

**Amendment No. 02****Date: 30/11/2019****Sub: Amendment No.02 to the Tender Enquiry Document****Ref: (i) Tender No: HITES/PCD/AIIMS-BBSR/05/19-20 Dated: 18.10.2019****Section I**  
**Notice Inviting Tenders(NIT)**

Tender timeline:

**For:-**

Sl. No.	Description	Schedule
c.	Closing date & time for submission of online bids	30.11.2019, 01:00 PM
d.	Closing date & time for submission of <b>tender processing fee and EMD in physical form*</b>	30.11.2019, 02:00 PM
e.	Time and date of opening of online bids	02.12.2019, 02:30 PM

**Read As**

Sl. No.	Description	Schedule
c.	Closing date & time for submission of online bids	31.12.2019, 01:00 PM
d.	Closing date & time for submission of <b>tender processing fee and EMD in physical form*</b>	31.12.2019, 02:00 PM
e.	Time and date of opening of online bids	31.12.2019, 02:30 PM

**Section VII**  
**Technical Specifications**

Tender Page & Para	TENDER SPECIFICATION	READ AS
Pg 47 Para I.	<b>2. Scope of Work</b> Shielded Medical Cyclotron	Shielded Medical Cyclotron
Pg 47 Para XII.	<b>2. Scope of Work</b> Gases manifold: All target gases for cyclotron operation (including H2 and D2 for ion sources, For C11, N13, F18 production), PET-radiochemistry and QC system etc.	Gases manifold: All target gases for cyclotron operation (including H2 for ion sources, For C11, N13, F18 production), PET-radiochemistry and QC system etc.

Tender Page & Para	TENDER SPECIFICATION	READ AS
Pg 47 Para I.	<p><b>3. Cyclotron Parameter</b></p> <p>A negative ion Cyclotron with at least 18 MeV energy in order to allow production of conventional (F18, 11C, 13N) and non-conventional radioisotopes (I-124, I-123, 64Cu, 89Zr, 86Y) with liquid, gas and solid targets</p>	<p>A negative ion Cyclotron with &gt; <b>16 MeV</b> energy in order to allow production of conventional (F18, 11C, 13N) and non-conventional radioisotopes (I-124, I-123, 64Cu, 89Zr, 86Y) with liquid, gas and solid targets.</p> <p><b>Note: The productions of I-124, Cu-64, Zr-89, Y-86 are planned along with F-18, C-11 and N-13 are for present scope</b></p>
Pg 48 Para II.	<p>The cyclotron should be SELF SHIELDED and housed in a separate room. Operator should also be able to operate all equipment in manual mode for diagnostic and maintenance purpose</p>	<p>The cyclotron should be <b>SHIELDED</b> and housed in a separate room. Operator should also be able to operate all equipment in manual mode for diagnostic and maintenance purpose</p>
Pg 48 Para III.	<p>The cyclotron shall be capable of accelerating protons to an energy <math>\geq 18</math> MeV under completely automated mode with options for semi-automated or manual mode in an appropriate sequence so that the specified quantities of radionuclides in the specified chemical form can be synthesized using suitable radioactive synthesis equipment and precursor materials.</p>	<p>The cyclotron shall be capable of accelerating protons to an energy <math>\geq 16</math> MeV under completely automated mode with options for semi-automated or manual mode in an appropriate sequence so that the specified quantities of radionuclides in the specified chemical form can be synthesized using suitable radioactive synthesis equipment and precursor materials.</p>

Tender Page & Para	TENDER SPECIFICATION	READ AS
Pg 48 Para XI.	The control operations shall include one computer workstation and a backup workstation with online printer. It shall not require any other individual workstation to run each of the major systems or subsystems. The workstation environment shall provide a simple and automated scheme to record, recall and display & graph parameter information. It should be possible to fully control the cyclotron operation from external computer workstation	<b>It should be possible to fully control the cyclotron operation from computer workstation.</b>
Pg 49 Para 4. II.	<b>Target Systems</b> Each target must be fixed at best position. There must be one beam exit port per target, Minimum Two number of exits ports required. All beam exit ports must be equipped with extraction systems.	<b>All beam exit ports must be equipped with extraction systems.</b>
Pg 49 Para 4. VIII.	<b>Target Systems</b> Automated extraction of radionuclide should be in built. All the equipment necessary for Iodine-124 and other radionuclides production must be detailed	Automated extraction of radionuclide should be in built. All the equipment necessary for Iodine-124 and other radionuclides production must be detailed. <b>Hardware and software necessary for successful production in future must be provided.</b>
Pg 50 Para II.	<b>Vacuum System</b> An automated pumping system that can reduce the pressure in the cyclotron vacuum system from 1 Bar to the normal required operating pressure in < 2 hour	An automated pumping system that can reduce the pressure in the cyclotron vacuum system from 1 Bar to the normal required operating pressure in < <b>3 hour</b>

Tender Page & Para	TENDER SPECIFICATION	READ AS
Pg 51 Para 8. I. a.	<p><b>Radiochemistry Synthesis Modules with Suitably Shielded Hot Cells</b> One Synthesis module dedicated to synthesize [18F] FDG. The FDG synthesis must be an automated cassette based system installed in one hot cell with capability of consecutive FDG synthesis without the need to open the hotcell door. The quality control equipment should be selected according to latest version of European Pharmacopoeia. It should be current GMP compliant</p>	<p>One Synthesis module dedicated to synthesize [18F] FDG <b>should be quoted OPTIONALLY and will be considered only if the cassetts and consumables needed for production of FDG is not a proprietary item.</b> The FDG synthesis must be an automated cassette based system installed in one hot cell with capability of consecutive FDG synthesis without the need to open the hotcell door. The quality control equipment should be selected according to latest version of European Pharmacopoeia. It should be current GMP compliant. <b>However, if it is not purchased due to proprietary consumables, all cables/wires/additional arrangement must be done for smooth installation of third party synthesis module</b></p>

Tender Page & Para	TENDER SPECIFICATION	READ AS
Pg 51 Para 8. I. b.	<p><b>Radiochemistry Synthesis Modules with Suitably Shielded Hot Cells</b></p> <p>Second module should be general purpose nucleophilic synthesis module installed in another hot cell, for all other [F-18] radiopharmaceuticals like FLT, FET, FMISO, FAZA, FES, FDOPA etc. produced by nucleophilic substitutions. The module should integrate all necessary steps of production of [18F] based tracers, viz., Trapping of 18F-, nucleophilic substitution, semi prep HPLC hydrolysis, purification and formulation and all production steps should be fully automated. It should be current cGMP compliant.</p>	<p>Second module should be general purpose nucleophilic synthesis module installed in another hot cell, for all other [F-18] radiopharmaceuticals like FLT, FET, FMISO, FAZA, FES, FDOPA etc. produced by nucleophilic substitutions. The module should integrate all necessary steps of production of [18F] based tracers, viz., Trapping of 18F-, nucleophilic substitution, semi prep HPLC hydrolysis, purification and formulation and all production steps should be fully automated. It should be current cGMP compliant.</p> <p><b>All cassettes/consumables required in the modules must be non-proprietary items.</b></p>
Pg 51 Para 8. II.	<p><b>Radiochemistry Synthesis Modules with Suitably Shielded Hot Cells</b></p> <p>One suitably shielded synthesis module for making C-11 radiopharmaceuticals using the methylation using methyl iodide (CH<sub>3</sub>I) route. The module should be compatible with either [11C]-CO<sub>2</sub> or [11C]-Methane from the cyclotron target. The production of methyl iodide (CH<sub>3</sub>I) should be through iodine vapour route.</p>	<p><b>Automated Synthesis Unit for production of [C-11] based PET tracers. All cassettes/consumables required in the modules must be non-proprietary items.</b></p>

Tender Page & Para	TENDER SPECIFICATION	READ AS
Pg 52 Para 9. I.	<b>Cyclotron and Hot Lab Accessories (with details of Make and Model):</b> All gases required for operation of the cyclotron (Helium, Argon, Hydrogen, Nitrogen, Neon etc. with suitable purity levels). All types of required regulators, cylinders and gas pipes should be provided. The gas cylinder supplied should have approval of Indian Commissioner of Explosives.	All gases required for operation of the cyclotron (Helium, Argon, Hydrogen, Nitrogen, Neon etc. with suitable purity levels). All types of required regulators, cylinders and gas pipes should be provided. The gas cylinder supplied should have approval of Indian Commissioner of Explosives. <b>Note: All gases needed has to be provided for warranty period and should detailed the name and contacts of third party supplier if needed in future</b>
Pg 52 Para 9. VII.	<b>Cyclotron and Hot Lab Accessories (with details of Make and Model):</b> Quality Control equipment for Endotoxin Tests and Sterility Tests on site shall be offered including the respective enclosures.	Quality Control equipment for Endotoxin Tests and Sterility Tests on site shall be offered including the respective enclosures. <b>OPTIONAL</b>
Pg 54 Para IX.	Consumables: Vendor shall provide all the all target materials/ gases/ consumables needed for FDG synthesis / consumables needed for doing QC/ lab-ware including glass ware, chemicals, tool kits, chilling material for chiller etc. for TWO Years. For this purpose, it is assumed that for FDG synthesis at least 250 runs of cyclotron will be done per year to yield adequate quantity of F-18. 100 runs of cyclotron for <sup>13</sup> NH <sub>3</sub> , and 50 runs for C-11 radiopharmaceuticals in one year should be considered. All formalities regarding custom clearance of consumables will be the responsibility of the vendor.	Consumables: Vendor shall provide all target materials/ gases/ consumables needed for FDG synthesis / consumables needed for doing QC/ lab-ware including glass ware, chemicals, tool kits, chilling material for chiller etc. for <b>ONE Year</b> . For this purpose, it is assumed that for FDG synthesis at least 250 runs of cyclotron will be done per year to yield adequate quantity of F-18. <b>All formalities regarding custom clearance of consumables will be the responsibility of the vendor.</b>

Tender Page & Para	TENDER SPECIFICATION	READ AS
Pg 58 Para V.	<b>Scope of Turnkey</b> Total area to be constructed for entire building (Cyclotron bunker, radiopharmacy lab, PET-CT and isolation ward) is 13500 square feet (ground floor 8000 and first floor 5500 sqft). Note: Total 13500 square feet will be closed area	Total area to be constructed for entire building (Cyclotron bunker, radiopharmacy lab, PET-CT and isolation ward) is 13500 square feet (provisionally ground floor 8000 and first floor 5500 sqft). Note: Total 13500 square feet will be closed area. <b>However, the internal arrangement may change if cyclotron has to be placed in the basement.</b>
Pg 58 Para X. b)	Currently two floors ( <b>ground floor and + 1</b> ) need to be constructed.	Currently two floors need to be constructed.
Pg 58 Para X. c)	The cyclotron room outer walls should be of RCC. The cyclotron should be housed in a bunker <b>in the ground floor of the building</b> as per AERB norms.	The cyclotron room outer walls should be of RCC. The cyclotron should be housed in a bunker as per AERB norms
Pg 58 Para X. d)	Radiopharmacy laboratory adjoining the cyclotron (Must be GMP Complaint) and PET-CT area should be in the ground floor.	<b>Provisionally</b> Radiopharmacy laboratory (Must be GMP Complaint) and PET-CT area should be in the ground floor. <b>The internal arrangement may change according to site of cyclotron installation</b>
Pg 59 Para X. g)	Six isolation rooms for radionuclide therapy, Nursing station, dose administration area, housekeeping rooms, committee room, seminar room with all other amenities (toilets) etc. <b>on the first floor of building excluding bunker area.</b>	Six isolation rooms for radionuclide therapy, Nursing station, dose administration area, housekeeping rooms, committee room, seminar room with all other amenities (toilets) etc.
Pg 59 Para X. i)	Necessary lifts should be provided from Ground Floor to 1st Floor as per standard.	Necessary lifts should be <b>quoted optionally</b> from Ground Floor to 1st Floor as per standard. <b>However, for cyclotron placed in basement, lift is not required</b>

Tender Page & Para	TENDER SPECIFICATION	READ AS
Pg 59 Para XIII.	Timeline to complete construction of building should be maximum 12 months after getting AERB approval. Maximum time of 6 months can be considered for cyclotron installation. However, the entire project (construction and installation) should run in overlapping mode and maximum time for total project after AERB approval of site and layout must be 12 months	Timeline to complete construction of building should be maximum 12 months after getting <b>layout approval from AERB</b> . Maximum time of 6 months can be considered for cyclotron installation. However, the entire project (construction and installation) should run in overlapping mode and maximum time for total project after AERB approval of site and layout must be 12 months
Pg 59 Para XVI. 1.	<b>Civil work (scope of work):</b> 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.	Leveling and lowering the ground excavation in <b>all</b> 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.
Pg 61 Para 25.	There should be Access control for doors in the cyclotron facility and cyclotron vault	There should be Access control for doors in the cyclotron facility and cyclotron vault <b>for six persons</b>

**All other terms and conditions of the tender enquiry remain unaltered**