



18. RENEWAL REGISTRATION OF EQUIPMENT/DEVICES USED TO TREAT SHARPS, PATHOLOGICAL AND INFECTIOUS WASTES

Center/Office/Division	: CDRRHR-LRD
Classification	: Highly Technical
Type of Transaction	: G2B - Government-to-Businesses
Who May Avail	: Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	: Manufacturers/Distributors/TSD Facility A) Below Php 1,000,000.00: 3,000 + 1% LRF = Php3,030.00 B) Php 1,000,000 – Php 5,000,000: 3,000 + 1% LRF = Php3,030.00 C) Above Php 5,000,000: 3,000 + 1% LRF = Php3,030.00 Healthcare Waste Generators: 2,000 + 1% LRF = Php2,020.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Properly and completely filled-up application form. Form may be downloaded from the FDA website. - Must be signed by the company representative with date when signed	Applicant
2. Copy of issued CPR	Applicant
3. Result of valid Microbiological Tests/Leachate Characteristic Toxicity Test within the last 3 years. These tests should be conducted by the NRL. Performance evaluation testing is not required to be submitted given that the previous test results are still valid. - If the NRL performance evaluation conducted is beyond three (3 years) CDRRHR will endorse the application to NRL	Applicant
4. Location of installation - Location of Installation shall be filled-up since the equipment will be inspected and tested for performance evaluation if the latest NRL report is beyond three (3) years.	Applicant



5. Copy of valid License to Operate (LTO)	Applicant
<p>Notes:</p> <ol style="list-style-type: none"> 1. This office shall not accept applications with incomplete requirements. 2. All documents should be submitted in electronic copy format. 3. All information contained in this application form will be held strictly confidential. <p>* Application should be filed two (2) months prior to the expiration of the validity of the CPR.</p>	
<p>*Submission schedule is every Thursday from 8:00 AM to 5:00 PM.</p> <p>This schedule applies to working days only and excludes national and declared non-working days. In the event of a holiday/non-working day, then the regular schedule shall be followed on the next working and scheduled submission day.</p>	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to fdac.letters@fda.gov.ph following the correct schedule.	1. Receiving officer generates a Document Tracking Number (DTN) and sends an acknowledgment email / order of payment to the client.	None		FDAC Officer
2. The applicant company receives the Order of Payment and pays the assessed fee through FDAC Cashier or any other means prescribed by FDA. (e.g.	2. FDA receives the payment from the applicant company for posting.	See above table Php3,030.00/	Timeline starts after posting of	FDA Cashier



BANCNET, LANDBANK ONCOLL)		Php2,020.00	payment	
*The Order of Payment will only be valid for 24 hours				
3. The applicant company receives the official receipt and sends the proof of payment to FDA Action Center (FDAC) through email	3. FDAC forwards the application to CDRRHR.	None	1 working day	FDAC Officer
	4. CDRRHR assigns the application to the evaluator	None	1 working day	CDRRHR Admin Staff
*Equipment are subject for performance evaluation every three (3) years.	5. Technical evaluation of application. Issuance of a Notice of Deficiencies and endorsement to NRL for performance evaluation (if applicable)	None	5 working days	Technical Evaluator
	6. Performance Testing	c/o NRL	Timeline depends on the NRL	c/o NRL-EAMC
Client complies with the Notice of Deficiencies *Clients are given 30 days to comply with the NOD. Non-compliance would mean disapproval of the application.	7. Evaluator reviews compliance documents and review of result of performance testing. After evaluation, application may be endorsed for CPR if the requirements are complete. Otherwise, evaluator issues a re-application letters.		5 working days	Technical Evaluator
	8. Quality Assurance – Checking of	None	2 working days	LRD Chief



	recommendation of the Supervisor.			
	9. Drafting and finalization of CPR.	None	1 working day	CDRRHR Administrative Staff
	10. Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	11. Assigning of number	None	1 working day	CDRRHR Administrative Staff
	12. Transmittal to Records Section.	None	1 working day	CDRRHR Administrative Staff
	13. Scanning and Barcoding of CPR	None	1 working day	AFS Records Officer / Administrative Officer
	14. Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative Officer
	TOTAL			
		Php3,030.00/ Php2,020.00	20 working days**	

**Day 1 commences upon the receipt of the proof of payment / posting of payment.*

***Service is covered under Republic Act No. 3720 Section 21 as amended by Executive Order No. 175 Section 13.*