

**Procurement of National Center for Production of Positron Radiopharmaceuticals and two PET/CT camera with associated equipment, design, construction works, installation, fitting (turnkey) and commissioning No. IOP/40-2021/RD**

**AMENDMENT No. 2 TO TENDER DOCUMENTS  
Issued on August 12th, 2021**

Public Investment Management Office, No. 11 Nemanjina street, the Republic of Serbia, as the Employer, hereby notifies all persons concerned for procurement procedure: Procurement of National Center for Production of Positron Radiopharmaceuticals and two PET/CT camera with associated equipment, design, construction works, installation, fitting (turnkey) and commissioning No. IOP/40-2021/RD, that there has been an amendment made in the Tender Documents, in accordance with the Tender Documents, point 8. Amendment of bidding Document, Part I-Bidding Procedures, Section I-instructions to Bidders, as follows:

**1. Tender Documents, Part I-Bidding Procedures, Section II – Proposal Data Sheet, Point C. Preparation of Proposals, provisions ITB 22.2, that reads as follows:**

The Bidder must submit:

- (a) Technical Proposal: one (1) original and two (2) copies in hardcopy for as well as 1 (one) CD ROM;
- (b) Price Proposal: one (1) original and two (2) copies in hardcopy as well as 1 (one) CD ROM,

**has been changed and now reads as follows:**

"The Bidder must submit:

- (a) Technical Proposal: one (1) original and one (1) copies in hardcopy for as well as 1 (one) CD ROM;
- (b) Price Proposal: one (1) original and one (1) copies in hardcopy as well as 1 (one) CD ROM."

**2. Tender Documents, Part I-Bidding Procedures, Section III – Evaluation and Qualification Criteria, THE CRITERIA AND THE MANNER OF EVALUATION (SCORING) THE PROPOSALS, part 2. Qualification Requirements, point 2.4 Financial Requirements, that reads as follows:**

2.4 Financial requirements:

Bidders must meet the following requirements:

The Bidder's total annual turnover over the last 3 financial years closed (2017, 2018 and 2019) must be at least 20,000,000.00 (twenty million) EUR

Evidence:

- Balance sheets or BON JN (issued by the Serbian Business Registers Agency (SBRA) for a company established in the employer's country)

This requirement Bidders can meet individually or cumulatively, through at least one of the members in a joint venture/consortium.

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**3. Tender Documents, Part I-Bidding Procedures, Section III – Evaluation and Qualification Criteria, THE CRITERIA AND THE MANNER OF EVALUATION (SCORING) THE PROPOSALS, part 2. Qualification Requirements, point 2.6 Servicing capacity, sub-point A, that reads as follows:**

A. For servicing the equipment in position 1

Condition:

- 1) Two certified maintenance persons employed on a full-time basis with a local servicing organisation or with a sourced external service, whether local or foreign or engaged for work (work outside the employment relationship) on a temporary and periodical job/purchase order contract/supplementary work with the local servicing organization or with a sourced external service, whether local or foreign on the day of tender opening for the cyclotron model on offer.

Evidence:

- 1)- Photocopies of a certificate issued by the manufacturer of equipment for servicing the cyclotron model on offer;

- the copy of the M form or other evidence in accordance with the law of the country in which they are established (such as a valid executed contract or employment agreement with the current company or an employment verification letter from an employer that includes the employee's dates of employment, job title) for the persons employed with the local servicing organization or with a sourced external service, whether local or foreign on the day of publication of the procurement notice or the copy of a valid contract of engagement for work (work outside the employment relationship) with the local servicing organization or with a sourced external service, whether local or foreign on the day of tender opening.

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"A. For servicing the equipment in position 1  
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Evidence:

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4. **Tender Documents, Part I-Bidding Procedures, Section III – Evaluation and Qualification Criteria, THE CRITERIA AND THE MANNER OF EVALUATION (SCORING) THE PROPOSALS, part 2. Qualification Requirements, point 2.5 Personnel, Table - For preparing project documentation, (point 3.), that reads as follows:**

Personnel specialised in architectural design, graduate architects – responsible designer (2) no. 310 licence

**has been changed and now reads as follows:**

"Personnel specialised in civil engineering, graduate civil engineers – responsible designer (2) no. 310 licence"

5. **Tender Documents, Part I-Bidding Procedures, Section IV – Bidding Forms, part- Technical Proposal, part-Technical specification:**

**point 2. SPECIFICATIONS OF THE PET/CT CAMERA THAT WILL BE INSTALLED IN THE CLINICAL CENTRE OF SERBIA – SUBMITTED WITH THE TECHNICAL PROPOSAL, sub-point**

**2.1. Conformity with the technical requirements  
and**

**point 3. SPECIFICATIONS OF THE PET/CT CAMERA TO BE INSTALLED AT THE INSTITUTE FOR ONCOLOGY OF VOJVODINA – SUBMITTED WITH THE TECHNICAL PROPOSAL, sub-point 3.1. Compliance with the technical requirements, text in the table that reads as follows:**



No.	Description/specification		
		Technical specification offered	Reference to Technical documentation
<b>1.</b>	<b>Patient table:</b>		
1.1	Patient table with 220kg load, adjustable height, with movement controlled by the console.		
1.2	Scan range for hybrid acquisition (horizontal movement) min. 200 cm		
1.3	Laser system for orthogonal settlement		
1.4	Accessories related to the positioning and immobilization of the patient: mattress for patient table, extension for patient table head and armrests, knee support, fixation belts, PET / CT phantom positioning holder, a pediatric patient positioning kit		
1.5	Audio system for communication with the patient (between the control room and the exam room)		
<b>2</b>	<b>Main physical and technical characteristics, acquisition, processing and reconstruction:</b>		
2.1	Gantry opening diameter min. 70 cm		
2.2	Extended Field of View for attenuation correction at least 70 cm		
2.3	PET detector sensitivity according to NEMA NU2-2012 minimum 8.0 cps/kBq		
2.4	The width of the field of view of the PET scanner in the axial direction is at least 15 cm		
2.5	Automatic correction of random and scattered coincidences (PET)		
2.6	PET iterative reconstruction algorithms 3D-OSEM with variable point spread function (PSF)		
2.7	PET reconstruction technology to improve 2 times PET quantitation accuracy and SNR		
2.8	PET acquisition options: static, dynamic, whole-body, respiratory triggered acquisition, forming retrospective histograms and summarizing multiple acquisition cycles, list mod		
2.9	PET deviceless digital respiratory gating technology or Infrared based respiratory motion tracking – fully integrated into the clinical workflow.		
2.10	The number of CT reconstructed slices at one rotation is at least 32, at the total effective length of the detector line in an isocenter equal or greater than 20 mm		
2.11	The maximum time required to perform one rotation of		

	the X-ray tube-CT detector system is 0.5s		
2.12	Achievable CT cross-sectional thickness at spiral acquisition 0.625 mm or less		
2.13	High contrast CT resolution at least 15.0 lp/cm (at 10% MTF) or better		
2.14	CT automatic exposure control with combined modulation		
2.15	CT iterative reconstruction technology for patient dose reduction		
2.16	Simultaneous acquisition and processing		
2.17	CT kV range for radiography: 80 - 140 kV or wider		
2.18	maximum mA: at least 400 mA without equivalents values		
2.19	Possibility to perform CT studies with monitoring of bolus contrast agent (bolus tracking)		
<b>3</b>	<b>Diagnostic Server Workstation characteristics:</b>		
3.1	One (1) Diagnostic Client-server architecture with three (3) client workplaces		
3.2	Simultaneous operation of at least 3 clients/working places for advanced post processing.		
3.3	Clients computers with medical DICOM calibrated monitors with screen diagonal of at least 24 inches		
3.4	Remote server access with FULL ability to analyze and review studies		
3.5	Dynamic licenses distribution between clients (floatable licenses)		
3.6	Server image database storage, at least 2 TB		
3.7	Server must be equipped with the following permanent (unlimited time of use) licenses:		
3.8	Software package for processing, evaluation and interpretation of oncology PET / CT studies, at least three licenses		
3.9	Display of all images (corrected and uncorrected PET and CT images), projection images of maximum intensity in cinemode (rotating MIP), at least three licenses		
3.10	Fusion of PET and CT images, at least three licenses		
3.11	Multimodality Fusion package (image fusion between CT and MR, SPECT, PET), at least three licenses		
3.12	The following options: rotation, inverting, scrolling, zooming, annotations, measuring distances and angles, evaluation of regions and volumes of interest in 2D and		

	3D (ROI / VOI) including advanced smutting algorithms, adjusting the intensity and contrast of the PET image, at least three licenses		
3.13	Cursor correlation on different images (PET, CT and fusion images), at least three licenses		
3.14	Tools for quantification of Radiopharmaceutical download (SUVmax, SUV peak, TLG), at least three licenses		
3.15	Possibility of displaying all reforms: VRT (Volume rendering), MIP (projection images of the maximum intensity) thick / thin, MPR (multiplanar reconstruction), SSD, at least three licenses		
3.16	Possibility of adaptation and optimization of co-registered images, at least three licenses		
3.17	Software for quantitative processing of functional brain images by comparison with a database of healthy individuals, at least one license		
3.18	Automatic spatial normalization and the ability to mark 3D regions of interest (3D ROI)		
3.19	Quantification of glucose metabolism in nerve tissue based on voxels and 3D ROI, at least one license		
3.20	Software for creating your own database of normal values of functional images for various brain parameters function (RCBF, metabolism, amyloid imaging), at least one license		
<b>4</b>	<b>Hardware and software for quality control of PET/CT devices:</b>		
4.1	Set of 2 (two) phantoms (Ge-68 radioactive sources) for device calibration and daily quality control procedures.		
4.2	A set of phantoms from the NEMA test kit (for assessment of the spatial resolution, the influence of scattered and accidental coincidences, the sensitivity and quality of the medical image) for both the PET and CT component of the hybrid model device on offer		
4.3	A PET/CT phantom (PET NEMA 2012/IEC 2008) for (primarily) evaluation of the quality of a reconstructed PET medical image, and a more precise assessment of relation between count rate and applied patient dose		
4.4	A "whole-body" anthropomorphic phantom in the form of a torso, with inserts for the lungs, liver, spine, heart, breasts and spherical shells for simulating solid tumors, and the attendant analysis software		
4.5	The latest version of the quality control software (for the PET and CT components of the hybrid device model on offer) at the moment of delivery		



<b>5</b>	<b>Additional equipment:</b>		
5.1	Lead apron - 0.50 mm Pb protection - Frontal shield, 3 pcs.		
5.2	Lead apron - 0.50mm Pb protection Vest + Skirt, 2 pcs.		
5.3	Thyroid Collar - 0.50 mm Pb protection, 5 pcs.		
5.4	Gonad Shield - 0.50 mm Pb protection, 5 pcs.		
5.5	Gloves (pair) - 0.50 mm Pb protection, 5 pcs.		
5.6	Eyewear - 0.75mm Pb front and side protection, 5 pcs.		
5.7	PET Mobile Shield - 10 cm thick lead glass view port		
5.8	L Shield - Lead Thickness: 3.6 cm		
5.9	Syringe Shield - tungsten with 1,25 cm lead equivalency, 5cc, 2 pcs		
5.10	Universal Vial Shield - 2,5 cm Lead Equivalent, Tungsten Lead, Holds 10, 20 and 30cc Vials		
5.11	Rotund Container -24.5 mm lead shielding 44.5 mm lead equivalent on all sides		
5.12	Transporter II for PET - 0,3 cm lead on the top, bottom, front and back		
5.13	Lead Container - 1,25 cm lead walls;		
5.14	PET S Container Shield - Lead Lining: 2.5 cm		
5.15	Dose Calibrator PET		
5.16	Radiation monitor		
5.17	Contamination monitor		
5.18	Multichannel stationary system for radiation control ( 3 detectors)		
5.19	Electronic personal dosimeter, 5 pcs		
5.20	Semi-automatic Radiopharmaceutical Multidose Injector (Dispensing and Injection)		
5.21	Automatic Radiopharmaceutical Multidose Injector (Dispensing and Injection)		
5.22	An automatic system (robot) for burning disk and gluing label stickers		
5.23	Colour laser printer for printing images from PET/CT devices		
5.24	A laptop computer serving the needs of semi-automatic separation of administrative activities and quality control		
5.25	An injector for CT contrast		
5.26	A smart UPS of suitable capacity and with the possibility of connecting at least three workstations and all the		

	components of the server system for archiving		
5.27	A device for measuring Ambiental temperature and humidity		
6	<b>Additional services that the Bidder should provide:</b>		
6.1	The Bidder shall be obligated to submit to the Client, within the envisaged deadline, the technical-technological requirements for preparing the space for the installation of a PET/CT camera		
6.2	Installing the PET/CT scanner and the attendant equipment		
6.3	Fully implementing and documenting the results of status tests for the device delivered, in accordance with the NEMA Nu2-2007 standard and the manufacturer's instructions		
6.4	Providing training for the use of the device, to be conducted by a manufacturer's specialist in dedicated software applications at the Client's institution (the Clinical Centre of Serbia), lasting 15 working days overall, in three phases, over a period of 6 months from the date of installation – in agreement with the user		
6.5	Organising and financing, immediately after concluding the Contract, the training of nine people of various profiles (3 doctors, 3 technicians, 2 engineers and a physicist) lasting at least 5 working days for each participant, at the institution where the PET/CT device on offer or better, is used		
7	<b>Guarantee period, servicing and maintenance:</b>		
7.1	The guarantee period for the entire system (including additional equipment): 18 months		
7.2	A certified servicer (employed with a local servicing organisation or based on a temporary service agreement/contract of performing temporary or occasional jobs/additional work) for the PET/CT device model on offer		
7.3	At least one certified servicer for the maintenance of nuclear medicine devices (the PET, SPECT systems), employed with a local servicing organisation or based on a temporary service agreement/contract of performing temporary or occasional jobs/additional work		
7.4	Service response: up to 4 h (within the warranty period, from the moment of receipt of the written request, which could be sent from 8 a.m. to 2 p.m. during working days)		
7.5	The guarantee presupposes preventive maintenance of PET/CT devices on a monthly basis		
7.6	Uptime during the guarantee period: 95 % (this pertains to the whole system that is the subject of procurement,		



	from 8 a.m. to 5 p.m. on working days)		
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2.18	maximum mA: at least 400 mA without equivalents values		
2.19	Possibility to perform CT studies with monitoring of bolus contrast agent (bolus tracking)		
2.20	PET reconstructed resolution transverse (i.e. transaxial) at 1cm-max 3.0 mm		
2.21	PET detector in-field upgradable to Axial FOV min 25 cm with NEMA sensitivity min. 20 cps/kBq		
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7.5	The guarantee presupposes preventive maintenance of PET/CT devices on a monthly basis		
7.6	Uptime during the guarantee period: 95 % (this pertains to the whole system that is the subject of procurement, from 8 a.m. to 5 p.m. on working days)		

In all other aspects, Tender Documents for the procurement procedure: Procurement of National Center for Production of Positron Radiopharmaceuticals and two PET/CT camera with associated equipment, design, construction works, installation, fitting (turnkey) and commissioning No. IOP/40-2021/RD, remains unchanged.

This Amendment to Tender Documents, is the part of the Tender Documents and will be posted on the

Employer's web site: <http://www.obnova.gov.rs/english/public-procurement> and <http://www.obnova.gov.rs/cirilica/iavne-nabavke>

In order to submit a responsive proposal, tenderers are expected to prepare their proposals in accordance with this amendment.

Procurement Commission

