RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Food and Drugs Inspection and Safety Monitoring Department	
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RWANDA FDA Rwanda Food and Drugs Authority	**SOP ON LICENSING INSPECTIONS**	Revision Number	:0
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RWANDA FOOD AND DRUGS AUTHORITY

STANDARD OPERATING PROCEDURE (SOP) ON LICENSING INSPECTIONS

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Signature & Date						

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1.0 Purpose

The purpose of this Standard Operating Procedure (SOP) is to guide licensing inspections in ensuring that licensed establishments comply with laws and regulations governing licensing requirements.

2.0 Scope

This Standard Operating Procedure: Shall apply to all licensing inspections organized by Rwanda FDA

3.0. Responsibility

3.0.1. Head of Food and Drugs Inspection and Safety Monitoring Department: ensures that this SOP is correctly and consistently implemented during licensing inspections

3.0.2. Division Manager, Food and Drugs Inspections & Compliance: ensures the adherence of the staff to this SOP

3.0.3. Quality assurance analyst: ensures the use of update version of the SOP, recalls obsolete documents and keeps document master list

3.0.4. Inspectors: adhere to the SOP during licensing inspection

4.0. Distribution

4.0.1. Head of Food and Drugs Inspection and Safety Monitoring Department

4.0.2. Division Manager, Food Inspections & Compliance Division

4.0.3. Quality assurance analyst

4.0.4. Analyst

4.0.5. Specialists

5.0. PROCEDURE

5.0.1. Receipt and processing of applications:

5.0.1.1. 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.

5.0.1.2 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**.**

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

5.0.1.4. 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

5.0.1.5. 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.

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

5.0.1.**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

7.0.2. 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*

7.0.3. Preparation of the inspection

7.0.3.1. 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

7.0.3.2. The DM assigns the staff to draft the concept note and mission authorization of the inspection for approval,

7.0.3.3. For new applications, Inspectors conduct the inspection within 5 working days in Kigali City and 10 days outside Kigali City from the date of reception.

7.0.4. Preparation of inspection material

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: inspection books, PVs, 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

7.0.5. Conducting the inspection

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

7.0.5.2. 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,

7.0.5.3. The applicant introduces the responsible technician to provide technical details,

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

7.0.5.5. Inspectors use the inspection checklist to obtain required information,

7.0.5.6. Recommendations are given using the PV,

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

7.0.5.8. 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

7.0.5.9. 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 days from the inspection date,

7.0.5.10. 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.

7.0.6. Internal committee review

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

7.0.6.2. When the committee finds the inspection results fulfil the minimum requirements as per regulations and guidelines, the application is given the approval and,

7.0.6.3. 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,

7.0.6.4. 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

8.0 Records

Checklist, PVs, reports and other tools used during the inspection shall be maintained at the registry for a period of 5 years

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
16/11/2020	0	QMS Specialist	First issue