



17. INITIAL 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: 5,000 + 1% LRF = Php5,050.00 B) Php 1,000,000 – Php 5,000,000: 8,000 + 1% LRF = Php8,080.00 C) Above Php 5,000,000: 10,000 + 1% LRF = Php10,100.00 Healthcare Waste Generators: 3,000 + 1% LRF = Php3,030.00

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Properly and completely filled-up application form <ul style="list-style-type: none"> - Must be signed by the company representative and dated - 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 SEC Articles of Incorporation or DTI Certificate of Business Registration <ul style="list-style-type: none"> - 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
3. Technology Approval from DOST-ITDI for new technologies	Applicant
4. Technical Report:	
4.1. Company profile;	Applicant
4.2. Characteristics and Sources of generated waste;	Applicant



4.3. Detailed description of treatment equipment to be tested including manufacturer's instructions and technical specifications;	Applicant
4.4. Operating procedures and conditions including as applicable treatment time, pressure, temperature, chemical concentration, doses, feed rates and waste load composition;	Applicant
4.5. Storage, handling and volume capacity;	Applicant
4.6. Applicable emission controls for suspected emissions;	Applicant
4.7. Potential hazards/toxicities of waste residues;	Applicant
4.8. Energy efficiency	Applicant
4.9. Occupational safety and health assurance.	Applicant
5. Copy of Operation Manual	Applicant
6. Layout / Plans	Applicant
6.1. Location of installation;	Applicant
6.2. Design / Drawing or picture of the device / equipment applied for;	Applicant
7. Supplementary requirements for equipment / devices used for chemical disinfection:	Applicant
7.1. Material Safety Data Sheet (MSDS) of the chemicals to be used for disinfection	Applicant
7.2. 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
8. Copy of valid License to Operate (LTO)	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 Friday 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 cdrhr-productregistration@fda.gov.ph following the correct schedule.	1. Receiving officer sends an acknowledgment email to the client and decks the application to the evaluator for pre-assessment.	None	Timeline starts after posting of payment	CDRRHR Officer
	2. Pre-assessment and issuance of Order of Payment or Denial Letter. (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.	Below Php 1,000,000.00: 5,000 + 1% LRF = Php5,050.00 Php 1,000,000 – Php		FDA Cashier



		<p>5,000,000: 8,000 + 1% LRF = Php8,080.00</p> <p>Above Php 5,000,000: 10,000 + 1% LRF = Php10,100.00</p> <p>Healthcare Waste Generators: 3,000 + 1% LRF = Php3,030.00</p>		
The applicant company receives the official receipt and sends the proof of payment to cdrrhr-productregistration@fda.gov.ph through email	4. The CDRRHR will assign the application to evaluator	None	2 working days	CDRRHR Admin Staff
	5. Technical evaluation of application. Issuance of a Notice of Deficiencies or endorsement.	None	20 working days	Technical Evaluator
Client complies with the Notice of Deficiencies * Clients are given 30 days to comply with the NOD. Non-compliance would	6. Evaluator reviews compliance documents		10 working days	Technical Evaluator



mean disapproval of the application.				
	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	Administrative Officer
	11. Final Approval/Disapproval and signature of the Director	None	2 working days	CDRRHR Director
	12. Assigning of number and printing of certificate	None	1 working day	CDRRHR Admin Staff
	13. Transmit to Record Section	None		CDRRHR Admin Staff
	14. Scanning and Barcoding of CPR	None	1 working day	AFS Records Officer / Administrative Officer
	15. Queuing and Endorsement to Releasing Section	None	1 working day	AFS Records Officer /



				Administrative Officer
	TOTAL	Php5,050.00/ Php8,080.00/ Php10,100.00/ Php3,030.00	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.*