LICENCE CONDITIONS FOR ACUTE HOSPITAL SERVICE, AMBULATORY SURGICAL CENTRE SERVICE AND OUTPATIENT MEDICAL SERVICE LICENSEES PROVIDING OR INTENDING TO PROVIDE RADIATION ONCOLOGY AND RADIATION THERAPY

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1. Application

1.1. These licence conditions ("**LCs**") apply to:

(1) all persons that have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide:

(a) an acute hospital service ("**AHS**");

(b) an ambulatory surgical centre service ("**ASCS**"); and/or

(c) an outpatient medical service ("**OMS**"); and

(2) that provide or intend to provide, as part of the aforementioned service or services, RORT (as defined in clause 2.1(3));

(such persons referred to as "**Licensee(s)**").

1.2. A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:

(1) suspension or revocation of the Licensee's licence(s) to provide AHS, ASCS and/or OMS;

(2) shortening the term of the Licensee's licence(s) to provide AHS, ASCS and/or OMS;

(3) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or

(4) a direction requiring the Licensee to pay a financial penalty.

1.3. For avoidance of doubt:

(1) the defined terms as used in these LCs shall have the meanings ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated;

(2) the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions, codes of practice made thereunder; and

(3) these LCs do not override a healthcare professional's duty to make clinical decisions that are in the best interests of each patient.

2. Definitions

2.1 The following definitions shall apply to these LCs:

(1) "**Core Personnel**" means Radiation Oncologists, Radiation Therapists, Clinically Qualified Medical Physicists ("**CQMPs**"), and Medical Dosimetrists.

(2) "**Facility**" means the approved permanent premises where the Licensee provides, or intends to provide, RORT to patients.

(3) **Radiation Oncology and Radiation Therapy ("RORT")** means a treatment of any condition or disease using ionising radiation that is —

(a) emitted from —

(i) a sealed source (as defined in regulation 2 of the Radiation Protection (Ionising Radiation) Regulations 2023 (G.N. No. S 85/2023); or

(ii) an irradiating apparatus (as defined in regulation 2 of the Radiation Protection (Ionising Radiation) Regulations 2023; and

(b) does not involve the application of a proton beam.

(4) **"physics quality assurance**" means the quality assurance ("**QA**") for RORT-related machines and patient-specific QA.

3. Personnel

3.1 The Licensee shall ensure that RORT is provided to a patient only if there is a sufficient number of qualified personnel commensurate with the workload to allow for safe delivery of RORT, continuity of care and sufficient QA on treatment and processes, to that patient.

3.2 The Licensee shall ensure that the Licensee's Core Personnel:

(1) fulfil and/or comply with the relevant clauses of these LCs; and

(2) understand and acknowledge that they will be required to fulfil and/or comply with the same, before RORT services commence at the Facility.

A. Minimum Personnel

3.3 Before providing RORT to any patient, the Licensee shall:

(1) employ or engage at least two full-time equivalent Radiation Oncologists;

(2) employ or engage:

a. at least one CQMP; and
b. one Medical Dosimetrist or one other CQMP

where such personnel shall be two full time equivalent in total; and

(3) employ or engage at least two full-time equivalent Radiation Therapists.

3.4 Clause 3.3 does not apply to a Licensee who is approved to provide both proton beam therapy and RORT.

3.5 Before providing RORT to any patient, a Licensee who is approved to provide both proton beam therapy and RORT shall:

(1) employ or engage at least three full-time equivalent Radiation Oncologists and at least one Radiation Oncologist is employed by the Licensee on a full-time basis;

(2) employ or engage at least two CQMPs and one CQMP or Medical Dosimetrists, where such personnel shall be three full time equivalent in total and at least one CQMP is employed by the Licensee on a full-time basis; and

(3) employ or engage at least three full-time equivalent Radiation Therapists and at least one Radiation Therapist is employed by the Licensee on a full-time basis.

Radiation Oncologist

3.6 The Licensee shall ensure that for any RORT provided to a patient, a Radiation Oncologist is responsible for overseeing the provision of the RORT to that patient by members of a treatment team.

3.7 The Licensee shall ensure that for any RORT provided to a patient, a Radiation Oncologist employed or engaged by the Licensee oversees and manages the overall disease-specific treatment regimen of that patient, including ensuring a comprehensive evaluation of disease stage, co-morbidities, previous treatments, and a thorough exploration of various treatment options, to ascertain if RORT is an appropriate treatment for that patient.

CQMP

3.8 The Licensee shall ensure that each CQMP involved in the provision of RORT:

(1) is clinically trained in RORT;

(2) is responsible for directing the radiation oncology physics program

(3) oversees any technical aspects/components within the Facility; and

(4) is responsible for:

(a) the production of photon beams;

(b) the methods of creating a clinically useful dose distribution;

(c) the overall radiation safety within the Facility, including but not limited to:

(i) ensuring the safety of staff employed or engaged by the Licensee and the general public;

(ii) facility shielding;

(d) monitoring for radioactivation of RORT related treatment accessories and other machine components;

(e) managing the potential impact of secondary radiation on patients; and

(f) performing the operational responsibilities of a Medical Dosimetrist if there are insufficient Medical Dosimetrists onsite at the Facility.

Medical Dosimetrist

3.9 The Licensee shall ensure that each Medical Dosimetrist involved in the provision of RORT is familiar with his responsibilities, which shall include:

(1) designing and generating an optimal treatment plan when directed by a Radiation Oncologist; and

(2) generating approved treatment plan reports and performing plan checks to ensure safe transfer of treatment parameters to the treatment unit via the Oncology Information System.

Radiation Therapist

3.10 The Licensee shall ensure that each Radiation Therapist involved in the provision of RORT is familiar with his responsibilities, which shall include:

(1) ensuring the proper use of the patient immobilisation/repositioning system and fabricating or preparing them appropriately for photon therapy;

(2) performing initial CT simulation of the patient receiving or intending to receive photon therapy and generating the imaging data appropriate for the TPS system as part of treatment planning;

(3) implementing and delivering the treatment in accordance with the relevant therapy treatment plan; and

(4) ensuring the patient receiving RORT is prepared for treatment.

4 Credentialing

4.1 The Licensee shall ensure that all the Licensee's Radiation Oncologists undergo and comply with an internal credentialing plan, where such an internal credentialing plan shall include relevant continuing professional education relating to RORT.

4.2 The Licensee shall review their Physics Learning and Credentialing Plan ("**PLCP**") minimally every three years.

A. Radiation Oncologists

4.3 The Licensee shall ensure that each Radiation Oncologist involved in the provision of RORT is registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of radiation oncology.

B. Clinically Qualified Medical Physicists

4.4 The Licensee shall ensure that each CQMP involved in the provision of RORT complies with the Licensee's PLCP, where the CQMP's specific learning shall include all of the following areas:

(1) acceptance and beam commissioning (theoretical component);

(2) radiation safety;

(3) clinical and physics aspects of treatment planning and treatment;

(4) physics quality assurance and calibrations; and

(5) management of technical support and maintenance.

4.5 The Licensee shall ensure that each CQMP involved in the provision of RORT has completed the relevant criteria set out in the PLCP.

C. Medical Dosimetrists

4.6 The Licensee shall ensure that each Medical Dosimetrist involved in the provision of RORT has documented proof of continuing education or credential review for Medical Dosimetrists, to demonstrate evidence of continuing competency.

D. Radiation Therapists

4.7 The Licensee shall ensure that each Radiation Therapist involved in the provision of RORT satisfies the following criteria:

(1) is registered with the Allied Health Professions Council; and

(2) trained in the setup of the patient and use of the equipment, as demonstrated by a training log.

5 Process of Therapy

A. Treatment Planning

5.1 The Licensee shall provide RORT using photon beams to patients only if:

(1) photon dose calculations for treatment planning are based on CT data acquired from a CT scanner;

(2) each patient is provided with treatment site-specific immobilisation device(s) and CT imaging is performed for treatment dose planning and treatment;

(3) the treatment planning system is able to register CT images with images from all imaging modalities used by the Licensee;

(4) a motion management program relevant to imaging and treatment planning is established for patients for whom motion may be an issue;

(5) the treatment planning system used for photon treatment is commissioned and validated; and

(6) planning system calculations have been verified by phantom measurements during the commissioning process.

6 Policy and Procedures

6.1 Before providing any RORT to patients, the Licensee shall establish the following policies and procedures:

(1) philosophy, objectives and scope of the RORT;

(2) organisation structure of the Licensee;

(3) plans for the future development of services and staffing needs;

(4) staff development and education programmes;

(5) staff training and validating relevant skills of staff;

(6) maintenance and use of facilities and equipment;

(7) assessment of radiation safety for all staff, including but not limited to non-medical staff who have access to RORT facilities;

(8) emergency and contingency plans, including but not limited to the speed of activating such emergency and contingency plans;

(9) aseptic practices;

(10) infection control;

(11) incidents and adverse events reporting, root cause analysis and rectification procedures; and

(12) work instructions and standard operating procedures (SOPs) for critical processes.

7 Clinical Commissioning Prior to Commencement of Operations

7.1 Before providing any RORT to patients, the Licensee shall ensure there is a process in place to evaluate or review its clinical readiness prior to commencement of patient treatments, where the areas of evaluation or review shall include:

(1) clinical application of RORT; and

(2) impact on workflows, equipment, staffing, space utilisation, and possible new QA procedures, once operations commence.

8 Radiation Safety and Environmental Sustainability

8.1 The Licensee shall provide RORT to patients only if:

(1) the Licensee is licensed in accordance with the Radiation Protection Act 2007 ("**RPA**");

(2) the radiation shielding of the Licensee meets current standards specified under the RPA;

(3) parts that have become radioactive over time during operations (activated parts) are properly stored, monitored, managed, and disposed or re-exported in a safe and environmentally friendly manner;

(4) the Licensee takes into account any issues surrounding the decommissioning and dismantling of the Facility (or any part of the Facility thereof) and/or RORT equipment when the Facility (or any part of the Facility thereof) and/or equipment have reached the end of their useful life, including but not limited to disposal of concrete / steel shielding that may be activated; and

(5) personnel are monitored for accumulated exposure to radiation.

9 Maintenance of Facility and Equipment

9.1 The Licensee shall provide RORT to patients only if:

(1) the Facility and equipment are maintained in good operating condition and are fit for safe clinical use at all times;

(2) equipment are calibrated, maintained, monitored for proper function and used in accordance with the manufacturer's specifications. For the avoidance of doubt, the time interval for RORT-related equipment maintenance activities not be less than the time interval recommended by the relevant manufacturer;

(3) equipment problems are promptly addressed;

(4) appropriate cleaning of all equipment is carried out routinely; and

(5) an acceptance and commissioning of any RORT-related equipment shall be carried out at the time of initial installation and where there is any change or alteration to the configuration of the Facility or RORT-related equipment that could affect the photon beam output, patient treatment, or radiation safety.

10 Documentation

A. Staff Records

10.1 The Licensee shall properly document and maintain the record of the Licensee's personnels' roles, qualifications, competency assessments and training records, including exposure dose monitoring records for all radiation staff.

10.2 The Licensee shall ensure that radiation monitoring records of the Facility and staff exposures are updated in a timely manner.

B. Radiation Licences and Records

10.3 The Licensee shall properly document and maintain the record of all required licence(s) and authorization(s) from the Radiation Protection and Nuclear Science Department, National Environment Agency in relation to the use of irradiating apparatus.

10.4 The Licensee shall keep comprehensive and accurate radioactive waste disposal records.

C. Quality Records

10.5 The Licensee shall:

(1) ensure that all documents relating to QA and any treatment of any patient receiving, or has received, RORT from the Licensee are available in paper or electronic form;

(2) keep a record of all quality control measures, including but not limited to the maintenance of equipment, certification of facility and equipment by any external vendor;

(3) ensure that the delivery system is functioning as expected, in accordance and consistent with the initial acceptance and commissioning performance; and

(4) keep a record of any investigations and follow-up actions of adverse reactions associated with RORT.

D. Alternative Treatment Centres

10.6 The Licensee shall keep a written record of the plans set out in clause 12.1, including arrangements made with any other licensees for the provision of services.

11 Quality Assurance

A. Principles on Developing QA for RORT

11.1 The Licensee shall provide RORT to a patient only if:

(1) a record and verify system to keep track of the treatment charts and delivered dose for that patient is implemented by the Licensee; and

(2) the Licensee develops policies and procedures on RORT QA in accordance with failure mode and effects analysis ("**FMEA**") principles.

B. Patient-specific QA

11.2 The Licensee shall provide RORT to patients only if:

(1) policies and procedures related to quality, patient education, infection control, and safety have been developed and implemented by the Licensee;

(2) every patient's treatment charts (physical or electronic) are reviewed under the supervision of a CQMP prior to the start of any treatment of that patient; where the review shall include prescription, site, range (energy), and other treatment parameters;

(3) patient-specific physics quality assurance are done for every patient plan; and

(4) the frequency of QA tests from the likelihood and severity of the identified risks are derived, where the most likely failure modes that can cause harm to the patient or personnel shall be tested more frequently.

C. Machine QA

11.3 The Licensee shall provide RORT to patients only if:

(1) all elements of the regular machine QA program and its results are documented;

(2) there are proper documented QA processes for the use of treatment equipment and patient specific devices, including but not limited to apertures and compensators;

(3) QA on the photon treatment planning system to check the CT calibration, treatment unit configuration parameters and a sub-set of basic beam data is carried out at least once a year;

(4) additional treatment site-specific and manufacturer-specific QA recommendations are adopted, if any; and

(5) the rationale for any deviations from the additional treatment site-specific and manufacturer-specific QA recommendations is clearly documented and approved by the supervising CQMP.

12 Ensure Continuity of Treatment During Extended Downtime

12.1 The Licensee shall provide RORT to patients only if the Licensee has developed and implemented plans to ensure continuity of treatment during extended downtime, including but not limited to plans for alternative treatment sites and modalities of radiotherapy to ensure continuity of treatment to that patient in the event of extended downtime.