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

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

**CLARIFICATION NO. 1**

Issued on April 13, 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:**

On page 28, and 53, 55, you have requested Manufacturer’s Authorization and Manufacturer’s After Sales Authorization.

On page 60, is requested: Original Manufacturers Statement is allowed and can be used as a proof only in case where requested parameter is not stated in official manufacturer data sheet.

Since Europeans representative of the Manufacturers are usually a fully owned subsidiary of the manufacturers and also, we have all correspondence with them as well as the Distributor agreements, is it acceptable to get all this above mentioned requested documents from European representative of manufacturer?

**Answer 1:**

It is acceptable.

**Question 2:**

On page 59 of the Procurement document it is written: Maximum period for repair and replacement from the moment of declaring - 15 (fifteen) days. Please confirm that this request relates to a deadline for replacement of the defective part and not to the replacement of the complete system?

**Answer 2:**

The deadline is prescribed for replacement of the defective part

**Question 3:**

Also, we would like to ask you to extend this period for replacement of defective part to 30 days because the 15-day deadline is impossible for equipment declared as a source of ionizing radiation, since it is necessary to obtain a license from the Serbian Radiation and Nuclear Safety and Security Directorate and their legal dead line is 30 days.

**Answer 3:**

30 days for replacement of defective part is allowed for equipment with a source of ionizing radiation.

**Question 4:**

On page 62, Equivalency of Standards and Codes, point 2.2. , you specified the following

""The equipment offered should be manufactured in compliance with Quality Standard ISO 9001 certification for Manufacturer(s)""

The ISO 9001 certificate from the manufacturer is not mandatory for medical devices, it just covers the "general requirements"" for a quality management system.

The quality requirements for medical devices are covered with the ISO 13485 certificate.

Since ISO 13485 is an international standard for quality management of medical devices, and since it is based on the requirements of ISO 9001 is it acceptable to submit manufacturer's ISO 13485 as a specialized standard that applies exclusively to medical devices instead of manufacturer's ISO 9001?

**Answer 4:**

Yes, it is acceptable to submit manufacturer's ISO 13485 as a specialized standard that applies exclusively to medical devices or ISO 9001 for manufacturer.

**Question 5:**

General questions LOT 1 and LOT 2

1. Tender dossier requires also requests Manufacturer`s Authorisation for Sales and Aftersales (page 42, 54, 55), for Bidder and Service Company. Please confirm that these two documents should be issued only by manufacturer of the main systems (equipment) from the document “Technical specification with price schedule” as follows:

(ID 1-11 for LOT 1): Linear Accelerator, Patient immobilisation package for VMAT/IMRT/3D CRT treatment, MRI Scanner, Advanced visualisation system, Patient monitor for MRI environment, Portable color doppler ultrasound system, MR compatible anesthesia device, Rack with infusion pumps for up to 4 pumps mobile station MRI compatible, Transport Ventilator, Patient immobilisation package for VMAT/IMRT/3D CRT treatment (MRI adapted), Patient positioning and transfer system for Brachytherapy – MRI compatible

(ID 1-9 for LOT 2): MRI Scanner, Multislices CT scanner, Diagnostic workstation, 3D Digital Mammography System 1, 3D Digital Mammography System 2, Ultrasound system 1, Ultrasound system 2, Ultrasound system 3, Conference system

and not by the manufacturers of additional equipment listed in the detailed technical specification?

2. The purchaser requests that the copies of ISO 9001 should be submitted (page42, 62) , and that it refers to all manufacturers. Please confirm that the ISO 13485 are also acceptable instead, in case the manufacturer does not have the ISO 9001 certification.

3. On page 42 , 62 The purchaser requests that the copies of ISO certificates should be submitted for all manufacturers. Please confirm that this relates only with manufacturers of the main systems (equipment) from the document “Technical specification with price schedule” as follows:

(ID 1-11 for LOT 1): Linear Accelerator, Patient immobilisation package for VMAT/IMRT/3D CRT treatment, MRI Scanner, Advanced visualisation system, Patient monitor for MRI environment, Portable color doppler ultrasound system, MR compatible anesthesia device, Rack with infusion pumps for up to 4 pumps mobile station MRI compatible, Transport Ventilator, Patient immobilisation package for VMAT/IMRT/3D CRT treatment (MRI adapted), Patient positioning and transfer system for Brachytherapy – MRI compatible

(ID 1-9 for LOT 2): MRI Scanner, Multislices CT scanner, Diagnostic workstation, 3D Digital Mammography System 1, 3D Digital Mammography System 2, Ultrasound system 1, Ultrasound system 2, Ultrasound system 3, Conference system

and not for the manufacturers of additional equipment listed in the detailed technical specification?

4. The purchaser requests that the technical literature submitted – data sheets of offered goods should be signed by the manufacturer, or manufacturer`s representative for Europe. Please confirm that only the datasheets submitted for the main systems (equipment) from the document “Technical specification with price schedule” as follows:

(ID 1-11 for LOT 1): Linear Accelerator, Patient immobilisation package for VMAT/IMRT/3D CRT treatment, MRI Scanner, Advanced visualisation system, Patient monitor for MRI environment, Portable color doppler ultrasound system, MR compatible anesthesia device, Rack with infusion pumps for up to 4 pumps mobile station MRI compatible, Transport Ventilator, Patient immobilisation package for VMAT/IMRT/3D CRT treatment (MRI adapted), Patient positioning and transfer system for Brachytherapy – MRI compatible

(ID 1-9 for LOT 2): MRI Scanner, Multislices CT scanner, Diagnostic workstation, 3D Digital Mammography System 1, 3D Digital Mammography System 2, Ultrasound system 1, Ultrasound system 2, Ultrasound system 3, Conference system should be signed by the manufacturer or manufacturer`s representative for Europe, and the datasheets for additional equipment listed in the detailed technical specification can be accepted in hard copy, without the signatures?

**Answer 5:**

1. Yes, confirmed for: (ID 1-11 for LOT 1) and (ID 1-9 for LOT 2)
2. Yes, confirmed. ISO 13485 is also acceptable instead.
3. A certificate for the major systems that are specified is sufficient, (ID 1-11 for LOT 1) and (ID 1-9 for LOT 2).
4. Yes, confirmed. This request is related to the documentation submitted for the main systems (equipment) from the document “Technical specification with price schedule” for equipment (ID 1-11 for LOT 1) and (ID 1-9 for LOT 2).

**Question 6:**

We are contacting you as a potential Bidder in the following: Procurement of Radiotherapy and Diagnostic equipment, Belgrade IOP/36-2019/UHI , Lot 2 – Diagnostic Equipment and kindly ask for clarification of Bidding Documents:

In Bidding Documents in Price Schedule template, it is envisaged that the Bidder states the price on DAP parity, according to actual Incoterms. Also, in Bid Submission Form (page 47 of 94), the Total price should be given on parity DAP (insured and delivered on site, excluding VAT and Custom Duties on import), as in Contract Agreement Form (page 91 of 94). In Section II. Bidding Data Sheet (BDS), ITB 14.6, it is stated that customs duties on import and other related costs are specially declared (page 28 of 94).

Since above conditions/incoterms and templates are only applicable to foreign Bidders and not for Bidders from Republic of Serbia (Customs law and VAT law are not taken in consideration), the price of Bid by local Bidders must include import costs, customs duties and 20% VAT for turnover on the territory of Republic of Serbia, we kindly ask for instructions how Bidders from Republic of Serbia should give the price of Bid, especially as it is not allowed to change the bid form.

We suggest parity DDP with indication that VAT will be calculated according to the VAT law of Republic of Serbia. In terms of that we kindly ask for adjustment of all related templates and Tender forms which include pricing.

We kindly ask you to confirm if this project exempted form customs duties and VAT and in accordance to that provide instructions how local Bidders can be exempted from import customs duties and VAT for turnover within Republic of Serbia.

**Answer 6:**

You must submitte in the bid total price (total DAP price (insured and delivered on site, excluding VAT and Custom Duties on import)), on all forms where a total price is required and in Price Schedule.

This transaction will be qualified for the exemption from VAT, customs, import duties and other taxes, according to Serbian laws.

Pursuant to the Framework Contract Agreement between the Republic of Serbia and the Council of Europe Development Bank LD1981(2018) dated 15th of April 2019, the loan funds cannot be used to make payments of value added tax (VAT) chargeable on transactions and imports of goods and services, of customs and other import duties, and of taxes and other charges arising in the performance and implementation of the Project. Consequently, and considering that the procurement in question is funded under the aforementioned Financial Agreement, the Contracting Authority is required to exempt the goods from value added tax (Art. 24(1)(16b) of the Value Added Tax Law). This means that, upon signing the contract for the respective procurement, and fulfilling other obligations envisaged in the tender documents (submitting guarantees, etc.), the bidder shall submit a pro-forma invoice /invoice, invoicing the VAT, so that a tax exemption can be made on the basis thereof. Specifically, in accordance with the provisions of the Rules on the modalities and procedure for seeking VAT exemption with the right to deduct the input tax, the tax exemption shall apply to both imports and internal transactions. In the case of imports, for goods that have not been previously imported, the supplier shall submit a foreign invoice with translation (the end-user must be specified in the foreign invoice), and for VAT exemptions in internal transactions, the supplier shall submit a pro-forma invoice (the VAT must be invoiced in the pro-forma invoice). Upon being granted the tax exemption on imports, the supplier may import the goods concerned, and upon being granted the exemption from tax on internal transactions, he may deliver the goods concerned. Upon delivery, the supplier shall issue an invoice/bill of lading without invoicing the VAT, stating the obligatory tax exemption mention with the tax exemption number and date. The supplier shall take care of all customs liabilities, or any exemptions from customs duties.

Public Procurement Committee