Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

19 November 2020

FDA CIRCULAR
No. 2020-035

SUBJECT : **Interim Guidelines for the Conduct of Licensing Inspection for Radiation Facilities**

I. INTRODUCTION

Pursuant to the guidelines set forth by the Inter-Agency Task Force (IATF) for the Management of Emerging Infectious Diseases and the Civil Service Commission (CSC), the Food and Drug Administration (FDA) has adopted alternative work arrangements in light of the COVID-19 pandemic through the issuance of FDA Circular No. 2020-006. This issuance also suspended the acceptance of initial applications of radiation facilities and its subsequent licensing activities.

Since the IATF has already downgraded the community quarantine level in NCR to General Community Quarantine (GCQ), there is also a need to resume the authorization process while ensuring the protection and safety of FDA regulatory officers. As such, in the interest of service, this Circular is issued to provide the interim guidelines for the conduct of pre-licensing inspections of Health Physics teams of the Center for Device Regulation, Radiation Health, and Research (CDRRHR) of the FDA.

II. OBJECTIVES

This Circular aims to provide interim guidelines to all relevant stakeholders of the process of licensing inspection of a radiation facility in view of the transition in community quarantine guidelines.

III. SCOPE AND COVERAGE

This Circular shall apply to the following facilities applying for initial application for authorization on the use of radiation devices during all types of community quarantine:

1. Diagnostic X-ray Facilities
2. Therapeutic X-ray Facilities utilizing Medical Linear Accelerators
3. Dental X-ray Facilities
4. Industrial and Anti-Crime X-ray Facilities
5. Education and Research X-ray Facilities
6. Veterinary X-ray Facilities
7. Transportable X-ray Facilities
8. Magnetic Resonance Imaging Facilities

IV. GUIDELINES

A. The FDA shall resume the conduct of pre-licensing inspections for **Therapeutic X-ray Facilities utilizing Medical Linear Accelerators only**, parallel to the resumption of the acceptance of initial applications for LTO, COC, and COR of radiation facilities through FDA Circular No. 2020-026.

B. The pre-licensing inspections for Therapeutic X-ray Facilities utilizing Medical Linear Accelerators shall be done through on-line or virtual inspection with general procedures outlined in **Annex B**.

C. Issuance of authorization for all other types of radiation facilities shall be done following an interim radiation facility authorization process according to a risk-based approach shown in **Annex A** and to be verified through post licensing inspection after the lifting of quarantine measures.

V. REPEALING CLAUSE

All issuances, or parts thereof, which are inconsistent with the provisions of this Circular, including some provisions in the FDA Circular No. 2020-006, are hereby repealed, or modified accordingly

VI. EFFECTIVITY

This Circular shall take effect immediately. Notwithstanding, by virtue of the provisional or temporary nature of this Circular, subsequent guidelines and/or modifications may be issued, as the circumstances would warrant.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 20200715162709

ANNEX A

INTERIM RADIATION FACILITY AUTHORIZATION PROCESS FOR COVID-19

Authorization Track	Radiation Facility	Appropriate Action
A	• Therapeutic X-ray Facilities	Issuance of authorization shall be subject to conduct of pre licensing inspection through **on-line or virtual inspection (Annex B)**.
B	• Radiographic/ Fluoroscopic Machines (Stationary/ Mobile) • Cardiac Catheterization Machines • General Radiography (Stationary/Mobile) • Dental Panoramic/ CBCT/Cephalometric X-ray machines • Transportable X-ray Facilities • Industrial and Anti-crime X-ray facilities	Issuance of authorization shall be done after submission of the **Self-assessment form** outlined in ***Annex D*** in addition to the usual licensing requirements. Attached to these requirements are photos (if applicable and practicable). Scanned copies shall be transmitted through email in a properly labeled single pdf file. This will be verified through post licensing inspection after the lifting of quarantine measures.
C	• Computed Tomography Machines • Mammography Machines	Issuance of authorization shall be done after submission of the **Self-assessment form** outlined in ***Annex C*** in addition to the usual licensing requirements. Attached to these requirements are photos (if applicable and practicable). Scanned copies shall be transmitted through email in a properly labeled single pdf file. **Radiation scatter and leakage test** shall be included in the performance testing. If technical services for the conduct of performance tests is unavailable, a machine calibration certificate duly signed by the service engineer shall be provided as attachment to the application. Additionally, a notarized **Affidavit of Undertaking (*Annex E*)** shall be executed stating that the facility shall procure the services of a technical service provider for the conduct of performance testing **on or before the renewal of their authorization**.

D	• Magnetic Resonance Imaging (MRI) facilities • Bone Densitometry • Dental intraoral/Periapical X-ray • Education and research X-ray facilities • Veterinary X-ray facilities	Issuance of authorization shall be done after submission of usual licensing requirements to be verified through post licensing inspection after the lifting of quarantine measures.

ANNEX B

VIRTUAL INSPECTION PROCEDURES FOR A THERAPEUTIC X-RAY FACILITY

1. The licensee shall submit the complete and correct LTO documentary requirements as Listed in the Appendix III of AO No. 31 s. 2013 entitled "Requirements for the Operation of Therapeutic X-ray Facility Utilizing Medical Linear Accelerators".

2. The CDRRHR-RRD will evaluate the submitted LTO documentary requirements as usual.

3. If complete and correct, a self-assessment checklist for Therapeutic X-ray Facilities will be sent to the facility email to be accomplished by the Radiation Oncology Medical Physicist (ROMP) under the supervision of the Certified Medical Physicist in Radiation Oncology Medical Physics (CMP-ROMP) of the facility.

4. The accomplished self-assessment checklist and scanned copies of any additional requirements or documentary evidences shall be submitted by the licensee through existing email thread. All scanned copies will be uploaded in a google drive folder with the name of the facility as its primary folder name (Figure A) consisting of subfolders (Figure B). The CDRRHR-RRD shall have access to the google drive folder at any given time.

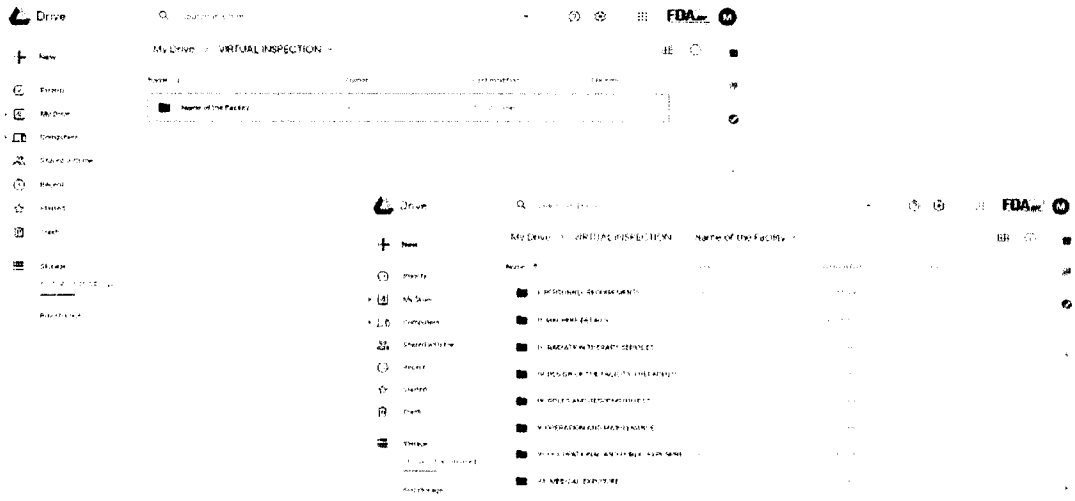

Figure A Primary Folder and its Subfolders

5. The CDRRHR-RRD will formally notify the applicant of the time and date of the virtual inspection one (1) week before its conduct. The virtual inspection of a therapeutic x-ray facility will be conducted for two (2) days.

6. The health physics team of CDRRHR-RRD shall initiate an online video conference and invite the licensee at the time and date agreed upon.

7. Opening conference shall be done as usual.

8. The health physics team shall interview the relevant persons as needed (ROMP, CMP-ROMP, Radiation Protection Officer (RPO), assistant RPO head of the facility and representative/s from the management of the therapeutic x-ray facility). Additionally, the presence of the chief radiation oncologist and the chief radiologic technologist will also be required.

9. The health physics team shall require the physical manifestation of requirements and /or documentary evidence as applicable. If possible, online viewing and/or tour of the facility shall be performed.

10. Additional documentary evidences (e.g. photos, videos, and documents) may be exchanged while conducting the inspection through shared google drive.

11. On the first day of the virtual inspection, the health physics team shall report to the licensee the initial findings of the inspection within the same day.

12. The facility may opt to comply with the initial findings within the inspection period by uploading additional evidences to the subfolder "COMPLIANCE" in the shared google drive.

13. On the second day of the virtual inspection, the health physics team shall review and evaluate all uploaded documents. An exit conference will be conducted as usual.

14. The Radiation Protection Survey and Evaluation (RPSE) report and Radiation Protection and Survey Form (RPSF) will be prepared and transmitted to the applicant's email within the same day.

15. Compliance to deficiencies or findings shall follow current authorization processes.

ANNEX C

THERAPEUTIC X-RAY FACILITY
SELF ASSESSMENT CHECKLIST
(Based on A.O. 124 s. 1992, A.O. 149 s. 2004, and A.O. 31 s. 2013)

Name of Facility	Date Accomplished
Facility Address	

Kindly put ✓ in the appropriate column with the specific requirement as stated below. Please provide evidence if necessary.

I. PERSONNEL REQUIREMENTS

REQUIREMENTS	YES	NO	N/A
1. One (1) radiation oncologist, who is an active member in good standing of the Philippine Radiation Oncology Society (PROS) and the Philippine College of Radiology. *(Refer to A.O. 31 s. 2013 Section 4.1.1)* a. A chief radiation oncologist who is certified in the practice of radiation oncology by the Philippine Board of Radiology in Radiation Oncology shall be appointed. *(Refer to A.O. 31 s. 2013 Section 4.1.2)* b. Please provide notarized employment contract between the facility and the Radiation Oncologist.			
2. A Certified Medical Physicist in Radiation Oncology Medical Physics (CMP-ROMP) who is certified by the Philippine Board of Medical Physics Section Radiation Oncology Medical Physics and is an active member in good standing of the Society of Medical Physicists in the Republic of the Philippines (SMPRP) shall be appointed. *(Refer to A.O. 31 s. 2013 Section 4.2)* a. The CMP-ROMP shall not be affiliated with not more than 3 facilities. *(Refer to A.O. 31 s. 2013 Section 4.2.2)* b. Please provide notarized employment contract between the facility and the CMP-ROMP.			
3. A full-time ROMP who is also an active member in good standing of SMPRP shall be hired. *(Refer to A.O. 31 s. 2013 Section 4.2)*			
4. The following documents and training certificates of ROMPs shall be provided: a. Notarized employment contract between the facility and the in-house ROMP; b. Structured clinical training in ROMP under the close supervision of a CMP-ROMP for a period of at least three (3) months *(Refer to A.O. 31 s. 2013 Section XV.C.2.b)*; c. One (1) week training on the facility's treatment planning system under the supervision of the supplier's application specialist; and d. One (1) week appropriate training in the equipment under the supervision of the supplier's application specialist.			

5. A minimum of four (4) full-time radiotherapy technologists (RTTs) shall be employed for each medical linear accelerator operating for an 8-hour shift. *(Refer to A.O. 31 s. 2013 Section 4.3.3)*			
6. Among the four (4) RTTs, a chief radiotherapy technologist who is registered with the Professional Regulation Commission (PRC) shall be appointed. *(Refer to A.O. 31 s. 2013 Section 4.3.5)*			
7. Refer to A.O. 31 s. 2013 Section 4.3.6-8 for provisions for additional RTTs in the facility.			
8. The following documents and training certificates of RTTs shall be provided: a. Notarized employment contract between the facility and RTTs. b. The RTTs shall have undergone training in a therapeutic x-ray facility for at least (6) months under the supervision of a senior RTT and CMP-ROMP. *(Refer to A.O. 31 s. 2013 Section 4.3.1)*			
9. RTTs shall undergo at least one (1) week appropriate hand-on training on the equipment under the supervision of the supplier's application specialist. *(Refer to A.O. 31 s. 2013 Section 4.3)*			
10. The Radiation Protection Officer (RPO) who is a medical physicist and has a proper training in radiation protection and safety in radiation therapy shall be appointed. Please provide appointment letter authorizing the RPO to stop all unsafe activities involving the operation of therapeutic equipment. *(Refer to A.O. 31 s. 2013 Section 4.4.1)*			
11. The Assistant RPO who has the same qualifications with the RPO shall also be appointed. Please provide appointment letter authorizing the RPO to stop all unsafe activities involving the operation of therapeutic equipment. *(Refer to A.O. 31 s. 2013 Section 4.4.3)*			

II. MACHINE DETAILS

A. Therapeutic X-ray Equipment

Name of manufacturer : _____
Address : _____
Model name and number : _____
Serial number : _____
Country of manufacture : _____
Year of manufacture : _____

**Please provide a photo of sticker of the therapeutic x-ray equipment.*

B. Diagnostic and Specialized X-ray Equipment Used in Radiotherapy

Manufacturer/Brand of Control Console : _____ **Serial Number** : _____
Manufacturer /Brand of X-ray Tube : _____ **Serial Number** : _____
Maximum mA : _____ **Maximum kVp** : _____
Shared with radiology department? : _____

C. Did the equipment undergo and pass the compliance testing before using the equipment to patients? If yes, please provide the following details and submit a copy of the conformance test results.

Type of imaging equipment : _____
Date of Testing : _____
Conducted by : _____
Test Result : _____

III. RADIATION THERAPY SERVICES

Level 1	☐ Conventional Radiation Therapy	
Level 2	☐ 3D Conformal Radiation Therapy	
Level 3	☐ Intensity Modulated Radiation Therapy	
Level 4	☐ Image Guided Radiation Therapy ☐ Stereotactic Body Radiotherapy ☐ Total Skin Electron Irradiation ☐ Tomotherapy/Arc Therapy ☐ Respiratory Gated Radiotherapy	☐ Stereotactic Radiosurgery and Radiotherapy ☐ Total Body Irradiation ☐ Intra-operative Radiotherapy ☐ Adaptive Radiotherapy ☐ Others: _____
Specialized	☐ Intraoperative Radiotherapy	☐ Others: _____

IV. DESIGN OF THE FACILITY, THERAPEUTIC X-RAY MACHINE AND ANCILLARY EQUIPMENT

REQUIREMENTS	YES	NO	N/A
1. The following documents shall be provided a. Commissioning results; b. Acceptance testing of therapeutic equipment; and c. Quality assurance program.			
2. Adequate ventilation shall be provided to protect the equipment from adverse heat.			
3. A physical inventory of all equipment and accessories to confirm that they are present and secure in their assigned locations.			
4. A dehumidifier shall be provided in the treatment room to protect the equipment from adverse heat.			
5. Fire detection and protection in the treatment room shall be provided.			
6. Mechanical door interlocks shall be provided and functioning.			
7. Standard warning sign and notice shall be installed on the door of the exposure room.			
8. Red warning light shall be installed at the top of the door leading to the exposure room.			
9. An intercom shall be provided to allow two-way communication between the patient being treated and the radiotherapy technologist at the control room.			
10. A CCTV cameral shall be provided to monitor the patient.			
11. The radiotherapy facility shall be equipped with ancillary equipment (Appendix V). Please provide a scanned copy of calibration certification of the following equipment: a. An ionization chamber of farmer type Brand/Model: _____ Serial Number: _____ Due date of Calibration: _____ b. A cylindrical ionization chamber (two sets per facility) Brand/Model: _____ Brand/Model: _____ Serial Number: _____ Serial Number: _____ Due date of Calibration: _____ Due date of Calibration: _____	,		

c. An appropriate radioactive source for checking the stability of the ionization chamber. Radioactive Material: _____ PNRI License No.: _____			
d. A plane-parallel ionization chamber for electrons. Brand/Model: _____ Serial Number: _____ Due date of Calibration: _____			
e. An electrometer compatible with the ionization chambers above and following the specifications of IAEA dosimetry publications. Brand/Model: _____ Serial Number: _____ Due date of Calibration: _____			
f. A water phantom for calibration (30cm x 40cm x 40cm) Brand/Model: _____ Serial Number: _____			
g. A radiation field analyzer/beam scanner to measure isodose distributions (50cm x 50cm x 40cm). Brand/Model: _____ Serial Number: _____			
h. Plastic slab phantom Brand/Model: _____ Serial Number: _____			
i. An aneroid type or digital barometer calibrated at a standards laboratory. Brand/Model: _____ Serial Number: _____ Due date of Calibration: _____			
j. A non-mercurial thermometer calibrated at a standards laboratory. Brand/Model: _____ Serial Number: _____ Due date of Calibration: _____			
k. In-house computerized treatment planning system Version number: _____			
l. An ionization chamber type radiation survey meter calibrated at a standards laboratory. Brand/Model: _____ Serial Number: _____ Due date of Calibration: _____			
m. Precision water level (bubble level) Brand/Model: _____ Serial Number: _____			
n. Graticule Brand/Model: _____ Serial Number: _____			
o. Portal verification device Brand/Model: _____ Serial Number: _____			
p. Patient specific QA tools (for level III and IV facilities) Brand/Model: _____ Serial Number: _____			
q. Mechanical isocenter phantom Brand/Model: _____ Serial Number: _____			

V. OPERATION AND MAINTENANCE

REQUIREMENTS	YES	NO	N/A
1. Adequate preventive and corrective maintenance shall be performed as necessary to ensure that design specifications for radiation protection and safety is retained throughout their useful life. Please provide the following documents: a. Preventive maintenance contract (or any document that supports the warranty of the therapeutic x-ray equipment); b. Planned preventive maintenance schedule (indicate frequency of the maintenance)			
2. The preventive and corrective maintenance of the equipment is performed only by the equipment manufacturer. Please provide scanned copy of training certificate.			
3. Records of preventive and corrective maintenance program shall be kept for reference.			

VI. OCCUPATIONAL AND PUBLIC EXPOSURE

REQUIREMENTS	YES	NO	N/A
1. Controlled and supervised areas in therapeutic x-ray facility are properly delineated. Please provide patient flow of the facility.			
2. Signs and notices at access points of controlled and supervised areas shall be provided.			
3. All personnel working in controlled areas are provided with individual dosimeters. **Service provider** : _____ **Subscription period** : _____ **Official Receipt No.** : _____ **No. of TLD/OSL** : _____			
4. Initial monitoring of radiation levels in the workplace shall be performed and documented. The area survey conducted by the facility shall indicate that the radiation room shielding is adequate and the dose rates around the room meet authorized radiation levels. The facility shall provide a copy of area monitoring performed in the facility.			
5. Medical supervision intended to ensure initial and continuous fitness of workers for their intended tasks shall be provided.			

VII. MEDICAL EXPOSURE

REQUIREMENTS	YES	NO	N/A
1. The facility shall provide a copy of patient chart with the following template: a. Pre-procedure assessment form (i.e. Radiation Oncologist's order form) b. CT order form; c. Radiotherapy prescription form; and d. Consent forms (i.e. pregnant patient)			
2. A comprehensive quality assurance program for medical exposures shall be developed and implemented in the facility. Please include this in the RPSP.			

VIII. EMERGENCY PLAN

REQUIREMENTS	YES	NO	N/A
1. The following emergency procedures shall be provided: a. In case of fire, flood and earthquake; b. In case the beam fails to terminated; c. In case of power failure; d. In case LINAC door fails to open (for automatic door only); e. Accidental medical exposure of a patient; f. Accidental exposure of a Member of the Public; and g. Accidental exposure of workers.			
2. The plan must be rehearsed at suitable intervals. Please provide proper documentations (i.e. photos, attendance, etc.).			

IX. ROLES AND RESPONSIBILITIES

REQUIREMENTS	YES	NO	N/A
1. The management shall develop, implement, maintain and document a radiation protection and safety program (RPSP) commensurate with the nature and extent of the risks associated with the practices in radiation oncology. Please refer to A.O. No. 31 s. 2013 Appendix IV *"Radiation Protection and Safety Programme"* for reference. The RPSP shall be completely signed with the appropriate signatories (prepared by, reviewed by, and approved by). Date of last program review: _____			
2. The management shall provide adequate resources (time and money) for personnel training.			
3. The RPO shall conduct initial training of workers. Please provide complete documentations (i.e. photos, attendance, handouts, certificates, etc.).			

X. DECLARATION

I hereby declare that this application has been accomplished by me, and that the foregoing information and attached documents required for the authorization are true and correct.

PREPARED AND ACCOMPLISHED BY:		
Name:	**Designation/Position:**	**Date:**

ATTESTED BY (FACILITY HEAD/MANAGER)		
Name:	**Designation/Position:**	**Date:**

ANNEX D

GENERAL X-RAY FACILITY SELF ASSESMENT CHECKLIST

(Adapted from the current FDA-CDRRHR Radiation Protection Survey and Evaluation (RPSE) Checklists)

Name of Facility	Date Accomplished
Facility Address	**X-ray Facility Level**

I. MACHINE DETAILS *(for those applied for initial authorization only)*

#	Machine Type	Manufacturer Name / Brand		Serial Number	
		Control Console	Tube	Control Console	Tube
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

II. PERSONNEL REQUIREMENTS

(please check "yes" if complied, "no" if not complied, and N/A if not applicable)

REQUIREMENT *(Based on DOH AO No. 35 s. 1994, AO No. 2-A s. 1996, and AO 149 s. 2004)*	**YES**	**NO**	**N/A**
1. The head of a diagnostic x-ray facility who is the person-in-charge of the activities shall be a qualified physician as defined in DOH Administrative Order No. 35 s. 1994 a. Diplomate or fellow of the Philippine Board of Radiology or the Philippine College of Radiology. b. Refer to section 4.1.1.2 to 8 of AO 35 s. 1994 if no physician with the qualification above. c. For Dental x-ray facilities, a PRC licensed dental practitioner with appropriate training in dental x-ray work as per DOH AO no. 2-A s. 1996.			
2. A fulltime x-ray/radiologic technologist who is registered with the Professional Regulation Commission (PRC) shall be hired for each machine. a. Required only for dental x-ray machines in lieu of an available duly qualified dental x-ray practitioner.			
3. The facility shall have a Radiation Protection Officer (RPO) who is one of the following: a. Head of the facility b. Medical Physicist c. Chief Radiologic Technologist of x-ray technologist with at least ten years working experience and attended a course on radiation protection conducted by an organization recognized by the CDRRHR. d. Dental practitioner with appropriate training for dental x-ray facilities.			

III. OPERATIONAL AND ADMINISTRATIVE REQUIREMENTS

(please check "yes" if complied, "no" if not complied. and N/A if not applicable)

REQUIREMENT *(Based on DOH AO No. 35 s. 1994, AO No. 2-A s. 1996, and AO 149 s. 2004)*	**YES**	**NO**	**N/A**
1. The facility shall establish a quality assurance program to ensure continuous compliance with the requirements set forth by the Department of Health under which the following policies should be included:			
a. The head of the facility shall establish a Quality Control (QC) Program/Manual for the x-ray facility under which the following policies should be included: ***(PROVIDE A SCANNED COPY)***			
i. List of individuals responsible for monitoring and maintenance.			
ii. Classification of areas as to controlled and supervised areas for occupational dose monitoring.			
iii. List of parameters to be monitored and frequency of monitoring.			
iv. Description of standards, criteria of quality, limits of acceptability for every machine to be monitored.			
v. Description of procedures to be done for every machine to be monitored.			
vi. Records of preventive and corrective maintenance done per machine including records of daily quality checks.			
vii. Records of frequency of changing solutions for darkroom image processing. *(if applicable)*			
viii. Operation manuals and circuit diagrams including tube rating charts and cooling diagrams.			
b. The Radiation Protection Officer (RPO) shall establish and be responsible for the conduct of a Radiation Protection/Safety Program under which the following policies should be included: ***(PROVIDE A SCANNED COPY)***			
i. Policy on dose monitoring for radiology personnel (including interns, OJTs), patients, carers, pregnant personnel, etc.			
ii. Policy on radiation protection/safety of pregnant women. (e.g. posting of notices, risk communication, etc.)			
iii. Records and analysis of personnel dose monitoring. Service Provider: _____ Subscription period: _____ Official Receipt No. _____ No. of TLD/OSL: _____			
iv. Records and policy on request and referral of x-ray examinations.			
v. Procedures and practices to reduce dose of patients, workers, and the public.			
vi. Guidelines of appropriate action for personnel/patient that exceeded dose limits. (action plan, corrective measures, risk communication, etc.)			
vii. Process of reporting and notification in cases of exceeded doses.			
c. All x-ray examinations should be justified by a qualified physician in which a proper request and referral policy should be established.			
d. Radiographic technique charts per x-ray machine posted near the control console. ***(PROVIDE A SCANNED COPY)***			
e. Records and analysis of image reject/spoilage. ***(IF APPLICABLE, PROVIDE PICTURE OF LOGBOOK)***			
f. Cleanliness and orderliness of the whole x-ray facility.			
g. File of written results signed by qualified physician.			

IV. GENERAL PHYSICAL PLANT REQUIREMENTS

(please check "yes" if complied, "no" if not complied, and N/A if not applicable) refer to individual machine checklist for physical plant requirements specific to an x-ray machine

REQUIREMENT *(Based on DOH AO No. 35 s. 1994, AO No. 2-A s. 1996, and AO 149 s. 2004)* ***(PROVIDE DIGITAL/SCANNED COPY OF FACILITY FLOOR PLAN/LAYOUT)***	**YES**	**NO**	**N/A**
1. For automatic/manual processing (Dark room processing)			
a. Adequate space *(2.0 m x 1.5m)*			
b. Processing tanks (*for manual processing only*)			
c. Separate paddles for processing tanks (*for manual processing only*)			
d. Light tight			
e. Well ventilated (with exhaust fan)			
f. Tinted standard safelight *(>1.3 m from working table)*			
g. Proper storage of unprocessed films			
h. Well-maintained intensifying screens			
i. Luminous timer/digital timer (*for manual processing only*)			
j. Non-mercurial thermometer (*for manual processing only*)			
2. For digital/computed radiography processing (DR/CR)			
a. Designated area for processing/viewing machine			
3. Waiting area for patients (provision/designated area)			
4. Film storage and/or reading area *(where applicable)* a. 1 m x 2 m for level one (1) x-ray facility *b.* 3 m x 3.5 m for level two (2) and three (3) x-ray facility			

V. INDIVIDUAL MACHINE REQUIREMENTS

Accomplish and attach applicable individual machine checklist (Annex C-I to IV)

I hereby declare that this application has been accomplished by me, and that the foregoing information and attached documents required for the authorization are true and corre

PREPARED AND ACCOMPLISHED BY:		
Name:	**Designation/Position:**	**Date:**

ATTESTED BY (FACILITY HEAD/MANAGER)		
Name:	**Designation/Position:**	**Date:**

INDIVIDUAL X-RAY MACHINE CHECKLIST

ANNEX D - I

Name of Facility
Facility Address

GENERAL RADIOGRAPHY AND FLUOROSCOPY X-RAY MACHINE REQUIREMENTS

(use additional sheets if necessary)

Machine # ☐

(based on Section I of the Annex C)

Applicable Type of Machines

Stationary X-ray Machine	Radio/Fluoroscopic X-ray Machine (RF)
Mobile X-ray Machine	Mobile C-arm Fluoroscopy Machine
Transportable X-ray Machine	Cardiac Catherization Fluoroscopic Machine

REQUIREMENT *(please check "yes" if complied, "no" if not complied, and N/A if not applicable)*	**YES**	**NO**	**N/A**
1. X-ray machine properly installed, operational, and duly accepted by the licensee with appropriate documents signed by installer/supplier and received by licensee representative/owner. ***(provide pictures/proof of installation/machine calibration certificate)***			
2. Audible and/or visible indication of x-ray production *(AO 35 s. 1994 sec. 5.1.14)*			
3. Means to set exposure factors ***(provide pictures of control console)*** *(AO 35 s. 1994 sec. 5.1.9)*			
4. Mechanically stable *(AO 149 s. 2004 sec. 3.2)*			
5. All moving parts move smoothly without obstructions to motion *(AO 149 s. 2004 sec. 3.2)*			
5. Adequate x-ray room size (for stationary x-ray & RF machines) ***(provide digital/scanned copy of facility floor plan/layout)*** *(AO 35 s. 1995 sec. 6.1)* a. X-ray w/o table: 2.5 x 3 m b. X-ray w table: 3.5 x 4 m c. X-ray w titling table: 4.5 x 4.5 m d. Transportable x-ray: 2 x 2 m			
6. Adequate shielding for the x-ray room (doors, walls, etc.) *(AO 35 s. 1995 sec. 6.2)* a. At least 6 inches thick poured concrete with a density of 2.35 g/cm^3 b. At least 1/6 in (1.5 mm) thick lead sheet glued onto and sandwich between wooden panels without any punctures during installation.			
7. Dressing Area ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.18)*			
8. Fixed/Movable Protective barrier with means of viewing patient (glass/acrylic with 1.5 mm lead equivalence) and with adequate shielding from x-rays similar to room shielding requirements. ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.4)*			
9. If windows are present, it should be elevated to height of at least 2 m from ground. ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.6)*			
10. With red warning light bulb ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.7)*			
11. With appropriate warning notice ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.8)*			
12. With adequate ventilation ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.1)*			
13. Toilet with door opening directly to x-ray room **if** examinations using contrast media will be performed ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.19)*			
14. Radiological accessories ***(provide pictures/proof of purchase)*** *(AO 35 s. 1995 sec. 6.20)*			
a. Caliper			
b. Contact gonadal shields all sizes *(>1.5 mm Pb equivalent) (not needed for x-ray facilities for chest, heart, and lung imaging only)*			
c. Upright gonadal shield *(>1.5 mm Pb equivalent)*			
d. Lead equivalent gloves *(>0.25 mm Pb equivalent) (not needed for x-ray facilities for chest, heart, and lung imaging only)*			
e. Lead equivalent apron *(>0.25 mm Pb equivalent)*			
f. Lead equivalent goggles *(for fluoroscopic machines only) (not needed for x-ray facilities for chest, heart, and lung imaging only)*			
g. Lead equivalent thyroid shields *(for fluoroscopic machines only) (not needed for x-ray facilities for chest, heart, and lung imaging only)*			

INDIVIDUAL X-RAY MACHINE CHECKLIST

ANNEX D - II

Name of Facility	
Facility Address	

COMPUTED TOMOGRAPHY X-RAY MACHINE REQUIREMENTS

(use additional sheets if necessary)

Machine # ☐

(based on Section I of the Annex C)

Applicable Type of Machines

Computed Tomography Machines	CT Simulator Machine for Radiation Therapy
PET CT Machines	
SPECT Machines	

REQUIREMENT *(please check "yes" if complied, "no" if not complied, and N/A if not applicable)*	**YES**	**NO**	**N/A**
1. CT unit assembly properly installed, operational, and duly accepted by the licensee with appropriate documents signed by installer/supplier and received by licensee representative/owner. ***(provide pictures/proof of installation)***			
2. Undergone and passed performance testing conducted by PLSD-CSL or by DTI-PAB accredited testing laboratory *(attach report of service provider)* *(BO 220 s. 2002)*			
3. Adequate x-ray room size (*manufacturers specifications*) *(AO 35 s. 1995 sec. 6.1.4)*			
4. Adequate shielding for the x-ray room (doors, walls, etc.) *(AO 35 s. 1995 sec. 6.2)* a. At least 6 inches thick poured concrete with a density of 2.35 g/cm^3 b. At least 1/6 in (1.5 mm) thick lead sheet glued onto and sandwich between wooden panels without any punctures during installation.			
5. Fixed/ Movable Protective barrier with means of viewing patient (glass/acrylic with 1.5 mm lead equivalence) and with adequate shielding from x-rays similar to room shielding requirements. *(AO 35 s. 1995 sec. 6.4)* ***(provide pictures/proof of installation)***			
6. If windows are present, it should be elevated to height of at least 2 m from ground. ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.6)*			
7. With red warning light bulb ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.7)*			
8. Dressing Area ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.18)*			
9. With appropriate warning notice outside x-ray examination room door. It shall be made up of a solid yellow equilateral triangle 180 mm long on each side. At the center of the triangle is a black tre-foil sign for radiation. Under the triangle are the words "**X-RAY ROOM: DO NOT ENTER WHEN THE RED LIGHT IS ON**". The Warning notice shall be on a 180 mm x 270 mm white background. ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.8)*			
10. With adequate ventilation ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.1)*			
11. Toilet with door opening directly to x-ray room **if** examinations using contrast media will be performed ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.19)*			
12. Radiological accessories ***(provide pictures/proof of purchase)*** *(AO 35 s. 1995 sec. 6.20)*			
a. Lead equivalent gloves *(>0.25 mm Pb equivalent)*			
b. Lead equivalent apron *(>0.25 mm Pb equivalent)*			
c. Quality control phantom *(AO 35 s. 1995 sec. 5.7.9)*			

INDIVIDUAL X-RAY MACHINE CHECKLIST

ANNEX D- III

Name of Facility
Facility Address

MAMMOGRAPHY X-RAY MACHINE REQUIREMENTS

(use additional sheets if necessary)

Machine # *(based on Section I of the Annex C)* [ ]

Applicable Type of Machines

Analog Mammography Machines
Digital Mammography Machines
3D Mammography Machines

REQUIREMENT *(please check "yes" if complied, "no" if not complied, and N/A if not applicable)*	**YES**	**NO**	**N/A**
1. Mammographic unit assembly properly installed, operational, and duly accepted by the licensee with appropriate documents signed by installer/supplier and received by licensee representative/owner. ***(provide pictures/proof of installation)***			
2. Undergone and passed performance testing conducted by PLSD-CSL or by DTI-PAB accredited testing laboratory ***(attach report of service provider)*** *(BO 220 s. 2002)*			
3. Adequate x-ray room size (*manufacturers specifications*) *(AO 35 s. 1995 sec. 6.1.4)*			
4. Adequate shielding for the x-ray room (doors, walls, etc.) *(AO 35 s. 1995 sec. 6.2)* a. At least 6 inches thick poured concrete with a density of 2.35 g/cm^3 b. At least 1/6 in (1.5 mm) thick lead sheet glued onto and sandwich between wooden panels without any punctures during installation.			
5. Fixed/ Movable Protective barrier with means of viewing patient (glass/acrylic with 1.5 mm lead equivalence) and with adequate shielding from x-rays similar to room shielding requirements. ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.4)*			
6. With red warning light bulb ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.7)*			
7. With appropriate warning notice outside x-ray examination room door. It shall be made up of a solid yellow equilateral triangle 180 mm long on each side. At the center of the triangle is a black tre-foil sign for radiation. Under the triangle are the words "**X-RAY ROOM: DO NOT ENTER WHEN THE RED LIGHT IS ON**". The Warning notice shall be on a 180 mm x 270 mm white background. ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.8)*			
8. With adequate ventilation ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.1)*			
9. Dressing Area ***(provide pictures)*** *(AO 35 s. 1995 sec. 6.18)*			

INDIVIDUAL X-RAY MACHINE CHECKLIST

ANNEX D - IV

Name of Facility
Facility Address

DENTAL X-RAY MACHINE REQUIREMENTS

(use additional sheets if necessary)

Machine # *(based on Section I of the Annex C)* [ ]

Applicable Type of Machines

Panoramic/Cephalometric
Peri-apical/Intraoral
Dental CT/CBCT

REQUIREMENT *(please check "yes" if complied, "no" if not complied, and N/A if not applicable)*	**YES**	**NO**
1. Dental x-ray unit assembly properly installed, operational, and duly accepted by the licensee with appropriate documents signed by installer/supplier and received by licensee representative/owner. ***(provide pictures/proof of installation)*** *(AO 2-A s. 1996 sec. 5)*		
2. With effective electrical grounding *(AO 2-A s. 1996 sec. 5.3)*		
3. Stability and quality of mechanical parts *(AO 2-A s. 1996 sec. 5.14)*		
4. Adequate x-ray room size (*manufacturers specifications*) *(AO 2-A s. 1996 sec. 6)* a. *Not a requirement for peri-apical/intraoral dental x-ray machines*		
5. Adequate shielding for the x-ray room (doors, walls, etc.) *(AO 2-A s. 1996 sec. 6)* a. Homogeneous concrete with a density of 2.35 g/cm^3 b. Lead sheet glued onto and sandwich between wooden panels without any punctures during installation. c. *Not a requirement for peri-apical/intraoral dental x-ray machines*		
6. Fixed/ Movable Protective barrier with means of viewing patient (glass/acrylic with 1.5 mm lead equivalence) and with adequate shielding from x-rays similar to room shielding requirements. ***(provide pictures)*** *(AO 2-A s. 1996 sec. 6.9 and 10)* a. *Not a requirement for peri-apical/intraoral dental x-ray machines*		
7. With red warning light bulb		
8. With appropriate warning notice outside x-ray examination room door. It shall be made up of a solid yellow equilateral triangle 180 mm long on each side. At the center of the triangle is a black tre-foil sign for radiation. Under the triangle are the words "**X-RAY ROOM: DO NOT ENTER WHEN THE RED LIGHT IS ON**". The Warning notice shall be on a 180 mm x 270 mm white background. ***(provide pictures)*** *(AO 2-A s. 1996 sec. 7.3.1)* a. *Not a requirement for peri-apical/intraoral dental x-ray machines*		
9. With adequate ventilation ***(provide pictures)*** *(AO 2-A s. 1996 sec. 6.2)*		
10. Radiological accessories ***(provide pictures/proof of purchase)***		
a. Thyroid shields (1/8 in lead equivalent) *(AO 2-A s. 1996 sec. 7.1.8)*		
b. Film holders for periapical & bitewing examinations *(if applicable)*		

ANNEX E

INDUSTRIAL/ANTI-CRIME FACILITY SELF ASSESSMENT CHECKLIST

(Adapted from the current FDA-CDRRHR Radiation Protection Survey and Evaluation (RPSE) Checklists)

Name of Facility	Date Accomplished
Facility Address	X-ray Facility Type

I. MACHINE DETAILS *(for those applied for initial authorization only)*

#	Type of Installation / Machine*	Manufacturer / Model	Max. mA	Max. kVp	Serial Number	Application/ Use**	Location
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

*Indicate whether: Cabinet Type, Closed Installation, Open Installation, Handheld, Linear Accelerator (LINAC)

**Indicate whether: Radiography, Fluoroscopy (Thickness Gauge/Analytical/Scanning Electron Microscopy/Spectrometry/Diffractometry/Photo-ionizer/Fat Analyzer/Computed Tomography/LINAC/Baggage Inspection)

II. PERSONNEL REQUIREMENTS

(please check "yes" if complied, "no" if not complied, and N/A if not applicable)

REQUIREMENT *(Based on DOH AO No. 40 s. 1996 and AO 149 s. 2004)*	YES	NO	N/A
1. The facility shall have and appoint a Radiation Protection Officer (RPO) who is an individual who has undergone training in radiation protection for industrial and anti-crime facilities conducted and/or recognized by the CDRRHR.			
2. The facility shall have operators who have completed training in radiation protection for industrial and anti-crime work conducted and/or recognized by the CDRRHR.			

III. OPERATIONAL AND ADMINISTRATIVE REQUIREMENTS

(please check "yes" if complied, "no" if not complied, and N/A if not applicable)

REQUIREMENT *(Based on DOH AO No. 40 s. 1996 and AO 149 s. 2004)*	YES	NO	N/A
1. The facility shall have or make available a radiation monitoring instrument for the purpose of carrying out regular radiation monitoring surveys of x-ray units. The radiation monitoring instrument shall be calibrated at least once a year.			
2. The Radiation Protection Officer (RPO) shall establish and be responsible for the conduct of a Radiation Protection/Safety Program under which the following policies should be included: ***(PROVIDE A SCANNED COPY)***			
a. Policy on dose monitoring for operators (including interns, OJTs), pregnant personnel, etc.			

b. Policy on radiation protection/safety of pregnant women. (e.g. posting of notices, risk communication, etc.)			
c. Records and analysis of personnel dose monitoring. Service Provider: _____ Subscription period: _____ Official Receipt No. _____ No. of TLD/OSL:			
d. Guidelines of appropriate action for operators/personnel that exceeded dose limits. (action plan, corrective measures, risk communication, etc.)			
e. Process of reporting and notification in cases of exceeded doses.			
f. Area Survey Monitoring for scattered radiation.			
g. Policy on the access of operators and other personnel to the site/location of the x-ray machine.			
h. Policy on monitoring of equipment for possible detection of significant leakage radiation.			
i. Policy on working procedures and protocols when operating the x-ray machine.			
j. For open installations, policy on continuous and competent supervision of the site during the conduct of x-ray exposure.			

IV. GENERAL PHYSICAL PLANT REQUIREMENTS AND PROTECTIVE DEVICES

(please check "yes" if complied, "no" if not complied, and N/A if not applicable)

REQUIREMENT *(Based on DOH AO No. 40 s. 1996 and AO 149 s. 2004)* ***(PROVIDE DIGITAL/SCANNED COPY OF FACILITY FLOOR PLAN/LAYOUT)***	**YES**	**NO**	**N/A**
1. Audible and visual warning signs shall be provided within the perimeter where the machine is installed or will be operated. The audible and visual warning signs shall be actuated before the irradiation and shall remain actuated until completion of the irradiation.			
2. Site Requirements:			
a. **For Closed Installations**			
i. all walls and doors shall be made of materials which will reduce radiation level to 2.5 μSv per hour (0.25 mR/hr).			
ii. there shall be functioning interlocks installed either in the machine or on the door.			
b. **For Open Installation**			
i. The boundaries of an open field shall be clearly defined by some appropriate means such as ropes, perimeter cords, or fences.			
ii. Dose equivalent rate outside the boundary shall not exceed 25 μSv per hour (2.5 mR/hr)			
3. Warning notices shall be posted along defined boundaries and shall be made up of a solid yellow equilateral triangle 180 mm long on each side. At the center of the triangle is a black tre-foil sign for radiation. Under the triangle are the words **"CAUTION – X-RAY EMITTING APPARATUS."** The warning notice shall be on a 180 mm x 270 mm white background.			

V. MACHINE OPERATORS (USE SEPARATE SHEETS IF NECESSARY)

Name	Position	Relevant Training in Radiation Protection

VI. TYPICAL SET-UP OF THE MACHINE DURING OPERATION

(Schematic Diagram or Brief Description)

X-ray Machine:	Location:

Radiation Measurements:

Readings:

A. _____	E. _____	I. _____	M. _____
B. _____	F. _____	J. _____	N. _____
C. _____	G. _____	K. _____	O. _____
D. _____	H. _____	L. _____	P. _____

*please indicate the measurement points in the room layout.

Instrumentation:

Radiation Dosimeter Used: _____

Serial Number: _____

Date of Calibration: _____

Calibration Due Date: _____

Calibration Factor: _____

I hereby declare that this application has been accomplished by me, and that the foregoing information and attached documents required for the authorization are true and correct,

PREPARED AND ACCOMPLISHED BY:		
Name:	**Designation/Position:**	**Date:**

ATTESTED BY (FACILITY HEAD/MANAGER)		
Name:	**Designation/Position:**	**Date:**

ANNEX F

REPUBLIC OF THE PHILIPPINES)
CITY/MUNICIPALITY OF _____) SS.

AFFIDAVIT OF UNDERTAKING

I, _____, _____, of legal age, _____, a resident of _____, after having been sworn in accordance with law hereby depose and state:

1. That I am the representative of _____ applying as an X-ray facility with the FOOD AND DRUG ADMINISTRATION (FDA) pursuant to RA 9711 or the Food and Drug Administration Act of 2009.

2. That in order to procure a License to Operate (LTO) an x-ray facility for computed tomography (CT) and mammography machines, a third party performance testing is needed pursuant to DOH Administrative Order No. 35 s. 1994 and Bureau Order No. 220 s. 2002.

3. That I hereby undertake to comply with the above-mentioned requirement on or before the expiration date of the LTO an x-ray facility to be issued by the FDA and failure to do so shall result to the non-renewal of the facility.

4. That this affidavit is executed in order to attest to the truthfulness of the foregoing narration of facts in compliance with the requirement of the FDA as basis for the approval of our application for an LTO and for whatever legal intents and purposes it may serve.

_____
Affiant

SUBSCRIBED AND SWORN TO BEFORE ME this _____ day of _____, 20__ in the City/Municipality of _____, Philippines. Affiant Exhibited to me his/her Tax Identification No. _____.

Doc No. _____
Page No. _____
Book No. _____
Series of _____