

Procurement of medical equipment for Clinical Centre of Vojvodina

NO. IOP/55-2021/UHI

Clarification No.3

Issued on 9th of September 2021

Question 1

We kindly ask the Employer to confirm that Manufacturer's Authorizations and Statements requested in tender documents on pages 30 and 59 can also be signed by the authorized EU or Regional representative of the Manufacturer?

Answer 1:

Yes, it would be also acceptable to submit the Manufacturer's Authorization and the Manufacturer's After Sales Authorization signed by the European or Regional representative of the Manufacturers.

Question 2

In the Section VI. Schedule of Requirements, 3. General Technical Requirements, point 2.2. *The equipment offered. should be manufactured in compliance with Quality Standard ISO 9001 certification for Manufacturer(s).* We kindly ask the Employer to confirm that it is acceptable for equipment offered to be manufactured in compliance with Quality Standard ISO 13485 for Manufacturer(s) or Quality Standard ISO 9001. Also, we kindly ask the Employer to confirm that the Quality Standard ISO 13485 or ISO 9001 should apply only to the medical devices in all 3 lots.

Answer 2:

Yes, it is acceptable for offered equipment to be manufactured in compliance with Quality Standard ISO 13485 for Manufacturer(s) or Quality Standard ISO 9001.

Also, Bidders can submit ISO certification 9001 or 13485 just for the medical devices in the technical specification for all 3 lots.

Question 3

In LOT 1 - Imaging, ID 1, MOBILE DIGITAL X-RAY DEVICE

Line Item 1.43 states the distance from the focus of the tube to the floor in the vertical direction range of at least **14000mm +/- 10mm**

We believe that the Employer accidentally oversized this requirement, as no global manufacturer can nearly meet the defined requirement, nor would such floor - focus distance make sense for diagnostic purposes. We kindly ask the Employer to modify the value to **1400mm +/- 10mm**.

Answer 3:

See Amendment no. 1, issued on September 9, 2021.

Question 4

Regarding the LOT 3_Common hospital needs, Lot ID 6 Intensive care hospital beds, item:

6.35	Extension of thigh and foot section while backrest lifting
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We kindly ask the Employer to confirm that for the fulfilment of the point 6.35 the bidder can offer *Extension between head and hip section* as an equivalent solution.

Answer 4:

The Purchaser will accept “*Extension between head and hip section*” as an equivalent solution for the point 6.35, ID 6, LOT 3.

Question 5:

In LOT3_Common hospital needs, Lot ID 4 Dining table adjustable in height, made from steel and Lot ID 5 Bedside cabinet

We believe that the Employer accidentally mismatched the description of the 2 positions. Some line descriptions for the item 4 belong to the item 5 and viceversa. We kindly ask the Employer to modify description of the ID 4 and ID 5 in the following way:

4	Dining table adjustable in height, made from steel	
	4.1	Mounted on double band castors.
	4.2	Table is used above bed, wheelchair or big chair.
	4.3	Adjustable height, in range from min 70 cm to max 110 cm
	4.4	Front wheelbase min 30 cm
	4.5	Fixed dining table, dimensions min 95 x 45 cm
	4.6	Thickness of full raisen table top min 7 mm
	4.7	Safe working load at center of table top min 30 kg
	4.8	Safe working load, stability at any point min 15kg
	4.9	Thickness of table top and support min 5 cm
	4.10	4 double band castors, diameter min 50 mm
	4.11	Column, foot and table top support plate in steel
5	Bedside cabinet	
	5.1	Bedside cabinet height min 90 cm±2cm
	5.2	Bedside cabinet width min 40 cm
	5.3	Bedside cabinet depth min 40 cm
	5.4	Bedside cabinet body material from Melamine
	5.5	Top plate material from high pressure laminate
	5.6	Hinge on left side
	5.7	Aluminium edges
	5.8	Fixed strip

5.9	4 castors, diameter min 50 mm
5.10	One drawer
5.11	One door
5.12	One shelf

Answer 5:

See Amendment no. 1, issued on September 9, 2021, by which Purchaser corrects the made it technical omission.

Question 6

Please find below our questions regarding the particular points of the Technical Specification for the Position ID 27 - X-Ray viewer with 2 panels in LOT3_Common hospital needs:

Point 27.2 - Question:

Is it acceptable for the Employer to change this request to: Light Source should be made of LED lights? Reasons: Since the technology of fluorescent tubes as the light source for X-Ray viewers is obsolete because of the existence of mercury in the very fluorescent tubes that is harmful to the environment, we consider that the X-Ray viewer with the LED light source is a better option for the orderer. This technology is clean for the environment, LED light sources have a longer lifespan and there is no need for their replacement during the entire life span of the device.

Point 27.6 - Question:

Is it acceptable for the Employer the offer of LED X-Ray viewers with the viewing area for two films with dimensions 42 x 72cm.

Reasons: The obsolete technology of X-Ray viewers with fluorescent tubes was limited in the area where films are set by the very size of the fluorescent tube. There is no such limitation with LED -Ray viewers and so these dimensions are better suited to viewing the films.

Point 27.8 - Question:

With regard to the change of the light source technology, is it acceptable to the Employer the option of the X- Ray viewers with the dimensions 817 x 505 x 30_{ТТ} +/-5%?

Reasons: Just like in request 27.6, these dimensions are better suited to dimensions of the films.

Point 27.9 - Question:

With regard to the improvement of the light source technology, is it acceptable to the orderer the option of the X-Ray viewers with LED light source with the most optimal light temperature of around 7200K?

Point 27.10 - Question:

With regard to the improvement of the light source technology, is it acceptable to the Employer the option of the X-Ray viewers with LED light source with adjustable light intensity from 30% to 100% and with luminance of 5000cd/mq?

Point 27.11 - Question:

With regard to the improvement of the light source technology and provision for light temperature of 7200K which we consider ideal for film viewing, is it acceptable to the orderer to change this request to read: Provision for quick turning on the light, when necessary, by the

very insertion of the film?

Point 27.12 - Question:

With regard to the improvement of the light source technology, is it acceptable for the Employer to offer X- Ray viewers with LED light source consuming up to 80VA?

Answer 6:

See Amendment no. 1. issued on September 09, 2021.

Public Procurement Committee

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