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RWANDA FDA Rwanda Food and Drugs Authority	Title: **SOP FOR ARCHIVING & RETRIEVAL OF APPLICATIONS OF LICENSING AND INSPECTION REPORTS**	

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1.0 Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure that:

1.1 Instructions for receiving, handling and storing inspections reports are implemented in a secure manner.

1.2 To ensure a consistent, efficient and secure process for the receipt, recording and storage of applications for Food and Drugs Inspection and compliance applications and operational licenses purposes.

1.3 Access of inspections reports is maintained for review by auditors, inspectors and other authorized persons.

2.0 Scope

This Standard Operating Procedure:

2.1. covers the life cycle of applications submitted to the RWANDA FDA for Food and Drugs licensing Inspection and compliance and it involves; recording of all licenses issued and application into the database, coding, application acceptance/rejection, storage, issuance, retention and disposal/ destruction.

2.2. Applies to archiving the inspections reports that are retained for at least 7 years or for longer duration depending on pre-identified needs. They should be accessible to auditors, inspectors and other authorized persons.

2.3. Copying files and documents for or by authorized representatives of the national authority is allowed when required.

3.0 Policy

3.1.Law no 47/2012 of 14/01/2013 relating to the regulation and inspection of food and pharmaceutical states in:

Article 47(1) . *"However, information constituting industrial or commercial secrets shall not be disclosed unless the disclosure is necessary to avoid anything that may pose a risk to human and animal health in accordance with relevant laws.*

3.2. The ISO 9001:2015 Clause 8.5.2. states that *"Documented information shall be retained to enable traceability."*.

4.0 Abbreviations and Definitions

DM:	Division Manager
FDIS:	Food and Drugs Inspection and Safety Monitoring
HOD:	Head of Department
PR:	Public Relations
QMS:	Quality Management System
Rwanda FDA:	Rwanda Food and Drugs Authority

5.0 Definitions

5.1. "**Author**" The Author shall be the person(s) who created a document or any subsequent revision of the controlled document.

5.2. "**Approved by**" Endorsement providing authority for a document to become officially valid and to be put into formal use.

5.3. "**Checked by/Authorised by**" Endorsement signifying that the internal document is ready for approval

5.4. "**Controlled Copy**" A document which is distributed to pre-determined persons or staff and if any change or revision is made on the document, the Quality Management Systems Specialist shall submit the revised document and make sure that the previous (superseded) document is retrieved,

5.5. "**Document**"

a) "Document" means readable information and its supporting medium.

b) A "document" describes any policy, procedure, work instruction or form that is to be controlled.

c) A "document" can be a Law, Regulation, standard, policy statement, manual, guideline, protocol, process flow outlines, standard operating procedure, work instruction, drawing, specification, form, record, chart, report, certificate, checklist, aide memoir, register, worksheet, textbook, poster, notice, memorandum, software, photograph, drawing, or plan.

d) A "document" may be on various media e.g. paper, magnetic, electronic or optical computer disc, and may be digital, analog, photographic or written.

5.6. "**Drug**" means any substance or preparation used or intended to be used for internal or external application to the human or animal body either in the treatment or prevention of disease or for improving physiological functions, or agricultural or industrial purposes

5.7. "**Effective Date**" A date after the concerned staff or persons have been formally trained or notified or oriented on the use of the document and records maintained, but shall not be later than 15 working days from the revision date.

5.8. "**Master Document**" Original of a controlled internal document that contains original signatures of the authorities that checked/authorized and approved the document.

5.9. "**Objective**" A brief statement(s) describing the purpose of the document.

5.10. "**Policy**" A short statements derived from the applicable law(s), regulation(s), standard(s), resolutions(s), decision(s) or concept(s) that govern the document or provide a mandate or basis for the document.

5.11. **"Inspections reports"** Readable information or data resulting from inspections conducted and its supporting medium.

5.12. "**Procedure**". When used as a title, e.g. in a Standard Operating Procedure (SOP), or Work instruction, a procedure shall be written as follows:

1) Write clear, concise, step-by-step instructions on how to perform the procedure.
2) Write the instructions chronologically for the user to follow, without a lot of theoretical background.
3) Indicate the preliminary steps that must be done before beginning the actual procedure.
4) Number each step so that repeat steps can be referred to rather than making the SOP very long.
5) Number each sentence so as to make reference to it easy under document revision history when it is revised.
6) Include explanations and an example of how to do any required calculations.
7) Create and indicate the Form(s) where the results, observations or data should be recorded.

5.13. "**Responsibility**" indicates the designations or titles of the Rwanda FDA staff or member and briefly describe their specific responsibilities in performing the procedure in a document and in ensuring that the document is implemented and performed correctly and consistently.

5.14. "**Review Due Date**". A date three years from the effective date, to ensure continued adequacy and suitability of a document. A document may remain valid beyond its review due date if no major change had happened in the process, until the revised document is authorized.

5.15. "**Review**". Assessment of the correctness, suitability and adequacy of a document including technical, legal, regulatory, health, safety, and environment compliance issues.

5.16. "**Reviewer**". The Reviewer shall be the person(s) who assesses a document for technical, legal, regulatory, health, safety, and environment compliance issues as per Section 9.3 of the Document Control SOP number QMS/SOP/001.

5.17. "**Revision Date**" The date when the document is approved and thereby becoming officially valid.

5.18. "**Revision Number**" A numerical figure that changes serially; the first document shall have revision number "0" and its first revision number "1", second revision number "2" and so on.

5.19. "**Safety Precautions**" When used in a procedure e.g. SOP, indicate all safety precautions that must be taken before the procedure is performed. Includes special precautions and protective garments (containment facility clothing, masks, hoods, goggles, gloves, cleanup of spills, etc.) for working with physical, chemical, radioactive, biological or microbiological hazards.

5.20. "**Scope**" A brief statement of where the document applies, when it need to be applied and any limitations of the document.

5.21. "**Title**" A title shall be a short, precise statement representing the contents of the procedures

5.22. "**Uncontrolled Copy**"
A document which is issued to persons or staff who are not part of the distribution list for that document for information purposes only and if any change or revision is made on the document, the Quality Management Systems Specialist is not in control of retrieval of the previous (superseded) document.

6.0 Responsibility

6.1. Head of Food and Drugs Inspection and Safety Monitoring Department: ensures that this SOP is correctly and consistently implemented during archiving & retrieval of inspection reports as well as required documents applied and licenses as well as feedback letters.
6.2. Division Manager, Food and Drugs Inspections & Compliance: ensures the adherence of the staff to this SOP.
6.3. Quality assurance analyst: ensures the use of update version of the SOP, recalls obsolete documents and keeps document master list.
6.4. Analysts/Specialists shall adhere to this SOP.

6.5. Secretariat Staff shall ensure the adherence of the staff to this SOP.

6.6. It is the joint responsibility of the Quality Management System Analysis for the Department and the Division Manager of Food and Drugs Inspection and Compliance to ensure that this SOP is updated.

7.0 Distribution

7.1 Head of Food and Drugs Inspection and Safety Monitoring Department
7.2 Division Manager of Food and Drugs Inspection and Compliance
7.3 Quality assurance analyst
7.4 Analysts/Specialists
7.5 Rwanda FDA Secretariat and Members

8.0 Safety Precautions

8.1. Received applications, issued licenses, inspection reports and required documents shall be recorded electronically on the FDIC computer and backed-up in the Rwanda FDA server.

8. 2. All applications, issued licenses, feedback letters, inspections reports, are archived in FDIC decision and after 6 months all documents shall be transferred to Central secretariate for archiving.

8.3. The applications on the CD (Compact disk for GMP) are copied and saved on a designated folder on the analyst and specialist 's computer, backed-up on FDIC Desktop and Rwanda FDA server. Copies should also be backed up on external drive and the external dive should be kept in a safe secured cupboard and accessed by authorized personnel only.

8.4. Information on the computer shall be entered promptly, precisely and accurately at all times by the analysts, Specialists and the Division Manager who assigns incoming applications. Analysts compile all assessed applications and ensure a weekly back-up on the FDIC desktop.

8.5. The applications, licenses, feedback letters, issued and inspection reports shall be stored according to the identification numbers, the category, the location, the month, and the year of the application of the client. Each Dossier composed of application letter, required documents, license if any, feedback letter if any, inspection reports if any should be kept together and filed in the boxes in the archiving room with the code/identification number of the file, the year and category of the premise to be retrieved. Each shelf or and drawer with a number should contains a unique, identifying box number of the file containing the different Dossiers. In this way it will not take more than 1 hour to retrieve a dossier. The dossier is kept in FDIC for six months and transfer in archiving room.

8.6. Every inspector shall provide a report after the inspection, and all documents required for submitted for an application for an operational license and license if it is a renewal.

8.7. For all inspection reports conducted, licenses , feedback letters and required documents submitted by the clients, the dossiers or files must be stored under conditions that prevent accidental or premature destruction of the documents in accordance with proof requirements.

8.8. The inspection reports should be stored safely in a suitable archive for the whole retention.

8.9. Documents may be stored electronically, onto human readable media or other new media as changes in technology demand.

8.10. If documents are to be stored and archived using electronic or optical media, the methods for transferring the data to these media should be validated.

8.11. A suitable back up-strategy must be implemented to prevent loss or destruction of data.

8.12. There must be a possibility to generate hard copies throughout the period of retention.

8.13. For inspections with critical findings and/or major findings should be shared, when necessary, with other divisions when necessary or requested.

8.14. Access to inspection reports and inspection files should not be provided to parties other than the other division of Rwanda FDA.

8.15. Each involved authority is responsible for ensuring observance of applicable data protection requirements.

8.16. If a specimen requests a test shall be stored in such a way as to protect the containers/packaging from physical damage or abrasion and submitted to the laboratory for testing.

8.17. The storage areas for dossiers shall be maintained clean, dry and free from dust and protected from water/ moisture and direct sunlight.

8.18. The inspection reports and feedback letter should be recorded based on the reference number of the application for operational license.

9.0 Materials and Equipment

9.1 Secured Cupboards

9.2 Sticker and labels

9.3 Files and folders

9.4. Marker with indelible blue or black ink

10.0 Procedure

10.1 Receiving Applications

10.1.1. Applicants submit their applications with relevant attachments duplicate at Rwanda FDA head office central secretariat and a copy of such application is stamped "Received" and returned to the applicant as a reference.

10.1.2.The received application is recorded with a reference number and a copy is filed at the central secretariat and sent to the Head Food and Drugs and safety monitoring department qs described in the guidelines.

10.1.3.Upon receipt of the applicant's file, the HOD shall assign it to the Division Manager of FDIC who shall then enter data from the submitted application to the database and assign it to the Analysts/Specialists for assessment. If not satisfied, then he/she shall inform the applicant for clarification of the application

10.1.4. The application is filed in shelves and arranged according to their category and application numbers respectively.

10.1.5.If satisfied the Analysts/Specialists shall organize for inspection of applicants proposed premises.

10.1.6. After inspection, inspection reports/checklists of the applications shall be recorded in the premise applicant's file.

10.2Inspections reports preparations and review

10.2.1. Inspections are prepared and first reviewed by specialists then in internal committee, findings of the inspections prepared by specialist are reviewed for approval. Analyst and DM and HOD and other members of the committee review the dossier based on the findings from the inspection and if successfully fulfilled, the license is issue. Analyst, DM and HOD review the application prior being sent to DG for signature.

10.2.2. Signed inspection reports are filed in folders per month, year After receiving the final inspections reports carefully reviewed through above steps,

10.3.Retrieving Inspections reports

10.3.1. The Rwanda FDA Central Secretariat will maintain Confidentiality (Division) of Rwanda FDA licenses issued.

10.3.2. The request for retrieval can only be made by Rwanda FDA Central Secretariat, auditor or other authorized persons who will request officially to in by filling up, signing and dating request form.

10.3.3. Retrieval of inspection reports can only be done when a request is made in the request form that is approved (signed and dated) by the Rwanda FDA Central Secretariat Chairperson/Member Secretary.

10.3.4. Rwanda FDA Central Secretariat can retrieve archived file(s) without having to require Rwanda FDA Central Secretariat Chairperson's approval. For this purpose, the Rwanda FDA Central Secretariat can authorize a staff member of the Rwanda FDA Central Secretariat to physically retrieve a file. In such a situation, the register/ log will be signed by the Rwanda FDA Central Secretariat member physically retrieving the file.

10.3.5. A member of Rwanda FDA Central Secretariat will retrieve archived document(s) and will return the remaining file back to its place.

10.3.6. The Rwanda FDA Central Secretariat maintains a register with following information related to retrieval:

10.3.7. File number, Name and designation of individual making a request for retrieval with his/hersignature, Date of approval of request by Rwanda FDA Central Secretariat chairperson, Date and time of retrieval, Name and signature of Rwanda FDA Central Secretariat retrieving the file, Date and time of returning the file.

10.3.8. Rwanda FDA Central Secretariat will also record, sign and date when the inspection reports has been returned and kept.

11.0. Coding of applicationsand inspection reports

11.1. The DM shall assign the identification code that is serially determined.

11.2. The application for each category shall be given an identification code designated as FDIC an application for Food and Drugs Inspection and Compliance followed by the month in number in two digital and the year.

11.3. GF for GMP Food products and Animal feed applications, GM for GMP medical products applications, IF for Incineration for Food and IP for Pharmaceutical products, MW, MR, MV, MOP, MOR, MS, ME, MME for Medical products for Wholesale pharmacies, Retail pharmacies, Veterinary pharmacies, Optical pharmacies, Orthopedic pharmacies, Small Compounding, Whole sale medical devices and Equipment, Manufacturer of Medical Devices and Equipment respectively:

"XXX" stands for Serial Alphabetical number and "**F"** stands for Food.
The 001 stands for incremental sequence/serial number of the application. These are 3 for all applications.

"XXX" stands for a 3-digit incremental sequence/serial number of the application. For example; **FDIC/01/2021/GM001** indicate the identification code of the first application received for GMP medical products.

11.4. All applications received shall be coded by writing the identification code for identification and for traceability.

11.5. The Analyst shall supervise the follow-up of all applications status in the database, and back-up of all applications dossiers on the FDIC computer later on the Rwanda FDA Server.

11.6. DM shall coordinate the transfer of all the applications for filing and archiving.

11.7. Access to clients dossiers should not be provided to parties other than the other divisions of Rwanda FDA.

11.8. Each involved authority is responsible for ensuring observance of applicable data protection requirements.

11.9. From the central secretariate, the reference number to be added prior the reference number of FDIC is the reception number followed by the Year and the department abbreviation (e.g.: 0001/2021/FDSM). The reference number will be then 0001/2021/FDSM/**FDIC/01/2021/GM001 or** 0001/**FDIC/01/2021/GM001.**

12.0. References

12.1. Union guidance on record keeping and archiving of documents obtained or resulting from pharmacovigilance inspections. 7 December 2016 EMA/INS/PhV/820053/2016 Committees and Inspection

13.0 Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
16 Jul 2021	0	Rwanda FDA Staff	First Issue

End of Document

ANNEXES

ANNEX 1. IDENTIFICATION AND TRACABILITY OF DOSSIERS SUBMITTED.

According to the ISO 9001:2015 (E), referring to the *Clause 8.5.2* Identification and traceability, FDIC - shall use suitable means to identify the outputs when it is necessary to ensure the conformity of products and services; FDIC shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. According to the ISO 9001:2015 (E), referring to the *Clause 8.5.3* Property belonging to customers or external providers, FDIC shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services. The following referencing approach is applied to all documents received by email are numbered based on the division abbreviation followed by the month and year and alphabetical numbering (see below in the table) and followed by a number.

REFERENCE CRITERIA

	DIVISION	**MONTH**	**NUMBERS**	**YEAR WHEN THE DOSSIER WAS RECEIVED**	**REFERENCING OF FDIC DIVISION APPLICATIONS**	**CATEGORY**	**ALPHABETICAL NUMBERING**

1	FOOD AND DRUDS AND INSPECTION AND COMPLIANCE	JANUARY FEBRUARY MARCH APRIL MAY JUNE JULY AUGUST SEPTEMBER OCTOBER NOVEMBER DECEMBER	1 2 3 4 5 6 7 8 9 10 11 12	2021	GMP FOOD	GMP FOOD PRODUCTS ANIMAL FEED	GF
					GMP MEDICAL PRODUCTS	PHARMACEUTICAL MANUFUCTURERS MEDICAL PRODUCTS	GM
					INCINARATION	FOOD PHARMACEUTICAL PRODUCTS	IF IP
					MEDICAL PRODUCTS	- PHARMACEUTICAL ESTABLISHMENTS: -PHARMACEUTICAL MANUFACTURERS (WHOLESALE, RETAIL PHARMACIES/ HUMAN MEDICINE/VETERINARY MEDICINE, ONLINE PHARMACIES) - OPTICAL SHOPS - ORTHOPEDIC	M

						SHOPS - SMALL COMPOUNDING - WHOLESALE OF MEDICAL DEVICES AND EQUIPMENT - MANUFACTURER OF MEDICAL DEVICES AND EQUIPMENT	
					FOOD PRODUCTS	MANUFACTURER OF FOOD PRODUCTS FOOD OUTLETS (FOOD IMPORTERS/ WHOLESALE FOOD PRODUCTS/ SUPERMARKETS) - RESTAURANTS - ANIMAL FEEDS	F