# Procurement of equipment for Mother and Child Institute Dr Vukan Čupić, Belgrade
# IOP/38-2019/UHI
# Clarification No. 3

## Issued on 30th January 2020

Question 1:
"QUESTION 1. PART 1

In your Bidding Documents you have envisaged the procurement of various equipment divided into 9 different lots. In order for each of the potential bidders to submit the adequate and appropriate bid, the bidder needs to fulfill all the required characteristics defined within one or more lots. Each lot defines the technical requirements of the products that are required by the minimum technical specification. Please note that with the required products as well as set general and additional conditions that need to be fulfilled, the required products (within the defined lots) have different purposes, functionalities, values, risk class, use as well as the fulfillment of different standards that certainly need to be met in order to be able to be sold in the Republic of Serbia at all. Also, according to both the Rulebook on Basic Requirements for Medical Devices, and in the document EU - MEDICAL DEVICES: Guidance document - Classification of medical devices (MEDDEV 2. 4/1 Rev. 9, June 2010) - GUIDELINES RELATING TO THE APPLICATION OF THE COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, all medical devices are classified according to classes and rules and categories. Your Bidding Documents required within the same lots to offer different classes and categories of medical devices that a potential bidder needs to offer in order to have the adequate bid. It is an indisputable fact that no provider of medical equipment based in the Republic of Serbia has a valid Decision of the Ministry of Health of the Republic of Serbia on the permit for import, export, purchase, storage and distribution of all classes and categories of medical devices required by the subject procurement, which represents a significant limitation in the in terms of activity classification. Also, the products you purchase within the same lots do not have any functional or use connectivity related to which they would have to be purchased in one lot. E.g. within Lot no. 4 Procurement of a mobile X-ray system and an infusion pump for operation in the MRi field do not have any use connectivity or functionality due to which they would have to be procured within the same lot. More precisely, there is no logical connection to procure the required products within the same lot. Here we even come to a paradoxical situation that even products of the same or similar purpose (e.g. ultrasound devices) are procured within different lots, while the products which have no essential connection (e.g. CT and fluoroscopy device, radiographic X-ray system and ultrasound device) are procured within the same lot. The values of individual items also represent the reason that needs to condition the separation of items within the requested lot into separate lots. E.g. in Lot no. 1 we come to a paradoxical situation that the choice of the highest value item no. 1.1 - Bi-plane angiography room (whose value exceeds a million EUR) may be determined by the Bidder offering Shiler ECG device requested under item 1.8 (which is worth a few hundreds to thousand EUR). "
"QUESTION 1 PART 2

It is also indisputable that there is no manufacturer in the world that produces all the required subject items. It is clear that the subject procurement can only be carried out through an intermediary who would collect bids from different bidders, aggregate them and submit a single bid for all the items. In this case, hiring and operation solely through an intermediary in the subject procurement has no advantages or logical and economic justifications for the following reasons:

1.1. The intermediary cannot offer the Contracting Authority nothing more (in terms of supplies, service, guarantee, financial security, delivery time, installation, service, training, etc.) than what the manufacturer or the agent or distributor thereof offered to the intermediary.

1.2. In this case, the Contracting Authority only further complicates communication through the intermediary with the manufacturer or the representative thereof, which complicates the level of communication and consumes valuable time.

1.3. The Contracting Authority needs to exercise all the rights thereof in terms of claims for damages, or rectification of errors within the guarantee period, or any other rights through an intermediary, who in turn needs to contact the manufacturer or the representative thereof further.

1.4. The intermediary certainly charges the cost of the services thereof as well as earnings when forming the final price of the bid, thereby consuming significant funds above the real market price limit.

Finally, we note that there are several hundred different technical requirements within the Lots, which themselves limit the offering of certain products.
From all the aforementioned, please define all individual items of defined Lots (from 1 to 9) as separate lots i.e. Lots and thus allow competition in the subject procedure.

If you do not accept our request, please explain in detail the reasons for that."

Answer:

The main objective of the procurement of the equipment for the needs of the Mother and Child Institute ,, Dr Vukan Čupić" is equipping each of the operational unit within the centre so that each unit becomes ready to function as a whole and in its full capacity. As such, it implies the procurement of a large number of devices for all departments of child hospital whose usage is defined by the nature of each unit's work and the by the workflow of the ward. Thus, the procurement is complex and challenging in terms of volume (435 items) and the type of devices to be procured.

The contracting authority has a duty to consider the appropriateness of dividing contracts into lots while remaining free to decide autonomously on the basis of any reason it deems relevant.

While preparing the tender documents, the Contracting Authority was making sure to reconcile the fact concerning the processes in the hospital, the number of examinations and interventions, volume, technical requirements and the main objective of the procurement in question on the one hand and the principles of public procurements on the other hand.

The Contracting Authority subdivided the procurement into several separate parts, into 9 lots, on the basis of the fact that a certain equipment is of the same kind i.e. for the same main purpose, primarily having in mind the usage of the equipment within each operational unit, wards or departments. Neither the law nor special regulations define more detailed criteria for subdividing goods into lots, and they also do not define in more detail the term of usage, but leave it to the Contracting Authority to decide how it will subdivide the procurement, taking into account the general provisions of having the goods of the same kind or for the same purpose into one lot.

In this regard, the Contracting Authority did not put all the necessary equipment used for hospital treatment into one lot, but interpreted the term 'being of the same kind' through functionality of the certain group of devices and their role in the functional units i.e their main usage, purpose – Operating Theatre, Intensive Care, Radiology, Laboratory, Equipment for Specialist Wards….

When analysing lots by items it is clear that the Contracting Authority was guided by the principle of equipment being of the same kind in terms of its functionality, usage. For instance, in Lot Operating theatre, the equipment and furniture to be procured are the goods that are used in Operating department. Having in mind that each department in hospital has the vital function within the hospital and that all equipment within the department function, primary goal of the Purchaser is that all systems and components of a department are delivered, installed, tested, operated in the shortest possible time.

Simultaneous and timely execution of the entire subject of public procurement is necessary for optimal functioning and for later work, the comprehensive support for the entire system of devices in the functional units is ensured this way.
Having all of the above in mind, the Contracting Authority believes that further subdivision would increase the risk in terms of functionality of the functional units, and that forming 435 separate lots following the lot-device principle would put at risk the fulfilment of the main objective of the procurement, which is equipping each of the operational unit within the Mother and Child Institute „Dr Vukan Čupić" so that each unit becomes ready to function as a whole and in its full capacity.

We underline that the procurement is formulated in this way based on the fact that the separate units are of the same kind, bearing in mind and respecting the main principles in public procurement, principle of efficiency and cost-effectiveness.

The Contracting authority underlines that, on the basis of the above-mentioned, the products purchased within the same lot do have the functional or use connectivity related to which they should be purchased in one lot, for example X-ray I infusion pump for MRI are equipment for Radiology department.

Furthermore, we believe that the competition is in no way compromised by subdividing devices into lots in a way it is done in the procurement procedure in question. The Contracting Authority did not prevent any bidder from participating in the public procurement procedure by using

discriminatory conditions, technical specifications and criteria. If you believe that discriminatory conditions, technical specifications and criteria are used, you need to point out the specific cases of that.
The Contracting authority will check each of the eventual allegations of such a case, and if determine any discriminatory condition, technical specification and criteria or not allowed determination, will react in a properly manner. In that sense and regarding the part of the question related to Lot 1 item 1.8 Holter ECG device (upgrade of the existing system), the Contracting authority made an appropriate amendment in the Technical specification for Lot no. 1 and exclude the item from the procurement, see Amendment No.3.

On the other hand, conditions of the tender predicts that the bid may be submitted by a group of bidders, where each bidder from the group of bidders must individually fulfill mandatory requirements, whereas additional requirements, which includes meeting the requirements concerning technical specification, have to be fulfilled jointly.

Having in mind all of the above, we find dividing contract into lots in a way that the potential bidder suggests in the procurement in question, by lots according to relevant classes/rules/categories, defining all individual items of defined lots from 1 to 9 as separate lots, inappropriate, especially having in mind the main objective of the procurement based on the needs of the Final User, Mother and Child Institute ,,Dr Vukan Čupić", as well as the fact that such division could risk rendering the execution of the contract excessively technically difficult or that the need to coordinate the different contractors for the lots could seriously risk undermining the proper execution of the contract and believe that no principle of public procurements was violated, and that the Contracting Authority reconciled the principles and the needs of the Final User in an optimum way and that they subdivided the procurement into lots in the way that doesn't put the objective of the procurement at risk.

Question 2:

In your Bidding Documents and the required technical specification, you have requested, among other things, medical products that emit ionizing radiation.
In accordance with the Law on Radiation and Nuclear Safety and Security (""Official Gazette of RS"", No. 95/2018 and 10/2019) and the fact that item 1.1 of Lot 1 as well as items 4.1, 4.3, 4.4.1, 4.4.2, 4.5 of Lot 4, medical devices with ionizing radiation, our question relates to the following:
Do the bidders offering the said products have to submit the following in accordance with the said law:
"Photocopy of the license for performing the activities of sales and service of devices producing ionizing radiation, issued by the Directorate for Radiation and Nuclear Safety and Security of Serbia or the Agency for Protection against Ionizing Radiation and Nuclear Safety of Serbia""

Answer:
Bidders offering the said products are not obliged to submit the above-mentioned documentation in accordance with the Law on Radiation and Nuclear Safety and Security ("Official Gazzete of RS", No. 95/2018 and 10/2019) and the said documentation will not be considered in the process of evaluation of the bids.

Question 3:

Is it acceptable to the Contracting Authority to offer a medical device that substantially responsive to the technical specification (not completely, i.e. if some requirements in the minimum technical specification do not fully match the required requirements), but functionality, quality and usability of devices is retained in terms of performing all required clinical procedures being the subject matter to public procurement? Please accept our suggestion, as medical devices of different manufacturers do not have the same technical specification (it is not standardized), therefore by different procedures and methods different manufacturers come to the same goal - meeting the required functionality and user demands.

Answer:

Contracting authority is obliged to purchase equipment in accordance with the technical requirements based on clinical needs. A substantially responsive Bid is one that conforms to all the terms, conditions, and specifications of the Bidding Documents without material deviation, reservation, or omission. The Purchaser could not accept deviations and exceptions of technical specifications, but some minor inconsistencies will be acceptable having in mind needs of hospital and clinical staff. We stay at your disposal for any information related to preparation of the bid. In this respect, if you consider that certain specification might limit the principle of competition, point out the specific part of specification and give us suggestion to amend it.

Public Procurement Commission