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RWANDA FDA Rwanda Food and Drugs Authority	Title: **LICENSING AND INSPECTIONS OF REGULATED PREMISES**	Revision Number Revision Date Effective Date Review Due Date	: 0 : 09 Jul 2021 : 16 Jul 2021 : 16 Jul 2024

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1.0 Purpose

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

1.1 To ensure that licensed establishments comply with laws and regulations governing licensing requirements.

1.2 To ensure that all inspectors follow the standard procedure when performing inspections and ensure consistency in in writing inspection reports

2.0 Scope

This Standard Operating Procedure:

1.1 Shall apply to all licensing inspections organized by Rwanda FDA

1.2 Applies to conducting inspections consistently and uniformly to ensure that licensed premises meet the stipulated requirements

3.0 Policy

3.1 Law No. 003/2018 of 09/02/2018 establishing Rwanda FDA, determining its mission, organization, and functioning states in:

Article 8 (2) ...” regulate compliance with quality standards relating to the manufacture”; and
Article 9 (2) …” grant or withdraw authorization relating to matters regulated under this law”.

3.2 The Law Nº 47/2012 of 14/01/2012 Relating to the regulation and inspection of food and pharmaceutical products states in:

Chapter I, Article 4 *“The license to operate premises used for carrying out activities under Article 3 of this Law is granted by a competent organ according to the types of licenses*

3.3 Regulations No.: CBD/TRG/001Rev. No 1 on Governing Licensing to Manufacture, to Operate as Wholesale and Retail Seller of Medical Products.

4.0 Abbreviations and Definitions

4.1 Licensing inspections: inspections conducted in order to “gather and examine all information, documents, and facts necessary to make an informed and responsible decision on license issuance or refusal” (NARA, 2000, p. 12).

4.2 Routine Inspection: The inspection that is conducted routinely to “determine if the regulated premises activities are being carried in accordance with the licensing guidelines”

4.3 Regulated Premises: Premises where the manufacture, import and export, distribution, sale of regulated products” pharmaceutical products, vaccines, human and veterinary processed foods and other biological products used in clinical as drugs food supplements, food fortificants fortified foods, poisonous substances, herbal medicines, medicated cosmetics, medical devices, tobacco and tobacco products, management of unfit pharmaceutical and food products and clinical trials on pharmaceutical products for human and veterinary use” are carried out (Law Nº 003/2018 OF 09/02/2018)

4.4 Announced inspection: An announced inspection is an onsite visit where a site to be visited and/or inspected is given a notification in advance prior to the actual inspection by the Commission. This means that a specific date of visit or inspection is given to the site to be inspected

4.5 Unannounced inspection: An unannounced inspection is an onsite visit to a service delivery site where the Commission provides no prior notification of the actual date of the inspection to the service delivery sites, or notice is given shortly before the scheduled time of the inspection

4.6 DG: Director General

4.7 HOD: Head of Department

4.8 CFO: Chief Finance Officer
4.9 DM: Division Manager
4.10 PV: Procès-Verbal de constant
4.11 SOPs: Standard Operating Procedures
4.12 FDA: Food and Drugs Authority

5.0 Responsibility

5.0.1 Head of Food and Drugs Inspection and Safety Monitoring Department: ensures that this SOP is correctly and consistently implemented during licensing and inspections
5.0.2 Division Manager, Food and Drugs Inspections & Compliance: ensures the adherence of the staff to this SOP and Maintaining the databases of premises regulated under this Law
5.0.3 Quality assurance analyst: ensures the use of update version of the SOP, recalls obsolete documents and keeps document master list
5.0.4 Inspectors: adhere to the SOP during licensing inspection

6.0 Distribution

6.0.1 Head of Food and Drugs Inspection and Safety Monitoring Department
6.0.2 Division Manager, Food Inspections & Compliance Division
6.0.3 Quality assurance analyst
6.0.4 Analysts
6.0.5 Specialists

7.0 Safety Precautions

7.0.1 Inspectors should have the service cards at all times during the inspection process
7.0.2 The inspector should be aware of dangers that can happen during the inspection

8.0 Materials and Equipment

8.1 Application forms for premise licensing
8.2 PV
8.3 Checklists for the regulated premise
8.4 Rwanda FDA Regulations and guidelines
8..5 Measuring tapes and GPS machine
8.6 Rwanda FDA cameras
8.7 Inspector's service card

8.8 Pens with indelible blue or black ink

9.0 Procedure

9.0.1 Receipt and processing of applications:

9.0.1.1 Applicants submit their applications in 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.

9.0.1.2 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 within prescribed time**.**

9.0.1.3 For online applications, the dossier is submitted via institutional email info@rwandafda.gov.rw and the application is acknowledged by the central secretariat

9.0.1.4 The central secretariat downloads and creates the file on Rwanda FDA server for reference purpose before the application file is submitted to Head of Food and Drugs and safety monitoring department

9.0.1.5 Upon receipt of the applicant's file, the Head of Food and Drugs inspection and safety monitoring department scrutinizes the application and assign it to the Food and Drugs Inspection and Compliance Division Manager who records the application in the relevant Food and Drugs Inspection and Compliance incoming dossier database and further assign it to the analyst /specialist for assessment.

9.0.1.6 The assigned Analyst/Specialist creates a file for the application in the relevant premises' file.

9.0.1.7 Upon receiving a complete and satisfactory application; the Division Manager of food and drugs inspection and compliance organizes for inspection of applicants proposed premises

9.0.2. Preparation of concept note of the licensing inspection

The concept note must show the *general introduction*, the *Rationale of the inspection for the targeted applications, the inspectors, the budget of the inspection and expected results*

9.0.3. Preparation for the inspection

9.0.3.1 The Division Manager of food and drugs inspection and compliance plans and coordinates the inspection, and designates at least two inspectors to conduct licensing inspection

9.0.3.2 The Division Manager assigns the staff to draft the concept note and mission authorization of the inspection for approval,

9.0.3.3 For new applications, renewal of the license and relocation of premise; inspectors shall conduct the inspection within 10 working days in Kigali City and outside Kigali City from the reception date of the application in the Division.

9.0.3.4 Before conducting the inspection, the inspectors shall prepare and/or have the following:

9.0.3.4.1 The inspection plan that include the list of premises to be inspected

9.0.3.4.2 Application forms for the premises to be inspected

9.0.3.4.3 Inspection report templates and checklists for conducting the inspections

9.0.4 Inspection materials

Once the concept note is approved, inspectors prepare all required tools to conduct the inspection and according to the premise category, different tools will be used but not limited to:

9.0.4.1 Inspection checklist books

9.0.4.2 PV de Constant measuring tape and camera/tablet in good condition and if any dysfunctional issue is noticed with tools to be used, it must be declared before the inspection

9.0.5 Conducting the inspection

9.0.5.1 The inspection should be conducted professionally in a calm and respectful mood,

9.0.5.2 The team of inspectors is chosen according to the premise category to be inspected and the relevant qualifications

9.0.5.3 The inspectors introduce themselves to the applicant and explain the reason and importance of the inspection and be identified by their uniforms, service cards or badges,

9.0.5.4 The applicant introduces the responsible technician to provide technical details,

9.0.5.5 The inspectors verifies if the technician (s) introduced at the site of inspection are the same with the ones in the submitted application,

9.0.5.6 Inspectors use the inspection checklist to obtain required information,

9.0.5.7 Recommendations are given using the PV,

9.0.5.8 When filling the PV, the inspector should start with the critical, major, moderate and end with minor recommendations

9.0.5.9 After the inspection, the inspectors discuss and agree with applicant on the inspection findings and both parties sign the PV. The inspectors give the signed copy of the PV to the applicant

9.0.5.10 The inspectors prepare a feedback letter highlighting all recommendations given to the applicant for hierarchy approval and the feedback has to reach to the applicant within 10 working days from the inspection date,

9.0.5.11 Applications whose premises are inspected and found to be satisfactory are tabled for approval in the internal committee meeting chaired by the Head of Food and drugs inspection and safety monitoring department every week. If the presentation is satisfactory, the application is recommended for approval.

9.0.6 Internal committee review

9.0.6.1 During this session, inspectors present their findings to the committee preferably with pictures to help members of the committee to take better decision,

9.0.6.2 When the committee finds the inspections, results fulfilling the minimum requirements as per regulations and guidelines, the application is given the approval and,

9.0.6.3 The inspection book, reports of the inspection and minutes of the internal committee review are handled to the staff assigned with the dossier to incorporate them in the application dossier,

9.0.6.4 The staff assigned with the dossier, prepares the operational license and submits the license for hierarchy approval and it must be issued within 10 days from committee review date

9.0.7 Handling of collected sample from the inspection

9.0.7.1 The samples collected from inspection must be transported with care to the laboratory for testing

9.0.7.2 The reception form for submitting the samples must be signed by the inspector and the person in charge of the laboratory

9.0.7.3 Test results should be shared to the inspector from Food and Drugs Inspection & compliance Division

9.0.7.4 The decision should be taken in the committee meeting chaired by different members (Head of Department, Division Manager, Analyst, Specialist in charge) based on the report interpretation of the laboratory results prepared by the inspector.

9.0.8 Publication of licensed premises on the Rwanda FDA Website

9.0.8.1 The recent licensed premises are regularly recorded in the existing database of licensed regulated premises

9.0.8.2 The list is prepared with respect to any variation including resignation of responsible technician, relocation, change of ownership, and temporary closure of the activities

9.0.8.3 The list to be published on the website is prepared by the Analyst/Specialist in charge of the database for regulated premises, and sent to the Head of Department through the Division Manager for review

9.0.8.4 The list is shared to the Quality Assurance Analyst to approve the format

9.0.8.5 The approved list is signed by the Director General

9.0.8.6 The endorsed list is sent to the IT for publication on Rwanda FDA website

9.0.8.7 The publication should be done at least once a quarter

9.0.9 Enforcements activities for regulated premises

9.0.9.1 Enforcement shall be conducted for follow up after the inspection of regulated premises at least once a year for premise suitability and to ensure that the condition in which the operational license was granted are still in line with requirements

10.0 Records

List of licensed regulated premises published on the Rwanda FDA website, Checklist, PVs, reports and other tools used during the inspection shall be maintained at the registry for a period of 5 years

11.0 References

11.1 Rwanda FDA guidelines for Licensing to Manufacture, to Operate as Wholesale and Retail Seller of Medical Products

12.0 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

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