ANNEX C

THERAPEUTIC X-RAY FACILITY
SELF ASSESSMENT CHECKLIST

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

(Based on A.O. 2020-0035, A.O. 2022-0022, and A.O. 31 s. 2013)

Name of Facility	**Date Accomplished**
Facility Address	

Please mark check (✓) if complied, (X) if not compliant, and N/A if not applicable). Proof/Evidence required only for virtual inspections

I. PERSONNEL REQUIREMENTS

REQUIREMENTS	Self-Assessment	Verification *(FDA Use Only)*
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 Radiosurgery and Radiotherapy
	☐ Stereotactic Body Radiotherapy	☐ Total Body Irradiation
	☐ Total Skin Electron Irradiation	☐ Intra-operative Radiotherapy
	☐ Tomotherapy/Arc Therapy	☐ Adaptive Radiotherapy
	☐ Respiratory Gated Radiotherapy	☐ Others: _____
Specialized	☐ Intraoperative Radiotherapy	☐ Others: _____

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

REQUIREMENTS	Self-Assessment	Verification *(FDA Use Only)*
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 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	Self-Assessment	Verification (FDA Use Only)
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	Self-Assessment	Verification (FDA Use Only)
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	Self-Assessment	Verification (FDA Use Only)
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	Self-Assessment	Verification (FDA Use Only)
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	Self-Assessment	Verification *(FDA Use Only)*
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 form has been accomplished by me, and that the foregoing information and attached documents, where applicable, are true and correct.

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

ATTESTED BY (FACILITY HEAD/MANAGER):		
Name & Signature:	**Designation/Position:**	**Date:**
VERIFIED BY (FDA USE ONLY):		
Name & Signature:	**Designation/Position:**	**Date:**
Name & Signature:	**Designation/Position:**	