5. PRE-OPERATIONAL PERMIT (POP) FOR THERAPEUTIC X-RAY FACILITIES

CHECKLIST OF REQUIREMENTS	Where to Secure
1. Proof of Business Name (SEC or DTI Registration and Mayor' Business Permit)	Mayor's office from the municipality where the facility is located/ Department of Trade and Industry/ Securities and Exchange Commission
2. Design of the medical linear accelerator facility indicating shielding details duly evaluated, verified, and signed by a board-certified ROMP	Equipment Manufacturer
3. Technical description/specifications of the following equipment: a. Therapeutic X-ray Machine b. Treatment planning system c. Patient data management software if available d. Radiotherapy simulator or computed tomography simulator, e. All other equipment listed in Appendix V of AO 2013-0031 or as revised	Equipment Manufacturer
4. Certification issued by the equipment manufacturer a. That the Therapeutic X-ray machine in its present condition is compliant with the performance and safety requirements of the International Atomic Energy Agency (IAEA) and the International Organization for Standardization / International Electrotechnical Commission (ISO/IEC) b. On the availability of spare parts, maintenance, and repair services.	Equipment Manufacturer

5. Personnel requirements: Notarized contract of employment between the facility and: a. The radiation oncologist/s b. The certified radiation oncology medical physicist c. The radiation oncology medical physicist d. The four (4) radiologic technologists	Human Resource Department of the Applicant
6. Radiation Protection and Safety Program	Applicant (in coordination with the Radiation Protection Committee of the hospital)
7. Emergency procedures during testing, commissioning, internal, and external quality audit, and during clinical operation, including a system of reporting a radiological accident/incident	Applicant (in coordination with their in-house Radiation Oncology Medical Physicist)
8. Emergency preparedness and response plan in the event of radiological emergencies such as: a. Accident medical exposure of a patient b. Accident exposure of a worker c. Accident exposure of a member of a public	Applicant (in coordination with their in-house Radiation Oncology Medical Physicist)

STEPS FOR THE ISSUANCE OF PRE-OPERATIONAL PERMIT OF THERAPEUTIC X-RAY FACILITY

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 evaluation.	-	-	CDRRHR-RRD Data controller
	2. Evaluates the application documents. *If correct, draft POP for quality assurance. **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 (LOD) shall be sent to the facility.	-	5 working days	CDRRHR-RRD Evaluator/ Technical Officer
	3. Reviews /recommends the POP/LOD for approval to the Center Director.	-	7 working days	CDRRHR-RRD Division Chief
	4. Approves/disapproves and signs POP/LOD.	-	2 working days	CDRRHR Director
	5. Encodes and endorses the approved POP/LOD to Records Section for releasing/for mailing.	-	1 working days	CDRRHR-RRD Data Controller/AFS Records Personnel
	TOTAL:	**None**	**15 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.***