RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Food and Drugs Inspection and Safety Monitoring Department	
Document Type: **Standard Operating Procedure**		Doc. Number	: QMS/SOP/073
RWANDA FDA Rwanda Food and Drugs Authority	Title: **SOP DESCRIBING THE CRITERIA'S FOR THE LICENSING OF DOMESTIC, FOREIGN, PUBLIC AND PRIVATE ESTABLISHMENTS**	Revision Number	:0
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RWANDA FOOD AND DRUGS AUTHORITY STANDARD OPERATING PROCEDURE (SOP) DESCRIBING THE CRITERIA'S FOR THE LICENSING OF DOMESTIC, FOREIGN, PUBLIC AND PRIVATE ESTABLISHMENTS

	Author	Checked by			Authorized by	
Title				Quality Management Systems	Director General	Page 1 of 18
Signature & Date						

RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance	
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1.0 Purpose

1.1 This Standard Operating Procedure (SOP) provides instructions on criteria for the licensing of domestic, foreign, public and private establishments conducted by Rwanda FDA inspectors

1.2 All applications submitted to the Rwanda FDA for the licensing of premises regulated under the Law are processed in a consistent and effective way

2.0 Scope

This Standard Operating Procedure:

2.1 Applies to all applications for licenses for premises dealing with domestic, foreign, public and private establishment.

3.0 Policy

3.1 The Law Nº 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning states in: Article 3 (13) … *"premises used in the manufacture of products regulated by this Law"* and

3.2 ISO 9001:2015 Clause 7.5.3.1 states that "*Documented information required by the quality management system and by this International Standard shall be controlled".*

4.0 Definitions and Abbreviations

4.1 "the Law"
Law Nº 003/2018 of 09/02/2018 Establishing Rwanda Food and Drugs Authority and Determining its Mission, Organization and Functioning

4.2 **Domestic**: existing or occurring inside a particular country; not foreign or international.

4.3 **Private**: a building, structure, or portion thereof that is owned, leased, controlled, or operated by a nongovernmental entity for a nongovernmental purpose.

4.4 **Foreign**: dealing or concerned with another country, area, people, etc

4.5**Public**: relating to or involving people in general, rather than being limited to a particular group of people

4.6 **Establishment**: a business organization, public institution, or household

5.0 Responsibility

5.1 The Head of Food and Drugs Inspection and Safety Monitoring is responsible for:

a) Ensuring that all applications for the registration and renewal of premises licences processed and filed according to this SOP.

b) Ensuring that all decisions to suspend or revoke the premises licences issued under the Law are effected.

c) Notifying all applicants and licensees of the decisions of the Authority regarding licensing of premises regulated under the Law.

d) Maintaining the register of premises regulated under the Law.

5.2 The designated staff for each Drugs, Food Inspections and Compliance Department/Division/Unit is responsible for ensuring that all new applications and applications for renewal of premises licences received are processed and filed; and that all licences to be suspended or revoked are suspended and revoked; and that the register of premises is updated accordingly.

6. Distribution

6.1 Head of Food and Drugs Inspection and Safety Monitoring

6.2. Division Manager, Food Inspections & Compliance Division

6.3.A QMS shared folder on Rwanda FDA head office server on the following link: (\\rwandafdaserver\qms\sopxxxx)

6.4 Hard copies to staff that have no access to the Rwanda FDA server.

7. Reference

7.1 Rwanda FDA Suitability and Licensing of Premises Regulations and Guidelines.

8.0 Safety Precautions

Not applicable to this procedure.

9.0 Materials and equipment

9.1 Regulations and Guidelines for suitability and licensing of premises

9.2 Checklists for receiving applications for premises licenses

10.0 PROCEDURES

10.1. Receipt and processing of new applications.

10.1.1A client submits relevant documents in accordance with specific checklists for the specific premises to be licensed, which meet the minimum requirements for the submission of a new application to the Authority.

10.1.2 A designated officer in the Drugs, Food Inspections and Compliance Department will be responsible for receiving of applications for consideration by the Authority. Applications are to be received by the specified deadline for each Licensing Meeting.

10.1.3 The officer receiving the application shall, upon receiving a complete and satisfactory application, open a file and ensure that the submitted documentation complies with the checklist for those particular premises.

10.1.4 Applicants who have submitted incomplete and/or unsatisfactory applications shall be notified in email writing of the deficiencies of the application and shall be required to rectify the application within the specified timeline of 15days. Applications not resolved within the 15days shall be rejected and the applicant notified in writing.

10.1.5 The officer receiving the application shall ensure that the correct application forms especially food premise application form have been completed in full with all required information**.**

10.1.6 The officer receiving the application shall verify that the correct and appropriate fee has been paid and receipted for each application.

10.1.7 The officer receiving the application shall record the application in the relevant Drugs, Food Inspections and Compliance work diary and submit the application for review by the Director, Drugs, Food Inspections and Compliance. The Director shall review the application before allocating an officer the file for inspection of the premises**.**

10.1.8. The Director of Food and Drugs inspection and compliance shall verify for the new incoming application to be filed in the food-manufacturing database before allocating to the responsible officer for assessment and handling

10.1.8 Once inspected, the officer shall assess the report of inspection whether all recommendations have given Corrective and Preventive actions especially the critical defects.

10.1.9 Once not inspected, the applicant shall be listed on the next incoming inspection list within 15 days upon reception of complete application.

10.1.10 Upon inspection, inspectors shall make sure that all information required in the appropriate inspection checklists is properly filled, signed, stamped by both applicant and inspector

10.1.11 a) from the inspection, a report must be prepared within 7 days from the inspection and submitted to the department for filing.

b) Once the report of inspection is complying with the requirements, the committee will meet to review for license approval and the responsible officer shall prepare a license to be submitted to the Director of Food and Drugs inspection within 2 days from the committee meeting

c) The license has to pass 5 days for the higher level to be signed and be sent to the applicant within 15 days from the inspection

d) Once the report of inspection does not comply with the requirements, a feedback is prepared and be sent to the applicant within 14 days from the inspection listing the recommendations

e) If the CAPA are not done within 3 months from the reception of the feedback letter, the application will be closed.

f) If the CAPA are submitted and implemented, a re-inspection is scheduled within one month from the submission of the CAPA

10.1.9 New applications for premises licences shall be tabled for approval by the Food and Drugs Inspection compliance department Licensing Meeting. If the application is complete and satisfactory and the inspection report is also satisfactory, the Food and Drugs inspection and compliance shall approve the issuance of a licence.

10.1.10 Once the Department has approved the issuance of a licence, the Licensing Officer shall proceed to issue the licence within five (5) days of the Licensing Meeting.

10.1.1 Applications whose premises are inspected and found to be unsatisfactory, issue of a licence shall be refused and the applicant advised in writing. The reasons for refusal shall be stated in the letter notifying the applicant.

10.2 Receipt and processing of applications for renewal of licences

10.2.1. a) A client submits relevant documents in accordance with specific checklists for the specific premises to be renewed, which meet the minimum requirements for the submission of a new application to the Authority.

b) Application for renewal of license must be submitted to the department 1 month before the expiration of the previous operational license.

10.2.2 An assigned officer in the Drugs, Food Inspections and Compliance Department will be responsible for receiving of applications for renewal for consideration by the Authority.

10.2.3. The officer receiving the application shall, upon receiving a complete and satisfactory application, place the application in the relevant premises file and ensure that the submitted documentation complies with the checklist for those particular premises.

10.2.4. The officer receiving the application shall ensure that the correct application forms have been completed in full with all relevant and required information.

10.2.5 Documents to be received include but not limited to:

a) A dully-filled application form

b) An application letter

c) A pay slip of a designated amount considering the activity to be done

d) A company registration certificate (RDB) compromising with the working location

e) A notified degree (of the relating technician)

f) A written contract of a responsible technician with a minimum period of not less than 1 year

g) One photo passport of a Managing Director

h) one photo passport of a responsible technician

i) A copy of identity card of both the Managing Director and the responsible technician

j) A commitment letter of a responsible technician

k) A process flowchart (if applicable)

l) A designed plant layout (if applicable)

m) A recent operational license

10.2.5. The officer receiving the application shall verify that the correct and appropriate fee has been paid and receipted for each application.

10.2.6. The officer receiving the application shall record the application in the relevant Drugs, Food Inspections and Compliance work diary and submit the application for review by the Director, Drugs, Food Inspections and Compliance. The Director shall review the application before allocating an officer the file for processing.

10.2.7. a) The designated officer shall check the premises file for any outstanding compliance issues and make recommendations regarding re-inspection of the premises prior to the renewal of the application.

b) The schedule of inspection for a premise that applied for license renewal has to follow the same instructions as the inspection of a premise applying for registration and licensing

10.2.8. If the application is complete and satisfactory and there are no outstanding compliance issues, the Food and Drugs inspection compliance shall approve renewal of the licence.

10.2.9. Once the Department has approved renewal of the licence, the Licensing Officer shall proceed to issue the licence within five (5) days.

10.2.10. Where applications for renewal have outstanding compliance issues, renewal of the licence shall be refused and the applicant advised in writing. The reasons for refusal shall be stated in the letter notifying the applicant.

10.3 Suspension and revocation of licences

10.3.1 Where a person granted a licence contravenes a provision of the Law or of any other applicable law or breaches a condition of the licence; or the person granted the licence fails to remedy a contravention of the Law or repeats a contravention of the Law or of a condition of the licence; the person to whom the licence is granted ceases to be fit to carry on the business for which the licence is granted, the Director General shall instruct the Director, Drugs, Food Inspections and Compliance to notify the licence holder, in writing, of the Authority's decision to suspend or revoke the licence. The notification shall state the reasons for the Authority's decision.

10.3.2 The notification shall also request the licence from the licence holder within the specified period.

10.3.3. Upon receipt of the licence, the Director - Drugs, Food Inspections and Compliance shall designate an officer to change the status of the applicant on the register

10.3.4 The designated officer shall endorse the returned licence with the words “suspended” or revoked, as applicable, and place the endorsed licence in the premises file.

10.3.5 The designated officer shall close and archive the premises file.

10.3.6 Once the person that was granted a license and revoked, corrects the reasons for license revocation and submit CAPA in 3 months and once CAPA declared in the same period, a designated team from the Drugs, Food Inspections and compliance shall conduct investigation to verify if CAPA have been implemented.

10.3.7 Upon correction and submission of CAPA, the team shall meet within 5 days from the investigation and conclude about the feedback and re-authorize the operational license

11.0. DESIGN LAYOUT AND SPECIFICATIONS

AUTHORIZATION LAYOUT

Specifications are so important to the construction process of the authorization providing clear instructions on the intent and design of the authorization reference the quality and standards which should be applied and clearly defined.

The authorization layout will fit in the following workings in bold:

- Rwanda FDA Logo. Upper left side of print design
- Reference number. Ref No: DIS/…… /FDA/year
- License to Operate a Retail or Wholesale Pharmacy, orthopaedics shop, optical shop…. etc.
- Reference to the Law Nº 003/2018 of 09/02/2018 Establishing Rwanda FDA
- Name of the establishment
- Business company code number
- Detailed Location of the company
- Names of managing director and contact number
- Names of responsible technician and registration number
- Validity (Extended period limit)
- Date of issue
- Signature and stamp of the Director general
- Rwanda FDA water mark
- Text will be printed in black

11.1 AUTHORIZATION SPECIFICATIONS

Procedures On Typing the Rwanda FDA Outgoing operational licenses and correspondences

STEP I: Typing Characters, Font size and Paragraph spacing and arrangement of the text

All outgoing operational licenses and correspondences texts shall type in Times New Roman, 12 Font size, 1.15 line and Paragraph spacing

- All Texts in tables will be typed in Times New Roman, 12 Font size, 1.0 line and Paragraph spacing
- All texts shall be aligned to both left and right margins in a Justify mode

STEP II: Margins of outgoing operational licenses and correspondences

The indent page layout margins of the outgoing operational licenses and correspondences shall be as following:

Top 0.5” Bottom 0.3”
Left 0.5” Right 0.5”

STEP III: use of Watermark

All outgoing correspondences will bear a watermark with agreed sizes and no one shall change it as he/she wants.

STEP IV: Numbering of outgoing operational licenses and correspondences

The numbering of all outgoing operational license and correspondences will appear with following information:

- Initials of the department in which the license or letter was drafted

- The numbers issued by the central secretariat as per the order of outgoing licenses and letters Register
- Initials of institution (FDA)

- The year of issue of that correspondence

NB: All of these shall be separated by a stroke symbol (/)

The initials of departments determined as follow:

- DIS: stands for Department of Inspection and Safety Monitoring
e.g.: Ref No: DIS/591/FDA/2021

11.2 *GENERAL DOCUMENT REQUIREMENTS*

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No	GENERAL DOCUMENT REQUIREMTS	REASON FOR THE DOCUMENT
1	Application letter	Motivation or reason for the request of the applicant(letter shall be addressed to the Director General of Rwanda FDA: letter must be signed and written by the owner of the company
2	Original of authorization for the establishment	authorization shall be presented for review and approval of any variation made on the details of the issued authorization (e.g.: Renewal, Change of Ownership and Responsible pharmacist)
3	Copy of certified RDB full information of the company certificate	RDB collaborates with institutions and works in harmony with Rwanda FDA to promote the economic development in private sectors; contents in the RDB company certificate essential are : e.g. business registration code, business company name, business location/address , business category and personal details of the Managing director
5	Certified copy of Valid License issued by Recognized Professional Council in Rwanda	Every registered and licensed personnel in a recognized professional council in Rwanda has a unique code identification which differs from others: Contents to extract are : e.g. full names, registration code, validity and the authenticity of the profession license to practice
6	Certified Sales Agreement	Notified copy of sales agreement by the notary of the Republic of Rwanda, for consent between two parties.
7	Certified copy of Degree (and equivalent if applicable) of Responsible technician	Degree of the responsible personnel acknowledged by the institution is A0 or second cycle degree and in most cases license to practice by recognized professional councils(where applicable)
8	Curriculum vitae of the responsible technician and Owner	CV of qualified personnel, details of personnel can be traced to for service delivered in each entity to avoid dual practices
9	Professional agreement between responsible technician and Owner	Proof agreement on services that will be delivered(when and how)

10	Photocopy of Identity Card/Passport of the responsible technician and the owner	the identity card contains the right full names it spreads the right birth names so personal names shall be extracted from the Identity card/passport of owner and technician
11	Proof of service delivered issued by the last employer of the technician	the responsible technician must provide these documents once the contract with the former managing director is terminated before engaging in new activities with the current managing director or another establishment this facilitates in traceability of activities from one entity to another and avoid dual practices
12	Resignation letter of former responsible technician	
13	Resignation letter with acknowledgement of employer of incoming responsible technicians (if he/she has been working)	
14	Lease contract for the pharmaceutical establishment	Lease contract is necessary to identify or assess whether the building or premise is fit to accommodate business activities or is for commercial purpose as prescribed in the guidelines
15	Proof of Payment of the prescribed fees	for any service delivered payment shall vary in accordance to the regulation of charges/tariff and fines

12.0. Suspension and revocation of licenses

12.0.1. Where a person granted a licence contravenes a provision of the Law or of any other applicable law or breaches a condition of the Licence; or the person granted the licence fails to remedy a Contravention of the Law or repeats a contravention of the Law or of A condition of the licence; the person to whom the licence is granted Ceases to be fit to carry on the business for which the licence is granted, the Director General shall instruct the Director, Drugs, Food

Inspections and Compliance to notify the licence holder, in writing, of the Authority's decision to suspend or revoke the licence. The notification shall state the reasons for the Authority's decision.

12.0.2 The notification shall also request the licence from the license holder within the specified period.

12.0.3. Upon receipt of the licence, the Director - Drugs, Food Inspections and Compliance shall designate an officer to change the status of the applicant on the register.

12.0.4. The designated officer shall endorse the returned license with the

Words "suspended" or revoked, as applicable, and place the

Endorsed license in the premises file.

12.0.5. The designated officer shall close and archive the premises file.

13.0. Appendices

13.1Checklists for receiving applications for premises licences

Will be attached when finished to formulate

13.2 Standard letter for approval/refusal of applications

Approvals_Guidance.pdf

13.3 Standard letter for suspension or revocation of licences

Will be attached when finished to draft

14 Document Revision History

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Author	Checked by			Autho by
Senior Licensing Officers, Drug and Food Inspectorate	Head, Drug Inspectorate Services	Head, Drug Assessment & Registration	Head, Quality Management	Execu Secre /Regi

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision

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