Amendment No. 07

Date: 15/04/2019

Sub: Amendment No.07 to the Tender Enquiry Document

Ref: (i) Tender No: HITES/PCD/AIIMS-BBSR/01-RT/18-19 dated: 22.10.2018.

Section I
Notice Inviting Tenders(NIT)

1) For:

Sl No	RFx No	Equipment	Quantity	Tender Processing Fee (INR)*	EMD (INR)
1	3000002824	128-Slice PET/ CT Scanner	1	5900	49,00,000
2	3000002825	Dual Particle Cyclotron	1	5900	50,00,000

Read As:

Sl No	RFx No	Equipment	Quantity	Tender Processing Fee (INR)*	EMD (INR)
1	3000002824	128-Slice PET/ CT Scanner	1	5900	**43,00,000**
2	3000002825	**Medical Cyclotron**	1	5900	**56,00,000**

2) The tender time line is revised as below:

Sl. No.	Description	Schedule
a.	Last date for receipt of Pre-bid queries	19.04.2019, 06:00 PM
b.	**Pre-bid meeting date, time**	**22.04.2019, 11:00 AM**
c.	Closing date & time for submission of online bids	**14.05.2019, 01:00 PM**
d.	Closing date & time for submission of **tender processing fee and EMD in physical form***	**14.05.2019, 02:00 PM**
e.	Time and date of opening of online bids	**14.05.2019, 02:00 PM**

SECTION - IV
GENERAL CONDITIONS OF CONTRACT (GCC)

3) GCC Clause 21- Terms and mode of payment

	Tender clause	**Clarification**
Documents to be submitted for payment GCC- Point No- 21.1 – Payment Terms –A(a)(v) Payment for Domestic Goods Or Foreign Origin Located Within India. (v) Certificate of origin for imported goods Page no -36	Certificate of origin for imported goods.	Certificate of origin needs to be submitted in case the major equipment tendered is of foreign origin and located within India. However, for accessories having foreign origin, certificate of origin need not be submitted.

	Tender clause	**Clarification**
GCC- Payment of Turnkey: Point No 21.1-C Page No.37	This will be paid on proof of final installation, commission and acceptance of equipment by the consignee	"Payment terms for the turnkey work shall be as below: -10% of the total Turnkey shall be payable after the completion of the DPCC & Foundation. - 20% of the total Turnkey shall be payable after the Ground floor slab is cast. - 20% of the total Turnkey shall be payable after the slab for second floor cast. - 20% of the total Turnkey shall be payable after delivery of the AC plant / Electrical panels / DG Set/ furniture items etc. - 30% after handing over of the site and final acceptance issued by the consignee.

SECTION - VI
LIST OF REQUIREMENTS

4) For:-

Sl No	RFx No	Equipment	Quantity	Warranty	CMC
2	3000002825	Dual Particle Cyclotron	1	10 years	15 years

Read As:-

Sl No	RFx No	Equipment	Quantity	Warranty	CMC
2	3000002825	**Medical Cyclotron**	1	10 years	15 years

5) For:-

Part II: Required Delivery Schedule:

Existing	**Amended As**
For Indigenous or for imported goods if supplied from India or for imported goods directly from foreign: Supply, Installation and commissioning to be completed within 120 days for 128-Slice PET/ CT Scanner and within 270 days for Dual Particle Cyclotron from the date of NOA or date of opening of LC or date of approval of layout drawing from AERB, whichever is later.	**For Indigenous or for imported goods if supplied from India or for imported goods directly from foreign:** **For 128-Slice PET/ CT Scanner** Supply, Installation and commissioning to be completed within 120 days from the date of opening of LC or date of approval of layout drawing from AERB or date of site handing over by institute along with commitment of permanent power , whichever is later." The date of delivery for 128 Slice PET-CT will be the date on which the consignment reaches the *Port of Destination.* **For Medical cyclotron** Supply, Installation and commissioning to be completed within 300 days from the date of opening of LC or date of approval of layout drawing from AERB or date of site handing over by institute along with commitment of permanent power , whichever is later." The date of delivery for Medical cyclotron will be the date on which the consignment reaches the Consignee site

6) Note:

Added para: (Custom Clearance)

128 Slice PET-CT
Custom clearance will be carried out by CHA appointed by HITES.

Medical cyclotron
Custom clearances if any would be the responsibility of the vendors. Concessional Custom Duty against CDEC will be reimbursed at actual in INR. (CDEC will be issued by the consignee)

The supplier is responsible to collect the CDEC from the consignee/AIIMS in time. Delay in getting CDEC shall not be attributed to the purchaser.

Section VII
Technical Specifications

Item sl. no. 01;
128-SLICE PET - CT SCANNER

The technical specification is revised as below:

Sl. No	Technical Specification
	Primary vendor shall be responsible for:
A	Design, planning, interiors and furnishing adhering to all the AERB prescribed safety guidelines and regulations. Vendor has to coordinate with cyclotron vendor and AIIMS, Bhubaneswar for Design and planning. (The interior finishing required for PET-CT will be done by the PET-CT vendor.)
B	Supply, Installation, Commissioning (functional delivery).
C	All the Application, Operating and Service manuals 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.
D	AERB Registration and site approval.
E	Vendor has to provide all the layout and drawings and support in getting the AERB approval.
	1) General
a	A latest technology whole body Positron Emission Tomography system with spiral CT scanner having capability of generating 128 slices per rotation, DICOM ready and isotropic volume acquisition designed for providing volume measurements of metabolic and physiological processes using positron emitters, as well as for producing accurate structural and anatomical fusion images and making attenuation maps for CT based attenuation correction.
b	The system should have capability for data acquisition, processing, image reconstruction & analysis and fusion of PET with CT images.
c	The system should operate on 220 (± 10) V A/C (Single phase) 50HZ and/or 440V (±20) A/C {3 phase) 50HZ.
d	Type approval certificate/ NOC from AERB, Mumbai for the quoted model must be attached with the technical bid or else the bid will be summarily rejected. Further quoted machine must be US FDA approved.

e	For acceptance of the equipment, all the QA tests as per NEMA guidelines and to fulfil the AERB requirements will be done and demonstrated by the company engineer(s)and all the required phantoms will need to be arranged by the vendor and submit a detailed report in stipulated time frame. The company will also arrange such phantoms during periodical QA tests. No additional charges will be levied by the company for such QA tests during the lifetime of the machine.
f	All the Application, Operating and Service manual sets in English language in duplicate 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.
g	Kindly separately quote all options not included in the standard configuration with prices. The vendor will have to deliver the latest state of the art model of the machine at the time of installation with all hardware and software available at that time at no extra cost.
h	PET data acquisition and CT image reconstruction should be concurrent process.
	2) Gantry and Detector
	a) Gantry should have integrated PET & CT hardware and should be a Single Gantry.
	b) The PET scanner should employ non-hygroscopic high light yield (≥ 80%) and low decay time scintillator material like Lutetium based crystals for detecting 511 KeV gamma photons in coincidence with crystal thickness ≥ 20 mm.
	c) Ring diameter should be ≥ 80 cm.
	d) The patient gantry aperture should be ≥ 70 cm and uniform for both PET and CT.
	e) It must be capable of acquiring 45 or more transverse cross sectional slices, simultaneously without undergoing any axial motion.
	f) Axial Field of view should be 15 cm or more.
	g) The transverse field of view should be ≥ 50 cm
	h) The separation (center to center) between slices acquired simultaneously without any axial motion should be : 5 mm or better.
	i) The scanner must have low power laser lines orthogonally mounted on the gantry for patient alignment and auto-contouring. The laser should be mounted in such a way that the patient can be positioned form either side of the gantry and the patient bed.
	j) The scanner must have a detection configuration of a continuous ring around the patient. It must not have "gaps" of detection or areas of decreased sensitivity around the ring of detection.
	k) Integrated CT simulation software for conformal radiotherapy planning with laser system (one moving & 2 fixed lasers of green color) to be provided. It is to be connected with main TPS in the radiotherapy department through Ethernet wiring. One out of 5 workstations to be installed in TPS room.
	l) Efficient Gantry cooling system for continuous running of the machine.
	3) CT Specifications
	a) Multi detector CT capable of generating 128 slice/rotation
	b) Rotation time should be ≤ 0.5 sec.
	c) Multiple pitch factor settings should be available
	d) Image slice width should be from: 0.5mm to 10 mm.
	e) Low contrast detectability should be at least 5 mm@ 0.3% on 20 cm CATPHAN phantom
	f) High contrast resolution should be better than 15 lp/cm.
	g) High frequency X-Ray generator tube with output of 70 kW or more, Anode heat storage capacity of 6.0 MHU or more, Tube Voltage between 80-140 kV, Tube Current of 20-600mA, Automatic self-testing system
	h) Controls located on each side.

	i) Adult and pediatric modes for filter and dose reduction device.
	4) Performance Specifications:
	a) All specifications must comply with NEMA Standards Publication NU 2-2012 or latest performance measurements without altering instrument parameters. QC Software to measure these parameters must be available in the system.
	b) NEMA Axial and Transverse Spatial Resolution at 256x256 matrix should be </= 7 mm at 1 and 10 cm distance
	c) System efficiency I sensitivity must exceed 5 cps/KBq at 350 KeV.
	d) System Energy Resolution should be ≤ 14.0%.
	e) 3-D scatter Fraction should be ≤ 40%.
	f) During image reconstruction system should use Time-of-flight algorithms, when required for better lesion detectability. Any other reconstruction algorithm if available should also be provided.
	g) System should have & capable to use HD technology during image reconstruction.
	h) Attenuation correction should be CT based. Protocol / Algorithm for attenuation correction should be independent of metal/mA/IV contrast related artifacts.
	5) Patient Bed:
	a) Precision bed with low attenuation carbon fibre pallet and minimum sag of the patient table top.
	b) It should be able to bear 180 kg or more patient weight.
	c) 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.
	d) A separate flat carbon fibre table top should be provided for radiotherapy treatment planning
	e) The horizontal travel of the bed should enable the full length scanning of a patient inone scan acquisition. Full body horizontal length should be 190 cm and vertical travel from 60 to 90 cm.
	f) 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.
	g) Pediatric support, headrest, armrests, knee-leg support are to be provided and low attenuation ergonomic head holder.
	6) Workstation (Data Acquisition, Processing & Management).
	a) One Acquisition station independent of main processing unit having HD, OSEM and Time-of-flight reconstruction and any other reconstruction algorithms as standard features. The workstation should be of latest specifications at the time of shipment.
	b) It should have both, serial and USB ports.
	c) One processing workstation having high performance CPU with multi tasking operating system having minimum of 4 GB RAM, 2.5 GHz processor speed, minimum 1GB graphic card, 1TB or more SDD hard drive (if less, another HDD maybe included), Optical Mouse, Key-board and high resolution flat panel dual view LCD monitor of minimum 19" size with minimum resolution of 1024 x 1024. It should also have CD and DVD combo drive preferably with writer facility.
	d) Intercom with user programmable patient.
	e) Reconstruction filters –latest available filters with the company for PET applications.
	f) Communications - Ethernet with TCP/IP protocols and DICOM and above i.e., latest networking of all possible equipment in the facility with their peripherals and PACS available in the department. PET CT must be connected to the PACS System as part of this order.
	g) Each Processing workstation should have concurrent licenses of image fusion, quantification facility and image comparison software for the baseline and follow-up studies.
	h) Five workstations with concurrent users for all applications in PET and CT.

	7) Software:
	i. Data Acquisition
	a) Acquisition Modes: Acquisition in Full 3-D mode must include Static, Whole Body, Dynamic and Gated acquisition provisions with prospective 3-D reconstruction algorithm.
	b) 4D PET-CT Scanning facility: 4D PET-CT Scan software shall be provided and separately there shall be 4D PET-CT Respiratory Gating hardware to be provided. 4D phantom for QA should be quoted as optional.
	c) Same PET CT protocol should be used for Contrast CT in single acquisition.
	d) Acquisition Protocols: The acquisition program should support pre-programmed scan protocols with acquisition and reconstruction parameters and patients information with simple, dynamic editing of parameters. These parameters would include all information necessary to acquire data on the PET scanner (e.g., scan duration, patient information frame / list mode, bed motion), as well as information necessary for reconstruction.
	e) 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.
	f) Dynamic frame Mode Acquisition: The acquisition setup software must support multi-frame acquisition of different (arbitrary) frame duration's with no loss of data between frames. Alternatively, list mode acquisition may be available as standard feature.
	g) Reconstruction: Image reconstruction should simultaneously start for the acquired image while acquisition is still in process.
	h) Time of Flight and HD must be available for image reconstruction.
	i) Fully 3-D Iterative reconstruction technique should be available as standard. Low dose iterative reconstruction algorithm should also be provided.
	j) Pixel Size: The User should have the option to specify the pixel size for reconstruction.
	k) The reconstruction program should support reconstruction in image sizes of at least128x128 or higher.
	l) Scatter Correction: Scatter correction must be provided based on scan of the actual patient whose scan is being corrected and processed automatically.
	ii. Clinical Application Software
	a) Software for data collection, CT based attenuation correction, reconstruction of image for co registration, Full 3-D prospective reconstruction with iterative scatter correction, advance 3-D Volume rendering with 3-D fusion, virtual endoscopy, Model based 3-D scatter correction, MIP, whole body acquisition, dynamic acquisition
	b) Neuro quantification software including assessment of dementia using SUV values. Provide detailed specification of s/w quoted.
	c) Quote complete cardiac package both for PET and CT with ECG gating as standard item
	d) System management software for computerized calibration, quality control for all scanner performance parameters, diagnostics and administration of the patients' records.
	e) Attenuation correction, quality control software and a latest version of DICOM facilities for clinical applications.
	f) Software for PET/CT/MRI fusion.
	g) Should be possible to evaluate different scans of same patients done over a time to give overall assessment of malignancies progression in oncology.
	h) Provision to make DICOM/ PDF/ JPEG /AVI /MPEG digital output.
	i) PET DICOM 3.0 or higher version must be implemented. It should have the ability to import MR/CT DICOM Data.
	j) Latest advanced CT radiation dose reduction technology and software that shouldoffer higher speed image reconstruction

	k) All future software updates including associated hardware during warranty period and CMC shall be free of cost.
	l) The CT Simulation workstation should be fully integrated and networked with the treatment planning system for 3D CRT, IMRT/IGRT and with portal imaging workstation at the linear accelerator console.
	m) It should have capabilities for 3D viewing of images along with tools for constructing and display of high resolution (512 X 512 pixels) DRRs and MPRs.
	n) Tools for auto-contouring of normal structures along with manual contouring of normal structures and target volumes should be included. Editing, copy and paste of structures.
	o) 30 margin tools from GTV to CTV to PTV should be available.
	p) Should have capability to do online CT simulation (while patient remains on CT couch) and also offline CT simulation at physician's workstation.
	q) Tools for beam placement including MLC of any make and isocentre determination should be included. The tracking laser system should be linked to the virtual simulation software
	r) The supplier will be responsible for complete networking and integration between the CT Simulation workstation, Treatment Planning System and portal imaging workstation for import and export of image and data.
	s) Should be a fully DICOM RT "plug and play" system for import and export of CT/MRI/PET images, RT structures
	u) 40TB online Archive from principal manufacturer of PET-CT supplier, inclusive of zero foot print viewer for diagnostic reading to be provided. The archive software and viewer should be FDA approved and viewer should support access on mobility devices (i-OS or android as well). quote as standard
	8) Peripherals / Accessories
	a) UPS for the whole system including CT with minimum 30 min backup at full load should be provided.
	b) Latest dual head pressure injector compatible with CT and 200 disposable CT syringes with tubing and connector (optional).
	c) High Resolution dry chemistry type DICOM laser film printer with online capability of 3 film sizes for x-ray films with minimum 5 packets (500 films) of films of 14x17 inch size
	d) Supply of sealed calibration source for QA of PET scanner for a period to be replaced during warranty and CMC period, as and when required. The old spent sources need to be sent back to the manufacturer by the vendor at their own cost
	e) High resolution colour laser printer (1200 x 1200 dpi) for colour hardcopy on paper with 5 sets of all cartridges.
	f) Standard NEMA Phantoms (Scatter/NECR, Sensitivity, Image quality and resolution, Fillable Uniform Flood phantoms) for PET QA, CT image quality phantom to be provided.
	g) Three dose calibrators (Two for PET and One for SPECT radionuclides).
	h) One dose cabinet with shielded L-bench for F-18 handling.
	i) One Decay drum for PET radionuclides as per standard
	j) Four waste bins with minimum 12 mm lead for PET Radiopharmaceutical waste.
	k) 40 Lead bricks and 8 lead corners for F-18 handling
	l) One dose drawing module for F-18 FDG (comecer or equivalent make)
	m) Four Tungsten syringe holders of 2 sizes (Two 2 ml and Two 5 ml).
	q) One decontamination kit.
	r) Onsite remote service diagnostic facility to be provided.
	s) I MAC desktop with 16 GB RAM, 1 TB storage and 27 inch monitor including wireless mouse and keyboard--one number. Provide as standard

	9) Others
	a) Dehumidifier: 4 nos.
	b) Standard Fumehood with HEPA filter for radioiodine ward
	c) Area zone monitor- 2 no.
	d) Tungsten Syringe carriers for PET Radiopharmaceuticals, 5 cc: 04 no.
	e) Tungsten Syringe carriers for PET Radiopharmaceuticals, 2 cc: 02 no.
	f) Lead Glass Window: 100 x 150 cm separating the scanner and console which should be sufficient to shield 511kev radiation optimally as per AERB guidelines.
	g) The complete system should have a guarantee including the radioactive reference source, crystals, detectors and x-ray tubes replacement for a period of FIVE years after the satisfactory commissioning (functional delivery) and handing over of the equipment. Warranty will include all the accessories and third-party items
	h) Rates for Comprehensive maintenance contract (CMC) for whole system including x-ray tube replacement as and when required and accessories for a period of **FIVE years** after the expiry of warranty period.
	i) The peripherals / accessories, electronic / electrical consumables (leads, probes, batteries etc.), calibration sources, air-conditioning units and batteries of UPS will also form part of the warranty and CMC. Service, repair and maintenance of all third party items will be the sole responsibility of primary vendor. Supplier shall be responsible for maintaining adequate humidity and temperature for proper functioning for PET CT.
	j) At least 95% uptime should be maintained during warranty as well as CMC period.
	k) One Physician to be trained outside country in an internationally reputed centre for 4 weeks and Two technologist to be trained onsite for 4 weeks
	m) After sale service to be available onsite through a service centre of the company located in Bhubaneswar.
	10)BOQ for the turn key to be submitted by the vendors after the survey and consultation with the institute.
	11)The vendor will render all necessary help and provide needed documents. The vendor has to provide all supporting documents, site plan, equipment details and drawings to facilitate AERB clearance and installation of the equipment.
	12) Deleted
	13)The offered warranty shall commence from the date of satisfactory handing over of the equipment (functional delivery) and start of its clinical use.
	14)Future updates/ revision of the software versions shall be done by the vendors without any additional cost. Vendor shall be responsible for updates of all software to the latest available throughout the warranty period.
	15)Vendor shall provide preventive maintenance of the equipment as per manufacturer factory recommendation at the convenience of the Institute.
	16) Arrangement of Demo of the machine to be quoted by vendor if in any centre installed in India.
	17) Installation
	a. The vendor should inspect the site before quoting. Complete layout site map and details of work(BOQ) should be part of technical bid.The PET-CT vendor has to liaise with the cyclotron vendor and AIIMS, Bhubaneswar for site design, layout approval and construction.
	b. Necessary furniture and fixtures for comfortable working conditions, storage of system components and consumable stand for protective aprons and gonad shields etc. should be provided.
	c. The vendor should provide the following furniture and accessories of standard make as described
	· Consultant table-4

	· Consultant chair - 6
	· Customize table for workstations -2
	· Wooden Cupboards - 6
	· Patient sofa for resting in post injection room - 4
	· 5 seaters visitor sofa for consultant room -1
	· CCTV facility for patient viewing in waiting area
	· Apron Stand -1
	· Protective aprons -3
	· Gonad shield -3. etc.
	· One executive table and chair for HOD
	· Three seater chrome plated patient waiting chair -8
	Preferred FURNITURE make - Hermen Miller / Godrej / Featherlite
	18) The vendor need to quote as OPTIONAL : 100mCi FDG packet delivered to AIIMS (doorstep calibrated and doorstep delivery)- 200 doses/year valid for first 2 years.
	19) CCTV and two way microphone and speaker system (one CCTV each in common waiting hall, post administration waiting area for PET) and monitoring screen in console room/phone.
	20) Onsite upgrade to digital PET quote as optional if available
	21) Please quote parametric imaging option as optional if available
	The scope of work for site modification for PET CT shall include PET examination room , console area , dose admin room , post admin room, hot lab cum radiopharmact room , radioactive store , radioactive waste store, active toilets, technician room, ups area/room.
	<u>SITE MODIFICATION - 128 Slice PET CT Scanner</u>
	1. Supplier shall ensure that the equipment model quoted is commissioned within the designated area without major structural changes to the building.
	2. Complete equipment layout site plan and details of work (BOQ) should be part of technical bid.
	4. Provisions should be made for placing the various accessories in console room, work-station and printer locations.
	5. It should also include Lead lined door with lead glass peeping window, radiation warning indicators and signages, Aluminium false ceiling, GVT floor tiles and full height wall tiles.
	6. All site modification works should comply with specified standards of the hospital.
	The SCOPE OF WORK for SITE MODIFICATION OF PET CT SYSTEM shall consist of the following rooms: **a. PET CT Examination Room** **b. Console room** **c. PET CT Equipment/Cabinet Room.** **d. Dose Admin Room** **e. Post Admin Waiting Area/Room** **f. Hot Lab cum radio Pharmacy Room** **g. Radioactive Source Storage Room** **h. Radioactive waste Storage** **i. Active Toilet** **j. Technologist Room** **k. UPS/Battery Room** **l. changing rooms**
	The area considered for Site Modification is 1500 sq feet. However bidder should quote the unit rate, payment will be made as per the actual sitemodification done by the bidder.

1	**Civil work**
a)	Civil construction work including construction/ modification / demolition of brick wall if any, plastering, flooring as per the approved plan and equipment layout plan.
b)	Additional strengthening of floor / Concrete bed of CT and equipment area, if required
c)	Platform for unloading and shifting the PET CT should be provided if necessary.
d)	Cable tray, trench & channel – necessary trenches, cable tray and channels at required location would be provided.
e)	**All the construction work to be done as per the final plan approved by end consignee in line with AERB guidelines.**
f)	**600x600 mm Vitrified wall tiles in PET CT examination room up to false ceiling level.**
a)	**Flooring**
i)	**600 x 600 mm glazed vitrified (GVT) tiles in PET CT Examination room and 600 x 600 mm glazed vitrified (GVT) tiles with 100 mm tile skirting all other rooms of Pet CT complex.**
ii)	**5mm-Vinyl flooring in PET CT equipment / UPS room.**
b)	**Painting**
i)	Two coats Plastic Emulsion Paint over 2 coats of wall putty including primer in Console, PET CT equipment / UPS room. **As per requirment all area to be developed based on AERB/RSD guidelines**
c)	**False Ceiling**
i)	Aluminum, acoustical-treated, powder coated tile for ceiling supported on grid or finished seamless with support above ceiling. Ceiling height to suit the equipment mount and clearances.
2	**Electrical work**
i)	The supplier shall be required to specify the total load requirements for the PET CT 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 PET CT Scan area. The distribution panel for UPS, PET CT shall be provided by the vendor. Few lights in each room shall be connected to the UPS to provide emergency lighting.
ii)	The electrical work shall include the following:
a.	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.
b.	Switches light and power points should be of modular type and of standard make as listed below.
c.	General lights –LED light fittings with minimum 500 Lux Illumination
3	**AIR CONDITIONING:**
a)	HVAC work by cyclotron vendor
c)	**Environment specifications:**
i)	Relative Humidity range: To be maintained between 60% and 80% in all areas except equipment room, which shall be as per requirement of the equipment?
4	**Fire detection system –** shall comprise of fire panel, smoke / heat detectors**.**
5	**Miscellaneous:**
a)	Fire extinguisher ABC type- 5kg - 3 no.s
	LIST OF ITEMS AND SUGGESTED MANUFACTURERS.
SL NO	**ITEMS** **PREFERRED MAKES**
A	**FLOORING VITRIFIED TILES** -Somany, Kajaria , H&R Johnson, RAK india

B	**PAINT**	- Dulux, Asian Paints , Nerolac
C	**PLUMBING**	- Kohler, Jaguar , Grohe , Roca
E	**ELECTRICAL**	
1	**CABLES**	- Finolex, Havells ,V-Guard
2	**SWITCHES**	- Legrand, L&T, Crabtree , Roma
3	**DISTRIBUTION BOX , MCB**	- Legrand, L&T, Siemens, Havels
4	**LIGHT FITTINGS**	- Philips / Crompton / Wipro/Syska
F	**AIR CONDINTIONING**	- Daikin, Hitachi, Blue Star, Voltas,
G	**FURNITURE**	- Hermen Miller , Godrej , Featherlite,Geeken.

Item sl. no. 02;

Medical Cyclotron

The technical specification is revised as below:

Sl. No	Technical Specification
	Technical Specifications for Medical Cyclotron
	Plan, Design, Supply, Installation, Testing, Commissioning and Maintenance of a Medium Energy Medical Cyclotron, PET-Radiochemistry and QC system for producing PET-Radiopharmaceuticals including Support and Expertise on the Building Design and Laboratory Layout According to GMP Guidelines.
1	**General**
i	Competitive bids (Technical and Price separately) are invited for installation of a Medical Cyclotron, PET-Radiochemistry and Radiopharmaceuticals QC laboratory at AIIMS Bhubaneswar.
ii	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.
iii	The quotations may be submitted for the latest technology available at the time of quotation. Any item not covered under standard set should be quoted separately.
iv	All the specifications quoted should be supported by the authentic data sheet. When the standard vendor data sheet disagrees with the bid response, clarification should accompany in the form of letter/certificate from appropriate authority in the absence of which data sheet will prevail for the purpose of evaluation and decision of the technical evaluation committee shall be final and binding on the supplier.
v	Manufacturer must have a demonstrated history of manufacturing cyclotron systems of similar size and scope.
vi	Vendor shall provide Certification from AERB for the type approval of the quoted Cyclotron.
vii	Equipment materials, devices and components shall be those that are routinely manufactured, produced and delivered. Devices equipment or component for which only a design or concept is available, will not be acceptable.
viii	All commercially available software for clinical use, and also research protocols should be supplied with the equipment at the time of installation. In addition, all future, free comprehensive software upgrade guarantee must be provided.

ix	Offer should comprise delivery, installation, official release and safety acceptance until handing over the system including the accessories necessary for operation.
x	Pre- requirements for safe and fast installation and commissioning of the Cyclotron and the PET-Radiochemistry and QC system should be explicitly mentioned.
xi	The vendoe must facilitate the department for all the radiation safety clearances, type approval from AERB/NOC for all equipment from AERB
xii	Together with the supply of the equipment, the proposal shall include support on GMP layout proposal, GMP rules application (training and consultancy)
xiii	The tenderers will give support to build the files for FDG Marketing Authorization submission to local authorities
2	**Scope of Work**
	Supply, installation and commissioning of the equipment on turn-key basis including site designing, planning and mandatory AERB approvals etc.
	Equipment to be provided and installed should consist of the following:
i	Self Shielded Medical Cyclotron
ii	Cyclotron control workstation
iii	System interlocks with relevant (radiation, vacuum, temperature, humidity etc.) monitors
iv	Power supplies
v	Target systems
vi	Vacuum system
vii	Automated chemistry (synthesis) modules
viii	Precursor chemistry equipment including dispensing / delivery system
ix	Hot chemistry lab (including all accessories for the production & QC of desired radionuclides and synthesis of final products)
x	Waste gas management
xi	Shielded delivery systems
xii	Gases manifold: All target gases for cyclotron operation (including H2 and D2 for ion sources, For C11, N13, F18 production production), PET-radiochemistry and QC system etc.
xiii	All systems shall be operable with a transparent status without requiring an entry into the vault for any task such as manual operation of valves, tilting traps, targets purging equipment, priming system, changing or cleaning columns and associated equipment. Systems that require manual intervention shall be located outside the vault.
3	**Cyclotron Parameters**
i	A negative ion Cyclotron with at least 18 MeV energy in order to allow production of conventional (F18, 11C, 13N) and non-conventional radioisotopes (I-124, I-123, 64Cu, 89Zr, 86Y) with liquid, gas and solid targets
ii	The cyclotron should be SELF SHIELDED and housed in a separate room. Operator should also be able to operate all equipment in manual mode for diagnostic and maintenance purpose
iii	The cyclotron shall be capable of accelerating protons to an energy ≥ 18 MeV under completely automated mode with options for semi-automated or manual mode in an appropriate sequence so that the specified quantities of radionuclides in the specified chemical form can be synthesized using suitable radioactive synthesis equipment and precursor materials.
iv	The System should operate on 440V (+/-20) A/C (3phase) 50 HZ.
v	Cyclotron should be capable of delivering a beam of 150 μA per port. Beam current to be adjustable

	from 1 μA - 150 μA and stable at any current settings.
vi	At the end of irradiation for two hours, the 18F produced from ~95% enriched [O-18] water shall be at least 8 Curie.
vii	It should be possible to automatically optimize and tune the operational parameters for the highest beam output while minimizing the power requirement, neutron activation and stray beam within cyclotron. Manual interaction on the initial start-up of the machine, after installation, for extensive maintenance will be allowed. However, manual interaction for a routine start-up of the cyclotron would not be desirable.
viii	Magnetic field from the cyclotron shall be within the safety limits at the interior surface of all adjacent walls in room adjoining the vault when the cyclotron is operated at maximum magnet current.
ix	All the safety interlocks should be identified and monitored separately.
x	The RF power supply should not have any stray RF radiation detectable outside the RF power cabinet and the RF cable.
xi	The control operations shall include one **server based computer workstation and a backup workstation with online printer**. It shall not require any other individual workstation to run each of the major systems or subsystems.The workstation environment shall provide a simple and automated scheme to record, recall and display & graph parameter information. It should be possible to fully control the cyclotron operation from external computer workstation
xii	Routine operation of the cyclotron shall not require the operator to enter the cyclotron room to manually operate valves, fill traps and targets, purge or prime systems, view system operation status etc
xiii	The cyclotron control computer shall allow fully automated operation of the cyclotron, including but not limited to, a) Loading of target with target material, b) Selection of target to be irradiated, c) Selection of particle type and beam current, d) Irradiation of target, e) Transfer of radioisotope to the selected delivery point, f) Automatically optimize and tune cyclotron operational parameters, g) Monitor, display and record cyclotron operational parameters and provide alerts when abnormal conditions are detected.
xiv	Full cyclotron operational information should be displayable on any of the workstations, including those not controlling the cyclotron at the time. The computer work stations should provide a simple and automated scheme to display, record, archive, recall and graph cyclotron operational parameters
xv	The design of the cyclotron should allow diagnosing and servicing its necessary components in a quick and user-friendly manner, so that the radiation dose received by the service personnel is as per ALARA principle.
4	**Target Systems**
i	The cyclotron should have should have minimum four target ports. Dual beam (bombarding two targets simultaneously) should be possible for production of [^{18}F] (for making [F-18] FDG and other PET tracers like FLT, FMISO, FDOPA etc.
ii	Each target must be fixed at best position. There must be one beam exit port per target, Minimum Two number of exits ports required. All beam exit ports must be equipped with extraction systems.
iii	It must have multiple number of extraction foils to reduce maintenance time and personal dose absorption.
iv	Two **^{18}F** targets (high yield Niobium targets) for production of **^{18}F** as the chemical form of the radioisotope based on use of the **^{18}O** (p, n) **^{18}F r**eaction, suitable for making [F-18] FDG and other

	PET tracers like ^{18}FLT, FMISO, FDOPA etc.
v	One target each (latest approved material for higher yield) for production of **^{11}C and ^{13}N (directly as ammonia**) for production of 11C-Methionine, ^{11}C-Choline, ^{13}N-Ammonia, etc.
vi	Target body material and entrance window material, Target volume and normal operating pressure must be mentioned.
vii	**Solid Targetary**: The cyclotron shall be capable of irradiating a solid target for production of I-124,I-123, 64Cu, 89Zr, 86Y etc. Thus, an external beam port allowing the uncomplicated attachment of a solid target assembly shall be offered. Any restrictions on the provision of an external beam port suitable for attaching a solid target assembly and thus irradiating a solid target shall be specifically stated. The solid target station should be equipped with high current.
viii	Automated extraction of radionuclide should be in built. All the equipment necessary for Iodine-124 and other radionuclides production must be detailed
ix	The tenderer shall specifically cite examples of active R&D programs using solid targetry that utilise the type of cyclotron the tenderer is advocating in their response to this tender.
x	Partnership / Network: The tenderer shall demonstrate his involvement in new PET compounds development and how he could be a partner to the Buyer by giving access to a network and/or to proprietary molecules
5	**Target Mounting Systems**
i	The target handling system shall have the capability to change, from using anyone of the mounted targets to any other target without manual intervention inside the bunker
ii	Switching between targets shall require only selection of a new target on the control workstation with automatic setting of parameters, and not require manual tuning or change to any systems.
iii	Vendor shall furnish and install shielding of sufficient thickness and in appropriate locations such that the radiation fields on the outside wall of the cyclotron room is as per AERB requirement.
iv	Targets mounting should be such that they can be removed and installed easily without any service engineer intervention.
6	**Vacuum System**
i	The vacuum system should be adequate and with built in extra capacity to maintain the required vacuum in the various systems.
ii	An automated pumping system that can reduce the pressure in the cyclotron vacuum system from 1 Bar to the normal required operating pressure in < 1 hour
iii	Suitable indicators to display the vacuum in unit of Torr, with minimum of 1 x 10^{-7} to10^{-8} Torr. An additional ability to display the status of the vacuum system on the computer/ workstation is desirable.
iv	A vacuum gauge (ion gauge) fitted into the cyclotron to read the cyclotron tank pressure at required locations
v	The vacuum system must be highly reliable and simple to maintain. All O-ring seals should be accessible and easy to change with minimal radiation dose to the technologist.
7	**Shielding and Safety Systems**
i	For Safety, vendor shall design, furnish and install an interlock system for the following purposes:
ii	**Protection of the equipment from damage** - **Internal interlock system:** The internal interlock system shall monitor necessary inputs required for the equipment operations building services such as electrical power, operation of the computer control workstation, chilled water flow, and chilled water temperature. A fault in any of these systems shall prevent the cyclotron from being started or will immediately shut the cyclotron down. A key switch (with the key removable only when in the

	"off" position) shall ensure that the cyclotron cannot be turned on while the key is in the "off" position and / or removed.
iii	**Preventing the exposure of the personal to hazardous conditions - External interlock system**: The external interlock system should be provided to protect workers from exposure to hazardous situation. The interlock system should prevent operation of the cyclotron in the event that a potential hazardous condition, such as the presence of unshielded RF fields and gamma and neutron radiation in an unsecured area.
iv	Interlocking between cyclotron control computers should be provided to ensure that only one of the control computers has control of cyclotron operation at any given time. Once one of the control computers has taken control of the cyclotron operation, other control computers should be locked out from controlling any of the cyclotron's operation until control is relinquished by the controlling computer.
iv	Equipment design concept shall be such that radiation exposures to operating personnel from leakage or from induced radioactivity (if any) in system components and accessories are minimised and under no circumstances exceed the relevant dose equivalent limits outlined by the Basic Safety Standards IAEA and AERB.
v	Interlocks / Provisions for **Last Man Out**
vi	To facilitate use of the system a display shall be furnished to show the status of all interlocks. There should be a provision to keep a continuous log of all interlocks for at least one month.
vii	Sufficient radiation shielding shall be incorporated in the vault design to ensure that the integrated equivalent dose (total gamma and neutron dose) limits in areas adjacent to the Cyclotron room shall be met (dose constraints shall be met at ≤ 1 m from the walls and above floor level in the indicated areas. Integrated equivalent dose during cyclotron operation for one hour at maximum sustainable beam current for dual F18- target proton irradiation (or dual F18- target irradiation at 2 * 75μA) shall be: ≤ 0.5 μSv in any of the rooms above the cyclotron, adjacent to the cyclotron, outside the cyclotron vault door entrance
8	**Radiochemistry Synthesis Modules with Suitably Shielded Hot Cells**
	System for automatic transfer of product from target to chemistry system. Automated radiochemistry modules for synthesis of various PET radiopharmaceuticals i.e. for 18F, 11C, 13N. The method of production of radiopharmaceutical should have appropriate regulatory approval.
i	**Nucleophilic Synthesis Module for [F-18] based PET tracers: 02 Nos**.:
a	One Synthesis module dedicated to synthesize [18F] FDG. The FDG synthesis must be an automated cassette based system installed in one hot cell with capability of consecutive FDG synthesis without the need to open the hotcell door. The quality control equipment should be selected according to latest version of European Pharmacopoeia. It should be current cGMP compliant
b	Second module should be general purpose nucleophilic synthesis module installed in another hot cell, for all other [F-18] radiopharmaceuticals like FLT, FET, FMISO, FAZA, FES, FDOPA etc. produced by nucleophilic substitutions. The module should integrate all necessary steps of production of [18F] based tracers, viz., Trapping of 18F-, nucleophilic substitution, semi prep HPLC hydrolysis, purification and formulation and all production steps should be fully automated. It should be current cGMP compliant.
ii	One suitably shielded **synthesis module for making C-11 radiopharmaceuticals** using the methylation using methyl iodide (CH3I) route. The module should be compatible with either [11C]-CO2 or [11C]-Methane from the cyclotron target. The production of methyl iodide (CH3I) should be through iodine vapour route.

iii	One suitably housed **synthesis module for 13NH3** with adequate shielding for producing ammonia through reduction & direct route and collection of ammonia so that it can be quickly delivered to PET scanner room.
iv	Two class 100 dual vertical hot cells having ≥ 75 mm lead thickness and 8" lead window, to suitably house FDG, FLT / FET and other modules. The inside of the hot-cell should be totally made of high quality fine brushed smooth stainless steel that can be sterilized with 70% ethanol. It should have requisite inlets for gases, air, vacuum, water and provision for ultraviolet light. The hot cell should be current cGMP compliant. These should be preferably of Comecer / Tema Synergie / Vohn Galen / Nuclear Interface / Synthra etc.
v	One suitably shielded fully automated Dispenser for sterile dispensing in a Class A area of individual patient's doses of PET tracers, in vials and syringes. It should be current cGMP compliant. One GMP compliant hot cell made of 75mm lead shielding (stainless steel finishing) with Laminar Flow Class A for placing the dispenser should also be supplied.
vi	Sequences for synthesis of all F-18, C-11, N-13 based radiopharmaceuticals should be provided, loaded and demonstrated. Sequences for solid targetary, if any, should also be provided, loaded and demonstarted.
vii	Sufficient consumables shall be provided with each synthesis unit to allow at least 10 batches to be produced for testing purposes.
9	**Cyclotron and Hot Lab Accessories (with details of Make and Model):**
i	All gases required for operation of the cyclotron (Helium, Argon, Hydrogen, Nitrogen, Neon etc. with suitable purity levels). All types of required regulators, cylinders and gas pipes should be provided. The gas cylinder supplied should have approval of Indian Commissioner of Explosives.
ii	Two air Compressors of appropriate capacity and pressure to continuously supply purified dry air on both sides in the chemistry synthesis as well as to the cyclotron.
iii	Two high energy type Dose Calibrators for PET isotopes
iv	One digital radio TLC analyzer
v	One radio-HPLC of minimum 2 columns for 18C with UV & radioactive detector
vi	Sterile HPLC grade water purification system with pre water purifier system
vii	Quality Control equipment for Endotoxin Tests and Sterility Tests on site shall be offered including the respective enclosures.
viii	Gamma ray spectrometer coupled with multi channel analyzer
ix	Two 500 L capacity side by side Refrigerators having 4 deg C and 8-19 deg C compartments.
x	Laminar airflow hood (24" depth x 40" width x 30" Height),
xi	One shielded laminar flow for placing the Ge68-Ga68 generator
xii	Fire proof chemical storage Cabinet - One
xiii	Analytical weighing balance - One
xiv	Electronic micro pH meter, Magnetic Stirrer, Cyclo-mixer – One each
xv	High temp autoclave 134*degree C - One
xvi	Incubator - One
xvii	Lab Oven - One
xviii	Ultrasonic Cleaners for glass and targets separately - Two
xix	Cappers, De-cappers – Two each.
xxi	L-Shield (high energy type with lead glass) with dispensing station.

xxii	Shielded Containers for cyclotron generated and PET (511 KeV) radioactive waste
xxiii	FIVE 511 KeV Tungsten containers for product vials (30 ml)
xxiv	Two sets of Type A liquid radioisotope transport containers (external polyethylene case and CF 18 Tungsten shielded container) by Comecer
xxv	Any other essential lab items appropriate for a PET-radiochemistry lab.
10	**Radiation and Other Safety Equipment**
i	PC based central monitoring with area gamma monitors, audio-visual alarm & logging system for radiation measurements in various locations in the cyclotron and radiochemistry area & in other areas including one for stack.
ii	Suitable temperature and humidity monitoring devices for cyclotron bunker & control room.
iii	Digital Neutron Monitors -1
iv	Digital Contamination Monitor -2 Nos.
v	Portable Radiation survey meter (micro Sievert per hour to milli Sievert per hour) – Two
vi	Digital Portable Personal Radiation Monitors -10 nos.
vii	Teletetector - One
viii	Microchip based waste gas control system for storage / release of waste gases.
ix	Air sampler for monitoring air contamination from stack
x	All details (make, model, specification) of the items should be mentioned.
11	**Others**
i	**Chiller:** Primary and Secondary water cooling system needed for Cyclotron should be included.
ii	**UPS**: An appropriate capacity 3 phase input / output UPS with maintenance free Batteries of reputed make.
iii	**Drawings**: Drawings showing complete layout and dimensions for fabrication, erection, elevations and all required utility connections with specific identification of each unit corresponding to sequence of installation and erection procedures. The drawing should show location and details of anchorage devices to be embedded in or fastened to other construction. Drawing shall include major cable interconnections. Additional drawing shall provide complete details of all electrical connections and signals. The drawing should reflect accurately the "as built" configuration. Contractor should furnish templates, if required, for accurate placement. Chart showing radiation levels at various locations in the facility should also be annexed.
iv	**Manuals**: One full set of documentation “User Guide & Maintenance Guide” in English and with metric units of measure relating to the supplies will be supplied. The manuals should also be explicitly related to preventive maintenance procedures, potentials problems and repair of systems. At least one of those manual sets to be provided in Computer readable format, preferably as Word for Windows format document.
v	**Certification:** The supply should meet all statutory requirements of AERB. Type Approval Certificate from AERB should be annexed.
vi	**Scheduling:** A tentative Schedule is established. Nonetheless it is absolutely required that the cyclotron complete with targetry, be delivered, installed and commissioned within 12 months from the date of getting the building lay out plan clearance from AERB, Govt. of India, Mumbai and establishment of L/C, whichever is later.
vii	**Warranty:** A Written un-conditional comprehensive warranty for **FIVE years** for complete unit should cover the complete system with its sub-systems, components, associated accessories and peripherals supplied by the vendor of its own. Warranty shall be signed by the manufacturer and

	must provide the guarantee that failures in materials and workmanship that occur within the warranty period will be corrected. Such failures will include those attributable to abnormal aging. The Warranty period shall commence upon the acceptance by the purchaser of all systems defined above. The maintenance and service of the third party items will also be the sole responsibility of the primary vendor. All software updates should be provided free of cost during Warrantyand CMC period.
viii	**Maintenance Contract:** Comprehensive maintenance contract (CMC) with all spare and labor should be quoted for a period of **Five Years** after the expiry of warranty period. The uptime during warrantee and CMC should be more than 98 %. Trained service engineer should be stationed at Bhubaneswar on 24 hrs x 7 days basis. As part of the contract, a remote support of 24 hrs x 7 days must be offered. This 24 hrs x7 days support must give direct access to cyclotron engineer-specialist.
ix	**Consumables:** Vendor shall provide all the all target materials/ gases/ consumables needed for FDG synthesis / consumables needed for doing QC/ lab-ware including glass ware, chemicals, tool kits, chilling material for chiller etc. **for TWO Years.** For this purpose, it is assumed that for FDG synthesis at least 250 runs of cyclotron will be done per year to yield adequate quantity of F-18. 100 runs of cyclotron **for 13NH3,** and 50 runs for C-11 radiopharmaceuticals in one year should be considered. All formalities regarding custom clearance of consumables will be the responsibility of the vendor.
x	**Operation of Cyclotron:** During the warranty period, the vendor will make provisions to operate the cyclotron, synthesis of isotopes, to do quality assurance & all necessary maintenance so as to produce necessary isotopes for the PET scanner. For this purpose, he will provide ONE Nuclear Medicine Physicist and One Radiochemist.
xi	**Training:** Onsite Training & certification for all the End-User assigned staff for FOUR weeks by qualified and experienced physicists and radio-chemist, so as to familiarize them with the working procedures and maintenance of the Supplies. The training shall be given in English.
	Decommissioning: The Tenderer must detail how its cyclotron design will reduce the neutron activation of the vault and what are its recommendations for the vault design.
xii	**Global Support:** Tendered is requested to provide information on User's meetings that have been previously organized by the company. It must describe the content and give the participants feed-back.
xiii	**Acceptance Testing**: Purchaser may engage independent testing consultants to conduct tests & perform other services required for quality assurance. Contractor shall provide reasonable access to installation site & to the materials for testing and must cooperate with testing personnel. The test specified in the following paragraph shall be performed.
a	Determination of Cyclotron output magnitude and stability and verification that these are in conformance with specifications in bid including any new specifications that the vendor may develop or may be necessary as per regulations from time to time.
b	Determination that the general operation of the Cyclotron is correct
c	Determination that the user interface for controlling the Cyclotron is complete, correct, and properly documented
d	Determination of integrity of radiation shields.
e	Determination of safety interlocks for equipment and personal safety
f	Determination of function and performance of targets and related system.
g	Determination of performance of automated radiochemistry and synthesis system.

h	Determination of integrated computer operation of Cyclotron target automated chemistry, safety system.
i	Any other test which is required and deemed to be necessary by the expert / consultant.
xiv	**FDG Marketing Authorization Support**
i	The tenderer will provide the deliverables to support the preparation of the final submittal file to local authorities for obtaining the Market Authorization for FDG manufacture.
ii	All deliverables will be in English language and in accordance with European Good Manufacturing practice.
12	**TURNKEY**
	Building Engineering File Specifications
i	The GMP layout proposal will be prepared in consultation with the end-user after contract signature.
ii	Once agreed upon, the successful Tenderer shall work, in full consultation with the AIIMS, Bhubaneswar, in preparing detailed site plan for the installation of the cyclotron and associated equipment and PET-CT.
iii	The site plan shall include all requirements for the operation of the cyclotron and associated equipment in accordance with the Specifications.
	The proposal of tenderers must include the price of building engineering files as described here below:
A	**Architectural Design**
a	Overall layout
b	Highlights of building specific aspects such as (but not limited to):
	- Cyclotron connections
	- transfer line trenches
	- clean room & lab finishing aspects
c	1/100 scaled plans and sections of the concerned part of the building
d	Architectural Basic Design shall be offered and scope of supplies will include above files
B	**Structural design**
a	Load capacity for supplied heavy equipment on architectural drawings.
b	Structural Design information shall be given
C	**HVAC Design**
a	Air conditioning, heating and cooling system – aeraulic and hydraulic diagrams
b	Cooling system including chilled water for technical equipment cyclotron cooling
c	Definition and dimensioning of ventilation equipment
d	Unifilar drawings of ducts, piping and ventilation grids
e	HVAC Design shall be offered and scope of supplies will include above files
f	Temperature ranges: 22± 2° C in all areas except equipment room which shall be as per requirement of the equipment (PET-CT included)
D	**Sanitary & Fluids**
a	Description and unifilar drawings for sanitary, cold water, hot water, waste water,compressed air and gas systems
b	Specification book
c	Sanitary & Fluids files shall be offered and scope of supplies will include above documents
E	**Electrical design**

a	Electricity design works concern the power distribution LV: main and divisional switchboards, all lighting installation and electrical installation for small appliances.
b	Principal unifilar electrical layout
c	Implementation of all lighting points, power plugs, all related boards and various other equipment
d	Dimensioning and electrical equipment selection leading to complete unifilar drawings with schematic tables
e	Specification book
f	Electrical Design shall be offered and scope of supplies will include above documents
F	**GMP Turnkey references list**
	Expertise in building GMP compliant PET laboratories must be given by providing a references list.
	References list of successful project realization including building engineering and GMP support will be supplied.
	Scope of Turnkey
	Conditions for PET Centre Building including medical cyclotron housing:
i	The cyclotron bidders have to quote for the turnkey work of the entire building as a green field project. The bidder must visit the site before the submitting the tender and must certify the suitability of site for cyclotron and PET facility.
ii	The cyclotron bidders are required to **quote separately** for the equipment and Turnkey Work as per Price Schedule. The Turnkey Work costs may be quoted in Indian Rupee and the same will be added for Ranking Purpose. The vendor should provide detailed construction drawing
iii	The Turnkey Work should completely comply with AERB requirement. The entire construction of cyclotron bunker, PET-CT area and radionuclide therapy isolation ward should be in conformity with AERB norms only.
iv	The vendor should consult the department of Nuclear Medicine, AIIMS, Bhubaneswar and cyclotron supplier while preparing the layout. All the construction work to be done as per the final plan approved by AERB in consultation with Dept of Nuclear Medicine, AIIMS, Bhubaneswar.
v	Total area to be constructed for entire building (Cyclotron bunker, radiopharmacy lab, PET-CT and isolation ward) is 13500 square feet (ground floor 8000 and first floor 5500 sqft). **Note: Total 13500 square feet will be closed area**
vi	The actual area of turnkey works done will be considered for payment, based on the site measurements.
vii	The drawings pertaining to structural and architectural features of the building are to be prepared by the vendor from reputed firm and the same is to be approved by the user department as well as AERB before execution.
viii	The internal arrangements of the rooms for all the floors are to be consulted with the nuclear medicine department, AIIMS, Bhubaneswar.
ix	All the necessary documentation such as SBC of that particular site, rain fall, soil details, seismic zone details to be collected by the vendor for AERB clearance.
x	The cyclotron bidders have to provide a detailed plan for construction of building for housing cyclotron, laboratory for radio pharmaceutical production and quality control and commissioning of PET-CT. This plan should incorporate the following features.
a	The **Foundation** of the building should be constructed such that it could go upto ground floor + 5 floor in future.
b	Currently two floors (ground floor and + 1) need to be constructed.
c	The cyclotron room outer walls should be of RCC. The cyclotron should be housed in a bunker in the

	ground floor of the building as per AERB norms.
d	Radiopharmacy laboratory adjoining the cyclotron (Must be GMP Complaint) and PET-CT area should be in the ground floor.
e	PET-CT area should include PET-CT equipment rooms (2 in number, one for future expansion), console room, UPS room, Patient preparation area, Nursing area with Nurses changing room, dose admin room, post admin waiting area (4 separations), radioactive store, general store, medical record room, office, reception, radioactive waste store, recovery room, active toilets, staff toilets, pantry, changing room, technician room, consultant room (three in numbers), HOD room (one in number), patient examination rooms (2 in number) and reporting rooms (2 in numbers). Separate toilets for Ladies and Gents should be provided apart from separate public toilet facilities for men & women and store for sanitary items.
f	Cyclotron area should have cyclotron vault room, cyclotron control unit room, hot laboratory for hot cells, QC lab, One Room for Gallium 68 radiopharmaceuticals, General store, RSO room (1), radiochemist room (1), Other staff (1), electrical and UPS room, chiller and gases area (outside), one room for laboratory equipment like refrigerators etc.
g	Six isolation rooms for radionuclide therapy, Nursing station, dose administration area, housekeeping rooms, committee room, seminar room with all other amenities (toilets) etc. on the first floor of building excluding bunker area.
h	Delay tank for 6 bed radionuclide isolation ward as per the AERB standard
i	Necessary lifts should be provided from Ground Floor to 1st Floor as per standard.
j	Separate room for D-G set, electrical panel etc
k	Chimney with stack monitor as per the AERB requirement
xi	**Water and power connnection will be provided close to the proposed site by the Hospital authority**
xii	No escalation charges will be paid for the building and its allied works.
xiii	Timeline to complete construction of building should be maximum 12 months after getting AERB approval. Maximum time of 6 months can be considered for cyclotron installation. However, the entire project (construction and installation) should run in overlapping mode and maximum time for total project after AERB approval of site and layout must be 12 months
xiv	The penalty clause will come into effect if the work is not completed within the stipulated time as mentioned.
xv	Vendor has to provide maintenance of turnkey work for 5 years. Service, repair and maintenance of all third party items will be the sole responsibility of primary vendor.
xvi	**Civil work (scope of work):**
	Leveling and lowering the ground excavation in oil types of soil/rock etc., to facilitate the required foundation for building including back filling, providing and injecting chemical emulsion for free constructional anti-termite treatment under and around the column pits, wall trenches, plinth filling junction of wall floor etc.
	Building should be a framed structure with Burnt Brick masonry walls with plain plastering.
	No occupancy above the cyclotron as per AERB rule. The future expansion floor will be for general room purpose
	Structural glazing and Alcobond glazing elevation should be provided as per architectural drawing.
	Roof height of each floor of the building should be upto 3.60 mtr (cyclotron vendor may suggest different heights if required for cyclotron)
	All internal walls should be provided with color glazed full height wall tiles.

	M20 concrete should be used for Bed concrete as per specification. **(Grade of Concrete will be based on Structure design requirement)**
	M20 concrete is used for window cills lintels and plinth beam etc. **(Grade of Concrete will be based on Structure design requirement)**
	Providing and filling cinder concrete is used for sunken portion of toilet. **(Grade of Concrete will be based on Structure design requirement)**
	M20 ready mix concrete for column footing, columns and bases of columns including cost of centering and shuttering for said work is to be considered with all transportation lead lift etc., to the work spot. **(Grade of Concrete will be based on Structure design requirement)**
	High yield strength De-formed bars or steel bars of grade Fe 415 confirming to IS 1786-1985 are to be used including fabrication of steel. **(Grade of steel is based on structural design)**
	Conference room walls should be provided with acoustic veneer paneling system
	Wooden flush doors with laminate finish to be provided for all door opening except area where lead lined doors are required as per AERB.
	Glazed vitrified (GVT) tiles of marbanate finish of approved quality size 600 x 600mm with 100mm tile skirting should be used for the all areas like patient preparation area, Radiopharmaceutical lab, Quality assurance lab, Control room, Reporting room, Equipment room, Consultant room, Conference room and rest of area not using radioactive material (where vitrified files should not be put as per AERB)
	Ceramic tiles flooring of approved make and shade 300 x 300mm for flooring for all toilet and pantry area.
	Dadooing of glazed tiles of approved make 300 x 600mm is to be used as cladding for toilets.
	Delay tank for 6 bed isolation wards as per AERB regulations
	Aluminium plain/perforated/ mirror finish, acoustical treated, powder coated tile for false ceiling for all the internal rooms should be provided. Ceiling height to suit the equipment mount and clearances.
	Site fabricated with plywood/lamination sheets as per the requirement of the user department.
	Flagging concrete to a width of 1.0 mtr all round the building and designer tiles paving for the remaining set back area at outside the building should be provided.
	Two coats Plastic Emulsion Paint over 2 coats of wall putty including primer in all the internal walls. Apex paint on external surface of the building.
	Platform for unloading and shifting the cyclotron should be provided if necessary.
	Cable tray, trench & channel – necessary trenches, cable tray and channels at required location would be provided.
	Necessary water proofing treatment over the first floor terrace should be made.
	There should be Access control for doors in the cyclotron facility and cyclotron vault
xvii	**Plumbing works**
	All plumbing lines of area sizes of CPVC type with accessories are to be provided inside and outside the building from the main water supply source available in the campus along with 7.5 HP submersible pump with texmo/Atlanta**/Kirlosker/Crompton Greaves** or equivalent make.
	Necessary sanitary fittings and sanitary line should be provided according to the size of the building
	All sanitary **and water supply** lines are to be drawn till the existing drainage point
	Over head tanks of PVC sintex or equivalent make are to be used with a capacity as per the requirement.

xviii	**Structural glazing**: Providing and fixing combination of 3mm thick aluminum composite panels of approved make and quality for the front elevation of the building is to be provided (optional).
xix	**Fire alarm system:**
	Supply, installation and commissioning of Fire Alarm System at each floor with adequate smoke detectors with hooters and MCP & Panels are to be provided.
	Sprinkler type fire fighting systems with MS pipes are to be provided.
	Adequate number of firefighting equipment should be provided.
	The building should comply with fire regulation norms.
	The number of firefighting equipment must be as per the fight-fighting norms. The regulatory approval for fire-fighting will be responsibility of the vendor.
xx	**Electrical work:**
	The total load of electrical power requirement to be calculated by vendor.
	A separate independent transformer of appropriate capacity may be provided for the whole project if needed - quote optinally
	Power supply by the institute will be terminated at close to proposed site
	All electrical provisions including earthing etc. will be vendor's responsibility.
	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
	The light power socket (MK/North Wet or equivalent) to be provided in each room as per scope.
	Switches light and power points should be of modular type and of standard make as listed below.
	LED light fittings with minimum 500 Lux Illumination
	Dimmer controlled incandescent light fixtures are to be provided in the console room – 2 numbers.
	Mains incomer MCCB for entire area under scope with adequate safety measures, volts meter, ammeter, frequency, phase indicator and earth leakage protection
	Two independent earths to be provided for equipment with copper flexible cable up to electrical room with suitable copper earthing bus bar.
	Main LT panel as per design for distributing adequate power supply.
	Distribution boards for lighting and power separately for individual floors as per distribution SLD.
	DATA and telephone cabling for consultant rooms, and PACS room. Telephone cabling for isolation bed rooms and nursing station.
	Piped music system for common areas only.
	CCTV camera 16 Nos with 16 channel DVR system, LCD monitors (5 Nos.) with 1 TB storage space.
	One LED TV in general wairting area and LED TV in each radionuclide therapy ward room alongwith D2H connections
	One water cooler with water filtering unit in the general reception area
	Electrical inspection approved is mandatory for DG set.
	Intercom connectivity in each rooms in entire building.
	The site should be rendered pest/rodent free.
xxi	**Passenger lifts:**
	Providing and installing lift from OTIS or equivalent (machine room less) for 06 passenger (including one patient trolley) with02 stops, automatic center opening door enamel painted, S.S. handrail inside, emergency alarm,facia plate, press and speak intercom, emergency light, PVC flooring inside car, car ceiling/panelswith enamel paint.

	All the regulatory permission to operate the lift will be taken by vendor.
xxii	**Air Conditioning works:**
	The total load of AC should calculate in each area and air conditioners required for each area have to be provided by the vendor. The heat load calculations and maintaining the desired temperature and humidity shall be the responsibility of the bidder.
	Unit rate to be quoted.
	Duct-able package air conditioners and split air conditioners may be used according to room as well as equipment requirement and suitability. Necessary ducting to the standard of AERB is to be done.
	Humidity control should be effective to eliminate moisture condensation on equipment surface.
	The outdoor units of AC should have grill coverings to prevent theft and damage.
	Relative Humidity range: To be maintained between 60% and 80% in all areas except equipment room, which shall be as per requirement of the equipment
	Temperature ranges: 22± 2° C in all areas except equipment room which shall be as per requirement of the equipment.
xxiii	**Furniture works**
	The scope of work includes supplying and fixing of necessary furniture for the entire area as per requirements with approved quality and shade.
	All the rooms should be furnished with hard wood materials as per the user department requirement
	All furniture items should be of standard make as mentioned in the table below
	Office table, Chair, 2 waiting chairs in all offices
	Table for workstations – 5 numbers
	Revolving chairs height adjustable, medium-back with hand-rest – 8 numbers
	Patient waiting chairs - 10 sets of three chairs each
	Cupboard with laminate door shutters for storage of spare parts and accessories and records as per requirement. – 5 number
	Name boards for all rooms
	Provisions should be made for placing the various accessories in console room, work-station and printer locations
	Any other furniture to make department functional
xxiv	**LIST OF ITEMS AND SUGGESTED MANUFACTURERS**
	ITEMS PREFERRED MAKES
	FLOORING VITRIFIED TILES - Somany/Kajaria/ H&R/ Johnson/RAK india
	PAINT - Asian/Berger/Nerolac brands
	PLUMBING - Kohler/ Jaguar/ Grohe/Roca / equivalent
	ELECTRICAL
	CABLES - Finolex/Havells /V-Guard
	SWITCHES - Legrand, L&T/ Crabtree/ Roma
	DISTRIBUTION BOX , MCB - Legrand/ L&T/ Siemens/Havels
	LIGHT FITTINGS Philips / Crompton/ Schneider/Wipro make.
	AIR CONDINTIONING - Daikin/Hitachi/Blue Star/Voltas/Carrier
	FURNITURE - HermenMiller / Godrej /Featherlite/Geeken

7) For:-

B. GENERAL POINTS (Pg. 81,82 of TED):

B. GENERAL POINTS	**Existing**	**Amended As**
1) Warranty Clause 1c) Page No-81	During the Warranty period, desired Uptime of 95% of 365/366 (Leap Year) days (24hrs), if downtime more than 5%, the warranty period/CAMC period will be extended by double the downtime period. In addition a penalty equal to amount of 0.25 % of the total cost of equipment per day will be liveable for the excess downtime period. Complaints should be attended properly, maximum within 8 hrs.	**• During warranty , the uptime of the system shall be at least 95% calculated at all business hours of the institution. If downtime exceed 5% there shall be a penalty of Rs. 50000 per day .Necessary logbooks shall be provided by the supplier. Penalty will be calculated 8 hours after telephonic/ SMS/ Email information to the vendor.**
4. Comprehensive Annual Maintenance Contract (CAMC) of subject equipment: Clause 4e) Page No-82	During the CAMC period, desired Uptime of 95% of 365/366 (Leap Year) days (24 hrs),if downtime more than 5%, the warranty period/CAMC period will be extended by double the downtime period. In addition a penalty equal to amount of 0.25% of the total cost of equipment per day will be liveable for the excess downtime period. Complaints should be attended properly maximum within 8 hrs.	**During the CAMC period, e uptime of the system shall be at least 95% calculated at all business hours of the institution. If downtime exceed 5% there shall be a penalty of Rs. 50000 per day .Necessary logbooks shall be provided by the supplier. Penalty will be calculated 8 hours after telephonic/ SMS/ Email information to the vendor.**
5. Uptime & Downtime Penalty Clause: Clause 5b) Page No-82	During the Warranty period and CAMC period, desired Uptime of 95% of 365/366(Leap Year) days (24 hrs), if downtime more than 5%, the warranty period/CAMC period will be extended by double the downtime period. In addition, a penalty equal to amount of 0.25% of the total cost of equipment per day will be imposed for the excess downtime period. Complaints should be attended properly, maximum within 8 hrs.	**During the Warranty period and CAMC period, desired Uptime of 95% calculated at all business hours of the institution. If downtime exceed 5% there shall be a penalty of Rs. 50000 per day .Necessary logbooks shall be provided by the supplier. Penalty will be calculated 8 hours after telephonic/ SMS/ Email information to the vendor.**

Section IX
Qualification Criteria

Present Tender Specification	**Proposed**
1. The tenderer must be a manufacturer. In case the manufacturer does not quote directly, they may authorize an agent as per proforma of Manufacturer authorization form as given in the tender enquiry document to quote and enter into a contractual obligation.	1. The tenderer must be a manufacturer. In case the manufacturer does not quote directly, they may authorize an agent as per proforma of Manufacturer authorization form as given in the tender enquiry document to quote and enter into a contractual obligation.
2(a) The Manufacturer should have supplied and installed in last **Five** years from the date of Tender Opening, at least 25% of the quoted quantity (rounded off to next whole	2(a) The Manufacturer should have supplied and installed in last **Five** years from the date of Tender Opening, at least 25% of the quoted quantity (rounded off to next whole number) of the

Present Tender Specification	**Proposed**
number) of the similar equipment meeting major parameters of technical specification which is functioning satisfactorily. 2(b) The Tenderers quoting as authorized representative of the manufacturer meeting the above criteria should have executed at least one contract in the last five years from the date of tender opening of medical equipment anywhere in India of the same manufacturer. 3. The bidders/ firms identifying as MSME and or start-up firms are exempted from fulfilling criteria at S. No. 2 (a) and 2(b) stated above. However, this does not exempt any bidder/ firm/ manufacturer from fulfilling the quality requirements. *Note: "If the bidder is a MSME, it shall declare in the bid document the Udyog Aadhar Memorandum Number issued to it under the MSMED Act, 2006. If a MSME bidder do not furnish the UAM Number along with bid documents, such MSME unit will not be eligible for the benefits available under Public Procurement Policy for MSEs Order 2012."*	similar equipment meeting major parameters of technical specification which is functioning satisfactorily. 2(b) The Tenderers quoting as authorized representative of the manufacturer meeting the above criteria should have executed at least one contract in the last five years from the date of tender opening of medical equipment ~~anywhere in India~~ of the same manufacturer. 3. The bidders/ firms identifying as MSME and or start-up firms are exempted from fulfilling criteria at S. No. 2 (a) and 2(b) stated above. However, this does not exempt any bidder/ firm/ manufacturer from fulfilling the quality requirements. *Note: "If the bidder is a MSME, it shall declare in the bid document the Udyog Aadhar Memorandum Number issued to it under the MSMED Act, 2006. If a MSME bidder do not furnish the UAM Number along with bid documents, such MSME unit will not be eligible for the benefits available under Public Procurement Policy for MSEs Order 2012."*

All other terms and conditions of the tender enquiry remain unaltered