



**MINISTRY OF HEALTH
WORLD BANK PROJECT MANAGEMENT UNIT**

1-3 Cristian Popișteanu St., room 235-236, Sector 1, 010024, Bucharest, ROMANIA

TEL: +40-21-307.25.90; FAX: +40-21-307.25.87

Our ref.no: ⁴⁹⁷⁷...../August 5, 2019

To: All prospective bidders that received the Bidding Documents

Ref: Health Sector Reform - Improving Health System Quality and Efficiency Project - Loan No. 8362-RO. Procurement of radiotherapy equipment - ICB No. G/C1/3.3 (2 lots)

Dear Mrs. /Mr.

Please find attached the following documents:

1. Clarifications and amendments no. 1 of August 5, 2019 to the Bidding Document for Procurement of radiotherapy equipment – ICB No. G/C1/3.3 (2 lots), consisting of 4 pages that includes the responses to the clarification requests received from the potential bidders
2. Amendment no. 1, consisting of 6 pages that includes amended clause/technical specifications/forms as a result of the responses given to the requests for clarifications received;

Please confirm the receipt of the documents above and that you will take into account the provisions of the above documents in preparing your bid.

Considering the provisions of amendment no. 1, we are kindly inform you that the deadline for bids submission will remain as established in the bidding documents, respectively **August 12, 2019, 12:00 hour's local time.**

Yours sincerely,

Răzvan Vieru,
Head of WBPMU





ROMANIA, Ministry of Health
World Bank Project Management Unit

Health Sector Reform – Improving Health System Quality and
Efficiency Project
(IBRD Loan no. 8362-RO)



APROB,
MINISTRUL SĂNĂTĂȚII

SORINA PINTEA

ADDENDUM NO. 1 of August 5, 2019
to the Bidding Documents for
“Procurement of radiotherapy equipment” (ICB No. G/C1/3.3)

According with the *ITB 8 – Amendment of the Bidding Document*, the Bidding Documents is hereby amended as follows:

Section II. Bid Data Sheet (BDS)

Article 1. The provisions of ITB 1.1 under Section II Bid Data Sheet are hereby modified and they will be read as follows (all changes are written in green text):

“

LOT II: Radiotherapy equipment for Emergency County Clinical Hospital “Sf. Apostol Andrei” Galati, consisting of:

- Level 1 single energy medical linear accelerator (LINAC – 6MV);
- Level 1 treatment planning system/contouring station (TPS/CS) – 2/2;
- Level 1 record and verify system (R&V) – 5 work stations with all licenses needed;
- One complete set of immobilization system (for LINAC);
- One complete set of dosimetry (PSQA - Patient Specific Quality Assurance);
- ⁶⁰Co unit decommissioning;
- Additional civil works required to achieve the objectives of the project.

.....”

Section IV. Bidding Forms

Article 2. The “Price Schedule” forms for LOT no. II of Section IV. Bidding Forms, are hereby modified and they will be in the format included in ANNEX 1 of the present Addendum. All changes are written in green text.

Section VII. Schedule of Requirements

1. List of Goods and Delivery Schedule

Article 3. The “1. List of Goods and Delivery Schedule” form for LOT no. II of Section VII. Schedule of Requirements, are hereby modified and they will be in the format included in ANNEX 2 of the present Addendum. All changes are written in green text.

2. List of Related Services and Completion Schedule



Article 4. The “2. List of Related Services and Completion Schedule” form for LOT 9 of Section VII. Schedule of Requirements, is hereby modified and it will be in the format included in ANNEX 3 of the present Addendum. All changes are written in green text.

3. Technical Specifications

Article 5. The requirement A. V.3. Expected Works of Lot no. II: Radiotherapy equipment for Emergency County Clinical Hospital "Dr. Apostol Andrei" Galati under 4. *Specific information for the radiotherapy centers, chapter 4. Technical Specifications of the Section VII – Schedule Requirements* is hereby modified and will be read as follows (all changes are written in green text):

“The entire radiotherapy center was rehabilitated in 2018, including some civil works for the second bunker, proposed for installation of the new Linac.

The center will become operational starting with September 2019.

The awarded bidder for this lot will execute just the additional small civil works that are needed for the proper installation of the second Linac ~~and to decommission the old 60CO equipment with the beneficiary unit support.~~

The bid should include additional shielding, fire and smoke detection systems, firefighting systems, electrical installation, and plumbing network installation to make equipment be fully functional; complementary to the executed works.”

Article 6. The requirement under 4. *Specific information for the radiotherapy centers, chapter 4. Technical Specifications of the Section VII – Schedule Requirements* is hereby modified and will be read as follows (all changes are written in green text):

~~“Actual 60CO equipment will be decommissioned by the supplier with the support of the beneficiary unit before starting the rehabilitation works needed for a proper installation of the new equipment.”~~

Article 7. The requirement under 4. *Specific information for the radiotherapy centers, chapter 4. Technical Specifications of the Section VII – Schedule Requirements* is hereby modified and will be read as follows (all changes are written in green text):

“

SITE	Energy	EXISTENT BUNKER (estimation of radioprotection upgrade needed)	BUNKER DOOR (estimation of radioprotection upgrade needed)	BUNKER VENTILATION (estimation of upgrade needed)	Existent RT machine / Year of Installation / Actual State	Construction works complexity - estimation
BAIA MARE	6MV	YES - upgrade needed	YES – new door must be installed	YES – new HVAC must be installed	There is NO RT machine inside the bunker	MINIMAL
GALAȚI	6MV	YES – minimal upgrade needed	YES – new door must be installed	NO – new HVAC installed in 2018	60CO will be decommissioned by the beneficiary unit before delivery of the new linac	MINIMAL

”

Article 8. All other parts, clauses and provisions of the *Bidding Documents* that are not amended as per the articles above shall remain valid and unchanged.



Price Schedule Forms

LOT II - Radiotherapy equipment for Emergency County Clinical Hospital "Sf. Apostol Andrei" Galati Price Schedule: Goods Manufactured Outside the Purchaser's Country, to be Imported

Date: _____ ICB No: G/C1/3.3 - Lot no. II Alternative No: <i>Not applicable</i> Page N° _____ of _____								
(Group C bids, goods to be imported)								
Currencies in accordance with ITB 15								
1	2	3	4	5	6	7	8	9
Line Item N°	Description of Goods	Country of Origin	Delivery Date as defined by Incoterms	Quantity and physical unit	Unit price CIP at Elias University Emergency Hospital in accordance with ITB 14.8(b)(i)	CIP Price per line item (Col. 5x6)	Price per line item for inland transportation and other services required in the Purchaser's country to convey the Goods to their final destination specified in BDS	Total Price per Line item (Col. 7+8)
[insert number of the item]	[insert name of good]	[insert country of origin of the Good]	[insert quoted Delivery Date]	[insert number of units to be supplied and name of the physical unit]	[insert unit price CIP per unit]	[insert total CIP price per line item]	[insert the corresponding price per line item]	[insert total price of the line item]
1	Level 1 single energy medical linear accelerator (LINAC - 6MV);			1			<i>Not applicable</i>	
2	Level 1 treatment planning system/contouring station (TPS/CS) - 2/2;			1			<i>Not applicable</i>	
3	Level 1 record and verify system (R&V) - 5 work stations with all licenses needed;			1			<i>Not applicable</i>	
4	One complete set of immobilization system (for LINAC);			1			<i>Not applicable</i>	
5	One complete set of dosimetry (PSQA);			1			<i>Not applicable</i>	
6	⁴⁶ Co-unit decommissioning			+			<i>Not applicable</i>	
							Total Price	



Name of Bidder [insert complete name of Bidder] Signature of Bidder [signature of person signing the Bid] Date [Insert Date]

Price Schedule: Goods Manufactured Outside the Purchaser's Country, already imported*

Date: _____
 ICB No: G/C1/3.3, Lot no. II
 Alternative No: Not applicable
 Page N° _____ of _____

(Group C bids, Goods already imported) Currencies in accordance with ITB 15

1	2	3	4	5	6	7	8	9	10	11	12
Line Item N°	Description of Goods	Country of Origin	Delivery Date as defined by Incoterms	Quantity and physical unit	Unit price including Custom Duties and Import Taxes paid, in accordance with ITB 14.8(c)(i)	Custom Duties and Import Taxes paid per unit in accordance with ITB 14.8(c)(ii), [to be supported by documents]	Unit Price net of custom duties and import taxes, in accordance with ITB 148 (c) (iii) (Col. 6 minus Col.7)	Price per line item net of Custom Duties and Import Taxes paid, in accordance with ITB 14.8(c)(i) (Col. 5x8)	Price per line item for inland transportation and other services required in the Purchaser's country to convey the goods to their final destination, as specified in BDS in accordance with ITB 14.8 (c)(v)	Sales and other taxes paid or payable per item if Contract is awarded (in accordance with ITB 14.8(c)(iv))	Total Price per line item (Col. 9+10)
[insert number of the item]	[insert name of Goods]	[insert country of origin of the Good]	[insert quoted Delivery Date]	[insert number of units and name of the physical unit]	[insert unit price per unit]	[insert custom duties and taxes paid per unit]	[insert unit price net of custom duties and import taxes]	[insert price per line item net of custom duties and import taxes]	[insert price per line item for inland transportation and other services required in the Purchaser's country]	[insert sales and other taxes payable per item if Contract is awarded]	[insert total price per line item]
1	Level 1 single energy medical linear accelerator (6MV);			1							
2	Level 1 treatment planning system/contouring station (TPS/CS) - 2/2;			1							
3	Level 1 record and verify system (R&V) - 5 work stations with all licenses needed;			1							
4	One complete set of immobilization system (for LINAC);			1							
5	One complete set of dosimetry (PSQA);			1							
6	Co-unit decommissioning			+							
										Total Price	

Name of Bidder [insert complete name of Bidder] Signature of Bidder [signature of person signing the Bid] Date [insert date]

* [For previously imported Goods, the quoted price shall be distinguishable from the original import value of these Goods declared to customs and shall include any rebate or mark-up of the local agent or representative and all local costs except import duties and taxes, which have been and/or have to be paid by the Purchaser. For clarity the bidders are asked to quote the price including import duties, and additionally to provide the import duties and the price net of import duties which is the difference of those values.]



Price Schedule: Goods Manufactured in the Purchaser's Country

Purchaser's Country _____

(Group A and B bids)

Date: _____

ICB No: **G/C1/3.3, Lot no. II**

Alternative No: *Not applicable*

Page N° _____ of _____

Currencies in accordance with ITB 15

1	2	3	4	5	6	7	8	9	10
Line Item N°	Description of Goods	Delivery Date as defined by Incoterms	Quantity and physical unit	Unit price EXW	Total EXW price per line item (Col. 4x5)	Price per line item for inland transportation and other services required in the Purchaser's Country to convey the Goods to their final destination	Cost of local labor, raw materials and components from with origin in the Purchaser's Country % of Col. 5	Sales and other taxes payable per line item if Contract is awarded (in accordance with ITB 14.8(a)(ii))	Total Price per line item (Col. 6+7)
[insert number of the item]	[insert name of Good]	[insert quoted Delivery Date]	[insert number of units to be supplied and name of the physical unit]	[insert EXW unit price]	[insert total EXW price per line item]	[insert the corresponding price per line item]	[insert cost of local labor, raw material and components from within the Purchaser's country as a % of the EXW price per line item]	[insert sales and other taxes payable per line item if Contract is awarded]	[insert total price per item]
1	Level 1 single energy medical linear accelerator (LINAC – 6MV);		1				Not applicable		
2	Level 1 treatment planning system/contouring station (TPS/CS) – 2/2;		1				Not applicable		
3	Level 1 record and verify system (R&V) – 5 work stations with all licenses needed;		1				Not applicable		
4	One complete set of immobilization system (for LINAC);		1				Not applicable		
5	One complete set of dosimetry (PSQA);		1				Not applicable		
6	*Co-unit decommissioning		1				Not applicable		
Total Price									

Name of Bidder [insert complete name of Bidder] Signature of Bidder [signature of person signing the Bid] Date [insert date]



1. List of Goods and Delivery Schedule

LOT II – Radiotherapy equipment for Emergency County Clinical Hospital “Sf. Apostol Andrei” Galati

[The Purchaser shall fill in this table, with the exception of the column “Bidder’s offered Delivery date” to be filled by the Bidder]

Line Item N°	Description of Goods	Quantity	Physical unit	Final (Project Site) Destination as specified in BDS	Delivery (as per Incoterms) Date		
					Earliest Delivery Date	Latest Delivery Date	Bidder’s offered Delivery date [to be provided by the bidder]
[insert item No]	[insert description of Goods]	[insert quantity of item to be supplied]	[insert physical unit for the quantity]	[insert place of Delivery]	[insert the number of days following the date of effectiveness the Contract]	[insert the number of days following the date of effectiveness the Contract]	[insert the number of days following the date of effectiveness the Contract]
1	Complete solution, consisting of: - Level 1 single energy medical linear accelerator (LINAC – 6MV) - Level 1 treatment planning system/contouring station (TPS/CS) – 2/2; - Level 1 record and verify system (R&V) – 5 work stations with all licenses needed; - One complete set of immobilization system (for LINAC);; - One complete set of dosimetry (PSQA); @CO-decommissioning	1	Package	As per Site Table	100 days	150 days	

Authorized Representative: _____

Name and position: _____

Bidder’s name: _____



**Health Sector Reform - Improving Health System Quality and Efficiency Project - IBRD Loan no. 8362-RO
International Competitive Bidding No. G/C1/3.3 - Procurement of radiotherapy equipment**

**APROB,
MINISTRUL SĂNĂTĂȚII**

Data: August 5, 2019

SORINA PINJĂRĂ NIA
CLARIFICATIONS and AMENDMENTS No. 1 of August 5, 2019 to the Bidding Document



A. GENERAL CLARIFICATIONS AND AMENDMENTS FOR ALL 2 LOTS:

No.	Request for clarification	Clarification Response	Clarification or Amendment to the Bidding Document
Section VII. Schedule of Requirements			
1.	<p>(i) The specifications requested for the TPS/CS Equipment can be fulfilled (cumulatively) by only one potential bidder (the producer of "Manufacturer name..." equipment) thus completely denying competitive bidding As per the Schedule of Requirements, the Borrower requests, for the TPS/CS equipment, "100% compatibility and integration with existing system". This requirement entails that the equipment requested may be provided only by the same producer of the existing system - "Manufacturer name...", as 100% compatibility cannot be claimed by third party products. Nevertheless, there is no clinical reason to request "100% compatibility and integration with existing system" as user's needs (and therefore, the Borrower's objective needs) may be entirely met by non-"Manufacturer name" products throughout interconnectivity between offered TPS and existing R&V system. Allowing the bid of an interconnectable solution would ensure the same (and even better) user experience since the "Manufacturer name" existing products do not have integration of their TPS and R&V software solution either, which means that the workflow of the clinical personnel will be exactly the same, only using a different (and better)</p>	<p>The principle used for the technical specifications for this bidding is the same with the one used for the first procurement procedure, respectively ICB G/C1/1.1 (see lot no. 1 - OIB - "(UPGRADE OF EXISTING TPS/CS, R&V system - YES, THOSE LINKED TO VARIAN LINACs** - ** Existing TPS, CS, R&V linked to VARIAN infrastructure (e.g. LINAC) must be upgraded to the latest and newest version or replaced by adequate other equipment, assuring full connectivity and functionality with existing VARIAN equipment (e.g. LINACs, RT CTsimulators, lasers, etc.))". At that time, both bidders (VARIAN and ELEKTA) fully complied with the requested technical specifications without any deviation.</p>	<p>In addition, using a TPS system which is not</p>



No.	Request for clarification	Clarification Response	Clarification or Amendment to the Bidding Document
	<p>This workflow consists of preparing treatment plan in TPS system and exporting it to R&V system.</p> <p>Consequently, we request that the above described restrictive specifications be amended by allowing also the bid of an alternative interconnectable solution which fully meets the needs of the users and, at the same time, allows for competitive bidding in the Procedure, thus ensuring the Borrower the purchase of the most advantageous solution.</p> <p>(ii) The specifications requested for the R&V System can also be fulfilled (cumulatively) by the same sole potential bidder (the producer of "<u>Manufacturer name</u>" equipment) thus completely restricting competitive bidding.</p> <p>Similar to the TPS/CS Equipment, the Borrower requests that also the R&V System ensures "100% compatibility and integration with existing system", thus limiting the bid to the producer of the existing system - "<u>Manufacturer name</u>".</p> <p>Unlike the TPS/CS Equipment, an alternative interconnectable solution cannot be provided by any other party than "<u>Manufacturer name</u>" and consequently maintaining this requirement in the Bid Documentation completely blocks competitive bidding in the Procedure.</p> <p>Therefore, we request that the Borrower amend the restrictive specifications described above either by:</p> <ul style="list-style-type: none"> • eliminating the expansion of existing R&V system from the scope of the procedure, in order to allow competitive bidding for the other items from the Schedule of Requirements; or • maintaining the requirement related to the expansion of existing R&V system but also allowing for the alternative solution of a total replacement of this system, with a corresponding adjustment of the contracted value, if necessary, or • allowing a new R&V system truly integrated, not just interconnected, with the a new TPS system to be used in parallel with existing installed RT equipment. <p>(iii) The services for "Upgrade of the existing Radiotherapy Equipment on-site (e.g. LINACs, brachytherapy units, TPS/CS, R&V system, network infrastructure)" can only be provided by the same unique potential bidder (the producer of "<u>Manufacturer name</u>" equipment)</p> <p>Although obvious, for argumentation purposes, we note that upgrading a system of any type – especially one as specific and complex as the equipment to be purchased</p>	<p>compatible with the existing one on site will not allow the user to direct use of the existing commissioning data already acquired. It means that a new whole commissioning and verification procedure is needed for the existing LINAC, putting unnecessary stress on local staff and prologue of the implementation.</p> <p>In future, when experience of local team is gained (1-3 years of clinical use of the new installed RT systems), for more complex approaches/research, the possibility of having 2 different kind of TPS algorithms and to compare results, choosing the most suitable for a specific case could be of interest. In future, we will consider your suggestion.</p>	



No.	Request for clarification	Clarification Response	Clarification or Amendment to the Bidding Document
	<p>under the Procedure - may be performed, at least in substance, only by using the proprietary software native to the system to be upgraded.</p> <p>In the present case, this requirement leads again to a sole bidder – "<u>Manufacturer name</u>". More specifically, in what concerns Linac, TPS/CS and possibly R&V system, only Elekta can provide an upgrade solution as these systems operate on software proprietary to Elekta.</p> <p>Therefore, in order to allow competitive bidding and to ensure that the Borrower purchases the most advantageous solution, we request that the upgrade services which can be provided only by "<u>Manufacturer name</u>." be eliminated from the scope of the Procedure (and be purchased throughout a distinct procedure, suitable to the situation of a sole provider).</p> <p>Summarizing the above, we kindly request the amendment and/or further clarification of the Bidding Documents such as to allow for effective competitive bidding and to eliminate directing the bid to a sole bidder.</p> <p>Las but not least, please note that accepting our request would not only re-establish free competition within the Procedure but it would also ensure that the Bidding Documents are re-aligned with the Word Bank's Guidelines: Procurement of Goods, Works, and Non-Consulting Services Under IBRD Loans and IDA Credits & Grants By World Bank Borrowers", according to which "<u>standards and technical specifications quoted in bidding documents shall promote the broadest possible competition</u>".</p>		
2.	<p>Under technical tender book, there is a request for decommissioning existing Co60 unit currently installed in RT department at Emergency County Clinical Hospital "Dr. Apostol Andrei" Galati.</p> <p>After prompt investigation we came to the conclusion that decommissioning of existing Co system is a process that we as economic agent cannot control even having best wishes to perform it.</p> <p>There is only one company, ICCO Medical SRL Brasov, which has CNCAN license to perform such work. Also there is a possibility to transfer existing Co source to ICN</p>	<p>Decommissioning of the existing - ⁶⁰CO unit installed at Emergency County Clinical Hospital "Dr. Apostol Andrei" Galati (Theratron Elite 100) which is no longer in use since the end of June 2019 due to a major malfunction, will be performed by the hospital in collaboration with National Commission for Nuclear Activities Control and Sandia Laboratories within the project of US Department of Energy (surveillance of high</p>	<p>Amendment and clarification</p>



No.	Request for clarification	Clarification Response	Clarification or Amendment to the Bidding Document
	<p>Pitesti like in the previous cases when sanitary units were responsible for this part of the project. Having in mind that such process can last significant period of time we as economic agent have no influence on obtaining licenses for such procedure, dismantling system, removing and transporting depleted Co source to a final destination. This may last months before we can get clear space to start internal refurbishment for new linac installation. The time limit for complete project is even shorter for 60 days than in previous two tenders 3.1 and 3.2. Therefore, we kindly ask you to reconsider option of removing this request from tender book and transfer obligation of Co system decommissioning to ECCH "Sf. Apostol Andrei", Galati.</p> <p>In proposed way PMU and ECCH "Sf. Apostol Andrei" Galati as state institutions can easily speed up and influence such action and we can all gain precious time that we need to finish this projects before end of this calendar year which is quite possible if you agree on this proposal. Also cost of such operation would be much lower having in mind that there would be no intermediate company arranging paper works.</p>	<p>activity sources)</p> <p>The intention of the hospital is not to remedy the malfunction due to the high costs and the necessary time (2 months) and will deal with the decommissioning of the Theratron Elite 100 so that at the date of delivery of the new linear accelerator, all the procedures will be completed and the bunker empty.</p>	

