

**PROCUREMENT OF RADIOTHERAPY AND DIAGNOSTIC
EQUIPMENT, BELGRADE
(PROCUREMENT NO. IOP/36-2019/RD)**

CLARIFICATION NO. 8

Issued on July 24th, 2020

1. In technical specification item 1,4 it is required: „The shortest rotation time for one single full rotation of scanning (360°) max. 0.3 sec“. Do You accept this requirement to be changed to “The shortest rotation time for one single full rotation of scanning (360°) max. 0.35 sec”?

We as distributor of respectable manufacturer of CT systems are unable to submit an offer. For sure small decrease in rotation time does not make any change or decrease in diagnostic quality as cardiac scanning is the only one that requires fast rotation anyway, on the other hand this will increase number of potential bidders.

Answer: Change is not acceptable.

Subject of procurement is CT scanner for diagnostic and RT procedure for examination of most severe oncology patients. It is common that serious patients have problems with breathing, sometime are unconscious and cannot control the breathing. The fastest rotation is on crucial importance to achieve the fastest examination and the highest possible image quality without artifacts for precise and efficient diagnosis, especially important for the patients with lung cancer, where lung lesion can “move” during breathing.

CT technology has recently enabled high-speed gantry rotation time of 0,3 sec or less, contributing to the high temporal resolution important for all above mentioned examinations, not only, but including cardiac and pediatric, for achieving necessary examinations speed and precise diagnosis with high quality images without artifacts.

Also, three worldwide producers of CT scanner can fulfil this request and this specification is easily met by high-end CT scanners on the market. Potential bidder (who asked this question), distributor of respectable manufacturer of CT systems has also in product portfolio systems (2 models) which can fulfill requirements which is easily verifiable at the Internet.

2. In technical specification item 3,1. it is required: „Max. Generator power min. 80 kW “. Do You accept this requirement to be changed to: “Max. Generator power min. 72 kW”?

We as distributor of respectable manufacturer of CT systems are unable to submit an offer. If You take into account that maximum required current is 600 mA which is never reached on maximum kV setting which is required 130 kV, if we assume that first lower value for kV is 120 kV which is for all manufacturers true, then by multiplying 600 mA and 120 kV we get generator power of 72 kW. Therefore 80 kW is not really needed and this kind of requirement that has no backing in actual clinical need, and can only lead to reduction in competition and openness of procurement.

Answer: Change is not acceptable.

Please refer to request 3.2. “Maximal tube current min. 600 mA.” Where is written that maximal required tube current is MINIMUM 600mA and it is not “maximum required current of 600 mA” as per your question. That means that each potential bidder can offer bigger tube current than 600mA. Also, if you refer to request 3.2. Tube voltage range min. 80 – 130kV is described as a minimal request, but not limited to that range. That means that all potential bidders can offer systems with wider voltage range, including 70kV for pediatric and 140kV. Items 3.2. and 3.3. define just minimal range in order to assure bigger competition.

There are several benefits of higher generator power. High-frequency generators are very important to produce high voltage and transmit it to the x-ray tube. The power capacity of the generator determines the range of exposure techniques (kV and mA settings). Generator of higher power produces higher kV to increase the intensity of the beam, which will increase the penetrating ability of the x-ray beam and thereby reduce patient dose. In addition, a higher kV setting will help to reduce the heat load on the x-ray tube by allowing a lower mA settings. Reducing the heat load on the x-ray tube will extend the life of the tube etc.

Also, several worldwide producers of CT scanner can fulfil this request with even bigger generator power than 80kW, including potential bidder (who asked this question), distributor of respectable manufacturer of CT systems, with 2 models of CT scanners, which is easily verifiable at the Internet.

3. In technical specification item 4,5. it is required: „Indexing plate, same indexed as existing plate on linac“. This requirement is unclear, Institute for Oncology and Radiology of Serbia has several Linac units. Please state which indexing is required. On the other hand, if You are referring to Linac procured in Lot 1 then no one can know who will win this lot and which indexing plate will be delivered. In this case please remove this requirement from technical requirement.

Answer:

Item 4.5 Indexing plate, same indexed as existing plate on Varian existing linacs, with exact indexation.

4. In technical specification item 5,2 it is required: “Min. 128 acquisition slices, independent on number of detector rows or producer’s technology“. Since number of acquired slices on any system is directly equal to number of detector rows please confirm that it is actually required to offer CT system with 128 detector rows no matter number of tubes. If you are referring to something else please state under which scanning conditions should this requirement be met?

Answer: Change is not acceptable.

Your claim “number of acquired slices on any system is directly equal to number of detector rows” simply not true. There are several systems on the market where even higher number of the detectors rows produces less acquires slices and vice versa. As we declared in our request, Contracting Authority would not declare neither specify any of producer’s technology. From the

clinical perspective, the most important features of the CT system are high image quality, speed and the lowest dose for all patients. Any hardware like number of detector rows itself or number of tubes will not provide information like number of acquired and reconstructed slices per one rotation (we let possibility for several producers, with their different technology to participate) independent of number of detector rows or tubes and their technology to provide required number of acquired and reconstructed slices, which are asked under item 5.2 and 5.3. Number of acquisition and reconstruction slices will distinguish class of computed tomography systems.

5. In technical specification item 5,3 it is required: “Min. 256 reconstructed slices, independent on number of detector rows or producer’s technology“. Since number of reconstructed slices on any system is directly equal to two times number of detector rows please confirm that it is actually required to offer CT system with 128 detector rows no matter number of tubes. If you are referring to something else please state under which scanning conditions should this requirement be met?

Answer: Change is not acceptable. Please refer to answer 4.

Your claim “number of reconstructed slices on any system is directly equal to two times number of detector rows” simple not true. There are several systems on the market where number of reconstructed slices is even smaller, equal, doubled or tripled than number of detectors rows. As we declared in our request, Contracting Authority would not declare neither specify any of producer’s technology. From the clinical perspective, the most important features of the CT system are high image quality, speed and the lowest dose for all patients. Any hardware like number of detector rows itself or number of tubes will not provide information like number of acquired and reconstructed slices per one rotation (we let possibility for several producers, with their different technology to participate) independent of number of detector rows or tubes and their technology to provide required number of acquired and reconstructed slices, which are asked under item 5.2 and 5.3. Number of acquisition and reconstruction slices will distinguish class of computed tomography systems.

6. In technical specification item 7,5. it is required: „ 4D workflow with direct generation of axial, sagittal, coronal, or double-oblique images from standard scanning protocols “. Do You accept this requirement to be changed to “Workflow with direct generation of axial, sagittal or coronal from standard scanning protocols”?

We as distributor of respectable manufacturer of CT systems are unable to submit an offer. “4D Workflow” can be found many times mentioned on website of one CT manufacturer same is also mentioned in their brochures (we can provide you with links and brochures if needed). As this is specific for one manufacturer and eliminatory, and further more highly clinically irrelevant as on modern CT’s thin slices volumes are sent to workstation where doctor can view in MPR any possible axis or oblique, double oblique or curved reconstruction. This kind of requirement that has no backing in actual clinical need, and can only lead to reduction in competition and openness of procurement.

Answer: Request is partially accepted.

Request 7.5 will be changed as follows: 4D workflow with direct generation of axial, sagittal, coronal, or double-oblique images from standard scanning protocols or workflow with direct generation of axial, sagittal or coronal from standard scanning protocols.

7. In technical specification item 7,11. it is required: „High resolution flat screen monitor min.19“, resolution min. 1280 x 1024, 2 pieces for simultaneous display of two scans on two monitors within the 3D task card“. Do You accept this requirement to be changed to “High resolution flat screen monitor min.19“, resolution min. 1280 x 1024”?

We as distributor of respectable manufacturer of CT systems are unable to submit an offer. With installed base in Serbia of almost 30 CT units and tens of thousands systems in world, none of customers requested two displays. Our user interface and display on screen is optimized for usage of one display. Furthermore what is the need of radiographer to see two exams in the same time, he will not perform diagnosis? This kind of requirement that has no backing in actual clinical need, and can only lead to reduction in competition and openness of procurement.

Answer: Request is accepted.

Despite several benefits for radiographer to have two acquisition monitors like: It enables the comparison of two series from the same patient e.g. pre and post contrast or the comparison of two studies from the same patient e.g. pre and post surgery or in case that lesion is not visible on the current scan, radiographer can immediately compare it with previous scan of the same patients and make “double check” whether lesion is gone after some treatment etc. But in order to have better competitiveness and openness of the procurement, Contracting Authority decides as follows:

Item 7.11 will be changed: High resolution flat screen monitor min.19“, resolution min. 1280 x 1024

8. In technical specification item 7,12. it is required: “Software feature that enables user to obtain electron densities directly from the CT images, allowing patients to be scanned at any kV setting “. Do You accept this requirement to be changed to “Software feature that enables automatic kV setting”?

We, as distributor of respectable manufacturer of CT systems, are unable to submit an offer. Any patient can be scanned with any kV setting, it depends on the patient stature height and weight which kV setting is the best. But what you have described in this requirement is feature of single CT manufacturer called DirectDensity. Referring to website of this manufacturer it says for this feature: “Image value to relative electron/mass density conversion for the standard reconstruction was based on a two-linear-equations approach with individual calibration for each tube voltage. For DirectDensity images, a single tube-voltage-independent linear conversion was used.” So still conversion is needed anyway which in no way reduces or changes workflow. This kind of

requirement that has no backing in actual clinical need, and can only lead to reduction in competition and openness of procurement.

Answer: Change is partially accepted

As we mentioned, this CT system will be used mainly for diagnostic, but also as backup system for RT purpose. As you probably know, as distributor of one of the most respectable manufacturer of CT systems for diagnostic and RT purpose in the world, on the CT images, the density of a tissue is represented using the Hounsfield scale, with water having a value of zero Hounsfield units (HU), tissues denser than water having positive values, and tissues less dense than water having negative values HU. In radiotherapy, the current standard of practice for the calculation of photon and electron dose requires conversion of Hounsfield Units (HU) to Electron Density (ED) by applying a calibration curve specifically constructed for the corresponding CT tube voltage. This practice limits the use of the CT scanner to a single tube voltage (in RT usually those are higher kV values, usually 120kV and even 140kV if the system supports it) and hinders the freedom in selection of optimal tube voltage.

Our request was relayed on possibility that CT system has reconstruction algorithm which will provides direct ED images from CT raw data, independently of tube voltages used during acquisition. The ability of acquiring direct ED images simplifies the current practice at a safer level by eliminating CT calibration and HU conversion from commissioning and treatment planning respectively. Furthermore, it unlocks a wider range of tube voltages in CT scanner for better imaging quality while maintaining similar dosimetric accuracy. Also, allows Radiation Oncologists to get the best possible CT images for contouring without impacting the workflow of Physicists.

If potential bidder cannot provide mentioned software feature, it will be acceptable to offer Electron Density Phantom instead for precise correlation CT data to electron density of various tissues. It is very important for the Physicist to correct inhomogeneities and to document the relationship between CT number and tissue density. In addition, the bidder should offer software for analysis of the measurement achieved with the Phantom for CT numbers conversion to Electron density.

Therefore, Item nr. 7.12. will be changed to: “Software feature that enables user to obtain electron densities directly from the CT images, allowing patients to be scanned at any kV setting or Electron Density Phantom for precise correlation CT data to electron density of various tissues and software for analysis of the measurement achieved with the Phantom for CT numbers conversion to Electron density.”

9. Considering that 6MV FFF photon beam provides a considerable decrease in the treatment time, which may increase patient throughput, make treatment more tolerable for some patients and potentially decrease the risk of intrafraction movement please confirm that requirements “1.3 Minimum one Photon beam energy X-6MV” relates to 6MV FFF beam as a minimum requirement.

Answer: In a previous answer to a similar question it was said that it is desirable for the accelerator to have X-06 FFF energy. At the moment, 3 new accelerators purchased 3 years ago have been

installed at the Institute. All 3 accelerators have FFF energy. In order to avoid ambiguous interpretation of the requirement (whether it is mandatory or not) this condition for FFF energy is mandatory, i.e. the Accelerator must have a FFF energy of 6MV.

10. Considering both parameters – Beam symmetry at 0° gantry position and Symmetry dependency on the gantry and collimator angle (Deviation of dose distribution of square X-ray fields with angular positions) it may be concluded that their aggregated value might be up to 6%, meaning that the deviation of the dose delivered to different target regions might go up to 6%. Given this deviation and Institute intention to deliver High-quality RT treatments please confirm that “Beam Symmetry (%) \leq 2.0 or better” is the minimal technical requirement?

Answer: Not accepted.

Explanation: The analysis made in terms of symmetry is formally correct. However, the dose received by the patient is not automatically 6% lower than prescribed for therapy with Electra accelerators. The condition for symmetry to be \leq 2% is eliminatory for the other bidder and the condition for symmetry \pm 3% is accepted

11. "Taking into consideration 2019's significant investment of Serbian MOH in Oncology Information System unification at IORS, CC Kragujevac and CC Nis resulting on each site in:

- one single database for patients from prescription to treatment
- full integration of clinical data and images
- HL7 integration of existing ARIA oncology information systems with Heliant HIS (at IORS),
- full integration of Plan QA

please confirm that to avoid degradation of the current high level of integration of RT equipment, linear accelerators delivered should be fully integrated into existing Record and Verify system at IORS – ARIA ver. 15.5., meaning that no parallel Record & Verify System (Oncology Information Systems) will be accepted. Bidders are obliged to provide in their offers a short description of the integration method they plan to apply. "

Answer: For the end user, the degradation of a high degree of integration of radiotherapy equipment is unacceptable (currently 8 accelerators operate in the ARIA & Heliant environment).

Explanation:

The existing ARIA R&V system is integrated with the Heliant hospital system via HL7 protocols. The possible additional MOSAIQ R&V integration into the existing environment would include:

- Implementation of HL7 and IHE protocols (in MOSAIQ) for connection with ARIA
- The Implementation IHE protocol in ARIA and additional HL7 licences.
- The reduction “amount” of hardware in each workplace.
- The installation Citrix software on all ARIA and MOSAIQ workstations
- The Installation Citrix software on 100 ARIA/ECLIPSE workstations that currently operational.

It is up to the provider to assess how to integrate their components into the existing ARIA and Heliant environment (Heliant is a hospital information system). The end user does not have a mechanism to oblige manufacturers ARIA and Heliant to offer their components to other participants in the procurement process. Yet, we encourage and suggest that ARIA and Heliant manufacturers offer components to other participants in the procurement process.

Yet, only the connection of two new linear accelerators in the ARIA / Heliant environment ensures full integration of all devices into a functional whole.

We agree that bidders must provide a brief description of the integration methods they plan to apply in their bids.

12. Please confirm that considering all specific requirements for IORS premises adaptation, radiation protection and installation, a Bidder is obliged to check the dimensions of the space and its constructive elements before bid submission. Based on information acquired Bidder must demonstrate to the Purchaser, by drawings and protective barriers calculation submitted with the offer, that intended position of the equipment in the premises and the manner (type and thickness) of strengthening the primary and secondary barriers in the bunkers do not jeopardize existing constructive elements of IORS building and functionality of bunkers and control rooms.

Answer: Suggestions accepted.

Explanation: Certainly the bidder must look at the bunkers to accommodate the two new accelerators and the space that is the subject of the adaptation. Having in mind the deadlines provided for the adaptation of space and installation of equipment, the bidder must prepare a conceptual design and preliminary design for approval of works in accordance with the existing Law on Planning and Construction.

The bidder is obliged to prepare an executive/construction project.

If the bidder does not have an executive/construction project, he is obliged to submit the opinion of the authorized institution or person for radiation protection and fire protection on the basis of the documentation prepared by him.

Certainly before adaptation, the Contractor shall conduct the decommissioning and removal of 2 (two) linear accelerators (Elekta and Primus). This activity includes, but is not limited to: (1) discontinuing the operation of accelerator, (2) radioactive waste inventory, loading, transport and handing over of radioactive material to authorized institutions (3) dismantling of accelerators and (4) loading, transport and handing over of dismantled equipment to authorized institutions for treatment of communal and hazardous waste in line with the national waste management legislation.

Finally, we remind you that this is a "turn-key project" procurement and that each bidder should provide detailed project documentation. Before that, the bidder should consider what preparatory actions must be taken before the start of the adaptation of the space, including administrative tasks (obtaining various types of permits), technical control of the project, supervision of works, etc.

13. Within pos. 9.2 it is necessary for the small volume of the ionization chamber to fall in the range (0.01-0.015) cm³. Confirm that the PTW PinPoint 3D chamber type 31022, volume 0.016

cm³ is also acceptable.

Answer:

The ionization chamber with the offered volume of 0.016 cm³ is acceptable for small-field dosimetry in stereotactic therapy.

14. In reference to the published Amendment no. 3 to Procurement documents, dtd. 04/15/2020 for the Procurement of Radiotherapy and Diagnostic equipment, Belgrade no. IOP/36-2019/RD, particularly the amendment listed under no. 19, we do require additional clarification.

The amendment which now reads and the required EVIDENCE:

“The Tender evaluation criterion is "The Lowest Tender Price".

The Tenders will then be ranked from the lowest to the highest price. The lowest Evaluated Tender is the most favourable.

In a situation where there are two or more equal lowest evaluated bids, Purchaser shall make selection based on following criteria:

The greater business revenue in the past three accounting years (2017, 2018 and 2019).

Evidence: Report on solvency for public procurement (BON JN). If the bidders don't have Report on solvency for public procurement (BON JN) for 2019, they should submit a Balance Sheet, Income Statement and Statistical Report for 2019.

This provision applies to all lots.”

is not in total conformity with the applicable Law on Accounting in the Republic of Serbia.

We draw your attention to the Article 34 of the relevant Accounting Law (Official Gazette of RS no. 73/19) and the following link to Serbian Business Register Agency:

<https://www.apr.gov.rs/registri/finansijski-izve%C5%A1taji/uputstva-za-dostavljanje-finansijskih-izve%C5%A1taja-za-2018-godinu/rokovi-za-dostavljanje-izve%C5%A1taja-za-statisti%C4%8Dke-potrebe-i-finansijskih-izve%C5%A1taja.2124.html>

It is clearly stated that Reports for statistical purposes and financial reports for 2019 are to be submitted within deadlines determined by Articles 33 and 35 of the Law on Accounting (Official Gazette of RS no. 62/2013 and 30/2018 – the “old” Law), while the new deadline for those enterprises which are subject of auditing (article 34 of the applicable Law on Accounting) must submit their financial reports latest by June 30, 2020 together with the Audit report.

We kindly ask you to modify your request in terms that for those bidders who are subject to Auditing, the relevant evidence for year 2019 should be Report for statistical purposes only.

Answer: We confirm that the relevant document for submission is also Report for statistical purposes for 2019.

Public Procurement Commission

