtain calibration services from the Bureau shall make an official request through an official letter or calibration request form provided by Bureau.
	(2) Upon acceptance of the request, customers shall pay the prescribed fees before submission of device to be calibrated.
Submission of item to calibrated	16. (1) Without prejudice to sub-regulation (1) Each submitted device shall be accompanied by complete identification details, including equipment type, model, serial number, and the calibration parameters required.
	(2) The customer shall declare the operational condition of the device at the time of submission. Bureau reserves the right to reject devices that are damaged, contaminated, or unsafe for handling
	(3) The customer shall provide any necessary accessories, manuals, or instructions essential for the calibration process
	(4) The customer shall make sure the device to be calibrated is safe, clean, and suitable for calibration.
Receiving of items to be calibrated	17. (1) The device to be calibrated shall be officially received at the designated laboratory reception area by authorized Bureau personnel.
	(2) The custodian shall conduct a visual inspection to verify that the device is in a serviceable condition and free from damage that may affect calibration results.

	(3) All devices received shall be entered into the item to be calibrated Register maintained by the laboratory.
Handling of items to be calibrated	18. (1) All items to be calibrated shall be handled only by authorized personnel trained in proper metrological practices.
	(2) Items shall be protected from damage, contamination, or alteration that may affect the validity of the calibration results.
	(3) Environmental conditions, such as temperature, humidity, and cleanliness, shall be controlled as required by the calibration procedure.
Calibration of item	19. (1) Calibration shall be performed using certified reference standards that are traceable to national or international measurement standards.
	(2). The calibration interval shall be established based on manufacturer recommendations, stability data, and the laboratory's quality management requirements.
	(3) Each calibration shall be documented in an official calibration certificate containing the measurement results, uncertainties, and traceability references.
On site calibration	20. (1) Without prejudice to sub-regulation 15 (1) upon approval of director General, the lab shall conduct onsite calibration on the customer premises
	(2) Customer shall provide any necessary operational support, including power supply, network connectivity (if applicable), and physical workspace for calibration activities.
	(3) Customer shall prepare instruments for calibration according to Bureau's Laboratory instructions or manufacturer guidelines (e.g., cleaning, stabilization, or powering on).
	(4) If calibration cannot be performed due to improper preparation by the customer, the customer shall be liable for the failed calibration attempt and shall bear all related costs, including: a) Transportation costs for re-scheduling the on-site visit, b) Daily subsistence allowance, if applicable. c) Any additional costs incurred due to delays caused by improper preparation.
Issue of calibration certificate	21. (1) the Bureau shall issue a Calibration Certificate to the customer upon completion of calibration of item
	(2) The issuance of the calibration certificate shall comply with these regulations
	(3) Each calibration certificate issued by ZBS Laboratory shall be as prescribed in ZBS laboratory procedures.
	(4) The calibration certificate issued by ZBS Laboratory constitutes a technical and legal record of calibration shall not be altered, reproduced, or misused in a manner that may misrepresent the calibration outcome.
Validity and Authenticity	22.(1) The calibration certificate is valid only when issued in its complete form, bearing the authorized signature(s) and official identifiers of ZBS Laboratory.
	(2) Alteration, reproduction, or manipulation of a calibration certificate without written authorization is strictly prohibited and shall render the document invalid.
	(3) Electronic certificates shall be issued in secured, tamper-proof digital formats, and ZBS Laboratory shall maintain verification mechanisms to

	authenticate the validity of any certificate upon request.
PART VI WITNESS OF THE TEST AND CALIBRATION	
Request and Authorization	23. (1) A witness of the test shall be officially requested in writing by the customer prior to the commencement of the testing and calibration activity, stating the purpose and scope of witnessing.
	(2) No person shall witness any test conducted within ZBS laboratories unless such written request has been approved and formal authorization granted by the Director General
	(3) Authorized witnesses shall fill in the official laboratory witness form, and such record shall include the name, affiliation and purpose of witnessing
	(4) The Laboratory Management reserves the right to restrict, suspend, or terminate witnessing where it is determined that the presence of the witness may compromise the integrity, confidentiality, or safety of the testing process.
Witness Fee	24. (1) The customer requesting the witness shall pay a witness fee as prescribed by ZBS
	(2) Payment of the witness fee must be completed prior to or on the day of the test, unless alternative arrangements have been formally approved by ZBS.
	(3) Failure to pay the witness fee shall render the witnessing request invalid, and the witness shall not be permitted to attend the test.
Rights and Limitations of the Witness	25. (1) The witness shall have the right to observe the testing process within the defined scope of authorization.
	(2) The witness shall not participate in testing or calibration activity, influence, or interfere with any aspect of the test performance or result interpretation.
	(3) The witness shall comply with all safety, ethical, and confidentiality provisions as prescribed by ZBS procedure
	(4) Any act of misconduct, obstruction, or breach of confidentiality by a witness shall constitute grounds for immediate removal and may result in legal or administrative action.
Confidentiality and Data Protection	(26) All information obtained by a witness during or after the test shall remain confidential and shall not be disclosed to any third party without prior written consent of the Director General. Any breach of confidentiality shall attract disciplinary or legal consequences in accordance with the applicable laws.

PART VII SUB-CONTRACTING TESTING AND CALIBRATION	
Identifying and selecting testing or calibration laboratories	27.-(1) The Bureau may identify and select third party laboratories for testing of samples or calibration of item when need arise.
	(2) Subject to sub-regulation (1), in selecting such laboratories, the following criteria shall be taken into account:
	(a) Accreditation status;
	(b) Prequalification status of accreditation;
	(c) Laboratories which had complied with prior audit conducted by the Bureau;

	(d) Desk review of laboratories which complies with quality management system requirements; and
	(e) The cost of analysis of the sub-contracted laboratories.
	(f) Duration of results
	(3) Subject to sub-regulation (1), the Burau shall maintain a register of sub-contracting laboratories which shall be reviewed from time to time .
	(4) Subject to sub-regulation (1), the Bureau shall obtain a written consent from the customer before sub-contracting samples for analysis or item for calibration.
Contract signing	28.-(1) The Bureau shall enter into written agreement with the sub-contracting laboratories before sending samples for analysis or item for calibration.
	(2) Subject to sub-regulation (1), the terms and conditions of the contract including the format to be used shall be specified by the Bureau.
Sending samples for testing	29.-(1) When sending samples or item to be calibrated to the sub-contracting laboratories for Analysis or calibration, the Bureau shall take all measures to ensure that the samples remain intact and in acceptable integrity
	(2) Subject to sub-regulation (1), the cost of sample or item transportation and testing or calibration fee to the sub contracted laboratories shall be borne by the customer
Receipt and review of results	30.-(1) The Bureau shall review results obtained from the sub- contracting laboratories for any discrepancies and if all parameters have been tested or calibrated as agreed.
	(2) Subject to sub-regulation (1), the Bureau shall be accountable for results obtained from the sub-contacting laboratories.
	PART VIII DISPOSAL OF SAMPLES ORWASTE AND RETURNING OF CALIBRATED ITEM
Disposal of samples analyzed	31. (1) sample to be analyzed shall be retained for a defined period (as per ZBS laboratory procedure) after analysis, then they shall be disposed.
	(2) Destruction of tested samples shall only be affected after completion of analysis and verification of results.
	(3) Disposal of laboratory reference sample shall only be affected after completion of analysis, verification of results, and closure of any related client query or dispute if arise.
	(4) Samples that were not subject to destructive test may be returned to the client in accordance to the ZBS laboratory procedure.
	(5) Disposal of samples under these Regulations, shall comply with the Environmental Management Act in force.
Disposal record	32.-(1) Notwithstanding the provisions of regulation 31, disposal of samples shall be reconciled by the number of units disposed.
	(2) Subject to sub-regulation (1), all records related to disposal of samples shall be maintained to allow for audit by any relevant authorities.
Disposal of biological, radioactive, physical and chemical wastes	33.-(1) All hazardous substances and agents including biological, radioactive and chemical wastes shall be identified, labelled as such and properly stored by the laboratory before disposal

	(2) Subject to sub-regulation (1), in handling such wastes, precautionary measures shall be taken by the laboratory staff to avoid any cross-contamination that might lead to health hazards.
	(3) Subject to sub-regulation (1), all biological wastes shall be deactivated before disposal.
	(4) Subject to sub-regulation (1), the Bureau may enter into agreement with Companies approved by the Bureau responsible for environmental management to dispose wastes.
	(5) Subject to sub-regulation (1), once the contracted disposal company/Institution has finalized disposal of wastes, shall issue proof of disposal to the Bureau.
RETURNING OF CALIBRATED ITEM	34. (1) The Bureau shall ensure that all calibrated items are returned to the respective customer upon completion of calibration activities
	(2) Customers shall collect their calibrated items directly from Bureau during official working hours.
	(3) If the customer fails to collect the calibrated item within thirty (30) days after notification of completion, ZBS reserves the right to apply storage charges as provided under its service regulations.
	(4) The bureau shall not be liable for any loss, misuse, or operational failure of the calibrated item after it has been collected by the customer or their representative.

	PART IX LABORATORY RESULTS DISPUTES HANDLING
Handling of disputed laboratory results	35.-(1) Where there is any objection of laboratory results issued by the Bureau, the customer shall submit grounds thereof.
	(2) Subject to sub-regulation (1), such grounds shall be submitted in a written notice within 14 days from the date of receipt of the results.
	(3) Subject to sub-regulation (2), upon receipt of objection from the customer, the Bureau shall review the results and conduct a thorough investigation of the method used for analysis of the sample or calibration of item.
	(4) Subject to sub-regulation (3), when the Bureau is satisfied that the issued results were correct, it shall notify the customer within 14 -28days after completion of the review.
	(5) Subject to sub-regulation (4), where the customer is aggrieved by the decision of the Bureau may request to witness the testing of the samples.
	(6) Subject to sub-regulation (5), in witnessing the testing of the samples, the Bureau shall conduct the analysis of the samples together with the customer or his representative.
	(7) Subject to sub-regulation (6), where the results are still disputed, an agreement shall be made between the customer and the Bureau to send samples to an alternative laboratory for analysis.
	(8) Subject to sub-regulation (7), the cost of analysis shall be borne by the customer.
	(9) Subject to sub-regulation (7), the Bureau in agreement with the customer may re-sample products from the agreed source to avoid any testing bias.

	(10) Subject to sub-regulation (7), in case of contradicting results between the ZBS laboratory and the agreed laboratory, an alternative laboratory shall be sought for testing of the samples upon shared cost to settle the dispute and the results shall be final.

PART X LABORATORY TECHNICAL COMMITTEE	
Establishment of Committee	36. The Laboratory Technical Committee shall be established within the Directorate of Testing and Metrology to provide technical guidance, quality system, accreditation and technical competence.
Composition of Committee	37. The Committee shall consist solely of internal representatives' members from key laboratories and metrology division. External stakeholders shall not be the member of the Committee.
Functions of the Committee	38. the function of the Committee shall
	(a) Develop, review and approve laboratory testing and calibration procedures and methods
	(b) Advise on technical competence, equipment needs, and calibration programs;
	(c) Develop training programs;
	(d) Monitor compliance with ISO/IEC 17025 and related quality system requirements;
	(e) Evaluate proficiency testing and inter-laboratory comparison results;
	(f) Review technical non-conformities and recommending corrective actions;
	(g) advise matters related to costs of analysis and calibration including fees and charges
	(h) advise waste management practices;
	(i) Provide guidance on training and capacity-building for laboratory personnel;
	(j) advise in laboratory information management system;
	(k) Recommend improvements to ensure consistency, accuracy, and reliability of testing services.
	(l) perform any other matters related to the operations of laboratory.
Chairperson and Secretary	39. -(1) The Chairperson of the Committee shall be elected from amongst the members.
	(2) The Chairperson shall guide and chair the proceedings of the Committee meetings.
	(3) In the absence of the Chairperson, the Acting Chairperson shall be elected from amongst the members to preside over the meeting.
	(4) The secretary of the committee shall not be the member of the committee and shall be selected from any Bureau's laboratory
Responsibility of Secretary	40. The responsibility of the secretary shall be to:
	(a) distributing notice of meetings and respective documents;
	(b) work in close collaboration with the Chairman to ensure efficient and effective performance of the Committee;

	(c) preparing agenda items of the meetings;
	(d) taking minutes and keeping records of the meetings; and
	(e) providing logistical support to Committee members
Co-option of Experts	41. The Committee may, during its deliberation at any meeting, co-opt any person with special knowledge or skills to attend any of its meetings for purposes of providing expertise on a particular matter when deliberating its business.
Meetings of Committee	42. The Committee may hold an ordinary meeting at least once every quarter or as may be required by the Bureau.

PART XI APOINTMENT OF ANALYSTS/ METROLOGIST	
Appointment	43. (1) No person shall perform independent laboratory testing /calibration or issue test results/calibration certificate under the name of ZBS unless officially appointed as an Analyst or metrologist by the Bureau.
	(2) Appointment shall be granted only after the individual has demonstrated technical competence and adequate understanding of relevant test or calibration methods, quality system requirements, and safety procedures.
Criteria for appointment	44. Subject to regulation (42), in appointment of analysts or metrologist, the Bureau Shall consider the following criteria:
	(a) Relevant academic qualifications in the respective technical field;
	(b) Adequate training and practical experience in laboratory testing or calibration;
	(c)Demonstrated proficiency through competency assessment and supervised practice;
	(d) Satisfactory performance in internal or external proficiency testing programs
	(e) Compliance with laboratory ethical and professional conduct standards.
Appointment of analyst or metrologist	45. (1) The Board shall, at the request of the Bureau, appoint qualified officer/officers of the Bureau from directorate of testing and metrology as analyst or metrologist
	(2) Every appointed analyst or metrologist appointed under sub regulation (1) of this regulation shall be furnish with a certificate of appointment signed by the Director General starting that the person is authorized by the Board to act as analyst or metrologist
	(3) The Board may, at the request of the Bureau, cancel the appointment of the analyst or metrologist as may reasonable decides
Gazetting	46. Analysts appointed under regulation 39, shall be gazetted in the official Government Gazette as provided under the Act and assigned identification cards issued by the Authority.
Conflict of interest	47. Any analyst or metrologist shall refrain from any undertaking that may conflict with his roles and where the analyst or metrologist has any potential interest declare the same in writing to the Bureau.

	PART XII HANDLING OF LEGAL SAMPLES
Collection of samples	48. (1) Samples collected for legal proceedings shall be divided into three parts, whereby one portion shall be retained by the customer, the second portion by the Bureau and the third to be analyzed.
	(2) Collection and apportioning of samples under sub-regulation (1) for legal proceedings which is against the Bureau shall be done by the Standard inspector and each part of sample shall be marked, sealed and secured in the manner permitted by its nature.
Safe custody of samples	49. (1) Samples collected for legal proceedings including those submitted by law enforcement agencies shall be stored as per manufacturer's instructions, in a secure place, with special coding and under lock and key.
	(2) Subject to sub-regulation (1), such samples shall be stored as exhibit samples until after the legal proceedings have been settled.
Analysis of samples	50.-Subject to regulation 48and 49, analysis of samples shall be as specified in Part IV of this regulation

	PART XIII NATIONAL AND INTERNATIONAL COLLABORATIONS
National collaboration	51. In the performance of its functions, the Bureau may as far as be practicable, maintain a system of consultation and cooperation with other laboratories include-
	(a) regulatory Governmental laboratories
	(b) both government and private Research laboratories
	(c) both Government and private academic laboratories
	(d) quality assurance private laboratories

International cooperations	52.-(1) The bureau may cooperate with regional and international laboratories on matters related to analysis of products and calibration of items under these Regulations.
	(2) The bureau may collect and share laboratory results for products that pose public health risks with other bodies at regional and international levels.
Harmonization of laboratory requirements	53-The Bureau may participate in regional and international laboratory harmonization initiatives that aim at-
	(a) harmonizing systems for analysis of products, calibration of items, quality management, information management and any other laboratory activities as maybe appropriate;
	(b) providing for the use of accredited quality control laboratories within the harmonization framework;
	(c) providing for the recognition of regional, continental and other international technical laboratory guidelines;

	(d) participating in intra and inter laboratory proficiency testing schemes;
	(f) establishing networks with other laboratories and collaborate in protecting public health;
PART XIV CONFIDENTIALITY OF DATA AND RECORD KEEPING	
Confidentiality	**54.-**(1) All data generated in the laboratory including results of analysis or calibration shall be treated as confidential information.
	(2) Subject to sub-regulation (1), all staff working in the laboratory and laboratory stakeholders shall sign a confidentiality form issued by the bureau.
	(3) Disclosure of any confidential information by the Bureau shall only be made upon order of the court or any other lawful directive.
Electronic data management	51.-(1) The Bureau shall maintain an electronic data management system to allow for safe custody of data generated in the laboratory.
	(2) Subject to sub-regulation (1), access to the electronic data management system shall be controlled through use of individual username and password.
	(3) Subject to sub-regulation (1), the electronic data management systems shall allow for an audit trail to be conducted to provide source, sequence and evidence of data stored.
Archiving and record keeping	55-(1) The Bureau shall keep and maintain laboratory records to allow for traceability and reproducibility of results. -
	(2) The records referred to in sub-regulation (1), shall include but not limited to the following-
	(a) test request forms;
	(c) sample analysis reports;
	(c) test report
	(e) calibration certificates
	(f) equipment calibration and maintenance records;
	(g) environmental monitoring records;
	(h) validation master plan and records;
	(i) disposal records;
	(j) training records;
	(k) accreditation records;
	(l) customer complaints and compliments records;
	(m)change and out of specification records;
	(n) laboratory events records including spill-overs;
	(o) reference and working standards record;
	(p) process flow charts and standard operating procedures; and
	(q) any other records as it may deem necessary.
	(3) Subject to sub-regulation (1), all electronic and paper-based records except training records shall be retained for a period of 5 years before archive.

PART XVI GENERAL PROVISIONS

Appeals	56.-(1) Notwithstanding the provisions of these Regulations, any person aggrieved by a decision of the Bureau may, within sixty days, appeal in writing to the Minister.
	(2) The appellant shall copy the appeal to the Bureau who shall within fourteen days submit a written response to the Minister and copy the appellant.
	(3) Where the Minister is of the opinion that a case has been made, he may summon parties for additional information or make a decision to allow or dismiss the appeal.
Offences and penalties	57. Any person who contravenes or fails to comply with these Regulations directly or indirectly aids any other person to do what is prohibited under these Regulations shall be guilty of an offence and on conviction, shall be liable to a penalty prescribed in the Act.