
Technical Specification for High Dose-Rate Brachytherapy Remote After-Loading System

Sealed tenders (sealed separately as the "Technical Bid & the Price Bid-in duplicate) are invited directly from the manufacturers/principles for the supply of a latest technology High Dose-Rate (HDR) Brachytherapy Remote After-Loading System. The High Dose-Rate (HDR) Brachytherapy Remote After-Loading System includes Treatment Unit, Control Unit, Treatment Planning System and applicators and other required accessories for clinical application. The HDR system should be capable for the treatment of intracavitary, intraluminal, interstitial and surface mould brachytherapy. The offer system should be of the latest model. The vendor should provide commitment to be able to provide service and support for the offered new unit for atleast 10 years from the date of installation.

Technical Specification

1. Brachytherapy Treatment Unit:

- 1.1 The system should be capable for the treatment of intracavitary, intraluminal, interstitial and surface mould brachytherapy
- 1.2 The HDR system should be latest microprocessor and PC controlled and it must have latest hardware and advanced software.
- 1.3 The system should have minimum 20 channels or more for all types of brachytherapy treatments.
- 1.4 The system should be on wheels for easy mobility in the treatment area and provided with storage safe of lead/ tungsten alloy to guarantee and compatible with guidelines of international safety regulations especially AERB.
- 1.5 Specify the in-built radiation safety measures provided in the unit including power failure, emergencies, channels indexer, activity of the source and dose rate, verification system for channel number and connectivity of the applicator etc.
- 1.6 Specify the surface dose rate of the system source container when full strength of the source is loaded.
- 1.7 The treatment unit should have an in-built integrated radiation detector to check the safe return of the source (GM Type tube).
- 1.8 The source must be retractable and reach in the safe position in the events of an emergency/ power failure etc specifies the source retraction methods.
- 1.9 Refurbished / reconditioned unit should not be offered. The vender shall quote month and year of the fabrication of the unit and provide the certificate of the same of its being original.
- 1.10 The Source head should have adequate shielding and its height should be adjustable.

1.11 The system should have the dummy cable to check the treatment parameters prior to treatment.

2. Radioactive Source

2.1 The system should use radioactive sources of either Ir-192 or Co-60

2.2 source strength should be of at least 10Ci Ir-192 or 2Ci Co-60

2.2 Please specify the activity, physical characteristics and dimensions of the source being supplied with the unit. Specify the number of source offered and usability period of the each source quoted. Please specify the following:

(i) Specify the maximum source extension

(ii) Specify the dwell position per catheter

(iii) Specify the maximum dwell time per position in the catheter

(iv) Specify the maximum treatable length in cm

(v) Specify the accuracy in position in mm.

(vi) Specify the active diameter and length of the source.

(vii) Specify the mode of source movement in each channel of the unit

(viii) Source cable must be able to pass through catheters of curvature 1.5 cm or less

3. Treatment Control Console:

3.1 Stand alone and independent PC based control unit should be provided with flat panel 27" or larger LED monitor, keyboard, mouse build in audio card, network card, backup media, printer etc and direct link with 3D-TPS to be supplied.

3.2 It should have protection circuit inbuilt to prevent treatment without proper applicator connection, door closing and proper index locking.

3.3 It should have all self-testing provision necessary for the treatment

3.4 Control unit software should run on window application

3.5 Access must be limited to authorized users with password protection

3.6 The treatment times must be automatically corrected for the decay of the radioactive source

3.7 There should be higher dwell position for the source in each channel

3.8 On-line extensive display of status codes with an indication of the action required

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- 3.9 Large patient's database should be provided with a backup option to an external storage device
 - 3.10 The system should provide real-time information during treatment.
 - 3.11 Provision for checking of complete operation of the system prior to actual treatment including electronic and radiation safety checks should be available.

4. Brachytherapy Treatment Planning System (TPS)

- 4.1 A state-of-the-art brachytherapy planning system capable for performing conventional 2D and advanced 3D-treatment planning with dose-volume histogram analysis methods and different methods of optimization of the treatment plan and also inverse planning modules for planning of all treatment techniques like intracavitary, interstitial, intraluminal, and surface mould.
- 4.2 System should have input capability of receiving patient information i.e patient data through scanner, digitizer, and directly from CT, MRI, X-ray unit through DICOM 3.0/RT compatible interface.
- 4.3 The system should be capable of doing multimodality image registration and also should have the features of auto-contouring of the organs and applicator etc.
- 4.4 The 3D planning and viewing of dose distribution in coronal and sagittal cuts and any other possible cuts should be provided.
- 4.5 The system should include the plan library, source and applicator library, optimization and isodose sharper tools and reporting tools etc. specify the features.
- 4.6 The treatment times must be automatically corrected for the decay of the radioactive source
- 4.7 The system should be capable of summation of brachytherapy and external beam dose distribution and 3D viewing.
- 4.8 The Networking (on-line) between HDR treatment unit and TPS should be provided and it should be connected with CT machine and simulator and other imaging modalities.
- 4.9 Hardware: Treatment planning system should have a latest computer with high speed with most modern graphics workstation, fast processor with RAM of maximum latest availability and should have a Hard Disk with large storing capacity of maximum available memory, Key Board, Mouse of latest configuration.
- 4.10 The system should have at least 23" TFT LCD Screen with high resolution for good visualization
- 4.11. For patient data input, high resolution FILM SCANNER should be provided.
- 4.12 One color printer A3/A4 size for printing the treatment planning and plotting of isodose should be provided.

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- 4.13. The vendor should provide advanced model-based dose calculation algorithm for inhomogeneity correction in dose calculation as per the AAPM TG-186 recommendations.

5. Applicators for HDR Unit

- 5.1 Supply the standard accessories for the application of intracavitary, intraluminal, interstitial brachytherapy of cervix, vagina, rectum, head and neck, esophagus and bronchial, biliary, breast and prostate applications. Applicators to be provided for;
- 5.2 Gynecological applicator Fletcher-Suit type – 6 sets
- 5.3 Gynecological application templates -2 set each (2 sets Syed-Neblet and 2 Sets of MUPIT with all required accessories)
- 5.4 CT / MRI compatible gynecological Fletcher-Suit type applicators – 2 sets
- 5.5 Vaginal / Rectal applicator – 3 sets
- 5.6 Esophagus applicator – 3 sets
- 5.7 Nasopharyngeal applicator – 3 sets
- 5.8 Breast and Prostate templates – 2 sets each
- 5.9 Biliary Applicators – 2 Each
- 5.10 Intrabronchial Applicators (reusable) – 2 sets
- 5.11 All kinds of x-ray dummy markers (two sets) for the applicators supplied (wherever relevant). Vendor shall provide (i) Flexible Implants complete set with at least 100 Numbers of needles (ii) Rigid Needle Implants complete set with at least 100 Numbers of needles (iii) Flexible Implants Tubes complete set with min. 1000 tubes
- 5.12 Hybrid combined interstitial and intracavitary applicators -2 sets
- 5.13 Provide the catalogues of the all the applicators. All the guide-tubes must be functional for 5 years.
- 5.14 Vendor should provide extra two sets of transfer tubes for Gynecological applicator Fletcher-Suit type.
- 5.5 Vendor should provide two sets of Freiberg applicator for surface mould brachytherapy.

6. Radiation Dosimetric, Quality Assurance (QA) and Safety System/Tools

- 6.1 Quote necessary QA tools and radiation monitoring and measuring instrument being supplied with the unit.
- 6.2 Emergency container/ source container as per AERB norms

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- 6.3 Brachytherapy treatment table with all accessories (Motorized/Hydraulic locking clamp mounting and Lithotomy position support)
 - 6.7 Source position simulator and source check ruler
 - 6.8 Two online UPS with 30 min backup for total system (HDR machine and TPS)
 - 6.9 Closed Circuit TV systems along with standby camera
 - 6.10 X-ray reconstruction jig.
 - 6.11 X-ray marker wire for all applicators.
 - 6.12 Well-type chamber with calibration certificate should be provided.
 - 6.13 Vendor should provide the Last-man-out switch (LMOS) for offered HDR machine as acceptable by AERB
 - 6.14 **Gamma Zone (Area) Monitors** (one number): Gamma-Zone (Area) Monitor is used for radiation area monitoring around the interior walls of brachytherapy equipments. Gamma-Zone (Area) Monitors shall be able to measure and monitor x-rays and gamma-rays (dose/dose rates) of varying energy levels in minimum possible timeframe. System should have capability of warning alarm condition whenever the emergency exposure is in the treatment room. The measurement range: 0.1mR/h to 100mR/h and display units: μ R/h, mR/h, μ Sv/h, mSv/h. The detector shall be of GM based. Specify the details of the offer system.
 - 6.15 Two-way communication between patient & console should be provided as standard.

7. Equipment Warranty and Service:

- 7.1. The vendor must quote for five years comprehensive warranty (including all spares and labour from the date of completion of the satisfactory installation. The warranty charges shall not be quoted separately otherwise the offer shall be summarily rejected. The vendors must submit their quote (Rate) also for subsequent five years CAMC (including all Spares and labor) in the price bid, failure to comply this condition will entail the rejection of the bids.
- 7.2. Five years warranty to be commenced from first patient treated as per AERB norms.
- 7.3 CAMC year-wise for quoted machines, UPS, Battery and other accessories for next 5 years after warranty
- 7.4 Spare parts should be available for minimum of 10 years.
- 7.5 **Source:** (i) minimum 15 sources of Ir-192 source or one source of Co-60 should be offered for 5 years period (one source in every four months interval or as and when required) to maintain HDR treatment delivery. All sources cost should be quoted separately and this will be considered for L1 calculation. Loading of new source and unloading of the decayed source, source transportation, source export and disposal will be part of the offer.

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- 7.6 Quote the rates of consumables recommended valid for 5 years block.
 - 7.7 Factory trained service engineer/Applications specialists should be available at site to look after the installation and maintenance of the system without patient treatment interruption.

8. Staff Training and Manual/documentations

- 8.1 Training should be provided to one Radiation Oncologist and one Medical Physicist for one week in the centre of excellence at developed countries and also on-site training of two week to staff of department.
- 8.2 User / Technical / Maintenance manuals to be supplied in English
- 8.3 Certificate of calibration and service inspection should be provided.

9. National Regulatory Body and Radiation Safety and Protection Requirement:

The vendors should visit the site and user department to get the Plan Layout and should facilitate and coordinate with user department in communicating with AERB in providing all required information pertaining to radiation safety compliance of the concerned equipment till the clinical commissioning process of first patient treatment commencement.

Scope of the Trunk work for bunker

General Requirements

1. The Supplier should inspect the proposed site offered by the Consignee, wherein the HDR BRACHYTHERAPY SYSTEM has to be installed. They are required to submit the plan for the project. The scope of work includes complete Electrical, Wall finishing, Air-conditioning, Flooring for the proper functioning of the HDR brachytherapy system. The supplier shall assist the user by providing necessary documentations/technical data for regulatory clearances and approvals from AERB.
2. The cost of the site modification work should be quoted separately and this cost will be considered for L1 calculation.
3. Vendor will have to quote Unit Rates of the following components of Site work.
 - i. Electrical work
 - ii. Air conditioning (HVAC)
 - iii. Flooring
 - iv. Wall Finishing & Painting
 - v. False Ceiling
4. The payment for site modification work shall be based on the Unit Price quoted by the supplier applied to the actual measurement of Site work executed at the supplier at the site.

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5. Bidder should clearly mention break up price of each component of Site work separately.
 6. The system should be installed and handed over in working condition with all necessary electrical, wall finishing, air conditioning, flooring and plumbing work undertaken by the vendor in consultation with the user dept.
 7. Rate quoted for Site work, Furniture like desks, chairs, shelves etc; and the price quoted for 7 TR HVAC is included for L1 calculation of the bids.
 8. The HDR brachytherapy facility shall consist of the following rooms:
 - a. HDR brachytherapy treatment room with console area
 - b. HDR brachytherapy treatment planning room
 9. The supplier shall be required to specify the total load requirements for the HDR brachytherapy facility including the load of air conditioning, room lighting and for the accessories if any. The supply line will be provided by the Institute up to one point within the HDR brachytherapy facility. The mains panel and distribution panel for HDR brachytherapy system, HVAC, and LIGHTING should be provided by the supplier. Few lights in HDR brachytherapy system, treatment room with console area, UPS ROOM shall be connected to the UPS to provide emergency lighting.
 10. The bidder may quote the unit rates of any other site work activity which is not mentioned in the list below.

THE ELECTRICAL WORKS:

1. Wiring – All interior electrical wiring with main distribution panel board, necessary MCBs, DB, joint box, switch box etc. the wires shall be of copper of different capacity as per the load and should be renowned make as listed below.
2. All necessary cabling like LAN, DICOM & PACS for data interface between TPS and HDR brachytherapy system; CT-SIMULATOR & HDR brachytherapy system should be provided with adequate number of terminals.
3. All the internal wiring including that of telephone, LAN, DICOM & PACS etc) will be concealed variety.
4. Earthing: Double-Earthing shall be provided with copper plate for the HDR brachytherapy system and all accessories like UPS. The earthing for the AC should also be done by the suppliers. The earthing cable/wire shall be routed end-to-end through an insulated conduit.
5. Switches light and power points should be of modular type and of standard make as listed below.
6. General lights – Ceiling mounted LED lighting panels, recessed 600 x 600mm, should be provided. Light dimming facility should be provided wherever it is necessary.
7. All wires used must be FRLS (Fire Retardant with low smoke) type only.

AIR CONDITIONING WORKS:

1. The area marked for site work needs to be air-conditioned. Package Air Conditioners may be used according to room requirement and suitability. Humidity control should be provided to effectively eliminate moisture condensation on the equipment. The Air conditioning system should be designed with standby unit(s) to provide uniform air-conditioning 24 x 7.
2. The outdoor units of AC should have grill coverings to prevent theft and damage.
4. Stand-alone room Dehumidifiers of adequate capacity for HDR brachytherapy system room, Console room and TPS room to be provided to ensure condensation-free atmosphere for the high value equipment.
5. **Environment specifications:**
Humidity range: Relative humidity 60% and 80% in all areas except equipment room which shall be as per requirement of the equipment.
Temperature ranges: $22 \pm 2^{\circ}$ C in all areas throughout the year, except equipment room which shall be as per requirement of the equipment.
6. **Air conditioning load:** The heat load calculations and maintaining the desired temperature and humidity shall be the responsibility of the supplier.

FLOORING WORKS:

1. "600x600 mm vitrified tiles with 100mm matching tile skirting in HDR brachytherapy system room & Console room.
Note: Providing and laying approved quality, colour, design and shade fully homogeneous 600 x 600 mm (thickness to be specified by the manufacturer) Vitrified tile flooring (Marbonite or Granamite, confirming to IS code 15622 with water absorption less than 0.08%) flooring in pattern as detailed in drawing or as directed by the institute and grouted with matching colour approved quality readymade grout, curing, cleaning etc to required line level etc. all complete at all leads, lifts and heights to the entire satisfaction of the institute. Providing and fixing 2-3mm thick POP protection over polythene covering sheet to flooring areas till handed over and cleaning, etc all complete as per drawings & specification.
2. Floor leveling if required to be done by supplier. All installation related floor modification non structural) like Turntable pit, trench etc to be done by supplier.

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3. The HDR brachytherapy system room, treatment console room will be made rodent / pest proof.
 4. Mode of measurement (finished surface area of the tiles shall be measured and paid. Rate shall be inclusive of providing and laying leveling course, PVC spacers, providing and applying epoxy grout and no additional payment shall be made for wastage.

WALL FINISHING & PAINTING

1. Two coats Plastic Emulsion Paint over 2 coats of wall putty including primer in all areas not covered by wall tiles. Colour to be approved by institute.
2. Wall Tiles-High quality density Vitrified Tiles clad on the side walls up to a uniform height of 1200mm in all rooms; except UPS & equipment rooms. Colour to be approved by institute.
Note: Providing all tools, tackles, materials, manpower for applying plastic enamel paint over
3. Coats of wall putty including primer in all areas, of approved brand and manufacture and approved shade finished with roller to wall & ceilings surfaces, in 2 coats over a coat of approved quality primer on the plastered/POP surface, POP board/Gypsum board surfaces including scaffolding, preparation of surface, sanding, light sanding, work platform, painting equipment/apparatus etc. required to complete interior grade finish etc. at all heights & levels complete as per drawings & Specifications.

FALSE CEILING

1. Acoustical tile for ceiling with light weight insulating material of high quality supported on grid or finished seamless with support above ceiling. To be finished with white paint or powder coated with white paint, if metallic. The false ceiling panels should be of reputed brands.

MISCELLANEOUS:

1. The HDR brachytherapy system room shall be provided with wall-mounted storage cupboards within HDR brachytherapy system room; to store: Dosimetry & QA Items, HDR brachytherapy system accessories.
2. Sufficient number of Open Racks of high Quality vendors should be provided to house the immobilization materials; within HDR brachytherapy system room
3. TPS room should be provided with LED X-ray film viewer with adjustable brightness; capable of holding 3 films of 14"x17" size-2 nos.

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4. The treatment console room shall be provided with Wall mounted storage cupboards with MDF laminate shutters; to be fixed on the wall above the workstation (approx 1800mm length; 750 mm height; 300 mm depth).

FURNITURE:

1. Revolving chairs height adjustable, medium-back with hand-rest for Control room, TPS room - 10 Nos.
2. "Workstation/Tables for treatment console room & TPS room:
The treatment console room and TPS room should be provided with suitable workstations(s) of reputed brand, to accommodate the various Terminals in console room, TPS room. The Workstation shall be providing with enough power sockets, LAN sockets etc. to enable smooth functioning of the HDR brachytherapy system and TPS."
3. Bookshelves: Four-door bookcase with glass doors, height approx 1700mm; to store manuals; CD/DVDs, spares etc-4 Nos.
4. Shoes Rack - 2 Nos.

LIST OF ITEMS AND SUGGESTED MANUFACTURERS.

A ELECTRICAL

1. **CABLES** - Gloster, Universal, Polycab
2. **WIRES** - Finolex, Havells, V-Guard, RR Kabel, Gloster, Anchor
3. **SWITCHES** - Legrand, L&T, Crabtree , Roma, MK, Crabtree
4. **DISTRIBUTION BOX**, MCB - Legrand, L&T, Siemens, Havels
5. **LIGHT FITTINGS** - Philips / Crompton / Kesselec-Schreder / Wipro.

B AIR CONDINTIONING -Daikin, Hitachi, Blue Star, Voltas

C FURNITURE -Hermen Miller, Godrej, Featherlite, Wipro

D FALSE CEILING - Armstrong, Saint Gobain, Luxalon.

AERB Approval

1. AERB Approval for Site and Facility Layout plan to be obtained by the vendor