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

THE TANZANIA MEDICINES AND MEDICAL DEVICES ACT,
(CAP 219)

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REGULATIONS

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(Made under section 122(1) (n)(v))

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LABORATORY ANALYSIS OF MEDICAL AND NON-MEDICAL PRODUCTS REGULATIONS, 2021

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LABORATORY ANALYSIS OF MEDICAL AND NON-MEDICAL PRODUCTS REGULATIONS, 2021

PART I PRELIMINARY PROVISIONS	
Citation	**1.** These Regulations may be cited as the Tanzania Medicines and Medical Devices, Laboratory Analysis of Medical and Non-Medical Products Regulations, 2021.
Application	**2.** These Regulations shall apply in the laboratory analysis of regulated and non regulated products to include medicines, medical devices, diagnostics, medical gases, soil, human and animal biological specimens and hospital supplies in Mainland Tanzania.
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;
Cap. 219	"Act" means the Tanzania Medicines and Medical Devices Act;
	"agreement" means the arrangement undertaken by and legally binding on parties;
	"analyst" means a person designated as such under the Act;
	"analyst blinding" means the process by which an analyst is kept unaware of the identity of a sample allocated to him for analysis to avoid results bias;
	"animal biological specimens" means any material drawn from animals such as blood, urine, tissues, organs, saliva, spinal fluid, hair, nail clippings, or any other material of animal origin;
	"Authority" means the Tanzania Medicines and Medical Devices Authority or its acronym "TMDA" established under the Act;
	"batch" or "lot" means a defined quantity of a product manufactured in a single manufacturing cycle and which has homogeneous properties;
	"certificate" means a certificate issued by the Authority under these Regulations;
	"commercial samples" means samples submitted by the customer for testing purposes which do not form part of marketing authorization
	"contract" means a legally binding agreement between the Authority and the customer for the performance of any laboratory related work at a specified price;

	“controlled drug samples” means samples of any narcotic drug, psychotropic substance or precursor as listed under the Act;
	“country of origin” means a country in which the product has been manufactured or supplied;
	“customer” means a person who receives laboratory services offered by the Authority;
	“Director General” has the meaning ascribed under the Act;
	“disposal” means the process of donating samples fit for human consumption or rendering unfit samples or laboratory wastes such that they are harmless;
	“hospital supplies” means items that used for curative, prosthetic or medical care in the health facilities;
	“human biological specimens” means any material drawn from a human being such as blood, urine, tissues, organs, saliva, spinal fluid, hair, nail clippings, or any other material of human origin;
	“inspector” means an a person appointed, authorised or recognised as such under the Act;
	“manufacture” means all operations involved in the production, preparation, processing, compounding, formulating, filling, refining, transformation, packing, packaging, re-packaging and labelling of regulated and non-regulated products;
	“manufacturer” means person or firm that is engaged in the manufacture of a product regulated under the Act;
	“medical products” means medicines, medical devices or diagnostics;
	“medicinal product” means a substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action;
	“medical device” has meaning ascribed under the Act;
	“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;
	“Minister” means the Minister for the time being responsible for health;
	“non-medical products” means all products that do not meet the definition of a medicine, medical device or diagnostics as set out in these Regulations;
	“non-regulated products” means products other than regulated products;
	“post marketing surveillance programme” means a programme for sampling and testing selected medical products to assess their quality after marketing authorization;
	“quality assurance programme” means a programme designated by the Authority to sample and test selected products imported into the country before release to the market;
	“quality management system” means coordinated activities, processes and procedures focused on ensuring quality and consistently meeting customer requirements including enhancing their satisfaction;
	“regulated products” means medicines, medical devices, diagnostics, laboratory equipment, blood and blood products, medical gases, antiseptics, disinfectants and other related medical products and health technologies;
	“risk management” means a systematic process for the assessment, control, communication and review of risks to the quality of services;
	“sample" means a portion of a material or product collected for testing according to a defined sampling procedure;

	"sampling" means operations designed to obtain a representative portion of a material or product, based on an appropriate statistical approach for a defined purpose to include acceptance of consignments or batch release;
	"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 on behalf of the Authority;
	"substance" means any natural or artificial substance, whether in solid or liquid form or in the form of a gas, vapour or radiation; and
	"testing bias" means a systematic error from unfair sampling and testing that does not estimate or give accurate results.
PART II POWERS OF THE AUTHORITY IN LABORATORY ANALYSIS	
General powers	**4**.-(1) Subject to the provisions of the Act, the Authority shall have powers to conduct laboratory analysis and all things which are necessary or desirable to give effects to the provisions of these Regulations.
	(2) Nothing in these Regulations shall be construed to limit or affect in any way the Authority's power to take actions or any other measures under these Regulations, the Act or other applicable laws.
Powers of Authority to analyze regulated and non-regulated products	**5.**-(1) For the purposes of analyzing regulated and non-regulated products, the Authority shall:
	(a) take samples of medicines, medical devices and diagnostics as specified in the Act;
	(b) receive commercial samples from different customers for testing in its laboratories;
	(c) receive samples of non-regulated product samples from different customers for testing in its laboratories
	(d) sub-contract testing of regulated product samples when need arise;
	(e) develop and validate methods of analysis of products
	(f) offer training services on laboratory analytical techniques to industry experts, students, institutions and other stakeholders from within or outside Mainland Tanzania.
	(g) offer accreditation services to various institutions to comply with laboratory quality management system requirements
PART III SAMPLE CATEGORIES	
Types of samples	**7.** There shall be the following types of samples to be analyzed at TMDA laboratories-
	(a) port of entry samples
	(b) registration samples
	(c) inspection samples

	(d) post marketing surveillance samples
	(e) controlled drugs samples
	(f) commercial samples
	(g) any other samples as it may be required.
Port of entry samples	**8.** (1) All batches of samples of anti-malarials, anti-tuberculosis, anti-retrovirals and antibiotics shall be collected from ports of entry and tested for conformity to specifications as part of the quality assurance programme.
	(2) Notwithstanding sub-regulation (1) in case of suspicious batches of samples, the same shall be collected by inspectors at ports of entry for testing in the laboratories.
	(3) Subject to sub-regulation (1), all batches of samples of rapid test kits for malaria and Human Immunodeficiency Virus, condoms, intrauterine devices and pregnancy test kits shall be sampled from ports of entry and subjected to quality testing.
	(4) Without prejudice to the generality of regulation (8) any other sample as it may deem fit may be subjected to testing as part of quality assurance programme of regulated products from time to time.
	(5) All batches of samples which will fail laboratory testing shall be re-exported back to the country of origin or disposed as it may deem fit and as provided for in the Disposal Regulations in force.
	(6) Notwithstanding the provisions of this regulation, in case three different batches of the same product fails to conform with laboratory testing requirements, the entire product shall be condemned and either re-exported back to the country of origin or disposed as deemed necessary and as provided for in the Disposal Regulations in force.
Registration samples	**9.** (1) Samples submitted to support marketing authorization applications may be analyzed as it may deem necessary
	(2) Subject to sub-regulation (1) both compendial and non-compendial methods, as appropriate, shall be used when testing samples for registration.
Inspection samples	**10. (1)** In case of any suspicious products samples will be collected from the market during routine inspections, and shall be screened using minilab kits, scanners or any other instruments followed by confirmatory testing, where appropriate.
	(2) All batches of products which will fail laboratory testing, shall be recalled from the market and disposed as specified in the Recall and Disposal Regulations in force.
Post marketing surveillance samples	**11. (**1**)** Samples collected from the market through post marketing surveillance programme shall be screened using minilab kits, scanners or any other devices and tested in the laboratories to confirm their conformity to specifications.
	(2) Subject to sub-regulation (1), in case one batch fails laboratory testing, such batch shall be recalled and disposed off as specified in the Recall and Disposal Regulations in force.
	(3) Subject to sub-regulation (2), in case three batches of the same product fails laboratory testing, the entire product shall be condemned, recalled from the market and disposed as such.
Controlled drugs samples	**12**.-(1) Samples of narcotic and psychotropic substances shall be recorded in a separate register and tested like other regulated products.
	(2) Subject to sub-regulation (1), each unit shall be reconciled at each stage of analysis including its final disposal.

Commercial and Non- regulated samples	**13**.-(1) Subject to these Regulations, the TMDA laboratories may, but not limited to, accept and test the following categories of commercial and non-regulated products:
	(a) Samples of all regulated products
	(b) Soil samples
	(c) Human biological specimens originating from health facilities including hospitals, health centres and dispensaries
	(d) Animal biological specimens drawn from different species and originating from animal clinics, ambulatory services and other veterinary facilities
	(e) Samples from research institutes
	(f) Samples of herbal medicines originating from traditional healers
	(g) Environmental samples suspected to contaminate water and food chain
	(h) Hospital supplies samples to include aprons, bed sheets, medical equipment and others
	(2) Without prejudice to sub-regulation (1), the parameters to be tested for the samples specified in sub-regulation (1), shall be but not limited to the following:
	(a) Drug residues;
	(b) Heavy metals such as mercury, lead, arsenic, cyanide, cadmium, copper, chromium and selenium;
	(c) pH;
	(d) Sterility (e) Endotoxins;
	(f) Microbial contamination;
	(g) Mycotoxins;
	(h) Residual solvents such as benzene, chlorobenzene, toluene, chloroform, dichloromethanes, dichloroethanes, dichloroethenes, trichloroethanes, hexane, tetrahydrofuran, pyridine, formamide, ethyleneglycol, 1,4-dioxane, acetic acid, butanols, ethanol, ethylacetate, formic acid, methanol, acetone, acetonitrile, carbontetrachloride, isooctane and isopropyl ether;
	(i) Related substances;
	(j) Inorganic impurities;
	(k) Uniformity of content;
	(l) Dissolution;
	(m) Disintegration;
	(n) Assay;
	(o) Identification;
	(p) Osmolarity;
	(q) Viscosity;
	(r) Veterinary drug residues
	(s) Pesticide residues
	(t) Drug metabolites
	(u) Alcohol content; and
	(v) Sensitivity and specificity.
PART IV SAMPLE SUBMISSION AND TESTING	

Submission of samples	**14.** (1) Samples submitted for testing at all TMDA laboratories shall be accompanied by the following:
	(a) dully filled test request form clearly indicating the parameters to be tested as prescribed in Schedule I of these Regulations
	(b) physical samples in their original containers;
	(c) analysis fees as prescribed in the Fees and Charges Regulations in force;
	(2) Subject to sub-regulation (1) (b), the minimum number of units to be submitted for testing depending on the nature of the medicinal product and medical devices or diagnostics is as prescribed in Schedule II and Schedule III, respectively, of these Regulations.
	(3) Notwithstanding this regulation, samples submitted for testing shall have a remaining shelf life of not less than 3 months.
	(4) Without prejudice to sub-regulation (3), the Authority may request samples which are close to expiry for investigation purposes, and such samples shall be drawn from Manufacturer's retained sample room.
	(5) Subject to sub-regulation (4), the close to expiry date shall be as specified in the request note issued by the Authority.
Receipt of samples	**15. (**1**)** The Authority shall receive samples in their original containers and which have not been tampered.
	(2) For samples from foreign countries, all shipping and clearance costs shall be borne by the customer.
	(3) Upon receipt of samples the Authority shall verify the physical appearance, completeness of test request forms and proof of payment.
	(4) Samples submitted shall be recorded in the sample receiving register specified in Schedule IV.
Handling of samples	**16. (**1) Samples received shall be stored in accordance with the manufacturer's instructions.
	(2) In assigning samples for analysis measures shall be taken by the Authority to blind analysts to avoid testing bias.
	(3) In handling of samples during analysis, preservation and storage conditions of samples at all stages shall be maintained by the Authority.
Testing of samples	**17.** (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 methods including equipment have been calibrated, verified and validated as appropriate, for the intended purpose.
Issuance of certificate of analysis	**18.** (1) The Authority shall issue a certificate of analysis to authenticate that samples were tested and found to either comply or not comply with specifications.
	(2) Subject to sub-regulation (1), the certificate of analysis or testing issued shall be in the format and content as prescribed in Schedule V for medicinal products and in Schedule VI for medical devices and diagnostics to which a certificate of analysis do not apply.
PART V SUB-CONTRACTING TESTING	
Identifying and selecting testing laboratories	**19**.-(1) The Authority may identify and select third party laboratories for testing of samples 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;
	(c) Laboratories which had complied with prior audit conducted by the Authority;
	(d) Desk review of laboratories which complies with quality management system requirements; and
	(e) The cost of analysis of the sub-contracted laboratories.
	(3) Subject to sub-regulation (1), the Authority shall maintain a register of sub-contracting laboratories which shall be reviewed from time to time.
	(4) Subject to sub-regulation (1), the Authority shall obtain a written consent from the customer before sub-contracting samples for analysis.
Contract signing	**20**.-(1) The Authority shall enter into written agreement with the sub-contracting laboratories before sending samples for analysis.
	(2) Subject to sub-regulation (1), the terms and conditions of the contract including the format to be used shall be specified by the Authority.
Sending samples for testing	**21**.-(1) When sending samples to the sub-contracting laboratories for analysis, the Authority 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 transportation shall be borne by the Authority.
Receipt and review of results	**22**.-(1) The Authority shall review results obtained from the sub-contracting laboratories for any discrepancies and if all parameters have been tested as agreed.
	(2) Upon satisfaction of the review under sub-regulation (1), the Authority shall issue a certificate of analysis specified under Schedule V and VI.
	(3) Subject to sub-regulation (1), the Authority shall be accountable for results obtained from the sub-contacting laboratories.
	PART VI DISPOSAL OF SAMPLES AND WASTE
Disposal of samples analyzed	**23**.-(1) All samples analyzed in all TMDA laboratories shall be disposed in accordance with the Disposal Regulations in force
	(2) Subject to sub-regulation (1), as part of disposal, the Authority may donate samples, which have been tested and found to comply with specifications to public institutions and health facilities.
Cap. 119	(3) Disposal of samples under these Regulations, shall comply with the Environmental Management Act in force.
Disposal of biological, radioactive and chemical wastes	**24.-**(1) All hazardous substances and agents including biological, radioactive and chemical wastes shall be identified, labelled as such and properly stored by the Authority 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 Authority may enter into agreement with companies approved by the institution responsible for environmental

	management to dispose wastes.
	(5) Subject to sub-regulation (1), once the contracted disposal company has finalized disposal of wastes, shall issue proof of disposal to the Authority.
Disposal of controlled drug samples	**25.-**(1) Notwithstanding the provisions of regulation 23, disposal of controlled drug samples shall be reconciled by taking into account the following:
	(a) number of samples received;
	(b) number of units subjected into analysis;
	(c) number of units and empties remaining after analysis; and
	(d) number of units disposed.
	(2) Subject to sub-regulation (1), all records related to disposal of controlled drug samples shall be maintained to allow for audit by any relevant authorities.
	(3) Records referred to in sub-regulation (1), shall be retained for a period of one year post expiry of controlled drug samples.
	PART VII LABORATORY RESULTS DISPUTES HANDLING
Handling of disputed laboratory results	**26.-**(1) Where there is any objection of laboratory results issued by the Authority, 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 Authority shall review the results and conduct a thorough investigation of the method used for analysis of the sample.
	(4) Subject to sub-regulation (3), when the Authority is satisfied that the issued results were correct, it shall notify the customer within 14 days after completion of the review.
	(5) Subject to sub-regulation (4), where the customer is aggrieved by the decision of the Authority may request to witness the testing of the samples.
	(6) Subject to sub-regulation (5), in witnessing the testing of the samples, the Authority 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 Authority 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 Authority 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 TMDA laboratory and the contracted laboratory, an alternative laboratory shall be sought for testing of the samples upon shared cost 1to settle the dispute and the results shall be final.
PART VIII LABORATORY TECHNICAL COMMITTEE	
Establishment of Committee	**27.-**(1) Subject to the provisions of the Act, there shall be a Committee to be known as Laboratory Technical Committee to advise the Director General on

	matters related to analysis of regulated and non-regulated products.
	(2) The Committee referred to in subregulation (1), shall be composed of members with knowledge and experience in the fields of pharmaceutical analysis, quality control and quality assurance, microbiology, chemistry, laboratory technology, biomedical engineering, biotechnology, radiology, statistics, or any other related field.
Functions of the Committee	**28.** (1) The Committee may advice the Director General on the following:
	(a) Development and validation of analytical methods;
	(b) Analysis of regulated and non-regulated products;
	(c) Development of training programmes;
	(d) Management of accreditation schemes;
	(e) review of analytical processes and how to improve them;
	(f) propose and review areas of research;
	(g) matters related to costs of analysis including fees and charges
	(h) waste management practices;
	(i) laboratory quality management systems;
	(j) laboratory information management system;
	(k) any other matters related to the operations of laboratory.
Chairman and Secretariat	**29.-**(1) The Chairman of the Committee shall be elected from amongst the members.
	(2) The Chairman shall guide and chair the proceedings of the Committee meetings.
	(3) In the absence of the Chairman, the Acting Chairman shall be elected from amongst the members to preside over the meeting.
	(4) The Authority shall provide the secretariat services to the Committee.
Responsibility of secretariat to the committee	**30.** The responsibility of the secretariat shall be to-
	(a) providing leadership and strategic advice on management of the Committee;
	(b) distributing notice of meetings and respective documents;
	(c) work in close collaboration with the Chairman to ensure efficient and effective performance of the Committee;
	(d) preparing agenda items of the meetings;
	(e) taking minutes and keeping records of the meetings; and
	(f) providing logistical support to Committee members.
Committee may regulate its own proceedings	**31.** Subject to the provisions of these Regulations, the Committee shall regulate its own proceedings.
Co-option of Experts	**32**. 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.
Tenure of Committee	**33.** Members of the Committee shall serve for a period of three years and may be eligible for reappointment for one further term.
Cessation of membership	**34.** A member shall cease his membership upon occurrence of the following-
	(a) failing to attend three consecutive Committee meetings:
	(b) resignation at any time upon written notification to the Authority;
	(c) termination by the Authority on grounds of poor performance or any other reason thereof that may be judged to impair his performance;
	(d) dissolving the Committee on grounds of poor performance, conduct or

	absence of the need of such Committee;
	(e) conviction of any offence and sentences to imprisonment for a period exceeding six months; or
	(f) death.
Quorum	**35.** The quorum during Committee meetings shall be fifty plus one percent of members.
Meetings of Committee	**36**.-(1) The Committee may hold an ordinary meeting at least twice a year.
	(2) The Authority may convene extra ordinary meeting at any time when deemed necessary.
	(3) Any member who is unable to attend a meeting for known reasons may be allowed to submit written comments on the matter under discussion but shall not be allowed to send a representative to attend on his behalf.
	(4) The Committee shall provide specialist advice after reaching consensus.
Disclosure of Conflict of Interest	**37**.-(1) Any member of the Committee shall refrain from any undertaking that conflict his roles as Committee member.
	(2) Any member of the Committee shall be required to observe respective professional code of ethics and public service code of conducts including declaration of conflict of interest.
Remuneration of members	**38.** While attending Committee meetings, members and the Secretariat shall be remunerated in accordance with the existing Tanzania Medicines and Medical Devices Authority Internal Financial and Staff Regulations, government financial regulations or as may be decided by the Director General.
Liability of members	**39.** Anything done by a member while executing activities under these Regulations if done in good faith, shall not render such a member personally liable for the matter or thing done.
PART IX APPOINTMENT OF ANALYSTS	
Appointment	**40.** Appointment of analysts shall be as prescribed in the Act.
Qualifications	**41.** Subject to regulation (40), in appointing analysts, the Minister shall consider the following disciplines:
	(a) Pharmacy;
	(b) Laboratory Technology;
	(c) Medical Laboratory Science;
	(d) Pharmaceutical Technology;
	(e) Chemistry;
	(f) Microbiology;
	(g) Biotechnology;
	(h) Biomedical Engineering;
	(i) Biomedical Science; or
	(j) Radiology.
Gazetting	**42**. Analysts appointed under regulation (40), shall be gazetted in the official government gazette and assigned identification cards issued by the Authority.
Conflict of interest	**43**. Any appointed analyst shall refrain from any undertaking that may conflict with his roles and where the analyst has any potential interest declare the same in writing to the Authority.

	PART X HANDLING OF LEGAL SAMPLES
Collection of samples	**44**- (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 Authority and the third to be analyzed.
	(2) Collection and apportioning of samples under sub-regulation (1), shall be done by the inspector and each part shall be marked, sealed and secured in the manner permitted by its nature.
GN.312	(3) When collecting samples, the customer or his representative, shall be available to witness and sign sample collection form prescribed in the Registration of Premises, Importation and Exportation of Pharmaceutical Products and Raw Materials Regulations, 2015.
Safe custody of samples	**45**- (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	**46**.-Subject to regulation 44 and 45, analysis of samples shall be as specified in Part IV.
	PART XI ACCREDITATION AND TRAINING
Powers to accredit medical laboratories	**47**.-(1) The Authority shall have powers to accredit public and private medical laboratories to ensure that they have the competence to offer the services defined in the scope of these Regulations.
	(2) Subject to sub-regulation (1), the accreditation services to medical laboratories shall be given in the following disciplines:
	(a) Clinical biochemistry;
	(b) Hematology;
	(c) Microbiology and infectious diseases serology;
	(d) Molecular Testing;
	(e) Diagnostic Radiology;
	(f) QA Testing
	(g) Any other service as it may deem fit.
Cap. 136	(3) Without prejudice to the provisions of sub-regulation (1), the licensing of private health laboratories shall be in accordance with the Private Health Laboratory Regulation Act
Scope of accreditation services	**48**. The Authority, shall offer accreditation services to the areas specified by the medical laboratory in the accreditation application form:
Application for accreditation	**49**. An application for accreditation submitted to the Authority, shall be accompanied by the following:
	(a) Dully filled application form for accreditation of medical laboratories in the format and content as specified by the Authority.
	(b) Laboratory Information File (or Laboratory Quality Manual) in the format and content as specified by the Authority; and
	(c) Application fees as specified in the Fees and Charges Regulations in force.

Issuance of accreditation certificate	**50**. The Authority shall conduct audit of the medical laboratory and upon satisfaction issue accreditation certificate as prescribed in Schedule VII.
Validity of accreditation certificate	**51**. The accreditation certificate issued under regulation (50), shall be valid for a period of 3 years.
Surveillance audits	**52**. The Authority may conduct surveillance audits on annual basis to retain the accreditation certificate issued under regulation (50).
Renewal of accreditation certificate	**53**. The application for renewal of accreditation certificate shall be made to the Authority at least ninety days before its expiry by submitting the items listed under regulation (49).
Extension of scope	**54**. Where the applicant intends to extend the scope of accreditation, he shall express in writing and submit to the Authority relevant additional information including applicable fees as prescribed in the Fees and Charges Regulations in force.
Training services	**55-** (1) The Authority may offer training services to various customers including laboratory personnel upon receipt of expression of interest to do so.
	(2) Subject to sub-regulation (1), the type of training to be offered shall include but not limited to the following:
	(a) general management of the laboratory;
	(b) laboratory quality management systems;
	(c) analytical methods development and validation;
	(d) analytical techniques
	(e) equipment preventive maintenance, calibration and qualification;
	(f) laboratory risk management;
	(g) health and safety;
	(h) disposal and waste management;
	(3) Subject to sub-regulation (1), the Authority may advertise the training on any official media to invite applications for training participation, as it may deem necessary.
	(4) Subject to sub-regulation (1), the training fees shall be as prescribed in the Fees and Charges Regulations in force.
	(5) Subject to sub-regulation (4), the cost of participating in the training shall be advertised in the official call for expression of interest and determined depending on the type of training to be offered.
Issuance of training certificates	**56-** Upon completion of the training, the successful candidates shall be issued with a training certificate as prescribed in Schedule VIII.
	PART XII NATIONAL AND INTERNATIONAL COLLABORATIONS
National collaboration	**57.** In the performance of its functions, the Authority may as far as is practicable, maintain a system of consultation and cooperation with other laboratories to include-
	(a) Government Chemist Laboratory;
	(b) National Institute for Medical Research Laboratory;
	(c) The Tanzania Atomic Energy Commission Laboratory;
	(d) Tanzania Bureau of Standards Laboratory;
	(e) National Health Laboratory Quality Assurance and Training Centre; (f) Tanzania Veterinary Laboratory Agency;
	(g) Tanzania Pesticide Research Institute Laboratory; and

	(h) any other laboratory established by or under any other written laws.
International cooperations	**58**.-(1) The Authority may cooperate with regional and international laboratories on matters related to analysis of products under these Regulations.
	(2) The Authority 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	**59**-The Authority may participate in regional and international laboratory harmonization initiatives that aim at-
	(a) harmonizing systems for analysis of products, quality management, information management and any other laboratory activities as may be 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;
	(e) participating in post-marketing surveillance activities;
	(f) establishing networks with other laboratories and collaborate in protecting public health;
PART XIII CONFIDENTIALITY OF DATA AND RECORD KEEPING	
Confidentiality	**60.**-(1) All data generated in the laboratory including results of analysis shall be treated as confidential information.
	(2) Subject to sub-regulation (1), all staff working in the laboratory shall sign a confidentiality agreement form issued by the Authority.
	(3) Disclosure of any confidential information by the Authority shall only be made upon order of the court or any other lawful directive.
Electronic data management	**61**.-(1) The Authority 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	**62**-(1) The Authority 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;
	(b) analysis request forms;
	(c) sample analysis reports;
	(d) certificates of analysis;
	(e) procurement and supplies records ;
	(f) equipment calibration and preventive 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 records;
	(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 disposal.
PART XIV GENERAL PROVISIONS	
Appeals	**63**.-(1) Notwithstanding the provisions of these Regulations, any person aggrieved by a decision of the Authority may, within sixty days, appeal in writing to the Minister.
	(2) The appellant shall copy the appeal to the Authority 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	**64**. Any person who contravenes or fails to comply with these Regulations or 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.

SCHEDULES

SCHEDULE I
TEST REQUEST FORM

(Made under Regulation 14(1) (a))

Laboratory code number……
Customer's name and address……
Customer code number (if applicable) ……
Sample Information
Product name (including brand name, form and strength if applicable)……
Description (appearance of container & contents): ……..

Batch number…… Expiry date……Manufacturing date ……..

Manufacturer ……

Sample size (quantity): ……Submission date ……

Reason(s) for requesting the analysis……..
Sample submitted by…….. Signature.....

S/N	Test requested	S/N	Test requested

Statement of conformity required: YES/NO (tick as appropriate)
Applicable decision rule (If required)……
Analysis fees and charges…….....
Customer name: …….. Signature: ..... Date: ……
I accept/reject to carry out tests specified above
Laboratory Manager (LM) or Laboratory Supervisors (LS) Remarks (In case of rejection)…….....
LM or LS name: …… Section…….
Signature: ..... Date: ……

Subcontracting

Agreement for sub-contracting work: YES or NO (tick as appropriate) If no Reason (s) …….

LM or LS (Signature)…….....Date……

Customer (Signature): ..... **Date**……
Test request deviation or amendment/ additional test(s) (when applicable)……
Customer Name…… **LM or LS Name**……
Signature …….. **LM or LS signature** ……..
Date… …… **Date**……

SCHEDULE II

MINIMUM NUMBER OF UNITS REQUIRED FOR CHEMICAL AND MICROBIOLOGICAL TESTING

(Made under Regulation 14(2))

No.	Formulation	Pack Size	Minimum Sample Submission
1.	Injectables	≤ 10 mL 10 - 100mL 100 - 2000ml	30 vials/ampoules 12 vials/ampoules 6 bottles
2.	Powders for oral suspension	1-50g ≥ 50g	30 Sachets 15 Sachets
3.	Eye or ear drops	< 10 mL > 10 mL	100 bottles 50 bottles
4.	Tablets or capsules	All	100 tablets/capsules
5.	Suspensions or syrups	≤ 10 mL 10 – 500 mL 500 – 2000 mL	20 bottles 15 bottles 4 bottles
6.	Transdermal patches	5 – 100 g > 100 g	100 sachets 50 sachets
7.	Sprays or inhalers	All	10 Packs
8.	Creams, emulsions or gels	< 5 g 5 – 50 g > 50 g	20 tubes 10 tubes 5 tubes
9.	Disinfectants or antiseptics	< 50 mL 50 – 250 mL 500-1000 mL 5000 mL	8 bottles 4 bottles 2 bottles 1 bottle
10.	Active Pharmaceutical Ingredient (s)	Solids Liquids	5 g 1000 mL

SCHEDULE III

MINIMUM NUMBER OF UNITS REQUIRED FOR MEDICAL DEVICES AND DIAGNOSTICS TESTING

(Made under Regulation 14(2))

No.	Product	Pack Size	Minimum Sample Submission
11.	MRDT Test Kit	20 – 25 tests	4 kits
12.	HIV Test Kit	20 – 25 tests	4 kits
13.	Urine Pregnancy Test (UPT) Kit	25 tests	4 kits
		50 tests	2 kits
14.	Absorbable surgical sutures	All	20 units
15.	Male condoms	All	144 units
16.	Female condoms	All	144 units
17.	Surgical sutures	10 – 20	13 units
18.	Surgical blades	All	9 units
19.	Cotton wool	Rolls	2 rolls
20.	Surgical gloves	100/box	213 units
21.	Examination gloves	100/box	213 units
22.	Baby diapers and pads	All	20 units
23.	Absorbent gauze	All	1 roll
24.	Absorbent cotton	All	9 units
25.	Absorbent viscose wadding (bandage)	All	9 units
26.	Needles & syringes	50 pcs	1 box
27.	Plaster of Paris and zinc oxide	All	6 units
28.	Face mask	All	5 units

SCHEDULE IV
SAMPLE RECEIVING REGISTER

(Made under Regulation 15(4))

S/N	Registration number of the sample	Date of receipt	Specific unit to which the sample was forwarded	Number of units issued for analysis	Number of units remaining after analysis

SCHEDULE V

CERTIFICATE OF ANALYSIS

(Made under Regulation 18(2))

Lab code #: ……

Name of the laboratory: ……

Customer name and address: ……

Tanzania Medicines and Medical Devices Authority (TMDA) Laboratory do hereby certify that, it has received on the ……day of …… from …….. sealed or unsealed pack marked ……..

TMDA analysed the contents of the pack, and do hereby declare the results of analysis as follows:

Product Name: ……
Product Form/Presentation: ……
Customer Code/Application No: …….

Manufacturer: …….. **Lot/Batch No**.: ……
Date of Manufacture: ……. **Expiry Date**: ……

Date of Analysis: ……..

Active Ingredient(s) (If applicable): …….

Product Specification: (If applicable)……

Test parameter (s)	Method	Specification (s)	Result (s)	Remarks (Pass/Fail)

CONCLUSION:
……
……

	Analyzed by (Analyst)	Reviewed by (Laboratory Manager or Supervisor)	Approved by (Director of Laboratory Services or Laboratory Head)
Name			
Signature			
Date			

SCHEDULE VI

CERTIFICATE OF CONFORMITY

(Made under Regulation 18(2))

Lab code #: ……

Name of the laboratory: ……

Customer name and address: ……

Tanzania Medicines and Medical Devices Authority (TMDA) Laboratory do hereby certify that, it has received on the ……day of ……. from …….. sealed or unsealed pack (where applicable) marked …….

TMDA tested or analyzed the device or diagnostic (where applicable) and do hereby declare the results as follows:

Device or Diagnostic Name: ……
Physical appearance: …….
Customer Code/Application No: …….

Manufacturer: …….. **Lot or Serial No**.: ……
Date of Manufacture (where applicable): …….
Expiry Date (where applicable): …….

Date of testing or analysis: ……..

Device or Diagnostic specification: (If applicable)……

Test parameter (s)	Method	Specification (s)	Result (s)	Remarks (Pass/Fail)

CONCLUSION:
……
……

	Tested or analyzed by (Analyst)	Reviewed by (Laboratory Manager or Supervisor)	Approved by (Director of Laboratory Services or Laboratory Head)
Name			
Signature			
Date			

SCHEDULE VII
ACCREDITATION CERTIFICATE
(Made under 50)

Tanzania Medicines and Medical Devices Authority
Qaulity Control Laboratory Accrediatation Services

Certificate of Accreditation

The Tanzania Medicines and Medical Devices Authority's Quality Control Laboratory has assessed the Laboratory of

Name of the Laboratory being accredited

Physical address of the laboratory being accredited

(Hereinafter called the Organization) and hereby declares that the Organization is accredited in accordance with the recognized TMDA Standard:

Standard Code name and number

This accreditation demonstrate technical competence for defined scope and operation of a laboratory quality management system
(As outlined by the joint……dated……)

Chemical Testing of ……
(As detailed in the supplement)

Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.

For TMDA

Director General

SCHEDULE VIII.
TRAINING CERTIFICATE
(Made under 56)

DODOMA

……..., 2021

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Minister for Health, Community Development, Gender, Elderly and Children