

ANNEX D

CENTER FOR DEVICE REGULATION, RADIATION HEALTH, AND RESEARCH

I. RADIATION FACILITIES

Category	LICENSE TO OPERATE	Fees (in Php)* (per machine)
		per year
Group A	Radiation facilities utilizing radiation emitting devices used for General Radiography/Fluoroscopy (fixed, mobile or transportable), Computed Tomography (CT), Single Photon Emission Computed Tomography/Computed Tomography (SPECT/CT), Positron Emission Tomography/Computed Tomography (PET/CT), Mammography (fixed or transportable), Lithotripsy, Dental Radiology (Panoramic/Cephalometric), Dental Cone Beam CT, Magnetic Resonance Imaging (MRI) and other emerging radiation devices in this category used for diagnosis of diseases	3,200.00
Group B	Radiation facilities utilizing radiation devices used for open-type industrial radiography, non-destructive testing and other emerging technologies in this category used for anti-crime and industrial applications	1,000.00
Group C	Radiation facilities utilizing equipment for interventional radiology (Cardiac Catheterization) and emerging radiation devices in this category used for interventional radiology procedures	5,000.00
Group D	Radiation facilities utilizing, Linear Accelerator, Tomotherapy or any combination, and emerging radiation devices in this category used for therapeutic/treatment of diseases	8,900.00
Group E	Radiation facilities utilizing Linear Accelerator for anti-crime and industrial application and emerging radiation devices in this category used for anti-crime and industrial application	3,100.00
	FACILITY REGISTRATION	
Group F	Radiation facilities utilizing radiation emitting devices used for bone densitometry (DEXA), security and baggage inspection system, education, training, research, closed-type industrial radiography, dental radiography utilizing periapical/intraoral x-ray devices and other emerging radiation devices in this category	1,900.00
OTHER AUTHORIZATIONS-RADIATION FACILITIES		
Certification / Permit Category		
Certificate of Safety Evaluation (CSE) for Non-Ionizing Radiation Facility (Extremely Low Frequency (ELF) and Radiofrequency Radiation (RFR) Facilities		2,600.00
Certificate of Radiation Measurement for ELF and RFR Facilities		9,200.00

Pre-Operational Permit for radiation facilities utilizing Linear Accelerator, Tomotherapy and emerging radiation devices in this category used for therapeutic/treatment of diseases and Medical Magnetic Resonance Imaging facilities	12,000.00
Clearance for Customs Release (CFCR)	900.00**
AMENDMENT/ VARIATION (Facility License/Registration)	
1. Inclusion of additional machine	Initial Fee shall apply
2. Change in business name or ownership 3. Change of authorized personnel 4. Removal/deletion of machine from issued authorization	2,400.00

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

**per unit

MEDICAL DEVICES AND HEALTH-RELATED DEVICES

LICENSE TO OPERATE	Fees per year (in PhP)*			
	Initial	Renewal	Variation (Minor) Per variation	Variation (Major) Per variation
Medical Device, Water Purification/Treatment Devices/System, Healthcare Waste Treatment (equipment or devices used for treating sharps, pathological, and infectious waste)				
1. Manufacturer (Low Risk)	30,900		1,600	13,200
2. Manufacturer (Medium-High Risk)	50,860			
3. Distributor (Importers, Exporters and Wholesalers) & Trader	8,500			
4. Retailer of Medical Device	3,900			
Treatment, storage and disposal (TSD) Facility Operator				
TSD Operator	3,800			

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

PRODUCT REGISTRATION (Medical Device)	Fees per year (in PhP)*			
	Initial	Renewal	Variation Minor	Variation Major
1. CIVDR Class A (Registration)	14,500		3,000	4,000
2. CIVDR Class B (Registration)	19,400			
3. CIVDR Class C (Registration)	20,000			

4. CIVDR Class D (Registration)	20,400			
5. Medical Device Listing	3,400			
Certificate of Medical Device Notification/Registration	13,500			
Certificate of Medical Device Registration - Class B	18,000	15,300		
Certificate of Medical Device Registration - Class C	18,500			
Certificate of Medical Device Registration - Class D	19,500			
1. CPR Reapplication	2,800			
Compassionate Special Permit	1,200			

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

PRODUCT REGISTRATION (Water Purification/Treatment Device)	Fees per year (in Php)*			
	Initial	Renewal	Variation Minor	Variation Major
Water Purification System - Initial	9,700	7,800	3,000	4,000
Water Purification Device - Initial				
CPR Initial - Healthcare Waste Treatment Equipment (below 1M)	17,500	15,700		
CPR Initial - Healthcare Waste Treatment Equipment (1M-5M)				
CPR Initial - Healthcare Waste Treatment Equipment (5M and above)				
CPR Initial - Healthcare Waste Generators				

* All fees are subject to an additional 1% for Legal Research Fee (LRF)

In Vitro Diagnostic (IVD) Registration	Fees per year (in Php)*			
	Initial	Renewal	Variation Minor	Variation Major
IVD Pregnancy Test Kits - Initial Existing	18,800	16,500	3,000	4,000
IVD - Existing	17,700	15,400		

* All fees are subject to an additional 1% for Legal Research Fee (LRF)