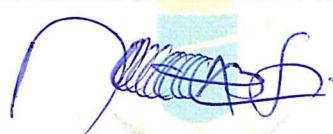


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<b>SIGNATURE</b>			
<b>DATE</b>	20 July 2020	20 July 2020	27/07/2020
<b>INSTRUCTIONS</b>			
<p>1. Controlled issues of this manual may <b>not</b> be copied</p> <p>2. All amendments are written on the page provided</p> <p>3. Only authorized, numbered, stamped copies of this manual as described in the document control section above, are used</p> <p>4. This Manual shall <b>not</b> be used outside the Rwanda FDA Quality Control Laboratory without the authority of the authorizing personnel.</p>			

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### 1.0 Quality Control Laboratory Quality Policy Statement

- This Quality Policy is issued under the authority of the Director General Rwanda Food and Drugs Authority (Rwanda FDA).
- Quality Control Laboratory management is committed to provide the highest quality of testing services in compliance with the governing standards ISO/IEC 17025:2017 and strives to demonstrate compliance to the selected recognized accreditation body through but not limited to internal audits, management reviews, effective corrective action system and participation in proficiency tests.
- Quality Control Laboratory management is committed to continually improving the competence of employees through trainings and evaluation of training effectiveness.
- Quality Control Laboratory management is committed to impartiality of its laboratory activities and do not allow commercial, financial or other pressures to compromise impartiality.
- Quality Control Laboratory tests and services are always carried out in accordance with stated standardized methods and/or our client's requirements.
- Quality Control Laboratory staff concerned with testing activities within laboratory familiarize themselves with the quality documentation and implement these policies and procedures.

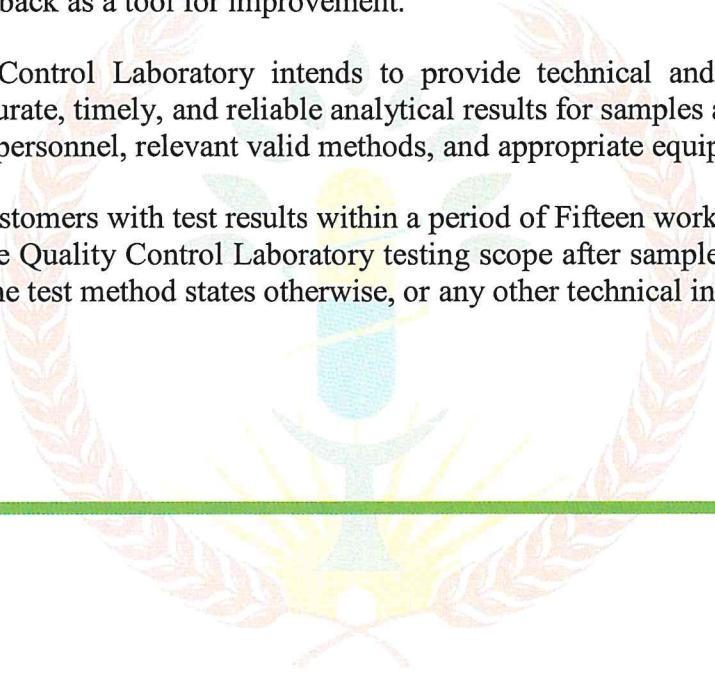
Director General Rwanda FDA,  
Signature.....  
Date:..... 27/7/2020



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### **2.0. Quality objectives**

- The Quality Control Laboratory Management ensures that personnel performing analytical testing and support services are trained and competent through internal trainings and capacity building plan, personnel competence is evaluated by different measures such as performance in both internal and external quality control tests.
- The Quality Control Laboratory strives to meet or exceed the customer's needs and expectations through established mutual contact with customers and regular evaluation of customer feedback as a tool for improvement.
- The Quality Control Laboratory intends to provide technical and analytical services, providing accurate, timely, and reliable analytical results for samples analyzed through use of competent personnel, relevant valid methods, and appropriate equipment.
- To provide customers with test results within a period of Fifteen working days for samples covered by the Quality Control Laboratory testing scope after sample reception, except in cases where the test method states otherwise, or any other technical interruption.



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### Abbreviations and acronyms

<b>AAS</b>	Atomic Absorption Spectrometer
<b>CAPA</b>	Corrective and Preventive Actions
<b>CO2</b>	Carbon dioxide
<b>DAD</b>	Diode Array Detector
<b>DO</b>	Dissolved Oxygen
<b>EAC MRH</b>	East African Community Medicines Regulatory Harmonization
<b>HPLC</b>	High Performance Liquid Chromatography
<b>ICH</b>	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
<b>ICT</b>	Information and Communications Technology
<b>IEC</b>	International Electro-technical Commission
<b>IR</b>	Infra-Red
<b>ISO</b>	International Organization for Standardization
<b>PT</b>	Proficiency Testing
<b>Rwanda FDA</b>	Rwanda Food and Drugs Authority
<b>SOP</b>	Standard Operating Procedure
<b>Uv/Vis light</b>	Ultra/Violet light
<b>QCL</b>	Quality Control Laboratory
<b>QMS</b>	Quality Management System
<b>WHO</b>	World Health Organization
<b>WHO GPPQCL</b>	World Health Organization Good Practices for Pharmaceutical Quality Control Laboratories

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### 1. INTRODUCTION

#### 1.1 Background

This Manual and its provisions shall be cited as the "Laboratory Quality Manual" which is one of the manuals of the Rwanda FDA.

One of the goals of Rwanda FDA is to have a functioning Laboratory Quality Management System (QMS) in accordance with national and internationally recognized standards. This document provides requirements for implementing quality management systems in accordance with ISO/IEC17025: 2017. The Manual defines:

- a) The scope of the laboratory quality management system, including details of, and justification for, any exclusions;
- b) The documented information established for the laboratory quality management system, or reference to them;
- c) Description of the interaction between the processes of the laboratory quality management system; and the organisational quality management system.

#### 1.2 Objectives of this Manual

This manual is prepared for the purpose of defining Rwanda FDA's interpretation of the ISO/IEC17025:2017 international standard, as well as to demonstrate how the Rwanda FDA complies

- a) To define and describe the laboratory quality management system, authorities and responsibilities of the management personnel involved in the operation of the system, and provide references to the laboratory procedures for all activities affecting the quality of test results.
- b) To communicate the laboratory quality management system to the Rwanda FDA staff, customers, stakeholders, development partners and other interested parties and to inform them of the specific controls that are implemented by Quality Control Laboratory to assure evidence-based regulatory decision.

#### 1.3 Mandate of the manual

The Article 08 of the Law No. 003/2018 of 09/02/2018 paragraph 6 mandates the authority to establish quality assurance and quality control of regulated products. Rwanda FDA Quality Control Laboratory is

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mandated to perform regulatory samples only and the success of the authority in protection of public health depends on the ability of the laboratory to quickly, accurately analyze samples supported with documented quality management system.

### **1.4. Scope of the quality management system**

This manual describes the Quality Management System (QMS) of Rwanda FDA laboratories based on the ISO/IEC17025:2017 standard and World Health Organization Good Practices for Pharmaceutical Quality Control Laboratories (WHO GPPQCL) guidelines. It specifies the requirements for the competence, impartiality and consistent operation of the laboratories and applies to all activities contributing to the quality of services they offer.

The laboratories interact with the different Divisions/Units of the organization and support the key regulatory services of Rwanda FDA like:

- 1) Registration of products (medicines; processed food for humans and animals, food supplements and fortified foods; medicated cosmetics; and medical devices);
- 2) Inspection of premises for verification of Good Manufacturing Practices, Good Distribution Practices, Good Laboratory Practices, Good Hygiene Practices, Hazard Analysis Critical Control Point (medicines; processed food for humans and animals, food supplements and fortified foods; cosmetics; and medical devices),
- 3) Control of import and export (medicines; processed food for humans and animals, food supplements and fortified foods; cosmetics; and medical devices, tobacco and tobacco products);
- 4) Pharmacovigilance (medicines; cosmetics; and medical devices);
- 5) Safety monitoring for processed food, food supplements and fortified foods, tobacco and tobacco products;
- 6) Post-marketing surveillance;
- 7) Licensing of facilities (medicines; processed food, food supplements and fortified foods; cosmetics; and medical devices);
- 8) Authorization of clinical trials and inspection of clinical trial sites; and
- 9) Control of advertisements and promotion materials;

The quality management system described in this Manual applies to the Quality Control Division of Rwanda FDA.

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Rwanda FDA uses product regulatory guidelines described in the national guidelines and guidelines from the East African Community (EAC) Medicines Regulatory Harmonization (MRH), World Health Organisation, International Council for Harmonisation of Technical Requirements for pharmaceuticals for Human Use (ICH), Codex Alimentarius, and other international bodies.

Clauses for impartiality and confidentiality have been included in this Manual in accordance with the ISO/IEC17025:2017 standard.

### 2. TERMS AND DEFINITIONS

Rwanda FDA adopts the following terms and definitions within its Quality Management System. Where no definition is provided, the organization typically adopts the definitions provided in *ISO 9000: Quality Management – Fundamentals and Vocabulary*. In some cases, specific procedures and documentation may provide different definitions to be used in the context of that document; in such cases the definition will supersede those provided for in this Quality Manual or ISO 9000.

#### **Customer**

The recipient of a product/service provided by Rwanda FDA Quality Control Laboratory.

#### **Complaint**

Expression of dissatisfaction by any person or organization to the laboratory, relating to the activities or results of that laboratory, where a response is expected.

#### **Decision rule**

Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

#### **Document**

Any record or information that provides direction including instructions, policy statements, textbooks, reference materials and their origins, procedures, specifications, calibration tables, charts, posters, notices, memoranda, plans, software, drawings, regulations and standards, rules and guidelines, on how an activity is done.

#### **Documents of External Origin**

These are documents generated outside Rwanda FDA and have a significant contribution to its function. These include letters, standards, test methods and international compendia.

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### Document Control

It is a system that regulates the handling and management of documents including archiving, storing and destruction of documents containing information which communicates policies, processes, procedures as well as records.

### Impartiality

The presence of objectivity. Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the laboratory. Other terms that can be used for impartiality include “freedom from conflicts of interest”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “evenhandedness”, “detachment”, “balance”

### Interlaboratory comparison

Organization, performance, and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

### Intralaboratory comparison

Organization, performance and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with predetermined conditions.

### Laboratory

A body that performs one or more of the following activities:

- Testing;
- Calibration;
- Sampling, associated with subsequent testing or calibration

### Non-conforming work

This refers to any work that does not comply with the set standards. It can be identified from many sources, including audits, quality control, staff comments and customer complaints.

### Process

Series of inter-related steps involved in an activity or examination that uses resources and manages to transform inputs into outputs.

### Procedure

Written work instructions that specify a way to carry out an examination or steps in a process.

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### Proficiency testing

Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

### Quality Management System

A program developed to support efficient, effective, appropriate and high quality laboratory and supporting services. This will include appropriate test selection, accurate and precise results, correct interpretation of results, recommendations for further tests and timely reporting.

### Quality

The degree to which a set of inherent characteristics fulfil specified requirements. It is also the Conformance to specified requirements.

### Quality Manual

A document which describes the quality management system.

### Record

Any information that produces objective evidence that a task has been fulfilled. This includes the following: requisitions, examination results and reports, instrument printouts, laboratory workbooks, worksheets, calibration records, quality control records, records of audit, complaints and action taken, external quality assessment records, instrument maintenance records, incident/accident reports, staff training, competency records and personnel records.

### Technical Signatory

An analyst who has been deemed competent in a certain technique or test method (e.g. HPLC technique) by the accreditation body who is responsible and accountable for test results produced.

### Regulated products

Human and veterinary drugs and vaccines; processed food, food supplements and fortified foods; medicated cosmetics; and medical devices, tobacco and tobacco products, laboratory and cleaning chemicals and pesticides as per Article 3 of the Rwanda FDA Law.

### Verification

Provision of objective evidence that a given item fulfils specified requirements

### Validation

Verification, where the specified requirements are adequate for an intended use.

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### **3. CONTEXT OF RWANDA FOOD AND DRUGS AUTHORITY**

#### **3.1.Understanding the context of Rwanda FDA**

Rwanda FDA Quality Control Laboratory has determined the external and internal issues that affect its ability to achieve the intended result(s) of its quality management system and that are of concern to its interested parties. It has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the organization. Monitoring and reviews are done through annual performance reviews as per the annual division action Plan.

#### **3.2.Understanding the needs and expectations of interested parties**

The issues determined as per 3.1 above are identified through an analysis of risks facing Rwanda FDA Quality Control Laboratory and its interested parties. The laboratory has determined its interested parties and their requirements that are relevant to the quality management system through development of a stakeholders' requirement analysis in the annual action plan. "Interested parties" are those stakeholders who receive laboratory services, or who may be impacted by them, or those parties who may otherwise have a significant interest in the laboratory activities.

The information on the needs and expectations of interested parties is then used by senior management to determine the laboratory's strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

#### **3.3.Determining the scope of the quality management system**

This manual applies to all activities that affect the quality of services delivered by Rwanda FDA Laboratory Services in their support of the following key regulatory activities:

- a) Assessment and registration of regulated products;
- b) inspection and licensing of pharmacies, medicine shops and local pharmaceutical manufacturers;
- c) GMP inspection of domestic and foreign manufacturers of pharmaceutical products;
- d) control of pharmaceutical and other regulated products' imports and exports;
- e) pharmacovigilance;
- f) clinical and field trials;
- g) vetting of publications and advertising relating to regulated products;
- h) post-marketing surveillance;
- i) Quality Control Laboratory testing of samples; and
- j) enforcement processes.

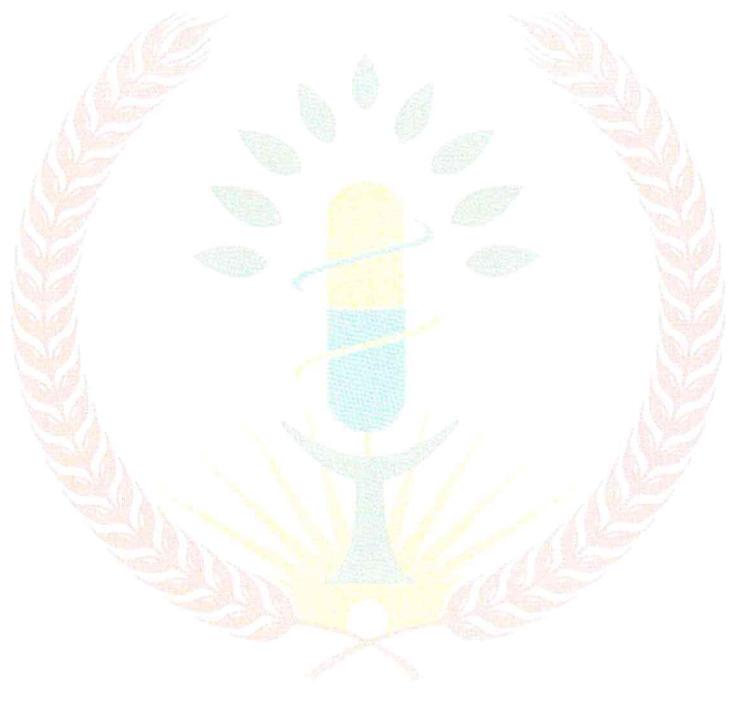
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It also includes support functions of Rwanda FDA such as finance and audit, procurement, information communication technology (ICT), legal services, human resource and administration, public relation and others as applicable.



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## **4. GENERAL REQUIREMENTS**

### **4.1. Impartiality**

Rwanda FDA senior management has structured organograms for the Quality Control Division which ensure and safeguard impartiality. The Quality Control Laboratory division which is autonomous is headed by the Division Manager who has quality oversight over the laboratory activities. The Quality Control division has four laboratories namely: Medicine, cosmetics and poison testing laboratory, food testing laboratory, medical devices and Instrumentation Laboratory and microbiology laboratory with competent laboratory officers who report directly to the Division Manager; and then, the Division Manager reports independently to the Director General.

Rwanda FDA has a policy on impartiality that is approved by the Director-General that will reflect commitment of Laboratory management on impartiality.

The Authority has arrangements to ensure that personnel are free from any undue influence that may adversely affect the quality of their work. This is achieved by ensuring the following:

- i. That all employees and board members of Rwanda FDA declare any conflict of interest;
- ii. Employees are not allowed to communicate directly with customers except through the Division Manager.

The Laboratory manages its activities to periodically identify and minimize any identifiable risks to impartiality. Risks to impartiality may emerge as a result of changes over time, operational risk trending and analysis. All Rwanda FDA laboratories are mandated to record operational risks arising from their activities on an ongoing basis.

Risks might also emanate from relationships which might affect the impartiality of the laboratories. These relationships include but are not limited to:

- 1) Relationship with the Authority;
- 2) Relationship with management within the Authority;
- 3) Relationship with related companies or organizations;
- 4) Relationship with customers.

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Rwanda FDA has put in place impartiality risk mitigation measures which include:

- 1) Ethical code of conduct
- 2) Setting up anti-corruption a tip offs facility independent of the Authority
- 3) Risk registers which are maintained and reviewed regularly and reports submitted in Quality Management Review meetings

### 4.2. Confidentiality

Rwanda FDA laboratories have policies and procedures in place to ensure confidentiality of information contained in marketing authorisations, Certificates of Analysis (CoA), reports and archived data (paper and electronic).

Rwanda FDA as a legal entity is responsible for the management of all its information as guided by Law No. 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and determining its mission, organisation and functioning on preservation of secrecy. Authority Members, Committee Members, employees, visitors, contractors and personnel of external bodies are required to comply with confidentiality requirements.

Release of customer information is subject to contractual obligations and is also governed by applicable laws and statutes of the country.

Information obtained from sources other than the customers (e.g. complainants, other regulatory authorities, whistle-blowers) is also held in strict confidence. The information source shall be confidential to the laboratory, and shall not be shared with the customer, unless agreed to by the source.

All laboratory personnel, Authority and Committee members sign confidentiality declaration forms upon assumption of employment. Contractors, visitors, personnel of external bodies sign Declaration of Confidentiality and Visitors forms for controlled access.

### 5. Structural requirements

Rwanda FDA was established by a Law No. 003/2018 of 09/02/2018 of Parliament and is held legally responsible whenever disputes arise. The contact details of Rwanda FDA are; **Physical Address:** Kicukiro-Kigali, P.O Box.: 84 Kigali.

Rwanda FDA has managerial and technical personnel with authority and adequate resources needed to carry out their duties. The responsibilities are outlined below;

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### The Designated Quality Management System Officer

- Has quality oversight over the laboratories and has direct access to the highest level of management.
- Ensures that the Quality Management System is implemented and followed at all times.
- Prepares audit schedules and ensures that audits are conducted as per plan
- Reports to management on the performance of the quality management system.
- Collects and prepares information/data for use by management for management review.
- Is responsible for the document management system including reviews and approvals
- Acts as a management representative on issues of Quality Management Systems.
- Liaises with accreditation and relevant international bodies on Quality Management Systems assessments.
- Ensures that all Quality Control Laboratory staff are effectively trained on Quality Management Systems.

### Quality Control Division Manager:

- Has authority to ensure proper use of available resources in the laboratory
- Supervises all technical management (Laboratory Officers and technicians in the Quality Control of Medicines, cosmetics and poison testing laboratory, food testing laboratory, medical devices and microbiology laboratory)
- Ensures the generation of authentic, accurate and good quality reports by laboratory staff
- Reviews and approves laboratory procedures
- Ensures implementation and maintenance of the procedures in the laboratory.
- Ensures the planning, logistics, smooth and efficient running of the laboratory.
- Liaises with customers.

The deputies for key laboratory managerial personnel are as follows:

#### Position

1. Director – General
2. Division Manager
3. Laboratory Officer

#### Deputy

- |                                   |
|-----------------------------------|
| Division Manager                  |
| Human Medicine Laboratory Officer |
| Laboratory Technician             |

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Rwanda FDA laboratories undertake the physical, chemical and microbiological analysis of regulated products. The mentioned tests are conducted in Medicines, cosmetics and poison testing laboratory, food testing laboratory, medical devices and microbiology laboratory. The major tests carried out by the Quality Control Laboratory and related costs are found on Rwanda FDA website ([www.rwandafda.gov.rw](http://www.rwandafda.gov.rw)).

The Analysis is carried out by use of high-technique equipment and other small instruments for specific tests depending on standard requirements and individual monographs. The list of major equipment is found on the **Appendix I**.

Rwanda FDA provides adequate resources for the laboratory activities which are suitable for meeting customer, statutory and regulatory requirements as well as requirements for the organisations providing recognitions. This includes appropriate equipment; qualified, skilled and competent personnel. Rwanda FDA has suitable infrastructure and a conducive environment for the operation of all processes at its premises.

Laboratory activities are guided by ISO/IEC17025:2017, WHO-GPPQCL, other applicable scientifically recognised international standards and documents of external origin.

The Authority has laboratory procedures to ensure the consistent application of its laboratory activities and the validity of the results. The current Rwanda FDA and laboratory organograms are found in **appendix II** (Quality Control Laboratory position in Rwanda FDA). A summary of the Roles and responsibilities of personnel as attached in **Appendix III**.

Rwanda FDA has managerial and technical personnel with authority and adequate resources needed to carry out their duties.

Laboratory management ensures that information regarding effectiveness of the management system, the importance of meeting customer's and other requirements communicated through reports which are presented at the Quality Management Review meeting held annually.

The laboratory management ensures that the integrity of the system is maintained through the change control process when changes are planned and implemented as guided by the procedure QMS/SOP/001 document control procedure.

Rwanda FDA senior management communicates to all personnel through memoranda, emails, notices, circulars and announcements. The Director-General communicates feedback from Authority board of directors meetings to management through summary reports. Management communicates feedback from Annual Strategic Planning meetings, Senior Management meetings, Management meetings and Quality Management Review meetings to all staff through Divisional meetings.

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The Authority has a Communication Matrix which cascades to Divisional level. All communication with external customers and interested parties is on behalf of the Director General. All formal letters are printed on the Rwanda FDA letterhead.

## 6. RESOURCE REQUIREMENTS

### 6.1. General

Rwanda FDA determines and provides resources through approval of an annual budget for the establishment, implementation, maintenance and continual improvement of the QMS. Resources provided to support the operation of all processes include personnel, facilities, equipment, systems and support services. The terms of employment vary from short term contract to permanent. The resources are managed to ensure effective and efficient performance of the QMS.

### 6.2 Personnel

All laboratory personnel that could influence the laboratory activities must be competent and work in accordance with the laboratory's management system. Rwanda FDA establishes the competence of Laboratory personnel by continuously ensuring that they are participating in relevant training and proficiency testing schemes. All laboratory trainees work under supervision until deemed competent. All staff carrying out work in the laboratory sign declaration of confidentiality and conflict of interest forms so as to counter impartiality.

All Rwanda FDA laboratories ensure that personnel carrying out work in the laboratory are qualified and competent on the basis of appropriate education, training, technical knowledge, skill and experience. Every laboratory has a training and competence assessment matrix. Documentation of the competence assessment activities is maintained by the Division Manager.

The Division Manager declares the competence of its personnel to perform work by means of a certificate of competence which is issued under the authority of the Director General. All competent personnel have the capacity to evaluate the significance of deviations. The procedure for analyst validation will also be developed.

Laboratory Management communicates duties, responsibilities and authorities to laboratory personnel through their job descriptions and performance contracts.

The laboratories have procedures in place for:

- i. Determining the competence requirements
- ii. Selection of personnel
- iii. Supervision of personnel

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- iv. Training of personnel
- v. Authorization of personnel and
- vi. Monitoring competence of personnel

As part of the competence assessment, laboratory staff are authorized to perform specific laboratory activities such as method modification, verification and validation as well as preparation and reporting test results where relevant.

### **6.3 Facilities and environmental conditions**

- 6.3.1 Rwanda FDA laboratory facilities are appropriately designed and maintained being well lit, ventilated and air conditioned, to facilitate a conducive environment for performance of tests and assure validity of results.
- 6.3.2 The laboratories have procedures in place which stipulate the required environmental conditions for conducting tests and procedure for laboratory safety. The Laboratory Information File (LIF) shows the design of the facilities and their specifications.
- 6.3.3 Rwanda FDA laboratories monitor and control environmental conditions, as required by the relevant specifications where they influence the quality of the results. The environmental conditions monitored include temperature and humidity which are specific for each laboratory, the procedure for cleaning of Quality Control Laboratory will be also developed. A record is kept for the environmental conditions by the relevant laboratory. Limits for the parameters measured are documented in the specific laboratory SOPs as the degree of environmental control and monitoring varies from one location to another. Temperature mapping is also done.
- 6.3.4 There is controlled access to Laboratory areas where tests are done, Entry restriction labels are mounted on each entrance to the laboratory areas and the laboratory will elaborate a procedure for entry and exit. Rwanda FDA ensures that there is effective separation between neighbouring areas in which there are incompatible activities. Isolators, Biosafety cabinets and fume hoods are housed in the relevant laboratories. Measures are taken to prevent cross contamination by restricting access to authorized personnel.
- 6.3.5 In the event that Rwanda FDA laboratories perform their activities away from the main site, the environmental procedures should be followed at the sub-contracted site. The facilities should be suitable for the tests to be performed.
- 6.3.6 Measures are taken to ensure good housekeeping in the laboratory through adherence to the procedure for cleaning of laboratory facilities.
- 6.3.7 All personnel will be appropriately trained on Safety and Health issues. All personnel are

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responsible for implementing the prescribed safety and health requirements when conducting their duties. All personnel shall handle laboratory materials according to prescribed procedures. Rwanda FDA laboratories provide appropriate personal protective equipment (PPE)

- 6.3.8 All accidents/incidents that occur during work are handled in accordance with the appropriate standard operating procedures.
- 6.3.9 All personnel are trained to handle laboratory materials according to prescribed procedures.

### **6.4 Equipment**

- 6.4.1 Rwanda FDA provides adequate facilities, furnishings and equipment for the correct performance of tests. The equipment includes high-technique equipment and other small instruments found in the **appendix I**.
- 6.4.2 In the event that the laboratory uses equipment outside its permanent control, the equipment shall be qualified and deemed fit for use. The relevant laboratory equipment procedures shall be followed.
- 6.4.3 Rwanda FDA laboratories have procedures in place for equipment qualification, safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and prevent contamination or deterioration. All equipment is qualified prior and during use where necessary.
- 6.4.4 After the maintenance/repairs of defective equipment, the appropriate checks/calibrations and re-qualifications are done before using the equipment again.
- 6.4.5 Rwanda FDA laboratory equipment is properly calibrated by qualified metrologists whose reference documents are traceable to international standards. Maintenance of equipment is done by qualified engineers.
- 6.4.6 Rwanda FDA laboratory equipment is calibrated when:
  - 6.4.6.1 Equipment is out of calibration affecting measurement accuracy or measurement uncertainty.
  - 6.4.6.2 After servicing and maintaining equipment
  - 6.4.6.3 When major changes such as replacement of parts that affect accuracy of results after refurbishment
- 6.4.7 Rwanda FDA laboratories have calibration schedules which are monitored by laboratory officers.

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- 6.4.8 The calibration status of equipment is indicated on the equipment by way of stickers highlighting name of equipment, date of calibration and next date of calibration.
- 6.4.9 Any equipment giving inconsistent results is investigated and if necessary taken out of service and marked as such. Correction and corrective actions will be taken appropriately.
- 6.4.10 Intermediate checks on equipment are performed by competent authorized senior analysts according to the laboratories' procedures. System suitability tests and equipment verification tests are performed before analysis.
- 6.4.11 Rwanda FDA laboratories have procedures in place for the application of correction factors which are applied after calibration, service and during routine testing to ensure specified requirements are met.
- 6.4.12 Major laboratory equipment is operated by competent and authorized personnel whose access to the equipment is password controlled with different access levels to prevent unintended adjustments of equipment from invalidating results.
- 6.4.13 Rwanda FDA laboratories have equipment records in the form of logbooks, hardcopy and electronic folders to cater for equipment details which include but are not limited to equipment identification, manufacturer's details, and evidence of verification, current location, maintenance records and details of malfunction.

## **6.5 Metrological traceability**

All equipment used for tests by Rwanda FDA including equipment for subsidiary measurements will be calibrated or verified by an accredited National Metrology Institute before being put into service. For non-accredited service providers not meeting the requirements of traceability, the service provider should be accredited by the manufacturer of the equipment to perform the calibrations service.

- 6.5.1 For all equipment used for tests and measurement the laboratory shall use reference standards with metrological traceability and shall also provide a documented unbroken chain of the calibrations each contributing to measurement uncertainty.
- 6.5.2 All laboratory measurements should be traceable to the international system of units through calibration provided by a competent laboratory or use of traceable certified reference materials provided by a competent producer.
- 6.5.3 In the event that metrological traceability and use of certified reference materials is not technically possible, the laboratories shall demonstrate traceability to an appropriate reference for example

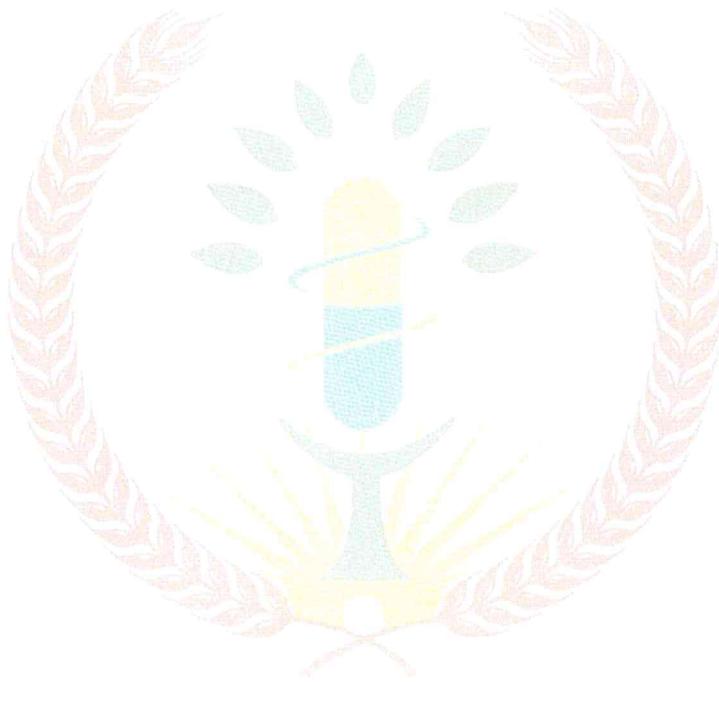
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certified values of certified reference material provided by a competent producer or use specified methods or standards that are clearly described or accepted as providing results fit for intended use and ensured by suitable comparison



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### **6.6 Externally provided products and services**

External provision of products and services includes any processes, supplies or services that Rwanda FDA needs for inclusion into the execution of the laboratory activities.

The Authority is responsible for ensuring that externally provided processes, supplies and services conform to the requirements of the QMS. To that end the Authority has put in place the following:

- 6.6.1 A list of approved suppliers (non-blacklisted companies) is available on Rwanda Public Procurement Authority website([www.rppa.gov.rw](http://www.rppa.gov.rw)).
- 6.6.2 The laboratory has approved purchasing and procurement procedures for defining, selecting, monitoring of external providers performance and their re-evaluation, the procedure for procurement. Appropriate action is taken to address any issues arising from the exercise. Compliance of laboratory goods and services is also verified using the stated procedures. Documentation is retained as appropriate.
- 6.6.3 The laboratory communicates the following requirements to external providers:
  - 6.6.3.1 Products and services to be provided
  - 6.6.3.2 Acceptance criteria
  - 6.6.3.3 Competence and qualification of personnel where necessary
  - 6.6.3.4 Any activities that the laboratory and its customers intend to carry out at the external provider premises
- 6.6.4 The Division Manager is responsible for supplier site visit evaluation when required and monitoring performance of external service providers.

## **7. PROCESS REQUIREMENTS**

### **7.1. Review of requests, tenders and contracts**

Rwanda FDA laboratories have a procedure for reviewing Requests, Tenders and Contracts. The Division Manager or designate has the responsibility to review the technical, regulatory, customer and any other requirements as requested by customers. The review of Requests, Tenders and Contracts is performed before work commences. The procedure ensures that:

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- i. All requirements including the test method/procedures to be used, are adequately defined, documented and understood.
- ii. The laboratories have adequate resources and competent personnel to meet the requirements
- iii. Under normal circumstances, Rwanda FDA does not subcontract its services for sample analysis. Should the need arise due to unforeseen circumstances, testing activities should be subcontracted to other competent and accredited laboratories according to the laid down global procedure for subcontracting testing activities to other Laboratories.
- iv. The procedure for Purchasing Services and Supplies should be followed when engaging external providers. The Division Manager or designate advises the customer in writing of the proposed subcontracting arrangement which can only proceed on the customer's approval.
- v. The Division Manager or designate informs the customer in writing when the requested method is considered to be inappropriate or outdated.
- vi. Should the customer request a statement of conformity, the laboratories will clearly define the specifications or standard to be used. Where a decision rule is required, it shall be clearly defined, communicated and agreed with the customer.
- vii. Any changes to Requests, Tenders and Contracts are resolved before work commences. The laboratories will only accept deviations from customers that do not impact on the validity of final result. Requests, Tenders and Contracts are acknowledged through signing by both Laboratory and customer.
- viii. The Division Manager or designate informs the customer in writing of any deviation from the contract.
- ix. If any changes have to be made to the Contract after work has commenced, the contract review process is repeated by completing the requisite form or any relevant form. The amendments will be documented and communicated to all affected personnel.

Rwanda FDA values its customers and strives to ensure that their requirements are met at all times. The laboratories cooperate with customers who may wish to monitor laboratory performance in relation to testing activities. Measures to ensure confidentiality to other customers are taken as per the Customer Service Charter.

Records of reviews as well as correspondence pertaining to the Reviews of Requests, Tenders and Contracts are maintained by the designated Quality Management Systems Officer.

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### 7.2. Selection, verification and validation of methods

#### 7.2.1. Selection and verification of methods

The laboratories use appropriate test methods which meet the needs of the customer. The methods used are those validated or published in the latest editions of International Compendia such as British, United States, International and European (BP, USP, IP and Eur) pharmacopoeia. Manufacturers' methods, customer methods as well as those published by Regional and International Standards bodies are also used. Where appropriate the evaluation of measurement of uncertainty and statistical techniques for data analysis is incorporated. The laboratory will put in place a procedure for qualification of test method.

Rwanda FDA Laboratories use the latest available versions of compendial test methods and international standards. In the event that reference data is required the updated copies are used. Procedures are reviewed biennially for relevance and scope or when necessary.

Rwanda FDA approves access for Quality Control Laboratory staff to Market Authorization (MA) file to ensure that testing requiring non-compendial methods are performed in accordance with the manufacturer's methods.

Rwanda FDA laboratories remove obsolete test methods and monographs, reference sources and procedures from points of use to ensure the use of latest valid methods. Supplementary reference information is applied whenever relevant.

In the event that the customer does not state the method of analysis, the laboratories select a suitable method from an international standards and pharmacopoeia in accordance with any relevant laboratory procedures.

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The Rwanda FDA laboratories verify that they can properly follow through a method to standard specifications before carrying out work for the customer. All methods will be verified to the extent necessary as per the procedure on Qualification of Analytical Methods and any relevant laboratory procedures. Records of such verification are maintained. Rwanda FDA laboratories do not develop any methods.

Deviations from laboratory activities occur only if the deviation has been documented, technically justified and accepted by the customer in advance through signing a contract.

### 7.2.2. Validation of methods

Rwanda FDA Quality Control laboratories validate methods when necessary. Where a method has to be validated, this shall be done in accordance with the procedure for analytical method validation.

Any required major changes in the method shall be referred to the manufacturer for validation or the laboratory can request for an updated method.

The laboratory shall adopt other suitable methods after verification. The verification shall be performed according to the method requirements and internal SOP for verification of methods. The laboratory shall maintain records for all verification of methods performed.

### 7.3. Sampling

Sampling of products to be analyzed at Rwanda FDA Quality Control Laboratory is done during marketing authorization or post-market surveillance as per related guidelines. The sampling plans and methods are readily available in Food and Drugs Inspection and Safety Monitoring Department. Sampling is done by the Inspectorate or Enforcement division where they collect samples as part of post marketing surveillance. Pre-approval samples are simply submitted by the applicant as part of the registration process.

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#### **7.4. Handling of test or calibration items**

The Quality Control Laboratory Division has procedures for the testing of samples, which cover the handling, distribution, disposal and storage of test items including all provisions necessary to protect the integrity of the samples.

The Quality Control Laboratory Division has a coordinated system for identifying test items. The identification is retained throughout the life of the sample. The sample is assigned a unique Rwanda FDA reference number. The system is designed and operated so as to ensure that test items cannot be confused physically or when referred to in any other document.

Upon receipt, samples are inspected for presentation/integrity. Depending on the outcome of the inspection, the samples will either be accepted or rejected. If rejected, samples will be returned to the customer immediately without being recorded. In the event that the customer requires testing to be conducted despite the noted deviation from specified condition, a disclaimer is included in the results. In the case of split samples, management of the samples is done accordingly.

Rwanda FDA laboratories samples are stored under controlled environmental conditions which are maintained, monitored and recorded. Any portions of samples remaining after performance of all required tests are stored in the Sample Room as retention samples. Medicine samples will be retained for a period spanning from date of expiry plus one year. Food and cosmetic samples will be retained for one month after release of certificate of analysis.

#### **7.5. Technical records**

Quality Control laboratory retain on record original observations, calculations, staff records, quality records (e.g. audit and review records) and a copy of each certificate of analysis for a period stated at the end of each procedure. The records for each test contain sufficient information to enable the test to be repeated under conditions as close as possible to the original. The records include the identity of personnel responsible for carrying out the test. All observations, data and calculations is recorded at the time they are made.

Laboratory staff are trained to adhere to Good Documentation Practices. Errors in observations are not erased, deleted or made illegible, but are crossed out by a single line (correct information entered alongside), then initialled or signed and dated. Original and amended data files are retained with an indication of the altered aspects and the personnel responsible for the alterations. All handwritten records are made using blue or black indelible ink. No pencils are used for recording data except on Thin Layer Chromatograms (TLC).

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### **7.6.Evaluation of measurement of uncertainty**

Rwanda FDA Laboratories have a procedure governing the Estimation of Measurement of Uncertainty. All possible components of uncertainty are identified before calculation of uncertainty of measurement, based on the theoretical principles or practical experience of the performance of the method.

### **7.7.Ensuring the validity of results**

Rwanda FDA laboratories have quality control procedures for monitoring the validity of tests that are undertaken. The resulting data will be recorded in such a way that trends are detectable. The monitoring will be planned and reviewed and will include one or more of the following;

- 7.7.1. The regular use of certified reference material and/or internal quality control using secondary reference materials.
- 7.7.2. Use of alternative instrumentation that has been calibrated to provide traceable results
- 7.7.3. Functional checks of measuring and testing equipment
- 7.7.4. Use of working standards with control charts were applicable
- 7.7.5. Intermediate checks on measuring equipment
- 7.7.6. Replicate tests or calibration using the same or different methods.
- 7.7.7. Re-testing or recalibration of retained items
- 7.7.8. Statistical correlation of results
- 7.7.9. Review of reported results
- 7.7.10. Intra-lab comparisons
- 7.7.11. Testing of blind samples

The laboratories participate in proficiency testing programs which are planned over a three year period and reviewed annually. Data from monitoring PT activities is analysed and used to control and improve laboratory activities.

The laboratory will establish a procedure for out of specification and out of trends results investigation in drugs analysis laboratory.

### **7.8.Reporting of results**

#### **7.8.1. General**

All laboratory results are reviewed and authorised prior to release to the customer. Rwanda FDA laboratories report test results accurately, clearly, objectively and unambiguously according to method specifications. Test results are reported in the form of Certificates of Analysis. Laboratory results can be transmitted electronically or as hard copies. When simplified versions of the Certificate of Analysis are requested by the

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customer, common requirements for the test reports may be excluded as long as the information is readily available.

### 7.8.2. Common requirements for test reports

Standard report formats are used to report results in the respective laboratories. The laboratories are responsible and accountable for information provided in all reports, except when information is provided by the customer. The laboratories include disclaimers in reports on information supplied by customers that affect validity of results. In cases where the laboratories have not been responsible for the sampling stage, the report will indicate that the results apply to the sample as received.

### 7.8.3. Specific requirements for certificates of analysis

Rwanda FDA laboratories provide certificates of analysis with the following details where necessary; Information on specific test conditions, statement of conformity with requirements or specifications, measurement uncertainty presented in the same unit as that of the measurand or as a relative to the measurand, opinions and interpretations, and additional information that may be required by specific methods, authorities, customers or group of customers.

### 7.8.4. Reporting statements of conformity

Rwanda FDA Laboratories will apply decision rules to declare statements of conformity to product specifications based on Pharmacopeia, relevant international standards and manufacturers' methods. Measurement uncertainty will be allocated regarding accepting or rejecting a product according to its specification and the result of a measurement. The laboratories report statement of conformity based on specifications of methods used, relevant standards and the application of decision rules applied.

### 7.8.5. Reporting opinions and interpretations

The laboratories have authorised personnel for release of opinions and interpretation statements. The opinions and interpretations are based on scientific data, regulatory requirements and specifications used. The laboratories report opinions and interpretations based on results obtained from the tested items and apply strictly to the tested sample. They are reported on laboratory Certificates of Analyses. All dialogue pertaining to opinions and interpretations with customers is recorded and retained by the laboratories.

### 7.8.6. Amendment of reports

When an issued report needs to be changed, amended or reissued, the change is clearly identified and reason for change included in the report. Amendments to reports are issued as further documents, as a form of addendum to the original report. Where a new report is issued, it shall be uniquely identified but making reference to the original report it is replacing.

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### 7.9.Complaints

Rwanda FDA handles complaints from internal and external customers including those related to laboratory services in accordance with the organizational procedure for Customer Complaints which describes receipt, evaluation, investigation, verification and the decision-making process.

The complaints forms are made available to any interested party through the website and at the Rwanda FDA main reception. On receipt of a complaint, the Director-General evaluates, verifies and conforms whether the complaint relates to the laboratory. The laboratory through the designated Quality Management Systems officer is responsible for collating all decisions at all levels of the complaints handling process. The Division Manager and designated Quality Management Systems officer are responsible for review, verification and approval of complaints.

The laboratory process of handling complaints includes the process of receiving, validating, investigating the complaint and deciding what actions are to be taken in response. The designated Quality Management Systems Officer acknowledges receipt of the complaint and provides the complainant with progress and outcome reports. The laboratory through the designated Quality Management Systems officer tracks and records complaints, including actions undertaken to resolve them.

The designated Quality Management System Officer and Laboratory Officer are responsible for gathering and verifying all necessary information to validate the complaint. The Director General gives formal notice of the end of the complaint handling to the complainant by way of feedback letter.

### 7.10. Non-conforming work

Rwanda FDA Laboratories handle non-conforming work as per the approved procedure for Control of Nonconforming work and laboratory specific procedures. The Division Manager or designate shall be responsible for authorization of the resumption of work when non-conforming work is identified. An investigation will be carried out on the significance of the non-conforming work.

The actions to address non-conforming work incorporate the risk levels identified by the laboratory on non-conforming work. The laboratories evaluate the significance of each non-conforming work including an impact assessment on previous results.

The laboratories take decisions on acceptability of the non-conforming work including notifying the customer and recalling of the work where necessary. The laboratory retains records of non-conforming work and actions as specified in the procedure. If evaluation indicates non-confirmed work could recur, or that there is doubt on the robustness of the Quality Management System, the laboratories implement corrective and preventative actions plan (CAPA).

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### **7.11. Control of data and information management**

Rwanda FDA provides adequate resources to access data and information needed to perform laboratory activities. Officers gain access to data and information by being granted New User authorization that is authorised by the Division Manager of the respective laboratory.

Officers are given access to data and information in accordance to access levels defined by the Division Manager of the respective laboratory. Rwanda FDA provides computer equipment needed to allow for access to laboratory data. The Laboratories use validated computerized systems for all their operations.

The laboratory Information Management System(s):

- a) Is protected from unauthorised access: Rwanda FDA laboratories use finger print to prevent unauthorised entry into the laboratory. All Rwanda FDA laboratory computer equipment are secured using passwords and usernames that are defined as per ICT policy to prevent unauthorised access to laboratory information.
- b) Is safeguarded against tampering and loss: The Laboratories work from a network folder that has access rights only to its owner to avoid information tampering by other employees. They use a local network backup server that replicates to an offsite backup server. Back up of electronic data is conducted at regular interval.
- c) Is operated in an environment that complies with the provider or the laboratory specifications. Where non-computerised systems are in use the laboratory provides conditions which safeguard the accuracy of manual recording and transcription by monitoring environmental conditions i.e. temperature using monitoring devices. All ICT equipment is regularly maintained as per ICT maintenance schedule.

All system failures or errors are recorded using automated error logs. An immediate action is initiated through requests to the ICT department.

The document control procedure: QMS/SOP/001 is in place for making, documenting and controlling changes to information stored in computerized systems.

When Rwanda FDA laboratory information is managed and maintained off-site or through an external provider, a contract indicating the requirements of this policy manual shall be signed to ensure that the provider or operator of the system complies with all applicable requirements of the policy document.

The laboratories use a central repository network storage area for sharing of instructions, manuals and reference data. The shared repository has access rights defined according to the different access levels.

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Where appropriate, the laboratories will carry out validation exercises whenever data is transferred from one working folder to the other. Due diligence and care shall be exercised whenever raw data is transcribed from the system to the record sheet.



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### **8. MANAGEMENT SYSTEMS REQUIREMENTS**

#### **8.1 . Management system documentation (Option A)**

- 8.1.1. Quality Control Laboratory management has established, documented, and maintain policies and objectives for the fulfillment of the purposes of this document and ensures that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.
- 8.1.2. The policies and objectives address the competence, impartiality and consistent operation of the laboratory.
- 8.1.3. Quality Control Laboratory management provides evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.
- 8.1.4. All Quality Control Laboratory documentation, processes, systems, records, related to the fulfillment of the requirements of this document are included in, referenced from, or linked to the management system.
- 8.1.5. All Quality Control Laboratory personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

#### **8.2. Control of management system documents (Option A)**

- 8.2.1 The Quality Control Laboratory controls both internal and external documents that relate to the fulfillment of ISO/IEC17025:2017.
- 8.2.2 The Quality Manual, all System Procedures, SOPs and other Quality management systems documents are reviewed and approved before use.
- 8.2.3 Documents are periodically reviewed and authorised editions of appropriate documents are made available in electronic form on a testing server and all Quality Control Laboratory staff has access to them
- 8.2.4 Changes and the current revision status of documents are indicated.
- 8.2.5 Relevant versions of applicable documents are available at points of use and testing server and, where necessary, their distribution is controlled.
- 8.2.6 Quality Control Laboratory documents are uniquely identified
- 8.2.7 Invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use.

Details on Control of management system documents are captured in QMS/SOP/001

#### **8.3. Control of records (Option A)**

- 8.3.1. The Quality Control Laboratory establishes and retains legible records to demonstrate fulfillment of the requirements in ISO/IEC 17025:2017, clause 8.4.1

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- 8.3.2. The Quality Control Laboratory implements the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records is consistent with the confidentiality.

### 8.4. Actions to address risks and opportunities (Option A)

- 8.4.1. The Quality Control Laboratory considers the risks and opportunities associated with the laboratory activities in order to:

- give assurance that the management system achieves its intended results;
- enhance opportunities to achieve the purpose and objectives of the laboratory;
- prevent, or reduce, undesired impacts and potential failures in the laboratory activities;
- achieve improvement.

Quality Control Laboratory has a plan to address risks and opportunities identified, how to integrate and implement these actions into its management system and how to evaluate the effectiveness of these actions. Actions taken by Quality Control Laboratory to address risks and opportunities are proportional to the potential impact on the validity of laboratory results.

### 8.5. Improvement (Option A)

- 8.5.1. The Quality Control Laboratory continually improves the effectiveness of its management system through regular review of quality policy (*QCL/MAN/001 page 2*), quality objectives (*QCL/MAN/001 page3*), audit results, analysis of data, corrective actions, suggestion from personnel, risk assessment procedure, preventive actions procedure and management review procedure, and proficiency testing results.
- 8.5.2. The Quality Control Laboratory seeks feedback, both positive and negative, from its customers. The feedback is analyzed and used to improve the management system, laboratory activities and customer service.

### 8.6. Corrective actions (Option A)

- 8.6.1. When nonconformity occurs, Quality Control Laboratory reacts to the nonconformity, takes action to control and correct it and address the consequences.
- 8.6.2. The Quality Control Laboratory evaluates the cause (s) of identified nonconformity and determine and implement the appropriate action to eliminate the cause (s) in order that it does not reoccur or occur else where

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- 8.6.3. Quality Control Laboratory reviews the effectiveness of any corrective action taken and if necessary updates risks and opportunities determined during planning and make changes to the management system.
- 8.6.4. The Quality Control Laboratory retains records as evidence of the nature of the nonconformities, cause (s) any subsequent actions taken and the results of any corrective action.

### **8.7. Internal audit (option A )**

- 8.7.1. The Quality Control Laboratory conducts regular internal audits of its activities to verify that its operations continue to comply with its documented Laboratory management system, ISO/IEC17025:2017 and verify that the system is effectively implemented and maintained.
- 8.7.2. Quality Control Laboratory plans, establishes, implements and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits.
- 8.7.3. Quality Control Laboratory defines the audit criteria and scope for each audit and ensures that the results of the audits are reported to relevant management.
- 8.7.4. Quality Control Laboratory implements appropriate correction and corrective actions without undue delay and retains records as evidence of the implementation of the audit program and the audit results.

### **8.8. Management reviews (Option A)**

- 8.8.1. Quality Control Laboratory's senior management conducts a review of the Quality Control Laboratory management system at least once a year and testing activities to ensure their continuing policy and objectives suitability, adequacy, effectiveness, and to introduce necessary changes or improvements.
- 8.8.2. **The review takes account of:**
  - a) changes in internal and external issues that are relevant to the laboratory;
  - b) fulfillment of objectives;
  - c) suitability of policies and procedures;
  - d) status of actions from previous management reviews;
  - e) outcome of recent internal audits;
  - f) corrective actions;
  - g) assessments by external bodies;

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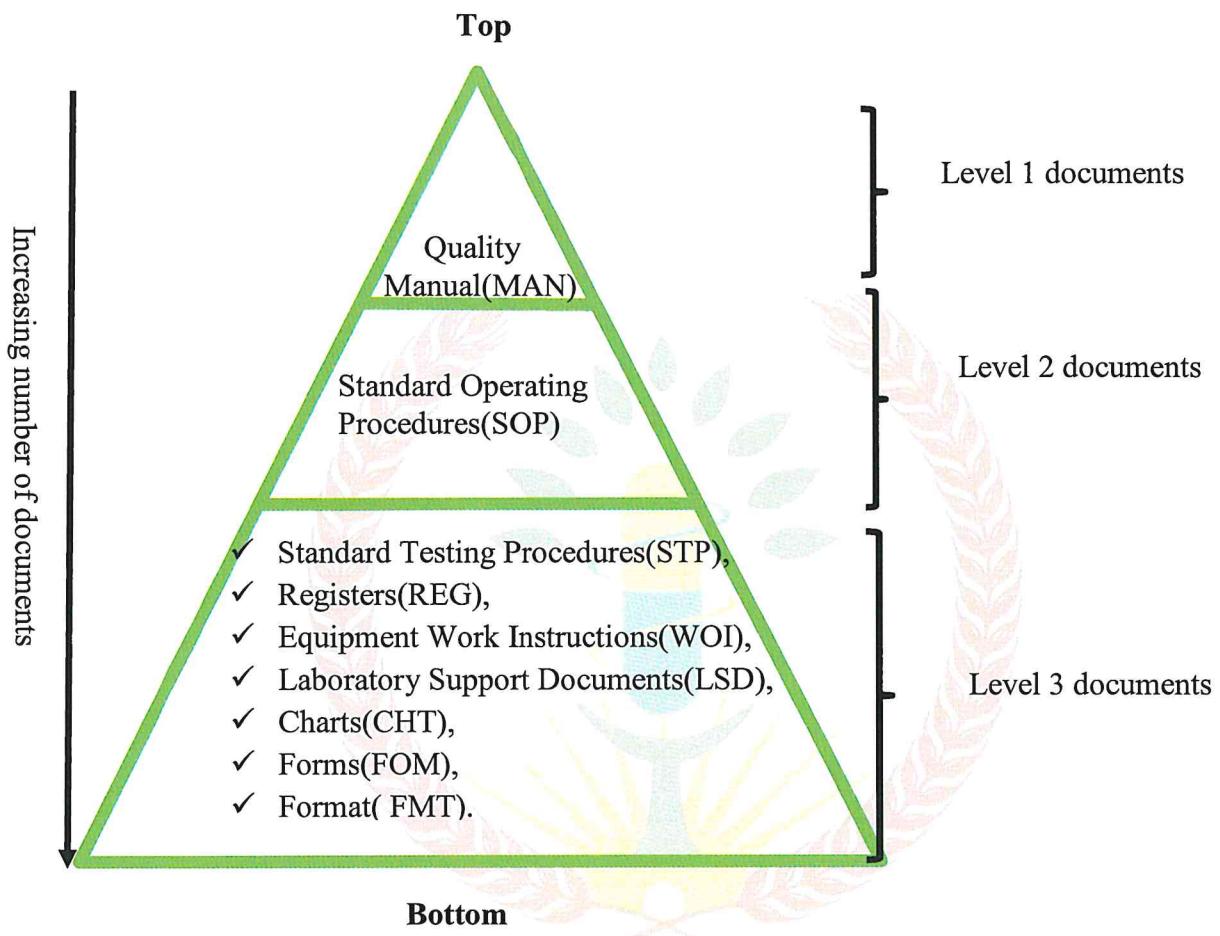
- h) changes in the volume and type of the work or in the range of laboratory activities;
  - i) customer and personnel feedback;
  - j) complaints;
  - k) effectiveness of any implemented improvements;
- 8.8.3. The Quality Control Laboratory management review committee is composed by Laboratory Division Manager, designated Quality Management Systems Officer and Laboratory Officers.
- 8.8.4. The Quality Control Laboratory records the output from the management reviews, decisions and actions related to at least:
- a) effectiveness of the management system and its processes;
  - b) improvement of the laboratory activities related to the fulfillment of the requirements of this document;
  - c) provision of required resources;
  - d) Any need for change.



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## 8.9. QMS Documentation Structure



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### **9. APPENDICES**

#### **9.1. Appendix I: List of Major Equipment of Quality Control Laboratory**

<b>SN</b>	<b>PRODUCT DESIGNATION</b>
1	High Performance Liquid Chromatography with DAD, Fluorescence and Refractive Index Detector.
2	High Performance Liquid Chromatography with DAD and Fluorescence Detector.
3	HPLC with DAD Detector
4	Inductively Coupled Plasma Mass Spectrometer(ICP/MS)
5	High Performance Thin Layer Chromatography-Complete system
6	Near Infra-Red Feed And Forage Analyzer
7	A Fully Automated System For Determinations Of Crude Fiber And Detergent Fiber
8	Gas Chromatography Flame Ionization Detector(GC/FID)
9	Dissolution machine
10	UV/VIS spectrophotometer
11	pH/Ion/Cond/DO meter
12	Gas Chromatography Mass Spectrometer, GCMS
13	Fourrier Transform Infra-Red spectrophotometer, FTIR
14	Atomic Absorption Spectrophotometer, AAS
15	Microwave Digestion System
16	CO <sub>2</sub> Incubator
17	Vacuum Incubator
18	Fourier Transform Infra-Red (FTIR) Milk Analyzer
19	Infra-Red Wine And Must Analyzer
20	Kjeldahl Analyzer
21	Automated 20 Position Kjeldahl Digestion System
22	Uv/Vis Spectrophotometer

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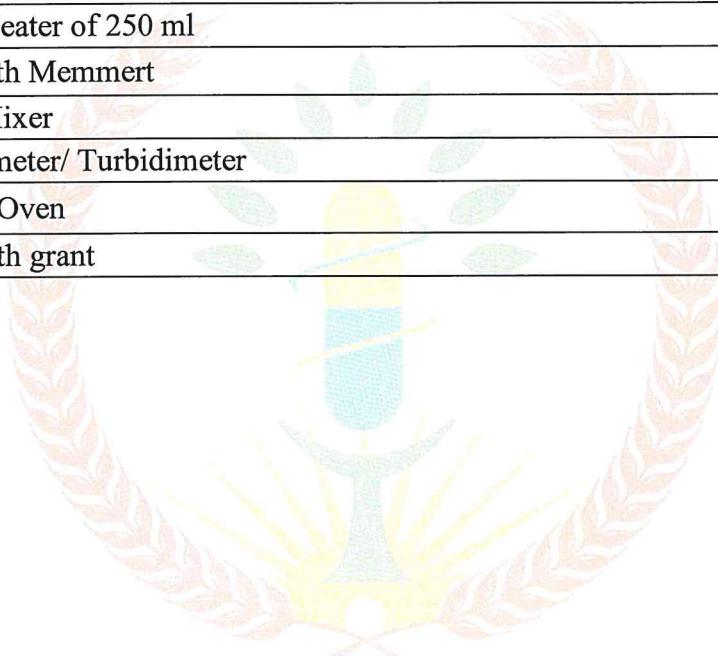
23	Karl Fischer automatic equipment
24	KBr disc presser
25	Hydrogen Generator
26	Analytical balances 4 digits
27	Analytical balances 5 digits
	Analytical balance 5100 g
	Mettler Toledo GmbH balance
28	Digital Polarimeter
29	Ultrasonic homogenizer
30	pH meter
31	Dry Oven machine big
32	Dry Oven machine small
33	Furnace
34	Rotary evaporator machine
35	IR moisture analyser
36	Viscometer
37	Melting point apparatus
38	Colony counter (manual)
39	Vertical laboratory Autoclave
40	Disintegration machine
41	Hardness tester
42	Friability tester
43	Digital and electronic microscopy binocular
44	Microscopy Trinocular
45	Centrifuge machine
46	Glassware washing machine
47	Quartz Water distiller
48	Water purification system
49	Digital Stirrer Hot plate
50	Magnetic stirrer
51	Disperser Homogenizers
52	Vacuum pumps

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53	Vacuum Manifold
54	Freezer
55	Refrigerator
56	Laminar Flow
57	Digital (Micro) Centrifuge
58	Incubator Shaker
59	Vacuum Incubator
60	Mantle Heater of 50 ml
61	Mantle Heater of 100 ml
62	Mantle Heater of 250 ml
63	Water bath Memmert
64	Voltex Mixer
65	Nephelometer/ Turbidimeter
66	Vacuum Oven
67	Water bath grant



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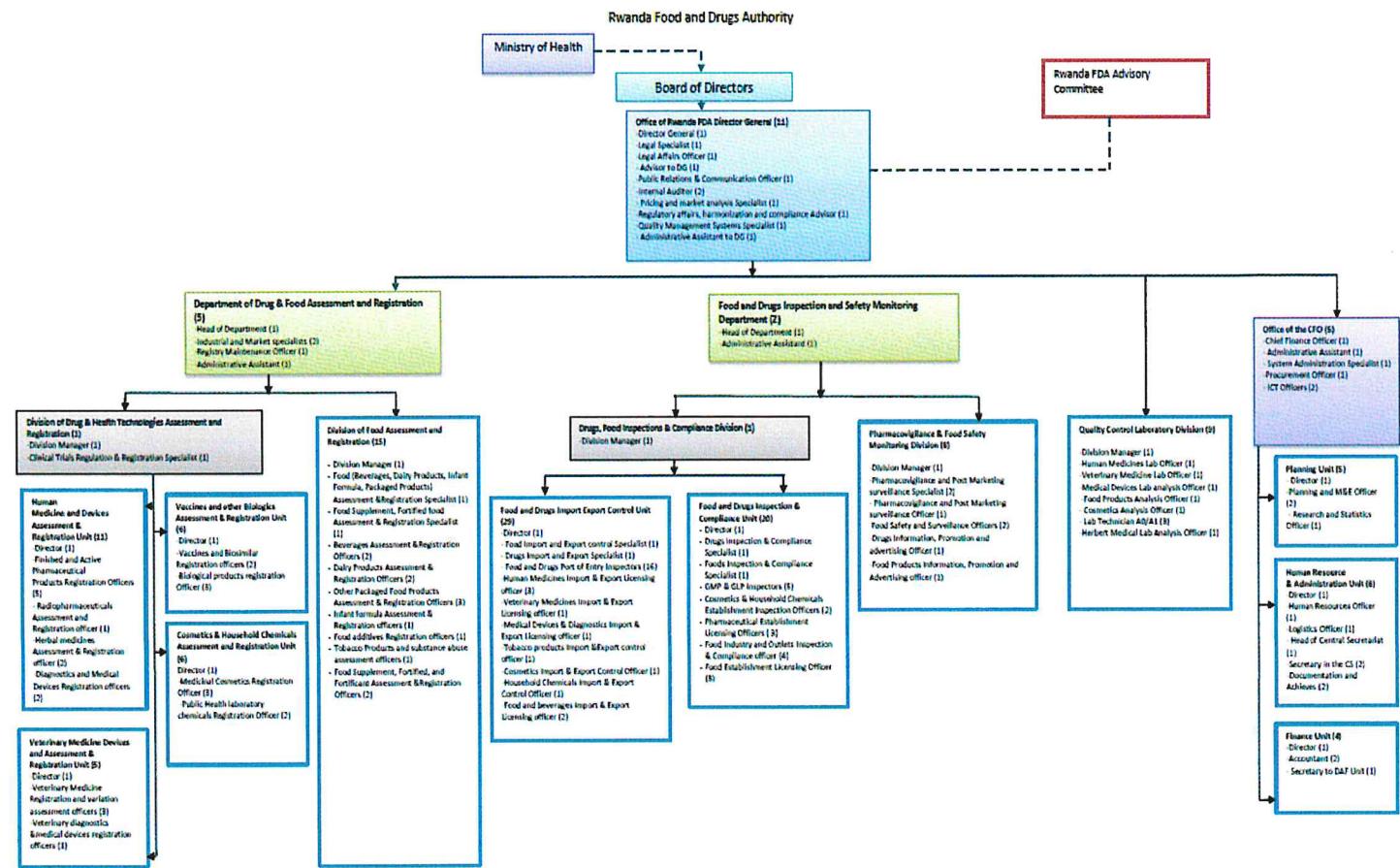
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## **9.2. Appendix II. Quality Control Laboratory position in Rwanda FDA Organisation Structure**



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### **9.3. Appendix III: Roles and responsibilities of personnel**

#### **9.3.1. Director-General**

The Director General shall;

- 9.3.1.1. Be the Chief Executive Officer,
- 9.3.1.2. Have the overall responsibility of all Rwanda FDA functions,
- 9.3.1.3. Approve all Level 1 documents,
- 9.3.1.4. Have authority to mobilize resources for the implementation of the QMS.

#### **9.3.2. Quality Control Laboratory Division Manager**

- 9.3.2.1. Monitor, evaluate and prepare the Division monthly, quarterly, annual work plan and reports
- 9.3.2.2. To coordinate laboratory analysis of regulated products ,
- 9.3.2.3. Verify the prepared division procurement plan and ensure its implementation
- 9.3.2.1. Coordinate/Monitor all subcontracted activities in the division,
- 9.3.2.2. Plan and chair division meetings and compile reports of the meeting and ensure implementation of resolutions taken,
- 9.3.2.3. Approve training specifications and submit training requests to the department in charge of capacity building,
- 9.3.2.4. Approve the internal and external Laboratory Quality Assurance
- 9.3.2.5. Approve and Authorize the QMS Level 2 documents,
- 9.3.2.6. Chairing division meeting including management review meetings,
- 9.3.2.7. Ensure that Regional and International activities related to the Division are implemented;
- 9.3.2.8. Develop and manage division annual budget,
- 9.3.2.9. Ensure all disinfectants, food products, tobacco, cosmetics, medical devices and diagnostics are correctly evaluated for quality, safety and efficacy
- 9.3.2.10. Managing division contracts including insurance contracts,
- 9.3.2.11. Act as a signatory to laboratories test certificates and reports,
- 9.3.2.12. Has authority to ensure proper use of available resources,
- 9.3.2.13. Supervises all technical laboratory management staff in the Division,
- 9.3.2.14. Ensures the generation of authentic, accurate and quality reports by laboratory staff,
- 9.3.2.15. Ensures the planning, logistics, smooth and efficient running of the laboratory,

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9.3.2.16. Liaises with customers.

### **9.3.3. Designated Quality Management Systems Officer**

- 9.3.3.1. Has quality oversight over the laboratories and has direct access to the highest level of management.
- 9.3.3.2. Ensures that the Quality Management System is implemented and followed at all times.
- 9.3.3.3. Prepares audit schedules and ensures that audits are conducted as per plan
- 9.3.3.4. Reports to management on the performance of the system.
- 9.3.3.5. Collects and prepares information/data for use by management for management review.
- 9.3.3.6. Is responsible for the document management system including reviews and approvals
- 9.3.3.7. Acts as a management representative on issues of Quality Management Systems.
- 9.3.3.8. Liaises with accreditation and relevant international bodies on Quality Management Systems assessments.
- 9.3.3.9. Ensures that all Rwanda FDA Quality Control Laboratory staff are effectively trained on Quality Management System.
- 9.3.3.10. Perform any other duties assigned by immediate supervisor.

### **9.3.4. Designated Laboratory Officer**

- 9.3.4.1. Ensure internal efficiencies on document reviews, formatting and implementation of Quality Management Systems (QMS),
- 9.3.4.2. Training of employees on reviewed policies, procedures and guidelines,
- 9.3.4.3. Reviews and checks level 3 QMS documents to ensure implementation and maintenance of the systems in the laboratory,
- 9.3.4.4. Conduct spot audits as well as scheduled internal audits,
- 9.3.4.5. Carry out follow-up activities on all audits to ensure full implementation of Corrective action,
- 9.3.4.6. Establish trends on QMS audits and customer complaints,
- 9.3.4.7. Ensure that all customer complaints are properly recorded, reported and addressed.
- 9.3.4.8. Assist in the operations of the Sample Repository Office by ensuring no delays in receipt of samples and release of test reports to customers.
- 9.3.4.9. Ensure the timely distribution and recall of all Rwanda FDA Quality Control Laboratory documents,
- 9.3.4.10. To be Secretariat to all QMS Review meetings,
- 9.3.4.11. Perform any other duties assigned by immediate supervisor.

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### **9.3.5. Laboratory Officer**

- 9.3.5.1. Carry out training of personnel,
- 9.3.5.2. Assists in planning the smooth and efficient running of the laboratory,
- 9.3.5.3. Assists in the technical management of the laboratory,
- 9.3.5.4. Carry out verification of calibration status of equipment to ensure that it operates according to specification,
- 9.3.5.5. Conducts method verification,
- 9.3.5.6. Receiving and ensuring proper storage of test samples, chemicals and reagents;
- 9.3.5.7. Prepare and standardize solutions, materials and reagents used in analysis;
- 9.3.5.8. Carrying out tests, interpreting results and estimating uncertainties of measurement,
- 9.3.5.9. Prepare and maintain a variety of records and reports;
- 9.3.5.10. Participating in the development of new test methods in liaison with the division manager.
- 9.3.5.11. Maintain inventory of laboratory equipment;
- 9.3.5.12. Maintain the assigned equipment using the manufacturer's instruction or the applicable work instruction;
- 9.3.5.13. Establish a maintenance plan and request for its implementation.
- 9.3.5.14. Documentation of laboratory Standard Operating Procedures (SOP's) and submit them for approval;
- 9.3.5.15. Participate in quality control programs and prepare statistical reports
- 9.3.5.16. Implementing and participating in review of the laboratory quality system,
- 9.3.5.17. Give recommendation on equipment, chemicals and reagents required for testing;
- 9.3.5.18. Preparation of proposal of technical specification of equipment spare parts and laboratory consumables for purchase;
- 9.3.5.19. Participation in evaluation of new equipment after commissioning and maintaining inventories of laboratory supplies,
- 9.3.5.20. Releases of test results,
- 9.3.5.21. Deputizes;
- 9.3.5.22. Perform any other duties assigned by immediate supervisor.

### **9.3.6. Medical Devices Testing Officer**

- 9.3.6.1. Receiving and ensuring proper storage of test samples, chemicals, materials and reagents;

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- 9.3.6.2. Prepare and standardize solutions, materials and reagents used in laboratory analyses;
- 9.3.6.3. Carrying out tests, interpreting results and calculating uncertainties of measurement especially in cases of marginal test results;
- 9.3.6.4. Prepare and maintain a variety of records and reports;
- 9.3.6.5. Participating in the development of new test methods in liaison with other lab officer,
- 9.3.6.6. Maintain inventory of laboratories equipment;
- 9.3.6.7. Maintain the assigned equipment using the manufacturer's instruction or the applicable work instruction;
- 9.3.6.8. Establish a maintenance plan and request for its implementation;
- 9.3.6.9. Participate in quality control programs and prepare statistical reports;
- 9.3.6.10. Implementing and participating in review of the laboratory quality system;
- 9.3.6.11. Preparation of proposal of technical specification of equipment spares parts and laboratory consumables for purchase;
- 9.3.6.12. Participation in evaluation of new equipment after commissioning;
- 9.3.6.13. Maintaining inventories of laboratory supplies;
- 9.3.6.14. Perform any other duties assigned by immediate supervisor.

### **9.3.7. Laboratory Technician**

- 9.3.7.1. Organizing, indexing, control and storing of all chemicals and consumable items under appropriate storage conditions;
- 9.3.7.2. Conducts safety inspections of chemical stores, fire control, hazardous chemicals, and first aid supplies;
- 9.3.7.3. Monitoring the quality, quantity, cost and efficiency of the movement and storage of goods;
- 9.3.7.4. Organization of Quality Control Laboratory chemical store;
- 9.3.7.5. Receiving and Indexing of all items received in chemical store;
- 9.3.7.6. Registering (assigning numbers) to submitted samples in the sample Test Request Form;
- 9.3.7.7. Timely forwarding the submitted samples to the laboratories;
- 9.3.7.8. Maintaining and keeping up to date sample register,
- 9.3.7.9. Maintaining a register of certificates of analysis released,
- 9.3.7.10. Receiving tested samples and keeping them in the appropriate conditions until they are disposed;
- 9.3.7.11. Supervise the samples disposal process and ensure appropriate method is used,
- 9.3.7.12. Monitoring and recording the performance of the autoclave used for decontamination;
- 9.3.7.13. Cleaning of glassware and laboratory coats including decontamination of microbiology laboratory ware and wastes
- 9.3.7.14. Identifying and requisitioning of laboratory cleaning consumables,

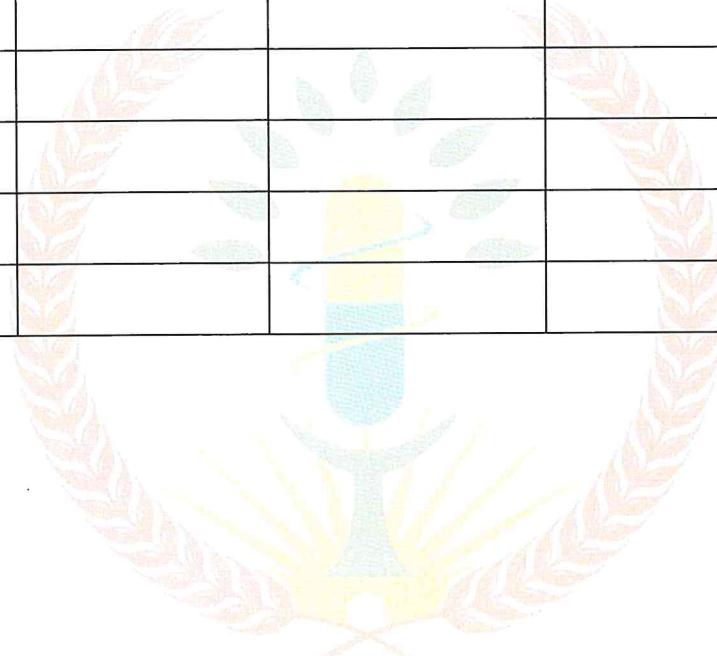
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9.3.7.15. Ensures correct disposal of samples.

**9.4. Appendix IV: Document Revision History**

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
10 March 2020	0	A. Mukunzi	First Issue



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**10. References:**

- 10.1.ISO/IEC 17000: Conformity Assessment-Vocabulary and General Principles,
- 10.2.ISO/IEC Guide 99: International Vocabulary of Metrology-Basic and general concepts and associated terms (VIM),
- 10.3.ISO/IEC 17025:2017: General requirements for the Competence of Testing and Calibration laboratories,
- 10.4.ISO 9001:2015 Quality Management Systems – Requirements,
- 10.5.WHO Good Practices for Pharmaceutical Quality Control Laboratories WHO Technical Report Series, No. 957, 2010,
- 10.6.Rwanda FDA Quality Manual,
- 10.7.British Pharmacopoeia 2018,
- 10.1.United States Pharmacopoeia National Formulary USP41 NF 36,
- 10.2.International Pharmacopoeia 2019,
- 10.3.Health and Safety Manual,
- 10.4.Standard Operating Procedure for Document Control of Rwanda FDA, QMS/SOP/001,
- 10.5.Standard Operating Procedure for document control, QCL/SOP/001.

*Note: Signed Quality Policy kept on file*

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End of Document

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