Technical Specification PET CT Scanner (KGMU)

One latest technology 3D Positron Emission Tomography system PET with integrated 16- slices or more CT scanner, for supply and commissioning.

Scope of the work: Primary vendor shall be responsible for supply, installation and commissioning of the PET/CT on turn-key basis.

The radiation equipment offered against this tender shall duly conform to the prescribed international/national standards and norms of radiation safety. Type approval certificate/NOC for AERB, Mumbai for the quoted model MUST be attached with the technical bid or else the bid will be summarily rejected.

All the QA / acceptance tests as per NEMA-NU-2-2018 and AERB need to be carried out by company engineer in the presence of Nuclear Medicine Physicist of the department. A detailed report needs to be submitted in a stipulated time frame for onwards transmission to AERB to get the license for operation of the equipment. All the required. Phantoms for QA tests will need to arrange by the vendor. The Company will also arrange such phantoms during periodical QA tests during the duration of warranty and CMC period.

The tenders along with all the commitments, claims, specifications, guarantee, warrantee etc. pertaining to the equipment should be submitted directly by the Manufacturer/Principal Company or their Vendors who shall be wholly and solely responsible for all the statements/commitments in this connection.

Old disused machine specific radioactive source required for calibration of the system will be transported back by the vendor to the manufacturer without any payment, to fulfill the AERB conditions.

Any options or added facilities not indicated in the specifications may also be quoted as optional items, if not a standard feature. Any improved modifications or updated versions of the system can be included in the quotation.
The final price comparison of rates for awarding the contract will be made after addition price of all the components (price of the PET/CT including accessories & CMC and turnkey part).

Vendor should visit the department to have a look of the space available for installation of the new system. A certificate should be attached that the space is adequate for the installation of the quoted systems.

1. The system should have capability for simultaneous data acquisition, processing, image reconstruction & analysis and fusion of PET with CT images.

2. The system should operate on 220 (±10) or 440V (±20) V A/C, 50 HZ.

3. System should be on latest PET and CT platform. The acquisition & processing software should be of latest version.
4. System must be FDA approved at time of bidding and shipping. Attach relevant certificates.
5. All the Application, Operating and Service Manuals in English language in duplicates should be provided by the vendor at the time of handing over the machine. At least one of these manual sets to be provided in computer readable format, preferably as Word for Windows format document.

Gantry and Detector:

1. Gantry should have integrated PET & CT hardware.

2. The patient gantry aperture size should be ≥70 cm and uniform for both, PET and CT.

3. Should have dynamic PET acquisition capability to acquire PET images independent of CT

4. The PET scanner should employ non-hygroscopic high light yield (80%) for detecting 511 KeV gamma photons in coincidence.

5. The scanner must have a continuous ring of detectors without any gaps.

6. Gantry Bore diameter should be 69 cm or more and uniform for both PET and CT. .

7. PET crystal dimension Minimum= 4 mm x 4 mm x 20 mm or more

8. The transverse field of view should be ≥ 65 cm.
9. System sensitivity must be ≥5.5 cps/KBq at center.
10. System energy resolution should be ≥12.0%
11. 3-D scatter fraction should be ≤40%.
12. The scanner must have low power laser lines orthogonally mounted on the gantry for patient alignment and auto-contouring. The laser should be mounted is such a way that the patient can be positioned from either side of the gantry and the patient bed with treatment planning
13. Efficient Gantry cooling system for continuous running of the machine, the detector performance should be maintained over temperature variations.

CT specifications:

1. Multi detector CT with capability of generating 16 or more transverse cross-sectional slices simultaneously in one rotation.
2. Multiple pitch factor setting, variable between 0.5 to 1.5 or more and should freely selectable by the user.
3. Rotation time should be ≤0.5 sec for 360 degree.
4. Image slice thickness should be from ≤1 mm to 10 mm and freely selectable.
5. High contrast spatial resolution should be ≥15.0 Lp/cm at 0% MTF.
6. Low contrast resolution should be <5 mm @ 0.3% with 20 cm CATPHAN phantom.
7. Microprocessor controlled high frequency ≥70 kW x-ray generator.
8. Tube Voltage range should be between 80 - 140 kV.
9. Anode heat storage capacity of 7.0 MHU or more.

10. Tube Current of 20-600 mA.

11. Laser alignment light should control the iso-centric position of the patient in all planes.

12. Filters / Collimators and other specific features to reduce radiation dose to the patient (with separate adult and pediatric protocols.

13. Automatic self-testing system.

Patient Bed:

1. Precision bed having low attenuation pallet and minimum sag of the patient table top.

2. It should be able to bear 190 kg or more patient weight.

3. A digital readout of the horizontal and vertical position of the bed must exist and must be located near the aperture controls for the bed to provide ease in positioning.

4. The horizontal motion of the patient bed must be electrically motorized and computer controlled with an independent operator control option as well. Operator controls accessible from both sides of the patient must be provided for both horizontal and vertical movements.
5. Full body horizontal length should ≥190 cm and cover whole body imaging (Head to Feet) in a single go.

6. The table height should be good enough to unload the stretcher and wheel chair patients without footrest.

7. Arm support (two) for patient positioning .

8. Low attenuation ergonomic head holder, pediatric pallet / restrain, knee-leg support and other accessory pallets.

Performance Specifications:

1. All specifications must comply with latest NEMA Standard Publication NU2-2018 performance measurements without altering instrument parameters. QC Software to measure these parameters must be available in the system.

2. Additional feature that helps to enhance the NEMA spatial resolution values must be offered as a standard part.

3. Advanced reconstruction algorithms for better lesion detectability.

Data Acquisition Workstation and Software:

One high performance multi-tasking Acquisition Workstation independent of main processing unit. The workstation should have a minimum 2TB SSD storage, high processor speed, and high resolution (1024 x 1024 or more) antiglare flat panel Dual LCD monitor of minimum 19: size. The workstation should be of latest specifications at the time of shipment.

Acquisition Modes: Acquisition in full 3-D mode must include Static, Whole Body, Dynamics and Gated (cardiac & respiratory) acquisition.

Acquisition Protocols: The acquisition program should support pre-programmed scan protocols with acquisition and reconstruction parameters. These parameter would include all information necessary to acquire data on the PET scanner (e.g., scan duration, patient information, bed motion), as well as information necessary for reconstruction.

Whole Body Acquisition: Multi bed acquisitions (e.g. for the purpose of whole-body oncology studies) should advance the bed from one position to the next automatically. Dynamic frame Mode Acquisition: The acquisition set-up software must support multi-frame acquisition of different (arbitrary) frame durations with no loss of data between frames.

List Mode Acquisition for cardiac studies should also be available as standard feature. ECG Gating should be part of the offer and is to be provided with necessary hardware and software.

Intercom with user programmable patient instruction system.

Ultralow dose CT protocols should be available for hybrid PET/CT protocols.

Same PET CT protocol should be used for Contrast CT in single acquisition.

CT based attenuation correction.

Reconstruction: PET data acquisition and image reconstruction should be concurrent process i.e.; image reconstruction should simultaneously start for the acquired image while acquisition is still in process.

Fully 3-D speedy iterative reconstruction with scatter correction, **attenuation correction**, High definition (HD) **and advanced** reconstruction algorithms. Must be standard features.

Reconstruction time: At least 25 frames/sec.

Advanced 3-D Volume rendering with 3-D fusion, Model based 3-D scatter correction, virtual endoscopy & bronchoscopy.

Low dose iterative reconstruction algorithm should also be provided.

Pixel Size: The User should have the option to specify the pixel for reconstruction. The reconstruction program should support reconstruction in image sizes of at least 256 x 256 or higher.

Scatter Correction: Scatter correction must be provided based on scan of the actual patient whose scan is being corrected and processed automatically.

System management software for computerized calibration, quality control for all scanner performance parameters, diagnostics.

Data editing facility for acquired data.

Latest DICOM based networking and compatible software for both PET & advanced CT applications.

Processing Workstation and Clinical Application Software:

Two high performance multi-tasking post processing independent work station having minimum 20 GB RAM or more , 2.67 GHz processor speed, minimum 512 MB graphic card, minimum 2 TB or more SSD, Optical Mouse, Key-board and high-resolution anti-glare flat panel dual view LCD monitor of ≥19" size with minimum resolution of 1280 x 1240. It should have both, serial and USB ports. The graphical user inter-face (GUI) should be identical to that of the acquisition unit.

The computer workstation should be of latest specifications at the time of shipment.

Communications - Ethernet with TCP/IP protocols and DICOM-3.0 or latest networking of all possible equipment in the facility with their peripherals, seamless connectivity to acquisition station and image server.

Image comparison software for review with longitudinal evaluation of baseline-follow up studies using PERCIST.

Dynamic PET processing and viewing software.

Fusion software for PET/CT/MRI/SPECT data, including imported data and provision for multiple phases in 3-D demonstration.

Computer aided diagnosis software with quantification ability for neurological applications including assessment of dementia by measuring relative SUV).

Complete cardiac package with ECG gated studies (prospective and retrospective tagging) and ECG gated dose modulation.

Cardiac PET viability review application software.

PET DICOM 3.0 or higher version facilities for clinical applications must be implemented. It should have the ability to import MR/CT DICOM Data.

Provision to make DICOM/PDF/JPEG/AVI/MPEG digital output.

On site remote service diagnostic facility with Wi-Fi enabled Gigabit broadband internet connection.

System should have required software and hardware for transferring the data to TPS for RT-planning

The vendor will assure smooth functioning of the machine & if any up gradation of installed version of software during the duration of warranty and CMC period.

One latest dual head pressure injector compatible with CT and 400 sets of 200 ml disposable CT syringes with tubing and connector, per year during the warranty and CMC period.

One latest single head pressure injector required during CFR studies with 50 syringes and tubing sets.

ECG gating device & necessary electronics to enable gated cardiac acquisition

Survey Meter-1, Gamma Zone Monitor-1, Gun Monitor-1

One dose calibrators (Capintec- CRC 25 PET or equivalent).

One shielded L-bench for F-18 handling.

Decay drum for PET radionuclide: 2 units
Tungsten lined Carriers (160 mm) for carrying the radiopharmaceuticals

Two waste bins with minimum 12 mm lead for PET Radiopharmaceutical waste.
Set of total 104 units of Lead bricks with corners for F-18 handling.

Four Tungsten syringe holders of 2 sizes (Two 2 ml and Two 5 ml).

Four digital pocket dosimeters (Rad-60R by Rados Technology or equivalent)

Lead Pot with dispensing arm - 1no

One Decontamination kit.

Machine specific source for calibration of the system, to be replaced as and when required for the period of warranty and CMC. At the time of replacement, old disused source will be transported back by the vendor to the manufacturer without any payment, to fulfill the AREB conditions.

Colour printer, 1no.

200 reams of A-3 sized glossy paper of 150 GSM also need to be supplied.

One Lead Mobile Shield Barrier of 4' height.

One stainless steel side trolley with lockable storage provision in the PET/CT room for interventional procedures.

Crash Cart with one each 20 liter oxygen cylinder, umbo bag, and adult and child laryngoscope.

Automated defibrillator.

Minimum two stretchers of latest model with side rails to be provided for shifting the patients.

RADIOTHERAPY PLANNING (RTP)

Flat table top insert

Patient positioning & fixation accessories (Head, arm, IV contrast injection)

Laser Tracking System (Moving Lasers)

Matrix detector

Digital Camera & Printer for patient position record

Network connectivity to Varis/ Eclipse/ Cadplan / Plato/ Brainscan / Lantis/ Sunrise etc.

Archiving with CD/DVD Writer & CD-ROM

Virtual Simulation (& Software)

Hardware: Specify

Software:

Image display

Volume definition

Contour tracing & editing

Beam placement & Beam Shaping

DRR feature

DICOM/DICIM-RT Connectivity with other verification & planning systems as above

Respiratory Gating

RPM devise with laser beam and console hardware

Mounting bracket for RPM devise on PET CT table

Phase matched PET & CT reconstruction and fusion software

Retrospective reconstruction software for CT Bin reconstruction

Post processing application to review gated PET CT images

Connectivity with systems MONACO/XIO/ONCENTRA etc. avliable in the department of radiotherapy KGMU to be added.

SITE PREPRATION (PART II)

i. The supplier shall be required to undertake all the site preparatory work in the area where the PET/CT will be installed, as per the turnkey details.

ii. Equipment is to be installed as per AERB requirements. Qualified personnel from the company should install and commission the scanner.

iii. Appropriately sized lead glass in the acquisition terminal room.

iv. Warranty: The complete system should have a guarantee / warranty including the radioactive reference source, crystals, detectors and CT x-ray tubes replacement for a period of FIVE years after the satisfactory commissioning and handing over of the equipment. Warranty for the air-conditioning system will also be part of the main equipment.

v. **CMC:** Comprehensive maintenance contract for whole system including CT x-ray tube replacement as and when required and accessories for a period of **FIVE** years after the expiry of warranty period. CMC for the air-conditioning system will also be part of the main equipment.

vi. The peripherals/ accessories, electronic / electrical consumables (leads, probes, batteries etc.), phantom source and calibration source and batteries of UPS will also from part of the warranty and CMC. Service, repair and maintenance of all third-party items will be the sole responsibility of primary vendor. Replacement / Replenishment of the coolant for gantry will also form the part of warranty as well as CMC.

vii. DICOM networking so that all the data from this PET/CT workstations is transferred to the existing server available in the PET Centre.

viii. At least 95% uptime should be maintained during warranty as well as CMC period. Other rules as per tender conditions.

ix. Commissioning should be completed within 90 days from the date of receiving AERB clearance for the layout plan to be prepared by vendor in consultation with the department.

x. After sale service to be available locally in Lucknow with availability of an onsite engineer.

xi. Onsite training by trained engineers and application specialists (both, PET and CT applications) to nuclear medicine physicians and technologist/ staff for at least 2 weeks period.

xii. The acceptance of the installation shall be subject to satisfactory handing over of the system to the department and certificate to this effect will be issued by the institute.

Warranty of equipment will start from the date of receiving of all documents and satisfactory acquisition of first patient.

TURNKEY SPECIFICATIONS FOR THE PET CT FACILITY AREA

1. The site earmarked for the purpose by the institute authorities is in the basement of Shatabdi Building, at KGMU campus. The total area is approx. **2000 square feet.** The prospective vendor must inspect the site before submission of tender and submit the certificate that the site is suitable for installation of a PET/CT scanner.
2. Vendor shall provide an accurate architectural & structural layout plan. Logical workflow and radiation safety norms should be adhered to in the layout.
3. The layout plan should be made in consultation with the user. The vendor should facilitate the user department for getting the same approved from AERB.
4. The whole work should be carried out as per local authorty and AERB norms.
5. Suggestive layout plan (as attached) may have the following rooms.
6. PET Scanner and Console room.
7. Recovery room
8. Radiopharmaceutical injection room
9. Three to four post injection waiting rooms based on space available.
10. One hot toilets
11. General public toilets
12. Waiting area
13. Electrical equipment room
14. AHU equipment room
15. Passage connection with the existing PET centre

SCOPE OF WORK

Civil Work: In the civil work, following works are required to be undertaken

1. All walls, as per AERB requirements, will be of RCC.
2. The room walls should be finished with acrylic / plastic emulsion.
3. The walls in the corridor, patients waiting area should be finished with tiles.
4. Whole area shall be finished with false ceiling.

5. All the doors should be provided with necessary fittings with hydraulic type door closures) and mortised locks.
6. Joinery: All the doors / windows shall be in glazed aluminum with adequate thickness of glass with etching work wherever required.
7. Flooring should be done with vitrified antiskid tiles of 600 X 600 mm in room's area and antiskid ceramic tile of size 300 X 300 mm in toilet area. Floor tiling need to be done in the existing PET centre also.
8. In radiopharmaceutical injection room, the shelves should have granite stone.
9. Plumbing work has to be carried out as per requirement. The material to be used should be as per approved makes.
10. Oxygen supply line and vacuum pipelines with manifolds need to be installed in the new PET area. It should be connected with the centralized supply of the hospital.
11. All the material should be of approved make.
12. Equipment should be installed based on layout and water drainage in the PET-CT rooms.

Electrical Work: The vendor is required to specify the total load requirement i.e.,

1. Required for the PET/CT scanner, the air conditioning, room lighting and for the accessories, if any. The electrical work should have:
2. Earthling with copper plate for the main equipment and the air-conditioning equipment as per equipment requirements. The use of earth leakage circuit breaker will be required.
3. A distributed panel of appropriate capacity (TTA as per IEC 61439 with gas suppression system) is to be provided and installed. The load will be provided by the Institute. However, the power supply from existing PET Centre Panel to the new distribution panel along with cables of appropriate size will have to be provided and fixed by the vendor.
4. In the new PET area, the lighting fixture should be LED type.
5. Provision of networking outlet points, telephone points and UPS points shall be made.
6. Networking switch to be provided and fixed as per the requirements in existing and new PET area.
7. The external peripheral area should be lighted.
8. All switches and other materials to be used should be as per approved makes.

9. Fire stop seal to be used on cable entries in the building.

Fire Protection:

Non water based fire protection is to be integrated as per requirement Addressable type fire alarm system should be provided and connected with main fire control room of the institute. Other works include.

Fire extinguishers as per norms (Clean agent, CO2 & ABC).

Fire door for the electrical panel room and AHU.

Gas suppression system for electrical panel and UPS.

Battery isolation switch between battery bank and UPS is needed to be provided.

LED based exit and fire signage to be installed as per location.

Air-conditioning:

The complete area should be centrally air-conditioned as per norms. The work scope should include

It shall be equipped with synthetic filters of suitable capacity complete with ducting work, grill work, drain Work, insulation, work including providing and fixing of electrical panel for HVAC system.

The temperature range should be between 22 ± 2 degree Celsius. The variation in temperature should not exceed one degree Celsius per hour. The humidity should be less than 50%.

Control and power cables should be provided and fixed in all respect. An electrical cable if required from / to the AC panel will be supplied and fixed by the vendor.

Proper Ventilation along with necessary inline fan shall be provided for toilets and UPS room.

Vendor need to supply the dehumidifier.

Additional AC other than the centralized AC if required to be maintained by vendor during duration of warranty and CMC period.

Warranty: 05 years and CMC of 05 Years after the expiry of warranty period shall be part of the tender.

Others:

The successful vendor should also include following in the scope of work:

Lead Glass of required size and thickness should be fixed in the console room.

Control console and computer platform should include Table with Keyboard drawers as per the requirement.

Music and Public Address System for calling / information the patients.
Furniture and fixtures for all the area should be provided as per requirement.
Proper signage, both external and internal.
Aesthetic Interiors, Landscaping
Any other required work but not mentioned in the turnkey specifications.
Dismantling of the existing structure and clearance of all the material will be done by the vendor.
Whole turnkey work including commissioning should be completed within 90 days from the date of receiving AERB clearance for the layout plan to be prepared by vendor in consultation with the department.

Defect Liability:
The works to be executed shall be guaranteed for a period of 5 years from the date of commissioning against any defective material / workmanship. The warranty and CMC of the Air Conditioning units will from the part of main equipment.
Certification to the effect that all civil/electrical/AC the work has been executed as per the specifications incorporated in the above document will be by the Engineering Department of the Institute.

All dispute will be in jurisdiction of Lucknow courts

Dr. Pankaj Tandon,
Head, Technical Services Section,
Radiological Safety Division,
Atomic Energy Regulatory Board,
Mumbai - 400 094