



STEPS- RENEWAL/AMENDMENT APPLICATION FOR COC AND INITIAL/RENEWAL/AMENDMENT APPLICATION FOR COR

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Submits the required documents to FDA through email.	1. Decking of application to the assessor for pre- assessment.	-	-	CRRRHR-RRD Data controller
	2. Pre-assessment of the applications and attached documents. *If complete, issue order of payment. **If not complete, assessor will send a notification of lacking documents. ***If the noted deficiencies are not submitted on or before the deadline, the application is denied.	-	-	CRRRHR-RRD Assessor
2. The applicant/authorized officer downloads the issued order of payment and pays the corresponding fee to the FDA recognized payment centers. The proof of payment is sent to the assessor through email.		Refer to Table of Fees Above	-	Applicant
	3. The FDA will receive the payment from the applicant for validation and posting.	-	-	FDA Cashier Personnel



	4. Evaluates the application documents. *If correct, draft COC/LTO/COR for quality assurance. **If not, the evaluator shall notify the applicant of the lacking regulatory requirements. ***If the facility fails to comply within the prescribed period, a Letter of Disapproval (LOD) shall be sent to the facility.	-	7 working days	CDRRHR-RRD Evaluator/ Technical Officer
	5. Reviews /recommends the COC/LTO/COR/LOD for approval/disapproval to the Center Director.	-	7 working days	CDRRHR-RRD Division Chief
	6. Approves/disapproves and signs COC/LTO/COR/LOD.	-	3 working days	CDRRHR Director
	7. Encodes and endorses the approved COC/COR/LOD to Records Section for releasing/for mailing.	-	3 working days	CDRRHR-RRD Data Controller
	TOTAL:	Refer to Table of Fees Above	20 working days	
<p>Please be advised that as per RA No.11032 IRR, page 22 of 48, Section 3, b) The maximum time prescribed in Section 9 (b) (1) of the Act may be extended only once for the same number of days, which shall be indicated in the Citizen's Charter.</p> <p>Note: *For Amendment applications, additional working days for inspection as deemed necessary. **Day 1 commences upon posting of payment.</p>				