



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

<input type="checkbox"/>	1.	Duly accomplished medical x-ray license 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 or certificate of subscription 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 radiologist/s and radiologic/x-ray technologist/s.
<input type="checkbox"/>	5.	Photocopy of the certificate of all the radiologist/s for being a Fellow of the Philippine College of Radiology (FPCR) or Diplomate of the Philippine Board of Radiology (DPBR). <b>(FOR RENEWAL APPLICATION WITH NO CHANGES ON CURRENT RADIOLOGIST/S, THIS REQUIREMENT IS OPTIONAL)</b>
<input type="checkbox"/>	6.	Photocopy of the PRC board certificate of all the radiologic/x-ray technologist/s. <b>(FOR RENEWAL APPLICATION WITH NO CHANGES ON CURRENT RADIOLOGIC/ X-RAY TECHNOLOGIST/S, THIS REQUIREMENT IS OPTIONAL)</b>
<input type="checkbox"/>	7.	For Radiologic/X-ray Technologist who will act as the radiation protection officer (RPO), photocopy of the certificate of training as proof that he/she had completed the RPO training provided by the FDA/DOH recognized training service provider. <b>(FOR RENEWAL APPLICATION WITH NO CHANGES ON CURRENT RADIATION PROTECTION OFFICER, THIS REQUIREMENT IS OPTIONAL)</b>
<input type="checkbox"/>	8.	Certificate of training of the head of the facility in radiology if he is not a FPCR/DPBR for government facilities and in areas with no FPCR/DPBR within 45 km vicinity radius.
<input type="checkbox"/>	9.	Photocopy of valid notarized contract of employment of all the radiologist/s and radiologic/x-ray technologist/s. The CDRRHR recommends that the contract be valid for at least one year.
<input type="checkbox"/>	10.	Photocopy of performance test report from FDA – CSL/DTI – PAB accredited testing body. <b>(FOR INITIAL/VARIATION APPLICATION OF CT SCAN/MAMMOGRAPHY ONLY)</b>
<input type="checkbox"/>	11.	Duly filled-up and notarized affidavit of continuous compliance. <b>(FOR RENEWAL APPLICATION ONLY)</b>
<input type="checkbox"/>	12.	Photocopy of the business/mayor's permit or SEC/DTI registration of the facility. <b>(FOR INITIAL/VARIATION APPLICATION ONLY)</b>
<input type="checkbox"/>	13.	Photocopy of the latest License to Operate. <b>(FOR RENEWAL APPLICATION ONLY)</b>
<input type="checkbox"/>	14.	Photocopy of a valid vehicle LTO registration (OR/CR). <b>(FOR TRANSPORTABLE X-RAY FACILITIES ONLY)</b>

**Schedule of Fees (per x-ray machine)**

mA RANGE	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
100 and below	810.00	410.00	1,250.00	1,290.00	1,330.00	1,370.00	1,770.00
101 up to 300	1,111.00	560.00	1,715.00	1,770.00	1,825.00	1,880.00	2,431.00
301 up to 500	1,414.00	710.00	2,180.00	2,250.00	2,320.00	2,390.00	3,094.00
501 up to 700	1,717.00	860.00	2,645.00	2,730.00	2,815.00	2,900.00	3,757.00
greater than 700	2,020.00	1,010.00	3,110.00	3,210.00	3,310.00	3,410.00	4,420.00

**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.



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



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**APPLICATION FORM FOR A LICENSE TO OPERATE A MEDICAL 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 # _____ Reason/s for amendment: _____		<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 medical x-ray facility</b>		
<b>Head of the Facility (Radiologist) :</b>  Name : _____ Qualification : <input type="checkbox"/> FPCR <input type="checkbox"/> DPBR <input type="checkbox"/> Others: _____ PRC ID#/ Validity : _____ <b>SIGNATURE:</b>	<b>Radiation Protection Officer</b>  Name : _____ Qualification: _____ <b>SIGNATURE:</b>	
<b>Chief Radiologic/X-ray Technologist :</b>  Name : _____ Qualification : <input type="checkbox"/> RRT <input type="checkbox"/> RXT PRC ID#/ Validity : _____ <b>SIGNATURE:</b>	<b>Medical/Health Physicist *</b>  Name : _____ Qualification: _____ <b>SIGNATURE:</b>  *if available	
<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 diagnostic and/ or interventional radiology facility)**

Manufacturer		Model	Maximum mA	Maximum kVp	Serial No.		Application/Use	Location
Control Console	Tube				Control Console	Tube		

\* For Application/Use, indicate whether  
 - Radiography (Stationary/Mobile)  
 - Radiography/Fluoroscopy (Mobile C-Arm)  
 - Bone Densitometry  
 - Radiography/Fluoroscopy (Stationary)

- Lithotripsy  
 - Mammography  
 - Computed Tomography  
 - Tumor Localization/Simulation

\*\* For Location, indicate location of x-ray machine such as :  
 - Radiology Department (Room Number)  
 - Floor, Building

**V Name and qualifications of other radiologists and radiologic/x-ray technologists working in the diagnostic and/ or interventional radiology 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, cardiologist, interventionalist, etc.) working in the diagnostic and/or interventional radiology facility:**

Name	Designation	Qualification	PRC License	Validity	Signature

Please use separate sheet if necessary

**VII X-ray Service Category: (Tick appropriate radiology services)**

<b>General Radiography</b>		
<b>Level One x-ray facility which is capable of performing the following non-contrast radiographic examinations:</b>		
<input type="checkbox"/> Chest for Heart and Lungs	<input type="checkbox"/> Vertebral Column	<input type="checkbox"/> Shoulder Girdle
<input type="checkbox"/> Extremities	<input type="checkbox"/> Localization of Foreign Body	<input type="checkbox"/> Thoracic Cage
<input type="checkbox"/> Skull	<input type="checkbox"/> Pelvis	<input type="checkbox"/> Abdomen
<b>Level Two x-ray facility which is capable of performing examinations done in the primary category and the following non-contrast and contrast radiographic examinations:</b>		
<input type="checkbox"/> Upper G.I. series	<input type="checkbox"/> Esophagography[Ba. Swallow]	<input type="checkbox"/> Paranasal Sinuses
<input type="checkbox"/> Small Intestinal Series	<input type="checkbox"/> Pelvimetry	<input type="checkbox"/> Scoliotic Series
<input type="checkbox"/> Barium Enema	<input type="checkbox"/> Fetography	<input type="checkbox"/> Skeletal Survey
<input type="checkbox"/> Hysterosalpingography	<input type="checkbox"/> Cardiac Studies with Barium	<input type="checkbox"/> Imperforated Anus
<input type="checkbox"/> Oral Cholegraphy	<input type="checkbox"/> Myelography	<input type="checkbox"/> Intravenous Pyelography
<b>Level Three x-ray facility which is capable of performing examinations done in the primary and secondary categories and the following invasive procedures:</b>		
<input type="checkbox"/> Sinuography	<input type="checkbox"/> Tomography	<input type="checkbox"/> All Non-Cardiac Percutaneous Procedures
<input type="checkbox"/> Fistulography	<input type="checkbox"/> Pacemaker Implants	<input type="checkbox"/> Visceral & Peripheral Angiography
<input type="checkbox"/> Sialography	<input type="checkbox"/> Retrograde Cystography	<input type="checkbox"/> Operative & Post-operative Cholangiography
<input type="checkbox"/> Bronchography	<input type="checkbox"/> Cerebral Angiography	<input type="checkbox"/> Endoscopic Retro. Cholangio. Pancreatography
<input type="checkbox"/> Retrograde Urography		<input type="checkbox"/> Lymphography/Lympangiography
<b>Specialized Diagnostic and Interventional X-ray Services</b>		
<input type="checkbox"/> Computed Tomography	<input type="checkbox"/> Mammography	<input type="checkbox"/> Digital Subtraction Angiography
<input type="checkbox"/> Lithotripsy	<input type="checkbox"/> Bone Densitometry	<input type="checkbox"/> Percutaneous Transluminal Angioplasty
<input type="checkbox"/> Cardiac Catheterization		<input type="checkbox"/> Tumour Localization and simulation