19. TURNED INITIAL REGISTRATION OF EQUIPMENT/DEVICES USED TO TREAT SHARPS, PATHOLOGICAL AND INFECTIOUS WASTES (For CPR's that are expired beyond 120 days/4 months and above)

Center/Office/Division	:	CDRRHR-LRD
Classification	:	Highly Technical
Type of Transaction	:	**Government-to-Businesses**
Who May Avail	:	Medical Device Manufacturers/Distributors (Importer/Exporter/Wholesaler)/Trader
Fees to be Paid	:	**(4 Months and Above) – TURNED INITIAL**

Manufacturers/ Distributors/ TSD Facility	Surcharge	Penalties 40%	Initial Fee	LRF 1%	Total
Below Php 1,000,000.00	6,000	2,000	5,000	50	Php13,050
Php 1,000,000 – Php 5,000,000	6,000	3,200	8,000	80	Php17,280
Above Php 5,000,000	6,000	4,000	10,000	100	Php20,100
Healthcare Waste Generators	4,000	1,200	3,000	30	Php8,230

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Properly and completely filled-up application form - Must be signed by the company representative with date when signed - Location of Installation shall be filled-up since the equipment will be inspected and tested for performance evaluation.	Applicant. Form may be downloaded from the FDA website.
2. Copy of issued CPR	Applicant
3. Copy of valid License to Operate (LTO)	Applicant

4. Copy of SEC Articles of Incorporation or DTI Certificate of Business Registration - The activity of manufacturing, importing or distributing the equipment should be reflected in the Articles of Incorporation - The DTI Certificate of Business Registration must be valid.	Applicant
5. Technology Approval from DOST-ITDI for new technologies	Applicant
6. Technical Report:	
6.1. Company profile;	Applicant
6.2. Characteristics and Sources of generated waste;	Applicant
6.3. Detailed description of treatment equipment to be tested including manufacturer's instructions and technical specifications;	Applicant
6.4. Operating procedures and conditions including as applicable treatment time, pressure, temperature, chemical concentration, doses, feed rates and waste load composition;	Applicant
6.5. Storage, handling and volume capacity;	Applicant
6.6. Applicable emission controls for suspected emissions;	Applicant
6.7. Potential hazards/toxicities of waste residues;	Applicant
6.8. Energy efficiency	Applicant
6.9. Occupational safety and health assurance.	Applicant
7. Copy of Operation Manual	Applicant
8. Layout / Plans	Applicant
8.1. Location of installation;	Applicant
8.2. Design / Drawing or picture of the device / equipment applied for;	Applicant
9. Supplementary requirements for equipment / devices used for chemical disinfection:	Applicant
9.1. Material Safety Data Sheet (MSDS) of the chemicals to be used for disinfection	Applicant
9.2. The chemical to be used should be registered with the DENR-EMB or must be compliant with the WHO guidelines for hazardous wastes.	Applicant

For healthcare waste generators (e.g. hospitals) and Treatment, Storage and Disposal (TSD) Facilities, the Environmental Compliance Certificate (ECC) issued by the Environmental Management Bureau-Department of Environment and Natural Resources (EMB-DENR) and the License to Operate issued by the Department of Health shall be submitted together with the above documentary requirements. - License to Operate should be valid.	Applicant
Notes: 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.	
*Submission schedule is every Thursday from 8:00 AM to 5:00 PM. 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.	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME*	PERSON RESPONSIBLE
1. Client sends an email containing the PDF of their application to cdrrhr-productregistration@fda.gov.ph following the correct schedule for application.	1. Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None		CDRRHR Officer
	2. Pre-assessment and issuance of Order of Payment or Denial Letter.	None	10 working days	Technical Evaluator

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. BANCNET, LANDBANK ONCOLL). *The Order of Payment will only be valid for 3 working days.	3. FDA receives the payment from the applicant company for posting.	Refer Table Above Php13,050/ Php17,280/ Php20,100/ Php8,230	**Timeline starts after posting of payment**	FDA Cashier
3. The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email.	4. CDRRHR assigns the application to an evaluator.	None	2 working days	CDRRHR Administrative Staff
	5. Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	20 working days	Technical Evaluator
4. 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.	6. Evaluator reviews compliance documents.	None	10 working days	Technical Evaluator
	7. Once fully complied, endorsed to NRL for Performance Evaluation	None	1 working day	Technical Evaluator

.	Performance Testing	c/o NRL	**Timeline depends on the NRL procedure**	c/o EAMC-NRL
	8. Review of Performance Evaluation report	None	5 working days	Technical Evaluator
	9. Quality Assurance - Checking of recommendation of the Supervisor	None	5 working days	LRD Chief
	10. Drafting and finalization of CPR.	None	2 working days	CDRRHR Administrative Staff
	11. Final Approval/Disapproval and signature of the Director	None	1 working day	CDRRHR Director
	12. Assigning of number.	None	1 working day	CDRRHR Administrative Staff
	13. Transmittal to the Records Section.	None	1 working day	CDRRHR Administrative Staff
	14. Scanning and barcoding of CPR.	None	1 working day	AFS Records Officer / Administrative Officer
	15. Queuing and endorsement to the FDA Releasing Section.	None	1 working day	AFS Records Officer / Administrative

				Officer
	TOTAL	**Php17,280/ Php20,100/ Php8,230**	**50 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.*