Procurement of Medical Imaging Equipment
no. IOP/5-2017/RD
Clarification no. 3
Issued on 04.10.2017.

Question 1:

Under Financial capability requirements (page 35/86), the Purchaser requests a certificate that the Bidder did not have any registered blockage of their account from the beginning of previous year (2016). Since these data are publicly available, is it acceptable for the Purchaser that the bidders with Serbia as place of registration submit an excerpt from the official webpage of National Bank of Serbia where the data on account blockage is publicly available for the period of past three years?

Also, the requested period for proving no blockage of the bidder`s account is beginning of 2016. For legal entities with establishment date after January 1st 2016 (i.e. official account opened after this date), please be aware and confirm that this certificate can be issued with different date, i.e. starting from the date of entity establishment, or starting from the date of account establishment.

Answer 1:

Yes, It is acceptable for the Purchaser to submit an excerpt from the official webpage of National Bank of Serbia. Also, the entities with establishment date after January 1st 2016 will submit document with the date of establishment or account establishment.

Question 2:

Regarding technical capability and service capacity on page 35, please state if the documentary evidence remains the same in the case if the Bidder is not authorized service organization of the Manufacturer (copy of work booklet or copy of labour contract, and copy of certificates). Should the Purchaser deem that other documentary evidence is necessary, we kindly ask him to state what are they.

Answer 2:

Requirements are the same in case where the Bidder is not authorized service organization of the Manufacturer.

Question 3:

On page 44, Manufacturer`s Authorization, the last sentence states: „Duly authorized to sign this Authorization on behalf of: (insert complete name of Bidder)".

Having in mind that the manufacturer issues this statement, and that the duly authorized person of the **manufacturer** is signing it, did you mean: „Duly authorized to sign this Authorization on behalf of: (insert complete name **of *Manufacturer***)?“

Answer 3:

Yes, sentence in this statement is „„Duly authorized to sign this Authorization on behalf of: (insert complete name **of Manufacturer**)“

Question 4:

On page 45, Manufacturer`s After Sales Authorization, the last sentence states: „Duly authorized to sign this Authorization on behalf of: (insert complete name of *Bidder*)“.

Having in mind that the manufacturer issues this statement, and that the duly authorized person of the **manufacturer** is signing it, did you mean: „„Duly authorized to sign this Authorization on behalf of: (insert complete name **of *Manufacturer***)?

Answer 4:

Yes, sentence in this statement is „„Duly authorized to sign this Authorization on behalf of: (insert complete name of **Manufacturer)**“

Question 5:

Having in mind that the project is to be realized on turnkey basis, and if the bidder is solely responsible for the project completion, please confirm the following – sub-suppliers who the bidder acquires the items listed under additional equipment from and other requirements for bidder from technical specification – Medical Imaging equipment, (please bear in mind that the manufacturer of the main equipment – subject of this procurement does not manufacture these items), do not need to be reported as subcontractors? Please confirm that therefore the documentary evidence proving legal, financial, business, technical and personnel capacity – requirements listed on pages 33, 34, 35, 36 - are to be submitted just for the bidder and the manufacturer of main equipment that is the subject of the procurement – Multislice CT scanner for cardiovascular procedures, Digital angiografy system for cardio-vascular diagnostic and interventional procedures, Magentic resonance system 1.5T, Digital angiography system for diagnostic cardiac and interventional procedures, Digital radiography system and Premium ultrasound system only.

Answer 5:

The supplier can notify the Purchaser in writing of all subcontracts awarded under the Project after signing of the Contracts. Such notification, in the original bid or later shall not relieve the Supplier from any of its obligations, duties, responsabilities, or liability under the Contract.

The documentary evidence proving legal, financial, business, technical and personal capacity has to be submitted for the Bidder and should refer to Multislice CT scanner for cardiovascular

procedures, Digital angiografy system for cardio-vascular diagnostic and interventional procedures, Magentic resonance system 1.5T, Digital angiography system for diagnostic cardiac and interventional procedures, Digital radiography system and Premium ultrasound system only, not for additional equipment and services.

Question 6:

We kindly ask you to confirm whether: Manufacturer`s Authorization, Manufacturer`s After Sales Authorization, certificates for qualified service personnel, work booklet or copy of labour contract, certificate ISO 9001 for service company, ISO 9001 for Manufacturers, are to be submitted for subjects of procurement (main equipment) wich are Multislice CT scanner for cardiovascular procedures, Digital angiografy system for cardio-vascular diagnostic and interventional procedures, Magentic resonance system 1.5T, Digital angiography system for diagnostic cardiac and interventional procedures, Digital radiography system and Premium ultrasound system only?

Answer 6:

Yes, we confirm that Manufacturer`s Authorization, Manufacturer`s After Sales Authorization, certificates for qualified service personnel, work booklet or copy of labour contract, certificate ISO 9001 for service company, ISO 9001 for Manufacturers has to be submitted for subjects of procurement (main equipment) wich are Multislice CT scanner for cardiovascular procedures, Digital angiografy system for cardio-vascular diagnostic and interventional procedures, Magentic resonance system 1.5T, Digital angiography system for diagnostic cardiac and interventional procedures, Digital radiography system and Premium ultrasound system only.

Question 7:

Also, in the technical specifications, the bidders are required to mark and fill in the table for "**other requirements for the bidder** (points 8,9 or 10 of technical specifications, depending on main item – e.g. – warranty period, SW upgrading, location projects, training of staff, operator manuals, system up time, service response, spare parts availability, etc…) by marking the location in technical specification or original producer statement. Please bear in mind that not the producers/manufacturers, but the Bidders warrant for these requirements, and please confirm if these requirements can be covered by the statement of Bidder, under full material and criminal responsibility, and referring to this statement when fulfilling technical specification?

Answer 7:

Yes, we confirm that Bidder's statement is sufficient for the Purschaser for "other requirements for the bidder (points 8,9 or 10 of technical specifications, depending on main item – e.g. – warranty

period, SW upgrading, location projects, training of staff, operator manuals, system up time, service response, spare parts availability, etc…

Question 8:

In technical specifications for **Digital angiography system for cardio-vascular diagnostic and interventional procedures Institute for cardiovascular diseases "Dedinje"**, the bidders are required to offer under point 8.3. Electric power distribution box. As new system is going to replace the existing angiography system with existing electric power distribution box, is it acceptable to use existing power distribution box, if it fits completely to manufacturer technical requests instead of offering new power distribution box?

Answer 8:

New power distribution box is requested. Use of existing PDB is not recomended due to couple of reasons. It has been in use for over 10 years so its reliabillity is questionable (it may introduce unwanted resistance for instance).

Question 9:

In technical specification for **Digital angiography system for cardio-vascular diagnostic and interventional procedures Institute for cardiovascular diseases "Dedinje"**, the bidders are required to offer under point 5.3. Detector size 295 mm (or more up to 305 mm) x 395 mm or more, rotatable. As all Siemens systems are equipped with high end large Trixell detector with little bit different dimensions, is it acceptable to offer following without any loss in quality and impact on any procedure:

5.3. Detector size 295 mm (or more up to 305 mm) x **382** mm or more

Answer 9:

It is acceptable about dimension of flat detector to be 295 mm (or more up to 305 mm)x382 mm or more.

Question 10:

In technical specification for **Digital angiography system for cardio-vascular diagnostic and interventional procedures Institute for cardiovascular diseases "Dedinje"**, the bidders are required to offer under point 6.14. System capacity to be 50 000 (or more) images in 2000x1500 (approximately) matrix; 12 bits; with antivirus integrated system protection and data protection. As all systems store images in compress standard format 1024x1024, please change request in following:

6.14. System capacity to be 50 000 (or more) images in **1024x1024** (approximately) matrix; 12 bits; with antivirus integrated system protection and data protection.

Answer 10:

Image matrix has different measures depending of manufacturers so both matrix would be acceptable to IKVB Dedinje: 50000 images of 2k x1,5 k or 100000 images on 1kx1k. It is based on acquired image because the dimension of the flat panel detector is 40x30 cm.

Question 11:

In technical specification for **Digital angiography system for cardio-vascular diagnostic and interventional procedures Institute for cardiovascular diseases "Dedinje"**, the bidders are required to offer under point 6.19. Cone beam CT or equivalent. As angio system will be used for cardio-vascular procedures, please explain if cone beam CT has to provide acquisition parameters specifically designed for cardiac imaging for precise imaging of cardiac chambers and vessels with strong cardiac motion which will enable a low-contrast 3D-reconstruction of ventricles and vessels of the heart from projection images of a rotational angiography. Please explain if cone beam CT or eqv. acqusition together with requested 3D Roadmapping funcionality should provide worflow for 3D Roadmapping for Structural Heart Interventions (TAVI)?

Answer 11:

The role of Cone beam CT is just to provide checking of immediate result of procedure like are EVAR, TEVAR, liver or any other embolisation…

Question 12:

In technical specification for **Digital angiography system for cardio-vascular diagnostic and interventional procedures Institute for cardiovascular diseases "Dedinje"**, the bidders are required to offer under point 7.8. among DICOM functions some functions like **DICOM Modality Worklist and DICOM Radiation Dose Structured Report,** which belong only to acquisition modality of digital angiography system and they are already requested under point 6.16. which belong to modality part. Please delete these DICOM functions under point 7.8.

Answer 12:

It is just to make easier work flow which is repeated over ten times per angio room daily.

Question 13:

In technical specification for **Digital angiography system for cardio-vascular diagnostic and interventional procedures Institute for cardiovascular diseases "Dedinje"**, the bidders are required to offer under point 8.6. Integrated FFR, iFR (or equivalent), integrated OCT (or equivalent) on system in angio-suite. Real time angio-optical coregistration. Integrated in patient table and under point 8.7. IVUS integrated system in angio-suite. Both systems are using only catheters which come from manufacturer of these systems (closed system) and final price of the system depends primary on planned quantity of catheters which will be used. As these systems belong to consumables consumption business model, all bidders have to pay and finally offer high price of these systems, because we don`t know yearly obligatory consumption of catheters. Also,

these systems present high end technology and only one manufacturer can offer to potential bidders, which brings bidders who represent manufacturers of digital angiography systems in non transparent position which will lead to over budget final offers for more than 150.000 Eur. From above mentioned reasons, we kindly ask you to delete points 8.6. and 8.7. from technical specification and provide to all bidders fair and equal conditions to make offers within published budget.

Answer 13:

Due to multitude of tasks that are present frequently in our institution, we have to provide best clinical decision by optimal tools. That is the reason why we need combination of functional and imaging optimization of angiographic findings. We need combination of FFR+OCT or FFR+IVUS in coregistration with angiography. Any combination will be accepted. Points 8.6 and 8.7 will be rearranged in mentioned meaning.

Question 14:

Both systems **Multislice CT and Digital angiography system for cardio-vascular diagnostic and interventional procedures Institute for cardiovascular diseases "Dedinje"** will replace existing systems. Please confirm that the Beneficiaries are responsible for timely deinstallation/decommissioning of the existing systems? And we would ask you to please state if the equipment has to be decommissioned in professional way, and packed accordingly so that it can be used on a different location, or is the equipment planned to be scrapped? Please also state the location where the system should go, and who will be responsible to bring out the existing equipment?

Answer 14:

Beneficiary will be responsible for deinstallation/decommissioning of the existing systems.

Question 15:

In technical specification for **Digital angiography X-ray system for diagnostic cardiac and interventional procedures for Clinical Hospital Center „Zemun"**, the bidders are required to offer under point 1.12 Possibility of C-arm continuous movement in lateral direction (left/right) when C-arm is set above patient head with coverage of at least 45 cm to the left and right side without moving of patient table or rotating C-arm. This function is not needed as interventions is always done from one arm (left or right) so there is no need for lateral movement of heavy ceiling C-arm, patient table is already requested with free floating function and only one vendor can fulfill this request. Please delete this request from technical specification to provide all leading vendors to submit their offer.

Answer 15:

Lateral movement of C-arm enables positioning of C-arm in such way that ROI is in isocenter of C-arm. From that moment onwards whatever angulation is performed ROI remains in isocenter.

And all this can be performed without moving patient table which is least wanted movement in contemporary angio-suite as it requires movement of staff risk of plugging out vital signs cables or even worse IV hoses. There will be no change in tender request. Market survey has shown that on several tenders similar requirements have been published and all major vendors fulfilled them.

Question 16:

In technical specification for **Digital angiography X-ray system for diagnostic cardiac and interventional procedures for Clinical Hospital Center „Zemun“**, the bidders are required to offer under point 5.1. Total active area min. 195 x 195 mm, but max. 210 x 210 mm. Premium Trixell small flat panel detector used by leading vendors is off different smaller size than requested, so please change your request to following:

5.1. Total active area min. **177 x 177 mm**, but max. 210 x 210 mm

Answer 16:

Market survey has shown that all vendors but one can offer detector of requested size. Furthermore, human heart in Dilated cardiomyopathy can be as big as 16 cm or even more. In this case projection of heart on flat panel detector which is consequently shown on display of the system can be easily larger than 18 cm. In this case imaging of whole heart with detector size of 177x177 is impossible. For reasons stated there will be no change in point 5.1

Question 17:

In technical specification for **Digital angiography X-ray system for diagnostic cardiac and interventional procedures for Clinical Hospital Center „Zemun“**, the bidders are required to offer under point 8.1.3. Ceiling monitor stand with rotation of ±180° along vertical axis with possibility of longitudinal movements along patient table at least 300 cm and lateral movement at least 280 cm for symmetrical operation from both, left and right side of the patient, femoral radial/brachial access. Vendors has different solutions for same monitor position functionality, so please change request to following:

8.1.3. Ceiling monitor stand with rotation of **at least 300°** along vertical axis with possibility of longitudinal movements along patient table at least 300 cm and lateral movement at least **240** cm for symmetrical operation from both, left and right side of the patient, femoral radial/brachial access.

Answer 17:

Only full rotation of monitors in examination room enables direct line of sight from any angle depending if operator is from one or the other side of patient table. This system is intended for all kinds of cardiac interventional procedures. Potential bidders request is to decrease the quality and view ability of displays inside examination room leads to decrease in quality and therefore cannot be accepted.

Question 18:

In technical specification for **Digital angiography X-ray system for diagnostic cardiac and interventional procedures for Clinical Hospital Center „Zemun“**, the bidders are required to offer under point 8.2.1. System color monitor. Most leading vendors use live system monitor also as their user interface and acquisition software is on higher level, so there is no need for third monitor in control room. Please delete this request from technical specification to provide all leading vendors to submit their offer.

Answer 18:

Three monitors enable in parallel one patent to be examined and other patients exam to be reviewed in control room at the same time, while current patent data is always available as well commands to control the system. Obviously, if Live display is used as interface display than this kind of freedom in work process is not possible and working in user interface which is in shades of gray rather than in color can be called archaic and tiresome rather than higher level. Request leads to decrease in functionality and cannot be accommodated.

Question 19:

In technical specification for **Digital angiography X-ray system for diagnostic cardiac and interventional procedures for Clinical Hospital Center „Zemun“**, the bidders are required to offer under point 3.5. Generator has at least double inverter and in case of malfunction of one inverter, second must insensibly take over operation. Most leading vendors have different technology for inverter protection, so double inverter is not the only and best solution and only one vendor can fulfill request. Please delete this request from technical specification to provide all leading vendors possibility to submit their offer.

Answer 19:

As Serbia is not highly advanced EU country, electricity fluctuations and short outages can happen and cause failure of equipment. As this system is intended to save lives any redundancy is highly appreciated especially on parts that are most stressed like tube and generator. As request does not provide alternative but leads to decrease in quality it cannot be accepted.

Question 20:

In technical specification for **Magnetic resonance system 1.5T equipped and suitable for whole body examinations for Clinical Hospital Center „Zemun“**, the bidders are required to offer under point 1.6 “Field of view - not less than 55x55x50 cm (XxYxZ)”. Siemens Healthacare doesn’t have Magnetic resonance system 1.5T with field of view larger then 50cm. Is it acceptable for purchaser/customer to change this requirement to: “Field of view - not less than 50x50x45 cm (XxYxZ)”?

Answer 20:

Decrease in field of view 5 cm in each direction on spherical volume represents 25% decrease in acquired volume. This is dramatic decrease in quality of system and cannot be accepted.

Question 21:

In technical specification for **Magnetic resonance system 1.5T equipped and suitable for whole body examinations for Clinical Hospital Center „Zemun“**, the bidders are required to offer under point 4.5 “Extremity coils: Two flexible coils of different sizes with minimum of 16 coil elements in a row each, for examination of joints”. Is it acceptable for purchaser/customer that potential bidders can offer dedicated rigid coils for joints and change request to following: “Extremity coils: Two coils of different sizes with minimum of 15 coil elements in a row each, for examination of joints”?

Answer 21:

Rigid coils depending on size of patient do not have tight contact with joint which leads poor image quality comparing to flexible ones. There will be no change in requirement.

Question 22:

In technical specification for **Magnetic resonance system 1.5T equipped and suitable for whole body examinations for Clinical Hospital Center „Zemun“**, the bidders are required to offer under point 5.1 “Minimal height position of patient table- 45 cm or less”. Is it acceptable for purchaser/customer to change this requirement to: “Minimal height position of patient table- 52 cm or less”

Answer 22:

Better or lower minimal height of patient table enables better accessibility to patients, there will be no change of requirement.

Question 23:

On page 54, under section 3.General Technical Requirements, the Purchaser requests related to the Technical Specification: „Supliers shall be required to demonstrate that the offered specifications are responsive to the requirements given in the Technical Specification identifying model, manufacturer and country of origin of each individual item in their specification offered. In the specification offered, the supplier must clearly state the manufactureers name and the Country of origin for each item tendered.“

Please confirm that for „each item tendered“, model, manufacturer and country of origin must be submited for main equipment that is the subject of the procurement – Multislice CT scanner for cardiovascular procedures, Digital angiografy system for cardio-vascular diagnostic and interventional procedures, Magentic resonance system 1.5T, Digital angiography system for diagnostic cardiac and interventional procedures, Digital radiography system and Premium ultrasound system only?

Answer 23:

The supplier must clearly state the manufacturers name and the Country of origin for each item tendered. It means that bidder has state it for all additional equipment in addition to main equipment.

Question 24:

On page 55. under section 2. Equivalency of Standardas and Codes, the Purchaser requests: „The equipment offered should be manufactured in in compliance with Quality Standard ISO 9001 certification for Manufacturer(s) and Service company.“.

We kindly ask you to clarify if this understanding is right: ISO certificates 9001 are to be submitted for the bidder, for the service company and for the manufacturer of main equipment that is the subject of the procurement – Multislice CT scanner for cardiovascular procedures, Digital angiografy system for cardio-vascular diagnostic and interventional procedures, Magentic resonance system 1.5T, Digital angiography system for diagnostic cardiac and interventional procedures, Digital radiography system and Premium ultrasound system only?

Answer 24:

ISO 9001 has to be submitted for for the bidder, service company and for the manufacturer of main equipment that is the subject of the procurement – Multislice CT scanner for cardiovascular procedures, Digital angiografy system for cardio-vascular diagnostic and interventional procedures, Magentic resonance system 1.5T, Digital angiography system for diagnostic cardiac and interventional procedures, Digital radiography system and Premium ultrasound system only.

Question 25:

Under section 4. Quality Control Standards, the Purchaser requests: „Certificates – ISO 9001 certification (QMS) – it refers to all manufacturers. Please submit copies of certificates“.

We kindly ask you to clarify if this understanding is right: ISO certificates 9001 are to be submitted for the bidder, and for the manufacturer of main equipment that is the subject of the procurement – Multislice CT scanner for cardiovascular procedures, Digital angiografy system for cardio-vascular diagnostic and interventional procedures, Magentic resonance system 1.5T, Digital angiography system for diagnostic cardiac and interventional procedures, Digital radiography system and Premium ultrasound system only?

Answer 25:

ISO 9001 has to be submitted for for the bidder, service company and for the manufacturer of main equipment that is the subject of the procurement

Question 26:

In Bidding Documents in Price Schedule template it is envisaged that the bidder give the price on parity DAP + unloaded, according to the actual Incoterms. Also, in Bid Submittion Form (page 40 of 86), the Total price of Bid should be given on parity DAP (insured and delivered on site, excluding VAT and Customs Duties on import).

In Section II. Bidding data Sheet, ITB 14.6 , it is stated that customs duties on import and other related costs are specially declared.

We kindly ask you to confirm if this project is examped from import duties and VAT and in acordance to that provide instructions how local bidders can be examped from customs and VAT for turnover within Republic of Serbia.

Answer 26:

The Purchaser's evaluation of a bid will exclude and not take into account: in the case of Goods manufactured outside the Purchaser's Country, already imported or to be imported, customs duties and other import taxes levied on the imported Good, sales and other similar taxes, which will be payable on the Goods if the contract is awarded to the Bidder.

After signing of the contract, the purchaser will provide the supplier by documents on the basis of which the supplier can be exampted from income customs and VAT in the purchaser country.

If the Purchaser fails to submit these documents, the Purchaser will be obliged to pay these taxes.

Question 27:

Having in mind that the project is on turn-key basis, please confirm if the company performing the civil works has to be reported as subcontractor. If this is the case, please indicate if this notification can occur in accordance with Article 20 of the GCC „in the original bid or ***later*****“** –later meaning after the Purchaser awards the Contract to the Bidder?

Answer 27:

The supplier can notify the Purchaser in writing of all subcontracts awarded under the Project after signing of the Contracts. Such notification, in the original bid or later shall not relieve the Supplier from any of its obligations, duties, responsabilities, or liability under the Contract.

Question 28:

On page 4 of Technical Specifications for Multislice CT Scanner for cardiovascular procedures, under Item 9.2. requested: DICOM color printer on photo paper or X-ray grey scale film.

Could you, please be so kind to clarify whether it is necessary to offer:

DICOM color printer on photo paper or DICOM color printer on X-ray gray scale film

Or

DICOM color printer on photo paper AND X-ray grey scale film (one printer with both possibilities)?

If you mean „DICOM color printer on photo paper AND X-ray grey scale film (one printer with both possibilities)“ would you be so kind to explain the following:

a) Whether it is intended to use photo paper AND X-ray grey scale film for diagnostic purposes?
b) Whether it is necessary to provide ALIMS registration for printer and related media for printing (photo paper AND X-ray gray scale film)?

Please advise which document should be presented as a proof stated above.

Answer 28:

It should be DICOM color printer that can print on photo paper AND on X-ray grey scale film as well (one printer with both possibilities).

a) yes

b) no, it is not necessary to provide ALIMS for device which is not subject to ALIMS registration

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