

Amendment – III (For Schedule 5 & 6)

Date: 16.10.2014

Ref.: Tender Enquiry No. HSCC/PUR/LHMC/2014 dt. 16.7.2014.

Sub.: Procurement of Radiotherapy Equipment for Lady Hardinge Medical College & Hospital,
New Delhi.

Final Amended Technical Specifications

Schedule 5 - Technical Specifications an Isocentric Mobile C-arm X-ray

Imaging System

1. System Description

1.1 The C-arm needs to be capable of performing fluoroscopy / radiography during brachytherapy procedures in pelvis, abdomen, chest, head & neck, limbs for all patient sizes.

2. Operating requirements

2.1 Should be a mobile unit including C-Arm and image processing / viewing system with large wheels for easy transportation and with easy maneuverability.

2.2 Patient support system (C-Arm table) shall be versatile, adjustable, having removable sections equipped with removable x-ray film cassette tray & grid.

2.3 Should provide the integration of the function with 3D TPS and HDR Unit.

3. Technical Specifications

3.1 C-Arm Mechanical:

3.1.1 The system shall be equipped with cable pushers on the C-Arm wheels so that cable lying on the floor will not limit the C-Arm movements.

3.1.2 The C-Arm shall have a minimum distance of 90 cm between the source & image receptor to facilitate large imaging space and clearance around the patient/table.

3.1.3 The system shall allow interchanging the positions of X-ray tube and imaging system.

3.1.4 The C-Arm shall be able to rotate $\pm 180^\circ$ to allow the image chain to accomplish angled projections.

3.1.5 The system shall have vertical C-Arm travel capability to adjust the imaging chain height.

3.2 Movements:

Orbit Rotation motor driven or manual, multiple angulations, with provision to take orthogonal views of the application from multiple angulations, Horizontal Travel, Swivel travel, Free space, Electromagnetic brakes for precise positioning of the arms.

3.3 X-ray Tube:

3.3.1 The x-ray tube shall be preferably rotating anode type.

3.3.2 Dual focal spots of sizes 0.3 & 0.5/0.6 mm

3.3.3 Higher anode heat storage capacity would be preferred (Please specify)

3.3.4 Higher anode cooling capacity would be preferred (Please specify).

3.4 X-ray Generator:

3.4.1 should be of microprocessor controlled.

3.4.2 The generator shall be 1.5 KHz or higher frequency or DC converter type.

3.4.3 The power load shall be of minimum 10 KW and KVp Range: 40 – 110 KV, Radiographic Current: 20mA or higher, Fluoroscopic Current: 0.2 – 15 mA.

3.4.4 The mAs range in radiographic mode shall be of minimum 120 mAs.

3.5 Collimator system: Shutters – Iris Diaphragms

3.6 Imaging and Image Intensifier TV system:

3.6.1 Should have DICOM imaging capabilities, image memory, Image processing, Text/graphics & other functions

3.6.2 Image intensifiers based panel for x ray imaging.

3.6.3 The image intensifier (II) shall be at least 9 – 12” to have wide coverage.

3.6.4 The minimum image resolution shall be 15 lp/cm at TV monitor

3.6.5 The image intensifier shall be equipped with a carbon fiber grid with 8:1 ratio.

3.6.6 The system should be DICOM compatible for image transfer to TPS and any other image workstation.

3.6.7 The system shall be equipped with a high resolution of minimum 1K x 1K imaging chain.

3.6.8 Image display shall be minimum 19” high resolution TFT monitor. TFT Color display 1280x1024, 2 monitors.

3.7 Radiographic Film Cassette Holder:

3.7.1 System must be supplied with minimum 10” x 12” film cassette holder with screen & grid.

4. System Configurations Accessories, Spares and Consumables

4.1 A. C-Arm compatible OT table top

The C-Arm compatible OT table top to be supplied along with standard accessories including (i) Radio-translucent table top for radiography, (ii) Cassette holder with provision for anterior-posterior and lateral radiographs, adjustable arm support for lithotomy position.

4.2 UPS of the required capacity for the C-arm system

4.3 Two-way intercom and CCTV system

4.4 Lead aprons of minimum 3 nos.

4.5 DICOM ready & compatible with connection to TPS, DICOM connectivity with all licenses, DICOM storage send / receive, DICOM image archiving DICOM print, DICOM Query / Retrieve.

4.6 DICOM DVD writer.

4.7 Additional workstation with 19” monitor and adequate and large image storage capacity

4.8 Offer should include complete spare parts kit for the C-arm and Table. The list of items to be supplied should be included.

5. Environmental Factors

5.1 All approvals such as FDA or European CE should be enclosed for the quoted model.

5.2 List of installation for the quoted model should be submitted.

5.3 Complete installation should include:

5.3.1 Room planning, designing and modifications, space requirements to be spelt out in advance. Site study in advance prior to submitting the bid.

5.3.2 Electrical Requirements to be specified and necessary power supply arrangements and cabling and points to be installed. Site visit a must before submitting the bid.

5.3.3 All AERB clearances and Environmental clearances to be arranged with local authorities. Institute will provide all the documentations.

5.3.4 Air Conditioning and monitoring of Temperature; Relative Humidity and Air changes (To specify no. per hour) to be installed.

5.4 The unit shall be capable of being stored continuously in ambient temperature of 0.50deg C and relative humidity of 15 – 90%

5.5 The unit shall be capable of operating in ambient temperature of 20 - 30 deg C and relative humidity of less than 70%.

6. Power Supply

6.1 Power input to be 220 – 240VAC (single phase), 400 – 440 V (3 phase) / 50 Hz as appropriate fitted with Indian plug.

6.2 UPS of suitable rating with voltage regulation and spike protection for 30 min back up.

7. Safety Standards and Training

7.1 Should be FDA, CE, UL or BIS approved product

7.2 Comprehensive warranty for 5 years and provision of CMC for next 5 years

7.3 Shall comply with AERB guidelines and type approved by AERB

7.4 Comprehensive training on application after installation for one week on site for one doctor, one physicist and 2 technologists.

7.5 Electrical safety conforms to standards for electrical safety IEC-60601-1 General requirements.

8. Documentation

8.1 User/Technical /Maintenance manuals to be supplied in English.

8.2 Certificate of calibration and inspection.

8.3 List of Equipments available for providing calibration and routine maintenance support as per manufacturer documentation in service/technical manual

8.4 List of important spare parts and accessories with their part number and costing.

8.5 Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist.

Schedule 6-Dosimetry, Radiation Safety and Quality Assurance Systems/Tools

The following dosimetry instruments / accessories, radiation safety equipments and quality assurance tools that are required for the optimal functioning of the radiotherapy department shall be provided by the vendor.

1. Dosimetry System

1.1 Absolute dosimetry System:

Secondary Standard Dosimeter Electrometer, Ion-Chambers, Water Phantom, Solid Water Phantom and Check Sources

- 1.1.1 A well-proven, reliable, high quality secondary standard dosimeter shall be provided. Two calibrated Farmer type thimble 0.6 cc ion chambers (N_{Dw} calibration factors) along with one check source, one large volume ion chamber (with calibration certificate), shall also be provided. The calibration certificates for the 0.6 cc ion chambers shall also contain the reading of the check source mentioned
- 1.1.2 The dosimeter/electrometer and all the detectors/ion chambers shall have triaxial TNC threaded connector to facilitate uniformity amongst all the dosimetry instruments.
- 1.1.3 The dosimeter/electrometer shall have wide measurement range and a large multifunction display. It shall be capable of measuring both current and charge with excellent resolution. It shall have negligible leakage current. There shall be provision for at least 2 different bias voltages.
- 1.1.4 Additionally it shall be possible to alter the polarity. BNC to TNC and TNC to BNC connector adapters shall also be supplied. The dosimeter shall have extremely good accuracy, repeatability, and stability. Two such dosimeters are to be supplied. Please provide specifications.
- 1.1.5 One simple, open-top water phantom of interior size 30 cm x 30 cm x 30 cm shall be provided for performing teletherapy dosimetry. The phantom shall have a Perspex slot for inserting the 0.6 cc cylindrical ion chamber at a position such that there is a clearance of at least 10 cm or more from the bottom of phantom. The outer surface of the phantom shall have accurate markings to know the water height above the center of chamber. At the bottom of phantom there shall be a rectangular marking with cross hairs to align the phantom and ion chamber with the central axis of the beam. There shall be a tap on one of the sides for draining out the water.
- 1.1.6 For the calibration of electron beams a parallel plate ion chamber system complete with a dedicated check source and N_{Dw} calibration certificate (with the

check source reading noted on it) shall be provided. The chamber shall be a ROOS type or Markus type or NACP chamber. The chamber shall preferably not have any water-proof caps, sheathing and should be directly immersible for use in water or alternately the chamber shall have water-proof caps, sheathing for use in water phantom. It shall have triaxial TNC threaded type connector.

- 1.1.7 Please provide exhaustive details about the items offered. Since these items shall form the backbone of dosimetry, stress will be on the quality of items offered.
- 1.1.8 A solid, water equivalent phantom made up of slabs of different thicknesses shall be provided by the vendor for external beam teletherapy dosimetry. It shall be possible to use this phantom for both photon and electron beam dosimetry. The phantom shall be free of contaminants and air bubbles. Guarantee should be provided for electron density and homogeneity and shall be certified to be within 0.5% of water at photon energies. The slabs shall be of 40 x 40 cm size totaling a thickness of 50 cm. The exact details of the slab thickness and their quantities shall be obtained from the user department. Different slabs (of 2 cm thickness) with appropriate cavities to accommodate the two 0.6 cc ion chambers, parallel plate ion chamber should be provided additionally. Please note that these special slabs are in addition to the simple, solid slabs totaling a thickness of 50 cm. The phantom shall be of rigid type and should not show any kind of charge build-up effects. It shall not be affected by any change in ambient temperature and humidity.
- 1.1.9 For the all linear accelerator, permanent cabling between the control console of two linear accelerators and the interior wall of the treatment room for dosimetry measurements shall be provided and installed. The permanent cabling shall be for the complete RFA setup that can also be used for absolute dosimetry measurements with 0.6 cc ion chamber and parallel plate chamber. Complete description must be provided.

2. Reference Dosimetry System

2.1 Latest model of Radiation Field Analyzer (RFA)/ Water Scanning System

- 2.1.1 A 50 cm X 50 cm X 50 cm water phantom with water drain kit, as well as motorized system with remote control must be provided. State the scannable dimensions of the water phantom. The positional resolution of the movement shall be 0.1 mm or better. Radiation hardened probe holders for all detectors must be provided with the system. The Servo system shall be supported from all sides and has position feedback mechanism for long term reliability.

- 2.1.2 Appropriate semi-conductor photon detector, semi-conductor electron detector, small volume ion-chamber (0.125 cc or 0.13cc approximately), reference detector shall be supplied. The ion chambers provided shall be completely water proof and totally immersible in water up to very large depths. Give details how the supplied detectors can be used to perform relative dosimetry for linacs' photon & electron beams.
- 2.1.3 Appropriate build-up caps shall be provided for the detectors provided to do in-air dosimetry for the photon energies of 6 MV, 15 MV. Provide complete details on this account.
- 2.1.4 The RFA computer system shall have Intel Xeon processors with at least 20 GB RAM, 500 GB hard disk space, 2 CD drives (out of which one shall be a DVD-Writer), at least 2 high speed USB ports, 21" TFT flat monitor, 4 GB storage capacity USB drive. A UPS system with 1 kVA capacity with 30 minutes backup time shall be supplied. A locally designed good quality mobile wooden rack (on strong wheels) for stacking the RFA control parts and computer shall be provided.
- 2.1.5 The RFA software shall have licenses for beam data conversion to the treatment planning systems. Besides these it shall also be possible to convert the curves / profiles into simple ASCII format and Excel format and transfer to other Windows applications.
- 2.1.6 For the quality assurance and the clinical implementation of the various features of the linear accelerator, and for comprehensive QA of film dosimetry software along with a 16-bit advanced scanner shall be supplied. The scanner shall have excellent scanning qualities with long term stability and shall be from a reputed manufacturer who is in the field of radiotherapy film dosimetry. The scanner shall be able to handle an optical density range of 0 to 3.5 or better. Its geometric accuracy shall be better than 1% or 2 pixels in both the axes.

3. Periodic QA/Safety Devices and Software Systems/Tools

- 3.1 A simple QA device (two numbers) that can measure accuracy of the gantry angle, collimator angle, couch angle, isocenter accuracy, optical-radiation field congruence, optical field readouts, etc shall be supplied.
- 3.2 Two sets of QA device that can perform daily QA like photon/electron energy checks; radiation field flatness, symmetry; output consistency, etc shall be provided. The detector instrument supplied shall get connected to a laptop (high resolution, high-end, 10 GB RAM, wide screen, at least 500 GB or more hard disk, DVD writer, Bluetooth technology, etc) that will be kept in the control console. One laptop must be provided with each such QA device. Permanent

cabling must be laid between the control console area and the interior wall of the treatment room for two linac machines or alternately a reliable wireless connectivity can be provided. Appropriate software must be provided that can store analyze all the data, store them and report the data in a user friendly format. Provide comprehensive details on the systems offered.

- 3.3 The institute has multiple CT scanners. A QA phantom for treatment planning system shall be supplied that has different electron density inserts for calibrating CT numbers (Hounsfield units) against electron density and mass. Furnish complete description about the phantom.
- 3.4 Two calibrated digital thermometers, two digital barometers, two ion chamber based survey meters, two digital survey meter, one neutron survey meter shall be provided. All survey meters and the barometers shall have proper calibration certificates.

4. Dosimetry System for IMRT/VMAT Pre-Treatment Patient-Specific Verification/QA

4.1 IMRT/VMAT Phantom

- 4.1.1 For performing QA of **IMRT/VMAT**, a latest, state-of-the-art water equivalent phantom (one number) shall be supplied. It shall be possible to do exposure of multiple directions for high accuracy in IMRT/VMAT verification. The phantom material shall be water / tissue equivalent. It shall have a universal design for both dose and dose distribution verification of patient-specific pre-treatment IMRT/VMAT treatment plans.
- 4.1.2 It should be possible to easily adjust the phantom on the Linac couch and on CT scanners couch top. It shall be possible to do absolute dose verification with different ionization chamber types that are being offered.
- 4.1.3 Appropriate markers shall be engraved on the surface of the phantom in different colors for its easy adjustment under the accelerator and in a CT scanner. Localizer plates for the use of the phantom in a CT scanner shall also be quoted.

4.2 IMRT/VMAT QA Detector and Software Systems

- 4.2.1 For easy verification of IMRT/VMAT fluences and doses, a separate fluence/dose verification device/equipment shall be supplied. The department requires one number of this device. All the necessary software shall be supplied. The device must be based on either ion chamber or diode array of detectors giving the highest resolution possible with the software. The active volume of the chamber/diode must be small. It must be possible to do both photon and electron measurements. Adequate amount of buildup materials of different thicknesses should be provided

for measurements with different energy beams. It must be possible to do automatic temperature and pressure verification devices. Latest available technology should be quoted for the transferring of data from the detector array to the processing laptop computer. In addition to the cable based connection, cable less technology also to be quoted.

5. Mould Room, Patient Fixation and Immobilization Accessories

1.1 General Specifications:

The following items are required in developing and implementing of a comprehensive, ultra-modern 3-D conformal radiotherapy, and intensity modulated radiation therapy/**volumetric modulated arc therapy** program in the department of Radiotherapy. For all the items the vendor should provide the product information brochures.

1.2 Deleted

5.3 Block Casting System

5.3.1 A block casting system should be quoted for filling the Styrofoam milled using the above system with lead or low melting point alloy. The system should have a solid-state alloy melter with digital readout. It should have precise temperature control and have advanced alloy dispenser.

6.1 Patient fixation / Immobilization Accessories

6.1.1 Head Rest - 8 sets

Should be made of soft rubber for patients' comfort and of different sizes for various treatment positions.

6.1.2 Head and neck fixation plates - 10 numbers

This should be made of perspex. It should be possible to immobilize the head rests with this device.

6.1.3 Prone head rests - 10 numbers

Vacuum based radio-translucent cushions for patient immobilization, which are filled with tiny polystyrene beads or of any similar material with same properties, for the following needs:

a. for treating head and upper thorax region (supine & prone) - 10 nos.

b. for treating head and upper thorax region (supine) - 10 nos.

- c. for prone head holder -10 nos.
- d. large cushion (bed type) with treatment windows - 10 nos.
- e. large cushion (bed type) without treatment windows - 10 nos.
- f. small cushion with treatment windows (for rectal / bladder cases)-10
- g. cushion for treating thorax region with arms up position - 10 nos.

6.1.4 **Appropriate storage racks** (10 sets), color tags (10sets), helping hand sets (10 sets), S-type hooks (10 sets), shall be provided.

6.1.5 **A motor / pump** shall be provided to mould the cushion (to suck out the air).

6.1.5 **Separation meter – 10 numbers**

Should be made up of light metal with accurate scales

6.1.6 Shoulder retractor for head and neck patients –5 numbers

6.2. Breast Immobilization System

6.2.1 For treating breast patients, a carbon-fiber based immobilization system using side mountable thermoplastic sheets should be supplied. The system should be complete in all respects with board, brackets, handles, 30 thermoplastic sheets etc. In addition to such a system, a complete set of breast treatment brassiere should also be provided. With this it should be possible to treat any size of breast.

6.3 Electron Foam Cutter (220 volts with Nickel Chrome Wire Assembly)

6.3.1 Two electron foam cutters with large cutting surface for cutting high density foam for making electron cut outs for radiotherapy patients. Appropriate high density flat foams of 30x30x1.5 size for making electron cutouts shall be provided (two cartons).

6.3.2 Cadmium free Low melting point alloy for making customized shields: 300 Kg

6.4 Thermoplastic sheets

6.4.1 For immobilization of patients (using the head rest and fixation plates provided), appropriate thermoplastic sheets of following sizes and quantities shall be supplied:

- a. Thermoplastic sheet for face / head region only- 100 numbers

- b. Thermoplastic sheet for head & neck region with shoulder area covered – 100 numbers.
- c. Please quote for appropriate base plate also (six numbers)
- d. Thermoplastic sheets for abdominal / pelvis region – 100 numbers.
- e. Please quote for appropriate base plate also (six numbers).

6.5 **Water Bath System**

- 6.5.1 One suitable water bath system with **digital** temperature control shall also be provided for preparing the thermoplastic mask for the patients.

- 6.6** The vendor shall provide 4 complete sets of multipurpose Base Plate, upgradable to SBRT, SRS/SRT frameless, made of carbon fibre, having a total solution for adult and pediatric to treat all body sites viz. Head, Head & Neck, Breast, Thorax, Abdomen, Pelvic SBRT, SRS & SRT. CT Markers – 300 nos.

Suppliers of both High Energy Linear Accelerator and Dosimetry Systems shall be responsible to co-ordinate with each other at site for their integration and their satisfactory installation and commissioning, training and hand-over.

Note: It is the responsibility of the bidders to quote in conjunction with Bid Document and all earlier Amendments issued so far against this Tender.

In view of the above Amendments, the due date is extended from 21.10.2014 to 29.10.2014. This is the final amendment being issued.

Rest all remains unchanged.

**Director
LHMC, New Delhi**