

RFP No: IOP/40-2021/RD

Procurement of Supplies

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

CLARIFICATION NO. 6

Issued on 30th August 2021

QUESTION 1:

Public Investment Management Office, no 11 Nemanjina Street, as the Employer, informed for site visit meeting on July 23rd, 2021, which took a place on July 30, 2021, at 11 a.m. at the address University Clinical Centre of Serbia, Pasterova street no 2, 11000 Belgrade, at the main entrance of UCC. Further on, the Employer issued Clarification letter no.2 – IOP40-2021RD, on August 12th, 2021, where was stipulated under Response 11, that In Section VII-Employer's Requirements at the end of Chapter, "Scope of Supply of Plant and Installation Services by the Contractor – Introduction", locations for installation and use of two additional modern PET/CT cameras has been stated. On the mentioned section of the Tender documents NCR_IOP40_2021RD valid-version-12.08.2021, on page no 154 stated: "...installation and use of two additional modern PET/CT cameras (one at the Clinical Centre of Serbia and at the Institute for Oncology of Vojvodina each) would significantly increase the capacity of the existing PET diagnostic centers...". In that way Employer clearly stipulated that second location for installation and use of the PET/CT camera would be Institute of Oncology Vojvodina. Therefore, we are kindly asking Employer to organize and provide site visit for second location (Institute for Oncology of Vojvodina) for installation PET/CT camera. We as interested party for this Procurement, as a distributor of well-established producer of modern PET/CT camera, should have possibility to visit planned room for installation, in order to have all appropriate and necessary information for proper offer preparation, keeping in mind that this procurement consists of, not only equipment but design, construction works, installation, fitting (turnkey) and commissioning.

RESPONSE 1:

At the moment, the conditions for organizing a site visit of the room planned for installation of PET/CT camera in the Institute for Oncology of Vojvodina are not met. Once the conditions for organizing a site visit of the room in question are being met, the Employer will organize a site visit and all parties interested for this public procurement procedure will be duly informed in writing about the date and location of a site visit, by publishing a relevant notification on the following website: <http://www.obnova.gov.rs/english/public-procurement>.

QUESTION 2:

Page 114, 119 and Clarification letter no.2 – IOP40-2021RD, on August 12th, 2021 Response 1. To “reinforce” the needed performance and functionality of the requested PET/CT cameras, Employer add several requirements. With such action all competition for this Procurement is strictly limited and forbidden. Added specifications exclude all other products and are created in favor of model Discovery IQ, produced by the GE Healthcare. Practically, they are copied from Data Sheet of mentioned product and specifications defined on a such way not allowing any competition to attend on this Procurement.

Point 2.21. PET detector in-field upgradable to Axial FOV min 25 cm with NEMA sensitivity min. 20 cps/kBq.

Please refer to Data Sheet of model Discovery IQ, GE Healthcare, page 4, Option: Scalability – “LightBurst PET detector design allows on site field upgrade from a 2 ring axial coverage up to a 5 ring extended axial FOV.”

Then on page 5 of the same Data Sheet: LightBurst Detector NEMA NU-2 2012 Performances for 5 rings system Axial FoV (cm) 26cm and NEMA Sensitivity 22 cps/kBq.

To allow fair competition, we are kindly asking you to change Point 2.21 as per following: PET detector in-field upgradable to Axial FOV min 22 cm with NEMA sensitivity min. 11 cps/kBq.

Point 2.7 PET reconstruction technology to improve 2 times PET quantitation accuracy and SNR compared to OSEM reconstruction.

Please refer to Data Sheet of model Discovery IQ, GE Healthcare, page 2, Option: Q-Clear “Full convergence iterative reconstruction technology providing up to 2 times improvement in PET quantitation accuracy (SUVmean) and up to 2 times improvement in image quality (SNR) for small lesion detection, fast and efficient reading and a more confident diagnosis.

To allow fair competition, we are kindly asking you to change Point 2.7 as per following: Option for improving image signal-to-noise which can be used to either enhance image quality, reduce dose, and/or reduce patient acquisition time.

Point.2.20 PET reconstructed resolution transverse (i.e. transaxial) at 1cm-max 3.0 mm. Do you accept Spatial resolution – transverse for FWHM at 1cm max 3,4 cm? This would allow other possible participants with their modern PET/CT camera to participate on this procurement?

RESPONSE 2:

Point 2.21. Referring to your request, we are asking minimum specification for Axial FOV and sensitivity that will meet the main purpose of a PET/CT scanner, meaning cancer detection and staging from very early phases. Also, we want to give access to more patients to the investigation. To be able to meet this requirement, a modern PET/CT scanner need to provide very high sensitivity that will allow detection of small lesions. Also, to scan more patients the scanner needs to be fast to allow scanning the patient in less than 20 minutes. So, both sensitivity and axial FOV are very important in PET/CT imaging for correct diagnostic from early stages. To accept an Axial FOV of minimum 22 cm with a sensitivity of 11 cps/kBq,

means to reduce dramatically the performance of the system for more than 50%. That would lead to numerous potential false positive or false negative results.

As conclusion, both parameters remain unchanged.

Point 2.7. Referring to your request, please be aware that every reconstruction technique introduce noise in the image that will potentially affect the quality of quantitation of small lesions. Two times improvement means that for small lesions the diagnostic accuracy will be improved and the patient won't need additional investigations on different diagnostic modality.

In conclusion, request remains as it was initially published.

Point 2.20. Considering that your request won't affect the scanner performance, we accept this deviation so request reads as follows:

"2.20 PET reconstructed resolution transverse (i.e. transaxial) at 1cm-max 3.4 mm"

The stated change in the technical specifications will be made and published in the Amendment no. 4 of the Tender documents.

QUESTION 3:

On page 154 Employer stipulated "The procurement, installation and use of two additional modern PET/CT cameras (one at the Clinical Centre of Serbia and at the Institute for Oncology of Vojvodina each) would significantly increase the capacity of the existing PET diagnostic centers, and Serbia would get closer to the accepted standard for the necessary number of PET cameras in relation to the number of inhabitants". Also, in Clarification letter no.2 – IOP40-2021RD, on August 12th, 2021 Response 1, Employer stated that subject of this tender procedure is procurement of high quality and high-performance PET/CT systems...

But with detailed analysis of the technical specification requested, we couldn't recognize main specific parameter that you requested which qualifies modern and high-quality PET/CT camera, like TOF (Time of Flight) in acquisition phase.

Due to you add several features to reinforce needed performance and functionality of the requested PET/CT cameras, we strongly believe that you missed (not intentionally) to add feature - TOF (Time of Flight) technology in acquisition phase. Do you accept recommendation to add Point 2.22 TOF (Time of Flight) technology in acquisition phase, because represent the latest technology which clinically makes differences between modern, high quality PET/CT cameras and old fashion technology?

All the above-mentioned questions are related to technical specifications of both PET/CT cameras.

RESPONSE 3:

To your point we would like to kindly remind you that TOF (time of flight) is a reconstruction technique, not an acquisition method as you mention, that is used to improve signal to noise ratio. Simple internet search shows that TOF is not a modern algorithm, it is used since 1980. Till now different manufacturers developed new generations of TOF and also modern new iterative reconstruction techniques that allow the improvement of signal to noise ratio in PET imaging.

<https://www.sciencedirect.com/science/article/abs/pii/S0001299898800317>

Request for scanner feature which allows improvement of signal to noise ratio already exists within these specifications.

In conclusion we don't consider that introducing this request will significantly increase scanner performance, so our request remains unchanged.

QUESTION 4:

In the Technical Specification on page 116 and 121, the Employer requested under point 5.22 An automatic system (robot) for burning disk and gluing label stickers.

Is it acceptable for the Employer to offer an additional, more advanced solution of automatic printing of labels? If yes, we kindly ask the Employer to modify the point so now it reads as follows:

5.22 An automatic system (robot) for burning disk and gluing label stickers or automatic printing of labels.

RESPONSE 4:

We confirm that position 5.22, from both PET/CT cameras technical specifications, on pages 116 and 120, now reads as follows:

5.22 An automatic system (robot) for burning disk and gluing label stickers or automatic printing of labels.

The stated change in the technical specifications will be made and published in the Amendment no. 4 of the Tender documents.

All the above-mentioned responses related to PET/CT cameras, are related to technical specifications of both PET/CT cameras.

QUESTION 5:

Please confirm if the appeal by the Bidder according to ITB 47.1 has to be submitted in English language solely. (including attachments as documentary proof), since the language of the proposal is: English

All correspondence exchange shall be in English.

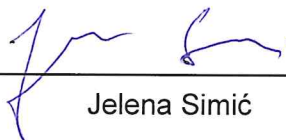
If the tender procedure requires any part of the appeal, or entire appeal and documentary proof to be submitted in Serbian, please state this explicitly, and state the nature of translation (if it has to be translated by the certified/court appointed translator).

RESPONSE 5:

According to ITB 47.1, all the documentation regarding the procedure for the protection of rights submitted by the Bidder, the entire appeal (complaint) and documentary proof, can be submitted in Serbian language.

If the appeal (complaint) is submitted in English language, all the documentation regarding the appeal (complaint) submitted by the Bidder, the entire appeal (complaint) and documentary proof, must be submitted with the translation into the Serbian language certified by the official court interpreter for the English language.

Procurement Committee



Jelena Simić