Procurement of equipment for new building of Institute for cardiovascular disease – Dedinje 2, Belgrade

NO. IOP/51-2021/UHI

Clarification No.5

Issued on 09th of July 2021

Question 1:

As a prospective Bidder, we have a question about LOT 7, regarding the Technical specification. In Technical specification for LOT 7, under ID 9, Purchaser requests: "GPS positioning of patient".
The mentioned request brings out number of difficulties in implementing the location services for identifying patient location, for the following reasons:

1. Personal data protection: Applying the location services is a risk for personal data protection as the software uses third party location identification packages (e.g. Google location service) which brings patient data outside of secure environment and is serious data security risk.

2. According to new GDPR rules, there has to be explicit patient consent for such kind of activities, which makes the administrative burden enormous and not justifiable. It has to be in written form, otherwise continuous tracking patient location will be in breach with the GDPR rules.

Given the above, we ask the Purchaser to remove this requirement from the technical specification.

Answer 1:

LOT 7; ID 9 "GPS positioning of the patient".

For the safety of patient it is of importance to locate vulnerable patient who could be lost in huge building. For those who wouldn't like to be GPS followed, that option can be switched off.

Suggestion for removing of the above requirement ***is not acceptable.***

Question 2:

1. Please confirm that Manufacturer`s Sales Authorization and documentary evidence/conditions regarding Postqualification requirements (ITB 37.2) as set forth in: "point e) Technical Capability:

Production capacity: Manufacturer's Sales Authorization (for Bidder)

Service capacity: Manufacturer's After Sales Authorization (for Service Company) Manufacturers - shall provide after sales service for equipment by the service company registered in the Republic of Serbia.Service company shall employ minimum number of qualified persons – certified by the manufacturer of equipment for servicing - 1(one) per item model offered. This provision applies to all lots.

Documentary evidence:
o Excerpt from register of the relevant authority, which proofs that Bidder is registered with the competent body,or entered in the appropriate register.
o For each qualified person (1) copy of certificates for offered system model and M form or copy of labour contract.
o The completed forms "Manufacturer's After Sales Authorization" as set forth in the tender documents"

are to be fulfilled and submitted for the main items listed in the technical specification and not for the additional equipment listed in the technical specs. for Lot 4, items under number 96-100?

2. Please confirm that the same applies to ISO certificates 9001/13485 and that they are to be submitted for the main items of the technical specification.

Answer 2:

1. In order to fulfill request under point e) Technical Capability, Bidders can submit all requested documents just for the main items in the technical specification and not for additional equipment.

2. Yes, Bidders can submit ISO certification 9001/13485 just for the main items in the technical specification and not for additional equipment.

Question 3:

"Question 1. LOT 5 - Item 1 - Digital Cardiovascular Angiographic System for Electrophysiological Procedures - For item no. 33 you defined the following: ""Variable focal spot to detector distance minimum in the interval: 90 – 120 cm"".
Since there are different limit values of SID among manufacturers and since they are not standardized, is it acceptable for the Contracting Authority to amend the technical requirement as follows:
""Variable focal spot to detector distance minimum in the interval: 90 – 120 cm"" (tolerance +/- 0,5 cm)

Question 2. LOT 5 - Item 1 - Digital Cardiovascular Angiographic System for Electrophysiological Procedures - for item no. 48 you defined the following: "" Vertical movement of the table top: minimum 75 to 100 cm""

Since there are different limit values of vertical table movement among manufacturers is it acceptable for the Contracting Authority to amend the technical requirement as follows:
"" Vertical movement of the table top: minimum 75 to 100 cm or vertical movement at minimal range - 25 cm""

Question 3. LOT 5 - Item 2 - Digital Cardiovascular Angiographic System for Cardiac Procedures - for item no. 48 you defined the following: "" Vertical movement of the table top: minimum 75 to 100 cm""
Since there are different limit values of vertical table movement among manufacturers is it acceptable for the Contracting Authority to amend the technical requirement as follows:
"" Vertical movement of the table top: minimum 75 to 100 cm or vertical movement at minimal range - 25 cm""

Question 4. LOT 5 - Item 3- Digital Neuro and Cardiovascular Angiographic System - for item no. 48 you defined the following: "" Vertical movement of the table top: minimum 75 to 100 cm""
Since there are different limit values of vertical table movement among manufacturers is it acceptable for the Contracting Authority to amend the technical requirement as follows:
"" Vertical movement of the table top: minimum 75 to 100 cm or vertical movement at minimal range - 25 cm"".

Question 5. LOT 5 Item 9 Digital X -Ray :

In your tender documentation, you defined item 13 for lot 5, ID 9, as follows: The rotation around the horizontal axis shall be at least ± 120 °, signaled at 0 ° and 90 °
Is it acceptable for the Contracting Authority to amend the technical requirement as follows: The rotation around the horizontal axis shall be at least ± 120 ° (tolerance ±5 °), signaled at 0 ° and 90 °. By allowing a tolerance of only ± 5 °, the Contracting Authority will not lose the functionality and quality of the device being the subject of this public procurement, because with the rotation around the horizontal axis of e.g. ± 115 ° all types of imaging can be performed without restrictions.

Question 6. LOT 5 Item 9 Digital X-Ray :

In your tender documentation, you defined item 28 for lot 5, ID 9, as follows: The longitudinal / transverse tabletop movement shall be at least ± 60 cm, ± 18 cm.""
Is it acceptable for the Contracting Authority to amend the technical requirement as follows: The longitudinal / transverse tabletop movement shall be at least ± 60 cm, ± 18 cm (tolerance ± 5 cm) . The movement of the tabletop is only one of the parameters of the patient's positioning with the movement and rotation of the tube stand as well as the dimensions of the patient table. By allowing this minimum tolerance, the Contracting Authority will still be able to perform all types of imaging and meet the required functionalities.

Answer 3:

Question 1 – LOT 5; item 1, ID 33 – ***suggestion is acceptable***.

Question 2 – LOT 5; item 1, ID 48 – there is a ***need for more precise explanation***. Request is that the lowest position of the patient table should be at maximum of 75 cm and the highest position of the PT should be at minimum of 100 cm.

Question 3 – LOT 5; item 2 , ID 48 - there is a ***need for more precise explanation***. Request is that the lowest position of the patient table should be at maximum of 75 cm and the highest position of the PT should be at minimum of 100 cm.

Question 4 – LOT5; item 3, ID 48 - there is a ***need for more precise explanation***. Request is that the lowest position of the patient table should be at maximum of 75 cm and the highest position of the PT should be at minimum of 100 cm.

Question 5 – LOT 5 ; Digital X-ray: ***suggestion is acceptable.***

Question 6 – LOT 5 ; Digital X-ray: ***suggestion is acceptable.***

Question 4:

Question 7. LOT 5 Item 9 Digital X-Ray:

3. In your tender documentation, you defined item 29 for lot 5, ID 9, as follows: The grid shall be focused on approximately 110 cm (tolerance +/- 5 cm), it shall allow imaging in the range of at least between 90 and 150 cm SID
Is it acceptable for the Contracting Authority to amend the technical requirement as follows: The grid shall be focused on approximately 110 cm (tolerance +/- 5 cm), it shall allow imaging in the range of at least between 90 and 150 cm SID (tolerance +/- 5 cm). Grids from different manufacturers have different parameters and are not standardized and by allowing this minimum tolerance, the Contracting Authority will not lose on the functionality and quality of the device.

Question 8. LOT 5 Item 9 Digital X-Ray :

In your tender documentation, you defined item 33 for lot 5, ID 9, as follows: Good permeability of the tabletop for X-rays, attenuation maximum 0.75 mm Al eq at 100 kV
Is it acceptable for the Contracting Authority to amend the technical requirement as follows: Good permeability of the tabletop for X-rays, attenuation maximum 1.2 mm Al eq at 100 kV because the required feature is not standardized, while the quality of the table and obtaining an X-ray diagnostic image are influenced by other numerous factors?

Answer 4:

Question 7 – LOT 5 ; Item 9 Digital X-ray: item 29 - ***suggestion is acceptable.***

Question 8 – LOT 5 ; Item 9 Digital X-ray: item 33 - if all other parameters meet premium x-ray digital machine then ***suggestion is acceptable.***

Question 5:

On page 30, 58 and 59, you have requested Manufacturer's Authorization and Manufacturer's After Sales Authorization.

On page 64, is requested: 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 5:

Yes, it would be also acceptable to submit the Manufacturer's Authorization and the Manufacturer's After Sales Authorization issued by the European representative of the Manufacturers.

Public Procurement Committee