

## APPENDIX 3o

### LOT 15 SPECIFICATION

#### RADIOTHERAPY TREATMENT SYSTEMS AND ASSOCIATED OPTIONS AND RELATED SERVICES

##### 1. Introduction

1.1. This Lot is for the supply of radiotherapy treatment systems, including external beam therapy, superficial X-Ray radiation therapy, brachytherapy, internal beam therapy, intraoperative radiotherapy, radiosurgery and stereotactic treatment. It will also cover the supply of associated options and related services including electrons, photons, lasers, software, hardware, licences, applicators, upgrades, spare parts, couches, CCTV, patient positioning systems, multi-leaf collimators, training, extended warranties, turnkey arrangements between trusts and equipment providers, and point of sale maintenance.

1.2. The core product lines within this Lot are as follows:

Line Number	
1	Linear Accelerator (Photon and Electron) with integrated image guidance
2	Linear Accelerator (Photon) with Integrated Image Guidance and Treatment Planning
3	Superficial X-Ray Radiation Therapy Treatment System
4	Brachytherapy HDR (High Dose Rate) After Loader
5	Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) Device
6	Intraoperative Radiation Therapy System
7	Radiosurgery
8	MR Guided Radiotherapy Treatment System

1.3. All product line(s) must be supplied with a minimum 10 year expected lifecycle under proper use and maintenance.

##### 2. Line 1 – Linear Accelerator (Photon and Electron) with Integrated Image Guidance

2.1. This is the core technical specification for linear accelerators that can support the broadest range of radiotherapy treatments including 3D conformal radiotherapy, intensity modulated radiation therapy (IMRT), volumetric modulated arc therapy (VMAT) and image-guided radiation therapy (IGRT) with cone-beam computed tomography (CT).

2.2. The core components of a linear accelerator (photon and electron) with integrated image guidance:

2.2.1. Linear accelerator beam source mounted on a rotating gantry.

Document #: LEGAL TEMP 810-o6		
Revision: 4		Page 1 of 16

- 2.2.2. Dosimetry system.
- 2.2.3. Electronic portal (megavoltage) imaging.
- 2.2.4. Cone beam CT (kilo voltage or megavoltage) imaging.
- 2.2.5. Multi-leaf collimator (MLC).
- 2.2.6. Motion management.
- 2.2.7. Patient positioner.
- 2.2.8. User control terminal /user control room.
- 2.2.9. Ancillary equipment.

2.3. Linear accelerator:

- 2.3.1. The linear accelerator must be capable of providing photon and electron beams for radiation therapy.
- 2.3.2. The maximum field size for an un-wedged photon beam must be at least 40cm x 40cm.
- 2.3.3. At least two photon energies must be selectable:
  - 2.3.3.1. < 10MV
  - 2.3.3.2. >= 10MV
  - 2.3.3.3. A range of Flattening Filter Free (FFF) energies must be selectable 6-10MV
- 2.3.4. The system must be capable of delivering a maximum dose rate of at least 600MU/min measured at the depth of maximum dose at isocentre for photons of 6MV and higher and 1200MU-2400MU/min for FFF.
- 2.3.5. The beam fluence must be variable to produce modulated dose.
- 2.3.6. The maximum variation in dose over the central 80% of the radiation field at a depth of 10cm and at isocentre (flatness) must not exceed +/- 3% excluding FFF beams.
- 2.3.7. The maximum difference between the dose delivered at any two points equivalent and symmetrical about the central axis within the central 80% of the field measured at isocentre (symmetry) must not exceed 3%.
- 2.3.8. The times required from radiation turn-on for the beam to achieve stable conditions (i.e., dose rate selected, specified beam flatness, and specified beam symmetry) must not exceed 1 second.
- 2.3.9. At least five electron energies, ranging from 6MeV to 20MeV must be available as an option to purchase by the customer.
- 2.3.10. The system must be capable of delivering a dose rate of at least 400MU/min for electrons.
- 2.3.11. A range of electron applicators must be available as an option to purchase.
- 2.3.12. Electron beam profiles must not differ by more than 1.5% for all gantry angles.
- 2.3.13. The electron dose rate must be variable from 100MU/min to the maximum.
- 2.3.14. Photon and electron dose rates must be controllable with a precision of 1MU or 1% of any selected dose rate, whichever is greater at that dose rate.
- 2.3.15. The mechanical and radiation isocentres must be congruent within a sphere of 2mm diameter for gantry, collimator, and couch axes of rotation.
- 2.3.16. The gantry must rotate bi-directionally for both photon and electron treatments.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 2 of 16

- 2.3.17. An optical distance indicator (target to skin distance) with a 3mm accuracy must be provided.
  - 2.3.18. An automatic collision protection system must prevent collision between the gantry and the patient.
  - 2.3.19. The linear accelerator must be capable of delivering modulated arc and/or helical treatments.
- 2.4. Dosimetry system:
- 2.4.1. Accumulated dose and dose rate must be independently monitored using two or more detectors.
  - 2.4.2. The system must warn the operator if a set dose and dose rate exceed the operator-defined maximum value.
  - 2.4.3. Accumulated dose and dose rate must be displayed on independent indicators at the treatment control console.
  - 2.4.4. A safety interlock must be provided to prevent and/or interrupt treatment in the event of a fault in any part of the dosimetry/monitoring system.
- 2.5. Electronic portal imaging:
- 2.5.1. The gantry must include a retractable electronic portal imaging device or other imaging system.
  - 2.5.2. The electronic portable imaging device must have coverage of 40cm x 40cm at isocentre.
  - 2.5.3. Images must be displayed on the control console within 5 seconds of exposure.
  - 2.5.4. Measurement tools must be provided to quantify patient positioning discrepancies.
  - 2.5.5. It must be possible to send images into a record and verify system.
- 2.6. Multi-leaf collimator (MLC):
- 2.6.1. An MLC with a minimum of 80 leaves must be provided.
  - 2.6.2. The minimum field size must be at least 0.5 cm x 0.5 cm.
  - 2.6.3. It must be possible to select a field size up to 40cm x 40cm.
  - 2.6.4. Leaf width at isocentre must be 1cm or less.
  - 2.6.5. The collimator must rotate at least 175 degrees in both directions.
  - 2.6.6. As a minimum, operation in static, dynamic, and conformal arc modes must be supported.
  - 2.6.7. It must be possible to emulate a wedge field with the multi-leaf collimator.
  - 2.6.8. The MLC leaves must be capable of inter-digitation.
  - 2.6.9. The interleaf radiation leakage must be less than 3% without backup jaws.
  - 2.6.10. The leaf transition speed must be at least 2.0cm/second.
- 2.7. Motion management:
- 2.7.1. It must be possible to integrate a means to control for patient motion.
- 2.8. Patient positioner:

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 3 of 16

- 2.8.1. The patient positioner (table) must be motorised and controllable from inside the treatment vault (table side and hand pendant) and the main control console.
  - 2.8.2. The table top must be free floating.
  - 2.8.3. The vertical range of motion must be at least 0.6 metres above the floor to the isocentre.
  - 2.8.4. The longitudinal range must be at least 90cm.
  - 2.8.5. The lateral range must be at least +/- 24.5cm.
  - 2.8.6. The overall positioning accuracy must be at least 1.0mm.
  - 2.8.7. The table top must be designed to accommodate patient positioning accessories.
  - 2.8.8. The maximum patient weight must be at least 200kg with full positioning accuracy.
  - 2.8.9. The table top must be sealed to prevent the ingress of bodily fluids and the whole system must be easy to clean with disinfectant and/or alcohol wipes.
  - 2.8.10. It must be possible to lower the patient table in the event of a power failure.
  - 2.8.11. The couch top must be free of artefact-creating materials in order to optimise radiographic and CBCT imaging.
- 2.9. User control terminal/user control room:
- 2.9.1. The user control terminal must include a graphic user interface.
  - 2.9.2. The user control terminal must be uncluttered and display all pertinent information on a single display terminal.
  - 2.9.3. The user control terminal must be seamlessly integrated (bi-directional interface) with record and verify, treatment planning, PACS, and radiation oncology information systems.
  - 2.9.4. The user control terminal must display the position of individual MLC leaves.
  - 2.9.5. The user control room must have the ability to visually monitor the patient.
- 2.10. Ancillary equipment:
- 2.10.1. Ancillary equipment to support a functioning linear accelerator system must be available as an option to purchase.

**3. Line 2 – Linear Accelerator (Photon) with Integrated Image Guidance and Treatment Planning**

- 3.1. This is the core technical specification for linear accelerators that can support the broadest range of radiotherapy treatments, including 3D conformal radiotherapy, intensity modulated radiation therapy (IMRT), and image-guided radiation therapy (IGRT) with cone-beam computed tomography (CT).
- 3.2. The core components of a linear accelerator (photon) with integrated image guidance and treatment planning:

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 4 of 16

- 3.2.1. Linear accelerator beam source mounted on a rotating gantry.
  - 3.2.2. Dosimetry system.
  - 3.2.3. Electronic portal (megavoltage) imaging and or Cone-beam (CBCT) (Kilovoltage) imaging.
  - 3.2.4. Multi-leaf collimator (MLC).
  - 3.2.5. Patient motion management.
  - 3.2.6. Patient positioner.
  - 3.2.7. User control terminal/user control room.
  - 3.2.8. Ancillary equipment necessary for linear accelerator operation including power distribution and conditioning, cooling, and interfaces to standard radiotherapy IT systems.
- 3.3. Linear accelerator:
- 3.3.1. The linear accelerator must be capable of providing photons for radiation therapy.
  - 3.3.2. The treatment size available must be at least 28cm x 28cm.
  - 3.3.3. The system must be capable of delivering a dose rate of at least 600MU/min measured at the depth of maximum dose at isocentre.
  - 3.3.4. The photon dose rate must be variable from 100MU/min to the maximum.
  - 3.3.5. The maximum difference between the dose delivered at any two points equivalent and symmetrical about the central axis within the central 80% of the field measured at isocentre (Symmetry) must not exceed 3%
  - 3.3.6. The times required from radiation turn-on for the beam to achieve stable conditions (i.e., dose rate selected) must not exceed 10 seconds.
  - 3.3.7. Dose rates must be controllable with a precision of 1MU or 1% of any selected dose rate, whichever is greater at that dose rate.
  - 3.3.8. The mechanical and radiation isocentres must be congruent within a sphere of 2mm diameter for gantry, collimator, and couch axes of rotation.
  - 3.3.9. The design of the system must prevent collision between the linear accelerator and patient.
  - 3.3.10. The linear accelerator must be able to deliver modulated arc and/or helical treatments.
- 3.4. Dosimetry system:
- 3.4.1. Accumulated dose and dose rate must be independently monitored using two or more detectors.
  - 3.4.2. The system must interrupt treatment if a predetermined dose or dose rate is exceeded.
  - 3.4.3. Accumulated dose and dose rate must be displayed on independent indicators at the treatment control console.
  - 3.4.4. A safety interlock must be provided to prevent and/or interrupt treatment in the event of a fault in any part of the dosimetry/monitoring system.
- 3.5. Electronic portal imaging and/or Cone-beam (CBCT) (Kilovoltage) imaging and/or Cone-beam (CBCT) (Megavoltage) imaging.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 5 of 16

- 3.5.1. The gantry must include an electronic portal imaging device and or cone beam imaging system.
  - 3.5.2. The electronic portable imaging device and or cone beam imaging system must have coverage of the entire treatment volume in one or multiple images.
  - 3.5.3. Images must be displayed on the control console within 5 seconds of exposure.
  - 3.5.4. Measurement tools must be provided to quantify patient positioning discrepancies.
  - 3.5.5. It must be possible to incorporate images into a record and verify system.
- 3.6. Multi-leaf collimator:
- 3.6.1. An MLC must be provided.
  - 3.6.2. The leaf width projected at isocentre must be 1cm or less.
  - 3.6.3. As a minimum, operation in static, dynamic, and conformal arc and/or helical modes must be supported.
  - 3.6.4. It must be possible to emulate a wedge field with the multi-leaf collimator.
  - 3.6.5. The interleaf radiation leakage must be less than 3% without backup jaws.
  - 3.6.6. The leaf transition speed must be at least 2.0cm/second.
- 3.7. Patient motion management:
- 3.7.1. It must be possible to integrate a means to monitor patient motion.
- 3.8. Patient positioner:
- 3.8.1. The patient positioner (table/chair) must be motorised and controllable from inside the treatment vault by means of at least 1 of the following methods (Gantry control panel, table side, hand pendant or onboard touchscreen) and the main control console.
  - 3.8.2. The vertical range of motion must be at least from 63cm above the floor to the isocentre.
  - 3.8.3. The longitudinal range must be at least 90cm.
  - 3.8.4. The overall positioning accuracy must be at least 1.0mm.
  - 3.8.5. The table top must be designed to accommodate patient positioning accessories.
  - 3.8.6. The maximum patient weight must be at least 200kg with full positioning accuracy.
  - 3.8.7. The table top must be sealed to prevent the ingress of bodily fluids and the whole system must be easy to clean with disinfectant and/or alcohol wipes.
- 3.9. User control terminal/user control room:
- 3.9.1. The user control must include a graphic user interface.
  - 3.9.2. The user interface must be uncluttered and display all pertinent information on a single or dual display terminal.
  - 3.9.3. The user control console must seamlessly integrate (bi-directional interface) with record and verify, treatment planning and radiation oncology information systems.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 6 of 16

- 3.9.4. The user control must display the position of individual MLC leaves.
- 3.9.5. The user control room must have the ability to visually monitor the patient.

3.10. Treatment planning:

- 3.10.1. An IMRT treatment planning system must enable image import, appropriate registration, segmentation, contouring, planning, and plan evaluation.
- 3.10.2. The treatment planning system must include computing hardware.
- 3.10.3. The treatment planning system must support the full range of IMRT treatment applications.
- 3.10.4. The treatment planning system must enable both forward and inverse planning.
- 3.10.5. The treatment planning system must have full connectivity with the treatment delivery system.
- 3.10.6. The treatment planning system must include functions to reduce user error.
- 3.10.7. The proposed system must be DICOM RT compatible and support the import of CT, MRI, PET and fused images for planning purposes.
- 3.10.8. Cumulative and differential dose volume histograms must be available as analytical planning tools for planning and plan evaluation.
- 3.10.9. The finally selected plan must comply with DICOM RT for export.
- 3.10.10. Treatment planning system must enable traceable electronic approval/authorisation of all processes.
- 3.10.11. The treatment planning system must support at least TYPE B dose calculation algorithm.

3.11. Ancillary equipment:

- 3.11.1. Ancillary equipment to support a functioning linear accelerator system must be available as an option to purchase.

**4. Line 3 – Superficial X-Ray Radiation Therapy Treatment System**

4.1. This is the core technical specification is for a superficial X-Ray radiation therapy treatment system designed to treat superficial lesions (squamous and basal cell carcinomas and other dermatological conditions).

4.2. The core components of a superficial X-Ray radiation therapy treatment system:

- 4.2.1. X-Ray generator.
- 4.2.2. X-Ray tube mounted on an articulated arm, floor standing or ceiling rail.
- 4.2.3. Applicators.
- 4.2.4. Control console.
- 4.2.5. Ancillary equipment.

4.3. X-Ray generator:

- 4.3.1. The X-Ray generator must be high frequency.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 7 of 16

- 4.3.2. The voltage must be at least 65kV.
  - 4.3.3. The power must be at least 100W.
  - 4.3.4. The X-Ray generator must be powered from a standard of at least (13AMP 240V single phase) power supply.
- 4.4. X-Ray tube, articulated arm, floor stand and ceiling rail:
- 4.4.1. The X-Ray tube in a multi-energy machine must have the ability to have adjustable filtration.
  - 4.4.2. The heat capacity of the X-Ray tube must be sufficient to avoid treatment interruptions.
  - 4.4.3. The X-Ray tube must be mounted on a freely adjustable articulated arm, floor stand or ceiling rail.
  - 4.4.4. It must be possible to lock the position of the X-Ray tube at any arbitrary orientation.
  - 4.4.5. The articulated arm, floor stand or ceiling rail must be easy to position on all patients.
  - 4.4.6. The X-Ray tube must have means to monitor radiation output during treatment.
- 4.5. Applicators:
- 4.5.1. At least three standard applicators must be provided to treat field sizes from 1cm to 3cm diameter.
  - 4.5.2. It must be possible to visually confirm the alignment of the applicator.
- 4.6. Control console:
- 4.6.1. The system must include a means to prevent unauthorised use.
  - 4.6.2. A remote operator control console must be provided.
  - 4.6.3. It must be possible to position the console up to 30 metres from the X-Ray generator.
  - 4.6.4. The control console must include tools to enable a physicist's calibration.
  - 4.6.5. Calibration values must be stored on the control console.
  - 4.6.6. The control console must display the X-Ray parameters, including filtration, kVp, mA, dose rate, exposure time, time remaining and the applicator.
  - 4.6.7. Exposure must be prevented unless all setup steps have been performed.
  - 4.6.8. The control console must automatically terminate an exposure if the radiation dose rate does not match pre-set values.
  - 4.6.9. The control console must include an emergency off switch.
  - 4.6.10. It must be possible for the system to connect with the Hospital or Oncology Information System for the exchange of patient data via data interchange standards such as HL7 or DICOM
- 4.7. Ancillary equipment.
- 4.7.1. Ancillary equipment to support a functioning X-Ray system must be available as an option to purchase.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 8 of 16



## 5. Line 4 – Brachytherapy HDR (High Dose Rate) After Loader

- 5.1. This is the core technical specification is for a brachytherapy after loader used for high dose rate brachytherapy radiation treatments.
- 5.2. The core components of a brachytherapy HDR (high dose rate) after loader:
  - 5.2.1. Remote after loader.
  - 5.2.2. Control console.
  - 5.2.3. Treatment planning system.
  - 5.2.4. Safety requirements for remote after loader.
- 5.3. Remote after loader:
  - 5.3.1. The after loader must be designed for high dose rate (HDR) treatments.
  - 5.3.2. The after loader must accommodate IR-192 or CO-60 sources.
  - 5.3.3. The initial source activity must be at least 370GBq.
  - 5.3.4. The after loader must have at least 18 channels.
  - 5.3.5. The length of the source capsule must not exceed 5mm.
  - 5.3.6. The diameter of the source capsule must not exceed 1mm.
  - 5.3.7. The diameter of the wire must not exceed 0.9mm.
  - 5.3.8. The wire must extend at least 130cm.
  - 5.3.9. Each channel must support at least 48 dwell positions.
  - 5.3.10. The maximum dwell time must be at least 999 seconds/per position.
  - 5.3.11. The minimum step increment must not exceed 1mm.
  - 5.3.12. The precision of the wire positioning (reproducibility) must be 0.5mm or better.
  - 5.3.13. The supplier must be able to provide applicators for the following treatments: gynaecological, bronchial, oesophageal, nasopharynx, rectal, implants, intraluminal, interstitial, breast and skin.
  - 5.3.14. Applicators suitable for use with either CT and/or MR must be available if requested by the customer.
- 5.4. Control console:
  - 5.4.1. The control console must be dedicated to brachytherapy treatment delivery.
  - 5.4.2. The control console must include security features to prevent unauthorised access.
  - 5.4.3. The control console must include features to ensure the correct patient is selected.
  - 5.4.4. The control console must include quality assurance tools.
- 5.5. Treatment planning system:
  - 5.5.1. A brachytherapy treatment planning system must enable image import, appropriate registration, segmentation, contouring, planning, and plan evaluation.
  - 5.5.2. The treatment planning system must include computing hardware.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 9 of 16

- 5.5.3. The treatment planning system must support the full range of brachytherapy treatment applications as specified in paragraph 5.3.13.
- 5.5.4. The proposed system must be DICOM RT compatible and support the import of ultrasound, CT, MRI, PET, and fused images for planning purposes.
- 5.5.5. Inverse planning with dose optimisation must be supported.
- 5.5.6. Cumulative and differential dose volume histograms must be available as analytical planning tools for planning and plan evaluation.
- 5.5.7. The finally selected plan must comply with DICOM RT for export.
- 5.5.8. Selected dwell positions and times must be exportable to HDR treatment console.

5.6. Safety requirements for remote after loader:

- 5.6.1. The after loader must have a redundant emergency source retraction mechanism.
- 5.6.2. The emergency source retraction mechanism must have a battery backup in case of power failure.
- 5.6.3. The emergency source retraction mechanism must have a manual backup.
- 5.6.4. An emergency source container must be supplied.
- 5.6.5. The after loader must be equipped with a radiation monitor to ensure the source has been returned.
- 5.6.6. All necessary quality assurance tools must be supplied.
- 5.6.7. The radiation shielding must be sufficient to accommodate 407GBq.

**6. Line 5 – Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) Device**

- 6.1. This is the core technical specification for a stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) device.
- 6.2. The system must be able to deliver photon beams with a nominal energy of 6MV.
- 6.3. The isocentric accuracy must be < 1.5mm (nonisocentric).
- 6.4. The computerised system must be able to treat intracranial and extracranial lesions using three and/or four-dimensional planning of stereotactic beam technologies.
- 6.5. The system must be able to deliver hypo-fractionated treatments.
- 6.6. An option to localize the target(s) by stereotactic methods must be available and treatment must be delivered using multiple beam directions.
- 6.7. The system must be capable of image guidance and/or motion tracking throughout the treatment.
- 6.8. A cooling system must be supplied.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 10 of 16

6.9. The system must be IGRT capable and patient correction must have submillimetre accuracy.

6.10. A treatment planning system must be available as an option to purchase by the customer.

6.11. The system must be able to integrate at least one imaging modality such as 4D CT image data into the treatment planning process.

## **7. Line 6 – Intraoperative Radiation Therapy System (IORT)**

7.1. This is the core technical specification is for intraoperative radiation therapy used for internal radiation therapy, performed during surgery or after the removal of a tumour.

7.2. The core components of intraoperative radiation therapy:

- 7.2.1. X-Ray generator.
- 7.2.2. X-Ray tube and articulated arm.
- 7.2.3. Control console.
- 7.2.4. Ancillary equipment necessary for IORT.

7.3. X-Ray generator:

- 7.3.1. The X-Ray generator must be high frequency.
- 7.3.2. The X-Ray generator must provide high voltage up to 50kV.
- 7.3.3. The X-Ray generator must be powered from a standard power supply (i.e. 240V 50Hz electrical outlet).
- 7.3.4. The system must be mobile and easily transportable within an operating theatre and surrounding area.

7.4. X-Ray tube and articulated arm:

- 7.4.1. The heat capacity of the X-Ray tube must be sufficient to avoid treatment interruptions.
- 7.4.2. The X-Ray tube must be mounted on a mobile stand with freely adjustable articulated arm (6 degrees of freedom), designed for intraoperative use.
- 7.4.3. The system must be small and weight-balanced for positioning.
- 7.4.4. It must be possible to lock the position of the X-Ray tube at any orientation.
- 7.4.5. The X-Ray tube must provide energy X-Rays up to 50keV with isotropic dispersion.
- 7.4.6. The X-Ray tube must have means to monitor radiation output during treatments. The radiation dose must be measured independently from the electrical parameters supplied to the tube.

7.5. Control console:

- 7.5.1. The system must include a means to prevent unauthorised use.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 11 of 16

- 7.5.2. A remote-control console must be provided so that the operator is able to control the treatment from outside of the operating theatre.
  - 7.5.3. The control console must include tools to enable a physicist's calibration.
  - 7.5.4. The control console must display the X-Ray parameters, including filtration, kVp, uA, dose rate, exposure time, time remaining and the applicator.
  - 7.5.5. Exposure must be prevented unless all setup steps have been performed.
  - 7.5.6. The control console must automatically terminate an exposure if the radiation dose rate does not match pre-set values.
  - 7.5.7. The operator must be able to fail-safe the system at any time.
  - 7.5.8. The control console must include an emergency off switch.
  - 7.5.9. The system must include an interface to trigger radiation warning signs.
- 7.6. Ancillary equipment necessary for IORT:
- 7.6.1. A set of applicators designed to distribute a uniform dose to all surfaces of the tumour cavity must be supplied.
  - 7.6.2. The diameter of applicators must be in the range of 1cm-6cm and be available in a range of shapes including spherical, cylindrical, needle and flat.
  - 7.6.3. If reusable, the applicators must be suitable for sterilisation.
  - 7.6.4. A set of quality assurance tools to enable routine quality control and calibration must be available as an option to purchase.

## **8. Line 7 – Radiosurgery**

- 8.1. This is the core technical specification for a Radiosurgical System using a head positioning system designed for intra-cranial and/or neck radiosurgery, delivering multiple radiation beam paths.
- 8.2. The core components of Radiosurgery systems:
  - 8.2.1. Radiation delivery system.
  - 8.2.2. Motorised Patient table.
  - 8.2.3. Control console.
  - 8.2.4. Stereotactic head positioning system.
  - 8.2.5. IGRT system:
  - 8.2.6. Treatment planning system.
- 8.3. Radiation delivery system:
  - 8.3.1. The system must be able to irradiate the target from multiple angles.
  - 8.3.2. The system must be supplied with a fully integrated automatic system for controlling multiple collimators and couch movements.
  - 8.3.3. The system must be able to treat targets with diameters as low as 4mm, with spatial accuracy of 0.5mm.
  - 8.3.4. The system must be able to modulate the target radiation dose distribution in 3 dimensions using multiple target points (isocentres) with different collimators.

Document #: LEGAL TEMP 810-o6		
Revision: 4		Page 12 of 16

- 8.3.5. The radiation emissions must be confined within the protective housing which is secured with radiation shielding doors and a collimator system.
- 8.3.6. The radiation leakage must be less than 0.00002631 Gy/ Leakage outside the patient plane at 1m is <0.5%.
- 8.3.7. The system must have at least 3 different collimator sizes with the smallest size at 4mm.
- 8.3.8. The system must have a treatment timer with an accuracy better than 0.2%.
- 8.3.9. Dosimetric accuracy must be better than 3% for all beam configurations.

8.4. Motorised patient table:

- 8.4.1. The patient positioner (table) must be motorised and controllable from inside the treatment vault, table side, hand pendant, and the main control console.
- 8.4.2. The table must offer lateral, vertical and longitudinal motion of +/- 100mm around the isocentre.
- 8.4.3. The table must support patient weight to at least 135kg.
- 8.4.4. The table motion must be integrated with the system.

8.5. Control console:

- 8.5.1. The system must automatically record treatment parameters including as a minimum:
  - 8.5.1.1. Treatment time per isocentre.
  - 8.5.1.2. Isocentre position.
  - 8.5.1.3. Collimator size(s) per isocentre.
  - 8.5.1.4. All patient positions during treatment.
  - 8.5.1.5. Date and time of treatment.
- 8.5.2. The control console must be seamlessly integrated (bi-directional interface) with record and verify, treatment planning, PACS, and radiation oncology information systems.
- 8.5.3. The control console must include an emergency stop and security features to prevent unauthorized access.
- 8.5.4. The control console must include features to ensure the correct patient is selected.
- 8.5.5. The control console must include analysis and quality assurance tools.
- 8.5.6. The control console must display all pertinent information on a display terminal or terminals.
- 8.5.7. The control console must include the ability to visually monitor the patient.
- 8.5.8. The control console must include a graphic user interface

8.6. Stereotactic head positioning system:

- 8.6.1. If requested by a customer, the system must be supplied with coordinate frame kits with integrated insulated fixation post and reusable fixation screws and pins. Alternatively, supplied with a head and neck fixation board to enable the use of disposable thermoplastic masks for non-invasive fixation.

Document #: LEGAL TEMP 810-o6		
Revision: 4		Page 13 of 16

- 8.6.2. The coordinate frame kit or head and neck fixation system must be compatible with all imaging modalities including MRI and CT scanners.
- 8.6.3. The system must have a positioning system with accuracy better than 0.5mm.

8.7. IGRT system:

- 8.7.1. The system must be equipped with a KV image guidance system capable of 3D patient registration for image guidance and the possibility of automated re-alignment both prior to and throughout each radiosurgical treatment.

8.8. Treatment planning system:

- 8.8.1. The treatment planning system must be able to automatically co-register non-stereotactic images with stereotactic images to use both sets in treatment planning.
- 8.8.2. The treatment planning system must include computing hardware.
- 8.8.3. The treatment planning system must support the full range of head and/or neck applications.
- 8.8.4. The treatment planning system must enable both forward and inverse planning.
- 8.8.5. The treatment planning system must include functions to reduce user error.
- 8.8.6. The treatment planning system must be DICOM RT compatible and support the import of ultrasound, CT, MRI, PET, and fused images for planning purposes.
- 8.8.7. Multiplanar digitally reconstructed radiographs must be supported.
- 8.8.8. Cumulative and differential dose volume histograms must be available as analytical planning tools for planning and plan evaluation.
- 8.8.9. The selected plan must comply with DICOM RT for export.
- 8.8.10. The treatment planning system must be fully integrated with the treatment delivery device.
- 8.8.11. The treatment planning system must support alternate dose plan and multiple target treatments.

**9. Line 8 – MR Guided Radiotherapy Treatment System**

- 9.1. This is the core technical specification for MR guided radiotherapy treatment systems that can support the broadest range of radiotherapy treatments including intensity modulated radiation therapy (IMRT), and image-guided radiation therapy (IGRT) with MR imaging.
- 9.2. The system must include a minimum 6MV un-flattened filter photon beam linear accelerator.
- 9.3. The system must include a  $\geq 0.34T$  MRI scanner capable of continuously scanning the patient during treatment delivery.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 14 of 16

- 9.4. The gantry must be capable of rotating > 355 degrees.
- 9.5. The gantry must have a minimum 0.5RPM.
- 9.6. The system must have a multi-leaf collimation system (MLC) with a minimum of 130 leaves.
- 9.7. The system must be capable of delivering a maximum dose rate of at least 400MU/min measured at the depth of maximum dose at isocentre.
- 9.8. The bore of the system must be  $\geq 70$ cm diameter.
- 9.9. The system must be capable of delivering intensity modulated radiotherapy treatment (IMRT).
- 9.10. The ability to deliver adaptive treatment must be available.
- 9.11. The system must have a patient positioning system with indexing.
- 9.12. The system must have RF receiver coils to facilitate imaging throughout the body in the treatment position.
- 9.13. A user control terminal must be provided with the system.
- 9.14. A patient communication system must be provided with the system.
- 9.15. A patient monitoring system, including cameras, must be provided with the system.
- 9.16. The system must use a monitor unit check methodology.
- 9.17. All required safety interlocks and warning systems must be provided with the system.
- 9.18. A treatment planning system capable of planning MR guided radiotherapy treatment must be provided with the system, if required by the customer.
- 9.19. A treatment record and verification system capable of processing a storing MR guided radiotherapy treatment related data must be provided with the system, if required by the customer.
- 9.20. The system must be able to be connected to a customer's existing oncology information management system, or a dedicated database server must be made available, if required by the customer.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 15 of 16

9.21. A functional imaging facility must be available, if required by the customer.

Document #: LEGAL TEMP 810-06		
Revision: 4		Page 16 of 16