Procurement of Medical Devices for Clinical Centre Dr Dragiša Mišović

IOP/6-2017/RD

Clarification no.6

Issued on 21.09.2017.

Question1:

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.

Question3:

On page 45, 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 47, 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 from whom the bidder acquires the items listed under additional equipment and other requirements for bidder from technical specification –Imaging equipment, Lot 7, (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 – PACS Workstation for diagnostics, PACS Workstation for Mammography, PACS System Upgrade, Radiography System Mobile Ultrasound color doppler device with 2 probes, MR System 1.5T with open bore Ultrasound for Radiology with 4 probe, Digital remote controlled multi-purpose, Digital Fluroscopy/Radiography X-Ray System with dynamic Flat Panel Detector, Mobile radiography digital system with wireless FPD (Flat Panel Detector), Medical CD/DVD robot, Advanced metal detection system, Volume CT Scanner, Portable Ultrasound table concept with 2 probe, Mobile multi-purpose Ultrasound for Anaesthesia and Emergency, 4D Color doppler cardiac ultrasound system , Digital angiography system for cardiovascular diagnostic and interventional procedures, Digital Transcranial Doppler (TCD) System?

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 PACS Workstation for diagnostics, PACS Workstation for Mammography, PACS System Upgrade, Radiography System Mobile Ultrasound color doppler device with 2 probes, MR System 1.5T with open bore Ultrasound for Radiology with 4 probe, Digital remote controlled multi-purpose, Digital Fluroscopy/Radiography X-Ray System with dynamic Flat Panel Detector, Mobile radiography digital system with wireless FPD (Flat Panel Detector), Medical CD/DVD robot, Advanced metal detection system, Volume CT Scanner, Portable Ultrasound table concept with 2 probe, Mobile multi-purpose Ultrasound for Anaesthesia and Emergency, 4D Color doppler cardiac ultrasound system , Digital angiography system for cardiovascular diagnostic and interventional procedures, Digital Transcranial Doppler (TCD) System.

Question 6:

Also, in the technical specifications, the bidders are required to mark and fill in the tables for "**other requirements for the bidder** (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, system uptime 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 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).

Question 7:

In technical specification for Lot 7, item16. Digital angiography system for cardiovascular diagnostic and interventional procedures, regarding additional requirements for the bidders, under point 111. the Purchaser requests Installation of the offered system- "Turn key" project (preparation of facilities- technical room, examination room and control room. For item MR system in this procurement and in many other procurements for other hospitals purchaser note was that HV cable from HV substation to technical room has to be provided by Beneficiaries. Please add this note also under this point 111 for Item 7.16.

Answer 7:

HV cable will be provided by Beneficiary.

Question 8:

In technical specification for Lot 7, item 6. MR System 1.5T with open bore, regarding additional requirements for the bidders, under point 87. the Purchaser requests Installation of the offered system- "Turn key" project (preparation of facilities- technical room, examination room and control room). HV cable from HV substation to technical room has to be provided by Beneficiaries. During on-site visit in order to get more detailed information needed for turn-key offer, we have noticed that it is necessary to reconstruct connecting corridor with opening to existing hospital building with waiting hall for patients and to reconstruct doctor room and staff room in order to get complete functional MR department. Also, the toilettes for patients and staff should be completed. Please clarify if all of this is the bidder's obligation - additional to preparation of facilities- technical room, examination room and control room - or will it be done by Beneficiaries.

Answer 8:

Bidder's obligation is connecting corridor. Doctor and staff rooms, toilettes for patients and staff are not in turn-key obligation.The others as per requirements in Technical specification.

Question 9:

On page 56, 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 only for main equipment that is the subject of the procurement – Lot 7 Imaging equipment – for: PACS Workstation for diagnostics, PACS Workstation for Mammography, PACS System Upgrade, Radiography System Mobile Ultrasound color doppler device with 2 probes, MR System 1.5T with open bore, Ultrasound for Radiology with 4 probe, Digital remote controlled multi-purpose, Digital Fluroscopy/Radiography X-Ray System with dynamic Flat Panel Detector, Mobile radiography digital system with wireless FPD (Flat Panel Detector), Medical CD/DVD robot, Advanced metal detection system, Volume CT Scanner, Portable Ultrasound table concept with 2 probe, Mobile multi-purpose Ultrasound for Anaesthesia and Emergency, 4D Color doppler cardiac

ultrasound system , Digital angiography system for cardiovascular diagnostic and interventional procedures, Digital Transcranial Doppler (TCD) System only?

Answer 9:

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.

Question10:

On page 56-57 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 in Lot 7 – Imaging: for PACS Workstation for diagnostics, PACS Workstation for Mammography, PACS System Upgrade, Radiography System, Mobile Ultrasound color doppler device with 2 probes, MR System 1.5T with open bore, Ultrasound for Radiology with 4 probe, Digital remote controlled multi-purpose, Digital Fluroscopy/Radiography X-Ray System with dynamic Flat Panel Detector, Mobile radiography digital system with wireless FPD (Flat Panel Detector), Medical CD/DVD robot, Advanced metal detection system, Volume CT Scanner, Portable Ultrasound table concept with 2 probe, Mobile multi-purpose Ultrasound for Anaesthesia and Emergency, 4D Color doppler cardiac ultrasound system , Digital angiography system for cardiovascular diagnostic and interventional procedures, Digital Transcranial Doppler (TCD) System only?

Answer 10:

ISO 9001 has to be submitted for bidder, service company and for manufacturer of main equipment that is the subject of the procurement in lot 7.

Question11:

On page 60 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 PACS Workstation for diagnostics, PACS Workstation for Mammography, PACS System Upgrade, Radiography System, Mobile Ultrasound color doppler device with 2 probes, MR System 1.5T with open bore, Ultrasound for Radiology with 4 probe, Digital remote controlled multi-purpose, Digital Fluroscopy/Radiography X-Ray System with dynamic Flat Panel Detector, Mobile radiography digital system with wireless FPD (Flat Panel Detector), Medical CD/DVD robot, Advanced metal detection system, Volume CT Scanner, Portable Ultrasound table concept with 2 probe, Mobile multi-purpose Ultrasound for Anaesthesia

and Emergency, 4D Color doppler cardiac ultrasound system , Digital angiography system for cardiovascular diagnostic and interventional procedures, Digital Transcranial Doppler (TCD) System only?

Answer11:

ISO 9001 has to be submitted for bidder and for manufacturer of main equipment that is the subject of the procurement in lot 7.

Question12:

In Bidding Documents in Price Schedule template it is envisaged that the bidder gives the price on parity DAP + unloaded, according to the actual Incoterms. Also, in Bid Submission Form (page 41 of 88), 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 customs 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 12:

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 examped 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 13:

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 13:

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.

Question14:

In Section VIII - Special Conditions of Contract, on page 82/88 of Tender documents, condition of payment are given as follows:

-Advance Payment: 50 (fifty) percent of the Contract Price shall be paid upon submission of invoice and a bank guarantees: (1) for performance security of the contract and (2) for advance payment in equivalent amount in the form provided in the bidding documents or another form acceptable to the Purchaser.
-On receiving: 40 (forty) percent of the Contract Price shall be paid upon on receipt of the Goods.
-Implementation of Related Services: Ten (10) percent of the Contract Price of the Goods shall be paid upon implementation of all related services stipulated, related to proper functioning of goods, such as but not limited - installation, burn testing, training etc. (per item).

We would like to emphasise that according to the VAT Law of Republic of Serbia, all equipment which is subject to installation and putting into operation/start up is ment "delivered" only when all related services (installation and training) is finished, because the equipment can not be used unless it is installed and training is performed for users. In other words, delivery date and issuing of the invoice is possible yet after all mentiond is finishid an therefore payment conditions defined by this Procurement for Lot 7 are not applicable.
We kindly ask for change of payment conditions for Lot 7 like following:
-Advance Payment: 50 (fifty) percent of the Contract Price shall be paid upon submission of invoice and a bank guarantees: (1) for performance security of the contract and (2) for advance payment in equivalent amount in the form provided in the bidding documents or another form acceptable to the Purchaser.
-Payment upon delivery, installation and training: 50 (fifty) percent of the Contract Price of the Goods shall be paid upon delivery of goods and implementation of all related services stipulated, related to proper functioning of goods, such as but not limited - installation, burn testing, training etc. (per item).

Answer 14:

This suggestion is not acceptable. If supplier issue invoice after implementation all related services, the payment would be made in ammount of 50% of the Contract price. In some cases the moment od delivery and implementation is not the same, so the payment would be made as follows: 40% of the Contract price after delivery and receipt of the invoice and 10 % of the Contract price after implementation of all related services and receipt the relevant documentation. We want to emphasize that payment in ammount of 40% of the Contract price is option in that cases.

Question15:

Lot 7 – Imgaging, techncal specification for Volume CT scanner ID 7.12:
Item 5. requested: Vertical movement of patient couch in range of at least 60cm with the lowest height maximum 40cm.
Is it acceptable for the Purcaser to offer patient couch in range of 37cm, with the lowest height maximum 55cm, keeping in mind that requested gantry aperture is at least 78 cm, and vertical movement of 60cm is practicaly impossible with a patient on the table. Also such lowest height of

40cm is not nececery in the clinical use, since a movable patient can sit on the patient table regardless of the height, while disabled and hendicapped patients come on wheelchairs or stretcher with average height of 50cm.

Answer 15: Suggestion is acceptable

Question16:

Lot 7 – Imgaging, technical specification for Volume CT scanner ID 7.12:
Item 17. Requested: Number of detector elements in one detector row excluding reference detector elements at least 890
Do you accept State of the Art dual source technology with 4608 projections on each data acquisition unit, with 1472 channels on Detector A and 960 channles on Detector B?

Answer 16:

Dual tube and dual detector technology is not acceptable.
Dual tube and dual detector configuration is not acceptable because that kind of configuration rises exploitation costs dramatically because two tubes and two sets of detectors are used at the same time. That configuration requires higher preparation costs because additional chiller is required but it is not foreseen according to the project. It is necessary to provide two times more electricity because there are two tubes so system needs 200 kW of electric power. Also, maintenance costs are much higher because it is necessary to change both tubes at the same time, every time when one tube brakes.

Question17:

Lot 7 – Imgaging, techncal specification for Volume CT scanner ID 7.12:
Item 18. requested: Total active detector length (coverage and collimation), in submillimeter mode, in "Z" direction and iso-center in axial mode without patient couch moving at least 160mm.
Scanning in axial mode with large detector without patient table movement, can be applicable only to limited number of examinations and has several disadvantages, for example image quality on the borders caused by "cone beam" artifacts. Also, keeping in mind that 16cm coverage for 4D CTA examination is not sufficent and pateint couch must any how be moved. All leaders in CT technology have developed several technology solutions, with pretty same clinical outcome, and technology solutions cannot be a limiting factor for participation.

Answer 17:

Do you accept Total active detector length (coverage and collimation), in submillimeter mode, in "Z" direction and iso-center in spiral mode at maximal pitch at least 160mm in 1 sec?Answer 17: Volume scanning is requested. This request is not acceptable.
The Benficiary do not need scanning of 160 mm per second. The need is Volume Scanning of 160 mm when system scans volume of 160 mm in 0,35 second without moving of patient. Proposed scanning of 160 mm per second means that we will have, at least, 2 heart beats in period necessary to scan complete heart which

produces stitched image of heart parts in different phases. On the other side, with Volume Scanning of 160 mm in 0,35 second we will have complete heart scanned in one scanner rotation in 0,35 second. Volume scanning brings us much better images without artefacts created by patient moving. That is important for scanning of every Region of Interest where there are moving organs like: heart, chest, abdomen. With 160 mm Volume Scanning it is also possible to cover greater scanning regions (like angiography of Abdominal Aorta together with lower extremities) in much shorter time.
That reduces dramatically total radiation dose that patient is absorbing and dramatically reduces quantity of contrast media required for examination and that reduces risk on patients health.

Question18:

Lot 7 – Imgaging, techncal specification for Volume CT scanner ID 7.12:
Item 20. requested: Ability to choose from at least 5 different scan fields
Do you accept possibility of unlimited choice and selection of the reconstructed field of view in range from 5 up to 50cm?

Answer 18:

Suggestion is acceptable

Question19:

Lot 7 – Imgaging, techncal specification for Volume CT scanner ID 7.12:
Item 21. requested: Greatest scan field at least 50cm and smallest maximum 20 cm.
Could you please explain why is for purchaser important the size of the smallest field of view of 20cm, and not 25 cm from the clinical point of view?
Do you accept possibility to offer greatest scan field at least 50cm and smallest maximum 25 cm?

Answer 19:

Suggestion is acceptable

Question20:

Lot 7 – Imgaging, technical specification for Volume CT scanner ID 7.12:
Item 33. Requested: On-line storage capacity at least 800.000 non-compressed images in 512x 512 pixel matrix
Keeping I mind that all local storage archiving on all modalities are temporary, number of images which can be stored vary from producer to producer. In order to alow as many potental producers as possible to participate, do you accept "On-line storage capacity at least 520.000 non-compressed images in 512x 512 pixel matrix?

Answer 20: Suggestion is acceptable

Question21:

Lot 7 – Imgaging, techincal specification for MR System 1.5T with open bore ID 7.6:
Item 43. Requested: Three workstations:One acquisition workplace and Two workplaces for evaluation with advanced applications.

Taking into consideration that under items 54-60 are requested advanced applications for **only one** workplace for evaluation is it acceptable to change item 43 to following: "Two workstations: One acquisition workplace and one workplace for evaluation with advanced applications." and item 53 to following:" Basic 3D post-processing techniques – VRT, Multi Planar Reconstruction (MPR), Maximum Intensity Projection (MIP), Shaded Surface Display (SSD) on both workplaces".
This will not affect working precess of phisicians at all, specially having in mind that PACS system which is also subject of this procurement will be connected with MR system. Such PACS workstation/client can be used as second workplace for evaluation.

Answer 21:

Suggestion is not acceptable because we need one acquisition workplace and two workplaces for evaluation with advanced applications.

Question22:

In Technical specification for Lot 7, Imaging equipment, under item 6 – MR device – point 93 the Purchaser requests system uptime of 98% of working days during warranty period, i.e. min. 256 days. We kindly ask you to consider accepting the following standard - system uptime of min. 95% of working days during warranty period, i.e. 248 days, having in mind that the customs procedure for spare parts import can significantly prolong the system down time, which is not under control of the bidder/service organisation.

Answer 22:

Suggestion is not acceptable

Question 23:

During the survey of space designated for Angiography we noticed serious damage of reinforced concrete beams on the ceiling caused by previous construction work on the sewage pipes of the floor above. Since the repair would be necessary, could you please be so kind to explain who will bear the costs for such repair?

Answer 23:

Stated works are in turn key requirements.

Public Procurement Commision