1. PURPOSE

To describe how to identify, store, protect, retrieve, retain, and dispose records

2. SCOPE

The SOP applies to all records generated as the result of service realization processes and Human resources records.

3. POLICY

3.1. Law Nº 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning,
3.2. ISO 9001:2015 Quality Management System Requirements clause 7.5.3
3.3. Rwanda FDA Quality Manual Clause 7.5.1

4. RESPONSIBILITY

- The Executive organ has overall responsibility for the implementation of this SOP.
- All employees of Rwanda FDA are accountable for the records which they create, use or manage and, regardless of their level, must be aware of their responsibilities to manage the records created or used by them, or under their control or custody.

5. DEFINITIONS AND ABBREVIATIONS

4.1. "**Quality Records**": information generated from the processes described in quality system documents, and retained as indicated in this procedure.
The following terminologies and acronyms have been used in this document;

SOP	Standard Operating Procedure
EAC	East African Community
Rwanda FDA	Rwanda Food and Drugs Authority
QMS	Quality Management Systems

6. DISTRIBUTION

All staff electronically (protected from any alteration)

7. REFERENCES

NA

8. SAFETY AND PRECAUSTIONS

NA

9. MATERIALS AND EQUIPMENTS

9.1. RECORD CENTRE TRANSFER FORM

10. PROCEDURE

10.1. Identification

101.1 Records shall be assigned identification numbers appropriate to the record.

10.1.2. Quality records shall be identified/coded or referenced in accordance to the SOPs of control of documents QMS/SOP/001

10.1.3 General files of records shall be kept at the registry and assigned file reference numbers.

10.2. Storage

10.2.1 All records of service realization shall be stored in files which shall be kept in racks/cabinets at the central secretariat or at the respective Departments.

10.2.2 Personnel records and training records shall be maintained at the Human resources Department.

10.2.3 Confidential human resource records shall be maintained at the office of Director General.

10.2.4 Records shall be arranged in cabinets alphabetically, geographically and numerically for easy identification and retrieval.

10.2.5 All active files of records, which are full, shall be closed at the registry and transferred to records centre (Archives).

10.2.6 After every 5 years (in accordance to the national laws) decongestion of records shall be done at the registry and send all inactive records to records centre.

10.2.7 All soft copy of records shall be maintained in Management Information System (MIS) database or any other system in place.

10.2.8 Records maintained in electronic media shall be subjected to back-up and the back-up information shall be stored in a protected and secured management information system database (MIS) or any other system in place.

10.2.9 Only authorized personnel shall access records in hard and soft copy form.

10.2.10 Rwanda FDA shall observe restrictions on access to information, under the provisions of the law, with the aim to protect confidential information, private life of a person, and national security, as well as to ensure the security of information he/she is responsible for from unauthorized access, modification or damage.

10.2.11 All employees leaving the service of Rwanda FDA shall surrender all or any record within their custody to their immediate supervisors.

10.2.12 Documents shall be transferred to storage during annual/periodic clearing in the following order:

Nº	Type of document	Duration
1	Annual, Semi Annual Reports, Audit reports,	Kept forever
2	Monthly accounts, vouchers and budgets	Kept for 10 years
3	Minutes from the Board of Directors and Senior management meetings	Kept for 10 years
4	Minutes from internal department and divisions meetings, former staff personal files, vehicle records, general correspondence and other general documents	Kept for 5 years
5	Applications and CVs (not recruited), covering letters	Kept for 6 months
6	Personnel Records	Kept forever
7	Records on regulated products and services	Kept forever
8	Unbounded Newspapers and Magazines, Publications, News Letters	Kept forever

10.3 Storage of closed records

10.3.1 All files of closed records shall be registered in records centre transfer form at the registry and sent to records centre in boxes or any other means in place.

10.3.2 The boxes shall be given a number and the number shall be the same as have indicated in the record centre transfer.

10.3.3 The boxes containing records shall be kept at records centre office.

10.3.4 The appraisal of records shall be done after every three to five (according to national laws) years.

10.4 Protection

10.4.1. Records shall be maintained indelibly. Any person initiating a correction shall cross the wrong information and insert the correct one and then write his/her initials and date where change was made. The alteration should permit the reading of the original information; where appropriate the reason for the alteration should be recorded.

10.4.2. The use of erasing fluid or any other means of rendering information illegible is forbidden.

10.4.3. Approved records shall not be changed.

10.4.4. Records shall not be exposed to any agent of deterioration.

10.4.5. The file movement register at each department shall be used to track the files for easy traceability of the records.

10.5 Retrieval

10.5.1. Only authorized personnel shall retrieve records.

10.5.2. All records shall be organized and stored with a record index to allow retrieval in a timely manner.

10.5.3. General records at the registry shall be retrieved by the registry staff on request.

10.5.4. Confidential human resources records shall be retrieved by the Admin Assistant to the Director General.

10.6 Retention time

10.6.1 The Archive and documentation Officer in charge of Indexing and record keeping shall create both electronic and hard file records for all clients and personnel.

10.6.2 A Register of files opened shall be maintained and updated periodically by the Officer in charge.

10.6.3 On each client's file shall be records of client's details including name, location address, postal address, phone number, email, and website where applicable.

10.6.4 External request of a client's file shall be addressed to the Director General office while an internal request shall be addressed to the head of Unit.

10.6.5 Original client's files shall be kept for at least 10 years except for audit and investigation purposes.

10.6.6 Personal records (whether employed permanently, on Contract and internship) shall be kept by the Officer in charge of Human Resource and administration in a safe and in confidence.

10.6.7 Records on personnel shall contain all relevant information on personnel in relation to their employment with Rwanda FDA. This information shall include, date of birth, educational background, employment history, medical certificate, contact details and details of next of kin.

10.6.8 The Officer in charge of Human Resource shall maintain a Register of personnel files and update them periodically.

10.6.9 Rwanda FDA shall maintain a record clearance and retention system in consultation with the National Public Records and Archives Administration Department.

10.6.10 Unless specified otherwise in the respective procedures, all records shall be retained for a period of 15 years.

10.6.11 Records that have permanent value shall be kept permanently at the records centre office.

10.6.12 Employee records shall be maintained by human resources Unit for a period specified in the National laws and regulation.

10.7 Disposition

10.7.1 Out-dated and/or obsolete records shall be shredded, torn and/or burnt.

10.7.2 Obsolete document retained for reference purpose shall be stamped obsolete.
10.7.3 Computer generated records shall be erased from the computer media.
10.7.4 Backup information for soft copy records shall be retained for reference purpose.

10.8 Records Issued to customers

10.8.1 All copies of records issued to customers shall be maintained in their respective customers file at the registry.
10.8.2 Customers shall be informed to keep records issued to them protected for the whole period of validity of the record and then return them once they have expired.

11. REFERENCES

The following documents will be useful when controlling documents of Rwanda FDA;

a) Rwanda FDA Quality Manual
b) National Laws and regulation for medicines, cosmetics, medical devices, diagnostics and other regulated products
c) National Policy, Laws and regulations for archiving

12. REVISION HISTORY

Revision No:	Date	Section(s) Modified	Description of change
0	05/03/2021	NA	First Issue