TECHNICAL SPECIFICATIONS OF MEDICAL DEVICES FOR RADIOTHERAPY DEPARTMENT

Ministry of Health and Family Welfare
Government of India

INDEX

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INTRODUCTION

Medical devices are a very important part of health care and their use is increasing by the day. Technical specifications play an important role in identification, selection and procurement of appropriate and cost effective medical devices. Consistency and standardization in technical specifications promotes positive competition and reduces effective costs. It also promotes uniformity in user training and smooth maintenance of equipment. In order to address the variation in technologies many of which could be add-ons, separate exercises were undertaken for specific categories of medical devices procured under National Health Mission. The experts consulted for specifications formulation exercises included clinicians, medical technologists, maintenance experts and also representatives from manufactures' industry associations/government organizations.

National Health Systems Resource Centre which is also a WHO collaborating centre for priority medical devices & health technology policy; in consultation with experts has formulated technical specifications for commonly used medical devices. Specifications are suggestive in nature and any specific requirement needs to be incorporated at the time of procurement. While effort has been made to make the specifications as generic as possible and consensus and technical appropriateness has been the corner stone of this technical exercise.

In the consultative meeting experts has mentioned the following activities needs to be considered wisely while procuring medical devices.

(1) The public health facility that intend to house medical devices (especially electrical/electronic based) must ensure before installation ,
(a) Proper grounding at electrical sockets,
(b) Wherever generator or UPS or solar power is used as back up energy source, should ensure the stabilizer/surge protector to prevent malfunction of medical devices. The same may be undertaken at facilities having voltage/energy fluctuations.
(2) Procurer may form rate contract on reagents/consumables anticipating yearly demand, on Medical devices which require periodic supply of reagents/consumables for its day to day operation.
(3) Appropriate filtering mechanism to be housed at public facility to ensure maximum longevity on Medical devices which operates efficiently depending on quality of pneumatics/water supply source.
(4) Ensure compliance for Medical devices which are regulated under various laws/regulatory body like CDSCO, AERB, Pollution control Board, PC PNDT, PESO etc.
(5) Procurer/public health facility must ensure scheduling calibration and preventive maintenance (incl. replacement of parts that are expected to be worn out after certain operation) as recommended in Medical device manufactures operational/service manual.
(6) Wherever necessary warning/safety information required, has to be placed at public health facilities.
(7) User/ In-house service training to be procured along with Medical devices for effective utilization.
(8) Public health facility may actively engage with MoHFW initiative, Post market surveillance /Materiovigilance program of India.
(9) Public health facility have to rely on manpower availability or utilization or IPD/OPD load factor to decide on quantity of medical devices to be procured and not just on number of bed at each level.

Brachytherapy System

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name. institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		20352
UMDNS code(s)		Brachytherapy Systems
GENERAL		
1. USE		
1.1	**Clinical purpose**	Systems designed to perform radiotherapy by administering a radioisotope directly into tissue (e.g., tumor, intravascular) to prevent or reduce tissue proliferation. These systems typically include a radiation delivery unit, a source safe, applicators, and controls. Brachytherapy systems (e.g., remote after loading systems) are used to treat cancer and other types of abnormal proliferative tissue (e.g., intravascular restenosis), minimizing the radiation dose to surrounding tissue and avoiding hospital staff exposure to radiation.
1.2	**Used by clinical department/ward**	Radiotherapy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	**Radiation source and transfer mechanism:** i. The system should be capable of using Co-60 / Ir-192 source. ii. Mention the source half-life and clinical working life Co-60/Ir 192 source during supply. Minimum half life of Co60 should be 5year and 3 months for Ir 192. iii. Mention the diameter of source and its characteristics of clinical usage, transfer guarantee, declaration to supply Co-60 and Ir 192 for a minimum period of 10 year and usability. iv. The source cable connection must be tested to withstand maximum number of transfers per source. The source transfer guarantee must be high to ensure optimal usage of each individual source. (Higher is preferred) v. The source cable must be a multi strand type and must be able to negotiate treatment curvature of 1 cm radius. vi. The source cable should have a safe movement (forward/backward) with a source positional accuracy of ±1 mm and must be controlled by stepper motors. vii. The source drive out length from indexer should be mentioned along with variable step size (Smaller is preferred) and treatment length (higher is preferred) viii. The source transfer guarantee must be enhanced in such a way that each source – must be utilized for an extended period of time (higher is preferred).Provision for manual retraction of source in the event of power failure to be available. ix. In case of source offered is Co-60 then 2 nos. based on the useful clinical life/if Ir192 then 30 sources be offered including all the charges, disposal and including the import duty charges for use at hospital for a period of min 10 years. x. The source should be dispatched as and when required by the hospital and all paper work relating to the source import has to be

		provided to the hospital for necessary approval. xi. The cost of radioactive source for second five years should be quoted separately. xii. Specify that insurance, Freight and cost of the sources for both onward and return of used source should be borne by the company. The clearance and transport of the source and the re-export/disposal of the decayed sources for a period of 10 years must also be included in the offer with Guarantee letter from the company to take back the decayed source should be included, if not the tender will not be considered. A high dose rate remote after loading Brachytherapy system capable of performing intracacitary. Intra luminal, interstial, intra operative and surface mould application. i. The HDR system should be microprocessor based with PC control unit. ii. The HDR system must be from a well Established company with a Documented history of Reliability. iii. The HDR system manufactures should have ISO/FDA/CE/Type approval from AERB. iv. The HDR system must have a "check cable" that automatically checks the operation of the complete system prior to treatment, the check cable must also be possible to use as a "Dummy" source to allow simulation of particular source locations. v. The system needs to be flexible for use in all type implants and the source integrity must be certified for maximum source transfers. vi. The system should be in use in recognized centers in India /abroad. The tender offer must be accompanied with letters of reference with performance certificate from existing users should be enclosed. vii. Any other specific advantage of the equipment may be mentioned. **Detailed specifications of HDR system** **a) Treatment Unit – HDR** i. Treatment unit should be on wheels for easy mobility within the room. ii. Treatment unit should be have telescopic head to adjust for various heights/separate stepper motors to control the dummy check cable and radiation source cable. Patient treatment should be radiolucent for X ray imaging. iii. A safe to contain the radiation source which complies with international safety regulations. iv. Treatment unit should have a-integrated radiation detector (GM tube type). v. Multichannel indexer with a minimum of 20 channels and above having an automatic/optical verification of channel number and applicator connection should be offered. vi. The source must be retractable in the event of an emergency/power failure by following methods: • By an independent DC motor. • Manual source retraction through hand crank. Also status to be displayed under power failure (using backup source). vii. Battery back-up and a detailed circuit for checking the battery condition viii. Mention the safety features and also measure to be taken

		during source struck. **b) Control Unit** i. Stand alone and independent PC based control unit with colour monitor, keyboard, mouse, printer for hardcopy (capable of printing entire treatment protocol), built in audio card, network card and back-up media. ii. Control unit should have user friendly console and a graphical user interface and should contain an extensive reporting facility, iii. Control unit software should run on Windows Application. Software to be upgraded as and when its released by manufacturer. iv. Control unit should have a self testing including battery, indexer/RAM. v. Control unit must allow storage of multiple standards and keep track of patients for fractioned treatment. vi. Access must be limited to authorized users with password protection. vii. The treatment times must be automatically corrected for the decay of the source. viii. Wide treatment length should be covered with adjustable minimum step source size. ix. Display of Total reference Air Kerma and dose. x. The control unit should contain: • An inbuilt protection circuit to prevent treatment without proper applicator connection and proper indexer locking • Online extensive display of status codes with an indication of the action required. • Large patient database should be provided with a backup option to an external storage device. • Control unit should contain an built-in log book and all events should be recorded. • The Brachytherapy system supplied should be provided with all treatment licenses and connectivity licenses to Record and Verify System. **Treatment Planning System:** • The HDR Brachytherapy system should have a dedicated 3D treatment planning system compatible to HDR unit so that the planning can be transferred directly network for execution to the independent HDR machine control computer linked to it. • The Radiotherapy treatment planning system should be fully computerized, integrated system having hardware and software to perform all kinds of Brachytherapy planning calculations, isodose plotting and display of patient files and other related parameters. Software to be upgraded as and when it's released. Software should include dose optimization. **Hardware:** **i. Workstation** The treatment planning system should have a separate computer (in addition to the control of the HDR Brachytherapy machine) and should have a most modem graphics workstation working at 3GHz speed or higher speed with CPU, fast processor with min 2 GB of Ram memory and it should have a Hard disk with large storing capacity of 500 Giga Bytes of more of memory and external mass storage unit of 1 Tera Bytes of External hard drive & CD – R&W with keyboard and must. It should have all Brachytherapy dose calculation Algorithms supported by the vendor. II. Digital Radiography should be available with unit.

		iii. Display/terminal The system should have at least two display monitor 19" (TFT/LCD screen with high resolution for good Visualization) for planning and contouring in different terminals. **iv. Printer/Plotter** The system should have a fast multi – colour plotter to print out various data's and Isodose curves. It should be possible to print out entire treatment protocol. **v. Ports** The system should have the 1 parallel, 2 serial and Ethernet port for Networking and SCSI ports to connect SCSI devices like scanner, magnetic tape drive and DVD/CD drive.
2.2	**User's interface**	a. The main Host computer should have a 19 inches or more high resolution LCD TFT color monitor with 1024 x 1024 matrix display b. The system should have image storage capacity of 100 GB for at least 2,00,000 images in 256x256 matrix. c. The reconstruction speed should be at least 1300 or more for full FOV 256 matrix. d. The main console should have facility for music system for patient in the magnet room. The system should have DVD / CD / flash drive archiving facility. The system should be provided with auto DVD writer. e. Two way intercom system for patient communication.
2.3	**Software and/ or standard of communication(where ever required**	The system must provide software to perform the following functions: **vi. Operating System** a.The system should have a latest enhanced operating system which offers multitasking, multiuser facilities. Password defined access for all users. b. Software to be upgraded as and when its released.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Maximum 120 dBA
3.4	**Heat dissipation**	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism with less than 1˚ c change during scan
3.5	**Mobility, portability**	Stationary installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	1. Should work on relevant source in the Institute possibly 2. UPS of suitable rating with voltage regulation and spike protection for 30 minutes backup. UPS should be capable of providing back up power to ensure safe source, dummy retraction

		in the event of power failure.
4.2	**Battery operated**	NO
4.3	**Protection**	1. Resettable over current breaker shall be fitted for protection. 2. All necessary clearances required for operation of the facility should be borne by the vendor.
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional);** **Spare parts (main ones);** **Consumables/reagents (open, closed system)**	**Applicators** i. Cervix for intracavitary Fletcher type – 3 sets ii. CT/MR compatible metallic Ring applicators (Titanium based– 2 sets) iii. Vaginal Cylinders – 2 sets (CT/MRI compatible) iv. Esophagus applicator – 2 sets each v. dummies & X-ray marker for all applicator. vi. Flexible implant tubes 100 nos. and rigid steel needle of each 20 nos. of different sizes should be quoted. Minimum 2 different sizes should be offered. vii. Patient viewing (CCTV with monitor) viii. Brachytherapy patient table with automatic height adjustment features and leg rest features should be offered. ix. Patient table should have head plate, removable leg plates, seat plate extension etc. **Quality Assurance Tools:** • Necessary source calibration devices (Well chamber-~~jig~~/Phantom along with Electrometer. • Ion chamber based survey meter & contamination meter. • Gamma zone monitor • Source position check device. • Specify and other necessary quality assurance tools and supply.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	1 .Operating Condition: Capable of operating continuously in ambient temperture of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required.
7. STANDARDS AND SAFETY		

7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. Shall meet internationally recognized standard for Electromagnetic Compatibility(EMI/EMC). for electro-medical equipment:61326-1. 5. Certified to be complaint with IEC 61010-1-3, IEC 61010-1-2, IEC 61010-2-54, IEC 61010-1-6 and IEC 62304. 6. AERB type approved. 7. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
7.2	**Local and/or international**	Manufacturer/Supplier should have ISO 13485 certificate for quality standard.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	The supplier should install and commission the Brachytherapy Unit and quoted items within 6 months from date of letter intend adhering to AERB directions/guideline.
8.2	**Requirements for sign-off**	Certificate of calibration and inspection of parts from the manufacturer. Post installation QA from AERB recognized agency must be conducted and submitted to purchaser for submission to AERB.
8.3	**Training of staff (medical, paramedical, technicians)**	• 1 week training to be provided to radiation oncologist, technologists and medical physicist on any reputed premier cancer center in India. • Onsite: 1 weeks training to be provided for in-house (Biomedical engineers) preventive/corrective maintenance (hardware/software).
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares and calibration. CMC for Air condition unit/UPS/Battery till decommission of Brachytherapy system. All hardware (computer) and software (including planning/clinical diagnosis or therapy/operating system etc) should be made available free of cost for up gradation in every 5th year. or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		

10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital. • Manufacturer should have ISO certifications for Quality standards, source certificate, performance and source transfer guarantee certificate should be enclosed. • User manual in English, service manual in English should be included along with the system. • List of important spare parts and consumable and accessories with their part number and costing fixed for a period of 5 years should be quoted. • List of equipments available to providing calibration and routine maintenance support as per manufacturer documentation in Service/Technical manual.
10.2	**Other accompanying documents**	1.List of essential spares and accessories, with their part number and cost; 2.Document illustrating frequency of calibration or preventive maintenance by manufacturer.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	1.Contact details of manufacturer, supplier and local service agent to be provided; 2.Any Contract(AMC/CMC/add-hoc) rate available to be declared by the manufacturer. 3. Manufacture/Supplier of medical devices should provide price quote for spare part of medical device or supply item, against requisition/Purchase order from biomedical engineers/technicians. 4. The system (equipment) transport to end user shall be in accordance with the international standards that are applicable.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed. Radiation Warning should be available in Regional/National language.

Rotational Cobalt Machine

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Rotational Cobalt Machine
UMDNS code(s)		16972
GENERAL		
1. USE		
1.1	**Clinical purpose**	Cobalt therapy or is the medical use of gamma rays from the radioisotope to treat conditions such as cancer.
1.2	**Used by clinical department/ward**	Radiotheraphy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	**I Cobalt Radiotherapy Machine** 1. Source: 180 RMM or higher ; Source head capacity should be upto 250RMM(15000Ci) 2. Minimum field size should be 2cm X 2cm 3. Maximum field size should be 35cm X 35cm 4. Should have a networking facility for hospital data management system 5. Should have an ISO wedge (Manual/motorized) to generate custom wedge profiles 6. Should have an asymmetric collimator(Motorized). 7. The unit should have remote/auto patient set up 8. Should have remote diagnosis facility for unit operation. 9. Gantry motion should be of 360 degree 10. Should have variable/fixed gantry speed for ARC and rotational therapy 11. Gantry angle should be digitally displayed on remote control console 12. Should have an iso centric accuracy of 1mm 13. It should have pneumatically driven source drawer for moving the source between the shielded position and treatment position. The pneumatic cylinder should return the source automatically to radiation off position in case of system failure 14. It should have a collimator rotation ±90 degree or ±180 degree from its central position 15. It should have collimator rotation with continuous speed control 16. The field size should be digitally displayed on room monitor and remote control console. 17. It should have a field light. 18. It should have a optical distance indicator 19. Unit should have automatic collimator closure to reduce the field size to minimum during movement irregularities 20. Unit should have emergency stop switches 21. Unit should have treatment door interlock 22. Unit should have air pressure interlock 23. Unit should have beam modifier interlock 24. Unit should have anti collision device

		25. Unit should have gantry motion interlocks. 26. Unit should have fully motorized pit mounted iso centric couch with vertical, longitudinal, lateral and isocentric rotational motorized motion. 27. Table top of treatment couch should be radiolucent carbon fiber top. Also should have limit switch and rubber damper to avoid overshooting. 28. Should have a battery back up for entire machine for 8 hours. 29. The control system and indicators should consists of: a) Remote computerized control console with control computer, processor cabinet, interface module b) Unit mounted controls and indicators 30. Remote computerized control console should consists of a) Display monitors-19" TFT monitors to be placed at the control console and inside the treatment room b) Treatment panel should have: i. Source position indicators ii. Gantry enable feature iii. Treat and pause feature iv. Emergency stop v. Power key switch vi. Inhibit and power indicators 31. Should be provided with all essential computer hardware accessories like keyboard, Mouse, Laser printer etc. 32. Computer hardware should also include facility for patient data storage and retrieval. 33. Last man out switch to be provided to ensure safety.
2.2	**User's interface**	
2.3	**Software and/ or standard of communication(where ever required**	Software's Required. a) Perfusion CT, Lung CT, Bone CT, Virtual endoscopy and CT angiography b) Quantitative CT measurement tools should be provided. c) 3D small volume analysis software for solitary nodules is desirable. d) The operating system and other softwares used in clincal diagnosis or therapehy should have latest version and shall offer multitasking and multi user access.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Maximum 120 dBA
3.4	**Heat dissipation**	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism with less than 1˚ c change during scan
3.5	**Mobility, portability**	Stationary installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	1. Should work on relevant source in the Institute possibly 2. UPS of suitable rating with voltage regulation and spike protection for 30 minutes backup.
4.2	**Battery operated**	NO

4.3	**Protection**	1. Resettable over current breaker shall be fitted for protection. 2. All necessary clearances required for operation of the facility should be borne by the vendor.
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Should contain all machine specific accessory for clinical diagnostic and treatment purposes designed by manufacturer: Should provide patient immobilization devices-Arm, Leg and Head support kits. i. Head and neck base plate (Carbon fibre)- 1no ii. Pelvic Base Plate(Carbon fiber) -1no iii. Head and neck base plate (High Pressure Laminate) – 1no iv. Pelvic Base Plate(High Pressure Laminate) -1 no v. Wing board-1no vi. Breast board – 1no vii. Feet Fix lock – 2nos viii. Knee Fix – 2nos ix. Index bar – 2nos x. Prone pillow – 3nos xi. kBolus 0.5cm – 10Nos xii. Shoulder retractor – 2nos xiii. Headrest Set of three (1,3&5) – 3sets xiv. Positioning Blocks and Wedges for Headrest (set of four2,4&6) – 3sets xv. Foam for block cutout- mention the quantity xvi. Cerrobend Alloy – mention the quantity xvii. Styrofoam cutter-1no xviii. Alloy melter for cerrobend- 1no xix. Water Bath 1m x 1m with digital heat control for thermoplastic cast Preparation – 1no xx. Thermoplastic immobilization precuts For Brain - 100no.s xxi. Head and neck - 100nos xxii. Supine abdomen- 50nos xxiii. Prone abdomen - 20nos xxiv. Thermoplastic mould cutter and heat gun – 1 no xxv. Tissue Compensator set - 1no
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	1 .Operating Condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required.
7. STANDARDS AND SAFETY		

7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1.The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. Shall meet internationally recognized standard for Electromagnetic Compatibility(EMI/EMC). for electro medical equipment:61326-1. 5. Certified to be complaint with IEC 61010-1-3, IEC 61010-1-2, IEC 61010-2-54, IEC 61010-1-6 and IEC 62304. 6. AERB type approved. 7. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
7.2	**Local and/or international**	Manufacturer/Supplier should have ISO 13485 certificate for quality standard.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	The supplier should install and commission the cobalt machine within 6 months on receipt of letter of intent adhering to AERB directions/guideline.
8.2	**Requirements for sign-off**	Certificate of calibration and inspection of parts from the manufacturer. Post installation QA from AERB recognized agency must be conducted and submitted to purchaser for submission to AERB.
8.3	**Training of staff (medical, paramedical, technicians)**	a) The vendor should provide comprehensive training on site for 1 week for in-house (Biomedical engineers) preventive/corrective maintenance (hardware/software) for one week. b) Besides that training in a advanced center/premier cancer institute for Radiation Oncologist & Radiation Physicists (at AERB approved site) & RT Technologist designated employees of the Institute also to be provided and included. The training period should be at least for two weeks and all costs included.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares and calibration. CMC for Air condition unit/UPS/Battery till decommission of Cobalt machine. All hardware (computer) and software (including planning/clinical diagnosis or therapy/operating system etc) should be made available free of cost for up gradation in every 5th year. or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		

10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	1.List of essential spares and accessories, with their part number and cost; 2.Document illustrating frequency of calibration or preventive maintenance by manufacturer.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	1. Contact details of manufacturer, supplier and local service agent to be provided; 2.Any Contract(AMC/CMC/add-hoc) rate available to be declared by the manufacturer. CMC for Air condition unit/UPS/Battery till decommission of Simulator. Self-Declaration on Total estimated life cycle of equipment by manufacturer. 3. Manufacture/Supplier of medical devices should provide price quote for spare part of medical device or supply item, against requisition/Purchase order from biomedical engineers/technicians.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed. Radiation Warning should be available in Regional/National language.

Radiotherapy Simulator

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		20547
UMDNS code(s)		Radiotherapy Simulation Systems,
GENERAL		
1. USE		
1.1	**Clinical purpose**	Radiotherapy simulation systems that perform radiographic and/or fluoroscopic imaging to determine, document, and externally mark the area to be treated. These systems combine technologies from both therapeutic and diagnostic radiology; they consist of a radiographic CT /fluoroscopic simulator that includes an x-ray system and a mechanical system (collimator, gantry, table, controls) that mimics the movement of a linear accelerator and/or a cobalt unit.
1.2	**Used by clinical department/ward**	Radiotheraphy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	CT scanner should have 1. Whole body 2. Multi-slice scanner with very fast scanning time (minimum 16 slices at a time) 3. Ability to perform large studies with narrow slice thickness for production of good quality DRR 4. High heat capacity anode for larger data sets 5. Directly cooled anode preferable (to eliminate delay in anode heating & enable fast acquisition scans) 6. Wide aperture preferably 78 cm or more 7. Scanned Field of View (SFOV) > 60 cms 8. Number of detectors in the x-y plane to scan the full 60 cm field of view 9. Extended reconstructed FOV (RFOV) of >70-80cms 10.True SFOV to be provided 11.Gantry • Should have tilt of ± 30 degrees • Gantry must support rotations of 0.5 second or less 12.Provide Internal-positioning lights 13.Provide facility for voice and visual breathing instructions 14.The gantry must have laser positioning lights with a positioning accuracy of ± 1mm or better. 15.Effective and accurate connectivity between CT simulator and RTPS (Radiotherapy treatment planning system) - essential **X-ray System** a) High frequency X-ray generator with power rating of at least 80kW or more. b) This should in the range of 90 kV to 140 kV or better. c) The mA range must be from 20 mA to 600mA or better depending on kV, with step size of 5mA or better. d) Heat capacity: > 7 MHU

		e) Peak Anode heat dissipation rate of at least 700 kHU / min or better. f) X-ray tube should have dual focal spot. Please mention the size of the focal spots g) X-Ray tube with anode heat storage capacity of at least 7 MHU h) Automatic selection of the focal spot should be possible i) Optimizing x-ray tube voltage (kV) to patient size and shape should be possible. j) The adjustment of tube current to patient attenuation, but the adjustment of kV protocol optimization. **Detectors** a) The detector system should be a high performance, low noise, high data density, active response data acquisition system. b) The detectors should be solid state. c) It should be free from repeated calibrations. d) Number of Detector elements: to be specified (number per row to be mentioned) **Scan parameters** a) Slice thickness should be user selectable from 1 mm to 10 mm. b) KV: 90 - 140kV or better c) mA: 20 - 600mA in increments of 5mA or better. d) Scan time of 0.5 second or less for full 360 degree rotation. Other options (sub-second scan time) must be quoted e) Retrospective reconstruction should be possible on raw data files with change in parameters such as FOV. f) The following scanning modes should be possible: Scano-gram, Axial, Spiral. g) The scanogram length should be more than 1500mm long and the width must be at least 600mm. h) It must be possible to obtain the scanogram from AP or PA or left to right or right to left directions. i) The accuracy of slice prescription from the scanogram should be ± 0.5mm or better. j) The accuracy of distance measurements in the scanogram. (taken at isocenter distance) must be better than ± 0.5mm or better than twice the pixel dimension. k) Accuracy of slice location < 1mm. l) Reference scan should be possible on an arbitrary slice with the proposed treatment volume. m) High contrast spatial resolution: It should be at least 15 lp/cm maximum at 0%MTF. n) Low contrast detestability: 5mm or less @ 0.3% using 20cm CATPHAN on 10mm slice thickness. o) The CT number accuracy must be better than ± 4 HU for water and ± 10 HU for air. Necessary phantoms to check the spatial resolution of the

		scanner should be provided. A special phantom to check the electron density – HU relationship for the different body tissues must be provided. **Image Quality** a) The reconstruction matrix must be 512 x 512 or higher. The reconstruction time should be as less as possible. Simultaneous scanning and reconstruction should be possible. It should be possible to do: b) Spatial resolution (minimum parameters): • High contrast: better than 15 line pair per centimeter (at 0 % MTF) & • Low contrast: 5mm at 3% resolution c) Simultaneous scanning & routine analysis. d) Simultaneous scanning & archiving and / or hard copying and e) Simultaneous scanning and transfer to second console / workstation. f) The system must have automatic mA control software that automatically adjusts mA for patient size, adjust mA along the z-axis, modulates mA during rotation. Spiral Parameters a) Different selection of pitch should be possible, in 0.1 increments. Please mention the pitch available. Mention the single run coverage and the table scannable range. b) Inter Scan Delay in different group of spiral should not be more than 5 sec. c) Intra-plan delay of 5 sec or more should be possible d) Retrospective reconstruction should be possible on raw data files with change in parameters such as FOV e) The following scanning modes should be possible: Scanogram, Axial, Spiral, Cine and biopsy mode Pilot scan: The pilot scan field size should be more than 1500 mm long. The reconstruction time for pilot scan should be 3 secs for a 512 matrix and 5 secs for a matrix of larger size Reference scan should be possible on an arbitrary slice within the proposed treatment volume Specify the table speed to the scan in terms of Z-axis coverage. **Couch** a) The couch top must be a carbon fibre, flat bed type. It must be a Stateof-the-Art; indexed couch top matching the Medical College's linear accelerators' couch tops to facilitate accurate treatment delivery with ease and convenience. b) The couch top material must be carbon fibre with minimum dimensions

		of 235cm x 40cm, having horizontal moving range of 160 cm or more. c) The speed of horizontal movement must be variable with a maximum speed of at least 100mm per second. d) The accuracy (reproducibility) of the table tope must be better than ±0.25mm. e) The scannable horizontal range should be at least 150cm or more. f) The couch must meet the following vertical movement ranges: 55 to 95cm or better when outside the gantry; within the gantry it must have a moving range of 20cm; the minimum height outside the gantry must be specified. g) It must be able to take a maximum weight of 180kg or more without any change in stated performance specifications (like the positioning accuracy). h) Couch should be suitable for all kinds of radiotherapy immobilization system i) Laser system facility for radiation therapy placement of treatment fields and marking of radiation field portals on patient's skin is required without moving the couch. T j) he The CT-simulator should have at least three laser sets for marking the field reference points, consists of a single overhead moving laser to project the sagittal plane, two moving lasers to project coronal plane and two moving lasers to project the axial plane. This should eliminate the need for manual couch movements. k) The CT scanner should also have conventional in-built lasers for positioning the patient along with all positional devices. **Support for respiratory management system:** a) Seam less integration to the interface of the linear accelerator respiratory management system. b) The CT scanner firm is required to provide all licenses and necessary interface hardware for seamless integration for the purpose of gated & IGRT radiotherapy. **Computer Hardware** a. 2a. Computer System for the CT scanner i. State-of-the-Art, high end main computer system, must be provided. With all the relevant software and manuals and licences for Virtual simulation CT scan RT planning 2D/3D/4D/IMRT/IGRT/ whole body SRS/SRT). ii. The connectivity, compatibility for the same to existing Radiotherapy Network and planning system in the department (i.e., Teletherapy (2D/3D/IMRT/IGRT/SRS/SRT) / Brachytherapy HDR/LDR) must be

		ensured by the CT sim vendor. iii. All necessary Licenses shall be provided or obtained by the vendor for ensuring the smooth operation towards Virtual simulation for (2D/3D/4D/IMRT/IGRT/ whole body SRS/SRT) is to be ensured by the vendor. iv. The system must have parallel processors; RAM size must be at least 4 GS or better. v. There must be two monitors in the console and they must be 19" TFT flat screen LCD monitors. One of these will be used for acquisition and the other will be used for review and processing. vi. The hard disk capacity of the main computer system must be at least 140GB or more. vii. In the hard disk meant for image storage, the number of uncompressed 512 x 512 images that can be stored should be at least 250,000 or more. The maximum possible hard disk capacity must be provided. viii. For archiving, DVD writer should be provided for providing copies of individual studies. Please supply 1000 rewritable DVD's. ix. All necessary accessory hard ware like UPS for computers, printers and consumables (DVD / DAT cartridges) to be specified and provided. b. The CT-Simulator system should be fully DICOM complaint and any other relevant image protocols meant for (i.e., Teletherapy (2D/3DjIMRT/IGRT/SRS/SRT) / Brachytherapy HDR/LDR). The DICOM/ /image should support the following: i. Dicom 3.0 Print service class as a user. ii. Dicom 3.0 Storage class as a user. iii. Dicom 3.0 Storage class as a provider. iv. Dicom 3.0 Send / Receive v. Dicom 3.0 Query / Retrieve service class as a user. vi. Dicom 3.0 Query / Retrieve service class as a provider. vii. Dicom compliance statement should be provided. A bi-directional speaker communication must be provided between the operator and the patient. Computer System for Moving Laser System a) The laser system provided must be 3 moving lasers for marking the isocenter without moving the table top. b) Following the isocenter localization in the CT simulator workstation, the isocenter coordinate will be sent directly to the computer system that is controlling the movements of the lasers. This computer in turn should drive all the lasers, so that without moving the table top, the lasers point to the isocenter.

		c) Complete quality assurance tool (as stated above) must be provided. d) The control computer system must be latest Windows based system with Pentium 4 processor or higher. Connectivity a. The entire CT Simulation system must be interconnected (all the workstations, laser systems, printers etc.) and must be integrated into the department's treatment planning system for smooth transferring of images (for Teletherapy (2D/3D/IMRT/IGRT/SRS/SRT) / Brachytherapy HDR/LDR) and DICOM-RT structures. b) The system should be networking with all radiotherapy treatment planning system in the department. Quality Assurance and Acceptance tests: a) All QA and Acceptance to be done before commissioning as per DAE AERB / FDA guidelines **b) All QA & Dosimeter, Maintenance tools (Hardware and software) to be provided** **c) Target localization: < 1 pixel Tolerance** **d) DRR accuracy: Ray line angular displacement < 0.1 degree tolerance** **e)Last man out switch to be provided to ensure safety.**
2.2	**User's interface**	a. The main Host computer should have a 19 inches or more high resolution LCD TFT color monitor with 1024 x 1024 matrix display b. The system should have image storage capacity of 100 GB for at least 2,00,000 images in 256x256 matrix. c. The reconstruction speed should be at least 1300 or more for full FOV 256 matrix. d. The main console should have facility for music system for patient in the magnet room. The system should have DVD / CD / flash drive archiving facility. The system should be provided with auto DVD writer. e. Two way intercom system for patient communication. f. CT simulator System should be DICOM ready in all parameters with no additional requirement of license for connectivity to any PACS/HIS and Radiotherapy treatment planning system.
2.3	**Software and/ or standard of communication(where ever required**	Software's Required. a) Perfusion CT, Lung CT, Bone CT, Virtual endoscopy and CT angiography b) Quantitative CT measurement tools should be provided. c) 3D small volume analysis software for solitary nodules is desirable
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Maximum 120 dBA
3.4	**Heat dissipation**	Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanismwith less than 1˚ c change during scan
3.5	**Mobility, portability**	Stationary installation

4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	1. Should work on relevant source in the Institute possibly 2. UPS of suitable rating with voltage regulation and spike protection for 30 minutes backup.
4.2	**Battery operated**	NO
4.3	**Protection**	1. Resettable over current breaker shall be fitted for protection. 2. All necessary clearances required for operation of the facility should be borne by the vendor.
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Should provide One set of the following patient positioning accessories should contain all machine specific accessory for clincal diagnostic and treatment purposes designed by manufacturer: a) UPS: On line UPS with MF batteries for the backup of the entire system for at least thirty minutes. b) Lead Glass: 100 cm X 150 cm or more with lead equivalent to meet the AERB's radiation safety requirements. e) Pressure Injector: CT compatible pressure injector with remote console 500 disposable syringes. f) Quality assurance accessories and phantom: The quality assurance, Dosimetry tools and phantom for Virtual simulation should be included with all details. g) Remote diagnostic monitoring: Remote diagnostics tool and software should be included along with modem and telephone connection with ISDN line for on-line remote diagnosis. All such running costs will be at supplier's account for the duration of warranty and CMC.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	1 .Operating Condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.

7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. Shall meet internationally recognized standard for Electromagnetic Compatibility(EMI/EMC). for electro medical equipment:61326-1. 5. Certified to be complaint with IEC 61010-1-3, IEC 61010-1-2, IEC 61010-2-54, IEC 61010-1-6 and IEC 62304. 6. AERB type approved. 7. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
7.2	**Local and/or international**	Manufacturer/Supplier should have ISO 13485 certificate for quality standard.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	The supplier should install and commission the Linear accelerator within 6 months on receipt of letter of intend adhering to AERB directions/guideline.
8.2	**Requirements for sign-off**	Certificate of calibration and inspection of parts from the manufacturer.Post installation QA from AERB recognized agency must be conducted and submitted to purchaser for submission to AERB.
8.3	**Training of staff (medical, paramedical, technicians)**	a) The vendor should provide comprehensive training for clincal staff on the CT-Simulator on site for 2 week and in-house (Biomedical engineers) reventive/corrective maintenance (hardware/software) for one week. b) Besides that training in a advanced center/premier cancer institute for-Radiation Oncologist & Radiation Physicists (at AERB approved site) & RT Technologist designated employees of the Institute also to be provided and included. The training period should be at least for two weeks and all costs included.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares and calibration. CMC for Air condition unit/UPS/Battery till decommission of Simulator. All hardware (computer) and software (including planning/clinical diagnosis or therapy/operating system etc) should be made available free of cost for up gradation in every 5th year. or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in

		English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	1.List of essential spares and accessories, with their part number and cost; 2.Document illustrating frequency of calibration or preventive maintenance by manufacturer.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	1.Contact details of manufacturer, supplier and local service agent to be provided; 2.Any Contract(AMC/CMC/add-hoc) rate available to be declared by the manufacturer. Self-Declaration on Total estimated life cycle of equipment by manufacturer. 3. Manufacture/Supplier of medical devices should provide price quote for spare part of medical device or supply item, against requisition/Purchase order from biomedical engineers/technicians.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed. Radiation Warning should be available in Regional/National language.

Single energy photon LINAC (LOW ENERGY LINEAR ACCELERATOR)

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		12364
UMDNS code(s)		Radiotherapy Systems, Linear Accelerator
GENERAL		
1. USE		
1.1	**Clinical purpose**	Radiotherapy systems designed to produce electron beams of varying energies for low to high-energy photons using a linear accelerator (linac) as a generator. A linear accelerator consists of a modulator, an electron gun, a radio-frequency power source (either a magnetron or a klystron), and an accelerator guide. The range of the energy levels provided by linacs is very wide, from 4- to 6-megavolt (MV) photons for low-energy units and 25 MV photons and up to 22 mega-electron-volt electrons in high-energy units. These systems also include control units, filters, and collimators. Low-energy linear accelerator systems are mostly used to treat tumors of the head, neck, and breast.
1.2	**Used by clinical department/ward**	Radiotherapy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		

2.1	**Technical characteristics (specific to this type of device)**	Linear Accelerator technology requirements: **The Machine must have the latest technology such as:** **• Magnetron/Klystron as the RF power source** **• Standing Wave Accelerator guide** **• • Sealed Ionization chambers** **• Dose rate should be selected in fixed steps for 6 MV photon energy beam** **• Computer controlled** **• Triode/diode Electron Gun and flat panel based technology intensifier** **Photon Energies and Beam data** One photon energy-6 MV **Dose rates for 6 MV photon Beam:** • Photons energy must have a variable dose rate atleast from range 100-500 MU/min • Representative central axis profile dose curves, as well as flatness and symmetry profiles measured on the accelerator to be installed shall be provided. These curves need not be warranted by the vendor for clinical use. • An optical distance indicator which indicates the SSD to at least + 5 mm over the 80 to 130 cm range shall be provided. Accuracy at 100 cm shall be +1mm. A mechanical indicator which indicates the SSD to within 2 mm maximum error over the range 90 to 110 cm should be provided. • The maximum dose rate shall equal or exceed 500 monitor units (MU) per minute for a field size of 10 x 10 cm at 100 cm TSD. The dose rate at isocentre shall be variable from 100 MU/minute to the maximum dose rate. Please indicate minimum and maximum dose rate and number of intermediate dose rates available. • Beam stability should be achieved within 200 milliseconds to ensure dynamic applications. • There shall be one laser installed in the ceiling and two on the walls whose beams shall intersect at isocentre. The diameter of the laser beams as shown on a phantom located at isocentre shall be less than 2mm. **Arc Therapy facilities:** The linear accelerator must be able to provide arc therapy facilities for photons clockwise and counterclockwise. The dose rate should be at least 0.5 to 10 MU per degree. **Field Size:** • 0.5 x 0.5 cm to 40 x 40 cm field size collimation continuously variable must be provided (the full square field shall be atleast 35 x 35cm) • The field size is defined as the distance along the radial and transverse axes between the points of 50 % density on an x-ray film taken at 100cm TSD with minimum buildup. The digital display, light field size and mechanical display should be accurate to within + mm. • The accelerator shall provide a continuously variable rectangular. Unclipped field size from 1 x1cm to 35cm at 100 cm SSD. The maximum clipped field size should equal or exceed 40 x 40cm at 100cm SSD. Clipped corners are unacceptable for fields smaller than 35 x 35cm. **Wedge Systems:** A dynamic/virtual/ motorized wedge system providing various angles must be provided. The hard wedges with 15,30,45 and 60 degrees must also be provided as optional. **Patient table:** The patient table must be of extended travel range providing a lateral travel range of + 25 cm a longitudinal travel range of 150 cm and a vertical travel range of at least 100cm. The patient table should also have the following features:

		• **Fully carbon fiber table top.** • **Emergency off buttons on the both sides of couch.** • **A complete line of indexed Immobilization accessories.** **Collimator Jaws:** • Both X and Y collimator-should be independent and should have asymmetrical collimation. • Automatic delivery of multiple Co-planner fields in sequence should be possible in the Linear Accelerator. **Radiation Leakage** • Radiation leakage limits shall be within appropriate regulatory agency guidelines as follows. • Photon leakage. The photon leakage rate at any point one meter from the target outside the cone defined by the primary X-ray collimator shall be less than 0.1% of the absorbed dose at the isocenter. Collimator transmission. The movable collimators shall not permit transmission of radiation exceeding 0.5% of the central axis dose at Dmax measured in air. • No surface accessible to the operator should be radioactive such that the dose rate in contact with that surface exceeds 50 mrem/hr **Oncology Information and networking system** 1. Complete networking system 2. Record & verify system should be integrated or capable of integrating with radiology database of institution/hospital. 3. Transfer of all parameters from simulator & treatment planning system of the Accelerator for automatic treatment setup & deliver should be provide 4. Transfer of Fluoroscopy images from simulator to portal imaging system for Comparison should be provided. 5. Transfer & Execution of MLC position parameters for normal treatment & IMRT treatment including step & shoot & sliding window (Dynamic) techniques from Treatment planning system should be complete and full networking system between Linear Accelerator, HDR Brachytherapy unit, TPS, MLC of minimum 5 mm size, EPID and CT scanner should be provided. Dosimeter **Photon Ionization Chamber** • A transmission ionization chamber shall be used for the photon mode. The chamber shall incorporate completely separate collection electrodes consisting of two plates for dose monitoring and a quadrant plate for field symmetry **Dual channels** • The dosimetry system should be there shall utilize two completely independent channels for monitoring accumulated dose (i.e a primary and a redundant channel.) A dose rate channel and a channel for monitoring differential field symmetry shall be provided. The redundant channel will terminate an exposure of no more than 40 MU higher than the machine setting. The system shall also provide a backup timer with a minimum significant time setting of 0.01 minute. The backup time shall be automatically calculated and set at a user specified value above expected duration of the treatment. **Monitor chamber** • The dose monitoring chambers shall be sealed and shall operate independent of temperature and pressure. The dosimetry electronics shall incorporate circuitry to permit interrogation of the accumulated dose, dose rate and symmetry channels prior to each patient treatment. This interrogate function shall check cable continuity, electrical calibration and interlock trip levels before each treatment. All

		dosimetry and patient safety – related interlocks must be sensed and controlled by hardware. Primary software sensing and control of safety-related interlocks is not acceptable. • The dosimeters shall be reproducible to within ±2% or 1 monitor unit, whichever is greater, at any fixed gantry angle form 0 to 360 degrees. • The linearity of the dosimeters shall be ±1% or 1 monitor unit, whichever is greater, for accumulated doses between 50 and 999 monitor units. **Back up counter** • The integral dose shall be retained on a counter which indicates the monitor units delivered to that time with the unexpected loss of power or malfunction of the accelerator or dose measuring system. The dose shall be retained for at least 20 minutes after power interruption. **Dose rate** • The reproducibility of the dosimeters shall be ±1% or 1 monitor unit, whichever is greater, at a fixed dose rate. With variations in the dose rate from minimum to maximum, the reproducibility of the dosimeters shall be ±2%. Please specify the dose rate range over which the latter specification is valid. **Energy** • The dosimetry system shall monitor the beam energy and shall terminate irradiation should energy change by more than ±3% from the nominal 6MV value. -Last man outswitch to be provided to ensure safety.

2.2	**User's interface**	a. The main Host computer should have a 19 inches or more high resolution LCD TFT color monitor with 1024 x 1024 matrix display b. The system should have image storage capacity of 100 GB for at least 2,00,000 images in 256x256 matrix. c. The reconstruction speed should be at least 1300 or more for full FOV 256 matrix. d. The main console should have facility for music system for patient in the magnet room. The system should have DVD / CD / flash drive archiving facility. The system should be provided with auto DVD writer. e. Two way intercom system for patient communication. f. MRI System should be DICOM ready in all parameters with no additional requirement of license for connectivity to any PACS/HIS and Radiotherapy treatment planning system. **Multileaf Collimator (MLC):** • A multileaf collimator shall be provided with multiple leaves giving wide field coverage • The isocentre resolution of the leafs should be 1 cm and less • MLC should be capable of executing all IMRT Treatments • MLC system must be capable of performing all types of IMRT treatments such as multiple static fields, step and shoot, dynamic treatments. • All accessories including hardware and the necessary licenses needed for IMRT treatments in Linear accelerator should be offered. • Maximum field size shall be no less than 40 x 40 cm. • X- ray transmission through leaf shall not exceed 4% of the central axis dose at Dmax, and X- ray transmission shall not exceed 0.5% of the central axis dose at Dmax for the smallest rectangular field outside a shaped MLC field. This specification shall apply to both photon energies. • Positional accuracy shall be netter than +1% • Time for all leaves to travel from fully opened to fully closed shall be no greater than 14 seconds, as timed from when the leaves start moving. Leaf velocity shall be atleast 1.54 cm /second. **IGRT Systems** • Latest hardware and software should be provided for IGRT system Latest flat panel detectors should be provided (Please specify resolution) The system must be capable of performing MV-MV imaging and Fully integrated with latest R&V system and TPS. **Digital Portal Imaging:** • The portal Imaging system shall replace the necessity of port films, therefore the system must be capable of producing Images at 6 MV photon energy • The system shall be using latest solid state amorphous silicon electronic portal imaging device. • The imaging system should be retractable motorized counterweight mounted supports arm fixed on the counterweight, should be able to take images at any gantry angles from control room. • (Removable type portal imaging systems will not be preferred • Portal imaging system should be fully integrated with the Linear accelerator gantry

2.3	**Software and/ or standard of communication(where ever required**	The system must provide software to perform the following functions: **i. Operating System** The system should have a latest enhanced operating system which offers multitasking, multiuser facilities.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Maximum 120 dBA
3.4	**Heat dissipation**	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism with less than 1˚ c change during scan
3.5	**Mobility, portability**	Stationary installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	1. Should work on relevant source in the Institute possibly 2. UPS of suitable rating with voltage regulation and spike protection for 30 minutes backup.
4.2	**Battery operated**	NO
4.3	**Protection**	1. Resettable over current breaker shall be fitted for protection. 2. All necessary clearances required for operation of the facility should be borne by the vendor.
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Accessories for Low energy Linear accelerator should contain all machine specific accessory for clinical diagnostic and treatment purposes designed by manufacturer:: • Accessory mount • Wedges manual • Solid block tray with standard shaped shielding blocks • Hand pendants -2 Nos • Universal Accessory clamps/ indexer • Manuals • Data Book **Supporting Accessories:** • Chiller for Linear Accelerator • Heavy Duty UPS for Linear Accelerator unit & TPS with back up of atleast 30 minutes. • Solid state laser system (2 cross and 1 sagittal) to be provided and installed. • Two individual patient monitoring interactive CCTV system one with digital zoom and another with wide angle coverage to be provided. • All the above equipments should be transported, be installed and made functional and ready for patient treatment in the bunker and obtain necessary Governmental clearances (as per DAE/AERB regulations) for commissioning. The whole unit should be made ready and handed over to the Institute in specified time period ready for Patient Treatment.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		

6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	1 .Operating Condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Should be egrnomically designed for user.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. Shall meet internationally recognized standard for Electromagnetic Compatibility(EMI/EMC). for electro medical equipment:61326-1. 5. Certified to be complaint with IEC 61010-1-3, IEC 61010-1-2, IEC 61010-2-54, IEC 61010-1-6 and IEC 62304. 6. AERB type approved. 7. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
7.2	**Local and/or international**	Manufacturer/Supplier should have ISO 13485 certificate for quality standard.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	The supplier should install and commission the Linear accelerator within 6 months from date of issual of letter of intent adhering to AERB directions/guideline.
8.2	**Requirements for sign-off**	Certificate of calibration and inspection of parts from the manufacturer.Post installation QA from AERB recoganised agency must be conducted and submitted to purchaser for submission to AERB.
8.3	**Training of staff (medical, paramedical, technicians)**	1. At least One week hands on training for Medical Physicist , Radiation Oncologist at any leading RT center / Learning center of the vendor / Clinical school in one of the premier cancer institute. 2. Onsite training for the two operators and in-house maintenance engineers (Biomedical engineers) for one week to be provided on preventive/corrective maintenance (hardware/software).
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares and caliberation.CMC for Air conditinon unit/UPS/Battery till decommission of LINAC. All hardware (computer) and software (including palnning/clincal diagnosis or theraphy/operating system etc) should be made available free of cost for upgradation in every 5th year. or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		

10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation5.Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	1.List of essential spares and accessories, with their part number and cost; 2.Document illustrating frequency of calibration or preventive maintenance by manufacturer.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	1.Contact details of manufacturer, supplier and local service agent to be provided; 2.Any Contract(AMC/CMC/add-hoc) rate available to be declared by the manufacturer. Self Declaration on Total estimated life cycle of equipment by manufacturer. 3. Manufacture/Supplier of medical devices should provide price quote for spare part of medical device or supply item, against requisition/Purchase order from biomedical engineers/technicians.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed. Radiation Warning should be available in Regional/National language.

Multiple energy LINAC (HIGH ENERGY LINEAR ACCELERATOR)

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		12364
UMDNS code(s)		Radiotherapy Systems, Linear Accelerator
GENERAL		
1. USE		
1.1	**Clinical purpose**	Radiotherapy systems designed to produce electron beams of varying energies low to high-energy photons using a linear accelerator (linac) as a generator. A linear accelerator consists of a modulator, an electron gun, a radio-frequency power source (either a magnetron or a klystron), and an accelerator guide. The range of the energy levels provided by linacs is very wide, from 4- to 6-megavolt (MV) photons for low-energy units to 25 MV photons and up to 22 mega-electron-volt electrons in high-energy units. These systems also include control units, filters, and collimators. Low-energy linear accelerator high-energy systems are used to treat deep-seated neoplasms and tumors of the pelvis and thorax.
1.2	**Used by clinical department/ward**	Radiotheraphy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		

2.1	**Technical characteristics (specific to this type of device)**	Linear Accelerator technology requirements: **The Machine must have the latest technology such as:** **1. Three dimensional Conformal Radiotherapy (3D CRT)** **2. Intensity Modulated Radiation Therapy (IMRT)** **Photon Energies and Beam data** photon energy- Low: 6MV; High: 15MV Electron energies :- 6MeV to 18MeV with minimum of five energy ranges. **Dose Rate:** Variable in steps. Should quote the maximum dose rate available with the Vendor for both photon beams. **Arc Therapy facilities:** a. The accelerator must be able to deliver a preset dose over a preset arc of 3600 or any fraction thereof. A range of variable dose rates should be available. b. The maximum variation in integrated dose delivered over an arc between 450 and 900 shall not exceed ± 3% or 1MU, whichever is greater. The maximum variation in integrated dose delivered over any arc of 900 or greater shall not exceed ± 2% or 1 MU, whichever is greater. c. Gantry rotation shall be possible clockwise and counter clockwise for arc therapy. The MU/degree shall automatically be computed. **Field Size:** Specify the maximum percent difference of average dose for the longitudinal and transverse axes of the field at 100cm SSD and 10cm depth at four orthogonal gantry angles for all field sizes from 10 cm2 to 40cm2. **Wedge Systems:** A dynamic/virtual/ motorized wedge system providing various angles must be provided. The hard wedges with 15,30,45 and 60 degrees must also be provided as optional. **Patient table:** The patient table must be of extended travel range providing a lateral travel range of + 25 cm a longitudinal travel range of 150 cm and a vertical travel range of at least 100cm. The patient table should also have the following features: • **Fully carbon fiber table top.** • **Emergency off buttons on the both sides of couch.** • **A complete line of indexed Immobilization accessories.** **Collimator Jaws:** • Both X and Y collimator should be independent and should have asymmetrical collimation. • Automatic delivery of multiple Co-planner fields in sequence should be possible in the Linear Accelerator. **Radiation Leakage** • Radiation leakage limits shall be within appropriate regulatory agency guidelines as follows. • Photon leakage. The photon leakage rate at any point one meter from the target outside the cone defined by the primary X-ray collimator shall be less than 0.1% of the absorbed dose at the isocenter. Collimator transmission. The movable collimators shall not permit transmission of radiation exceeding 0.5% of the central axis dose at Dmax measured in air. • No surface accessible to the operator should be radioactive such

		that the dose rate in contact with that surface exceeds 50 mrem/hr - Portal Dosimetry package should be provided. **Oncology Information and networking system** 1. Complete networking system 2. Record & verify system 3. Transfer of all parameters from simulator & treatment planning system of the Accelerator for automatic treatment setup & deliver should be provide 4. Transfer of Fluoroscopy images from simulator to portal imaging system for Comparison should be provided. 5. Transfer & Execution of MLC position parameters for normal treatment & IMRT treatment including step & shoot & sliding window (Dynamic) techniques from Treatment planning system should be complete and full networking system between Linear Accelerator, HDR Brachytherapy unit, TPS, MLC, EPID and CT scanner should be provided. 6. Prospective & retrospective 4D CT image acquisition for performing respiratory gated radiotherapy. 7.The linear accelerator vendor would provide one set of hardware of the respiratory management system and **Photon Ionization Chamber** • A transmission ionization chamber shall be used for the photon mode. The chamber shall incorporate completely separate collection electrodes consisting of two plates for dose monitoring and a quadrant plate for field symmetry **Dual channels** • The dosimetry system shall utilize two completely independent channels for monitoring accumulated dose (i.e a primary and a redundant channel.) A dose rate channel and a channel for monitoring differential field symmetry shall be provided. The redundant channel will terminate an exposure of no more than 40 MU higher than the machine setting. The system shall also provide a backup timer with a minimum significant time setting of 0.01 minute. The backup time shall be automatically calculated and set at a user specified value above expected duration of the treatment. **Monitor chamber** • The dose monitoring chambers shall be sealed and shall operate independent of temperature and pressure. The dosimetry electronics shall incorporate circuitry to permit interrogation of the accumulated dose, dose rate and symmetry channels prior to each patient treatment. This interrogate function shall check cable continuity, electrical calibration and interlock trip levels before each treatment. All dosimetry and patient safety – related interlocks must be sensed and controlled by hardware. Primary software sensing and control of safety-related interlocks is not acceptable. • The dosimeters shall be reproducible to within ±2% or 1 monitor unit, whichever is greater, at any fixed gantry angle form 0 to 360 degrees. • The linearity of the dosimeters shall be ±1% or 1 monitor unit, whichever is greater, for accumulated doses between 50 and 999 monitor units. **Back up counter** • The integral dose shall be retained on a counter which indicates the monitor units delivered to that time with the unexpected loss of power or malfunction of the accelerator or dose measuring system. The dose shall be retained for at least 20 minutes after power interruption.

		Dose rate • The reproducibility of the dosimeters shall be ±1% or 1 monitor unit, whichever is greater, at a fixed dose rate. With variations in the dose rate from minimum to maximum, the reproducibility of the dosimeters shall be ±2%. Please specify the dose rate range over which the latter specification is valid. **Energy** • The dosimetry system shall monitor the beam energy and shall terminate irradiation should energy change by more than ±3% from the nominal 6MV value. -Last man outswitch to be provided to ensure safety.

2.2	**User's interface**	a. The main Host computer should have a 19 inches or more high resolution LCD TFT color monitor with 1024 x 1024 matrix display b. The system should have image storage capacity of 100 GB for at least 2,00,000 images in 256x256 matrix. c. The reconstruction speed should be at least 1300 or more for full FOV 256 matrix. d. The main console should have facility for music system for patient in the magnet room. The system should have DVD / CD / flash drive archiving facility. The system should be provided with auto DVD writer. e. Two way intercom system for patient communication. f. MRI System should be DICOM ready in all parameters with no additional requirement of license for connectivity to any PACS/HIS and Radiotherapy treatment planning system. **Multileaf Collimator (MLC):** • A multileaf collimator shall be provided with multiple leaves giving wide field coverage • The isocentre resolution of the leafs should be 1 cm and less • MLC should be capable of executing all IMRT Treatments • MLC system must be capable of performing all types of IMRT treatments such as multiple static fields, step and shoot, dynamic treatments. • All accessories including hardware and the necessary licenses needed for IMRT treatments in Linear accelerator should be offered. • Maximum field size shall be no less than 40 x 40 cm. • X- ray transmission through leaf shall not exceed 4% of the central axis dose at Dmax, and X- ray transmission shall not exceed 0.5% of the central axis dose at Dmax for the smallest rectangular field outside a shaped MLC field. This specification shall apply to both photon energies. • Positional accuracy shall be netter than +1% • Time for all leaves to travel from fully opened to fully closed shall be no greater than 14 seconds, as timed from when the leaves start moving. Leaf velocity shall be atleast 1.54 cm /second. **IGRT Systems** • Latest hardware and software should be provided for IGRT system Latest flat panel detectors should be provided (Please specify resolution) The system must be capable of performing MV-MV imaging and Fully integrated with latest R&V system and TPS. **Digital Portal Imaging:** • The portal Imaging system shall replace the necessity of port films, therefore the system must be capable of producing Images at 6 MV photon energy • The system shall be using latest solid state amorphous silicon electronic portal imaging device. • The imaging system should be retractable motorized counterweight mounted supports arm fixed on the counterweight, should be able to take images at any gantry angles from control room. • Removable type portal imaging systems will not be preferred • Portal imaging system should be fully integrated with the Linear accelerator gantry
2.3	**Software and/ or standard of communication(where ever required**	The system must provide software to perform the following functions: **i. Operating System** The system should have a latest enhanced operating system which offers multitasking, multiuser facilities.

3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Maximum 120 dBA
3.4	**Heat dissipation**	Should maintain nominal temp and the heat should be disbursed throgh a cooling mechanismwith less than 1˚ c change during scan
3.5	**Mobility, portability**	Stationary installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	1. Should work on relevant source in the Institute possibly 2. UPS of suitable rating with voltage regulation and spike protection for 30 minutes backup.
4.2	**Battery operated**	NO
4.3	**Protection**	1. Resettable over current breaker shall be fitted for protection. 2. All necessary clearances required for operation of the facility should be borne by the vendor.
4.4	**Power consumption**	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Accessories for high energy Linear accelerator should contain all machine sepecific accessory for clinical diagnostic and treatment purposes designed by manufacturer: • Accessory mount • Wedges manual • Solid block tray with standard shaped shielding blocks • Hand pendants -2 Nos • Universal Accessory clamps/ indexer • Manuals • Data Book **Supporting Accessories:** • Air conditioner for Linear Accelerator which maintain LINAC at optimum operating temperature. • Heavy Duty UPS for Linear Accelerator unit & TPS with back up of atleast 30 minutes. • Solid state laser system (2 cross and 1 sagittal) to be provided and installed. • Two individual patient monitoring interactive CCTV system one with digital zoom and another with wide angle coverage to be provided. • All the above equipments should be transported, be installed and made functional and ready for patient treatment in the bunker and obtain necessary Governmental clearances (as per DAE/AERB regulations) for commissioning. The whole unit should be made ready and handed over to the Institute in specified time period ready for Patient Treatment.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	1 .Operating Condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient

		temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	1.Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover. 2. Sterilization not required.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. Manufacturer should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements(or equivalent BIS Standard). 4. Shall meet internationally recognized standard for Electromagnetic Compatibility(EMI/EMC). for electro medical equipment:61326-1. 5. Certified to be complaint with IEC 61010-1-3, IEC 61010-1-2, IEC 61010-2-54, IEC 61010-1-6 and IEC 62304. 6. AERB type approved. 7. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
7.2	**Local and/or international**	Manufacturer/Supplier should have ISO 13485 certificate for quality standard.
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	The supplier should install and commission the Linear accelerator within 6 months on receipt of letter of intend adhering to AERB directions/guideline
8.2	**Requirements for sign-off**	Certificate of calibration and inspection of parts from the manufacturer. Post installation QA from AERB recoganised agency must be conducted and submitted to purchaser for submission to AERB.
8.3	**Training of staff (medical, paramedical, technicians)**	1. At least One Medical Physicist and One Radiation Oncologist at any leading RT center / Learning center of the vendor / Clinical school in one of the developed countries and two persons in India for two weeks (all put together). 2. Onsite training for the two operators for one week to provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares and calibration. CMC for Air condition unit/UPS/Battery till decommission of LINAC. or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		

10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	1.List of essential spares and accessories, with their part number and cost; 2.Document illustrating frequency of calibration or preventive maintenance by manufacturer.
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	1.Contact details of manufacturer, supplier and local service agent to be provided; 2.Any Contract(AMC/CMC/add-hoc)rate available to be declared by the manufacturer. Self Declaration on Total estimated life cycle of equipment by manufacturer. 3. Manufacture/Supplier of medical devices should provide price quote for spare part of medical device or supply item, against requisition/Purchase order from biomedical engineers/technicians.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed. Radiation Warning should be available in Regional/National language.

Radiotherapy Treatment Planning System

Version no. :		Ver_1
Date:		15/02/2018
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Workstations, Radiotherapy Planning
UMDNS code(s)		21955
GENERAL		
1. USE		
1.1	**Clinical purpose**	Radiotherapy planning workstations designed to optimize the calculation of the expected radiation energy (dose) distributions within patients from both external sources of radiation (teletherapy) (Photon & Electron beam) -This system should have capability of integration with Simulators, CT scanner/ MRI & Linear Accelerators of any vendor. The TPS should be capable of 3D treatment planning with independent work station for virtual simulation.. These workstations typically consist of a computer, software for dosage calculation, and input and output devices (e.g., keyboards, monitors, printers) for graphic and alphanumeric data. Radiotherapy planning workstations usually follow the instructions of appropriate software that enables clinicians to choose the best combination of radiation beams and modalities for eradicating tumors while reducing radiation-related complications in healthy tissue. They are used mainly for treatment of cancer and related diseases.
1.2	**Used by clinical department/ward**	Radiotherapy Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		

2.1	**Technical characteristics (specific to this type of device)**	**<u>Treatment Planning System & Contouring Systems</u>** A. 2 planning systems (this is the minimum and to be increased as and when teletherapy machines are purchased) and 3 contouring systems (this is the minimum and to be increased depending on the number of oncologist using system) with individual licenses and having the common patient database should be provided B. The Planning System should be capable of planning for 3D Conformal Radiotherapy (3DCRT), Intensity Modulated Radiotherapy (IMRT) and VMAT for all the machines in the department (Varian LA, Elekta LA, Cobalt Teletherapy or others etc) and all required licenses should be quoted along with details. It should support FF and FFF beams. C. A virtual simulation software should be part of the Planning System D. It should have an integrated common data base. E. It should work on Client-Server architecture F. The rack mount server provided should not be counted as a Planning System G. The Planning system offered should be latest version available with the company H. Calculation Algorithm : All calculation algorithms available with the vendor for the quoted TPS to do calculation of Electron beam, Photon 3DCRT, 4D Planning, IMRT, VMAT should be supplied I. If the supplied TPS and contouring systems are not integrated with Record &Verify system supplied and have separate database, the vendor will upgrade or replace the hardware and software free of cost if an unified database system is released by the vendor during the warranty or CMC period J. Onsite Physics support for TPS data acquisition, beam modeling and commissioning. **<u>Planning and contouring software</u>** a. Contouring Tool to provide 3D auto margin and 3D variable margin b. Automatically create margins in all six directions c. Edit/draw all contours, contour names, CT densities and colour d. Continuous trace, point –to-point and auto contour via MR or CT threshold e. Automatic contouring of body structures for any given body volume f. Contour on primary image study (CT) , secondary image study (MR and PET) or fusion images g. Outline tumour volumes and critical structures on transverse; visualize on sagittal and coronal planes including real time 3D visualization h. Contour Interpolation i. Asymmetric stretch and resize j. Rapid copy to superior or inferior slice k. Virtual fluoroscopy Isocentre placement from AP and lateral DRRs l. Auto computation of isocentre from target volume m. Editing of origin placement in the reference slice and

		computation of isocentre with reference to origin n. Should calculate each phase of treatment plan independently and as a composite plan o. Should plan for the following combinations: Photon-photon, Photon-electron (all energy combinations), Electron-electron (all energy combinations) p. Dose and Marker point definition q. Export of isocentre coordinates with reference to origin to Laser control system r. The system should support multi vendor laser marking software. s. Provide predefined structure templates that can be used for all types of treatment. t. Must be able to add/subtract predefined organs and/or parts of organs for defining areas of interest. u. Should do fusion MRI, CT and PET images with reference image set. SUV calculation of PET images to be provided. v. Mutual matching algorithms must be available to auto match images using different modalities w. It should be possible to display the calculated dose on sagittal, coronal and arbitrary planes and on MR, PET and fusion images x. Should be fully integrated with the record and verify system y. Should support addition of bolus of different thicknesses z. Dual registration (both rigid and deformable) for adaptive planning along with workflow details. aa. Library based self learning auto contouring tool along with complete anatomical atlas **Imaging tools** a. Real time high resolution DRRs b. Adjustable W/L presets for primary, secondary and DRR images c. The DRR generation methods should include normal summed, MIP and volume rendered (for soft tissue / bone weighted DRR) d. Tool to perform plan dose summation or subtraction, side-by-side plan comparison and plan comparison using DVH. e. Facility to copy opposing fields including MLC, blocks and wedges (mirrored) f. Interactive BEV with DRR controls g. Mouse and/or keyboard driven gantry, collimator and couch positions h. Multi-structure/ multi-slice auto contouring i. Slice-to-slice contour duplication and interpolation j. Variable 3D auto margin generation k. Auto conformation of blocks or MLC to targets with gantry, collimator and table adjustments. **IMRT and VMAT** a. Support for coplanar and non-coplanar beam and arc arrangements b. QA data generation tools per beam/arc and per plan c. Should be able to do 3DCRT/IMRT/VMAT for multiple vendor MLC

		d. IMRT / VMAT QA Tools e. Ability to run IMRT and VMAT plans on phantoms to create digital composite files for film comparison f. Dose QA export to IMRT / VMAT plan verification software g. Intensity map BEV display h. DRR with widest MLC position of segments i. Should be able to do Dynamic/ static IMRT plans j . Should have full integration with IGRT – should be able to sent DRR of desired gantry orientation to IGRT system for comparison with KV radiographic image to determine patient shift. It should also be able to sent CT images to IGRT system to compare with reference CT images k. Should be able to import Cone beam CT images from Treatment machine and compute dose on the imported images to evaluate dose to critical structures of the patient during treatment l. Should support 4D images. m. Should be able to do rigid and deformable registration **<u>Import and Export</u>** a. CT/MRI/PET Software interface of any vendor b. The planning system must be integrated with the CT simulator system. Should be able to import plans and structure sets from the CT simulation software. c. DICOM import through network from Imaging (CT, MRI, PET, Simulator) and contouring systems d. CT interface via CD/DVD e. DICOM RT (Structure and Plan) export to all vendor treatment units f. The contouring system should export structures and plans to all the vendor TPS vice-versa g. RTOG DICOM export h. DICOM Print i. Export isocenter coordinates to all vendor laser positioning systems **Essential Furniture and accessory infrastructure equipment's:** -Reputed brand (Godrej, Methodex, Blowplast) supporting furniture, air conditioner for TPS room, air conditioner for server room, storage, for hardware must be supplied with the system. The air conditioner provided will be part of CMC of the supplied items. -Complete installation of the system and interior of the TPS room to the user's satisfaction. -UPS to be provided for all computer systems and Server and will be part of CMC.
2.2	**User's interface**	Should have Ergonomically designed user interface.
2.3	**Software and/ or standard of communication(where ever required**	- Should comply with Electronic medical record standard 2016 of MoHFW, GOI. -Software and hardware refresh to be done at the end of every 5 years.

3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Not applicable
3.4	**Heat dissipation**	Not applicable
3.5	**Mobility, portability**	Not applicable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	1. UPS of suitable rating with voltage regulation and spike protection for 30minutes backup.
4.2	**Battery operated**	Not applicable
4.3	**Protection**	Should have hardware and software firewall in addition to anti-virus software's which are regularly updated without additional cost till the date of decommission of all LINAC/Cobalt/Brachytherapy unit connected with software.
4.4	**Power consumption**	Not applicable
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	1 .Operating Condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Not applicable
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. The medical devices should be US FDA/CE/BIS/CDSCO/AERB approved (US FDA/CE requirements will be applicable only when the Indian standards on medical devices laid by organization like BIS/CDSCO/AERB is not available). 2. History of adverse events and actions (Recall/Filed safety correction etc) taken by manufacturer on the product should be made available to procurer. Such Information (as and when happen) after commission of

		product should be continued to be provided to purchaser till manufacturing of same type product is curtailed.
7.2	**Local and/or international**	Not applicable
8. TRAINING AND INSTALLATION		
8.1	**Pre- installation requirements: nature, values, quality, tolerance**	The supplier should install and commission software within 6 months on receipt of the Letter of intent. All software license or product key must be supplied to purchaser after installation. Software license should not expire before decommissioning of of all LINAC/Cobalt/Brachytherapy unit.
8.2	**Requirements for sign-off**	Certificate of calibration and inspection of parts from the manufacturer
8.3	**Training of staff (medical, paramedical, technicians)**	2 weeks training to be provided to Radiation Oncologist and Medical Physicist/RSO of the whole system and for the software part (TPS, OIS) in any reputed cancer center in India. • At site: 2 weeks training to be provided to the hospital medical physicist team in house (Biomedical engineer) maintenance (Preventive /corrective) and the technologists. • Manufacturer should have ISO certifications for Quality standards,. • User manual in English, service manual in English should be included along with the system..
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 year warranty or State/UT may also include the medical devices in NHM Biomedical Equipment management and maintenance program.
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. Service and operation manuals(original and Copy) to be provided; 3. Advanced maintenance tasks documentation; 4. Certificate of calibration and inspection, 5. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	1.Contact details of manufacturer, supplier and local service agent to be provided; 2.Any Contract(AMC/CMC/add-hoc)rate available to be declared by the manufacturer.
11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed in Regional or National Language.