

Amendment No. 10**Date: 08.09.2023****Sub: Amendment No.10 to the Tender Enquiry Document****Ref: (i) HITES/PCD/AIIMS/CYCLOTRON/08/23-24 Dated: 16.05.2023****Section I**
Notice Inviting Tenders (NIT)

For:-

Sl No	Tender ID	Equipment	Quantity	Tender Processing Fee (INR)*	EMD (INR)
1	2023_HLL_154323_1	Medical Cyclotron (AIIMS Bhubaneswar)	1	8850	100,00,000
2	2023_HLL_154323_2	Medical Cyclotron (AIIMS Jodhpur)	1	8850	100,00,000

Read As:-

Sl No	Tender ID	Equipment	Quantity	Tender Processing Fee (INR)*	EMD (INR)
1	2023_HLL_154323_1	Medical Cyclotron (AIIMS Bhubaneswar)	1	8850	100,00,000
2	2023_HLL_154323_3	Medical Cyclotron (AIIMS Jodhpur)	1	8850	100,00,000

SECTION - VI**LIST OF REQUIREMENTS****Existing****Part I**

Sl No	Tender ID	Equipment	Quantity	Warranty	CMC
1	2023_HLL_154323_1	Medical Cyclotron (AIIMS Bhubaneswar)	1	5 years	15 years
2	2023_HLL_154323_2	Medical Cyclotron (AIIMS Jodhpur)	1	5 years	15 years

Read As**Part I**

Sl No	Tender ID	Equipment	Quantity	Warranty	CMC
1	2023_HLL_154323_1	Medical Cyclotron (AIIMS Bhubaneswar)	1	5 years	15 years
2	2023_HLL_154323_3	Medical Cyclotron (AIIMS Jodhpur)	1	5 years	15 years

Section – VII
Technical Specifications
Medical Cyclotron

Tender ID-2023_HLL_154323_1 the technical specification of Medical Cyclotron for AIIMS Bhubaneswar may be read as:-

Revised Technical Specification For Medical Cyclotron Tender ID-2023_HLL_154323_1 (AIIMS Bhubaneswar)

PART A -TECHNICAL SPECIFICATION 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 should 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 update 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 vendor must facilitate the department for all the radiation safety clearances, type approval from AERB for all equipment from AERB
	XII. Together with the supply of the equipment, layout proposed by the vendor should be GMP compliant.
	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 facilitation for mandatory AERB approvals etc.
	Equipment to be provided and installed should consist of the following:
	I. Shielded Medical Cyclotron (Self shielded or Shielded with Bunker) to be installed in a separate room, as per AERB regulations
	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 for ion sources, For C11, N13, F18 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 Parameter
	I. A negative ion Cyclotron with 15 MeV or more energy in order to allow production of conventional (F18, 13N) and non-conventional radioisotopes (I- 124, 64Cu, 89Zr, 86Y) with liquid, gas and solid targets. (Note: There must be provision for production of I-124, 64Cu, 89Zr and 86Y in future and all required space for the same must be constructed now. The equipment should have provision for software and hardware upgradation for solid target in future)
	II. The cyclotron should be self SHIELDED or shielded with a bunker as per AERB guidelines. 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 with 15 MeV or more under completely automated mode with options for semi-automated or manual mode intervention for an appropriate sequence so as to produce specified quantities of radionuclides
	IV. The System should operate on 3-phase Indian electrical supply standards.
	V. Cyclotron should be capable of delivering a beam of 130 μ A or more. Added Para : There should be possibility to upgrade to higher beam current for the production of I-124, 64Cu, 89Zr, 86Y etc.
	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. It should be possible to fully control the cyclotron operation from computer work station.
	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

	<p>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.</p>
	<p>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</p>
	<p>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.</p>
4	Target Systems
	<p>I. The cyclotron should have minimum two target ports. Dual beam (bombarding two targets simultaneously) should be possible for production of [18F] (for making [F-18] FDG and other PET tracers like FLT, FMISO, FDOPA etc.</p>
	<p>II. All beam exit ports must be equipped with extraction systems.</p>
	<p>III. It must have multiple number of extraction foils to reduce maintenance time and personal dose absorption.</p>
	<p>IV. Two 18F targets (high yield Niobium targets) for production of 18F as the chemical form of the radioisotope based on use of the 18O (p, n) 18F reaction, suitable for making [F-18] FDG and other PET tracers like 18FLT, FMISO, FDOPA etc.</p>
	<p>V. One target each (latest approved material for higher yield) for production of 13N (directly as ammonia) for synthesis of 13N-Ammonia.</p>
	<p>VI. Target body material and entrance window material, Target volume and normal operating pressure must be mentioned.</p>
	<p>VII. Solid Targetry: The cyclotron shall have an external beam port allowing the uncomplicated attachment of a high current solid target assembly, for irradiating a solid target for production of I-124, 64Cu, 89Zr, 86Y etc.</p>
	<p>VIII. Deleted</p>
	<p>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.</p>
	<p>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</p>
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 < 3 hour
	III. Suitable indicators to display the vacuum in unit of Torr, with minimum of 1×10^{-7} to 10^{-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.

	<p>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.</p>
	<p>V. 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.</p>
	<p>VI. Interlocks / Provisions for Last Man Out</p>
	<p>VII. 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.</p>
	<p>VIII. 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 $2 * 65\mu\text{A}$) shall be as per AERB limits in any of the rooms above the cyclotron, adjacent to the cyclotron, outside the cyclotron vault door entrance</p>
8	Radiochemistry Synthesis Modules with Suitably Shielded Hot Cells
	<p>System for automatic transfer of product from target to chemistry system. Automated radiochemistry modules for synthesis of various PET radiopharmaceuticals i.e. for ^{18}F, ^{13}N. The method of production of radiopharmaceutical should have appropriate regulatory approval.</p>
	<p>I. Nucleophilic Synthesis Module for $[\text{F-18}]$ based PET tracers: 02 Nos.:</p>
	<p>a. One Synthesis module dedicated to synthesise $[\text{18F}]$ FDG should be provided. 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 hot cell door. The quality control equipment should be selected according to latest version of European Pharmacopoeia. It should be current GMP compliant. All cassettes and consumables required in the module must be quoted.</p>

	<p>b. One Synthesis module dedicated to synthesize all other [F-18] radiopharmaceuticals like F-DOPA, F-PSMA, FLT, FET, F-MISO, FAZA, F-CHOLINE, FES, etc. should be provided. The synthesis must be an automated cassette-based system installed in one hot cell with capability of consecutive synthesis without the need to open the hot cell door. The quality control equipment should be selected according to latest version of European Pharmacopoeia. It should be current GMP compliant. All cassettes and consumables required in the module must be quoted. Vendor will enter into rate contract for cassettes and all consumables for F-DOPA, F-PSMA, FLT, FET, F-MISO, FAZA, F-CHOLINE, FES, etc. Rate contract will be valid for five years. Institute will procure from the vendor as and when required.</p>
	II.Deleted
	<p>III. Latest target for fast and simple production of $^{13}\text{NH}_3$ using direct In-target $^{13}\text{NH}_3$ production, so that no separate process module is required.</p>
	<p>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 GMP compliant. These should be preferably of Comecer / Tema Synergie / Vohn Galen / Nuclear Interface / Synthra etc.</p>
	<p>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 / or syringes. It should be current GMP 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.</p>
	<p>VI. Sequences for synthesis of all F-18, N-13 based radiopharmaceuticals should be provided, loaded and demonstrated.</p>
	<p>VII. Sufficient consumables shall be provided with each synthesis unit to allow at least 10 batches to be produced for testing purposes.</p>
	<p>VIII.All the Automated Synthesis modules/units should be current GMP compliant.</p>
B.	GENERAL POINTS:
	1. Warranty:

	<p>a) 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 Warranty and CMC period.</p>
	<p>b) The warranty charges shall not be quoted separately.</p>
	<p>c) During warranty, the uptime of the system shall be at least 95% calculated at 24 (hrs) X 7 (days) X 365 (days) basis. Penalty shall be as follows</p> <p>1. No penalty for downtime of 20 days per year calculated at 24 (hrs) X 7 (days) X 365 (days) basis</p> <p>2. There shall be a penalty of Rs 10000 per day for downtime of 21 to 45 days per year. calculated at 24 (hrs) X 7 (days) X 365 (days) basis</p> <p>3. There shall be a penalty of Rs 50000 per day for downtime of 46 to 90 days per year calculated at 24 (hrs) X 7 (days) X 365 (days) basis</p> <p>4. If downtime exceeds 90 days per year calculated at 24 (hrs) X 7 (days) X 365 (days) basis, then supplier/manufacturer shall be Black listed/Terminated with forfeiture of performance security.</p> <p>.Necessary logbooks shall be provided by the supplier. Penalty will be calculated 8 hours after telephonic/ SMS/ Email information to the vendor.</p>
	<p>d) All software updates should be provided free of cost during Comprehensive Warranty period.</p>
	<p>2. After Sales Service:</p>
	<p>After sales service centre should be available at the city of Institution on 24 (hrs) X 7(days) X 365 (days) basis. Complaints should be attended properly, maximum within 8hrs. The service should be provided directly by Bidder/Indian Agent. Undertaking by the Principals in the "Manufacturer Authorisation Form" that the spares for the equipment shall be available for at least 10 years from the date of supply of equipment.</p>
	<p>3. Training:</p>
	<p>On Site training to Doctors/ Technicians/ staff is to be provided by Principal/Indian Agents (if they have the requisite know-how) for operation and maintenance of the equipment to the satisfaction of the User Department.</p>

	<p>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.</p>
	<p>4. Comprehensive Annual Maintenance Contract (CAMC) of subject equipment:</p>
	<p>a) 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 warranty and CMC should be more than 95 %. (Maximum Allowed down time shall be 20 days per year considering 24 (hrs) X 7 (days) X 365 (days) basis) Trained service engineer should be stationed at Bhubaneshwar and Jodhpur on 24 hrs x 7 day's 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.</p>
	<p>b) The cost of Comprehensive Annual Maintenance Contract (CAMC) which shall include preventive maintenance including testing & calibration as per technical/service/operational manual of the manufacturer, labour and all spares, after satisfactory completion of Warranty period may be quoted as per Section VI List of Requirement on yearly basis for complete equipment including third party items as per Price Schedule.</p>
	<p>c) The cost of CAMC may be quoted along with GST applicable on the date of Bid Opening.</p>
	<p>d) Cost of CAMC will be added for Ranking/Evaluation purpose on NPV basis.</p>
	<p>e) Before commencement of CAMC period, the suppliers shall furnish a Performance Bank Guarantee for 2.5% of the cost of the equipment (as per Performa given in bidding document) valid till 3 months extra after expiry of entire CAMC period. The Performance Bank Guarantee for CAMC will be applicable in case of equipment cost is more than Rs.10 lakh.</p>
	<p>f) During the CAMC period, The uptime of the system shall be at least 95% calculated at 24 (hrs) X 7 (days) X 365 (days) basis</p> <ol style="list-style-type: none"> 1. No penalty for downtime of 20 days per year calculated at 24 (hrs) X 7 (days) X 365 (days) basis 2. There shall be a penalty of Rs 10000 per day for downtime of 21 to 45 days per year.calculated at 24 (hrs) X 7 (days) X 365 (days) basis 3. There shall be a penalty of Rs 50000 per day for downtime of 46 to 90 days per year calculated at 24 (hrs) X 7 (days) X 365 (days) basis 4. If downtime exceeds 90 days per year calculated at 24 (hrs) X 7 (days) X 365 (days) basis ,then supplier/manufacturer shall be Black listed/Terminated with forfeiture of performance security. <p>.Necessary logbooks shall be provided by the supplier. Penalty will be calculated 8 hours after telephonic/ SMS/ Email information to the vendor.</p>
	<p>g) All software updates should be provided free of cost during CAMC. In case of failure by the supplier, the Bank Guarantee of CAMC will be forfeited.</p>
	<p>h) The payment of CAMC will be made on half yearly basis after satisfactory completion of said period duly certified by end User.</p>

	6. Demonstration of product:
	Demonstration of equipment with mentioned specification must be done at a reputed institute where the equipment is currently functioning.
	OTHERS
	<p>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.</p>
	<p>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.</p>
	<p>V. Certification: The supply should meet all statutory requirements of AERB. Type Approval Certificate from AERB should be annexed.</p>
	<p>VI. Scheduling: A tentative Schedule is established. Nonetheless it is absolutely required that the cyclotron complete with targetry, be delivered, installed and commissioned within 18 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.</p>
	<p>IX. Consumables: Vendor shall provide all consumables including glass ware, lab-ware, chemicals, tool kits etc.needed for F-18 FDG & N-13 NH3 synthesis and QC, sufficient for five runs during testing and commissioning. Additionally consumables for 250 runs for FDG, 20 runs each for F-DOPA, F-Choline, F-PSMA and 20 runs for N-13 NH3 synthesis, should also be supplied during the first year. Bidder should quote seperate price of consumables for 250 runs for FDG, 20 runs each for F-DOPA, F-Choline, F-PSMA and 20 runs for N-13 NH3 synthesis per year for use during the warranty period. All formalities regarding custom clearance of consumables will be the responsibility of the vendor. The vendor should supply the consumables in a staggered manner, as required by the consignee.</p>
	<p>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.</p>

	XII. Global Support: Tenderer 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 tenderers will provide necessary technical support and information for obtaining requisite license of cyclotron operation from the regulatory body of India (AERB).
	(ii) All deliverables will be in English language and in accordance with European Good Manufacturing practice.
	PART B- ACCESSORIES OF CYCLOTRON, AIIMS BHUBANESWAR
	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 recommended 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. All gases needed has to be provided during warranty & CMC period.
	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 GMP/GLP compliant HPLC system having BGO/LSO/LYSO/Na(I) TI crystal based radiation detectors with energy range of 60-1500keV or better and UV/VIS/PDA detector, having Ph.Eur/USP/CE certification, for high-performance quality control / analytics of F-18 FDG and other radiopharmaceuticals. It should have C-8, C-18 and RP HPLC column with Guard Column and SEC HPLC column with Guard Column.
	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. OPTIONAL
	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.
	XX. Deleted
	XXI. Shielded Containers for cyclotron generated and PET (511 KeV) radioactive waste
	XXII. FIVE 511 KeV Tungsten containers for product vials (30 ml)
	XXIII. Two sets of Type A liquid radioisotope transport containers (external polyethylene case and CF 18 Tungsten shielded container) by Comecer
	XXIV. Any other essential lab items appropriate for a PET-radiochemistry lab.
	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.
	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.
	PART C - MANPOWER REQUIREMENT, AIIMS BBSR
	Operation of Cyclotron: During the warranty period, the vendor will provide one Nuclear Medicine Physicist having RSO certification for cyclotron and One radiopharmacist/radiochemist as contract manpower to support cyclotron operation and production of PET tracers in the end-user's site at Bhubaneswar and also do necessary maintenance so as to produce necessary isotopes for the PET scanner. Price to be quoted separately and will be considered for L1 calculation
	PART D - TURNKEY REQUIREMENT, AIIMS BBSR
	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 dept of Nuclear Medicine, 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 - Clean room and lab finishes as per standard GMP certification requirement, Greenfield project. Added Para : Lab finishes as per standard GMP certification requirement and should be mentioned in the technical bid.
	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 and cooling system

	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) Comfortable temperature ranges 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 in India or Globally must be given for Bidder/Manufacturer Both cyclotron and hot lab facility has to be GMP compliant
	References list of successful project realization in India or Globally including building engineering must be given for Bidder/Manufacturer 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

	<p>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.</p>
	<p>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.</p>
	<p>V. Total area to be constructed for entire building (Cyclotron bunker, radio pharmacy lab, PET-CT and isolation ward) is 14000 square feet (provisionally ground floor 8000 and first floor 6000 sqft). Note: Total 14000 square feet will be closed area. However, the internal arrangement may change if cyclotron has to be placed in the basement. Total area is 14000 sq ft. The cyclotron may be placed in basement or ground floor depending upon AERB approval.</p>
	<p>VI. The actual area of turnkey works done will be considered for payment, based on the site measurements.</p>
	<p>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.</p>
	<p>VIII. The internal arrangements of the rooms for all the floors are to be consulted with the nuclear medicine department, AIIMS, Bhubaneswar.</p>
	<p>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.</p>
	<p>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.</p>
	<p>a) The Foundation of the building should be constructed such that it could go up to ground floor + 5 floors in future. Normal loading to be considered from 2nd floors to 5th floor during designing the whole building.</p>
	<p>b) Currently two floors (either ground floor and + 1 or basement and ground floor depending upon the installation of cyclotron) need to be constructed.</p>
	<p>c) The cyclotron room outer walls should be of RCC. The cyclotron should be housed as per AERB norms</p>
	<p>d) Radio pharmacy laboratory (Must be GMP Complaint) and PET-CT area. The construction should be according to standard GMP specification. The vendor will plan and design the Medical cyclotron and PET-CT facility as per stipulated GMP guidelines. The vendor will provide necessary technical support to the institute during GMP validation of its medical cyclotron and PET-CT facility within the warranty period.</p>

	<p>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. Note: Total closed area 14000 sq ft. The final internal arrangement of the rooms will be discussed after award of tender as it depends on AERB approval of layout.</p>
	<p>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.</p>
	<p>g) Six isolation rooms for radionuclide therapy, Nursing station, dose administration area, housekeeping rooms, committee room, seminar room with all other amenities (toilets) etc.</p>
	<p>h) Delay tank for 6 bed radionuclide isolation ward as per the AERB standard</p>
	<p>i) Necessary lifts should be quoted optionally from Ground Floor to 1st Floor as per standard. However, for cyclotron placed in basement, lift is not required</p>
	<p>j) Separate room for electrical panel etc</p>
	<p>k) Chimney with stack monitor as per the AERB requirement</p>
	<p>XI. Water and power connection will be provided close to the proposed site by the Hospital authority</p>
	<p>XII. No escalation charges will be paid for the building and its allied works.</p>
	<p>XIII. Timeline to complete construction of building should be maximum 18 months after getting layout approval from AERB. 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 18 months. Vendor may plan the civil work such that early completion of PET-CT area is possible and PET-CT installation could be done well before cyclotron installation and completion.</p>
	<p>XIV. The penalty clause will come into effect if the work is not completed within the stipulated time as mentioned.</p>
	<p>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.</p>
	<p>XVI. Civil work (scope of work):</p>

	<p>1. Leveling and lowering the ground excavation in all 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. Note: Vendor has to visit the site before quoting.</p>
	<p>2. Building should be a framed structure with Burnt Brick masonry walls with plain plastering.</p>
	<p>3. No occupancy above the cyclotron as per AERB rule. The future expansion floor will be for general room purpose</p>
	<p>4. Structural glazing and Alcobond glazing elevation should be provided as per architectural drawing.</p>
	<p>5. Roof height of each floor of the building should be upto 3.60 mtr (cyclotron vendor may suggest different heights if required for cyclotron)</p>
	<p>6. All internal walls should be provided with color glazed full height wall tiles.</p>
	<p>7. M20 concrete should be used for Bed concrete as per specification. (Grade of Concrete will be based on Structure design requirement)</p>
	<p>8. M20 concrete is used for window cills lintels and plinth beam etc. (Grade of Concrete will be based on Structure design requirement)</p>
	<p>9. Providing and filling cinder concrete is used for sunken portion of toilet. (Grade of Concrete will be based on Structure design requirement)</p>
	<p>10. 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)</p>
	<p>11. 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)</p>
	<p>12. Conference room walls should be provided with acoustic veneer paneling system</p>
	<p>13. Wooden flush doors with laminate finish to be provided for all door opening except area where lead lined doors are required as per AERB.</p>
	<p>14. 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)</p>
	<p>15. Ceramic tiles flooring of approved make and shade 300 x 300mm for flooring for all toilet and pantry area.</p>
	<p>16. Dadoing of glazed tiles of approved make 300 x 600mm is to be used as cladding for toilets.</p>
	<p>17. Delay tank for 6 bed isolation wards as per AERB regulations</p>

	18. Ceiling Metal plain/perforated/ mirror finish, acoustical treated, powder coated tile or Mineral fibre tiles for false ceiling for all the internal rooms should be provided. Ceiling height to suit the equipment mount and clearances.
	19. Site fabricated with plywood/lamination sheets as per the requirement of the user department.
	20. 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.
	21. 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.
	22. Platform for unloading and shifting the cyclotron should be provided if necessary.
	23. Cable tray, trench & channel – necessary trenches, cable tray and channels at required location would be provided.
	24. Necessary water proofing treatment over the first floor terrace should be made.
	25. There should be Access control for doors in the cyclotron facility and cyclotron vault
	Approached Road to Cyclotron should be considered.
	The foundation of the building will be for G+5.
	Vendor will provide all necessary documents to take clearance from Statutory Body (ies) i.e. BDA, Municipality, Fire Office etc.
	Structural drawings prepared by vendor must be approved by any structural Engineer and a copy submitted to AIIMS, Bhubaneswar for record and reference.
	Provision of required drainage including connecting them to existing drain is under vendor's scope.
	Vendor must install appropriate fire fighting equipment and integrate the same with the existing Fire Fighting System of the Main hospital building.
	Soil testing, Rainfall data, seismic data and information required for construction of the building is to be collected by vendor at own cost.
	Septic Tank connection is to be done by Vendor.
	Water requirement for making the building functional is to be informed to AIIMS, Bhubaneswar. AIIMS will provide one source of water near the building & vendor shall provide necessary arrangement for storage and distribution of water.

	<p>However the entire construction work (Civil + Electrical + Air conditioning) is a Turn key work. It is expected that the provisions to be made must comply to the equipment and AERB regulatory requirements and must fulfill the statutory norms/guidelines. 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.</p>
	<p>XVII. Plumbing works</p>
	<p>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 pumps with texmo/Atlanta/Kirlosker/Crompton Greaves or equivalent make.</p>
	<p>Necessary sanitary fittings and sanitary line should be provided for the building under scope.</p>
	<p>All sanitary and water supply lines are to be drawn till the existing drainage point</p>
	<p>Over head tanks of PVC sintex or equivalent make are to be used with a capacity as per the requirement.</p>
	<p>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</p>
	<p>XIX. Fire alarm system:</p>
	<p>Supply, installation and commissioning of Fire Alarm System at each floor with adequate smoke detectors with hooters and MCP & Panels are to be provided.</p>
	<p>Sprinkler type fire fighting systems with MS pipes are to be provided.</p>
	<p>Adequate number of firefighting equipment should be provided.</p>
	<p>The building should comply with fire regulation norms.</p>
	<p>The number of firefighting equipment must be as per the fight-fighting norms. The vendor will support all documents to take regulatory approval.</p>
	<p>XX. Electrical work:</p>
	<p>The total load of electrical power requirement to be calculated by vendor.</p>
	<p>Power supply by the institute will be terminated at close to proposed site</p>
	<p>All electrical provisions including earthing etc. will be vendor's responsibility.</p>
	<p>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</p>
	<p>The light power socket (MK/North Wet or equivalent) to be provided in each room as per scope.</p>
	<p>Switches light and power points should be of modular type and of standard make as listed below.</p>
	<p>LED light fittings with minimum 500 Lux Illumination</p>
	<p>Dimmer controlled incandescent light fixtures are to be provided in the console room – 4 numbers.</p>

	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 waiting 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 room in entire building.
	The site should be rendered pest/rodent free.
	The total load of electrical power requirement for whole system to be calculated by the Vendor.
	Diversity factor of load to be calculated & submitted by the Vendor.
	Voltage drop calculation sheets to be submitted by the Vendor before laying the cables/wire.
	UPS & DG capacity to be calculated by the vendor.
	UPS and Emergency Supply (DG) to be provided by the Vendor.
	The Vendor to be provided Automatic Voltage Controller to maintain the specified voltage to the system.
	All electrical copper earthing lead to be done by the Vendor.
	Chemical earthing to be provided by the vendor.
	All internal wiring to be carried out by FRLS copper wire/cables.
	Main incomer MCCB for entire area under scope with adequate safety measures as per I.E Rule and provide Voltmeter, Ammeter, Energy Meter, Frequency Meter, Phase Indicator with earth leakage protection and over current protection.
	Main LT Panel to be design with adequate spare switches ie. MCCB, MCB & etc.
	A separate independent power source can be provided by the Institution at close to proposed site.
	Power source to be feeded upto only to the control panel of proposed building by the Institution.

	<p>Added Para in Turnkey: Maintenance Contract: 5 years warranty and Comprehensive maintenance contract (CMC) should be quoted for a period of Five Years after the expiry of warranty period for electrical panels and HVAC.</p>
	XXI. Passenger lifts:
	<p>Providing and installing lift from OTIS or equivalent (machine room less) for 06 passenger (including one patient trolley) with 02 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/panels with enamel paint.</p>
	<p>The lift well has to be constructed for G+1 and lift has to be installed for G+1. However, the lift should cater G+5. Vendor should provide necessary documents to take regulatory approval.</p>
	XXII. Air Conditioning works:
	<p>The total load of AC should be calculated 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. Split ACs must be provided in specific area where required like isolation wards.</p>
	Preferred makes for Air Conditioning Hitachi/Mitsubishi/Voltas/Blue Star
	XXIII. Furniture works
	<p>The scope of work includes supplying and fixing of necessary furniture for the entire area as per requirements with approved quality and shade.</p>
	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

Added under technical specifications**For**

Tender ID-2023_HLL_154323_2 (AIIMS Jodhpur) the revised technical specification of Medical Cyclotron for AIIMS Jodhpur.

Read As

Tender ID-2023_HLL_154323_3 (AIIMS Jodhpur) the revised technical specification of Medical Cyclotron for AIIMS Jodhpur may be read as:-

PART A -TECHNICAL SPECIFICATION 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 Jodhpur
	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 should provide Certification from AERB for the type approval for 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 update 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 vendor must facilitate the department for all the radiation safety clearances, type approval from AERB for all equipment from AERB
	XII. Together with the supply of the equipment, layout proposed by the vendor should be GMP compliant.
	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 facilitation for mandatory AERB approvals etc.
	Equipment to be provided and installed should consist of the following:
	I. Shielded Medical Cyclotron (Self shielded or Shielded with Bunker) to be installed in a separate room, as per AERB regulations
	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 for ion sources, For C11, N13, F18 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 Parameter
	I. A negative ion Cyclotron with 15 MeV or more energy in order to allow production of conventional (F18, 13N) and non-conventional radioisotopes (I- 124, 64Cu, 89Zr, 86Y) with liquid, gas and solid targets. (Note: There must be provision for production of I-124, 64Cu, 89Zr and 86Y in future and all required space for the same must be constructed now. The equipment should have provision for software and hardware upgradation for solid target in future)
	II. The cyclotron should be self SHIELDED or shielded with a bunker as per AERB guidelines. 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 with 15 MeV or more under completely automated mode with options for semi-automated or manual mode intervention for an appropriate sequence so as to produce specified quantities of radionuclides
	IV. The System should operate on 3-phase Indian electrical supply standards.
	V. Cyclotron should be capable of delivering a beam of 130 μ A or more. Added Para : There should be possibility to upgrade to higher beam current for the production of I-124, 64Cu, 89Zr, 86Y etc.
	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. It should be possible to fully control the cyclotron operation from computer work station.
	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

	<p>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.</p>
	<p>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</p>
	<p>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.</p>
4	Target Systems
	<p>I. The cyclotron should have minimum two target ports. Dual beam (bombarding two targets simultaneously) should be possible for production of [18F] (for making [F-18] FDG and other PET tracers like FLT, FMISO, FDOPA etc.</p>
	<p>II. All beam exit ports must be equipped with extraction systems.</p>
	<p>III. It must have multiple number of extraction foils to reduce maintenance time and personal dose absorption.</p>
	<p>IV. Two 18F targets (high yield Niobium targets) for production of 18F as the chemical form of the radioisotope based on use of the 18O (p, n) 18F reaction, suitable for making [F-18] FDG and other PET tracers like 18FLT, FMISO, FDOPA etc.</p>
	<p>V. One target (latest approved material for higher yield) for production of 13N (directly as ammonia) for synthesis of 13N-Ammonia.</p>
	<p>VI. Target body material and entrance window material, Target volume and normal operating pressure must be mentioned.</p>
	<p>VII. Solid Targetry: The cyclotron shall have an external beam port allowing the uncomplicated attachment of a high current solid target assembly, for irradiating a solid target for production of I-124, 64Cu, 89Zr, 86Y etc.</p>
	<p>VIII. Deleted</p>
	<p>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.</p>
	<p>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</p>
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 < 3 hour
	III. Suitable indicators to display the vacuum in unit of Torr, with minimum of 1×10^{-7} to 10^{-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.

	<p>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.</p>
	<p>V. 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.</p>
	<p>VI. Interlocks / Provisions for Last Man Out</p>
	<p>VII. 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.</p>
	<p>VIII. 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 $2 * 65\mu\text{A}$) shall be as per AERB limits in any of the rooms above the cyclotron, adjacent to the cyclotron, outside the cyclotron vault door entrance</p>
8	Radiochemistry Synthesis Modules with Suitably Shielded Hot Cells
	<p>System for automatic transfer of product from target to chemistry system. Automated radiochemistry modules for synthesis of various PET radiopharmaceuticals i.e. for ^{18}F, ^{13}N. The method of production of radiopharmaceutical should have appropriate regulatory approval.</p>
	<p>I. Nucleophilic Synthesis Module for $[\text{F-18}]$ based PET tracers: 02 Nos.:</p>
	<p>a. One Synthesis module dedicated to synthesize $[\text{18F}]$ FDG should be provided. 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 hot cell door. The quality control equipment should be selected according to latest version of European Pharmacopoeia. It should be current GMP compliant. All cassettes and consumables required in the module must be quoted.</p>

	<p>b. One Synthesis module dedicated to synthesize all other [F-18] radiopharmaceuticals like F-DOPA, F-PSMA, FLT, FET, F-MISO, FAZA, F-CHOLINE, FES, etc. should be provided. The synthesis must be an automated cassette-based system installed in one hot cell with capability of consecutive synthesis without the need to open the hot cell door. The quality control equipment should be selected according to latest version of European Pharmacopoeia. It should be current GMP compliant. All cassettes and consumables required in the module must be quoted. Vendor will enter into rate contract for cassettes and all consumables for F-DOPA, F-PSMA, FLT, FET, F-MISO, FAZA, F-CHOLINE, FES, etc. Rate contract will be valid for five years. Institute will procure from the vendor as and when required.</p>
	II.Deleted
	<p>III. Latest target for fast and simple production of $^{13}\text{NH}_3$ using direct In-target $^{13}\text{NH}_3$ production, so that no separate process module is required.</p>
	<p>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 GMP compliant. These should be preferably of Comecer / Tema Synergie / Vohn Galen / Nuclear Interface / Synthra etc.</p>
	<p>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 / or syringes. It should be current GMP 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.</p>
	<p>VI. Sequences for synthesis of all F-18, N-13 based radiopharmaceuticals should be provided, loaded and demonstrated.</p>
	<p>VII. Sufficient consumables shall be provided with each synthesis unit to allow at least 10 batches to be produced for testing purposes.</p>
	<p>VIII.All the Automated Synthesis modules/units should be current GMP compliant.</p>
B.	GENERAL POINTS:
	1. Warranty:

	<p>a) 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 Warranty and CMC period.</p>
	<p>b) The warranty charges shall not be quoted separately.</p>
	<p>c) During warranty, the uptime of the system shall be at least 95% calculated at 24 (hrs) X 7 (days) X 365 (days) basis. Penalty shall be as follows</p> <ol style="list-style-type: none"> 1. No penalty for downtime of 20 days per year calculated at 24 (hrs) X 7 (days) X 365 (days) basis 2. There shall be a penalty of Rs 10000 per day for downtime of 21 to 45 days per year. calculated at 24 (hrs) X 7 (days) X 365 (days) basis 3. There shall be a penalty of Rs 50000 per day for downtime of 46 to 90 days per year calculated at 24 (hrs) X 7 (days) X 365 (days) basis 4. If downtime exceeds 90 days per year calculated at 24 (hrs) X 7 (days) X 365 (days) basis, then supplier/manufacturer shall be Black listed/Terminated with forfeiture of performance security. <p>.Necessary logbooks shall be provided by the supplier. Penalty will be calculated 8 hours after telephonic/ SMS/ Email information to the vendor. Downtime should not exceed 5% at a stretch.</p>
	<p>d) All software updates should be provided free of cost during Comprehensive Warranty period.</p>
	<p>2. After Sales Service:</p>
	<p>After sales service centre should be available at the city of Institution on 24 (hrs) X 7(days) X 365 (days) basis. Complaints should be attended properly, maximum within 8hrs. The service should be provided directly by Bidder/Indian Agent. Undertaking by the Principals in the "Manufacturer Authorisation Form" that the spares for the equipment shall be available for at least 10 years from the date of supply of equipment.</p>
	<p>3. Training:</p>
	<p>On Site training to Doctors/ Technicians/ staff is to be provided by Principal/Indian Agents (if they have the requisite know-how) for operation and maintenance of the equipment to the satisfaction of the User Department.</p>
	<p>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.</p>
	<p>4. Comprehensive Annual Maintenance Contract (CAMC) of subject equipment:</p>

	<p>a) 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 warranty and CMC should be more than 95 %. (Maximum Allowed down time shall be 20 days per year considering 24 (hrs) X 7 (days) X 365 (days) basis) Trained service engineer should be stationed at Bhubaneswar and Jodhpur on 24 hrs x 7 day's 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.</p>
	<p>b) The cost of Comprehensive Annual Maintenance Contract (CAMC) which shall include preventive maintenance including testing & calibration as per technical/service/operational manual of the manufacturer, labour and all spares, after satisfactory completion of Warranty period may be quoted as per Section VI List of Requirement on yearly basis for complete equipment including third party items as per Price Schedule.</p>
	<p>c) The cost of CAMC may be quoted along with GST applicable on the date of Bid Opening.</p>
	<p>d) Cost of CAMC will be added for Ranking/Evaluation purpose on NPV basis.</p>
	<p>e) Before commencement of CAMC period, the suppliers shall furnish a Performance Bank Guarantee for 2.5% of the cost of the equipment (as per Performa given in bidding document) valid till 3 months extra after expiry of entire CAMC period. The Performance Bank Guarantee for CAMC will be applicable in case of equipment cost is more than Rs.10 lakh.</p>
	<p>f) During the CAMC period, The uptime of the system shall be at least 95% calculated at 24 (hrs) X 7 (days) X 365 (days) basis</p> <ol style="list-style-type: none"> 1. No penalty for downtime of 20 days per year calculated at 24 (hrs) X 7 (days) X 365 (days) basis 2. There shall be a penalty of Rs 10000 per day for downtime of 21 to 45 days per year.calculated at 24 (hrs) X 7 (days) X 365 (days) basis 3. There shall be a penalty of Rs 50000 per day for downtime of 46 to 90 days per year calculated at 24 (hrs) X 7 (days) X 365 (days) basis 4. If downtime exceeds 90 days per year calculated at 24 (hrs) X 7 (days) X 365 (days) basis ,then supplier/manufacturer shall be Black listed/Terminated with forfeiture of performance security. <p>.Necessary logbooks shall be provided by the supplier. Penalty will be calculated 8 hours after telephonic/ SMS/ Email information to the vendor.Downtime should not exceed 5% at a stretch.</p>
	<p>g) All software updates should be provided free of cost during CAMC. In case of failure by the supplier, the Bank Guarantee of CAMC will be forfeited.</p>
	<p>h) The payment of CAMC will be made on half yearly basis after satisfactory completion of said period duly certified by end User.</p>
	<p>6. Demonstration of product:</p>
	<p>Demonstration of equipment with mentioned specification must be done at a reputed institute where the equipment is currently functioning.</p>
	<p>OTHERS</p>

	<p>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.</p>
	<p>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.</p>
	<p>V. Certification: The supply should meet all statutory requirements of AERB. Type Approval Certificate from AERB should be annexed.</p>
	<p>VI. Scheduling: A tentative Schedule is established. Nonetheless it is absolutely required that the cyclotron complete with targetry, be delivered, installed and commissioned within 18 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.</p>
	<p>IX. Consumables: Vendor shall provide all consumables including glass ware, lab-ware, chemicals, tool kits etc. needed for F-18 FDG & N-13 NH3 synthesis and QC, sufficient for five runs during testing and commissioning. Additionally consumables for 250 runs for FDG, 20 runs each for F-DOPA, F-Choline, F-PSMA and 20 runs for N-13 NH3 synthesis, should also be supplied during the first year. Bidder should quote separate price of consumables for 250 runs for FDG, 20 runs each for F-DOPA, F-Choline, F-PSMA and 20 runs for N-13 NH3 synthesis per year for use during the warranty period. All formalities regarding custom clearance of consumables will be the responsibility of the vendor. The vendor should supply the consumables in a staggered manner, as required by the consignee.</p>
	<p>Decommissioning: The Tenderer will have to explain the procedure of decommissioning of cyclotron and the associated vault as per the AERB Guidelines and should provide the decommissioning manual. Vendor should submit undertaking for the same from the Tenderer with legal binding.</p>
	<p>XII. Global Support: Tenderer 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.</p>

	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 tenderers will provide necessary technical support and information for obtaining requisite license of cyclotron operation from the regulatory body of India (AERB).
	(ii) All deliverables will be in English language and in accordance with European Good Manufacturing practice.
	PART B - ACCESSORIES OF CYCLOTRON, AIIMS JODHPUR
	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 recommended 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. All gases needed has to be provided during warranty & CMC period
	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. One high energy type Dose Calibrators for PET isotopes
	IV. Deleted

	V. One GMP/GLP compliant HPLC system having BGO/LSO/LYSO/Na(I) TI crystal based radiation detectors with energy range of 60-1500keV or better and UV/VIS/PDA detector, having Ph.Eur/USP/CE certification, for high-performance quality control / analytics of F-18 FDG and other radiopharmaceuticals. It should have C-8, C-18 and RP HPLC column with Guard Column and SEC HPLC column with Guard Column.
	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. OPTIONAL
	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 (With minimum weigh sensitivity of 0.0001 gm) - 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.
	XX. Deleted
	XXI. Shielded Containers for cyclotron generated and PET (511 KeV) radioactive waste
	XXII. FIVE 511 KeV Tungsten containers for product vials (30 ml)
	XXIII. Two sets of Type A liquid radioisotope transport containers (external polyethylene case and CF 18 Tungsten shielded container)
	XXIV. Any other essential lab items appropriate for a PET-radiochemistry lab.
	XXV:Gas Chromatography with Flame Ionization Detection (GC-FID)- one
	XXVI:Heating Plate- 2 nos
	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 stack (minimum 7 nos. in the cyclotron and radiochemistry area & minimum 3 nos. in other areas including one for stack).
	II. Suitable temperature and humidity monitoring devices for cyclotron bunker & control room.
	III. Digital Neutron Monitors -2 Nos
	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.
	XI. Decontamination Kit -One
	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.
	PART C - MANPOWER REQUIREMENT, AIIMS JODHPUR
	The vendor will provide one trained Nuclear Medicine Physicist (RSO-III) for a minimum period of two years who will support cyclotron operation with production (including radio labelling) of PET tracers in the end-user's site and also do necessary maintenance so as to produce necessary isotopes for the PET scanner. Price to be quoted separately and will be considered for L1 calculation
	PART D - TURNKEY REQUIREMENT, AIIMS JODHPUR
	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 dept of Nuclear Medicine, AIIMS Jodhpur in preparing detailed site plan for the installation of the cyclotron and associated equipment.
	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 - Clean room and lab finishes as per standard GMP certification requirement, Greenfield project. Lab finishes as per standard GMP certification requirement and should be mentioned in the technical bid.
	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 and cooling system
	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) Comfortable temperature ranges 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 in India or Globally must be given for Bidder/Manufacturer Both cyclotron and hot lab facility has to be GMP compliant”
	“References list of successful project realization in India or Globally including building engineering must be given for Bidder/Manufacturer 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 facilities”.

	<p>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</p>
	<p>III. The Turnkey Work should completely comply with AERB requirement. The entire construction of cyclotron bunker and the two PET-CT area should be in conformity with AERB norms only</p>
	<p>IV. The vendor should consult the department of Nuclear Medicine, AIIMS Jodhpur 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 Jodhpur.</p>
	<p>V. Total area to be constructed for entire building (Cyclotron bunker, radio pharmacy lab, and two PET-CT scanner facility) is 14000 square feet (provisionally basement/ground floor 8000 and ground/first floor 6000 sqft). Note: Total 14000 square feet will be closed area. However, the internal arrangement may change if cyclotron has to be placed in the basement. Total construction area remains 14000 sq. ft. The cyclotron may be placed in basement or ground floor depending upon AERB approval. SITE VISIT REQUIRED MUST BEFORE QUOTING for AIIMS Jodhpur”.</p>
	<p>VI. The actual area of turnkey works done will be considered for payment, based on the site measurements.</p>
	<p>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.</p>
	<p>VIII. The internal arrangements of the rooms to be constructed are to be consulted with the nuclear medicine department, AIIMS Jodhpur.</p>
	<p>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.</p>
	<p>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.</p> <ul style="list-style-type: none"> • The Foundation of the building should be constructed such that it could go up to ground floor + 5 floors in future. Normal loading to be considered from 2nd floors to 5th floor during designing the whole building.” • Currently two floors (either ground floor and + 1st floor or basement + ground floor depending upon the installation of cyclotron) need to be constructed. SITE VISIT REQUIRED FOR AIIMS JODHPUR.
	<p>Vendor also has to construct one Housekeeping room, one committee room, and one seminar room”</p>

	Chimney with stack monitor as per the AERB requirement
	a) The cyclotron room outer walls should be of RCC. The cyclotron should be housed as per AERB norms.
	b) The construction should be according to standard GMP specification and the completed building structure should be GMP ready. The vendor will plan and design the Medical cyclotron facility as per stipulated GMP guidelines. The vendor will provide necessary technical support to the institute during GMP validation of its medical cyclotron within the warranty period.
	c) The final internal arrangement of the rooms will be discussed after award of tender as it depends on AERB approval of layout.
	d) Cyclotron area should have cyclotron vault room, cyclotron control unit room, hot laboratory for hot cells, QC lab, One Room for Ge-68/Ga-68 radio-pharmacy, General store, RSO room (1), radiochemist room (1), Other staff (1), electrical and UPS room, chiller and gases (outside), One pit in the vault to store used Haver foil, Space (separate room outside bunker) for waste gas cylinders to collect radioactive gases, another space (separate room outside bunker) to store gas-station, one room for laboratory equipment like refrigerators, changing rooms, one radioactive waste storage room, one decontamination room, two toilets (at least one active toilet fitted with shower in case of contamination of staff member accidentally, etc.)
	e) Separate room for electrical panel etc.
	f) Provision for space for another two Hot cells to be used in future for the production of products labelled with I-124, I-123, 64Cu, 89Zr, 86Y etc. should be made now.
	g) Bidder also has to design the layout (with AERB approval) for two PET-CT facility and construct the same layout on Ground floor/1st floor. The layout should have PET-CT scanner rooms (2 nos.), console room, Patient preparation area, Nursing area with Nurses changing room, dose dispensing room, dose admin room, post admin waiting area (6 nos. = 2 nos. with patient-bed and 4 nos. with easy chairs), radioactive source storage room, general store room, PET utility room, medical record room, office, reception, radioactive waste storage room, recovery room, decontamination room, active toilets, staff toilets, pantry, changing room, technician room, consultant room (4 nos.), HOD room (1 no.), patient examination rooms (2 nos.), reporting rooms (2 nos.), UPS and Battery room. Separate toilets for Ladies and Gents should be provided (for patients and staff) apart from separate public toilet facilities for men & women and store-room for sanitary items. A Reception with Patient waiting area and one LED TV with D2H connection in patient waiting area. The final internal arrangement of the rooms will be discussed after award of tender as it depends on AERB approval of layout.
	h) Shifting of the current PET-CT scanner and all accessories of the current PET-CT facility to the new proposed and constructed PET-CT facility layout (mentioned above in section Xg) in the proposed Ground floor area in the proposed building housing the Cyclotron facility.
	i) Deleted

	j) Medical Gas pipelines to be installed in the two PET-CT scanner rooms (for patient use) as per the hospital norms.
	XI. Water and power connection 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 18 months after getting layout approval from AERB. 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 18 months. Vendor may plan the civil work such that early completion of PET-CT area is possible and PET-CT installation could be done well before cyclotron installation and completion
	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 10 years. Service, repair and maintenance of all third party items will be the sole responsibility of primary vendor.
	XVI. Civil work (scope of work):
	1. Levelling and lowering the ground excavation in all 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.
	Note: Vendor has to visit the site before quoting.
	2. Building should be a framed structure with Burnt Brick masonry walls with plain plastering.
	3. No occupancy above the cyclotron as per AERB rule. The future expansion floor will be for general room purpose
	4. Structural glazing and Alcobond glazing elevation should be provided as per architectural drawing.
	5. Roof height of each floor of the building should be upto 3.60 mtr (cyclotron vendor may suggest different heights if required for cyclotron)
	6. All internal walls should be provided with colour glazed full height wall tiles.
	7. M20 concrete should be used for Bed concrete as per specification. (Grade of Concrete will be based on Structure design requirement)
	8. M20 concrete is used for window cills lintels and plinth beam etc. (Grade of Concrete will be based on Structure design requirement)
	9. Providing and filling cinder concrete is used for sunken portion of toilet. (Grade of Concrete will be based on Structure design requirement)

	10. 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)
	11. 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)
	12. Wooden flush doors with laminate finish to be provided for all door opening except area where lead lined doors are required as per AERB.
	13. 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, Radiochemist room, RSO room, Consultant room, other Staff rooms, General store and rest of area not using radioactive material (where vitrified files should not be put as per AERB).
	14. Ceramic tiles flooring of approved make and shade 300 x 300mm for flooring for all toilet and pantry area.
	15. Dadoing of glazed tiles of approved make 300 x 600mm is to be used as cladding for toilets.
	17. 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.
	18. Site fabricated with plywood/lamination sheets as per the requirement of the user department.
	19. 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.
	20. 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.
	21. Platform for unloading and shifting the cyclotron should be provided if necessary.
	22. Cable tray, trench & channel – necessary trenches, cable tray and channels at required location would be provided.
	24. Necessary water proofing treatment over the first floor terrace should be made.
	25. There should be Access control for doors in the cyclotron facility and cyclotron vault
	Seminar room and Committee room walls should be provided with acoustic veneer panelling system”
	Approached Road to Cyclotron should be considered.
	Vendor will provide all necessary documents to take clearance from Statutory Body (ies) i.e. JDA, Municipality, Fire Office etc.

	Structural drawings prepared by vendor must be approved by any structural Engineer and a copy submitted to AIIMS for record and reference.
	Provision of required drainage including connecting them to existing drain is under vendor's scope.
	Vendor must install appropriate fire fighting equipment and integrate the same with the existing Fire Fighting System of the Main hospital building.
	Soil testing, Rainfall data, seismic data and information required for construction of the building is to be collected by vendor at own cost.
	Septic Tank connection is to be done by Vendor.
	Water requirement for making the building functional is to be informed to AIIMS Jodhpur. AIIMS Jodhpur will provide one source of water near the building & vendor shall provide necessary arrangement for storage and distribution of water
	However the entire construction work (Civil + Electrical + Air conditioning) is a Turnkey work. It is expected that the provisions to be made must comply to the equipment and AERB regulatory requirements and must fulfil the statutory norms/guidelines. 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.
	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 suitable capacity submersible pumps (minimum two pumps) with texmo/Atlanta/Kirlosker/Crompton Greaves or equivalent make.
	Necessary sanitary fittings and sanitary line should be provided for the building under scope.
	All sanitary and water supply lines are to be drawn till the existing drainage point
	Overhead 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 aluminium composite panels of approved make and quality for the front elevation of the building is to be provided
	XIX. Fire alarm system:
	Supply, installation and commissioning of Fire Alarm System with adequate smoke detectors with hooters and MCP & Panels are to be provided.
	Sprinkler (gas and liquid type as per the suitability of area/equipment) type firefighting systems with MS pipes are to be provided.
	Adequate number of fire-fighting equipment should be provided.
	The building should comply with fire regulation norms.
	The number of fire-fighting equipment must be as per the fight-fighting norms. The vendor will also provide support with all documents to take regulatory approval.
	XX. Electrical work:
	The total load of electrical power requirement to be calculated by vendor.

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	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 – 4 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 all rooms.
	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.
	Vendor will also provide adequate Cloud storage space for safe keeping of the data of cyclotron operation along with chemistry data, radiation safety data along with PET imaging data for the 10 years.
	One water cooler with water filtering unit in the general reception area
	Electrical inspection approved is mandatory for DG set.
	Intercom connectivity in each room in entire building.
	The site should be rendered pest/rodent free.
	The total load of electrical power requirement for whole system to be calculated by the Vendor.
	Diversity factor of load to be calculated & submitted by the Vendor.
	Voltage drop calculation sheets to be submitted by the Vendor before laying the cables/wire.
	UPS and Emergency Supply (DG) to be provided by the Vendor.
	UPS – An appropriate capacity 3 phase input / output UPS with maintenance free Batteries for Cyclotron, Synthesis lab, other sub systems, chiller, all accessory equipments, radiation safety systems, including the functioning of all room activities etc. with minimum 60 min power supply back-up at full load.

	To provide DG set of >500 KV (capacity to be calculated by the vendor) including transformer/meter room for providing the continuous supply of electricity in the event of power failure.
	The Vendor to provide Automatic Voltage Controller to maintain the specified voltage to the system.
	All electrical copper earthing lead to be done by the Vendor.
	Chemical earthing to be provided by the vendor.
	All internal wiring to be carried out by FRLS copper wire/cables.
	Main incomer MCCB for entire area under scope with adequate safety measures as per I.E Rule and provide Voltmeter, Ammeter, Energy Meter, Frequency Meter, Phase Indicator with earth leakage protection and over current protection.
	Main LT Panel to be design with adequate spare switches ie. MCCB, MCB & etc.
	A separate independent power source can be provided by the Institution at close to proposed site.
	Power source to be feeded upto only to the control panel of proposed building by the Institution.
	Preferred make of the Electrical item.
	MCCB - ABB, L&T, Schneider.
	MCB - Legrand, L&T, Siemens
	Cables - KEI, Finolex, Havells
	Light Fittings - Havells, Schneider, Philips
	Maintenance Contract: 5 years warranty and Comprehensive maintenance contract (CMC) should be quoted for a period of Five Years after the expiry of warranty period for electrical panels and HVAC.
	Passenger lift:
	Necessary lift should be quoted optionally from Ground Floor to 1st Floor as per standard. However, for cyclotron placed in basement, lift is not required.
	<ul style="list-style-type: none"> • Specifications of lift – Providing and installing lift from OTIS or equivalent (machine room less) with 01 stop, automatic centre opening door enamel painted, S.S. handrail inside, emergency alarm, facia plate, press and speak intercom, emergency light, PVC flooring inside car, car ceiling/panels with enamel paint. Lift-car should be able to carry a minimum of 06 passengers and one patient bed at a time. • If construction plan is for Basement + Ground Floor – The lift shaft has to be constructed at Ground floor and should be of size which will be able to accommodate a lift-car with specifications as mentioned above. • If construction plan is for Ground Floor + 1st Floor – The lift shaft has to be constructed for G+1 and should be of size which will be able to accommodate a lift-car with specifications as mentioned above. The lift has to be installed for G+1. However, the lift should cater G+5. Vendor should provide necessary documents to take regulatory approval.
	Price to be quoted separately and shall be considered for L1 comparison.
	XXI. Air Conditioning works:

	The total load of AC should be calculated 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. Split ACs must be provided in specific areas/rooms wherever required to maintain an optimal temperature
	Preferred makes for Air Conditioning Hitachi/Mitsubishi/Voltas/Blue Star
	XXII. 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 visitor chairs in all offices/rooms
	Adequate number of working tables for workstations, computers and accessories.
	Revolving chairs height adjustable, medium-back with hand-rest – adequate numbers
	Vendor will provide 15 sets of three chairs each at the reception. Vendor will also provide a 43 inch LED TV with DTH cable connection with installation at the reception for the period of warranty and CMC.
	Cupboard with laminate door shutters for storage of spare parts and accessories and records as per requirement. – adequate numbers.
	Name boards for all rooms.
	Provisions should be made for placing the various accessories in different rooms.
	Any other furniture to make the area functional.

**Section –IX –
Qualification Criteria:-**

For:-

**For Tender ID-2023_HLL_154323_1 (AIIMS Bhubaneswar) and
For Tender ID-2023_HLL_154323_2 (AIIMS Jodhpur).**

Read As:-

**For Tender ID-2023_HLL_154323_1 (AIIMS Bhubaneswar) and
For Tender ID-2023_HLL_154323_3 (AIIMS Jodhpur).**

Added Para- Evaluation of both the tenders ID's shall be done for each consignee separately.

Existing Clause	Read As
<p>Clause 2 (a) The Manufacturer/Bidder should have supplied and installed in last Five years from the date of Tender Opening, at least 02 No of such similar equipment meeting major parameters of technical specification which is functioning satisfactorily globally</p>	<p>Clause 2 (a) The Manufacturer/Bidder should have supplied and installed in last Five years from the date of Tender Opening, at least 01 No of such similar equipment meeting major parameters of technical specification which is functioning satisfactorily globally</p>
<p>Clause 4 & 12. Any bidder from a country which shares a land border with India will be eligible to bid in this tender only if the bidder is registered with Competent Authority, as specified in Annexure-C of order F.No.6/18/2019-PPD dated 23-July-2020 and subsequent order/amendments (if any) and bidder must comply with all provisions mentioned in the order. A self-declaration with respect to above order must be submitted.</p> <p>Bidder should submit following declaration on their letter head regarding GFR Rule 144 (xi) as per Department of Expenditure, Ministry of Finance Notification dated 23-Feb-2023 and its subsequent amendments/clarification, if any: https://doe.gov.in/sites/default/files/Order%20%28Public%20Procurement%20No.%204%29%20-%20Restrictions%20under%20Rule%20144%28xi%29%20of%20the%20General%20Financial%20Rules%20%28GFRs%29%2C%202017.pdf</p>	<p>Clause 4 & 12 Bidders quoting equipment manufactured in countries sharing land border with India shall have to comply with GFR Rule 144 (xi) and have relevant registration.</p> <p>Bidder should submit following declaration on their letter head regarding GFR Rule 144 (xi) as per Department of Expenditure, Ministry of Finance Notification dated 23-Feb-2023 and its subsequent amendments/clarification, if any:</p> <p>"I have read the clause regarding restrictions on procurement from a bidder of a country which shares a land border with India, I certify that this bidder is not from such a country or, if from such a country, has been registered with the Competent Authority. I hereby certify that this bidder fulfils all requirements in this regard and is eligible to be considered."</p> <p style="text-align: center;">or</p> <p>Evidence of valid registration by the Competent Authority shall be attached if applicable.</p> <p>The successful bidder shall not be allowed to sub-contract works to any contractor from a country which shares a land border with</p>

	India unless such contractor is registered with the Competent Authority. [Applicable for Works contracts, including Turnkey contracts]
<p>Clause 3. The bidders/ firms identifying as MSME and or start-up firms are exempted from fulfilling criteria at S. No. 2 (a) stated above. However, this does not exempt any bidder/ firm/ manufacturer from fulfilling the quality requirements.</p>	<p>Clause 3. The bidders/ firms identifying as MSE and or start-up firms are exempted from fulfilling criteria at Sl. No. 2a, 8 and 9 stated. However, this does not exempt any bidder/ firm/ manufacturer from fulfilling the quality requirements. In case any bidder is seeking exemption from above criteria, the supporting documents to prove his eligibility for exemption must be uploaded for evaluation by the buyer.</p> <p>Under MSE category, only manufacturers for goods are eligible for exemption from EMD and exempted from fulfilling criteria at Sl. No. 2a, 8 and 9 stated. Traders are excluded from the purview of this Policy.</p>
<p>Clause 8. The average annual financial turnover of 'The bidder' during the last three years, ending on 31st March of last Financial Year, should be at 80% of the Tender estimated value (or equivalent in foreign currency at the exchange rate prevalent on 'The Relevant Date') as per the annual report (audited balance sheet and profit & loss account) of the relevant period, duly authenticated by a Chartered Accountant/ Cost Accountant in India or equivalent in relevant countries."</p>	<p>Clause 8. The minimum average annual financial turnover of the bidder during the last three years, ending on 31st March of the previous financial year*, should be at least 50% of the Tender estimated value (or equivalent in foreign currency at the exchange rate prevalent on date of tender opening) as per the annual report (audited balance sheet and profit & loss account) of the relevant period, duly authenticated by a Chartered Accountant/ Cost Accountant in India or equivalent in relevant countries."</p> <p>In case the date of constitution / incorporation of the bidder is less than 3-year-old, the average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria.</p> <p><i>*For tenders floated in first two quarters of the financial year of 2023-24, then average annual financial turnover will be considered for last three years, ending on 31st March 2022. For tenders floated in last two quarters of the financial year of 2023-24, then average annual financial turnover will be</i></p>

	<i>considered for last three years, ending on 31st March 2023.</i>
Clause 9. The Bidder should submit a 'Credit Limit Certificate' of at least 110% of the Tender estimated value} (or equivalent in foreign currency at the exchange rate prevalent on 'The Relevant Date') duly certified by a Scheduled Nationalised Bank.	Clause 9. The Bidder should submit a 'Credit Limit Certificate' of at least 60% of the Tender estimated value (or equivalent in foreign currency at the exchange rate prevalent on date of tender opening) duly certified by a Scheduled Commercial Bank as per list issued by RBI from time to time. The credit limit certificate must be valid at the time of tender opening or the date of issuance of credit limit certificate should not be older than twelve (12) months at the time of tender opening.
Clause 10. The net worth of the bidder firm (manufacturer or principal of authorised representative) should not be negative on 31st March of last Financial Year and should have not eroded by more than 30% in the last three year, ending on 31st March of last Financial Year.	Deleted
Added Para	<p>1. Performance Security</p> <p>Within twenty one (21) days from date of the issue of notification of award by the Purchaser/Consignee, the supplier (OEM/Manufacturers), shall furnish performance security to the Purchaser/Consignee for an amount equal to ten percent (10%) of the total value of the contract, valid up to sixty (60) days after the date of completion of all contractual obligations by the supplier, including the warranty obligations, which is initially valid for a period of minimum six months plus number of months under warranty from the date of Notification of Award.</p> <p><u>BG should be submitted by OEM/Manufacturers directly from their bank, duly endorsed by the Scheduled Commercial Bank as per list issued by RBI from time to time.</u></p> <p>2. If EMD/BG validity is short as per tender requirement, a 2 weeks' time from the date of tender opening will be provided to the</p>

	bidder for re-submission/correction of the submitted EMD/BG.
Added Para	<p>3. Tender validity If not mentioned otherwise in the SIT, the tenders shall remain valid for acceptance for a period of 730 days (Seven hundred and thirty days) after the date of tender opening prescribed in the TE document. Any tender valid for a shorter period shall be treated as unresponsive and rejected.</p> <p>4. A Tenderer quoting imported items in INR will have to submit necessary documents like (This clause is applicable for Global tenders only).</p> <ul style="list-style-type: none">a. Declaration confirming that the quoted items would be imported for the intended project (Tender reference number is to be quoted) only.b. Bidder must submit Bill of Entry in the name of the project at the time of pre-dispatch inspection and with initial bill claimed documents. The documents should clearly state the name of the intended Project (Tender reference and/or Project Name) along with the quantities.

Section – XIX

Existing

Consignee List

Sl. No.	Name of Hopsital and Address	Consignee Code	State	Airport	Dry Port/ Seaport
1	The Director, All India Institute of Medical Science, AIIMS-Bhubaneswar, Near BijuPatnaik Police Academy, Village-Sijua, Bhubaneswar- 751019, Orissa	Bhubaneswar	Odisha	KOLKATA	KOLKATA
2	The Director, All India Institute of Medical Science AIIMS, Jodhpur Rajasthan	Jodhpur	Rajasthan	New Delhi	Tughlakabad

Read As

Consignee List

Sl. No.	Name of Hopsital and Address	Consignee Code	State	Airport	Dry Port/ Seaport
1	The Director, All India Institute of Medical Science, AIIMS-Bhubaneswar, Near BijuPatnaik Police Academy, Village-Sijua, Bhubaneswar- 751019, Orissa	Bhubaneswar	Odisha	KOLKATA	KOLKATA
2	The Director, All India Institute of Medical Science AIIMS, Jodhpur Rajasthan	Jodhpur	Rajasthan	New Delhi	Tughlakabad

Section – XIX

For:-

Consignee List

Sl. No.	Tender ID	Name of Hopsital and Address	Consignee Code	State	Airport	Dry Port/ Seaport
1	2023_HLL_154323_1	The Director, All India Institute of Medical Science, AIIMS-Bhubaneswar, Near BijuPatnaik Police Academy, Village- Sijua, Bhubaneswar- 751019, Orissa	Bhubaneswar	Odisha	KOLKATA	KOLKATA
2	2023_HLL_154323_2	The Director, All India Institute of Medical Science AIIMS, Jodhpur Rajasthan	Jodhpur	Rajasthan	New Delhi	Tughlakabad

Read As:-

Consignee List

Sl. No.	Tender ID	Name of Hopsital and Address	Consignee Code	State	Airport	Dry Port/ Seaport
1	2023_HLL_154323_1	The Director, All India Institute of Medical Science, AIIMS-Bhubaneswar, Near BijuPatnaik Police Academy, Village- Sijua, Bhubaneswar- 751019, Orissa	Bhubaneswar	Odisha	KOLKATA	KOLKATA
2	2023_HLL_154323_3	The Director, All India Institute of Medical Science AIIMS, Jodhpur Rajasthan	Jodhpur	Rajasthan	New Delhi	Tughlakabad

Note: If EMD is submitted in the form of BG, then the validity of the BG should be at least 775 days from the date of tender opening.

All other terms and conditions of the tender enquiry remain unaltered