

**Amendment No. 2**

06.12.2018

**Sub: Amendment to the Bidding Document**

**Ref.: Notice Inviting Bid ref. HITES/PCD/NCI-AIIMS/36/18-19 dated 26.09.2018 read with its Amendment no. 1 dated 19.11.18**

The following changes have been authorised and are being incorporated in the above referred Bidding Document.

**SECTION - VII****TECHNICAL SPECIFICATION AND GENERAL POINTS****A. TECHNICAL SPECIFICATION:****Item No. 2 (Rfx/ Event number 3000003420)****IORT Machine (Electron Based)**

| <b>Sl. No.</b> | <b>Ref. to the Bidding Document</b> | <b>Existing Tender Specification</b>   | <b>Amended as</b>  |
|----------------|-------------------------------------|--|--|
| 1              | Point 1.9<br>page 62                | <b>The Dose per pulse</b> shall be a value such that quality assurance (QA) procedures are simple to implement and are similar to those used in conventional radiotherapy treatment.   | <b>Deleted</b>   |
| 2              | Point 1.11<br>Page 62               | Dual (primary and backup) dosimetry system for measuring radiation output, based on vented ion chambers with <b>automatic pressure</b> and temperature compensation  | Dual (primary and backup) dosimetry system for measuring radiation output, based on vented ion chambers with temperature compensation. |
| 3              | Point 1.15<br>Page 62               | The <b>treatment head of the</b> equipment should have at least 5 degrees of freedom   | The equipment should have at least 5 degrees of freedom  |
| 4              | Point 1.21<br>page 63               | Range of motion and treatment flexibility:- The treatment head shall have the ability to move <b>in 5 axes</b> with following minimum ranges:-<br>Gantry: +/- 45 degrees<br>Tilt: +20/-10 degrees<br>Vertical: 30 cm total range | <b>The treatment equipment should have 5 degree of motion for facilitating treatment</b>   |

| Sl. No. | Ref. to the Bidding Document | Existing Tender Specification  | Amended as   |
|---------|------------------------------|--|--|
| 5       | Point 2.1<br>Page 63         | This software should be able to execute stability QA;report, print, and store machine calibration results, perform quality checks and <b>calculate the number of monitor units (MU)</b> required to administer a prescribed dose at a specified depth with all energies and all types of applicators.  | <b>Deleted</b>   |
| 6       | Point 2.3<br>Page 63         | Dose planning with the capability to mix different electron energies   | <b>Deleted</b>   |
| 7       | Point 2.5<br>Page 63         | The software shall be DICOM 3.0 Compliant and HL 7 compliant.  | <b>Deleted</b>   |
| 8       | Point 2.6<br>Page 63         | The software shall track and record daily QA sessions including:<br>- Beam energy and output statistics<br>- Functionality Tests<br>- Interlocks   | The software shall track and record daily QA sessions.   |
| 9       | Point 3.8<br>Page 63         | It should have at least two 19" or more TFT flat screen LCD colour monitor for display of 1024 x 1024 matrix or more.  | The system <b>should have 19" or more TFT flat screen LCD colour monitor</b> for display of 1024 x 1024 matrix or more.  |
| 10      | Point 3.9<br>Page 63         | Computer CPU systems should be running on a high-end workstation platform with UNIX/LINUX/ Window of latest configuration. RAM size must be at least 8 GB or better  | Computer CPU systems should be running on a high-end workstation platform with <b>latest configuration</b> . RAM size must be at least 8 GB or better  |
| 11      | Point 5 ,<br>Page 64         | <b>Dosimetry Equipment</b><br>1. Vendor must provide relevant QA device, Phantom and dosimetry equipment required for QA and dosimetric calibration.<br><br>a) PDA :- Photo Diode Array: 5 diodes positioned orthogonally to each other to measure the radiation of the miniaturized accelerator. The objective of this test is to assure the isotropy of the emitted beam.<br><br>b) PAICH :- Probe Adjuster Ion Chamber Holder: the output can be checked. An ion chamber is mounted onto the probe adjuster | <b>Dosimetry Equipment</b><br>Vendor must provide relevant QA device, Phantom and dosimetry equipment required as follows;<br><br>(i) Absolute Dosimetry Systems: Vendor should provide 3D mini water phantom. One water-proof cylindrical chamber and parallel plate chamber with suitable electrometer for output measurements as per IAEA TRS-398 protocol<br><br>(ii) Relative dosimetry Systems: Vendor should provide radiochromic films (two pockets of two different sizes) suitable for |

| Sl. No. | Ref. to the Bidding Document | Existing Tender Specification   | Amended as  |
|---------|------------------------------|---|---|
|         |                              | in such a way that the ion chamber window sits right above the tip of the miniaturized accelerator to enable for treatment planning until a coefficient has been computed | IORT depth dose measurements with suitable latest model flatbed film scanner system in addition to the system-specific dosimetric equipments and QA tools.<br><br>(iii) One solid water phantom for daily QA checks.<br><br>(iv) one specially designed water equivalent cylindrical phantom which is insertable with electron applicator for output factor measurements. |
| 12      | Point 9.1<br>Page 65         | The system should be integrated and connected to CT-Simulator, MR/PET-CT, PET-MRI and Treatment planning station of Radiotherapy department, etc.                         | <b>DELETED</b>  |

### Item No. 3 (Rfx/ Event number 3000003421)

#### IORT Machine (X-Ray Based)

| Sl. No. | Ref. to the Bidding document | Existing Tender Specification  | Amended as  |
|---------|------------------------------|--|---|
| 1       | Point 1.1<br>Page 66         | The machine should be dedicated Mobile Photon beam LINAC. It should have a point-source type x-ray emission, Spherical dose distribution around the isocentre of the miniaturized accelerator, Steep dose gradient (approx. 1/r3) in water (soft tissue equivalent). Positional accuracy of delivered dose +/- 1 mm. | The machine should be dedicated <b>Mobile X-ray based IORT</b> system. It should have a point-source type x-ray emission, Spherical dose distribution around the isocentre of the miniaturized accelerator, Steep dose gradient (approx. 1/r3) in water (soft tissue equivalent). Positional accuracy of delivered dose +/- 1 mm. |
| 2       | Point 1.2<br>Page 66         | The LINAC should have mounted on mobile stand/mounting for LINAC having multiple axis movement.  | The system should have mounted on mobile stand <b>and easily movable from room to room facilitating all treatments.</b>   |
| 3       | Pont 1.5<br>Page 66          | The equipment should have positional accuracy of delivered dose +/- 1 mm   | Either equipment positioning <b>or emitting source point</b> accuracy should be of <u>+</u> 1 mm  |

|    |                               |   |  |
|----|-------------------------------|---|--|
| 4  | Point 1.7<br>Page 66          | It should have inbuilt internal radiation monitor to enable real time measurement of dose delivered.  | It should have either inbuilt internal radiation monitor <b>or any alternative mechanism to ensure the precise dose delivery.</b>  |
| 5  | Point 1.9<br>Page 66          | High precision water phantom with < 100 µm accuracy for independent dose verification should be included in the offer.  | <b>The System should come with the proper QA phantom to allow the site tech personnel to execute the proper dosimetric verification tests.</b>   |
| 6  | Point 1.11<br>page 66         | The equipment should be in use globally for wide range of indications <b>(Breast Cancer, Endometrial Cancer, Lung Cancer, Soft tissue Sarcoma, Skin cancer etc.)</b> .                        | The equipment should be in use globally for wide range of indications <b>for IORT.</b>   |
| 7  | Clause. 5.1<br>Page No 67     | Equipment standard and safety should comply with the national regulatory AERB guidelines and offered model should have AERB type approval and NOC.  | <b>The model offered by the vendor may be of either AERB type approval/NOC approved or AERB type approval/ NOC pending.</b>  |
| 8  | Clause. 7.5<br>Page No 68     | Factory trained service engineer/Application specialists should be available in Delhi-NCR to look after the installation and maintenance of the system without patient treatment interruption | Factory trained service engineer/Application specialists should be available in Delhi-NCR to look after the installation and maintenance of the system without patient treatment interruption.<br><b>Supporting certificate should be furnished.</b>   |
| 9  | Clause. 8.1<br>Page No 68     | The system should be integrated and connected to CT-Simulator, MRI/PET-CT, PET-MRI and Treatment planning station of Radiotherapy department, etc.  | The system should be integrated and connected to <b>imaging system and Treatment planning system.</b>  |
| 10 | BOQ<br>Column D<br>Page No 69 | Number of x-ray tube required for treatment of 1000 Patients (for Bid ranking only)*  | Number of x-ray tube required for treatment of 1000 Patients (for Bid ranking only)*. <b>If the system uses, disposable x-ray tube along with required consumables for treatment, the following number of X-ray tubes with cooling tube and other consumable as below. Breast-500, Gynecological-300 and skin-200.</b> |

**Existing Specification (Ref: Point 4, Page 67):**

4. Vendor must provide relevant QA device, Phantom and dosimetry equipment required for QA and dosimetric calibration.

**Amended as:**

Dosimetry, QA and Safety Measurement Equipments:

Vendor must provide relevant dosimetry equipments and QA devices, Phantom required for QA and dosimetric calibration as follows;

1. The system which uses non-disposable x-ray tube should provide the following dosimetry and QA equipments.
  - (i) Absolute Dosimetry Systems: Vendor should provide specially designed water phantom with soft x-ray small volume parallel plate chamber with suitable holder and electrometer for output measurements as per AAPMTG-61 Protocol.
  - (ii) Relative dosimetry Systems: Vendor should provide radiochromic films (two pockets of two different sizes) suitable for IORT depth dose, profiles measurements along with suitable latest model flatbed film scanner system in addition to the system-specific dosimetric equipments/QA tools.
2. The system which uses disposable x-ray tube should provide the following dosimetry and QA equipments:
  - (i) Absolute Dosimetry Systems: vendor should provide in-built or standalone calibrated Well-Type chamber with suitable electrometer for source strength or output calibration as per AAPM TG-43 protocol
  - (ii) Relative dosimetry Systems: Vendor should provide radiochromic films (two pockets of two different sizes) suitable for IORT depth dose measurements with suitable latest model flatbed film scanner system in addition to the system-specific dosimetric equipments/QA tools.
3. Vendor should provide the mobile micro MOSFET wireless dosimetry system with suitable software and hardware reader for invivo dose verification during IORT treatment.
4. Vendor should provide the latest model one survey meter suitable for measuring low-energy x-rays and its contamination leakage measurements.
5. Vendor should provide System specific periodic quality assurance phantom and devices suitable for their systems.

**Item No. 4 (Rfx/ Event number 3000003422)**

**Mobile CT Scanner for IORT**

| <b>Ref. to the Bidding document</b> | <b>Existing Tender Specification</b>   | <b>Amended as</b>  |
|-------------------------------------|--|--|
| Para 1.8<br>Page 70                 | The system should have an Image reconstruction speed of at least 16 images per sec or more | The system should have an Image reconstruction speed of at <b>least 24 images</b> per sec or more. |

**All other contents of the Bidding Document including terms & conditions remain unaltered.**