



RWANDA FOOD AND DRUGS AUTHORITY OPERATIONS MANUAL

RWANDA FDA Rwanda Food and Drugs Authority

MAY, 2021

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ADOPTION AND APPROVAL

In EXERCISE of the powers conferred upon the Board of Directors of Rwanda Food and Drugs Authority by Article N° 15 of the Law N° 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning, the Board of Directors adopted and approved the Rwanda Food and Drugs Authority Operational Manual during the meeting held on 11th May 2021.



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Responsibility for the implementation

- The Board of Directors is responsible for approving this manual and reserves the right to interpret it.
- The Director General is responsible for overseeing the application of this manual to all employees and for approving of changes to this manual whenever justified.
- The heads departments shall be responsible for the effective and consistent implementation of this manual.
- All employees of Rwanda FDA are responsible for reading and understanding this manual in order to know their responsibilities, accountabilities, rights and limits.
- The in Charge of Quality Management Systems on Rwanda FDA Structure shall be responsible for coordinating the updating this Manual in accordance with authorization by Rwanda FDA.

Distribution

- Controlled hard copies shall be distributed to members of the Authority, the DG, Head of departments and divisions.
- Controlled electronic copies shall be distributed to all employees at the Head Office on Rwanda FDA server.
- Controlled hard copies shall be distributed to all employees that do not have access to the shared folders mentioned above.



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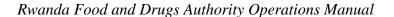
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ABBREVIATIONS AND ACRONYMS

CCTV Closed-Circuit Television

ICT Information Communication and Technology

MIS Management Information System

PC Personal Computer

Rwanda FDA Rwanda Food and Drugs Authority
SOP Standard Operating Procedures
QMS Quality Management Systems

VIP Very Important Person



Rwanda Food and Drugs Authority

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1. INTRODUCTION

Rwanda Food and Drugs Authority (Rwanda FDA), was established by the law N° 003/2018 of 09/02/2018 determining its mission, organization and functioning. Rwanda FDA is a regulatory body under the Ministry of Health, responsible for ensuring quality, safety and effectiveness through regulation of human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, tobacco and tobacco products.

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

The Key documents used are:

- 1. Law N° 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and determining its mission, organisation and functioning
- 2. Rwanda FDA Organizational Structure,
- 3. Law No 17/2020 of 07/10/2020 establishing the general statute governing public servants.
- 4. Presidential Order N° 099/01 of 18/09/2019 establishing special statutes governing employees of Rwanda Food and Drugs Authority.

1.1. Vision of Rwanda FDA

A world class regulatory Authority effectively protecting and promoting public health.

1.2. Mission of Rwanda FDA

To regulate medical products, processed foods, household chemicals, and tobacco and tobacco products to ensure their quality and safety so as to protect the population of Rwanda from defective, falsified and substandard products.

1.3. Core Values of Rwanda FDA

The conduct and performance of the Authority is underpinned by the following five core values:

- serving with **Professionalism** for excellent service delivery
- continuously working with **Integrity**
- promoting **Accountability** at all times
- nurturing **Teamwork** to achieve common objectives
- striving for **Innovation** to create value for our stakeholder and other interested parties

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1.4. Objective of the Manual

- To document policies and procedures for all employees in order to guide timely, consistent, equitable and transparent decision making.
- To define the rights and obligations of Rwanda FDA (the employer) and its employees in order to create a harmonious working environment to enhance organizational performance.
- To prevent legal challenges and employee grievances

1.5. Scope of the Manual

This manual applies to all Rwanda FDA employees and its work environment. Rwanda FDA derives its mandate from Law N° 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning; article 12; article 14; article 28(7) and article 34.

Operations of technical departments shall be described in their technical regulations, Guidelines and Standard Operating Procedures.

The operations manual covers the policies and processes for Administration, Communication, Management information Systems and Transport that are to be institutionalized at Rwanda FDA. It spells out the responsibilities of all staff that will ensure compliance and ultimately the smooth operations of Rwanda FDA. Office of the Director General, Office of the Deputy Director General, Office of the Chief Finance, Departments, Divisions, and units are expected to implement the policies and processes set out in this manual in addition to all other manuals approved for use in Rwanda FDA.

1.6.Governing Structure

The Board of Directors of Rwanda FDA is the supreme organ. The Director General is the administrative and technical head of the Authority. He is supported by (a) Deputy Director General(s), Heads of Departments, Chief Finance Officer, Divisions managers, Quality Assurance Analyst, Legal Analyst and Directors who form the Senior Management team of the Authority. However, other Analysts, specialists or any other staff member might be invited to the management meetings by the Director General when a need arises. The organizational interrelationships are defined in the organizational structure.

1.7. Organizational and Operational Structure

The organizational structure is attached as Annex 1. Rwanda FDA has the following Operational structures:

- Office of the Director General;
- Office of the Deputy Director General

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- Department of Drug & Food Assessment and Registration
 - o Division of Human Medicine and Devices Assessment & Registration
 - o Division of Cosmetics & Household Chemicals Assessment and Registration
 - o Division of Veterinary Medicine Devices and Assessment & Registration
 - Division of Food Assessment and Registration
- Department of Food, Drugs Inspection and Safety Monitoring
 - Division of Drugs, Food Inspections & Compliance
 - o Division of Pharmacovigilance & Food Safety Monitoring
 - Food and Drugs Import & Export Control Division
- Office of the Chief Finance Officer
 - o Planning Unit
 - Finance Unit
 - o Humana Resource and Administration Unit
- Quality Control Laboratory Division
 - Food Testing Unit
 - Medicines and Cosmetics Testing Unit
 - Medical Devices & Instrumentation Testing Unit
 - o Pesticides & Poisonous Substances and Chemical Unit

2. ADMINISTRATIVE POLICY AND PROCEDURE

2.1. Introduction

This part of the document shall be used as a guide in carrying out all administrative functions relating to the operations of Rwanda FDA. It is meant to ensure efficiency, consistency and responsibility in the execution of all administrative functions of Rwanda FDA.

2.2. Application

The manual shall be applicable to all Rwanda FDA permanent staff, contract staff and interns. Copies shall be made available to all staff for their adoption and will be used as part of their orientation for new staff.

This manual is mandatory for all staff. An employee shall undertake to agree to abide by the terms and conditions therein stated including such amendments as may be made periodically.

2.3. Operational Hours

Rwanda FDA's offices are opened for business on weekdays; Monday to Friday from 7:00 am to 5:00 pm.

One (1) hour break from 12:00 pm - 1:00 pm is allowed for staff.

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However, due to specific work requirements, the departments/divisions that would have difficulty to follow that timetable shall follow a different time table as proposed and approved by the Director General.

2.4. Archive Management

Rwanda FDA shall maintain an organized records system in a manner that will ensure easy accessibility, retrieval, security, accountability and confidentiality for effective and efficient operations as stated in Manual and in accordance with the SOP for Records control (No. QMS/SOP/034)

2.5. Records Management

2.5.1. Mails/Correspondences

Rwanda FDA's central secretariat shall be responsible for the receipt and dispatch of incoming and outgoing general correspondences.

Correspondences from Rwanda FDA shall be handled carefully to ensure that information is received and relayed promptly, reliably, securely and responsibly.

2.5.2. Outgoing Correspondences

To ensure that information is received and relayed promptly, reliably, securely, and responsibly:

- All letters leaving Rwanda FDA shall be signed by the Director General or as per the official delegation of Power.
- Copies of outgoing letters shall be filed and kept at central secretariat.
- All outgoing letters shall have reference numbers and shall be on letterheads bearing the Rwanda FDA's Logo. Outgoing letters shall be filed according to reference numbers and subjects where appropriate.
- Mode of delivery shall either be by hand (use of office Drivers/Dispatch Riders), normal postage or other courier services depending on the urgency, size or volume of item or correspondence.
- The content of outgoing correspondences should be checked properly by the responsible officer(s) to ensure that the items listed as attached/content is accurate and that a letter is duly signed.
- A dispatch book to record name of recipient, signature and date shall be given to the dispatch rider/officer to ensure that outgoing correspondences are delivered properly, at the right time and to the right recipient.
- Confidential documents, Records and materials and samples will be kept in a secure and

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controlled access area.

2.5.3. Incoming Mails/Correspondences

- Incoming mails, except that marked 'confidential' or bearing personal name shall be opened at the central secretariat, will be registered in the incoming mails book and delivered at the Director General's Office or to appropriate office. Personal or private mails shall be delivered unopened to the addressee.
- Dispatching of incoming mails will be in accordance with the delegation of authority by the Director General.
- Incoming letters shall be recorded at the central secretariat according to date and time of receipt, source and mode of delivery to the central secretariat. Addressees or receiving officers shall sign when receiving letters from the central secretariat.
- Letters received at the Director General and heads of department offices shall be brought to their immediate attention.
- Letters received at the Director General's office shall also be recorded according to date and time of receipt, subject of letter, source of letter, signing officer of letter and reference number of letter if any. Content of incoming mails shall be checked to ensure that all stated accompanying documents of attachments, if any, are included.
- Where applicable, original or photocopies of letters minuted by the Director General and heads of departments shall be brought to the attention of officers to whom they have been minuted within a maximum period of thirty minutes or earlier in the case of emergency.
- Where applicable, original or photocopies of letters shall subsequently be filed according to date of receipt and numbered accordingly in a folder according to volume or subject.
- The Administrative assistant shall have oversight responsibility of the mails book to ensure that mails are delivered promptly and to the intended recipients within the set timelines.

2.5.4. Electronic mails (E-mails)

- Soft copies of official electronic mails (E-mails) may be received at the central secretariat and forwarded to Director General for the necessary action to be taken. Details for handling electronic mails shall follow SOP on incoming of in/outgoing correspondences.

3. INTERNAL COMMUNICATION

Rwanda FDA shall keep staff informed on all matters affecting staff and its operations through written and verbal communication.

Rwanda FDA shall promote and support a culture where its employees can openly and respectively share their innovative ideas to contribute to the organizational development and performance.

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3.1. Mode of Communication

- Rwanda FDA shall use both the top-down and bottom-up modes of communication where Senior Management communicates decisions and directives to staff and staff also communicates suggestions, feedback and concerns to Senior Management.
- Mode of communication shall be through internal memos staff meetings, instant messaging system where appropriate.
- Communications shall be either written or verbal depending on the issue.
- Staffs are encouraged to read information posted on the Notice Boards.

3.2. Channel of Communication

- Staff shall communicate official matters to the Director General/ Deputy Director General(s) or his/her representative through their immediate supervisors on a Memo except when urgent, necessary and important.
- Staff may request through the Director General's admin assistant or advisor, to communicate directly to the Director General on personal matters.
- The Director General may demand to see or speak to any staff directly without prior notice.
- Rwanda FDA shall not entertain use of communication channel that does not promote the above. Use of anonymous letters and rumor mongering is a breach of the staff code of conduct.

3.3. Confidentiality

- Strict adherence to Rwanda FDA's rules on confidentiality of information shall be observed by all employees.
- Employees shall not speak of, give or display information on Rwanda FDA's operations to any person(s), the media/public without authorization by the Director General.
- Information meant for the public shall be conveyed to the public by Rwanda FDA's Public Relations Officer with prior consent of the Director General or his/her accredited representative.

3.4. Meetings

Rwanda FDA shall organize meetings regularly to communicate matters relating to the operations of the Authority to staff and stakeholders.

3.4.1. Board of Director Meetings

- Regular Board of Director's meetings shall be held once in every three months except in extraordinary sessions.

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- Meetings of committees and sub-committees of the Board shall be held once in every three months or when the need arises.
- The Board Chairman shall chair all Board of Directors meetings or in his/her absence, the Vice Chairman or in the absence of both of them, a member nominated from among members present at the meeting.
- The Director General shall coordinate and communicate notice and agenda for meetings to the Board of Directors to members in consultation with the Chairman and shall record proceedings of meetings.
- Notices of meetings shall be given at least fifteen (15) working days before the date of the meeting (meeting date exclusive) except in extraordinary sessions.
- Board of Directors meetings shall be held at Rwanda FDA's Board Room or any other venue agreed upon by the Chairman and the Director General.
- Seven (7) Members of the Board of Directors shall form a quorum for a meeting as spelt out in Board of Directors Manual.

3.4.2. Senior Management Team Meetings (Senior Managers)

- Senior Management meetings shall be held once two weeks and when deemed necessary.
- Notice and agenda for Senior Management team meetings shall be communicated through emails.
- Notices for Senior Management team meetings shall be given at least three days before the date for the meeting (meeting date exclusive) except in emergency situations.
- Members of Senior Management team and absent shall be recorded on the attendance form which shall be signed by members present.
- Written notices for Senior Management team meetings shall include agenda and records of previous meeting and any other information that may be the subject for discussion.
- Senior Management team meetings shall be chaired by the Director General or Deputy Director General in his/her absence.
- Two-thirds of Senior Management team members shall form a quorum for a meeting to be held by the Senior Management team meetings.
- Senior Management team meetings shall be held at Rwanda FDA's board room.
- Details of discussions during Senior Management team meetings shall be recorded by the Advisor to the DG or in his/ her absence, a senior officer appointed by the Director General.

3.4.3. Executive committee meeting

- Executive Committee meetings shall be held once a week.
- Notice and agenda for executive committee meetings shall be communicated through emails.
- Notices for executive committee meetings shall be given at one day before the date for

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- the meeting (meeting date exclusive) except in emergency situations.
- Members of executive committee team and absent shall be recorded on the attendance form which shall be signed by members present.
- Written notices for executive committee team shall include agenda and records of previous meeting and any other information that may be the subject for discussion.
- Executive committee meetings shall be chaired by the Director General or Deputy Director General in his/her absence.
- Executive committee meetings shall be held at Rwanda FDA's board room.
- Details of discussions during Executive committee meetings shall be recorded by the Advisor to the DG or in his/ her absence, a senior officer appointed by the Director General.

3.4.4. General Staff Meeting

- General staff meetings shall be organized twice a year and in accordance with Rwanda FDA's Annual Programme of Work, except in cases of emergency.
- Notice and agenda for staff meeting shall be communicated to staff through emails and or instant messaging system where appropriate by the Human Resource and Administration Unit.
- Notices to staff for General Meetings shall be given to staff at least five working days before the date for the meeting (meeting date exclusive) except in emergency situations.
- Notices for staff General Meetings shall include Agenda and records of previous general staff meeting.
- General staff meetings shall be held in Rwanda FDA's Conference room or any other appropriate venue within or outside Rwanda FDA premises where appropriate.
- General staff meetings shall be chaired by the Director General/ Deputy Director General or his/her representative in his/her absence.
- Names and position of all staff present at the meeting shall be recorded with their signatures in the attendance form.
- Details of discussions during staff meeting shall be recorded by HR officer.

3.4.5. Other Meetings

- Other technical meetings such as departments (bi weekly) divisions and operational unit (weekly) and when necessary.
- Such meetings shall be held at any of Rwanda FDA's Conference Rooms or any available and convenient room and shall be coordinated by the head of departments, divisions or units.
- Prior notices of meetings such as mentioned above shall be given and Senior Management informed.
- Details of discussions during staff meetings shall be recorded by the staff designated by the chair of the meeting.

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- Meeting for which Rwanda FDA is invited: Any delegated staff in a meeting to represent Rwanda FDA shall provide a report in the appropriate format in no more than 48 hours after end of the meeting.

4. EXTERNAL COMMUNICATION

4.1. Introduction

- This Communication chapter is designed to ensure that Rwanda FDA makes most of its Public Relations activities, protect and boost its reputation and support Rwanda FDA in the fulfillment of its mission.
- As a regulatory body, Rwanda FDA seeks to foster strong and professional relationships with its internal and external publics. Rwanda FDA is committed to ensuring that appropriate policies, procedures and monitoring arrangements are in place to support good internal and external communications.
- Rwanda FDA has an obligation to ensure that all information materials are disclosed to the public in an appropriate manner.
- Effective communication will help staff and other stakeholders to understand Rwanda FDA's mission, vision, core values, and objectives.

4.2. The Objectives and Scope of communication:

The Communication objectives are to:

- Raise local, national and international awareness of how Rwanda FDA communications should be handled internally and externally;
- Enable the public gain confidence in Rwanda FDA;
- Guide and support where necessary Rwanda FDA staff and Senior Management when they come into contact with the media (which includes television, radio, print and online media).

It covers areas including the use of Rwanda FDA facilities and grounds for filming and interviews with staff and Senior Management.

4.3. Communication Team

The Communication Team is made up of the following members:

- The Director General;
- Deputy Director General(s);
- Communication specialist
- Public Relations and communication officer;
- Any staff assigned by the Director General

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4.4. Duties of the Communication Team

In addition to being responsible for providing communications support, the Communication Team is responsible for:

- Ensuring that internal and external publics are fully informed about all relevant activities to enable them track and support the strategic direction of Rwanda FDA;
- Issuing timely responses to the media upon request;
- Supervising and monitoring reporters, photographers and camera crews when on Rwanda FDA premises;
- Providing advice and support to any staff responding to a media enquiry or wish to initiate a story themselves (a good news story) and may need help with a press release, for instance;
- Keeping a log of all media enquiries, responses and subsequent media coverage and preparing a daily media report for the attention of Senior Management;
- Keeping copies of all original press cuttings where Rwanda FDA's name or one of its staffs is mentioned in the report;

NB: All media enquiries should be referred to Rwanda FDA Communications specialist or Public Relation Officer so that the enquiry can be logged and dealt with appropriately.

4.5. Request for Information

All contacts from the media for information should be referred immediately to the Communication Specialist and/or Public Relations Officer or authorized person(s) appointed by the Director General. In line with Data Protection Legislation, clients' information is kept according to the confidentiality policy and will be shared on time by the authorized person.

4.6. Communication Engagement

- Communication Specialist and the Public Relations officer shall be responsible for generating all contacts with the media. This will ensure a consistent and accurate approach in dealing with issues pertaining to Rwanda FDA.
- The communication Specialist and Public Relations officer will be responsible for developing news releases, in consultation with the Director General or a designated officer(s). All press releases must be approved by the Director General, or a designated officer before issue.
- The communication Specialist and Public Relations officer will prepare staff for media interviews, including provision of briefing materials and interview technique training as the need arises.
- The Communication specialist and Public Relations officer will keep a record of all media coverage to assist in audit and evaluation processes.

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4.7. Handling the Communication

- The Public Relations and communication officer is the first point of contact for all communication enquiries, including both proactive (planned) and reactive (unplanned) enquiries;
- Should communication persons approach Rwanda FDA staff directly on any issue that relates to Rwanda FDA, or ask for an opinion or comment, they should be referred to the communication Specialist or Public Relations and officer;
- Staff should refrain from making public statements of personal opinion regarding Rwanda FDA and from presenting a personal opinion regarding Rwanda FDA as a fact;
- As part of Rwanda FDA's standard incident reporting routines, staff shall inform the Public Relations and communication officer if they know of an incident or event that has happened which may result in negative publicity and therefore affect Rwanda FDA's reputation. This will enable the Public Relations and communications officer to have more time to look into the facts and prepare a suitable response in case any media enquiries are received;
- The Public Relations and communication officer will endeavor to keep staff informed about key communication coverage that affects Rwanda FDA and also ensure stakeholders are fully briefed about any media enquiries/activities that could have an impact on them (or their members) directly or affect the reputation of Rwanda FDA.

4.8. Signing off Media Statements

Media statements will be prepared by the communication specialist and /or Public Relations officer and signed off by the Director General.

4.9. Very Important Person (VIP) Visits to Rwanda FDA

The Public Relations officer will be responsible for managing all VIP visits to Rwanda FDA in consultation with the Director General.

4.10. Media Filming and Photography Requests

- All requests for interviews, filming and photography should be forwarded to the Public Relations and communication officer so that a member of the team can give approval for this to go ahead and give out any necessary advice to staff taking part.
- Staff should exercise caution if approached for an interview/comment while on duty in the event of reporters posing as others (undercover reporter) who are looking for a story. All requests for comments/interviews should be referred to the communication Specialist and/or Public Relations officer who can offer the relevant advice.
- Media representatives usually have identification (for example ID card). However, they

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should never be unaccompanied when on Rwanda FDA premises. If any media representatives or film crews are seen on site and are unaccompanied, Staff is required to inform the Public Relations Officer and/or communication specialist.

 On the requests from Local Media for comment from Rwanda FDA on National Issues, local media may contact Rwanda FDA and ask for a comment or response to issues raised by National Media. The Public Relations officer and/or communication specialist will decide whether it is in Rwanda FDA's best interest to make a public comment on a national issue.

4.11. Information to the General Public

Rwanda FDA shall as and when it deems fit use the print and electronic media to disseminate information on its operations to internal and external publics.

The use of the mass media could be in the form of:

- Press Releases
- Press Conferences
- Press Soiree
- Interview sessions
- Feature Articles
- Advert placement
- Posts on social media accounts of the Authority
- Circulars

4.12. Communication Channels (Internal)

Various channels of communication shall be used in the dissemination of information to ensure effective feedback.

These include but not limited to:

- Inter Office Memorandum
- Memos shall be used to disseminate vital and urgent information to all staff
- Social Media
- Use of official emails

There shall be social media platforms in addition to other communication channels where Staff will receive information. Staff shall adhere to the principles attached to the use of the social media platforms.

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4.13. Communication Channels (External)

4.13.1. Official Letters

Rwanda FDA shall communicate with stakeholders and clients through official letters as a first option. Where Senior Management deems necessary, other means of communication would be added to ensure effectiveness.

4.13.2. Brochure

Rwanda FDA shall produce a brochure that summarizes its mandate, mission, vision, functions and services for the information of external publics.

4.13.3. E-Newsletter

An electronic newsletter that captures the activities of Rwanda FDA shall be hosted on the website for the information of external publics.

4.13.4. Publication

Rwanda FDA shall publish in scientific journals, articles related to the Authority Mandate. The Authority can also issue periodic safety bulletin as one means of communication of aggregated regulatory actions taken within a given period.

4.13.5. Flyers

Rwanda FDA shall produce flyers and leaflets containing information for distribution to external publics as and when it becomes necessary.

4.13.6. Suggestion Box

Suggestion boxes shall be provided at all offices of Rwanda FDA to enable external publics who wish to make suggestions to do so.

4.14. Website and Social Media

- Rwanda FDA shall have an official website which shall contain news items, events and links to useful information for internal and external publics.
- Postings on Rwanda FDA's official social media forums by Staff are restricted to authorized persons. The content of such postings must adhere to guidelines set from time-to-time by the Public Relations officer and communication specialist.
- All Electronic Communication Media platforms including Rwanda FDA's Website and

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social media accounts must comply with security regulations. Proper precautions should be taken when using electronic communications to discuss confidential materials and information.

4.15. Management of Call Centre

Rwanda FDA shall have a Call Centre and its management shall be under the close supervision of the Communication Specialist and Public Relations officer. The Call Centre shall operate from 7:00am – 5:00pm hour response service to clients and the general public. The Call Centre will provide timely and adequate response(s) to client(s).

5. EQUIPMENT FOR THE STAFF

- Rwanda FDA shall provide to its staff the necessary equipment permitting him/her to carry out her or his duties.
- All staff of Rwanda FDA shall be accountable for the equipment received. A Staff member shall be accountable for all resources under his/her competence.

5.1. Loss of office property

- Where office equipment gets missing or destroyed during the course of official duty, it should be reported immediately to the immediate supervisor or Unit Head who shall in turn inform the Logistics Officer.
- The logistics officer shall notify the Director for Human Resource and Administration.
- Where a theft is suspected to have resulted in the loss of office equipment, an incident report shall be submitted to the Security Company for action and the police for further investigations.
- A Staff who takes office equipment outside the office without permission and in whose custody the equipment got missing/destroyed shall be made to refund the value of the equipment at the time of loss or destruction or replace it with the same specifications and in the same condition as the missing/destroyed one.

5.2. Repair and Maintenance of Office Equipment

- Staff shall report faulty equipment to his/her immediate supervisor who shall in turn inform the HR and Administration Unit.
- Maintenance/repair form shall be completed and submitted to the logistics officer who shall coordinate with service provider to have the equipment repaired or serviced.
- No staff except a designated officer in charge of repairs of equipment shall repair or attempt to repair any equipment belonging to Rwanda FDA.

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6. USE OF OFFICIAL VEHICLES

Usage of Rwanda FDA vehicles shall be in accordance to Rwanda FDA's Fleet management SOP.

7. WORK ENVIRONMENT

The health, safety and welfare of staff while on the premises of Rwanda FDA are the responsibility of Rwanda FDA. The Authority shall therefore provide adequate security to protect employees and property. Staffs are however, encouraged to be security conscious whilst at work and report the presence of any questionable/suspicious personalities within Rwanda FDA's premises to immediate supervisor Senior Management or the Security company officer.

8. SAFETY AND SECURITY

- The premises of Rwanda FDA shall be under 24-hour Closed-Circuit Television (CCTV) surveillance;
- Security personnel shall be at post day and night (24/7) to secure the premises and safety of employees during weekdays and weekends;
- Staffs are responsible for the safety of all equipment, documents and other items at their disposal during office hours;
- Fire extinguishers shall be placed at vantage points on the office premises for use in cases of fire emergencies;
- Staff whose nature of work requires personal protective equipment or clothing shall be provided with protective tools/clothing;
- Staff shall ensure that all electrical equipment and gadgets are switched off at the close of work except specific equipment;
- Computers and servers that ought to be left on shall be regularly monitored by the IT Office:
- A first aid box shall also be kept in the custody of Human Resource and Administration office to assist staff who may experience minor illness or injuries during working hours.

9. CLEANLINESS

- Cleaning of Rwanda FDA offices and its environs shall be outsourced to Cleaning Agents or Companies. Staff are however, expected to keep their immediate environment or office space clean and tidy;
- There shall be no smoking or drinking of alcohol at Rwanda FDA premises during working hours.

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10. RECEIVING VISITORS & CLIENTS

- All visitors and clients shall first report at the reception;
- The receptionist shall attend to visitors/clients, note their particulars such as name, address and telephone number and direct them appropriately;
- Visitors/clients who shall be directed to the offices shall be issued with numbered visitors tags by the receptionist and shall be required to wear the tags during the period of stay at Rwanda FDA;
- Staff shall, as much as possible keep at minimal the number of personal visitors they receive during working hours.

11. DRESS CODE

Rwanda FDA shall provide uniforms for its employees and shall coordinate the activity of taking passport photos for staff cards and sizing for uniforms.

12. MANAGEMENT INFORMATION SYSTEM (MIS)

12.1. Introduction

- The Management Information System has been developed to guide all employees of Rwanda FDA in information management and other related activities.
- Specifically, an SOP for use of MIS in Rwanda FDA have been developed and is aimed at managing risk, establishing desired behavior, educating employees and maintaining uniformity.

12.2. General Guidelines on Email and Instant Messaging

- Each employee shall be assigned a unique email address that is to be used while conducting official business of the Authority via email.
- Employees authorized to use instant messaging programs shall be advised specifically on which instant message program(s) are permissible.
- The email/electronic messaging systems and all messages composed, sent, received or stored therein by any employee or non-employee shall be the property of Rwanda FDA.
- Employees shall be prohibited from unauthorized transmission, copying or distribution of Rwanda FDA's information, copyrighted materials or privileged information.
- Email or electronic messaging systems shall not be used for transmitting messages containing pornography, profanity, derogatory, defamatory, sexual, racist, harassing, or offensive material.
- Rwanda FDA provided electronic messaging resources shall not be used for the promotion or publication of one's political or religious views, the operation of a business or for any undertaking for personal gains.

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- Any employee in violation of these policies shall be subject to disciplinary actions of Rwanda FDA.
- Rwanda FDA shall provide and continually review appropriate guidelines for accessing and utilizing Internet through Rwanda FDA's network.
- Official use of Internet services must reflect the mission of Rwanda FDA and support its goals and objectives.
- Rwanda FDA shall be responsible for information or content accessed from its website

12.3. Use of Rwanda FDA Internet

In using Rwanda FDA provided Internet, employees are not permitted to:

- Access, upload, download, or distribute pornographic or sexually explicit material.
- Invade or abuse the privacy of others.
- Violate copyright or use intellectual material without permission.
- Use the network for personal financial or commercial gains to degrade or disrupt network performance

12.4. Password Security

- Rwanda FDA shall provide guidelines in appropriate management of passwords to maintain adequate security and integrity of all Rwanda FDA's information systems.
- Rwanda FDA shall provide access to network, electronic mail and other resources to its employees in support of the organization's mission. Passwords shall be assigned for access to each of these resources to authenticate user's identity, protect network users and provide security.
- It is the responsibility of each individual to protect and keep private all passwords issued to him/her by Rwanda FDA systems.
- The IT Office shall establish guidelines for issuing new passwords, deleting passwords and allowing employees to change their passwords as required.
- New employee credentials shall be granted by IT office.
- A network Administrator may approve any password change requested by a user
- The IT Office shall delete all passwords and email address of former employees upon notification from Human Resource and administration Unit.
- System Administrators and users assume the following responsibilities:
 - i. System Administrators must protect confidentiality of user's password.
 - ii. Users must manage passwords according to the Password Guidelines.
 - iii. Users are responsible for all actions, inactions and functions performed by his/her account.
 - iv. Suspected password compromise must be reported to the System Administrator.

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12.5. Additional Security Practices

- Ensure your workstation is reasonably secured in your absence.
 - Consider using a password-protected screen saver, logging off or locking your PC when not in use.

13. ACCESS AND SECURITY

This section provides guidelines on maintaining the highest level of security for our physical office assets and employees.

13.1. Keys are the Property of Rwanda FDA.

- Supervisors may request keys for authorized employees and shall be responsible for collecting the keys upon an employee separating from the Authority. Keys shall be assigned by employee name. Each individual assumes responsibility for protecting the security of his/her key and shall report losses or situation that possibly jeopardize building security to his/her Supervisor.
- Lost keys must be reported to the supervisor within 24 hours of loss.
- The following actions shall be in violation of this policy:
 - i. Giving out keys without authorization;
 - ii. Duplicating keys;
 - iii. Admitting unauthorized persons into building;
 - iv. Failure to return the key when requested by the supervisor or upon termination with Rwanda FDA.
- All employees are concerned with building lock-up and ensure that when entering and leaving the building after normal business hours, the doors and office windows are locked.
- Visitors are not allowed access to the Processing Center or Data Center without prior authorization.

14. PRIVACY AND HANDLING PERSONAL INFORMATION

- This section provides guidelines on appropriate management of employee and client privacy.
- The following section principles shall apply to the collection, usage, storage, disclosure of and access to personal information:
 - i. The collection and use of personal information shall relate directly to legitimate purposes of Rwanda FDA.
 - ii. Rwanda FDA shall take all reasonable measures to store personal information securely.

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- iii. Individuals are entitled to have access to their own records, unless unlawful.
- This Policy does not apply to personal information that is:
 - i. In a publication available to the public;
 - ii. Kept in a library, art gallery or museum for reference, study or exhibition;
 - iii. A public record under the control of the Keeper of Public Records that is available for public inspection.

15. COMPLAINTS

Any person, whether or not an employee of Rwanda FDA, who on reasonable grounds believes that he/she has been aggrieved within Rwanda FDA or aggrieved by Rwanda FDA decision, may complain to his/her supervisors or the management of Rwanda FDA.

16. INFORMATION SECURITY

This provides section guidelines that protect the data integrity and proprietary nature of the Rwanda FDA's information systems. The IT Office shall:

- i. Prescribe mechanisms that help identify and prevent the compromise of information security and the misuse of Rwanda FDA's data, applications, networks and computer systems.
- ii. Define mechanisms that protect the reputation of Rwanda FDA and allow Rwanda FDA to satisfy its legal and ethical responsibilities with regard to its networks' and computer systems' connectivity to worldwide networks.
- iii. Use a layered approach of overlapping controls, monitoring and authentication to ensure overall security of Rwanda FDA's data, network and system resources.
- iv. Ensure security reviews of servers, firewalls, routers and monitoring platforms on a regular basis.
- v. Provide appropriate training to data owners, data custodians, network and system administrators and users. The training should ensure that users understand data sensitivity issues, levels of confidentiality, and the mechanisms to protect the data.

17. DATA CLASSIFICATION

- It is essential that all Rwanda FDA data be protected. Different types of data require different levels of security. All data should be reviewed on a periodic basis and classified according to its use, sensitivity and importance.
- Rwanda FDA classifies data in the following three classes:

17.1. High Risk

Information assets for which there are legal requirements for preventing disclosure or financial

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penalties for disclosure.

- Payroll, personnel and financial information are also in this class because of privacy requirements.
- Rwanda FDA recognizes that other data may need to be treated as high risk because it could cause severe damage, if disclosed or modified. It is the data owner's responsibility to implement the necessary security requirements.

17.2. Confidentiality

- Data that would not expose Rwanda FDA to loss if disclosed, but that the data owner feels should be protected to prevent unauthorized disclosure. It is the data owner's responsibility to implement the necessary security requirements.

17.3. Public

- Information that may be freely disseminated.

18. TRANSPORT POLICY

18.1. For the Vehicles of Rwanda FDA Senior Officials

Refer to Ministerial Instructions N° 01/MOS/Trans/019 determining lump sum and other fringe benefits for government officials and people's representatives under the fleet policy of the government of Rwanda

18.2. For Rwanda FDA Vehicles

Refer to Standard Operating Procedure on Use of Rwanda FDA transport

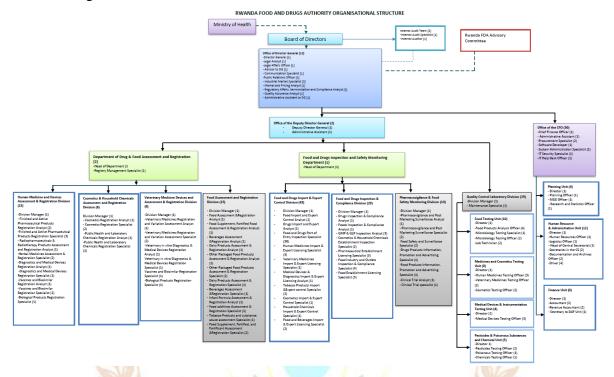
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19. APPENDICES

Annex 1: Organizational Structure of Rwanda FDA



20. REFERENCES

- 1. Law N° 003/2018 of 09/02/2018 determining its mission, organization and functioning
- 2. Law N° 017/2020 of 07/10/2020 establishing the general statute governing public servants.
- 3. Rwanda FDA Quality Manual
- 4. Rwanda FDA Internal Rules and Regulations

21. DOCUMENT REVISION HISTORY

Revision Date	Revision number	Summary of Changes
11 th May 2021	0	First issue

End of Document

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