Procurement of equipment for Mother and Child Institute Dr Vukan Čupić, Belgrade Clarification no. 2
Issued on January 28, 2020

Question 1:

It is not clear why technical requirement specifies equipment exclusively from Agilent Technologies when they are the only one who do not have certificate of the medical device registration for the mentioned equipment and why it is completely impossible to offer equipment from the manufacturer Waters or Sciex, who have registered products in the Register of medical devices in accordance with Medicines and Medical devices Act of the Republic of Serbia and with 98/79/EC to the IVD Regulation (EU) 2017/746.

As potential bidder for IOP/38-2019/UHI – Procurement of equipment for Mother and Child Institute Dr Vukan Čupić, Belgrade, Office for public investment management, we have to admit that we are surprised because the subject of the procurement in Lot 9 Laboratory, for articles 9.46, 9.47 and 9.48 is the equipment used for diagnosis of diseases of children. Mentioned equipment represents medical devices according to the provisions of the Law on Medicines and Medical devices of Republic of Serbia in accordance with 98/79/EC to the IVD Regulation (EU) 2017/746.

2. Please note that the way the terms, certifications, standards and licenses are defined are not safe and iligal:

(a) Certifications, standards and licences

2.For medical furniture and devices:

For offered medical devices, it is necessary to submit documentation (licence) of current valid registration in ALIMS -R. Serbia or CE certificate, if the device is not registered with ALIMS at the time of the bids submission. After the award decision is announced the successful Bidder is obliged to submit documentation of valid registration in ALIMS before signature of the contract.

- as it leaves the bidders the choice to offer products that meet the technical requirement, which are not medical devices or are not intended for medical use. In that case bidders are not obliged to submit any of the above requested evidence.

The tender documentation does not specify that the equipment in Lot 9 Laboratory, for articles 9.46, 9.47 and 9.48, must be a medical device because it is the equipment used to diagnose diseases of the children.

It is purchaser's obligation to specify what kind of equipment it procures and cannot depend the bidders' will and ability.

- As another disadvantage of the above request:

We point out the fact that CE certificate may or may not be certificate that determines whether device is medical or not. Please also note that CE certificate is only one of potential documents which is necessary for registration and sales of medical devices but not sufficient. In addition to the aforementioned certificate, a number of documents are also required, which are necessary for the legal circulation of medical devices in the territory of EU and RS.

CE certificate is not sufficient guarantee that the product is possible to register and cannot be alternative proof to the Certificate of the entry in the Register of Medical Devices (Law on Medicines and Medical devises of the Republic of Serbia in accordance with 98/79/EC to the IVD Regulation (EU) 2017/746.)

In Lot 9 Laboratory, articles 9.46, 9.47 and 9.48 are key medical tools/equipment for diagnostic of diseases not only on a case-by-case basis, but for screening the entire population of newborn babies.

As tender documentation is not written in such way to secure the lawful procurement of equipment in Lot 9 Laboratory, we propose for articles 9.46, 9.47 and 9.48 to exclude them from this purchase and to organize separate procurement for the mentioned articles in a lawful, responsible manner in order to satisfies both the professional objectivity and the substance for which the equipment is procured without discriminatory conditions and provisions enabling individuals to circumvent and comply with legal regulations, thus making them meaningless.
The wholesale of medical devices in the Republic of Serbia may be performed by a legal entity which, from the ministry responsible for health affairs, has obtained a wholesale marketing authorization for medical devices. A legal entity that has been granted a whole sale marketing authorization for medical devices may only sale those medical devises which are entered in the Register of Medical Devise.

ANSWER 1 : The Purchaser defined technical specifications of equipment that is the subject of this procurement based on clinical needs. In case the prospective Bidder considers that certain technical specifications of the tender documents might limit international competition or introduce an unfair advantage to some tenderers, he should write to the Purchaser with question to accept certain amendments to tender documents. The Purchaser will taking into account such suggestions having in mind clinical needs. Please, if you consider that certain specification might limit the prinicple of competition, point out the specific part of specification and give us suggestion to amend it.

Also for all medical devices Tender documents prescribes:

For offered medical devices, it is necessary to submit documentation (licence) of current valid registration in ALIMS -R. Serbia or CE certificate, if the device is not registered with ALIMS at the time of the bids submission. After the award decision is announced the successful Bidder is obliged to submit documentation of valid registration in ALIMS before signature of the contract.

Alims registration is not part of the technical specifications of the goods that are the subject of this procurement. Registration with the Alims for each medical device is condition for signing the contract. No medical device could not be placed on market without ALIMS registration.

The bidder is obliged to submit ALIMS registration for all medical devices before signature of the contract. It is not the choice of the bidder whether or not to submit the license, it is obligation of the succesfull bidder derived from the Law on Medicines and Medical devices of the Republic of Serbia.

Also, Purchaser does not consider CE certificate as a substitute for ALIMS. The CE certificate provides To the Purchaser information about complience with certain standards and followed directives or regulations in manufacturing the device and in line with that, Purchaser will know whether ALIMS is required at the moment of signing the contract.

Question 2:

1.Point 2. Patient couch. 2.1. requested: Vertical movement of patient couch in range of at least 50 cm with the lowest height maximum 50 cm.
Question 1: We suppose that producer with lowest position of the patient couch of 50.5 cm cannot be excluded due to difference of 0.5 cm? this cannot be treated as a substantial deviation. Could you please confirm?
Question 2: Please explain why is so important from clinical perspective to have vertical movement of the patient couch in exactly range of 50 cm? Is it acceptable to offer range of 43cm? (we suppose that lowest position is much important due to purpose of this CT scanner – examinations of the children and adolescents.)

ANSWER 2 : Yes, it is accepted.
Specification 2.1 is changed and now it is stated: „Vertical movement of patient couch in range of at least 43 cm with the lowest height, maximum 51 cm"

Question 3:
2.Point 2. Patient couch. 2.2. requested: Patient couch movement controls on gentry, on operators console and at patient couch.
Question: Could you please explain purpose of the controls on patient couch, because operator anyhow has possibility to move couch from gantry and operator console? If the patient couch moves together with patient for positioning, how will the operator push the button on the couch during movements? It is not usual neither practical solution. Could you please exclude the following phrase "and at patient couch" from request 2.2. and accept the following: Patient couch movement controls on gantry and on operators console?
ANSWER 3.: Yes, Specification 2.2 is changed and now stated: „Patient couch movement controls on gentry and operators console"

Question 4:
3.Point 2. Patient couch. 2.4. requested: Patient couch maximum load capacity at least 300 kg.
Question: Is it acceptable to offer patient couch maximum load capacity at least 227 kg keeping in mind purpose of this CT scanner – for examination of infants children and adolescents, where such patients are very rear weight of 300kg?

ANSWER 4: It ia acceptable to offer patient couch maximum load capacity at least 227 kg .

Question 5:

4.Point 5. Detector system. 5.1. requested: Number of detector elements in one detector row excluding reference detector elements at least 800.
Question: Do you accept system with 736 detector elements in one detector row with consistent and high image quality and the best spatial resolution, keeping in mind that particular number of the detector only does not refer to the image quality as an unique parameter for the consideration?
ANSWER 5: No, it is not accepted.

The higher number of detectors (detector elements) allows obtaining of more acquired data, which is important to create better slice and have better image resolution.

Question 6:
5.Point 5. Detector system. 5.2. requested: Total active detector length (coverage and collimation), in submillimeter mode, in "Z" direction and in iso-center in axial mode without patient couch moving at least 160 mm
Question: Scanning in axial mode with large detector without patient table movements, has significant disadvantages and can be applied only on limited number of examinations. Such kind of scanning has acceptable high image quality only on central slices, but on peripheral part spatial resolution is decreased, due to particular "cone beam" artefacts. CT angiography examinations request scanning range bigger than 16cm and table must be shifted anyhow. Such defined technical request gives advantage to only one producer and eliminate one brand-name producer, leader in medical healthcare environment.
We suggest to change request as per following: Total active detector length (coverage and collimation), in submillimeter mode, in "Z" direction and in iso-center in axial mode without patient couch moving at least 160 mm or in spiral mode with couch movement, with maximal pitch, at least 160 mm in one second.

ANSWER 6 : No, it is not accepted.
The fact that this specification defines detector coverage in axial scanning mode does not mean that axial scanning mode is going to be used in the higher number of examinations over the number of examinations which will be used in spiral (helical) scanniing mode. The axial scanning mode has been taken here, in this specification only for defining the detector coverage in simple and clear way.

Question 7:
6.Point 6. Acquisition parameters. 6.2. requested: Greatest scan field at least 50 cm and smallest maximum 25 cm.
Question 1: Please explain why is so important for clinical use to have smallest scan field maximum exactly 25cm, and not 30 for example?
Question 2: We understand that operator would use scan field of view less than 50cm in order not to over expose the patient during examinations of the smaller region of the interest, but please take into consideration some computed controlled exposure solutions, like dose modulation, when anyhow on some region patients would not be over exposed even with scan field of 50cm. Do you accept to change mentioned request in a following way: Greatest scan field at least 50 cm and smallest maximum 25 cm or reconstructed field of view in range 5 – 50cm with dose modulation during scanning acquisition phase?

ANSWER 7 : No, it is not accepted. Lower FOV means less dose for patient, which is very important for pediatric examinations. Computed controlled exposition is offered by all vendors as standard and it should not be mixed with physical or hardware radiation control. 25 cm is set as practical due to fact that in 25 cm FOV entire head, heart or spine can fit. Same organs would

fit in 30 cm FOV but with much larger dose. During the pediatric examinations it is very important to take care about patient dose, to reduce it as much as possible.

Question 8:
7.Point 6. Acquisition parameters. 6.5. requested: Dynamic study acquisition without patient couch movement at least 160 mm
Question: Do you accept: Dynamic study acquisition without patient couch movement at least 160 mm or dynamic studies up to a scan range of 480mm with continuously repeated bi-directional table movement during spiral acquisition?

ANSWER 8: No, it is not accepted.
Dynamic studies are perfusion and movement studies. Spiral acquisition with bi-directional table movement does not give same temporal information on entire scanned volume but each slice is acquired in different time and therefore incomparable.

Question 9:
8.Point 7. Console. 7.6. requested: Fastest image reconstruction time at least 55 images per second with all dose reduction options active.
Question: Keeping in mind that in most complicate cases, around 1000 images can be reconstructed in less than 1 minute and routine cardiac exam contains 200-300 images, could you, please change this request as per following: Fastest image reconstruction time at least 25 images per second with all dose reduction options active?

ANSWER 9: No, it is not accepted. Reconstruction time is one of the most important parameters of computer system of the CT scanner. CT scanner with higher reconstruction speed, produced by any of CT scanner producers is ranging as better quality system in relation to CT scanner of the same producer with lower image reconstruction speed.
Higher image reconstruction speed does not mean only higher number of examinations in time, but also it is very important feature which is needed for running of new advanced software applications.
Also, more complicated cases require 4000-5000 images. Cardiac examination for one part of heart cycle requires around 300 images, but entire heart study needs around 3000 images. For such cases higher image reconstruction speed is very welcome. This specification is easily met today by high-end CT scanners on the market.

Question 10:

Line item No. 4.4.1 Radiography Fluoroscopy system with dynamic Flat Panel Detector for diagnostic MSK procedures
1. Point 1. HV generator requested: mA range for pulsed fluoroscopy: 0,5-20 mA or more.
Question 1: Our premium system have different philosophy in dose reduction which use lower kV with higher mA values in pusled fluoroscopy. From that reason we have much wider mA range, but with different uo and down limits. Is it acceptable and will be evaluate as valid offer to offer system with mA range for pulsed fluoroscopy 4-84 mA?

ANSWER 10: Yes, it is acceptable to offer HV generator with mA range for pulsed fluoroscopy: 4 -20 mA or more

Question 11:

TENDER SPECIFICATION LOT 4. LINE ITEM 4.3. ID 6.5 REQUESTED " Pediatric exposure management dependent on patient weight".
QUESTION: IS IT ACCEPTABLE TO OFFER BETTER SOLUTION FOR CEILLING X-RAY:"Auto Exposure Control - sensors automatically set the proper X-ray conditions based on measurement of the patients body region thickness"? This feature prevents excessive radiation exposure for pediatric and adult patients

ANSWER 11: Yes, it is accepted.

Question 12:
In order to provide the end-user to excel the system at a wide range of applications and exams we suggest the following modification to be done:
2D convex probe. Bandwidth from 1.5 to 6 MHz (+/- 0.5 MHz). Depth of field: minimum 50 cm. Sector width: minimum 70 °

Answer 12: It is not accpeted.

Question 13: According to the LOT 1, line item 1.6 - Defibrillator with pace maker option and line item 1.7 - Hospital Defibrillator, you requested in both items under ID 7 "Device must have integrated minimum 6" display, readable in all conditions". Are you will accept device which have integrated 5.9" display readable in all conditions?

Answer 13: It is acceptable.

Question 14: Do we need to submit Supplier and Manufacturer Statements for 7. Spare Parts during the warranty period and during seven (7) years after the delivery?

Answer 14: Yes, the Supplier or Manufacturer statement about availability of spare parts must be submitted.

Question 15:
On page 62, you specified the following

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

ISO 13485 is the harmonized international standard requirement for a medical device quality management system. ISO 9001 is a quality management standard and is not specific to the type of product or service. The ISO 13485 standard is based on the requirements of ISO 9001.Just like these other standards, ISO 13485 includes the entire ISO 9001 standard with additional requirements. One major distinction of ISO 13485 is that it is intended to also be required for

regulatory purposes as well as a non-statutory requirement for a quality management system. Some countries which include Serbia require ISO 13485 certification to support regulatory approval for production of medical devices, whereas ISO 9001 is nowhere else required to support regulatory approval in any country for manufacture and manufacturers of medical devices.
Since ISO 13485 is an international standard for quality management of medical devices, and since it is based on the requirements of ISO 9001 and in many countries as well as in Serbia it is a regulatory requirement for obtaining a manufacturing license, is it acceptable to you manufacturer's ISO 13485 as a specialized standard that applies exclusively to medical devices to be submitted instead of manufacturer's ISO 9001?

Answer 15: ISO 13485 is acceptable instead of manufacturer's ISO 9001

Question 16: Are the bidders obliged to offer new supplies, i.e. from the current year of production?

Answer 16: All goods and materials to be incorporated in the goods must be new and unused.

Question 17:

Subject: Request for Clarification

With reference to the Project: Upgrade of Healthcare Infrastructure in Serbia, IOP/38 2019/UHI, please gives the answers to our question below:

1. With regard to the Lot 5, Position 5.6 Optiflow nasal high flow system, Item 10 - "Infant breathing circuit kit with pressure relief valve", is it acceptable to offer the Infant breathing circuit kit with pressure relief valve with the length 1.6m?

We are looking forward to your posting the clarification to the above question.

Answer 17:

It is acceptable**.**

Public Procurement Commitee