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

☐ 1. Duly accomplished medical x-ray license application form (2 copies).

☐ 2. License application fee (refer to the schedule of fees below). For mailed applications, Postal Money Order or Manager’s Check shall be payable to the FOOD AND DRUG ADMINISTRATION (PMO Address: Alabang Muntinlupa).

☐ 3. Photocopy of the Official Receipt of the personal dose monitor (TLD or OSL) from the provider of personnel dose monitoring service. (FOR RENEWAL APPLICATION ONLY)

☐ 4. Photocopy of the personal dose evaluation reports within the validity period of the previous license (FOR RENEWAL APPLICATION ONLY)

☐ 5. Photocopy of the certificate of the radiologist for being a Fellow of the Philippine College of Radiology (FPCR) or Diplomate of the Philippine Board of Radiology (DPBR) and a VALID Professional Regulation Commission (PRC) license.


☐ 7. Certificate of training of the radiologic/x-ray technologist in radiation protection if he/she acts as the radiation protection officer.

☐ 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.

☐ 9. Photocopy of valid notarized contract of employment of the Radiologist and Radiologic/X-ray technologist. The CDRRHR recommends that the contract be valid for at least one year.

☐ 10. Duly filled-up and notarized affidavit of continuous compliance (FOR RENEWAL APPLICATION ONLY).

☐ 11. Photocopy of the business/mayor’s permit or SEC/DTI registration of the facility (FOR INITIAL APPLICANTS AND RENEWAL APPLICANTS WITH NEW ADDRESS).

☐ 12. Photocopy of the latest License to Operate. (FOR RENEWAL APPLICATION ONLY).

☐ 13. Photocopy of a valid vehicle LTO registration (OR/CR). (FOR TRANSPORTABLE X-RAY FACILITIES ONLY)

Schedule of Fees (per x-ray machine)

<table>
<thead>
<tr>
<th>mA RANGE</th>
<th>INITIAL</th>
<th>RENEWAL (Valid LTO)</th>
<th>Renewal of Expired LTO</th>
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<tbody>
<tr>
<td></td>
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<td>1st Month</td>
<td>2nd Month</td>
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<td>100 and below</td>
<td>810.00</td>
<td>410.00</td>
<td>1,250.00</td>
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<td>101 up to 300</td>
<td>1,111.00</td>
<td>560.00</td>
<td>1,715.00</td>
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<td>301 up to 500</td>
<td>1,414.00</td>
<td>710.00</td>
<td>2,180.00</td>
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<td>501 up to 700</td>
<td>1,717.00</td>
<td>860.00</td>
<td>2,645.00</td>
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<td>greater than 700</td>
<td>2,020.00</td>
<td>1,010.00</td>
<td>3,110.00</td>
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Notes:
1. The surcharge/penalty for late filing of the renewal of LTO will be assessed pursuant to the Implementing Rules and Regulations (Book II, Article 1 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.”

2. 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.

3. Incomplete requirements shall not be processed.

4. For initial/renewal application, fee paid shall be forfeited when the facility fails to comply with the licensing requirements within 60 days upon proper notice from the CDRRHR. (Section 5 item no. 2 of the Bureau Order No. 005 s. 2005)
**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.

### TYPE OF AUTHORIZATION
- [ ] New application
- [ ] Renewal of LTO
- [ ] Amendment to existing LTO #________
- 
  Reason/s for amendment:________________________

### I General Information

<table>
<thead>
<tr>
<th>Name of Facility:</th>
<th>Facility Address:</th>
<th>Contact No./s:</th>
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| Name and Address of the Applicant, Legal Person, Company, Organization, etc. |
|-----------------|-----------------|-------------|
| Name:           | Position/Designation: |
| Address:        | Email Address:    |

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<tr>
<th>Contact No./s:</th>
<th>Email Address:</th>
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### II Name and qualifications of the personnel working in the medical x-ray facility

#### Head of the Facility (Radiologist):

- Name: ____________________________
- Qualification: [ ] FPCR [ ] DPBR
- PRC ID#/Validity: ____________________________
- SIGNATURE:

#### Radiation Protection Officer

- Name: ____________________________
- Qualification: ____________________________
- SIGNATURE:

#### Chief Radiologic/X-ray Technologist:

- Name: ____________________________
- Qualification: [ ] RRT [ ] RXT
- PRC ID#/Validity: ____________________________
- SIGNATURE:

#### Medical/Health Physicist *

- Name: ____________________________
- Qualification: ____________________________
- SIGNATURE:

*if available

### III Declaration of the veracity of information: To be signed by the legal person/owner

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.

**Printed Name and Signature**

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**Recommended Approval:**

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**Encoded by:**

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<th>Date:</th>
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IV  Equipment Specifications (All x-ray equipment in diagnostic and/or interventional radiology facility)

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Maximum mA</th>
<th>Maximum kVp</th>
<th>Serial No.</th>
<th>Application/Use</th>
<th>Location</th>
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<tbody>
<tr>
<td>Control Console</td>
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* For Application/Use, indicate whether
- Radiography (Mobile/Stationary)
- Mobile C-Arm Fluoroscopy
- Bone Densitometry
- Radio-fluoroscopy (Stationary)

** For Location, indicate location of x-ray machine such as:
- Radiology Department (Room 1.2.3 etc.)
- Lithotripsy
- 1st Floor, 2nd Floor, etc.
- Tumor Localization/Simulation

V  Name and qualifications of other radiologists and radiologic/x-ray technologists working in the diagnostic and/or interventional radiology facility

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
<th>Qualification</th>
<th>PRC License</th>
<th>Validity</th>
<th>Signature</th>
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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:

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<tr>
<th>Name</th>
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<th>PRC License</th>
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VII  X-ray Service Category: (Tick appropriate radiology services)

** General Radiography **

Level One x-ray facility which is capable of performing the following non-contrast radiographic examinations:
- Chest for Heart and Lungs
- Extremities
- Skull
- Vertebral Column
- Localization of Foreign Body
- Pelvis

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:
- Upper G.I. series
- Small Intestinal Series
- Barium Enema
- Hysterosalpingography
- Oral Cholecography
- Esophagography[Ba. Swallow]
- Pelvimetry
- Fetography
- Cardiac Studies with Barium
- Myelography

Level Three x-ray facility which is capable of performing examinations done in the primary and secondary categories and the following invasive procedures:
- Sinography
- Fistulography
- Sialography
- Bronchography
- Retrograde Urography
- Tomography
- Pacemaker Implants
- Retrograde Cystography
- Cerebral Angiography
- Lymphography/Lymphangiography
- All Non-Cardiac Percutaneous Procedures
- Visceral & Peripheral Angiography
- Operative & Post-operative Cholangiography
- Endoscopic Retro. Cholangio. Panreatography
- Lymphography/Lymphangiography

** Specialized Diagnostic and Interventional X-ray Services **

- Computed Tomography
- Lithotripsy
- Cardiac Catheterization
- Mammography
- Bone Densitometry
- Digital Subtraction Angiography
- Percutaneous Transluminal Angioplasty
- Tumour Localization and simulation