**PROCUREMENT OF RADIOTHERAPY AND DIAGNOSTIC EQUIPMENT, BELGRADE**

**(PROCUREMENT NO. IOP/36-2019/RD)**

**CLARIFICATION NO. 4**

Issued on April 15, 2020

Regarding the list of questions that the Purchaser, Public Investment Management Office Belgrade, No. 11 Nemanjina street, have received from the potential bidders, concerning the procurement procedure: Procurement of Radiotherapy and Diagnostic equipment, Belgrade no. IOP/36-2019/RD, we give you the following answers:

**Question 1:**

1. Please confirm that In procurement document Section I – Instructions to Bidders, 19. Documents Establishing the Qualifications of The Bidder (Page 14/94), 19.1 (b) word „Bidder“ should be replaced with „Manufacturer“ so 19.1 (b) should read as follows:

“that, if required in the BDS, in case of a Manufacturer not doing business within the Purchaser’s Country, the Manufacturer is or will be (if awarded the contract) represented by an Agent in the country equipped and able to carry out the Supplies maintenance, repair and spare parts-stocking obligations prescribed in the Conditions of Contract and/or Technical Specifications; and”

2. Please confirm that In procurement document, Section III – Evaluation and Qualification Criteria, 1. Evaluation Criteria (ITB 35.3(d)), (Page 38/94) it should be written:

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

instead of

„ The greater business revenue in the past three accounting years (2016, 2017 and 2018.)“

**Answer 1:**

1. In procurement document Section I – Instructions to Bidders, 19. Documents Establishing the Qualifications of The Bidder (Page 14/94), 19.1 (b) the allegations remain unchanged.
2. Yes, we confirm.

**Question 2:**

1.

Section I – Instructions to Bidders,

11. Documents Comprising The Bid, 11.1 (e) (Page 11/94)

Documentary evidence in accordance with ITB Clause 17, that the Goods and Related Services to be supplied by the Bidder are of eligible origin;

17. Documents Establishing the Eligibility of The Goods and Related Services (Page 13/94)

To establish the eligibility of the Goods and Related Services in accordance with ITB Clause 5, Bidders shall complete the country of origin declarations in the Table of Technical Specification, included in Section VI, Schedule of Requirements.

Section VI – Schedule of Requirements, 3. General Technical Requirements (Page 61/94)

“In the specifications offered, the supplier must clearly state the manufacturer's name and the Country of origin for each item tendered.”

Where exactly in Table of Technical Specification, Country of Origin information should be filled in?

Where exactly the country of origin declaration can be found in the Table of Technical Specification?

2.

Section VI – Schedule of Requirements, 2. Technical Specifications (Page 60/94)

“Manufacturers’ technical literature should be submitted for each item offered and suppliers shall provide necessary documentation- official datasheet of offered goods in original signed by manufacturer or manufacturer’s representative for Europe thus enabling the Purchaser to verify the information provided in the offer.

Original Manufacturers Statement is allowed and can be used as a proof only in the case where the requested parameter is not stated in the official manufacturer data sheet.”

Please confirm that in Bidding phase, because of current transportation and logistics restrictions, Bidders are allowed to submit scans of original documents signed by Manufacturers authorised person (e.g. scan of Original technical specs (catalogue) or scan of Original Manufacturer statement both signed by authorised Manufacturers person).

**Answer 2:**

1. It is sufficient to state the country of origin in Excel file-Technical specifications with Price Schedule, first sheet, Price Schedule, Column D -Technical Specification Offered(model)
2. Yes, we confirm that scans of original documents are allowed.

**Question 3:**

Is the submission of 1 of the professional certificates listed under ITB 37.2-e-3 sufficient?

**Answer 3:**

Prospective Bidder is obliged to submit all certificates listed in (e)Certifications, standards and licences, point 3:

* ISO 9001:2015
* ISO 14001
* ISO 45001:2018 (OHSAS 18001)
* ISO 20000-1 for lot 2

The joint venture can satisfy collectively qualification requirement.

**Question 4:**

In procurement document Section VI - Schedule of Requirements, 1. Related Services and Completion Schedule, page 59/94 Delivery period of 180 days has been defined.

Considering that:

- As-build design does not exist in soft form, meaning that the proposal also encompasses preparation of As-Built Design in .dwg form with all necessary preparation activities (comparison of data from archive projects with real measures onsite, compiling of background documents for designing etc.)

- The design process will include preparation of As-built design, Conceptual design, Preliminary design, Construction design, Design of as-built facilities and lot of interaction between Designers, PIU and end-user,

- Re-construction will include two bunkers and MR room as well as auxiliary spaces (control rooms, physicians rooms etc.) and common spaces (corridors) which must remain available for daily clinical work,

- Installation and acceptance tests of Linear accelerators and MR scanner takes several weeks

- Commissioning of linear accelerators and training for various sub-systems are time-consuming processes and often must be performed sequentially,

We found that required Delivery period of 180 days is absolutely unachievable, not taking care of all different phases of this complex project and their duration.

Similar Ministry of Health projects, we took part in during the last two years, had a Delivery period of 180 days as well. However, the key difference is that Design and obtaining of different approvals have been done in advance. Also, the mentioned delivery period did not include Commissioning and clinical training.

In order to be able to submit valid offer we strongly suggest an extension of Delivery period to minimum 10 months (optimally 12 months).

Because Data collection and Design phase will be strongly influenced by End-User/PIU we suggest that Clock Stops should be defined for situations when the process is waiting for decision/comments from PIU/End-user side.

**Answer 4:**

Extension of Delivery period would be made through the Amendment of PD.

**Question 5:**

1.

Section II – Bidding Data Sheet (BDS, ITB 14.6

Please confirm that goods imported under this Contract will be Custom Tax and VAT exempted. To whom Confirmation of VAT and Customs tax exemption will be issued – to Contractor itself or its Subcontractors?

2.

What abbreviation FAT stands for?

3.

Section I – Instructions to Bidders, 19. Documents Establishing the Conformity of the Goods and Related Services (Page 13/94), 18.3

Please clarify what is expected from Bidders related to the following:

“The Bidder shall also furnish a list giving full particulars, including available sources and current prices of spare parts, special tools, etc., necessary for the proper and continuous functioning of the Goods during the period specified in the BDS following commencement of the use of the goods by the Purchaser.”

Does it refer to most important Items e.g. Linacs and MR Scanner or to all various medical devices listed?

**Answer 5:**

1. Contract is Custom Tax and VAT exempted. VAT and Customs tax exemption will be issued to the Contractor itself.
2. FAT – Factory Acceptance Test
3. This provision is N/A. See Section II. Bidding Data Sheet (BDS), 18.3 (Page 29/94)

**Question 6:**

Your tender documents envisage that the subject procurement is with international invitation to bid. With your defined tender documents the participation of international bidders or international manufacturers is impossible because of the post-qualification requirements themselves of your tender documents. Please clarify in which way a bidder with a company based outside the Republic of Serbia can participate independently in the subject public procurement procedure?

**Answer 6:**

Subject procurement, as an international open procedure, is conducted in accordance with the CEB Guidelines, relevant legislation in the Republic of Serbia and with respect of all procurement principles. From the question of the prospective Bidder, the Purchaser could not conclude which part of post qualification requirement precludes the participation of international entities in particular public procurement.

**Question 7:**

Your tender documents for Lot 1 envisage the procurement of an MRi RT system ( MRi radiotherapy planning system). Taking into account that the manufacturers of MRi systems are not at the same times the manufacturers of linear accelerators, please separate the MRi RT system item into a separate lot.

**Answer 7:**

The Purchaser could not organize, compile or structure its procurement according to the production program of different manufacturers, nor to the sales program of potential bidders, but according to its own needs-specific setting, workflow, numbers of procedures done, and number of other variables that are specific for Institute of Radiology and Oncology of Serbia.

Public procurement is divided into two lots, Radiotherapy and Diagnostic, having in mind functional entities within the Institute and need for timely, coordinated, and as swift as possible realization of the contract in order to establish the functioning of the services of two departments that are the most loaded and with huge patient flow.

**Question 8:**

Your tender documents for Lot 2 define the procurement of various diagnostic equipment for diagnostic purposes. As part of this lot, you also defined a CT for the purposes of laser simulator radiotherapy. Please separate all items in Lot 2 into separate lots given that they represent separate medical devices of different classes and categories as well as different functional uses. The subject procurement is a high value procurement and the total number of items can be processed and defined within separate lots.

**Answer 8:**

See answer 7

**Question 9:**

Your tender documents envisage the submission of the Covenant of Integrity document for bidders. Taking into account that you envisaged an Authorization Letter by the manufacturer for service agents for offering maintenance and technical services within the warranty period, please clarify whether service agents must also sign the Covenant of Integrity. Please also include this requirement in your tender documents, because the service agents in this case offer supplies (installation services, warranty service maintenance, preventive maintenance, etc.) in the sense as defined in your tender documents.

**Answer 9:**

Service agent does not have status of a bidder, it is not in contractual relationships with the Purchaser and required Declaration of integrity in tender docuemnts refers only to a bidder.

**Question 10:**

Your tender documents envisage technical specifications of various medical devices with their minimum features. All items in Lot no. 1 have the required technical features except for items 5 and 6 - MRi patient monitors and portable ultrasound device with convex and linear probe for anesthesia needs. Since you did not define the technical features of these items, can you separate them into separate lots for the sake of achieving greater competition in the subject procedure?

**Answer 10:**

Patient monitor and portable ultrasound device are defined in manner that is sufficient for beneficiary, by their purpose. The purpose of MRi patient monitors is monitoring patient in MR environment. Ultrasound is defined as portable device with convex and linear probes for anesthesia needs. It is minimum of technical specification that prospective bidder must meet.

**Question 11:**

Your tender documents envisage minimum technical specifications of the subject equipment. Please clarify if deviations from the required minimum specifications are possible, taking into account that medical equipment is not standardized as well as that clinical and functional requirements are realized in different ways by different manufacturers?

**Answer 11:**

Contracting authority is obliged to purchase equipment in accordance with the technical

requirements based on clinical needs. A substantially responsive Bid is one that conforms to all

the terms, conditions, and specifications of the Bidding Documents without material deviation,

reservation, or omission. The Purchaser could not accept deviations and exceptions of technical

specifications, but some minor inconsistencies will be acceptable having in mind needs of hospital

and clinical staff. We stay at your disposal for any information related to preparation of the bid. In

this respect, if the prospective bidder considers that certain specification of product of their portfolio does not meet the required, they are kindly asked to point out the specific part of specification and give us suggestion to amend it.

**Question 12:**

Your tender documents envisage construction, electrical, mechanical and other works on the preparation of rooms intended for different types of devices, .i.e. medical devices – Terms of Reference. Construction - mechanical and other works, as well as works on the renovation of the premises of the Institute of Oncology and Radiology of Serbia, within your submitted documents -+ Terms of Reference it is evident that within the procurement of capital medical equipment you also defined the procurement of the renovation of the diagnostic and radiotherapy unit, with all the works and conditions of renovation, obtaining all permits and services that do not fall within the scope of procurement of the subject equipment. Within each Lot, you defined as a separate item (item no. 12 under Lot No. 1 and item 10 within Lot No. 2) the renovation of room and the design thereof as an integral item of the lot.

**Answer 12:**

Procurement of Radiotherapy and Diagnostic equipment is procurement of supplies-equipment for diagnostics and radiotherapy departments, and in in the prevailing part it includes supplies. Works and services are related and requisite to procurement of supplies, having in mind that every item of equipment has its own preinstallation conditions. Dividing procurement into two or more different tender or lots (for equipment and for service or works) would not make sense and could have serious consequences for functioning of the departments within the Institute. In that sense, procurement of equipment and works and services that are subject of procurement are technically and technologically inseparable. Also, it could cause problems in the realization of such contracts which would result in poor quality of the overall workmanship (the participation of several different contractors who are not jointly and severally liability towards contracting authority). The coordination and simultaneous and synchronized performing are the crucial moment in realization of this project, works are in function of adaptation of existing space to requirements of particular equipment. Otherwise, in practice, it is common to organize procurement in this form, the so-called combined procurement.

Public Procurement Committee