RFP No: IOP/40-2021/RD

Procurement of Supplies

Procurement of National Center for Production of Positron Radiopharmaceuticals and 2 PET/CT Camera with Associated Equipment, Design, Construction works, Installation, Fitting (Turnkey), Commissioning

CLARIFICATION NO. 2

Issued on **12th August 2021**

QUESTION 1:

Chapter: Technical Specifications, Item 3. SPECIFICATIONS OF THE PET/CT CAMERA TO BE INSTALLED AT THE INSTITUTE FOR ONCOLOGY OF VOJVODINA – SUBMITTED WITH THE TECHNICAL PROPOSAL

With detail analysis of the minimal requested technical features of PET/CT scanner, we may see that crystal as a heart of the detector and PET system is not specified neither explicitly defined, except in point 2.3 via detector sensitivity. Sensitivity is not only one criterion which could determine quality of the detector and crystal. It is unusually that technical features, which should describe requirements for PET/CT hybrid machine, contain more features representing CT scanner, comparing to features which representing PET part. Keeping in mind that this procurement is for purchasing system for nuclear medicine examinations, CT part represents only sub-system and is usually less relevant for nuclear medicine department and is used as a supporting system to PET scanner for anatomical and morphological localization. PET technology is changing, metamorphosing at a molecular level. The performance of PET/CT scanners depends on the type of scintillation crystal used in the detector. 3 main world – well established producers have been developed PET/CT scanners based on the latest technology crystals. (LBS, LYSO, LSO or equivalent). We believe that well-established institution would not buy, for also well-established institutions in Serbia, systems based on very old technology (BGO crystal – existing since 1970., more than 50 years outdated), **which cannot provide high quality images**. The purchase of old and outdated systems would conflict with the principle of proportionality under which contracting authorities are obliged to conduct procurement procedures in a manner that is proportionate to the objectives to be achieved via a particular procurement. For illustrative purposes on the importance of principle of proportionality, please note that even two 12 years old PET/CT systems that are currently installed in Republic of Serbia are based on LSO technology.

Refer to article: https://depts.washington.edu/imreslab/education/Physics%20of%20PET.pdf

page 4, where study is showing the features of all crystals (BGO crystal has the lowest light output and long light Decay Time). **Fast scintillators allow 3D imaging**, which provides the most counts you can get from a PET scanner. After emitting a flash of light in response to being struck by a high-energy photon, LSO/LYSO/LBS crystals rapidly return to a resting or passive state, ready to emit another flash in about 60 nanoseconds. BGO requires a period five times as long. The time needed to acquire the number of photon counts needed for a diagnostic quality image is thus much shorter for LYSO, LBS and LSO-based systems than those built around BGO. **Shorter scans translate into increased productivity and improved patient comfort. Scans with a PET/CT scanner using BGO take even 40 minutes**. PET/CTs with LSO, LBS and LYSO detectors are even faster. Attenuation correction is completed using the CT rather than a standard, slower emission source, which reduces scan times to about 15 minutes, in some cases even less than 10 minutes. Demand of end user is 10, 12, or even 16 studies a day (this is current situation with installed systems in Clinical center Serbia and Institute for Oncology Vojvodina with old PET/CT systems installed 12 years ago). **To be able to do that number of studies, PET/CT system should be equipped with an LSO/LYSO/LBS crystal.** BGO is not suited to 3D imaging.

Therefore, could you, please, confirm that detectors of the offered systems must include high-performance Lutetium based scintillator crystal named LBS, LYSO or LSO or equivalent?

RESPONSE: 1

The Employer defined minimum technical characteristics primarily considering the real needs and requirements of the Beneficiaries, focusing not on a specific parameter, but rather on the technical capabilities, outcomes, functionality, and performance that a PET/CT system can provide.

It is important for the Employer to provide Beneficiaries with goods enabling them to carry out daily clinical tasks in the most optimal and appropriate manner.

Therefore, among other goods required, subject of this tender procedure is procurement of high quality and high-performance PET/CT systems, where the evaluation is focused not on a specific parameter, but rather on the total clinical capabilities and outcomes, functionality and performance that a PET/CT system can provide.

The newest generation of crystal (BGO or LSO) based systems can provide easily:

- highest efficiency in term of injected dose, i.e. lowest possible dose for the patient that will ensure diagnostic confidence, for most common tracers.

- latest reconstruction technologies that will provide resolution for lesion detectability as low as 3.0 mm

- latest respiratory gating technologies that will allow to use it routine for every single patient without preliminary preparation.

- scalability and upgradability according to expected patient workflow load.

- Number of patients per day depends on amount of available tracers and system configuration, which could be from 15 up to 30 patients per day.

The overall performance of a system is a combination of detector/crystals type, acquisition hardware, signals processing, list data processing/reconstruction, available advanced reconstruction technology and advanced post-processing software capabilities. The main goal is to achieve high-end diagnostic level and earliest lesion detectability.

To reinforce the needed performance and functionality additional requirements will be implemented as follows:

point 2.20 „PET reconstructed resolution transverse (i.e. transaxial) at 1cm – max 3.0 mm"

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

point 2.7 will be changed to: „PET reconstructed technology to improve 2 times PET quantification accuracy and SNR compared to OSEM reconstruction".

The stated changes and additions in the technical specifications will be published in Amendment no. 2 to Tender Documents.

QUESTION 2:

Point 1.2 Scan range for hybrid acquisition (horizontal movement) min. 200 cm. Do you accept scan range for hybrid acquisition (horizontal movement) min. 195 cm keeping in mind that height of main population is not bigger of 190 cm (according to official statistic average height is 182 cm), and even for whole body PET/CT scanning scan range of min.195cm would be more than sufficient for almost every patient? In such case more competition can be achieved. Anyhow, with request for 200 cm scan range, in case of extremely high patient, with height of 203, 210 cm, whole-body procedure cannot be provided, which means that the current range of min. 200cm de facto limits the competition for reasons and criteria that are non-objective, unjustified and discriminatory.

RESPONSE: 2

The subject of this tender procedure is procurement of high quality and high performance PET/CT system. Since all reputable manufacturers are capable to provide models, that fulfil the requirement of scanning range for hybrid acquisition, this point remains unchanged.

QUESTION 3:

Point 2.3: PET detector sensitivity according to NEMA NU2-2012 minimum 8.0 cps/kBq.

Could you, please confirm that, under PET detector sensitivity is mentioned – PET effective sensitivity (cps/kBq)? Calculation and comparing PET detector sensitivity is different from producer to producer (provided under different conditions, for example, different Lower-Level Discriminator) and represents preliminary values delivered from internal testing. This means that this parameter is not precisely and sufficiently determined in a manner that potential bidders could understand the requested parameter and characteristic.

The newest NEMA standard (2018) includes protocols which were not there in previous NEMA standard. Manufacturers are now required to publish sensitivity, based on the new NEMA 2018 protocols.

All producers should simply amend data to be in compliance with the newest NEMA protocols (NEMA 2018). Therefore, all producers should their NEMA 2018 based values to the customers.

Do you accept value of effective sensitivity delivered by measurements performed with the factory LLD setting of 435 keV, according to PET NEMA 2018? This will allow and ensure the equal treatment and non-discrimination of all potential bidders in this tender, which principles are indisputably the most important principles in procurements.

RESPONSE: 3

The subject of this tender procedure is procurement of high quality and high-performance PET/CT system. Based on Effective and/or Equivalent values for sensitivity, the native performance evaluation cannot be performed and compared. All reputable manufacturers are capable to provide models, that fulfil the requirement for sensitivity of minimum 8.0 cps/kBq. Values for NEMA sensitivity @435 keV LDD in accordance with NU2:2018 will be accepted (The stated changes in the technical specifications will be published in Amendment no. 2 to Tender Documents). Effective and/or Equivalent values will not be accepted.

QUESTION 4:

Point 2.9: PET deviceless digital respiratory gating technology or Infrared based respiratory motion tracking – fully integrated into the clinical workflow.

Each producer has been developed different kind of respiratory motion trigger/control, and definition of this request should be based on proven outcome -control of respiratory motion and imaging in determined phases of the berating cycle.

Therefore, we kindly ask you to accept the following formulation of the point 2.9: PET deviceless digital respiratory gating technology or Infrared based respiratory motion tracking or software and hardware for respiratory gated list mod acquisition and reconstruction for organ

motion visualization– fully integrated into the clinical workflow? This will allow and ensure the equal treatment and non-discrimination of all potential bidders in this tender, which principles are indisputably the most important principles in procurements.

RESPONSE: 4

Requirement of fully integrated into the clinical workflow technology that will allows respiratory motion correction shall be on a level, which requires as less as possible preliminary preparation of usage. Applicable for any patient scan on the fly, which will improve patient workflow and clinical diagnosis confidence.

Requirement 2.9 will be changed to: „PET deviceless digital respiratory gating technology - fully integrated into the clinical workflow "

The stated changes in the technical specifications will be published in Amendment no. 2 to Tender Documents.

QUESTION 5:

Point 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 isocentre equal or greater than 20 mm.

Is it acceptable to offer system with min.32 reconstructed slices at one rotation, at the total effective length of the detector line in an isocentre equal or greater than 19.2 mm? Difference of 0.8 mm is not a substantial deviation and will not reflect to the image quality and much more competition would be enabled? In turn, this will allow and ensure the equal treatment and non-discrimination of all potential bidders in this tender, which principles are indisputably the most important principles in procurements.

RESPONSE: 5

Deviation of 5% will be accepted for that requirement.

The stated changes in the technical specifications will be published in Amendment no. 2 to Tender Documents.

QUESTION 6:

Point 2.11: The maximum time required to perform one rotation of the X-ray tube-CT detector system is 0.5s

Point 2.11 is not properly defined. We suppose that there is an error, and it should be defined in another way– The minimal time required to perform one rotation of the X ray tube CT detector system should be maximum 0.5 sec? Please clarify as this parameter is not determined in a manner that potential bidders could clearly understand it.

Is it acceptable to offer CT system as a part of the hybrid PET/CT system, with minimal time of one rotation max. 0.6 sec? In turn, this will allow and ensure the equal treatment and non-discrimination of all potential bidders in this tender, which principles are indisputably the most important principles in procurements.

Keeping in mind that this CT part will not be used for CT cardiac examination, but as a supporting system of PET system, for topogram and anatomical localization...FDG- most likely used radiopharmaceutical has half-life of 110 min and duration of the PET examinations is much longer than CT examination (between 8 and 15 min. depending on manufacturer), so difference of 0.1 sec in such case, for PET/CT examination, without cardiac has not clinically approved and visible impact.

RESPONSE: 6

There is a technical mistake in definition. Will be changed to: "The shortest time required to perform one full rotation of a CT detector system with an X-ray tube is maximum 0.5 s."

The subject of this tender procedure is procurement of high quality and high-performance PET/CT system. Since all reputable manufacturers are capable to provide models, that fulfil the requirement, the requested rotation speed remains max. 0.5 sec.

The stated changes in the technical specifications will be published in Amendment no. 2 to Tender Documents.

QUESTION 7:

Point 2.13: High contrast CT resolution at least 15.0 lp/cm (at 10% MTF) or better.

Comparing of High contrast CT resolution is depending on conditions, for example which phantom is been used, which technique for example Tungsten wire in air, mAs, rotation time, slice thickness and vary between different producers. Therefore, this parameter is not precisely determined in a manner that potential bidders could clearly understand the requested parameter and characteristic.

Therefore, we are kindly asking you to change your request: High contrast CT resolution at least 14.0 lp/cm (at 10% MTF) or better? In turn, this will allow and ensure the equal treatment and greater competition in this tender, which principles are indisputably the most important principles in procurements.

RESPONSE: 7

The subject of this tender procedure is procurement of high quality and high-performance PET/CT system. Since all reputable manufacturers are capable to provide models, that fulfil the requirement, this point remains unchanged.

QUESTION 8:

Point 2.17: CT kV range for radiography: 80 - 140 kV or wider.

As we told CT part will not be used for CT cardiac examination, but as a supporting system of PET system, for topogram and anatomical localization. Therefore, is on high importance not to irradiate patients with high level dose. For example, x-ray output is 1.5 times higher at 100 kV compared with 80 kV, 2.5 times higher at 120 kV, and 3.4 times higher at 140 kV. In other words, reduction in tube potential from 100 to 80 kV results in 1.5 times reduction in radiation dose.

(See article: https://www.ajronline.org/doi/pdf/10.2214/AJR.14.13281, Tube Potential and CT Radiation Dose Optimization)

Afterwards is simply clear that has no reason that 140 kV would be used in PET/CT examinations.

Could you please take in consideration our suggestion that this request should be changed in a way: CT kV range for radiography: 80 - 130 kV or wider, as this request is in line with the principle of proportionality under which to the objectives, to be achieved via a particular procurement, have to duly and properly taken into consideration?

RESPONSE: 8

The subject of this tender procedure is procurement of high quality and high-performance PET/CT system. The wider range of kV gives flexibility in term of patient tailored protocols configuration. Since all reputable manufacturers are capable to provide models, that fulfil the requirement, this point remains unchanged.

QUESTION 9:

Point 2.18: maximum mA: at least 400 mA without equivalents values.

Maximal mA cannot be reached during examination for all possible kV value applied.

It is always on radiographer to consider, of course depending on examination type, whether it will go with maximal mA and low kV value, or vice versa. For high value of kV, maximal mA simply cannot be reached nether used.

Do you accept to change this request: maximum mA: at least 345 mA without equivalents values, but at least 345mA should be available for all kV values? This would be complied with the principle of proportionality while at the same time would ensure the equal treatment and greater competition in this tender.

RESPONSE: 9

The subject of this tender procedure is procurement of high quality and high-performance PET/CT system. Since all reputable manufacturers are capable to provide models, that fulfil the requirement, this point remains unchanged.

QUESTION 10:

Point 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

Is it acceptable to offer following the latest version of postprocessing software which includes: 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 cinematic rendering which provides smooth photorealistic images, adjusting the intensity and contrast of the PET image, at least three licenses? This would be complied with the principle of proportionality while at the same time would ensure the equal treatment and greater competition in this tender.

RESPONSE 10:

This point remains unchanged.

The mentioned functionality above "cinematic rendering that allows smooth photorealistic images" is a type of advanced smutting algorithm and fulfils the requirement.

QUESTION 11:

In the tender dossier is written that two additional "modern" PET/CT cameras will be installed: one at the Clinical Centre of Serbia and another one at the Institute for Oncology of Vojvodina.

Due to is well known that two separate tenders for procurement of PET/CT scanners are already announced:

One for equipment for reconstructed Clinical center of Serbia were among other equipment is planned to purchase 2 PET/CT cameras, published by Ministry of Health Republic Serbia?

Second – common procurement of Ministry of Health of republic Serbia and Institute for Oncology of Vojvodina for ONE PET/CT camera with another equipment like linac, SPECT/CT camera.

Please provide information, where will be installed PET/CT camera which are subject this procurement?

Obviously is that it will not be at the Clinical Centre of Serbia neither at the Institute for Oncology of Vojvodina, as you mentioned in your tender dossier. And such information would be very important for offer preparation in terms of planning costs for installation, for maintenance during warranty period etc. Is not the same if you have to plan system installation in Belgrade, or in Nis for example?

RESPONSE: 11

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 have been stated.

Note: all the above-mentioned responses, related to PET/CT systems, are valid for technical specifications of both PET/CT cameras.

QUESTION 12:

Section I-II, ITB 11.3.d) (page 16 and 48), ITB 21.2 (page 24), ITB 30.2 (page 33)

– Could you please clarify what exactly has to be submitted as ''a written confirmation authorizing the signatory of the Bid to commit the Bidder'' in case the Bid will be signed by the Bidder's authorized persons (directors) who are registered at the Serbian Business Registry (Agencija za privredne registre)? Does this written confirmation is required only in case when a Bid is to be signed by a person who is not registered representative of Bidder?

RESPONSE 12:

Yes, the written confirmation authorizing the signatory of the Bid to commit the Bidder is required only in case when a Bid is signed by a person who is not a registered representative of the Bidder. Further, in the case that the Bidder is a JV, the Proposal shall be signed by an authorized representative of the JV on behalf of the JV, and so as to be legally binding on all the members as evidenced by a power of attorney signed by legally authorized representatives of each member of the JV.

QUESTION 13:

Section I-II, ITB 21.1 and 22.2 (page 24-25, page 50) – These clauses conflicts to each other, in regard to number of copies to be submitted. In concrete, ITB 21.1 (page 50) prescribes one copy plus one CD, while ITB 22.2 (page 50) prescribes two copies plus one CD. Please clarify.

RESPONSE 13:

One copy of the original offer, one copy of the bid in hardcopy, and one copy of the bid on CD should be submitted.

Accordingly, the Contracting Authority will amend the Tender Documentation, Part I-Bidding Procedures, Section II- Proposal Data Sheet, Point C. Preparation of Proposals, provisions ITB 22.2. (See Amendment no. 2 to the Tender Documents)

QUESTION 14:

Section III, 2.1 Legal Capability – Eligibility (General) (page 65-66) – The tender documentation does not explain what is a documentary evidence for ''It has been shown that, concerning some other tender procedure or donation awarded procedure under EU general budget, there has not been a serious breach of contract due to not fulfilling its contract obligations from the Bidder's side. Contracting authorities may exclude from participation in a procurement procedure a Bidder which has shown significant or persistent deficiencies in the performance of a substantive requirement under a prior public contract, a prior contract with a contracting entity or a prior concession contract which led to early termination of that prior contract, damages or other comparable sanctions.'' Are bidders obliged to provide any sort of evidence in regard to this requirement on legal capability?

RESPONSE 14:

The bidders are not obliged to provide any sort of evidence in regard to this particular requirement on legal capability.

QUESTION 15:

Section III, 2.4. Financial requirements (page 70) – This requirement asks for bidder's turnover in years 2017, 2018 and 2019, while it should ask in years 2018, 2019 and 2020. We assume this is a typo mistake, but please clarify.

RESPONSE 15:

The Contracting Authority will amend the Tender Documentation, 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 in such a way that it will require turnover for the last 3 accounting years (2018, 2019 and 2020).

(See Amendment no. 2 to the Tender Documents)

QUESTION 16:

Section IV, Technical Specifications (pages 96, 112, 113, 118) – Tender documentation prescribes, on several pages, the following (pages 96, 113, 118) ''In addition, it is necessary to submit, on the manufacturer's memorandum, the authorisation for the signatory of the

documentation, issued by the authorised person of the manufacturer.'' and (page 112) ''In addition to the above, it is necessary to submit, on the manufacturer's memorandum, the authorisation for the signatory of the statement, issued by the authorised person of the manufacturer.''

In case the respective manufacturer's authorization (p.96, 113, 118) and statement (p.112) are signed by the authorized person of the manufacturer, is it needed to support this authorization / statement with any further evidence / document?

RESPONSE 16:

In case the respective manufacturer's authorization and statement are signed by the authorized person of the manufacturer, it is no need to submit any further evidence/document.

QUESTION 17:

Regarding the tender requirement in the Section I - Instructions to Bidders (p. 18):

14.1 To establish the eligibility of the Plant and Installation Services in accordance with 1TB 5, Bidders shall complete the country-of-origin declarations in the Price Schedule Forms, included in Section IV, Bidding Forms.

Could you please clarify where exactly in the Price Schedule Forms the country-of-origin declaration can be found and filled in?

RESPONSE 17:

The Commission has already answered the above question and published the answer in Clarification No. 1, dated August 6, 2021.

QUESTION 18:

Regarding the tender requirement in the Section III (p. 67,68):

2.2 Legal Capability - Eligibility (Speciftc)

Bidders must meet the following requirements:

2.2 (a) The offered medical devices must be registered in ALIMS -R. Serbia or have a CE certificate, if the device is not registered with ALIMS at the time of the proposal submission.

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

In that sense, this provision applies to a bidder, or to one of the members in ajoint venture/consortium.

Considering high number of various medical devices included and consequently high number of their distributors/manufacturers, please confirm that bidders can submit in their bid ALIMS registration, for the goods out of their portfolio, only with the adequate Authorization from the company who is the holder of the registration without having that company as part of the joint venture/consortium?

RESPONSE 18:

We confirm that for the goods out of their portfolio, the bidders can submit the bid only with adequate Authorization from the company that is the holder of the registration without having that company as part of the joint venture/consortium.

QUESTION 19:

Regarding the tender requirement in the Section III (p. 68, 69):

2.2 (b) Have a License for performance of designingfacilities for the production of radioisotopes (P021G1, P021G3, P021E4, and P021M1), issued by Ministry of construction, transport and infrastructure of the Republic ofSerbia

Bidder is obliged to have evidence (license) that is registeredfor performance of designing facilities for the production of radioisotopes (P021G1, P021G3, P021E4, and P021M1), issued by Ministry of construction, transport and ufastructure of the Republic of Serbia.

2.2 (c) Have a License for performing activities of building facilities for the production of radioisotopes (И021Г1, И021Г3, and И021M1), issued by Ministry of construction, transport and infrastructure of the Republic ofSerbia.

Bidder is obliged to have evidence (license) that is registeredfor performing activities of building facilities for the production of radioisotopes (1021G1,1021G3, and I021M1), issued by Ministry of construction, transport and infrastructure of the Republic of Serbia.

The licenses will be sought only from the successfui Bidder and the successful Bidder wiil be given a sufficient time from the day award decision becomes flnal to provide those licenses and will not be penalized for any delay in issuance oflicenses not caused by the successfui Bidder.

Considering the complexity of the project, specificity of the construction works thus importance of the mentioned licenses for the implementation of the project, please confirm that possession of valid licenses under requirements 2.2 (b) and 2.2 (c) is a condition for signing the contract.

What penalty is foreseen for successful bidder being unable to provide aforementioned licenses?

RESPONSE 19:

If the successful bidder is not able to provide licenses in question before signing the contract, the Contracting Authority will not conclude the contract with him and will charge Tender Security.

QUESTION 20:

Regarding the tender requirement in the Section III (p. 74, 75, 76):

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 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 сотрапу 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.

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 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 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 сотрапу 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 organization or with a sourced external service, whether local or foreign 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 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 сотрапу 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 organization or with a sourced external service, whether local or foreign 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 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.

Considering the wording from the section beginning "The Bidder must demonstrate that it will have the following personnel hereafter.. " please confirm that bidder can fulfill requirements

under 2.6 by providing the requested evidences without having local servicing organization or a sourced external service (local or foreign) as a part of joint venture/consortium?

Please confirm that Condition under C, does not imply that (foreign) sourced external service must possess license of Serbian Radiation and Nuclear Safety and Security Directorate but license of relevant authorized institution from itfs own country.

Considering that two dates have been mentioned under - A. For servicing the equipment in position 1, Evidence -. .on the dav 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 dav of tender ppenmg.", please confirm that "on the day of tender opening" is valid one.

RESPONSE 20:

-We confirm that bidders can fulfill requirements under point 2.6 by providing the requested evidence without having a local servicing organization or a sourced external service (local or foreign) as a part of a joint venture/consortium.

-The condition under point C implies that a (foreign) company as sourced external service, must possess a license of Serbian Radiation and Nuclear Safety and Security Directorate. Namely, pursuant to Article 3 of the Rulebook on Conditions for Obtaining Radiation Activity ("Official Gazette of RS", No. 61 of 19 August 2011, 101 of 16 December 2016, 44 of 8 June 2018 - other law, 50 of 29 June 2018), a legal entity, i.e. an entrepreneur may perform radiation activity with sources of ionizing radiation if he obtains from the Agency for Ionizing Radiation Protection and Nuclear Safety of Serbia (i.e. Directorate for Radiation and Nuclear Safety and Security of Serbia) a certificate of registration of sources of ionizing radiation or a license for appropriate radiation activity.

-We confirm that "on the day of tender opening" is a valid one. Accordingly, the Contracting Authority will amend the Tender Documents. (See Amendment no. 2 to the Tender Documents).

QUESTION 21 :

Regarding the tender requirement in the Section III (p. 71):

2.5 Personnel

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

Personnel specialized in architectural design, graduate architects - responsible designer (2) no. 310 license

Considering the fact that the holder of the license no. 310 can only be a person specialized in civil engineering, please modify this requirement so now it says: Personnel specialized in civil engineering (2), no. 310 license.

RESPONSE 21:

The Contracting Authority will amend the Tender Documents regarding this circumstance.

(See Amendment no. 2 to Tender Documents)

QUESTION 22:

Regarding the point 17 of the Technical specifications (p. 111):

17. Conceptual design of the Production center: conceptual drawing of both levels (groundfloor and first floor) with short description of the function of each room. In line with The Rulebook on the Contents, Manner and Procedure of Preparing and the Manner of control ofTechnical documentation, according to the class andpurpose of the respective facility (The Official gazette of the RS, No. 72/2018)

Please confirm that it is sufficient to submit just the drawings of the ground floor and first floor at the conceptual design level together with the short description without the situation plan?

RESPONSE 22:

Yes, we confirm that it is sufficient to submit just the drawings of the ground floor and first floor at the conceptual design level together with the short description without the situation plan.

QUESTION 23:

Based on the information given on the page 156 of the Tender documents we understood that the facility shall consist of two floors, the ground floor and the first floor, the overall floor surface ~ 800 m2. (p. 156)

Please confirm that it is acceptable to have +5% of tolerance in the total area?

RESPONSE 23:

Yes, it is acceptable to have +5% of tolerance in the total area.

QUESTION 24:

Please confirm that the technical control of the project documentation should not be part of the bid?

RESPONSE 24:

Yes, we confirm that the technical control of the project documentation should not be part of the bid.

QUESTION 25:

Section II - Proposal Data Sheet (p. 51)

E. Evaluation, and Comparison of Proposals, ITB 30.14 (...the Proposal is responsive if meets the technical specifications and requirements of Section VII)

Please clarify how exactly the bidder is proving fulfillment of requirements of Section VII? Are the drawings of the conceptual design (ground floor and first floor) adequate proof of the fulfillment of the requirements of Section VII?

RESPONSE 25:

By signing the bid, the bidder proves the fulfillment of the conditions from Section VII.

QUESTION 26:

Section II - Proposal Data Sheet (p. 49)

ITB 11.3 The Bidders shall attach tender documents in the Technical Proposal in order as follows:

6. A copy of the Joint Venture Agreement entered into by all partners. Alternatively, a Letter of Intent to execute a Joint Venture Agreement. The JV agreement will be delivered with no financial information or if it contains any financial information, such information should be marked so to be hidden and not disclosed.

Since in the Section III - Evaluation and Qualification Criteria certain provisions apply to ‚ALL members in a joint venture/consortium?\ please confirm that a copy of a Consortium Agreement is also acceptable, as an equal form to the joint venture, for the fulfilment of the requirement under the point ITB 11.3?

RESPONSE 26:

Yes, we confirm that a copy of a Consortium Agreement is also acceptable, as an equal form to the joint venture agreement.

QUESTION 27:

Regarding the point ITB 16.2 on p. 19 of the tender documentation,

16.1 For major items of Plant and Installation Services as listed by the Employer in Section III, Evaluation and Qualification Criteria, which the Bidder intends to purchase or subcontract, the Bidder shall give details of the name and nationality of the proposed Subcontractors, including manufacturers, for each of those items. In addition, the Bidder shall include in its Proposal information establishing compliance with the requirements specified by the Employer for these items. Quoted rates and prices will be deemed to apply to whichever Subcontractor is appointed, and no adjustment of the rates and prices will be permitted. However, this information shall not be disclosed in the first stage of evaluation, but in the second stage of evaluation.

Please confirm that it is not mandatory to have mayor items manufacturer's as subcontractors in our Bid.

RESPONSE 27:

Yes, we confirm that it is not mandatory to have mayor items manufacturer's as subcontractors in bids.

Procurement Committee

Marija Stanisavljević