



STEPS FOR INITIAL APPLICATION FOR A LICENSE TO OPERATE (LTO) AND MAJOR VARIATION

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Encode required fields in the on- line application and upload the documentary requirements.		-	-	Applicant
	 Pre-assessment of the on-line applications and attached documents. *If complete, order of payment will be generated. **If not, a system generated notification will be sent to the facility stating that the application is hereby denied. 	-	-	CDRRHR- RRD Assessor
2. Download, print order of payment, pay the corresponding fee at the FDA recognized payment centers.	2. Validation and posting of payment.	Refer to Table of Fees Above	-	FDA Cashier
	3. Queuing/ decking of application to the assigned inspector.	-	3 working days	CDRRHR- RRD Evaluator





	IOTAL.	Fees Above		
4. Download and print the issued LTO/LOD.	TOTAL:	- Refer to Table of	- 20 worl	Applicant king days
4. Download and print the issued	6. Approves/disapproves the LTO/LOD.	-	3 working days	CDRRHR Director
	5. Reviews/ recommends the LTO/LOD for final approval/ disapproval to the center director.	-	7 working days	CDRRHR- RRD Division Chief
3. Applicant upload the compliance documents from the noted deficiencies during inspection in the RRD portal.	 4. Conducts pre-licensing inspection and upload inspection report in the RRD portal. *If compliant, application is recommended for the issuance of authorization. **If not, the assigned inspector shall notify the applicant of the lacking regulatory requirements. ***If the facility fails to comply within the prescribed period, a letter of disapproval shall be sent to the facility. 	-	7 working days	CDRRHR- RRD Assigned Inspector