Republic of the Philippines
Department of Health
Food and Drug Administration

CENTER FOR DEVICE REGULATION, RADIATION HEALTH, AND RESEARCH

CHECKLIST OF REQUIREMENTS FOR INITIAL ISSUANCE / RENEWAL OF CERTIFICATE OF COMPLIANCE (COC) OF A MEDICAL X-RAY FACILITY

☐	1.	Duly accomplished medical x-ray license application form (2 copies).
☐	2.	Photocopy of the machine-validated Land Bank of the Philippines (LBP) OnColl Payment Slip for the payment of the license application fee. (Refer to FDA Circular 2021-019 for further payment guidelines.)
☐	3.	Photocopy of the Official Receipt of the personal dose monitor (TLD or OSL) from the provider of personnel dose monitoring service.
☐	4.	Photocopy of the *VALID* Professional Regulation Commission (PRC) license of all the radiologist/s and radiologic/x-ray technologist/s.
☐	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)**.** **(FOR RENEWAL APPLICATION WITH NO CHANGES ON CURRENT RADIOLOGIST/S, THIS REQUIREMENT IS OPTIONAL)**
☐	6.	Photocopy of the certificate of training of the radiologic/x-ray technologist who will act as the radiation protection officer (RPO) as proof that he/she completed the RPO training provided by an FDA- or DOH-recognized training service provider. **(FOR RENEWAL APPLICATION WITH NO CHANGES ON CURRENT RADIATION PROTECTION OFFICER, THIS REQUIREMENT IS OPTIONAL)**
☐	7.	Photocopy of certificate of training in radiology of the head of the facility if he/she is not an FPCR/DPBR for government facilities and for facilities in areas with no FPCR/DPBR within 45 km vicinity radius.
☐	8.	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 (1) year.
☐	9.	Photocopy of machine calibration report from FDA – CSL/DTI – PAB-accredited testing body. **(FOR INITIAL/VARIATION APPLICATION)**
☐	10.	Duly filled out Self-Assessment Forms. Refer to FDA Circular 2020-035 for the guide. **(FOR INITIAL/VARIATION APPLICATION)**
☐	11.	Photocopy of performance test report from FDA – CSL/DTI – PAB accredited testing body. **(FOR INITIAL/VARIATION APPLICATION OF CT SCAN/MAMMOGRAPHY ONLY)**
☐	12.	Duly filled out and notarized affidavit of continuous compliance. **(FOR RENEWAL APPLICATION ONLY)**
☐	13.	Photocopy of the business/mayor's permit or SEC/DTI registration of the facility. **(FOR INITIAL/VARIATION APPLICATION ONLY)**
☐	14.	Photocopy of the latest DOH License to Operate / Certificate of Accreditation. **(FOR RENEWAL APPLICATION ONLY)**

Schedule of Fees (per x-ray machine)

mA RANGE	INITIAL	RENEWAL (Valid LTO)	Renewal of Expired COC				
			1st Month	2nd Month	3rd Month	4th Month	> 4 months
100 and below	2,430.00	2,050.00	6,250.00	6,450.00	6,650.00	6,850.00	7,230.00
101 up to 300	3,333.00	2,800.00	8,575.00	8,850.00	9,125.00	9,400.00	9,933.00
301 up to 500	4,242.00	3,550.00	10,900.00	11,250.00	11,600.00	11,950.00	12,642.00
501 up to 700	5,151.00	4,300.00	13,225.00	13,650.00	14,075.00	14,500.00	15,351.00
greater than 700	6,060.00	5,050.00	15,550.00	16,050.00	16,550.00	17,050.00	18,060.00

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 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 equivalentto 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, butin no case lower than ten pesos"* shall be collected.
3. Incomplete requirements shall not be processed.

Civic Drive, Filinvest City, Alabang, 1781 Muntinlupa City
Trunk Line: (632) 8857 1900; Fax No. (632) 807 0751
URL: http://www.fda.gov.ph; e-mail: cdrrhr.rrd@fda.gov.ph

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Form No:	QWP-CDRRHR/RRD-01-Annex 1
Revision:	00

APPLICATION FORM FOR CERTIFICATE OF COMPLIANCE OF A MEDICAL X-RAY FACILITY

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

TYPE OF AUTHORIZATION

☐ New application ☐ Renewal of COC ☐ Amendment to existing COC # _____
Reason/s for amendment: _____

I General Information

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: _____

II Name and qualifications of the personnel working in the medical x-ray facility

Head of the Facility (Radiologist) :

Name: _____
Qualification: ☐ FPCR ☐ DPBR ☐ Others: _____
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.

_____
Printed Name and Signature
Position: _____
Date: _____

For CDRRHR use

DTN No: _____

☐Thru mail
☐Walk-in

Fee Paid
PHP: _____
O.R. #: _____
Date Paid: _____

Assessed by:
_____
Date : _____

Evaluated by:
_____
Date: _____

Status of the Facility:
_____
_____

Action taken:
_____
_____
_____

Checked by:
_____
Date: _____

Printed by:
_____
Date: _____

Recommending Approval:
_____
Date: _____

Encoded by:
_____
Date: _____

Civic Drive, Filinvest City, Alabang, 1781 Muntinlupa City
Trunk Line: (632) 8857 1900; Fax No. (632) 807 0751
URL: http://www.fda.gov.ph; e-mail: cdrrhr.rrd@fda.gov.ph

IV Equipment Specifications (All x-ray equipment in diagnostic and/or interventional radiology facility)

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

* For Application/Use, indicate whether:
- Radiography (Mobile / Stationary)
- Mobile C-arm Fluoroscopy
- Bone Densitometry
- Radio-fluoroscopy (Stationary)
- Lithotripsy
- Mammography
- Computed Tomography
- Tumor Localization/Simulation
- Single Photon Emission Computed Tomography
- Positron Emission Tomography

** For Location, indicate location of x-ray machine such as:
- Radiology Department (Room 1, 2, 3, etc.)
- 1st Floor, 2nd Floor, etc.

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)

General Radiography		
Level One x-ray facility which is capable of performing the following non-contrast radiographic examinations:		
☐*Chest for Heart and Lungs*	☐*Vertebral Column*	☐*Shoulder Girdle*
☐*Extremities*	☐*Localization of Foreign Body*	☐*Thoracic Cage*
☐*Skull*	☐*Pelvis*	☐*Abdomen*
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*	☐*Esophagography[Ba. Swallow]*	☐*Paranasal Sinuses*
☐*Small Intestinal Series*	☐*Pelvimetry*	☐*Scoliotic Series*
☐*Barium Enema*	☐*Fetography*	☐*Skeletal Survey*
☐*Hysterosalpingography*	☐*Cardiac Studies with Barium*	☐*Imperforated Anus*
☐*Oral Cholegraphy*	☐*Myelography*	☐*Intravenous Pyelography*
Level Three x-ray facility which is capable of performing examinations done in the primary and secondary categories and the following invasive procedures:		
☐*Sinugraphy*	☐*Tomography*	☐*All Non-Cardiac Percutaneous Procedures*
☐*Fistulography*	☐*Pacemaker Implants*	☐*Visceral & Peripheral Angiography*
☐*Sialography*	☐*Retrograde Cystography*	☐*Operative & Post-operative Cholangiography*
☐*Bronchography*	☐*Cerebral Angiography*	☐*Endoscopic Retro. Cholangio. Pancreatography*
☐*Retrograde Urography*		☐*Lymphography / Lympangiography*

Specialized Diagnostic and Interventional X-ray Services		
☐*Computed Tomography*	☐*Cardiac Catheterization*	☐*Percutaneous Transluminal Angioplasty*
☐*Single Photon Emission Computed Tomography / Computed Tomography (SPECT/CT)*	☐*Mammography*	☐*Tumour Localization and Simulation*
☐*Positron Emission Tomography / Computed Tomography (PET/CT)*	☐*Bone Densitometry*	☐*Others (please specify):* _____
☐*Digital Subtraction Angiography*	☐*Lithotripsy*	