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## CLARIFICATION NO. 8

Published 29.01.2016.

ICB No. IOP/09-2015/NCE/2

Project: Public sector research and development Subproject: New capital equipment Procurement: Procurement of capital equipment

Clarific				No.
Clarification no: 8 ICB no: IOP/09-2015/NCE/2	Annex I, Technical Specification		Annex I, Technical Specification	Reference to PN/ Bidding documents
	<ol> <li>What is the necessary compressor capacity?</li> <li>What is the power of the generator?</li> <li>What is implied under "tool kit of aliminum"?</li> <li>What is implied under "pipe angle"? Is it some kind of tool for bending the pipes?</li> <li>What should an electric watch contain?</li> <li>What should the additional lighting be?</li> <li>For which fluid the manual pump is needed? Air, water, oil?</li> </ol>	Questions dated 13/01/2016	Questions date 11/01/2016  LOT 13 Item "one ionization source for all techniques -ESI, APCI"  1. Is it acceptable to offer "one ionization source for all techniques -ESI, APCI or separate ionization sources for ESI and APCI"? The users did not have good experience with one ionization source for all techniques -ESI, APCI, because the performances of both methods are compromised. Much better results and robustness are achieved with separate ionization sources for ESI and APCI, and this does not increase the expenses of the overall system.	Question
	<ol> <li>Compressor: capacity - 50l, power 1,8-2,2 kW</li> <li>Power of generator for the compressor must be greater than the power of the compressor, 3 kW</li> <li>Tool kit of aluminium is actually aluminium case for easier and more affordable storage and preservation tools.</li> <li>Pliers plumbing pipes.</li> <li>Stopwatch.</li> </ol>		Please refer to Corrigendum no. 5 of the Bidding document.	Answer

moving. The first, $\theta/\theta$ geometry should fulfil horizontal position of	1. In the specification 1. "Basic Platform" it is requested to supply the scintillation detector		
means that the source is stationary but the sample and detector are			
stationary where source and detector are moving and $\theta/2\theta$	Requests is related to LOT No. 16 X-Ray Powder Diffractometer	Annex I, Technical Specification	<b>)</b> -
a) Yes, it is acceptable. b) Yes, $\theta/\theta$ means that the sample is	1. Request for additional explanations:		
1.	Request is related to LOT No.16 X-Ray Powder Diffractometer		
	Questions dated 18/01/2016		
with clearly marked object which is being offered.	manuacuming documentation?		
which is compliant with the	the original of the manufacturer's manual for operating or other		
manual for operating or other	catalogue, is it acceptable, along with the technical specification and		
characteristics, submit the copy of the priorinal of the manufacturer's			
	along with the manufacturer's declaration that the offered model is the successor of the model described in the technical specifications?	Specification	<b>—</b>
ptable, together with	easier, safer and more efficient work with the patients. Considering that, is it acceptable to offer the current model of catheter 40 MHz,	Anney I Technical	
	characteristics, have improved performances which enable better,		
or better from the requested.	longer being produced. Current models of catheters 40 MHz for the		
can offer devices which are equal	coronary recording, 40 MHz of the older generation, which is no		
cal specifications. Bide	1. Technical specification defines that the catheter for ultrasound		
the requests from	IICIII 1.		
1 The offered characteristics must	Lot 23 Catheters for Coronary Department		
	Questions dated 15/01/2016		
of a certified gauge.			
we want the air as the fluid for manual testing			
7. Virtually all three possible fluid, but			
in van, for example, LED lamp.		i de de la desta del desta del desta del del del del del del d	

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**Question a)** Is it acceptable to quote other type of detector which has equal or better analytical performance for requested CuKa radiation?

In the specification 1. "Basic Platform..." the requirement: "**Must** be possible to use it as  $\theta/\theta$  or  $\theta/2\theta$ , or any other combination, without mechanical intervention for changing geometries" is up to the best of our knowledge not possible to fulfil on the way it is written by any supplier, or the requirement is related to one particular system of one particular manufacturer.

**Question b)** Is the meaning of " $\theta/\theta$ " and " $\theta/2\theta$ " general meaning of XRD goniometer geometries (where  $\theta/\theta$  means that the sample is stationary with source and detector are moving and  $\theta/2\theta$  means that the source is stationary but the sample and detector are moving)?

**Question c)** If the answer to the Question b) above is yes, does that mean that the offers that do not fulfil the above requirement will be rejected? If the answer on Question b) is no, please elaborate the meaning of terms " $\theta/\theta$ " and " $\theta/2\theta$ "

2. In the specification 1. "Basic Platform..." it is requested to supply " $\theta$ - $\theta$  vertical goniometer, with minimal diffraction radius of 285 mm"

**Question:** As this specification is written very specific, would it be acceptable to offer the system with smaller minimal radius?

3. In the specification 5. "Micro-Area Diffraction" it is requested to supply X-Y-Z- φ stage

Question a) Should all 4 axis be motorized and programmable via XRD experiment preparation

the sample.

- c) Offers that include only possibility for  $\theta/\theta$  geometries with horizontal position of the sample will be acceptable.
- Yes, it would be acceptable to offer smaller (but not significantly) minimal radius.

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- a) No, it is not mandatory to have all 4 axis motorized as long as it does not significantly prolong experimental
- b) The meaning is the ability to change geometries and conduct experiments in different geometries in short period of time (at most an hour or similar), without significant intervention of the users.
- 4. Detector of such characteristics would be acceptable. 1,000,000 cps/pxl means that counting linearity is 10<sup>6</sup> cps per detector strip.
- Yes, different rotation speed ranges are acceptable.

-		<b>,</b>				
Annex I, Technical Specification		Annex I, Technical Specification				
Please send us as soon as possible clarification on following questions regarding technical specification for LOT 15:	Questions dated 20/01/2016	Technical specification for LOT 13. Liquid chromatography requests mass range: 20-2000Da  Is the single quadrupole mass detector with the range from 30-1250Da acceptable?	Questions dated 19/01/2016	5. In the requirements 8. Sample Changer and 9. Diffraction Modes there are requirements "Sample spinner has also to be included with spinning regulation from 1 to 120 rpm" and "Capillary rotation mode with capillary rotation regulation from 1 to 120 rpm."  Question: Are different than "1-120 rpm" rotation speed ranges acceptable?	4. In the specification 7. "PSD-1D Detector" the requested specifications are written very specific.  Question: Would it be acceptable to offer 1D detector with different specifications, in particularly different dimensions of lines/strips, but the same or larger number of strips/lines as requested?  Please explain/elaborate the requested specification "Linear count: 1,000,000 cps/pxl or more" especially the meaning of "/pxl" in the specification	software package or it can be delivered as a combination of manual and programmable axis or even all manual?  Question b) Please elaborate what exactly is meant by requirement: "No mechanical intervention by the user during geometry changing from BB - to - PB - to - Micro-area diffraction modes."
Offered specification is not acceptable. The offered characteristics must fulfil the		The offered range is not within the requested limits.				

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Bidding document	Bidding document	Bidding document	Bidding document	
Reference is made to the above mentioned Tender, Section VIII. General Condition of the Contact, Clause 16.3 Terms of Payment, on page 85, wherein the following is specified: "Payments shall be made by the Purchaser, but later than sixty forty five (45) days after submission of an		Is there a tax exemption, respectively release of custom duties given for this project?	Reference is made to the above mentioned Tender, Section I, clause C. Preparation of Bids and Section II, Bid Data Sheet ITB 14.6, on page 32, wherein the following is specified: "Bidders shall submit separate bids for each lot taking into consideration that documents related to the Qualification of the Bidder shall be submitted once for all lots."  Is it acceptable to submit one bid for all the lots or at least to distribute them for example in 3 packages?	Is it acceptable to offer chamber where Site-VSWR is acc. to CISPR 16-1-4: <8dB at 90% of all measuring points?  Is it acceptable that the NSA deviation between 30MHz and 200MHz can be ±8dB in that frequency range?  Is it acceptable to offer chamber with following dimensions: 7.91×3.34×3.15m (internal shield to shield)?
Yes.	In case when one bidder submits the bids for multiple lots, he is obliged to submit, together with every bid Bank guarantee in the amount of minimum value 2.5% of submitted bid value, in accordance with the conditions on deadlines from the bidding document.  Pursuant to this, it is not possible to submit one Bid Security for all lots.	Please refer to Clarification no. 7 of the Bidding document.	Bidder is obliged to submit the separate (individual) bids for every lot, and all documents regarding the Qualifications he can submit only once for all lots, i.e. as an addendum of one of the submitted bids.	minimum requests of the technical specification.

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Bidding document	Bidding document	Bidding document	
Reference is made to the above mentioned Tender, Section IX. Special Conditions of Contact, Clause GCC 16.5, on page 99, wherein the following is specified: "The payment-delay period after which the Purchaser shall pay interest to the supplier shall be forty five (45) days upon receipt of invoice and other relevant documents."  It is assumed that this does mean that the payment-delay period after which the Purchaser shall pay interest begins after 45 days upon receipt of invoice and other relevant documents.	Reference is made to the above mentioned Tender, Section IX. Special Conditions of Contact, Clause GCC 16.1, on page 98, wherein the following is specified: "Implementation of Related Services: Ten (10) percent of the Contract Price shall be paid within forty five (45) days upon submission of Certificate or Minutes of acceptance confirming implementation of all related services stipulated for each item in Technical specifications and Technical requirements, related to proper functioning of goods, such as but not limited to- installation, burn testing, training etc."  It is assumed, that 10% of the Contract Price shall be paid upon Provisional Acceptance, i.e. start of the warranty period.	Reference is made to the above mentioned Tender, Section VIII. General Condition of the Contact, Clause 18.1, Performance Security, on page 86, wherein the following is specified: "The Performance Security shall be discharged by the Purchaser and returned to the Supplier no later than twenty-eight (28) days following the date of Completion of the Supplier's performance obligations under the Contact, unless specified otherwise in the SCC".  It is assumed that the definition "completion of the Supplier's performance obligations under the Contact" does refer to PAC (Provisional Acceptance Certificate and start of warranty period)?	invoice or request for payment by the Supplier, and after the Purchaser has accepted it?'  It is assumed that 'not later than forty five (45) days' after submission of an invoice or request for payment by the Supplier, and after the Purchaser has accepted it?
Yes.	Yes, 10% of the Contracted price shall be paid within forty-five (45) days from the day of Certificate or Minutes of Acceptance submission.	Instrument of financial security for Performance security has to be valid at least 28 days from the day of completion of supplier's obligations. The supplier's obligations are considered to be completed when all contract obligations are completed, i.e. when a Certificate or Minutes of Acceptance is submitted (in accordance with the GCC, clause 16.1, iii).	

	ICE /a	Clarification no. 0 ICD no. ICD/00 2015 AICE/	
	We kindly ask you to change this condition to:  2.Delivery time 6 months		
Please refer to Corrigendum no. 5 of the Bidding document.	In technical documentation for Lot 5, Item 5,1 Percival Low Temperature Plant Growth Chamber, the following is requested:  2.Delivery time: 90 days	Annex I, Technical Specification	4
Delivery period for LOT 16 is 90 days.	Lot 16- Technical specifications requires delivery period of 90 days, since the equipment is very specific and demanding, the manufacturer is not able to produce the requested device in the stated period, so the delivery of this equipment is not possible within this deadline. We kindly ask you for the change of the delivery deadline, for the equipment from the Lot 16 to 6 months (this is a real timeframe necessary for the production and delivery of the requested device).	Annex I, Technical Specification	. ω
Supplier is obliged to during providing evidence of fulfilment of his professional capacity, act according to the conditions foreseen in the bidding document and Corrigendum no.3 of the bidding document.	If the answer is negative, we kindly ask you to consider the option of collective value of two submitted contracts to be lower than the offered value by maximum of 10%.	Bidding document	2
Please refer to Corrigendum no. 3 of the Bidding document.	Regarding the Professional capacity of the bidders – is it acceptable to submit three contracts whose collective value is equal or exceeds the value of the offered lot, considering that the bids for some lots will be over 200.000,00 EUR?	Bidding document	1
	Questions dated 21/01/2016		
Data on total planned budget as well as the budget allocated to individual lots are not to be published.	Considering that according to the Law on public procurements of the Republic of Serbia, the budget is publically available information, and in this way you shall realize a successful realization of the tender (because there will be no bids over the budget, resulting in no additional negotiated procedures and the unnecessary waste of time) we kindly ask you to submit the information on planned budget per lot individually.	Bidding document	14
	states:" Residents of the Republic of Serbia shall be paid in RSD according to the middle exchange rate of the National Bank of Serbia on the day of the bids opening" Is it acceptable to, in case of the exchange rate change by more than +/- 3% from the day of bid opening to the moment of payment, correct the payment according to the difference. In order to protect the interest of the PIU and the bidder, in case of great exchange rate differences.		

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a microscope for cytogenetic analyses on materials which are of human origin, is it implied that the offered microscope should be registered in the Medicines and Medical Devices Agency, as well as that the potential bidder should submit the copy of registration and the authorization by the holder of the registration for participation in the Public procurement?  NOTE: Based on the governing Law on Medicines and Medical Devices, article 173 In vitro diagnostic medical devices, clearly defines the following: "In-vitro diagnostic medical devices shall include any reagents, reagent products, control and calibration materials, reagent kits, instruments, apparatuses, equipment or systems used independently or in combination intended to be used in-vitro for the examination of samples derived from the human body including human blood and tissues, in order to obtain the information."  Law also clearly defines it in the article 197 item 2, that Medical device can be placed on the market if the following conditions are met, - medical device is registered in the Register of Medical Devices kept by the Agency and in accordance with this Law and regulations passed in for the implementation of this Law.  Based on everything abovementioned in accordance with the Law on Medicines and Medical Devices, and considering that the Microscope in lot 12 is for cytogenetic analyses, we consider that it is necessary to demand in the bidding document, for this lot, the submission of copy of	This is a specific and complex equipment, which is produced according to the request of every buyer individually. The manufacturer is unable to produce such equipment within the period of 90 days.  LOT 20 In technical specification for Isolated Organ Bath, fully automated, 4-place the following characteristics are requested:20.bath vessels with volumina of 2,0ml, 2,5ml, 5,0ml, 10,0ml, 20,0ml,25,0ml, 50,0ml, 100,0ml  Question: is the following specification acceptable: Bath vessels with volumina of 5,0ml, 10,0ml, 25,0ml, 50,0ml?  Considering that the lot 12. Microscope for cytogenetic analyses, requests
Since the mentioned medical device is used in scientific and research purposes, it is not necessary for it to be registered in the Register of medical devices ALIMS. There is a special procedure for giving consent for the import of medical devices which are used in scientific and research purposes, and which relates to medical devices which are not in the Register of medical devices ALIMS.	No, it is necessary to offer the specification defined in the Bidding document.

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	Bidding document		Bidding document	
ISO13485 is required only if the offered equipment are medical devices?	Reviewing the Bidding Document, PROCUREMENT OF CAPITAL EQUIPMENT ICB No: IOP/09-2015/NCE/2 we have found that under General Technical Requirements, 2. Equivalency of Standards and Codes you have requested that:  "2.2The equipment offered should be manufactured in compliance with Quality Standard ISO 9001:2008 certification for Manufacturer(s), ISO 13485 and ISO 14001 in order to achieve the international accreditation according to EN ISO/IEC 17025:2005, EN 45003."  Considering that: ISO13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services and the ISO14000 family of standards provides practical tools for companies and organizations of all kinds looking to manage their environmental responsibilities.  Is it necessary to submit manufacturer's ISO13485 and ISO14001 in our bid?	Questions dated 22/01/2016	Regarding the professional capacity of the bidder – we kindly ask you to accept the contracts signed and started in 2016?	the decision of the Medicines and Medical Devices Agency, as well as the authorization by the holder of the registration for participation in the Public procurement (if the potential bidder is not the holder of the registration), considering that in the other case, there would be a direct violation of the Law on Medicines and Medical Devices.
	It is not necessary to submit the evidence on possessing the mentioned ISO standards. Bidding document requests that the offered equipment has to be manufactured in accordance with the mentioned ISO standards.		Please refer to Corrigendum no.3 of the Bidding document.	

