B.P. Koirala Memorial Cancer Hospital

Bharatpur, Chitwan

Invitation for Proposal: PET CT Scan and Cyclotron Detailed Financial and Technical Information

Notice Published: May 07, 2024

B.P. Koirala Memorial Cancer Hospital is embarking on the procurement of a PET CT Scan with Cyclotron through a competitive bidding process/tender. To facilitate cost estimation and gather technical specifications, the hospital has released a notice on December 24, 2023, inviting various options of technical and financial proposals, along with the opportunity for Physical/Virtual Presentations.

In continuation, the hospital invites detailed Financial and Technical Information for the equipment, with attached specifications, from capable and interested firms/companies. All interested parties are requested to submit their proposals directly to the hospital administration or via email to any of the following addresses: bpkmchhospital@gmail.com, gyan.alina@gmail.com, bpkmchprocurement@gmail.com within 15 days.

Attached herewith, you will find the preliminary specification document. Interested firms/companies are encouraged to submit any additional suggestions or requirements regarding the attached specification.

Poudel

Dr. Shivaji Poudel

Executive Director

B. P. Koirala Memorial Cancer Hospital

Bharatpur, Chitwan

Technical Specification of Medical Cyclotron System (Construction of Building, Supply, Delivery, Installation, Commissioning and Training)

S.N	Technical Specification	
	AN OVERVIEW TO SPECIFICATIONS:-	
A	Scope of work	
	Construction of Building, Supply, Installation, Testing, Commissioning, Operation and Maintenance of a Medium Energy (≥18MeV) Medical Cyclotron system, PET-Radiochemistry and QC system for producing PET-Radiopharmaceuticals on turn-key basis including Support and Expertise on the Building Design and Laboratory Layout. The quoted system must be capable of providing large volume and high yield of PET-radioisotopes and PET-radiopharmaceuticals. It must be fully functional and must provide all the required isotopes for PET imaging. Medical cyclotron system must have USFDA and CE approval.	
	Equipment to be provided and installed should consist of following:	
	A. Medical Cyclotron- 1 unit	
	B. Cyclotron control workstation: 1 unit	
	C. System interlocks with relevant (radiation, vacuum, temperature, humidity etc) monitors.: 1 set	
	D. Power Supply: as per system requirement	
	E. Target system: 4 Unit	
	F. Vacuum system: 1 set	
	G. Chemistry /synthesis modules, dispensing/delivery equipment	
	H. Hot Lab: all accessories for production and QC of desired radionuclides and synthesis of final products: 1 set	
	I. Waste gas management: As per system requirement	
	J. Shielded delivery systems: As per system requirement	
	K. All required gases supply: As per system requirement	
	L. Others Accessories: As per system requirement for smooth operation.	
B.	**Equipment and Accessories**	
B.1	Cyclotron:	
a.	A negative ion cyclotron with energy which can able to produce the conventional isotopes (F18,C11,N13,O15) an Non- conventional radioisotopes (I-124,Cu-64,Zr89,Y86) with liquid, gas and solid targets.	
b.	Operating Mode: The cyclotron shall be capable of accelerating protons to energy ≥ 18MeV under completely automated mode with option for semi-automated or manual mode.	
c.	Beam current: Cyclotron should be capable of delivering a beam of minimum150 μA. Beam current to be adjustable from 1 μA - 150 μA and upgradable to 200μA or higher	
d.	Production rate: minimum 20Ci of F18 in every two hours' of irradiation (run) and should be upgradable to higher production rate.	
e.	Target System: The cyclotron should have at least four target ports. Two target ports should be possible for the production of F-18 and others PET isotopes.	

B.2	**Radiochemistry Synthesis Modules with Suitably Shielded Hot Cells and QC equipment**	
a.	Should have System for automatic transfer of product from target to chemistry system. Automated radiochemistry modules for synthesis of various PET radiopharmaceuticals i.e. for F-18, C-11, N-13, O-15. The method of production of radiopharmaceutical should have appropriate regulatory approval. Must supply four numbers of Nucleophilic Synthesis Modules two dedicated for [F-18] based PET tracers and remaining two for other radiopharmaceuticals. Radiochemistry Synthesis Modules and equipment should have USFDA, CE approval and Should be WHO GMP compliant. Must supply adequate QC setup for radiopharmacy.	
b.	**Dispensing system for FDG with hotcell system**	
	i. Class A, WHO GMP compliant hot cells with adequate lead shielding (stainless steel finishing) with Laminar Flow, pre-chamber and dose calibrator: 4 units	
	ii. Dispenser for vials, Capable of handling radioactivity activity up to 20 Curie of F-18 radioisotope	
B.3	Radiation safety devices: complete set of radiation safety devices including Gamma ray survey meters, Contamination monitors, Hand foot cloth monitors, Neutron monitors, Central Radiation monitoring system etc	
C	Building and all utilities for cyclotron facility	
C.1	Building construction	
	i. The entire construction work (civil + electrical + plumbing+ sanitary+ HVAC) must comply with IAEA regulatory requirements and must fulfill the statutory norms/guidelines. ii. All the design and construction of cyclotron, radio pharmacy laboratories, QC rooms, synthesis room etc. Anything not included in the tender document/BOQ/turnkey specification but required for comprehensive completion of the job must have to be executed by vendor without any extra cost.	
	iii. The layout proposal will be prepared in consultation with the end-user. Once agreed upon, the successful Bidder shall work, in full consultation with BPKMCH, Bharatpur, in preparing detailed site plan for the installation of the cyclotron. The site plan shall include all requirements for the operation of the cyclotron, and associated equipment in accordance with the Specifications iv. Any modification in architectural layout, design, structural elements or aesthetic features shall require prior approval from hospital authority.	
.2	UPS: minimum 30 min backup for entire system at services.	
	Electric generator as per system requirement for whole Cyclotron and all operating system to run and building.	
	Rooms specifications: design layout provided by hospital.	
C.3	Production, QC and Packaging: The production of radio-isotope(s) and its quantity as per demand of BPKMCH (for in-house use and supply to other institutes') and packaging for transportation will be the supplier's responsibility for first three years.	
D	Comprehensive Maintenance Contract (CMC) of subject equipment	
D.1	i. shall include preventive maintenance including testing & calibration as per technical/service/operational manual of the manufacturer, labor and all	

	spares, after satisfactory completion of five years warranty period should be quoted for next five years (from sixth to tenth year) basis for complete equipment including third party items. ii. The cost of CMC (sixth to tenth years) will be taken for bid evaluation along with turnkey cost (TurnKey +CMC). iii. During the CMC period, uptime of the system shall be at least 97% calculated at all working hours of the institution. If downtime exceeds 3% there shall be a penalty of 3days for a day breakdown. Penalty will be calculated 8 hours after telephonic/ SMS/ Email information to the vendor and penalty days will be added to CMC days.	
D.2	Other terms and conditions	
	i. Product quality certificate of USFDA and CE must be submitted with the offer for 1) Cyclotron, 2) FDG module, 3) Hot cells 4) Dispenser, 5) QC equipment's separately.	
	ii. Human resource: The necessary qualified/trained human resources' (Cyclotron Operator/technologist, Radio-chemists/technologist, Medical Physicist/RSO, engineers) recruitment to manage, run cyclotron and management of radioisotopes for three years is manufacturer's responsibly	
E	Training	
E.1	**Cyclotron operation and maintenance training:** i. Two weeks on-site training for related professionals. ii. Four weeks training in well-established similar medical cyclotron centre in abroad for 3(three) cyclotron operators/technologists and 4(Four) radiochemists/Technologists, 2(two) RSO/ medical physicist, 4(four) nuclear medicine physicians/radiologists, 1(one) biomedical engineer, 1(one) civil engineer and 1 (one) HVAC engineer/technician. The training will in their respective fields and to cover routine operation and minor maintenance of the cyclotron.	
E.2	**Radiochemistry module operations, radiation protection and quality control equipment training:** i. Two weeks training on-site for up to radio-chemists/technologist and physicists, nuclear medicine physicians/equivalent, biomedical engineer and civil engineer for the radiochemistry module operations, radiation protection & QC equipment ii. Four weeks training in abroad in well-established similar medical cyclotron centre for 4(Four) nuclear medicine physicians/Radiologists, 4 (four) radio-chemists/technologists, 1(one) cyclotron operator and 2 (two) RSO/Medical physicists, 1(one) biomedical engineer and 1(one) civil engineer for the radiochemistry module operations, radiation protection & QC equipment.	

B. P. Koirala Memorial Cancer Hospital Bharatpur, Chitwan

Technical Specifications of PET CT System (Supply, Delivery, Installation, Commissioning and Training)

Technical Specifications of PET CT Scan Machine and Supporting System

Nomenclature of Standard Equipment

Construction of building, Supply, Installation, Testing, Commissioning operation and Maintenance of PET-CT scanner, PET hot lab and QC system. All the equipment must have USFDA and CE approval.

A high-resolution state - of - art Positron Emission Tomography – Computed Tomography (PET - CT) scanner solid state CT detectors with acquisition of generation of ≥ 64 slices per rotation with time-of-flight technology (ToF). Quantity:1 Unit and of introductory year should be latest.

A. Primary Vendor shall be responsible for :

1. Supply, Installation & Commissioning (functional delivery) on Site Modification Basis (BPKMCH, Bharatpur, Nepal)
2. Site preparation: Design, construction, interiors and furnishing, 'onsite modification basis,' adhering to all the IAEA prescribed safety guidelines and regulations with consultation with BPKMCH.
3. Providing latest technology DICOM ready state of art whole body Positron emission Tomography system integrated with spiral CT system with acquisition or generation of ≥ 64 slices per rotation.
4. Providing the QA tests as per NEMA guidelines and to fulfil the requirements for acceptance testing. Periodic QC tests with all related phantom and QA accessories as standard as per the IAEA regulations.

Technical Specifications:

B. Gantry and Detector

1. Gantry should have an integrated PET and CT hardware.
2. The patient gantry aperture size should be ≥ 70 cm and uniform for both, PET and CT.
3. The PET scanner should employ non-hygroscopic high yield (>80%) and low decay time scintillation like lutetium-based crystals for detecting 511KeV gamma photons in coincidence, with technology.
4. PET crystal thickness should be ≥ 20 mm to give system sensitivity of ≥ 5.5 cps/KBq standard with TOF.
5. Ring diameter should be ≥ 80cm.
6. The transverse FOV should be ≥ 65 cm.
7. The geometric axial FOV as measured from the outer edges of the crystals must be ≥ 24 cm.
8. Whole body (head to toe) for adult patient PET acquisition time: to be specified by the bidder.

C. Detector Performance (Please mention as per NEMA)

1. All specifications must comply with NEMA standards publication NU 2 2024 or latest performance measurements without altering instruments parameters. QC software to measure theses parameters must be available in the system.

D. CT Specifications

1. Multi detector CT having capacity of ≥64 transverse cross-sectional slices simultaneously in one rotation without undergoing any axial motion. Latest advanced CT radiation dose reduction technology and software that should offer higher speed image reconstruction.
2. Rotation time should be ≤ 0.6 sec. multiple pitch factor settings freely selectable by the user.
3. Low contrast detectability should be at least mm @ 0.3% on 20cm CAPTHAN phantom. Specify the low contrast detectability and associated dose.
4. High contrast resolution should be 15.0 Lp/cm or better.
5. Microprocessor controlled high frequency X-Ray generator with output of 70 KW or more, Tube Voltage range should be approx. range of 80 – 140 KV, Anode heat storage capacity of 7.0 MHU or more, Tube current of approx. range of 20-600 mA , Automatic self-testing system.

E. **Patient Bed:** A diagnostic curve table top and a separate removable flat table top should be provided for radiotherapy treatment planning. Patient poisoning and fixation accessories (Head, Arm, IV contrast injection) laser tracking system (Moving lasers)

F. **Data acquisition and Reconstruction Workstations: 5 Work stations (1 console and 4 processing work stations)**

1. **Image Storage Server and Processors:** Hardware to be high speed state of art processor with SSD storage of 20 TB expandable to 40 TB with ≥ 16 GB RAM with automatic archival system with high-speed volume rendering graphic cards.

G. **Data Acquisition Software:** Acquisition in full 3D mode must be including Static, Whole Body, Dynamic and Gated (cardiac and respiratory) acquisition. The acquisition program should support pre-programmed scan protocols with simple, dynamic editing of parameters. Time of flight at HD must be available for image reconstruction. Pixel size: The user should have the option to specify the pixel size for reconstruction. The reconstruction program should support reconstruction in image sizes of at least 128 x 128 or higher

H. **Clinical application software**

1. Software for data collection, CT based attenuation correction, reconstruction of image for co-registration, full 3D prospective reconstruction and iterative scatter correction, advance 3D volume rendering with 3D fusion, virtual endoscopy, model based 3D scatter correction, MIP, whole body acquisition & dynamic acquisition.
2. System management software for computerized calibration, quality control for all scanner performance parameters, diagnostics and administration of the patients.
3. Processing workstation should have image comparison software for the baseline and follow up studies should have viewing and processing software for dynamic acquisition date.
4. Provision of making DICOM/PDF/JPEG/AVI/MPEG digit output and archiving system should be USB 3.0, CD/DVD drive and PACS compatible.
5. 4D TOF or better or advanced respiratory gating software and hardware for PET /CT acquisition and processing should be standard features.
6. Should have Specified quantification software for brain & cardiac perfusion studies, cerebral blood flow and flow reserve. System must have neuro quantification software for neurological applications (including assessment of dementia by measuring relative SUV (SISCOM, SPM etc. provide detailed specification of the software quoted)
7. Dedicated licensed latest version of cardiac Toolbox including software
8. Software for qualification of metabolic parameters for oncology application including SUV volume, SUV standardized for BMI, SUV peak, SUV-L Glycotic index and latest software to calculate metabolic tumor volume (Threshold based, Gradient based, Iterative & Region growing method or equivalent) & for Radiation dose assessment.
9. Permanent site license (s) for all software applications should be available in all 4-processing workstations. All future software should be updated during the warranty period and CMC should be free of cost

I. **Peripheral and Hot Lab Accessories :**

1. A 3-phase input / output UPS (approved make) with maintenance free batteries for the complete system including PET-CT gantry, computer system, anesthesia delivery system, monitors and defibrillators, dehumidifiers, room lights with a minimum 30 min, backup at full load should be provided.
2. Latest dual head pressure injector: Digitally controlled CT injection system, remote monitor, syringe heater, along with 200 sets of 200 ml disposable CT syringes with tubing and connector.
3. Two single syringe pumps as required for dynamic perfusion studies.
4. Required phantoms for CT & PET quality Assurance and system calibration and Quality control set as required (Including NEMA Phantom).
5. High resolution color laser Printer for color hardcopy on paper with 5 sets of all cartridges per year during warranty and CMC period.
6. CT Printing software/application must be compatible with all kinds of printers and sizes of CT film
7. Two dose calibrators with adequate shielding for PET radionuclides with compatible label / ticket printer.
8. Mobile Trolley in injection room for placing a dose calibrator in it, with a mounted L-bench with lead glass for handing PET radionuclides (2 in number) for 18 FDG and 68 Gallium, and One dose drawing module for F-18 FDG: 2 sets
9. Mobile Trolley in injection room for placing a dose calibrator in it, with a mounted L-bench with lead glass for handing PET radionuclides (2 in number) for 18 FDG and 68 Gallium, and One dose drawing module for F-18 FDG: 2 sets
10. Two stainless steel side Trolley in the PET/CT room
11. Decay drum of at least 200L capacity for PET radionuclides: 2 unit

12. Four lead lined waste bins with minimum 12 mm (about 0.47 in) lead for PET Radiopharmaceutical waste.
13. 40 Lead bricks and 8 lead corners for F 18 Handing
14. Four Tungsten syringe holders of two sizes (Two 3 ml and two 5 ml)
15. Two digital radiation survey meters with beta and gamma windows
16. One digital uSv/Hr range contamination monitor
17. One Digital GM based Survey cum – Contamination meter with pancake probe
18. Five Digital pocket Dosimeters (reputed brand)
19. Four digital area Zone monitors
20. One set of decontamination kit and spill kit
21. Two Syringe needle destroyers.
22. One side by side refrigerator of minimum 500 L Capacity with microprocessor based temperature monitoring system
23. One electrical weighing machine for at least 200 kg
24. Set of emergency equipment and kits, One crash cart trolley, One biphasic defibrillator, One vital sign monitor, Two glucometers with 50 packs of blood glucose test strips,
25. Two latest specifications PCs (latest windows based OS having licensed operating system and software, MS office & antivirus software and along with two LaserJet printers for patient reports and data maintenance).
26. For X-ray LCD illuminators for minimum 2 films views for 14" x 17" size
27. One collapsible wheel's chair with rubberized swivel wheels.
28. One patient trolley with rubber foam mattress – 1 Number.
29. A lead glass window: 100 x 150 cm separating the scanner and console which should be sufficient to seal 511 KeV radiations optimally as per IAEA/ICRP guidelines.

J. Other items

1. Dehumidifiers:4 units
2. Fume hood for PET Radio pharmacy with sliding lead glass shield with HEPA filter (Germ free Radio pharmacy) hood or equivalent)- 1 units with warranty on HEPA filter and other accessories with periodic calibration for 5 years.
3. Class II Biosafety cabinet- 1 unit with warranty on HEPA filter and other accessories with periodic calibration for 5 years.

K. Warranty

1. The entire system should have a warranty including the radioactive reference source required for calibration of the scanner, crystals, detectors & CT X-ray tubes replacement for a period of 5 years after the satisfactory commissioning and handing over of the equipment. The warranty will include all accessories & third-party items. A pro-rata warranty is not acceptable
2. CQomprehensive maintenance contact (CMC) for whole system as in warranty clause including CT X-Ray tube replacement as and when required and accessories for a period of 5 year after the expiration of warranty period.
3. At least 97% uptime should be maintained during the warranty as well as CMC period.
4. After sale service to be available locally with availability of engineers.

L. Training

1. Onsite training by trained engineers and application specialists working in good PET centers to nuclear medicine physicians, radiologists, technologists, medical physicists, Biomedical engineer, civil engineer for at least 2 weeks period.
2. Four weeks training abroad in well-established similar medical PET-CT centre for 3(three) nuclear medicine physicians, 3 (three) radiologists, 6 (six) imaging technologist/ radio-chemists and 2 (two) RSO/Medical physicist, 1(one) biomedical engineer, 1(one) civil engineer and 1(one) IT engineer and 1 (one) HVAC engineer/technician for the radiochemistry module operations, radiation protection & QC equipment.

M. Turnkey works

1. Entire area for proposed site to be prepared and finished on turnkey basis as per hospital requirements.
2. The entire construction work (civil + electrical + plumbing+ sanitary+ HVAC etc.) must comply with IAEA regulatory requirements and must fulfill the statutory norms/guidelines along with seismic zone requirements.
3. Any modification in architectural layout, design, structural elements or aesthetic features shall require prior approval from hospital authority.
4. Necessary furniture and fixtures for comfortable working conditions, storage of system components and consumable stand for protective aprons, gonad shields and thyroid shields etc. should be provided, light weight lead aprons – 4 in No.

5.	CCTV surveillance system covering the entire common areas, corridors, waiting areas, uptake zones, Hot lab with monitoring and recording system.
6.	TV sets with cable connection in patient waiting areas: 2 sets (≥50 inch each)