

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. 5 TO TENDER DOCUMENTS
Issued on September 3rd, 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 have been the amendments 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. There has been an amendment made in the Tender Documents, **in introductory provisions of the Tender Documents, point 9. and in the Part I - Bidding Procedures, Section II - Proposal Data sheet, Point D. Submission and Opening of Proposals, provisions ITB.23.1 and ITB.26.1**, in accordance with the Tender Documents, point 8. Amendment of bidding Document, Part I - Bidding Procedures, Section I - Instructions to Bidders, that reads as follows:

- Upon the amendment of the Tender documents made later than fifteen (15) days prior to deadline for submission of the proposals, the Employer **extends the deadline for submission of proposals**. In that sense, **in introductory provisions of the Tender Documents, point 9. regarding the deadline for submission of proposals and the date of bid opening (technical proposals)**, has been changed and now reads as follows:

" 9. Proposals must be delivered to the address below on or before **September 17, 2021** not later than 11 a.m. by local time. Electronic bidding will not be permitted. All bids must be delivered in closed envelopes marked with the reference „IOP/40-2021/RD – Proposals from eligible Bidders for 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, Kancelarija za upravljanje javnim ulaganjima”, at the address: Nemanjina street no. 22-26, Belgrade, Administration for Joint Services of the Republic Bodies registry.

Bids received after the above-mentioned deadline shall be declared late, rejected and returned unopened to the bidder (upon request submitted by the bidder).

The bid opening (the technical proposals) shall take place at the address: Krunska street no. 58, Ground Floor, Belgrade, on **September 17, 2021** at 11.30 a.m. local time.

Opening of the bids is public and any interested person may be present. Only authorised representatives of Bidder's may be actively involved in the procedure of opening bids.

Opening of the price part of the tenders shall be performed after the examination of the technical part of the proposals. The Employer shall submit, to all tenderers who sent bids, a reasoned Decision on the qualification of the tenderer, as well as an invitation to all qualified tenderers to

participate in the opening of price proposals.”

- In the Tender Documents, **Part I - Bidding Procedures, Section II - Proposal Data sheet, Point D. Submission and Opening of Proposals**, provisions ITB.23.1 and ITB.26.1, have been changed and now read as follows:

”ITB 23.1: For **Proposal submission purposes** only, the Employer’s address is:
Attention: **Administration for Joint Services of the Republic Bodies**

registry

Street Address: **no. 22-26, Nemanjina street,**
City: **Belgrade**
ZIP/Postal Code: **11000**
Country: **The Republic of Serbia**

The deadline for proposal submission is:
Date: **September 17, 2021**
Time: **not later than 11 a.m. by local time**

ITB 26.1: The proposal opening of Technical Proposals shall take place at:
Street Address: **no. 58, Krunska street**
City: **Belgrade**
ZIP/Postal Code: **11000**
Country: **The Republic of Serbia**
Date: **September 17, 2021**
Time: **11.30 a.m. by local time.”**

2. Tender Documents have been changed in the part **regarding the locations for installation and use of the two cameras for positron emission tomography/computed tomography (PET/CT)** that are procured under this tender procedure, **so that instead of the Clinical Center of Serbia and the Institute for Oncology of Vojvodina, the new locations for installation and use of the two cameras for positron emission tomography/computed tomography (PET/CT) are:**

The University Clinical Center Niš in Niš and the Clinical Center of Vojvodina in Novi Sad.

Accordingly, the text in the Tender documents regarding the locations for installation and use of the two cameras for positron emission tomography/computed tomography (PET/CT) that are procured under this tender procedure, instead of: **”The Clinical Centre of Serbia and the Institute for Oncology of Vojvodina”, should be read as: ”The University Clinical Center Niš in Niš and the Clinical Center of Vojvodina in Novi Sad”** and therefore the following parts of the Tender documents have been changed and now read as follows:

- **Section IV – Bidding Forms, Letter of Price Proposal, point (d):**

”(d) Proposal Price: The total price of our Proposal, excluding any discounts offered in item (e) below is:

no	Name	Quantity	Price
1	The National Centre for the Production of Positron Radiopharmaceuticals, with the attendant equipment, design and works on the construction of the facility, installation and outfitting (the “turnkey” system)	1	
2	Delivery and installation of camera for positron emission tomography/computed tomography (PET/CT) at the University Clinical Center Niš in Niš	1	
3	Delivery and installation of camera for positron emission tomography/computed tomography (PET/CT) at the Clinical Center of Vojvodina in Novi Sad	1	
PRICE (excluding VAT)			
VAT ____% :			
PRICE (including VAT):			

NOTE: Garant period is: _____ (minimum 18 months).”

- **Section IV – Bidding Forms, Schedule of prices, PRICE SCHEDULE - SHOULD BE SUBMITTED WITH THE PRICE PROPOSAL, Column: Description of items in rows no. 12 and 13:**

12	PET/CT at the University Clinical Center Niš in Niš with all related services and additional equipment (turnkey)
13	PET/CT at the Clinical Center of Vojvodina in Novi Sad with all related services and additional equipment (turnkey)

- **Section IV – Bidding Forms, Technical Proposal, Technical specifications, the titles**

of the points 2. and 3:

" 2. SPECIFICATIONS OF THE PET/CT CAMERA THAT WILL BE INSTALLED IN THE UNIVERSITY CLINICAL CENTER NIŠ IN NIŠ – SUBMITTED WITH THE TECHNICAL PROPOSAL

3. SPECIFICATIONS OF THE PET/CT CAMERA TO BE INSTALLED IN THE CLINICAL CENTER OF VOJVODINA IN NOVI SAD – SUBMITTED WITH THE TECHNICAL PROPOSAL"

- **Section IV – Bidding Forms, Technical Proposal, Technical specifications Point 2.** SPECIFICATIONS OF THE PET/CT CAMERA THAT WILL BE INSTALLED IN THE UNIVERSITY CLINICAL CENTER NIŠ IN NIŠ – SUBMITTED WITH THE TECHNICAL PROPOSAL, sub-point 2.1. Conformity with the technical requirements, text in the table under No. 6.4 for Additional services that the Bidder should provide:

No.	Description/specification		
		Technical Specification Offered	Reference to Technical Documentation
6.	Additional services that the Bidder should provide:		
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 (University Clinical Center Niš in Niš), lasting 15 working days overall, in three phases, over a period of 6 months from the date of installation – in agreement with the user		

- **Section IV – Bidding Forms, Technical Proposal, Technical specifications Point 3.** SPECIFICATIONS OF THE PET/CT CAMERA TO BE INSTALLED AT THE CLINICAL CENTER OF VOJVODINA IN NOVI SAD – SUBMITTED WITH THE TECHNICAL PROPOSAL, sub-point 3.1. Compliance with the technical requirements, text in the table under No. 6.4 for Additional services that the Bidder should provide:

No.	Description/specification		
		Technical Specification Offered	Reference to Technical Documentation
6.	Additional services that the Bidder should provide:		
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 (Clinical Center of Vojvodina in Novi Sad), lasting 15 working days overall, in three phases, over a period of 6 months from the date of installation – in agreement with the user		

- **Section VII- Employer's Requirements, Scope of Supply of Plant and Installation Services by the Contractor, Introduction, the last paragraph:**

" The procurement, installation and use of two additional modern PET/CT cameras (one at the University Clinical Center Niš in Niš and at the Clinical Center of Vojvodina in Novi Sad each) would significantly increase the capacity of the existing PET diagnostic centres, and Serbia would get closer to the accepted standard for the necessary number of PET cameras in relation to the number of inhabitants."

- **Section X – Contract Forms, Appendix 5, Scope of Works and Supply by the Employer, the second paragraph:**

" The Employer shall be obliged, within 90 days from the date of submission of technical and technological requirements by the Contractor and in accordance with them, to prepare the facility for the installation and commissioning of PET/CT cameras in the University Clinical Center Niš in Niš and at the Clinical Center of Vojvodina in Novi Sad. In the event that the Employer fails to prepare the facility within the specified deadline, the deadline for completion of the task referred to in Appendix 4 shall be extended for the number of days of exceeding the deadline for the preparation of the premises."

3. 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 UNIVERSITY CLINICAL CENTER NIŠ IN NIŠ – 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 IN THE CLINICAL CENTER OF VOJVODINA IN NOVI SAD – 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		
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		Technical specification offered	Reference to Technical documentation
1.	Patient table:		
1.1	Patient table with min. 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)		
2	Main physical and technical characteristics, acquisition, processing and reconstruction:		
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 (or newer version) 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 compared to OSEM reconstruction		
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—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 \pm 5%		

2.11	The shortest time required to perform one full rotation of a CT detector system with an X-ray tube is maximum 0.5 sec		
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)		
2.20	PET reconstructed resolution transverse (i.e. transaxial) at 1cm-max 3.4 mm		
2.21	PET detector in-field upgradable to Axial FOV min 25 cm with NEMA sensitivity min. 20 cps/kBq		
3	Diagnostic Server Workstation characteristics:		
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		
4	Hardware and software for quality control of PET/CT devices:		
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		
5	Additional equipment:		
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 or automatic printing of labels.		
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	Additional services that the Bidder should provide:		
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 (University Clinical Center Niš in Niš/ Clinical Center of Vojvodina in Novi Sad), 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	Guarantee period, servicing and maintenance:		
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)		

has been changed and now reads as follows:

No.	Description/specification	Technical specification offered	Reference to Technical documentation
1.	Patient table:		
1.1	Patient table with min. 220kg load, adjustable height, with movement controlled by the console.		
1.2	Scan range for hybrid acquisition (horizontal movement) min. 195 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)		

2	Main physical and technical characteristics, acquisition, processing and reconstruction:		
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 (or newer version) minimum 6.3 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 reconstructed technology to improve 2 times PET signal-to-noise ratio (SNR) to support identification of small lesions		
2.8	PET acquisition options: static, dynamic, whole-body, respiratory triggered acquisition, forming retrospective histograms and summarizing multiple acquisition cycles, list mode		
2.9	PET deviceless digital respiratory gating technology or software and hardware for respiratory gated list mod acquisition and reconstruction for organ motion visualization - 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 19 mm		
2.11	The shortest time required to perform one full rotation of a CT detector system with an X-ray tube is maximum 0.6 sec		
2.12	Achievable CT cross-sectional thickness at spiral acquisition 0.625 mm or less		
2.13	High contrast CT resolution at least 14.0 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 - 130 kV or wider		
2.18	maximum mA: at least 345 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 3.4 mm		
2.21	PET detector in-field upgradable to Axial FOV min 22 cm with NEMA sensitivity min. 11 cps/kBq		
3	Diagnostic Server Workstation characteristics:		
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), 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 (metabolism, amyloid imaging), at least one license		
4	Hardware and software for quality control of PET/CT devices:		
4.1	Set of 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		
5	Additional equipment:		
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	Additional services that the Bidder should provide:		
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 (University Clinical Center Niš in Niš/ Clinical Center of Vojvodina in Novi Sad), 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	Guarantee period, servicing and maintenance:		
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)		

4. Tender Documents have been changed in the part **Section III – Evaluation and Qualification Criteria, Point 2. Qualification Requirements, sub-point 2.5 Personnel** so that the sub-point 2.5 Personnel now reads as follows:

"2.5 Personnel

The Bidder shall provide minimum personnel employed with the Bidder **on the day of publication of the procurement notice or on the day of tender opening** on a full-time or part-time basis for the key positions mentioned in the tables below that meet the following requirements:

For preparing project documentation				
No.	Position	Number	Licence, ONLY for a COMPANY established in the EMPLOYER 'S COUNTRY	Documentation Required
1	Personnel specialised in electrical engineering (low-voltage currents), graduate electrical engineers – responsible designer	2	352 or 353 licence	<p>Bidder must provide evidence, in accordance with the law of the country in which they are established, that they fulfil the mentioned requirements.</p> <p>For the Bidders from the Employer's Country the evidences are documents as specified below:</p> <ul style="list-style-type: none"> - photocopies of valid licences issued by the Serbian Chamber of Engineers, - photocopies of licences issued by the Ministry of Internal Affairs.
2	Personnel specialised in mechanical	2	no. 330 licence	- a copy of the M form for the employees: be it on a full-time or part-time basis.

	l engineerin g, graduate mechanica l engineers – responsibl e designer			The licences required within this requirement will be sought only from the successful Bidder and the successful Bidder will be given a sufficient time from the day award decision becomes final to provide those licenses and will not be penalized for any delay in issuance of licences not caused by the successful Bidder.
3	Personnel specialised in civil engineering, graduate civil engineers – responsible designer	2	no. 310 licence	The procedure for licenses issuing is described on the Serbian Ministry of construction, transport and infrastructure web site https://www.mgsi.gov.rs/cir/aktuelnosti/izdavanje-licnih-licenci-za-inzenjere-arhitekta-i-prostorne-planere and https://www.mgsi.gov.rs/en/aktuelnosti/ministrys-announcement-regarding-issuance-licenses-engineers-architects-and-spatial .
4	Personnel specialised in civil engineering, graduate civil engineers – responsible designer	2	no. 314 licence, or one contractor with a no. 313 licence and one with a no. 314 licence	The procedure for issuing of the license for producing the main project for protection against fire and a licence for designing and realising special systems and measures for protection against fire is described on the Serbian Ministry of Internal Affairs web site: http://prezentacije.mup.gov.rs/svs/2013-02-03%20polaganje%20strucnog%20ispita.html The procedure for personnel licenses issuing should be in accordance with Law on Regulated Professions and Acknowledgment of Professional Qualifications (Official Gazette 66/2019).
5	Personnel with a BSc degree specialized for protection against fire	1	licence issued by the Ministry of Internal Affairs for producing the main project for protection against fire and a licence for designing and realising special systems and measures for	Tenderers shall, in the performance of their works, in accordance with the type and nature of the works to be performed under this contract, comply with all applicable laws and by-laws of the Republic of Serbia, as long as it is aligned with the EIB Guide to Procurement.

			protection against fire	
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For performing the works contracted				
No	Position	Number	Licence, ONLY for a COMPANY established in the EMPLOYER 'S COUNTRY	Documentation Required
1	Personnel responsible contractor for building constructions and building-craftsmanship work on high-rise, civil engineering and hydraulic engineering facilities	2	410 licence	<p>Bidder must provide evidence, in accordance with the law of the country in which they are established, that they fulfil the mentioned requirements.</p> <p>For the Bidders from the Employer's Country the evidences are documents as specified below:</p> <ul style="list-style-type: none"> - photocopies of valid licences issued by the Serbian Chamber of Engineers, - a certificate of passed state exam for health and safety coordinating during construction works (Stručni ispit za obavljanje poslova koordinatora za izvođenje radova) issued by Ministry of Labour, Employment, Veteran and Social Affairs. Detailed description for this exam certification is given at the link: https://www.minrzs.gov.rs/lat/strucni-ispit-za-obavljanje-poslova-k5794ab2467d22.html - a copy of the M form for the employees: be it on a full-time or part-time basis.
2	Personnel responsible contractor for hydro-technical facilities and water supply and sewage systems installation	2	no. 414 licence, or one contractor with a no. 413 and one with a no. 414 licence	

3	Personnel responsible contractor for building constructions and building-craftsmanship work specialised in thermal engineering, water power engineering, process and gas technology	2	no. licence 430	<p>The licences required within this requirement as well as the certificate of passed state exam for health and safety coordinating during construction works will be sought only from the successful Bidder and the successful Bidder will be given a sufficient time from the day award decision becomes final to provide those licenses and certificate and will not be penalized for any delay in issuance of licences and certificate not caused by the successful Bidder.</p> <p>The procedure for licenses issuing is described on the Serbian Ministry of construction, transport and infrastructure web site https://www.mgsi.gov.rs/cir/aktuelnosti/izdavanje-licnih-licenci-za-inzenjere-arhitekta-i-prostorne-planere and https://www.mgsi.gov.rs/en/aktuelnosti/ministrys-announcement-regarding-issuance-licenses-engineers-architects-and-spatial.</p>
4	Employee, on a full-time or part-time basis, who has passed a professional exam qualifying him/her to perform work pertaining to safety and health care at work	1	N/A	<p>The procedure for issuing of the certificate of passed state exam for health and safety coordinating during construction works is described on the web site of the Ministry of Labour, Employment, Veteran and Social Affairs. Detailed description for this exam certification is given at the link: https://www.minrzs.gov.rs/lat/strucni-ispit-za-obavljanje-poslova-k5794ab2467d22.html</p> <p>The procedure for personnel licenses issuing should be in accordance with the Law on Regulated Professions and Acknowledgment of Professional Qualifications (Official Gazette 66/2019).</p> <p>Tenderers shall, in the performance of their works, in accordance with the type and nature of the works to be performed under this contract, comply with all applicable laws and by-laws of the Republic of Serbia, as long as it is aligned with the EIB Guide to Procurement.</p>

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

5. Tender Documents have been changed in the part **Section III – Evaluation and Qualification Criteria, Point 2. Qualification Requirements, sub-point 2.6 Servicing capacity** so that the sub-point **2.6 Servicing capacity** now reads as follows:

"2.6 Servicing capacity

The Bidder must demonstrate that it will have the following personnel hereafter:

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 publication of the procurement notice or 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 on the day of tender opening** 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 publication of the procurement notice or on the day of tender opening**.

B. For servicing the equipment in positions 2 and 3

Condition:

- 2) A certified at least one maintenance person employed on a full-time basis with a local servicing organization 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 publication of the procurement notice or on the day of tender opening** for the PET/CT device model on offer.

3) At least one certified maintenance person for performing maintenance work on nuclear medicine devices (PET, SPECT systems), 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 publication of the procurement notice or on the day of tender opening**.

Evidence:

2) - Photocopies of a certificate issued by the manufacturer of equipment for servicing the PET/CT device on offer with an ability to service the equipment within 48 hours of a notice given for the equipment 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 person employed with the local servicing organisation or with a sourced external service, whether local or foreign **on the day of publication of the procurement notice or on the day of tender opening** or a 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 publication of the procurement notice or on the day of tender opening**.

3) - Photocopies of a certificate issued by the manufacturer of equipment for servicing nuclear medical devices (PET, SPECT systems);

- 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 person employed with the local servicing organisation or with a sourced external service, whether local or foreign **on the day of publication of the procurement notice or on the day of tender opening** or a 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 publication of the procurement notice or on the day of tender opening**.

C. Professional capacity for servicing equipment in positions 1, 2 and 3:

Condition:

- the local servicing organization or a sourced external service, whether local or foreign must possess a valid licence for servicing devices that use ionising radiation, issued by the Agency for Protection against Ionising Radiation and Nuclear Safety, in accordance with the regulations currently in effect;

Evidence:

- photocopy of a certificate issued by the authorised institution,

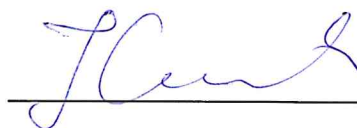
This requirement Bidders can meet individually or cumulatively, through at least one of the members in a joint venture/consortium.”

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

A handwritten signature in blue ink, appearing to read 'Jelena', is written over a horizontal line.

Jelena Simić