MINISTRY OF HEALTH
PROJECTS MANAGEMENT UNIT

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

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Our ref.no: 32097/29.05.2017

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/C1/3.1 (5 lots)

Dear Mrs. /Mr.

Please find attached the following documents:

1. Amendment no. 1 to the Bidding Documents for Procurement of radiotherapy equipment – ICB No. G/C1/3.1 (5 lots), consisting of 4 pages that include the amended clause/technical specifications as a result of the responses given to the requests for clarifications received;
2. The responses to the clarification requests related to the provisions of the bidding documents – Clarification no. 1 (14 pages), including the radioprotection doc. for Constanta.
3. Section IV Bidding forms and Section VII Schedule of Requirements, part of the bidding documents in editable version.
4. Section VI of the Bidding Documents, Schedule of requirements – Technical Specifications, scanned copy and editable pdf. that includes the revised Technical Specification in accordance with the provisions of Amendment no. 1 to the Bidding Documents and the answers to the clarification requests (77 pages).

   All changes related to the technical specifications are highlighted in green.

Due to the size, all the documents mentioned above will be sent only by e-mail to the address provided by your company.
Companies that could not access the technical project for Baia Mare radiotherapy center, provided together with the bidding documentation are invited to our office to pick up again the documents in electronic format.

Please confirm the receipt of the documents above and that you will take into account the clarifications no. 1 and the provisions of Amendment no. 1 to the Bidding Documents in preparing your bid.

Considering the provisions of amendment no. 1 and the clarifications no. 1, we are kindly asking to receive the final clarification requests no later than **May 31st, 2017, 10:00 hour's local time**. Late requests for clarifications received after this date will not be taken into consideration.

Yours sincerely,

Ministry of Health – Project Management Unit
Mircea-Sorin Zaharcu, PMU Interim Director

ROMANIA
Ministry of Health – Project Management Unit
Health Sector Reform - Improving Health System Quality and Efficiency Project (HSRIHSQEP) - *IBRD Loan No.* 8362-RO

AMENDMENT NO. 1 TO THE BIDDING DOCUMENTS FOR PROCUREMENT OF RADIOTHERAPY EQUIPMENT – 5 LOTS - ICB NO. G/C1/3.1

Under this addendum it is agreed that the provisions of the Bidding Documents shall be amended as follows:

Article 1: Section VII Schedule of requirements – 1. General requirements for all the radiotherapy equipment - point 3.
***Shall read*:** "Prior shipment the Manufacturer shall perform all conformity tests necessary to verify the characteristics and performances of the Goods supplied under the Contract."
***Instead of*:** "Prior shipment the Manufacturer independent recognized agency shall perform all tests/certification necessary to verify the characteristics and performances of the Goods supplied under the Contract. All tests/certification will be conducted by an independent agency prior to shipment for the goods to be imported, and at the warehouse/ factory for the goods already imported or locally manufactured."

Article 2: Section VII Schedule of requirements – 5. Inspections and tests - point a) and SCC GCC 26.1 of the Contract.
***Shall read*:** "**Pre-shipment tests** for Goods supplied from abroad, **to be imported:** prior shipment the the Manufacturer shall perform all conformity tests necessary to verify the characteristics and performances of the Goods supplied under the Contract, Schedule of Requirements section VII. The Manufacturer of the Goods shall issue the quality testing certificate that must confirm the compliance of the Goods to the Technical Specifications. The Supplier must submit the certificate to the Purchaser."
***Instead of*:** "**Pre-shipment tests** for Goods supplied from abroad, **to be imported:** prior shipment the independent recognized testing agency nominated by the Manufacturer of the Goods shall perform all tests necessary to verify that the technical specifications of the Goods that will be shipped to the Purchaser fully comply with the Technical Specifications of the Goods provided in the Contract, Schedule of Requirements section VII. At the end of the tests the independent recognized testing agency nominated by the Manufacturer of the Goods shall issue the quality testing certificate that must confirm the compliance of the Goods to the Technical Specifications. The Supplier must submit the agency testing certificate to the Purchaser."

Article 3: Section VII Schedule of requirements – Technical Specifications – Lot I - Item I.1; Lot II - Item II.1 and Lot III - Item III.1– Other specs:
***Shall read*:** "Isocenter accuracy: must be 2R≤1.5mm. „R" is the radius of the sphere;"
***Instead of*:** "Isocenter accuracy: must be 2R≤1mm. „R" is the radius of the sphere;"

Article 4: Section VII Schedule of requirements – Technical Specifications – All lots - PHOTON BEAM CHARACTERISTICS:
Shall read*:** "Flatness for flattened beams: Variation of X-ray intensity relative to the central axis shall not exceed ± 3% at 100cm SSD and 10cm depth over the central 80% of the field for the longitudinal and transverse axes of all field sizes from 10cm x 10cm to 40cm x 40cm ***or the field flatness for flattened beams – Maximum ratio of the maximum absorbed dose to the minimum absorbed dose does in the flattened area shall not exceed: For field sizes 5 cm x 5 cm to 30 cm x 30 cm, ≤ 106%; For field sizes greater than 30 cm x 30 cm, ≤ 110%"

***Instead of*:** "Flatness for flattened beams: Variation of X-ray intensity relative to the central axis shall not exceed ± 3% at 100cm SSD and 10cm depth over the central 80% of the field for the longitudinal and transverse axes of all field sizes from 10cm x 10cm to 40cm x 40cm"

Article 5: Section VII Schedule of requirements – Technical Specifications – All lots – Other specs:
***Shall read*:** "The target to axis distance should be 100 ± 0.2 cm"
***Instead of*:** "The target to axis distance should be 100 ± 0.1 cm"

Article 6: Section VII Schedule of requirements – 2. Maintenance requirements - point 2):
***Shall read*:** "All emergency responses on call and prompt phone support / remote system of service personnel within working hours. Authorized service centre has to respond by remote controlled service system within 4 hours (exceptionally until 12:00 a.m.) after request from the hospital was issued. If the problem is not solved using the remote controlled service the engineer must be present on-site not later than the next day during the working hours."
***Instead of*:** "All emergency responses on call and prompt phone support of service personnel within working hours. Authorized service centre has to respond within 4 hours (exceptionally until 12:00 a.m.) after request from the hospital was issued. Response has a meaning of on-site help of service personnel"

Article 7: Section VII Schedule of requirements – Technical Specifications – Lot no. II, III, IV and V – ESSENTIAL ACCESSORIES TO BE INCLUDED WITH THE SYSTEM:
***Shall read*:** "UPS system designated to ensure backup, to allow the images to be saved and moving the table in order to safely evacuate the patient which might be under examination at a given time"
***Instead of*:** "UPS: On line UPS with batteries for the backup of the entire computational system for at least 15 minutes;"

Article 8: Section VII Schedule of requirements – Technical Specifications – Lot no. I – Item 1, II – Item 1 and 2, III – Item 1 and 2, IV – Item 1 and 2, V – Item 1 and 2 – GOUVERNAMENTAL BODIES LEGAL LICENSES:
***Shall read*:** "The bidder will provide all necessary support (incl. financial: e.g. fees to Regulatory Body (CNCAN) and other authorities) for the preparation of the files needed by all parties involved to obtain all necessary legal licenses requested by Romanian legislation (except the one for clinical usage of the system)"
***Instead of*:** "All necessary legal licenses requested by Romanian legislation must be included in quotation (except the one for clinical usage of the system)."

Article 9: Section VII Schedule of requirements – Technical Specifications – Lot no. I to V – Item 1 – CONNECTIVITY:
***Shall read*:** "The compatibility with PACS configurations including HIS and RIS and all needed licenses highly recommended"
***Instead of*:** "Should be compatible with PACS configurations including HIS and RIS with all needed licenses;"

Article 10: Section VII Schedule of requirements – Technical Specifications –Item I.3, II.4, III.4, IV.4 and V.4 – REQUESTED FUNCTIONS:
***Shall read*:** "Radiation therapy charting"
***Instead of*:** "Medical oncology charting"

Article 11: Section VII Schedule of requirements – Technical Specifications –Item IV.1 - FUNCTION DESCRIPTION ***shall be read as follows*:** "***Single*** energy medical linear accelerator able to perform various specialized treatment techniques such as: 2D, 3D-CRT. LINAC must be capable of being upgraded with necessary software and hardware to perform specialized treatment techniques as: DART, IGRT, IMRT, IMAT, latest modalities. The system must be provided to the end-user as a complete "turn on key" system and ready to be commissioned and used clinically.

Article 12: Section VII Schedule of requirements – Technical Specifications – For all Item 1 of the 5 lots the technical requirement "Digital stainless steel thermoplastic water bath for masks." ***will be deleted.***

Article 13: Section VII Schedule of requirements – Technical Specifications – All lots - PHOTON BEAM CHARACTERISTICS:
***Shall read*:** "Symmetry: The maximum percent differences of average doses shall not exceed ± 2% for the longitudinal and transverse halves of all field sizes from 10cm x 10cm to 40cm x 40cm, at 100cm SSD and 10cm depth; Average dose is defined as the arithmetic average of minimum and maximum doses within the central 80% of the field for both axes or maximum ratio of absorbed doses at points symmetrically displaced from the axis of the beam and within the flattened area: For field sizes ≥5cm x 5cm: ≤103%"

***Instead of*:** "Symmetry: The maximum percent differences of average doses shall not exceed ± 2% for the longitudinal and transverse halves of all field sizes from 10cm x 10cm to 40cm x 40cm, at 100cm SSD and

10cm depth; Average dose is defined as the arithmetic average of minimum and maximum doses within the central 80% of the field for both axes"

Article 14:

Section II. Bid Data Sheet (BDS) - ITB 22.1.

***Shall read*:**
"For **bid submission purposes** only, the Purchaser's address is:
Attention: Mr. Mircea-Sorin Zaharcu, PMU Interim Director
Ministry of Health - Project Management Unit
Street Address: 1-3, Cristian Popișteanu Ent., Sector 1
Floor/Room number: 2nd floor, room 236
City: Bucharest
Postal Code: 010024
Country: Romania
The deadline for bid submission is:
Date: **June 14th, 2017**
Time: **12:00 hour's local time**
Bidders **shall not** have the option of submitting their bids electronically."

***Instead of*:**
"For **bid submission purposes** only, the Purchaser's address is:
Attention: Mr. Mircea-Sorin Zaharcu, PMU Interim Director
Ministry of Health - Project Management Unit
Street Address: 1-3, Cristian Popișteanu Ent., Sector 1
Floor/Room number: 2nd floor, room 236
City: Bucharest
Postal Code: 010024
Country: Romania
The deadline for bid submission is:
Date: **May 31st, 2017**
Time: **12:00 hours local time**
Bidders **shall not** have the option of submitting their bids electronically."

Article 15:
Section II. Bid Data Sheet (BDS) - ITB 25.1.

***Shall read*:**
"The bid opening shall take place at:
Ministry of Health - Project Management Unit
Address: 1-3, Cristian Popișteanu St., 2nd floor, room 225A (Conference room), Sector 1
City: Bucharest
ZIP Code: 010024
Country: Romania
Date: **June 14th, 2017**
Time: **12:00 hour's local time**"

***Instead of*:**
"The bid opening shall take place at:
Ministry of Health - Project Management Unit
Address: 1-3, Cristian Popișteanu St., 2nd floor, room 225A (Conference room), Sector 1
City: Bucharest
ZIP Code: 010024
Country: Romania
Date: **May 31st, 2017**
Time: **12:00 hours local time**"

Article 16:

Invitation for Bids – para. 6.

***Shall read*:** "Bids must be delivered to the address below at or before: **12:00 hour's local time on June 14th, 2017.** Electronic bidding will not be permitted. Late bids will be rejected. Bids will be publicly opened in the presence of the bidders' designated representatives and anyone who choose to attend at the address (2) below at **12:00 hour's local time on June 14th, 2017**"

***Instead of*:** "Bids must be delivered to the address below at or before: **12:00 hour's local time on May 31st, 2017.** Electronic bidding will not be permitted. Late bids will be rejected. Bids will be publicly opened in the presence of the bidders' designated representatives and anyone who choose to attend at the address (2) below at **12:00 hour's local time on May 31st, 2017.**"

All other parts, clauses and provisions of the original Bidding Documents that are not amended as per the articles above and the provisions of the Amendment no. 1 shall remain valid and unchanged.

----------**END OF DOCUMENT**----------

CLARIFICATIONS NO. 1

Bidding Documents ICB No. G/C1/3.1 "Procurement of radiotherapy equipment – 5 lots" dated April 6th, 2017.

Questions regarding provisions of the bidding documents - Part I and Part. III

1. Q. "Following the invitation to tender for the acquisition of equipment for radiotherapy, we kindly ask you to let us know what qualification criteria applies for new established companies, having in mind that these cannot fulfil the requests for turnover and similar experience."
A: The qualification requirements are included within the Section III Evaluation and Qualification Criteria – 3. Qualification requirements (ITB 36). No different criteria will be provided for newly established companies

2. Q. We kindly ask you to send us the password for opening the .dwg files of Baia Mare Hospital.
A. The technical project was downloaded from the national procurement website (SEAP) from the hospital bidding procedure for contracting of the civil works and a single potential bidder has trouble in accessing the documents. Anyway, technical project was received from the beneficiary unit and will be submitted to all the potential bidders together with the present clarification address.

3. Q. We also request that we receive cross sections of the existing bunkers and control rooms for Linac and CT Simulator, for Galati, Baia Mare and Constanta.
A: The documents will be submitted to all the potential bidders together with the present clarification address.

4. Q. We can't open the drop box for Oncological Institute, is it possible to receive them by "We transfer"
A: The documents will be submitted to all the potential bidders together with the present clarification address.

5. Q. In the technical specifications for CT simulator (CT) is required in the chapter GENERAL: "the supplier will present all necessary legal licenses (incl. CE certificate, ISO licenses from CNCAN, MS)".
If the manufacturer/representative of the manufacturer holds CNCAN authorization to provide CT simulator (X-ray equipment), can participate as subcontractor in the bid process? Or is mandatory to be associated with the main bidder?
A: The accepted form for association is "Joint Venture", consisting of maximum 3 companies. Please see the provisions of Section I.

6. Q. In the technical specifications for CT simulator (CT) is required in the chapter GENERAL: "All technical data requested in this specification must be clearly documented in hard copy by the manufacturer and accessible for evaluation process".
Is it enough to present the documentation in hard copy or is necessary a manufacturer's statement to mention that all requirements are fulfilled?
A: The manufacturer's statement can be included in the bid with all the technical documentation in hard copy that prove that the offered equipment comply with the requested technical specifications.

7. Q. Total price of the bid from Letter of Bid must include maintenance cost for 5 years (Y3-Y7)?
A: Yes. Maintenance costs for all 5 years (Y3-Y7) must be included in the letter of bid that will be supported also by the "Maintenance Cost Sub-Table" for each of the 5 lots.

8. Q. All Lots: Please explain the simulation of Service cost after initial 2 years warranty.
Example: Machine cost 1.000.000 Euro
Service & Maintenance cost /year including mandatory factory upgrades 120.000 Euro.
Please explain how the service price influences the bid evaluation.
A: The formula that will be applied for comparing the bids is detailed presented on Section III Evaluation and Qualification Criteria – 2.1 Evaluation Criteria (ITB 34.6). The recurrent Costs (R) will be determined using the equipment price and the maintenance costs for each of the 5 years (Y3-Y7).

9. Q. Section IV bidding form: Please specify the start of timing the deadline of the tender. Using the contract signature date is unfair as the hospital has to apply for CNCAN licenses, the buiding companies have to have the construction licences and permissions and it is not in the hand of the bidder to influence this burocracy time. In some tender the hospitals have to remove the old Cobald 60 source and get permissions for this first or this needs to be included in the rehabilitation works.

PROPOSITION: We propose to postpone the deadline if a certain timeframe from local public authorities will be extended or the hospital is delaying the start of the building works.

A: The old cobalt sources from Bucharest Oncology Institute and Constanta will be removed in a separate project by the NCNAC before the contract for supply of radiotherapy equipment will be signed. All the licenses and permissions will be obtained by the hospital before starting the rehabilitation works.

10.Q. Section IV Drawings: Still the requested drawings for Baia Mare site are not published. When will they be published?
A: Please see the answer to question no. 2

11.Q. Due to complex project and number of separated LOT's and the fact that still no proper documentation (Constanta wrong radiation protection calculation) is provided we ask for minimum 4 weeks of delay counting from the time when missing documentation is provided.
PROPOSITION: Postpone tender deadline at least 30 days after all requested documents are in place.
A: The revised radiation protection calculation will be submitted to all the potential bidders together with the present clarification address.

12. Q. Pre-Bid Meeting: During the pre-bid meeting it was announced that all questions that have been raised up will be published and answered. There has no publication with answers been seen so far.

PROPOSITION: Publish questions and answers and postpone deadline for questions 10 days after publishing.

A: In accordance with the provisions of the Bidding documents – Section II Bid data Sheet – clause no. ITB 7.1 the Purchaser will assure sufficient time (minimum 10 days) for the preparation and submission of bids after sending the final answers to the clarifications requests. Please see article no. 14-16 of the Amendment no. 1.

13. Q. We kindly ask you to accept the revision of the following technical requirement:

Pre-shipment tests (Section VII Schedule of Requirements page 104 & 203, Section IX Special Conditions of Contract clause 26.1 letter a) & 26.2 letter a) page 237-238

Pre-shipment tests for goods supplied from abroad ***to be imported****: prior shipment the independent recognized testing agency nominated by the Manufacturer of the Goods shall perform all tests necessary to verify that the technical specifications of the Goods that will be shipped to the Purchaser fully comply with the Technical Specifications of the Goods provided in the contract, Schedule of Requirements section VII.*

The present bidding procedure covers multiple goods provided by different manufacturers. The Goods to be supplied are very complex and they require special conditions to be installed. Only after the proper installation of the systems, they will be able to perform as an integrated solution, as required by the technical specifications.

In order to install the systems, certain permits must be issued by the National Commission for Nuclear Activities Control. In the absence of those permits, part of the technical specifications (such as X-Ray system, detectors or scan parameters) for Item III.2 CT simulator can't be tested since it is against the law to scan. Moreover, the proper performance of the systems which are included in every lot requires that all the systems, irrespective of the manufacturer or country of origin should be supplied and installed.

Under these circumstances, it is impossible to have the pre-shipment tests for the integrated solution, since prior to the shipment the minimum conditions are not met to test the Goods at the detailed level described by the technical specifications.

Therefore, we kindly ask you to revise the above-mentioned clauses, in order to accept the tests to be carried out after the installation of the systems, in the presence of a independent notified testing agency nominated by the Supplier. In order to comply with the World Bank regulations, we hereby propose to you to accept Manufacturer Data Sheets, Declarations of Conformity and/or EC certificate as proof of the technical specifications met by every system in every lot.

A: Please see the answer to question no. 16.

14. Q. In case of a bidder constituted as a Joint Venture – is mandatory that every member has to request the Bidding Documentation?

A: No.

15. Q. Considering the volume of work to be done in building a proper technical and financial offer for every lot in every town we request to extend the deadline for submission of bids with minimum 2 weeks per lot , in total with 10 weeks.

A: Please see the answer to question no. 12.

16. Q. Section VII Schedule of Requirements, 1. General Requirements for all the radiotherapy equipment:

3) Prior shipment the Manufacturer independent recognized agency shall perform all tests/certification necessary to verify the characteristics and performances of the Goods supplied under the Contract. All tests/certification will be conducted by an independent agency prior to shipment for the goods to be imported, and at the warehouse/ factory for the goods already imported or locally manufactured. (pg. 104)

Section VII. Schedule of Requirements, 5. Inspections and Tests

(a) **Pre-shipment tests** for Goods supplied from abroad, **to be imported:** prior shipment the independent recognized testing agency nominated by the Manufacturer of the Goods shall perform all tests necessary to verify that the technical specifications of the Goods that will be shipped to the Purchaser fully comply with the Technical Specifications of the Goods provided in the Contract, Schedule of Requirements section VII. At the end of the tests the independent recognized testing agency nominated by the Manufacturer of the Goods shall issue the quality testing certificate that must confirm the compliance of the Goods to the Technical Specifications. The Supplier must submit the agency testing certificate to the Purchaser (203).

Section VII. Schedule of Requirements, LOT I: ONCOLOGY INSTITUTE "PROF. DR. ALEXANDRU TRESTIOREANU" BUCHAREST;
Item I.1: Level 1 Single energy linear accelerator (LINAC) TESTING AND ACCEPTANCE
(pg. 131)

Section VII. Schedule of Requirements, LOT II: Elias University Emergency Hospital
Item II.1: Level 2 Dual energy linear accelerator (LINAC) (pg. 140)

Section VII. Schedule of Requirements, LOT II: Elias University Emergency Hospital
Item II.2: CT simulator (CT) (pg. 143)

Section VII. Schedule of Requirements, LOT II: Elias University Emergency Hospital
Item II.5: LEVEL 2 DOSIMETRY (pg. 150)

Section VII. Schedule of Requirements LOT III: EMERGENCY COUNTY HOSPITAL "DR. CONSTANTIN OPRIS" BAIA MARE
Item III.1: Level 2 Dual energy linear accelerator (LINAC) (pg. 157)

Section VII. Schedule of Requirements LOT III: EMERGENCY COUNTY HOSPITAL "DR. CONSTANTIN OPRIS" BAIA MARE
Item III.2: CT simulator (CT) (pg. 160)

Section VII. Schedule of Requirements, LOT III: EMERGENCY COUNTY HOSPITAL "DR. CONSTANTIN OPRIS" BAIA MARE
Item III.5: LEVEL 2 DOSIMETRY (pg. 167)

Section VII. Schedule of Requirements, LOT IV: EMERGENCY COUNTY CLINICAL HOSPITAL "SF. APOSTOL ANDREI" CONSTANTA
Item IV.1: Level 2 Single energy linear accelerator (LINAC) (pg. 173)

Section VII. Schedule of Requirements, LOT IV: EMERGENCY COUNTY CLINICAL HOSPITAL "SF. APOSTOL ANDREI" CONSTANTA
Item IV.2: CT simulator (CT) (pg. 177)

Section VII. Schedule of Requirements, LOT IV: EMERGENCY COUNTY CLINICAL HOSPITAL "SF. APOSTOL ANDREI" CONSTANTA
Item IV.5: LEVEL 2 DOSIMETRY (pg. 184)

Section VII. Schedule of Requirements, LOT V: EMERGENCY COUNTY CLINICAL HOSPITAL "SF. APOSTOL ANDREI" GALATI
Item V.1: Level 2 Dual energy linear accelerator (LINAC) (pg. 190)

Section VII. Schedule of Requirements, LOT V: EMERGENCY COUNTY CLINICAL HOSPITAL "SF. APOSTOL ANDREI" GALATI
Item V.2: CT simulator (CT) (pg. 194)

Section VII. Schedule of Requirements, LOT V: EMERGENCY COUNTY CLINICAL HOSPITAL "SF. APOSTOL ANDREI" GALATI
Item V.5: LEVEL 2 DOSIMETRY (pg. 201)

☐ The system, prior to shipment, must be tested for conformance of the system with manufacturer's performance specifications and the minimum requirements specified herein;
☐ The system, after installation, must be tested by the Contractor together with the End-User to demonstrate that the performance meets the manufacturer's performance specifications and the minimum requirements specified;
☐ The results of the testing of the System must be documented by the Contractor in an acceptance protocol that must be signed by the End-User

Clarification 1:

Considering the fact that:

- the linear accelerator by itself consists of a complexity of several pieces that are delivered in a consecutive manner, in order to create the equipment as a whole,
- independent certification is being performed in the frame of IEC testing of each equipment and FDA certification. Therefore, the quality and conformity are guaranteed by independent audits in the frame of Medical Device certification process,
- after the system installation, certain consecutive authorizations must be issued by the Romanian National Commission for Nuclear Activities Control,
- before becoming functional, the whole system is to be tested for conformity with manufacturer's performance specifications and with the minimum requirements specified in the tender book.

In that respect, we kindly ask you to accept the following amendment related to pre-shipment tests: in order to comply with the World Bank regulations, for the pre-shipment stage, please accept Manufacturer's conformity tests. Therefore, the conformance requests still apply, as detailed in the tender book:

„The system, prior to shipment, must be tested for conformance of the system with manufacturer's performance specifications and the minimum requirements specified herein";

"The system, after installation, must be tested by the Contractor together with the End-User to demonstrate that the performance meets the manufacturer's performance specifications and the minimum requirements specified";

„The results of the testing of the System must be documented by the Contractor in an acceptance protocol that must be signed by the End-User".

A: Accepted. Please see article no. 1 and 2 of the Amendment no. 1.

17. Q. Lot I. Section IV Bidding Forms (page 56), Lot II, Section IV Bidding Forms, (page 62), Lot III, Section IV Bidding Forms (page 68), Lot IV, Section IV Bidding Forms (page 74), Lot V, Section IV Bidding Forms (page 80) tender book statement is:
"**Maintenance Cost Sub-Table**
Cumulative Subtotal (to *[insert: currency]* entry for *[insert: **line item**]* in the Recurrent Cost Summary Table)"

Clarification:
We kindly ask you to detail over the "line item" requirement:
1. Are you interested in individual cost for each of the following activities?
- Corrective maintenance;
- Software updates;
- Remote telephone support;
- Remote servicing

2. Or should we present **cumulative** costs of the items detailed above but for each product from the lot we are bidding for?

A: The cumulative costs for maintenance services for each of the 5 years (Y3-Y7) should be presented in the requested form but in the same time the costs for Corrective maintenance/ Software updates/ Remote telephone support/Remote servicing will be detailed.

Questions regarding provisions of the bidding documents (Part II Schedule of Requirements)

18. Q. In order to make proper upgrade of the existing planning system, R&V as well CT Sim station and software requested by the tender book for Oncological Institute Bucuresti we need the following:

- Number of planning stations;
  A: This information should be acquired by potential bidders during site visits. All bidders were invited to visit the sites as many times as the bidders consider necessary to develop an optimum integrated project in accordance with the bidding requirements. All RT centres to be upgraded during this stage will provide full support.
- HW configuration;
  A: Idem
- Version of planning SW existing;
  A: Idem
- Which SW modules you want to add as un upgrade;
  A: Idem
- If this is an server client based configuration we need to know if server needs upgrade as well;
  A: Idem

- For R&V system to which SW level you want us to upgrade the existing system;
  A: Tender documentations "FUNCTION DESCIPTION", GENERAL, 4th paragraph: "All hardware and software must be latest and newest version from regular production"
- Do we need to upgrade R&V server;
  A: Idem above
- Which SW modules we need to add?
  A: All needed information for minimum requirements can be obtain directly from the tender technical documentation.
- Please tell us to which SW and HW level we need to upgrade the existing CT –Sim?
  A: Tender technical documentation mentioned only to upgrade existing unit with Virtual Simulation (VS) module (SW and HW). Please consult CTSIM specifications, "VIRTUAL SIMULATION" section.

19. Q. After carefully examining the bidding documents, we have noted a preference for the equipment produced by ……. major competitor, ……., a preference which we find to be in contradiction with several provisions of the Guidelines regarding procurement of goods, works, and non-consulting services under IBRD loans and IDA credits and grants by World Bank borrowers (hereinafter referred to as the "Guidelines")", notably the following:

- art. 1.8: *"Any conditions for participation shall be limited to those that are essential to ensure the firm's capability to fulfill the contract in question".*
- Art. 2.1: *"The objective of International Competitive Bidding (ICB), as described in these Guidelines, is to provide all eligibile prospective bidders with timely and adequate notification of a Borrower's requirements and an equal opportunity to bid for the required goods, works and non-consulting services"*
- Art. 2.16: *"Bidding documents shall be so worded as to permit and encourage international competition (...). In addition, the bidding documents, where appropriate, shall define the tests, standards, and methods that will be employed to judge the conformity of equipment as delivered, or works as performed, with the specification."*
- Art. 2.19: *"Standards and technical specifications quoted in bidding documents shall promote the broadest possible competition, while assuring the critical performance or other requirements for the goods and/or works under procurement. As far as possible, the Borrower shall specify internationally accepted standards (...)".*
- Art. 2.20: *"Specifications shall be based on relevant characteristics and/or performance requirements. References to brand names, catalognubers, or similar classifications shall be avoided. If it is necessary to quote a brand name or catalog number of a particular manufacturer to clarify an otherwise incomplete specification, the words <<or equivalent>> shall be added after such reference.* ***The specification shall permit the acceptance of offers for goods which have similar charachteristics and which provide performance at least substantially equivalent to those specified****".*

Our company offers advanced, state-of-art and efficient digitally controlled medical linacs solutions for radiotherapy treatment. However, the bidding documents for this tender preclude anything but the provision of analogue systems that are produced only by our competitor. We would like to emphasize that analogue equipment is outdated and will not be the optimal long term solution for the people in the Republic of Romania

……. believes that the mandatory tender specifications are in at least nine cases strongly biased towards …….. Thus, ……..is being disadvantaged from participating in a fair tender submission. ……. are hereby requesting clarification of the relevant points for the examples provided below.

…… is requesting a prompt clarification of the below provided issues. Should a relevant answer not be received within 10 days, we reserve the right to submit a formal complaint directly to the IBRD, in accordance with art. 22 from Appendix 3 of the Guidelines.

A: The present bidding procedure is conducted through the International Competitive Bidding procedure as specified in the World Bank's Guidelines: Procurement of Goods, Works and Non-Consulting Services under IBRD Loans and IDA Credits & Grants by World Bank Borrowers, January 2011 ("Procurement Guidelines"). Ministry of Health through the Project Management Unit will carry out the procurement procedure in accordance with the provisions of the above mentioned Guidelines and the bidding documents issued to all interested companies starting with April 6th, 2017.

20. Q. Lot 1.Section "OTHER SPEC"
"Isocenter accuracy: must be 2R≤1mm, „R" is the radius of the sphere"

a) The concept of "isocenter" can be described in terms of "mechanical isocenter" or in terms of MV (Radiation) Isocenter". In the clinical application, it is the "MV (radiation) isocenter" the most important to consider. It is assumed that the parameter indicated in this clause is the MV Isocenter.

b) The accuracy of the "MV (Radiation) isocenter" in Elekta accelerators is declared as 2R ≤1.5mm.

The difference between 1mm and 1.5mm in isocenter tolerance has negligible effect on the dose distribution delivered in the patient.

There are other parameters such as: CT images resolution and geometrical accuracy, dose calculation accuracy and resolution and most of all, the accuracy of the patient (target volume) positioning in the treatment MV isocenter, with a larger influence on the treatment dose delivered in the patient. We assume that the Elekta declaration 2R ≤1.5mm will be accepted as the clinical outcome is equivalent as shown in whitepapers.

c) The specifications of the linac in this LOT include: a system for Image Guidance with 3D-kV CBCT capability and a 6D-Couch patient positioning system. Such a linac configuration will allow the clinical user to perform stereotactic image guided radiotherapy and radiosurgery (IG SRT, IG SRS) treatments.

For IGRT applications in general, and for IG SRT/SRS in particular, it is essential to have the best possible coincidence between the MV-Isocenter and the Imaging (kV-CBCT) isocenter in order to achieve the required accuracy in the dose delivery to the tumour (target)

PROPOSITION
Taking in consideration the explanations given the points b) and c), Elekta proposes to the tender commission to replace the clause: "Isocenter accuracy: must be 2R≤1mm, „R" is the radius of the sphere"
With the following clause: "MV (Radiation) isocenter coincidence with Imaging isocenter to be ≤1.0 mm"

This requirement will ensure better accuracy of the dose delivered to patient and quality of the treatment. All potential bidder companies are able to fulfil this requirement and therefore a fair competition between companies will be possible. This will benefit the hospital in both clinical and economical (price) aspects.

A: 2R≤1.5mm isocenter accuracy is accepted as valid. Please see article no. 3 of the Amendment no. 1.

21. Q. Lot I, II, III, IV, V - Flatness for flattened beams

a) In the GENERAL requirements to the equipment in this LOT, it is specified that "System performance shall meet all International Electrotechnical Commission standards applicable (IEC) - Medical Electrical Equipment".

One of these applicable IEC standards is the IEC 976/977 "Medical Electron Accelerator – Functional Performance Characteristics". The performance parameters of the medical linear accelerators manufactured by Elekta are defined and declared according to the IEC 976/977 standards. One of these performance parameters is "Flatness of X-Ray (Photon) beams" which is defined and recommended as: "Field flatness –

Maximum ratio of the maximum absorbed dose to the minimum absorbed dose does in the flattened area shall not exceed:
– For field sizes 5 cm x 5 cm to 30 cm x 30 cm, ≤ 106%
– For field sizes greater than 30 cm x 30 cm, ≤ 110%"

b) In the section of PHOTON BEAM CHARACTERISTICS, the field flatness is defined differently as:
"Variation of X-ray intensity relative to the central axis shall not exceed ± 3% at 100 cm SSD and 10 cm depth over the central 80% of the field for the longitudinal and transverse axes of all field sizes from 10cm x 10cm to 40cm x 40cm;"

This description of flatness, range of field sizes and the tolerances are matched with the Varian linear accelerator specifications.

This definition, and also the applicable range are different from the international standard IEC 976/977 and therefore in contradiction with the GENERAL requirements of this tender document.

Both approaches to Flatness definition and tolerances have advantages and they are equivalent in general. From the point of view of the clinical applications and the quality of the patient treatment, there is not difference in using any of the two definitions.

If this tender requirement is applied to the offers only as written in the PHOTON BEAM CHARACTERISTICS, Elekta Company will be disadvantaged from the participation in the bid for this project. With no technical, clinical and/or operational benefits in using one "flatness method" versus the other, the EU rules protecting free competition in tenders would be violated as consequence.

Electron energies: There are no Electron engies and mandatory applicators specified in all LOTs. Please specify the Energies and what Applicators are requires.

PROPOSITION
- To change the definition and requirements of Flatness in the section PHOTON BEAM CHARACTERISTICS to match the method and values recommended in the international performance standard IEC 976/977
Alternatively
- To accept as valid and passing the tender requirements if either of the two methods and tolerances is used in the offered equipment.

A: For this bidding requirements both methods and tolerances are accepted as valid for flatness of photon beam. Please see article no. 4 of the Amendment no. 1

22. Q. Lot I, II, III, IV, V - Symmetry of photon beams
a) Elekta follows the definition and recommendations for Symmetry of X-Ray (photons) beams given in the IEC 976/977 as: "Maximum ratio of absorbed doses at points symmetrically displaced from the axis of the beam and within the flattened area: For field sizes ≥5cm x 5cm: ≤103%"

b) In the section PHOTON BEAM CHARACTERISTICS, Symmetry is defined in a different way, namely as:
"The maximum percent differences of average doses shall not exceed ± 2% for the longitudinal and transverse halves of all field sizes from 10cm x 10cm to 40cm x 40cm, at 100cm SSD and 10cm depth; Average dose is defined as the arithmetic average of minimum and maximum doses within the central 80% of the field for both axes"

Both approaches to Symmetry definition and tolerances are equivalent. From the point of view of the clinical applications and the quality of the patient treatment, there is not difference in using any of the two definitions.

On the other hand, if this tender requirement is applied as written in the PHOTON BEAM CHARACTERISTICS, Elekta Company will be set in a disadvantage from the participation in the bid for this project. As there are no technical, clinical and/or operational benefits in using one method and not the other.

PROPOSITION
- To change the definition and requirements of Symmetry in the section PHOTON BEAM CHARACTERISTICS with the definition provided in the international performance standard IEC 976/977
Alternatively
- To accept as valid and passing the tender requirements if either of the two methods and tolerances is used in the offered equipment.
A: For this bidding requirements both methods and tolerances are accepted as valid for symmetry of photon beam. Please see article no. 13 of the Amendment no. 1.

23.Q. Lot I, II, III, IV, V – Other spec

Clause describing the target to axis distance as "The target to axis distance should be 100 ± 0. 1 cm"
The target to axis distance is a nominal mechanical parameter, which in Elekta accelerators can differ between different machines up to 0.2cm, mechanically this is a tolerance of 0.2%.

This mechanical tolerance does not affect the accuracy of the dose delivered to the patient. E.g. the dose accuracy (linearity) in Elekta accelerators is better than 1% or 0.1MU from 1MU to 1000MU, which is significantly better than the dose linearity required in the tender document (1% or 1MU from 10MU to 1000MU). It is also better than the dose linearity in the linacs from competitor companies.

The tolerance required in this requirement will set Elekta in a disadvantage to participate in the bid. With no technical, clinical and/or operational benefits in a tolerance better than 100cm ±0.2cm.

PROPOSITION
To change the tolerance in this parameter to "The target to axis distance should be 100 ± 0. 2 cm"
This will have noc clinical disadvantage.

A: The target to axis distance 100 ± 0.2 cm is accepted as valid for this tender requirements. Please see article no. 5 of the Amendment no. 1.

24. Q. Section VII – page 105
Respone time for sevice on site engineer presence is 4 hours. Due to the badly infranstructure especially in winter time we would like to use our remote controlled service system to be accepted in the same way. This way of interacting with the machine will allow a faster response than 4 hours and is solving about 30% of any problems.

PROPOSITION: Please accept use of this remote system and accept it as an equal way to be present on site for inspection.

Alternative proposal would be to allow an engineer on site response time of 24 hours.

A: It is accepted the use the remote controlled service but if the problem is not solved the engineer must be present on site not later than the next day during the working hours. Please consider the minimum uptime of the equipment of 98%. Please see article no. 6 of the Amendment no. 1.

25. Q. Section VII – Schedule of requirements:
Please investigate to change the 15MV photon engery to 10 MV and include VMAT treatment capability for the machine. This is the recommodation from ESTRO and allows a western European treatment standard that is also reimbursed in Romania already.

As mentioned during meeting on April 27, we propose to implement in the offer systems having hardware and software that will allow modern IMRT and VMAT treatments beside requested 3D CRT. In order to do that we propose to deliver 10 MV systems and exclude 15MV as mandatory second photon energy. 10 MV will allow just like 15 normal 3D CRT. By this action PMU will invest at once in quality of the systems not in bunker walls and doors as well much more expensive ventilation systems. Future upgrades for which systems should anyway be ready will not be requested and systems can deliver modern, faster, cost effective treatments. Such proposal was discuss with Elias hospital who has knowledge and educated personal for instant implementation of VMAT.
For other sites it will be a progressive implementation after 3D CRT is fully implemented and personal is confident to start modern VMAT delivery.
More patients can be treated, shorter treatment times required, more than twice higher fraction incomes instead of 300 ROM about 640 RON and better life quality for patients faster obtained.

A. Please find below an extract from IAEA-TECDOC-1588 "Transition from 2-D Radiotherapy to3-D Conformal and Intensity Modulated Radiotherapy", pages 29,30:

".....**2.3. MILESTONES FOR IMRT**
An IMRT programme should be built on a firm foundation of expertise in conventional and three-dimensional radiotherapy. The questionnaire given in Appendix A provides a checklist of steps in the process. Before any resources are committed to the establishment of an IMRT programme, the following milestones have to be fulfilled. Numbers in brackets refer to the questions in the Appendix A.

Milestones that must be passed before resources are committed to the establishment ofIMRT:

- Facilities should be in place for the provision of conventional radiotherapy and 3-D CRT.
- Adequate diagnostic imaging facilities are in place.
- Adequate imaging facilities are in place for planning CT-scans.
- There is a sizeable population of patients with an indication for curative radiotherapy and IMRT.
- Previous 1-2 years' experience with 3-D CRT.

Milestones in the process once the project has started:

- IMRT Committee and Programme including budget plan.
- Appointment of sufficient staff so that conventional radiotherapy treatments are not compromised.
- Adequate maintenance facilities to ensure that the calibration of the MLCs can be maintained.
- Academic training of the staff in IMRT.
- Specification and purchase of IMRT-specific additional equipment.
- Practical clinical training of radiation oncologists and medical physicists.
- Commissioning of Radiation Treatment Planning System (RTPS) and treatment machines.
- Establishment of protocols for IMRT for defined anatomical sites...."

The Department of RT at Elias Hospital Bucharest was visited by IAEA Experts and on site assessment of existing capacities was conducted (staff and bunkers). The IAEA-TCR-09877 report recommends to purchase LEVEL2 LINAC.

26. Q. Section VII: There is no documentation and requirement of the rehabilitation works that need to be arranged by the bidder. Please specify the exactly what kind of rehabilitation needs to be included in each LOT.
POPOSITION: Provide detailed rehabilitation work list for the departments per LOT and Postpone deadline at least 30 days after publishing these documents.
A: Please see the provisions of Section III Evaluation and Qualification Criteria – 3. Qualification requirements (ITB 36) – point c): Section VII- Schedule of requirements – chapter 3 and Section IX Special Conditions of Contract – clause no. GCC 25.2.

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The supplier of the goods will execute all the necessary works for a proper functioning of the delivered equipment. The price of the technical design and the needed works that are required to install the complete package for each of the 5 lots will be included in the bid.

LOT Galati: Be more precise in specific site requests and building works. Some sites can not be done like Galati since the old bunker wall removal and construction of the new one is technically and financilly not useful at all. It would be cheaper and more efficient to construct a new bunker.
PROPOSITION: Reconsider constructions and rehabilitation works for all sites, especially Galati and specify the exact amount.
A. For Galati the supplier of the radiotherapy equipment will execute the construction works related to the rehabilitation and consolidation of the areas where the equipment will be installed (LINAC and CTsim).
Generally the works that must be executed must respect the general requirements that are included in the bidding documents, section VII, page 104

27. Q. We kindly ask you to accept the revision of the following technical requirement:
Maintenance requirements (Section VII Schedule of Requirements page 104 para 4, page 105 para 2

Authorized service center has to respond within 4 hours (exceptionally until 12.00 am) after request from the hospital was issued. Response has a meaning of on-site help of service personnel.

Our company has the capacity to diagnose remotely the systems within 4 hours after the request from hospital was issued. We would like to highlight that the last generation CT simulators are very much electronically and software driven, therefore most of the related malfunctions may be diagnosed/fixed from the distance over secured internet connection.

Moreover, please have in mind that in accordance with the provisions of art. 112 from the Labor code, the working day has 8 hours. Under these circumstances, we kindly ask you to revise the above-mentioned paragraph accordingly

Authorized service center has to respond within 4 hours (during the working hours 8.00-16.00) after request from the hospital was issued. Response has a meaning of remote intervention.

A: Please see the answer to question no. 24.

28. Q. Lot. II-V Item 2 Computer system for the CT simulator scanner. *Mass storage system for archiving clinical database must be included.*
Having in mind that the capacity of the system's console is designed to archive the clinical database for maximum 7 days of exams the producers usually recommend PACS systems or external USB hard drives. Considering this fact, please clarify if an external hard drive solution can be regarded as an acceptable solution and, if so, what should be the minimum storage capacity.
A: An external HDD based solution is acceptable. Minimum storage capacity 2 TB.

29. Q. Lot. II-V Item 2 Computer system for the CT simulator scanner *UPS: on line UPS with batteries for the backup of the entire computational system for at least 15 minutes*

We would like to mention that CT simulator is the only equipment included in every lot, for which a 15 minutes UPS solution is requested. However, the CT simulator scanner is only used for planning and not for radio therapy. Also, there must be taken into consideration that an exposure never lasts more than 2 minutes.

In the current practice, users require normally UPS solutions that ensure the functioning of the operator's computer and of the CT gantry and table (not the generator). The reason is that in case of power failure the user must be able to save a performed exam and to evacuate safely the patient from the gantry.

When we discuss about a UPS solution for the entire computational system, normally, one would understand that this solution should backup the functioning of all the components required by the technical specification like:

- CT system (generator, gantry, table and operator console)

- Post processing workstation
- Injector
- Laser simulation system

Please note that the X-ray exposure never lasts more than 2 minutes and the injection never lasts more than 1 minute, therefore we do not see the reason why the UPS should ensure 15 minutes of backup. Normally, all the UPS providers ensure standard backup for 3-7 minutes and this is to ensure the functioning until transfer a power generator or for proper shut down of the machine.

Nevertheless, an UPS solution that would ensure backup for the computational system (probably not less than 100 kVA) whether it is for 5 or for 15 minutes, takes a lot of space and generates big amounts of heat and noise (abt 70 dB) which makes it inappropriate to be installed in the examination room or in the control room. Some of the locations (e.g. Constanta) are not even big enough to allow the installation of such an UPS in the examination room.

For the above mentioned reasons, **we kindly ask you to accept the offering of an UPS system designated to ensure a backup to allow saving the images and moving the table, in order to safely evacuate the patient which might be under examination at the given time**, instead of *"on line UPS with batteries for the backup of the entire computational system for at least 15 minutes"*.

A: UPS system designated to ensure backup, to allow the images to be saved and moving the table in order to safely evacuate the patient which might be under examination at a given time is acceptable. Please see article no. 7 of the Amendment no. 1.

30.Q. Lot I. item I.1 (page 131) , Lot II, item II.1, (page 140) ,Lot III, item III.1 (page 157), Lot IV, item IV.1 (page 174), Lot V, item V.1 (page 190) tender book statement is :
"*All necessary legal licenses requested by Romanian legislation must be included in quotation (Except the one for clinical usage of the system)*
Please confirm the exact list of all necessary licenses and also if by the tender book requirements we can understand that "Bidder will provide all necessary support for the preparation the files needed by end user to obtain All necessary legal licenses requested by Romanian legislation and must be included in quotation (except the one for clinical usage of the system)

A: "The bidder will provide all necessary support (incl. financial: e.g. fees to Regulatory Body (CNCAN) and other authorities) for the preparation of the files needed by all parties involved to obtain all necessary legal licenses requested by Romanian legislation (except the one for clinical usage of the system). These must be included in quotation" it is also accepted. Please see article no. 8 of the Amendment no. 1.

31. Q. Section IV, Bidding forms, point 4 of the table, page 50, and tender book statement is: „*Upgrade of the existing TPS/CS and R&V system, linked to Varian LINACs (Existing TPS, CS, R&V linked to VARIAN infrastructure (e.g. LINAC) that 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 CT simulators, lasers, etc.)* „
We kindly ask you to confirm if requested full connectivity includes also the brachytherapy systems and RPM Respiratory Gating systems installed in RT department or not.

A: Full connectivity includes also the brachytherapy systems and RPM Respiratory Gating systems installed in the RT department.

32.Q. Section VII, Lot I, item I.1, page 128, "Robotic Positioning System for patient setup" tender book statement is: *Control of robotic module via software interface on touch screen should be available in the treatment room. Monitoring of setup accuracy throughout treatment via monitor at console room should be possible"*
Please confirm if it is mandatory placing touch screen monitor in treatment room. We kindly ask you to accept a technical configuration of an advanced technology that does not requires any user interface in the treatment room.

A: The bidder must provide all necessary technical documentation and information to the Purchaser in order to analyse this option. At this point, the bidder's proposal does not contain any technical information.

33.Q. Section VII, Item I.1 (page 130&131), Item II.1 (page 139), Item III.1 (page 156), Item IV.1 (Page 173), Item V.1 (page 189) tender book statements are: „Should be compatible with PACS configurations including HIS and RIS with all needed licenses;
The system should have the compatibility to be interfaced and connected to Hospital Information System (HIS) or having HL7 compatibility with all licenses needed."
We kindly ask you to accept connectivity only via R/V systems requested also by the tender book, considering that in present times direct connectivity of linear accelerators to HIS and RIS is under research and development at worldwide level.
A: Accepted. Please see article no. 9 of the Amendment no. 1.

34. Q. Section VII, Item I.3 (page 134), Item II.4 (page 146), Item III.4 (page 163), Item IV.4 (page 180), and Item V.4 (page 197) tender book statements are: *"Medical Oncology Charting"*
Please confirm if "medical oncology charting" used in medical oncology department is a mandatory request and kindly ask you to accept "Radiation therapy charting" as the function preferred in the Radiation Therapy Department as a replacement to initial statement.

A: Accepted. Please see article no. 10 of the Amendment no. 1.

35. Q. Section VII, Item I.3 (page 134), Item II.4 (page 147), Item III.4(page 164), Item IV.4(page 180), Item V.4 (page 197) tender book requirements are:
„The system should have the compatibility to be interfaced and connected to Hospital Information System (HIS) or having HL7 compatibility with all licenses needed; „
We kindly ask you to provide us all detailed information related to the existing type of HIS system in order that bidders will be able to prepare the technical configuration properly.

A: The potential bidders must require these information directly from hospital representatives. MoH - PMU organized 2 site visit at each of the beneficiary units and all potential bidders were encouraged to make additional visits in order to make the necessary assessments.

36. Q. SECTION VII, Item II.3 (page 144), Item III.3 (page 161), Item IV.3 (page 178), and Item V.3 (page 195) tender book requirments are:„Function description :Computerized Treatment Planning System for external beam planning able to perform at least the following irradiation techniques: 2D, 3D-CRT.TPS must be capable of being upgraded with necessary software and hardware to perform specialized treatment techniques as: DART, IGRT, IMRT, IMAT, latest modalities in conjunction with future upgrade of the equipment offered. The system must be provided to the end-user as a complete "turn on key" system and ready to be commissioned and clinically used. „
Combined with

„ Dosimetric Algorithms:Advanced dosimetric calculation algorithms for photon and electron shall be the latest and newest version from regular production, based on Monte Carlo algorithm or equivalent. Dosimetric results must be as close as possible comparing to those obtain with Monte Carlo approach (must be documented);
• Monte Carlo based algorithm for electrons;
• Minimum plan resolution:≤ 1mm3or less (for electron and photon dosimetric calculation);
• Forward and inverse planning;
• Optimizing algorithms, including biological aspects. „

All those features described in paragraph "Dosimetric Algorithms "are needed for above mentioned special treatment techniques for a Computerized Treatment Planning" NOT capable of using treating treatment techniques considering the future upgrade mentioned in first paragraph. We kindly ask you to accept the following statement that can be fulfilled and clear in relation to both statements mentioned above: "allow for

analytical algorithms such as AAA or Collapsed Cone (they provide equal results as Monte Carlo for standard treatment techniques).
A: Not accepted.

37. Q. SECTION VII, Item IV.1(page 169), tender book requirements are:
Title: 'Level 2 Single energy linear accelerator (LINAC)"
Function description Section „Dual energy medical linear accelerator"
Please confirm that the statement „Dual energy medical linear accelerator „ is a minor editing error." and will be understood as Single energy linear accelerator (LINAC)
A: Confirmed. It is an editing error. Please see article no. 11 of the Amendment no. 1.

38. Q. SECTION VII Schedule of Requirements, 3. Technical Specifications. 1 General requirements for all the radiotherapy equipment, paragraph 6 is stating: "Delivery and installation of the Goods: The Supplier is required under the Contract to transport the Goods to a specified place of final destination within the Purchaser's country. Transport to such place of destination in the Purchaser's country, (including insurance and storage, assembly and installation on site and training and related services), shall be arranged by the Supplier, and related costs are included in the Bid Price"

Since the Supplier is delivering the Goods to the designated site and the Beneficiary is securing the on-site storage availability, the Supplier is not able to control and ensure the goods after the delivery. Therefore, please confirm that the Supplier is no longer responsible for the storage of the Goods once they are delivered to the premises. The supplier will continue to be responsible for installation, training and related services.

A: Please take into account the other provisions, respectively that at the time of Contract implementation, the Purchaser will send to the Supplier the contact details of the Beneficiary's and will secure the onsite storage availability. At each site on delivery of the goods, a "Handing Over/ Delivery Protocol" will be signed in English and Romanian language. The Supplier will notify by e-mail the beneficiaries (with copy to Purchaser) with the dispatching schedule.
In addition, the beneficiary unit will be informed about the necessary conditions that must be assured for a proper storage of the Goods.

39. Q. Related to Section VII Schedule of Requirements, 3. Technical Specifications Lot 2, 3, 4 and 5.
For the immobilization systems, the "Digital stainless steel thermoplastic water bath for masks" is required for the CT Simulator and as well as for the Linac. Since the thermoplastic masks are formed only at the CT Simulator and they are used first for simulation and afterwards, the same mask, for treatment of the respective patient, there is no need for a water bath at the Linac. Please confirm if it is accepted that the immobilisation configuration for one lot - Linac and CT should contain only one water bath.

A: Confirmed. The equipment will be provided in connection with the CT Simulator. Please see article no. 12 of the Amendment no. 1.

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