6. CLEARANCE FOR CUSTOMS RELEASE

Center/Office/Division	Center for Device Regulation, Radiation Health and Research- Radiation Regulation Division
Classification	Simple
Type of Transaction	G2B- Government to Business
Who May Avail	Importer/Distributor of Radiation Emitting Devices
Fees to be Paid	PHP 310/ Unit

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
1. Written request for issuance of CFCR addressed to the Director of CDRRHR containing the following information documents: a. Number of units to be imported; b. Intended use of unit; c. Name and address of the facility where the unit will be installed (if available)	Applicant
2. A duly notarized letter guaranteeing submission to the CDRRHR of the name and address of the buyer of the device within fifteen (15) days of the sale/transfer of ownership of the device (if name of buyer is unavailable upon application).	Applicant
3. For radiation device item to be used for medical applications, a Certificate of Product Registration (CPR) or any equivalent document certifying that the product is safe and allowed to be sold in the country of origin issued by the Ministry of Health of the country of origin; 3.1 This document shall be duly authenticated by the Philippine Consulate if the country of origin is a non-apostille member; 3.2 This document shall be Apostilled if the country of origin is part of the Apostille Convention; 3.3 If the CPR is unavailable immediately, certificate of free sales and/or a duly notarized letter guaranteeing submission of this document to the CDRRHR, within sixty (60) days from receipt by the CDRRHR of the written request, shall be allowed in lieu of the CPR	3.1 Philippine Embassy in the country of origin 3.2 Philippine Embassy in the country of origin 3.3 Applicant/ Legal Person

4. Brochure/ Literature of the device/ devices.	Product Manufacturer
5. Copy of importer's permit.	Local government where the office of the importer is located
6. Copy of proforma invoice.	Importer

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.	-	-	CDRRHR-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.	-	-	CDRRHR-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 payment is sent to the assessor through email.		PHP 310.00/ unit	-	Applicant
	3. The FDA will receive the payment from the applicant for validation and posting.	-	-	FDA Cashier

	4. Evaluation of application. *If correct, application is recommended for the issuance of CFCR. **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 shall be sent to the facility.	-	1 working day	CDRRHR-RRD Evaluator
	5. Reviews/ recommends the draft CFCR/LOD for printing and final approval/disapproval of the Center Director.	-	1 working day	CDRRHR-RRD Division Chief
	6. Approves/disapproves and signs CFCR/LOD.			CDRRHR Director
	7. Endorses the CFCR/LOD to the Records Section for release/for mailing.	-	1 working day	CDRRHR-RRD Data Controller
	TOTAL:	**PHP310.00/ unit**	**3 working days**	

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.***

*Note: *Day 1 commences upon posting of payment.*