



Republic of the Philippines  
 Department of Health  
**FOOD AND DRUG ADMINISTRATION**  
 Filinvest Corporate City  
 Alabang, City of Muntinlupa



**CHECKLIST OF REQUIREMENTS FOR THE INITIAL ISSUANCE / RENEWAL OF  
 A LICENSE TO OPERATE (LTO) A THERAPEUTIC X-RAY FACILITY**

<input type="checkbox"/>	1.	Duly accomplished x-ray application form (2 copies).
<input type="checkbox"/>	2.	License application fee (refer to the schedule of fees below). Either a photocopy of the machine validated Land Bank of the Philippines (LBP) OnColl Payment Slip or Manager's Check or Cashier's Check payable to <b>FOOD AND DRUG ADMINISTRATION</b> . For LBP payment, you may visit FDA website through this link for the guidelines for payment portal: <a href="https://ww2.fda.gov.ph/index.php/issuances-2/cdrhr-laws-and-regulations-pertaining-to-all-regulated-medical-devices/cdrhr-fda-circular/508371-fda-circular-no-2018-004">https://ww2.fda.gov.ph/index.php/issuances-2/cdrhr-laws-and-regulations-pertaining-to-all-regulated-medical-devices/cdrhr-fda-circular/508371-fda-circular-no-2018-004</a> .
<input type="checkbox"/>	3.	Photocopy of the Official Receipt of the personal dose monitor (TLD or OSL) from the provider of personnel dose monitoring service.
<input type="checkbox"/>	4.	Photocopy of the <i>VALID</i> Professional Regulation Commission (PRC) license of all the radiation oncologist/s and radiotherapy technologists.
<input type="checkbox"/>	5.	Photocopy of the Philippine Radiation Oncology Society (PROS) or Philippine Board of Radiology in Radiation Oncology (PBR-RO) certificate/s of all radiation oncologists working in the therapeutic x-ray facility. <b>(FOR RENEWAL APPLICATION WITH NO CHANGES ON CURRENT RADIATION ONCOLOGIST/S, THIS REQUIREMENT IS OPTIONAL)</b>
<input type="checkbox"/>	6.	Photocopy of the PRC board certificate of all radiotherapy technologists and their certificates of training as specified in Section VI-A-4.3 of the AO No. 0031 series 2013. <b>(FOR RENEWAL APPLICATION WITH NO CHANGES ON CURRENT RADIOTHERAPY TECHNOLOGISTS, THIS REQUIREMENT IS OPTIONAL)</b>
<input type="checkbox"/>	7.	Photocopy of the Philippine Board of Medical Physics certificate s of all Radiation Oncology Medical Physicist/s (ROMP). For non-board certified ROMP/s, documentary evidence satisfying the provisions stated in section XV-C-2 of the AO No. 0031 series 2013. <b>(FOR INITIAL/VARIATION APPLICATION ONLY)</b>
<input type="checkbox"/>	8.	Notarized contract of employment between the facility and the <ol style="list-style-type: none"> <li>a. radiation oncologist/s</li> <li>b. radiation oncology medical physicist/s</li> <li>c. radiotherapy technologists</li> </ol>
<input type="checkbox"/>	9.	Notarized appointment of the Radiation Protection Officer (RPO) and the Assistant RPO. <b>(FOR INITIAL/VARIATION APPLICATION ONLY)</b>
<input type="checkbox"/>	10.	Duly filled-up and notarized affidavit of continuous compliance. <b>(FOR RENEWAL APPLICATION ONLY)</b>
<input type="checkbox"/>	11.	Photocopy of the latest License to Operate. <b>(FOR RENEWAL APPLICATION ONLY)</b>
<b>Additional documents to be submitted prior to the initial issuance of the LTO</b>		
<input type="checkbox"/>	1.	Acceptance Test Certificate signed by the technical representative of the equipment manufacturer/supplier and board certified ROMP (if available upon filing of application).
<input type="checkbox"/>	2.	Commissioning report of the equipment duly signed by the facility's certified ROMP.
<input type="checkbox"/>	3.	Conformance testing report of the x-ray units in the radiation oncology facility.
<input type="checkbox"/>	4.	LINAC output calibration report of the DOH- SSDL or of a third-party board certified radiation oncology medical physicist.

**Schedule of Fees (per machine)**

INITIAL	RENEWAL (Valid LTO)	Renewal of Expired LTO				
		1 <sup>st</sup> Month	2 <sup>nd</sup> Month	3 <sup>rd</sup> Month	4 <sup>th</sup> Month	> 4 months
2,020.00	1,010.00	3,110.00	3,210.00	3,310.00	3,410.00	4,420.00

*Note: For X-ray/CT Simulator, please refer to the schedule of fees for the diagnostic medical x-ray.*

**Notes:**

- The surcharge/penalty for late filing of the renewal of LTO will be assessed pursuant to the Implementing Rules and Regulations (Book II, Article I Section 3.A.2) of RA 9711 and to the FDA Circular No. 2011-004 as follows:  
*"An application for renewal of an LTO received after its date of expiration shall be subject to a surcharge or penalty equivalent to twice the renewal licensing fee and an additional 10% per month or a fraction thereof of continuing non-submission of such application up to a maximum of one hundred twenty (120) days. Any application for renewal of license filed thereafter shall be considered expired and the application shall be subject to a fee equivalent to the total surcharge or penalty plus the initial filing fee and the application shall undergo the initial filing and evaluation procedure."*
- Pursuant to FDA Circular No. 2011-003, a Legal Research Fee (LRF) amounting to "one percent (1%) of the filing fee imposed, but in no case lower than ten pesos" shall be collected.
- Incomplete requirements shall not be processed.
- For initial/renewal application, fee paid shall be forfeited when the facility fails to comply with the licensing requirements within 15 days upon proper notice from the CDRRHR.





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**APPLICATION FOR A LICENSE TO OPERATE A THERAPEUTIC X-RAY FACILITY**

**General Instructions:** Write legibly and in BLOCK letters. Put an "x" mark on appropriate tick box. Completely fill-up the required information and signatures. The CDRRHR will not receive and process unduly filled-up application forms. For requirements, please refer to the attached checklist.

<b>TYPE OF AUTHORIZATION</b> <input type="checkbox"/> New application <input type="checkbox"/> Renewal of LTO # _____ <input type="checkbox"/> Amendment to existing LTO # _____ <input type="checkbox"/> Hospital Based    Reason for amendment: _____ <input type="checkbox"/> Free Standing		<i>For CDRRHR use</i>  <b>DTN No.:</b> _____  <input type="checkbox"/> Thru mail <input type="checkbox"/> Walk-in  <b>Fee Paid</b> PHP: _____ O.R # _____ Date Paid _____  <b>Assessed by:</b> _____ Date : _____  <b>Evaluated by:</b> _____ Date: _____  <b>Status of the Facility:</b> _____ _____  <b>Action taken :</b> _____ _____  <b>Checked by:</b> _____ Date: _____  <b>Printed by:</b> _____ Date: _____  <b>Recommending Approval:</b> _____ Date: _____  <b>Encoded by:</b> _____ Date: _____
<b>I General Information</b> Name of Facility : _____ Facility Address : _____  Contact No./s : _____  Name and Address of the Applicant, Legal Person, Company, Organization, etc. Name : _____ Position/Designation : _____ Address : _____ Contact No./s: _____ Email Address : _____		
<b>II Name and qualifications of the personnel working in the therapeutic x-ray facility</b>		
<b>Chief Radiation Oncologist</b> Name : _____ Qualification : <input type="checkbox"/> FPROS <input type="checkbox"/> DPBR-RO PRC ID#/ Validity : _____ <b>SIGNATURE:</b> _____	<b>Radiation Oncology Medical Physicist (ROMP) / Radiation Protection Officer (RPO)</b> Name : _____ Qualification: _____ <b>SIGNATURE:</b> <b>ROMP / Assistant RPO</b> Name : _____ Qualification: _____ <b>SIGNATURE:</b> _____	
<b>Chief Radiotherapy Technologist :</b> Name : _____ Qualification : _____ PRC ID#/Validity : _____ <b>SIGNATURE:</b> _____	<b>Board Certified Radiation Oncology Medical Physicist (CMP-ROMP)</b> Name : _____ Qualification: _____ <b>SIGNATURE:</b> _____	
<b>III Declaration of the veracity of information: To be signed by the legal person/owner</b>  I hereby declare that all the information provided on the form and in support of this application is to the best of my knowledge complete and true in every particular.   <div style="text-align: right;">           _____  <b>Printed Name and Signature</b>            Position: _____            Date: _____         </div>		



**IV Equipment Specifications (All x-ray equipment in radiation oncology facility)**

**IV-A Linear Accelerator**

Manufacturer/ Brand	Model	Serial Number	Date of Manufacture	Country of Origin	Energy		Location
					Photon	Electron	

**IV-B Tumor Localization and Simulation**

*Type	Name of Manufacturer	Brand		Model		Serial Number		Max. kVp	Max. mA	Location
		Tube head	Control Console	Tube head	Control Console	Tube head	Control Console			

\*X-ray or CT-Simulator

**V Name and qualifications of other radiation oncologist/s, medical physicist/s, and radiologic technologist/s working in the radiation oncology facility:**

Name	Designation	Qualification	PRC License	Validity	Signature

Please use separate sheet if necessary

**VI Name and qualifications of other medical practitioners (i.e. nurses, nursing attendant, etc.) working in the radiation oncology facility:**

Name	Designation	Qualification	PRC License	Validity	Signature

Please use separate sheet if necessary

**VII Radiation Therapy Services:**

<input type="checkbox"/> Conventional Radiation Therapy	<input type="checkbox"/> 3D Conformal Radiation Therapy	<input type="checkbox"/> Intensity Modulated Radiation Therapy
<input type="checkbox"/> Image Guided Radiation Therapy	<input type="checkbox"/> Stereotactic Radiosurgery and Radiotherapy	<input type="checkbox"/> Stereotactic Body Radiotherapy
<input type="checkbox"/> Total Body Irradiation	<input type="checkbox"/> Total Skin Electron Irradiation	<input type="checkbox"/> Intra-operative Radiotherapy
<input type="checkbox"/> Tomotherapy/ Arc Therapy	<input type="checkbox"/> Adaptive Radiotherapy	<input type="checkbox"/> Respiratory Gated Radiotherapy
<input type="checkbox"/> Cyber Knife	<input type="checkbox"/> Others: Pls. specify _____	