

Request for Tender

Proton Treatment Planning System

Open Procedure

Central Denmark Region

Danish Centre for Particle Therapy



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1 Introduction

The Central Denmark Region is hosting Danish Centre for Particle Therapy (DCPT), for the purpose of treating a complex mix of pediatric and adult cancer patients, in total up to 1,180 patients per year. The Centre will be an integral part of the University Hospital of Aarhus.

DCPT has partnered with Varian Medical Systems for the delivery of the Proton Therapy System, this includes delivery of the "ProBeam" system with accelerator, energy selection system, beam line, three rooms with 360° gantries for patient treatments and a dedicated research room with horizontal beam line. All three treatment rooms have gantry integrated Cone Beam CT (CBCT) and the Oncology Information System (OIS) "Aria" is also included in the delivery.

DCPT is seeking a partnership with a supplier of a Proton Treatment Planning System (PTPS) that will allow for long term development of proton therapy at DCPT.

Tenderers should note the following high level needs for the PTPS:

- It must support the Varian ProBeam Pencil Beam Scanning (PBS) delivery system and Varian Aria OIS and the continued development of the technology involved
- It must have a user friendly graphically user interface
- It must provide efficient and state of the art multi modality image segmentation and proton planning functionality including robustness evaluation, robust optimization and single and multi field optimization
- It must provide efficient and state of the art functionality for comparison of photon and proton dose plans in order to support comparison of dose plans as part of the national referral of patients
- It must provide efficient and state of the art functionality for accounting for 4D respiratory motion and motion mitigation strategies
- It must provide efficient and state of the art physics modeling
- For efficiency and patient safety the PTPS must preserve data integrity and interconnectivity with the Varian Aria OIS and Varian ProBeam System including the CBCT system
- For efficient and easy access and deployment of the System it must be accessible remotely
- It must provide efficient and state of the art tools for supporting Adaptive Radiotherapy (ART)
- It must support a high level of automation
- The tenderer must support education and training of staff and relevant training courses hosted by Aarhus University Hospital and DCPT
- The tenderer must support research at DCPT

Specific requirements are listed in appendix 2.

2 Request for tender

2.1 Procedure

For the procurement of the PTPS, the Central Denmark Region ("the Contracting Authority") is using the *open procedure* under the Danish Law "Udbudsloven"¹ according to the contract notice published in the Official Journal of the European Union/TED (Tenders Electronic Daily).

These terms and specifications apply to the Contracting Authority's request for tender for the PTPS.

The Tender documents are available on the Contracting Authority's website www.udbud.rm.dk.

All information regarding the procedure will be published on this website.

Tenderers are therefore encouraged to keep themselves informed through this website.

¹ Act no. 1564 of December 15, 2015, implementing Directive 2014/23 EU of 26 February 2014 on public procurement

It is recommended that the tenderer thoroughly study the tender documents before starting to prepare the tender. The tenderer should note that it is exclusively the responsibility of the tenderer that a tender is complete and in compliance with the guidelines set out in the tender documents.

2.2 Contracting Authority

The Contracting Authority responsible for this procedure is:

Central Denmark Region
Skottenborg 26
DK-8800 Viborg

2.3 Contact information

The contact person appointed by the Contracting Authority from which further information, documentation etc. must be obtained is:

Procurement Lawyer Mrs. Sidsel Marcussen
Department of Procurement & Clinical Engineering
Olof Palmes Allé 15, 1.
DK-8200 Aarhus N
sidsel.marcussen@stab.rm.dk

All inquiries must be sent by email to the above listed email-address.

2.4 Scope of Contract

The scope of the contract is the design, delivery, installation and testing of a Proton Treatment Planning System (PTPS) for proton and photon therapy including all related functionalities and services.

The scope includes:

- Software and licenses for a complete PTPS
- Server hardware, required by the tenderer to be delivered by the tenderer
- Necessary server hardware and workstations to be installed centrally for remote access (ex. Citrix farm). (This part is optional for the Contracting Authority to buy)
- Service agreement

2.4.1 Software and licenses

The scope includes software and licenses and third party software and licenses needed for any functionality described in the tender, excluding possible research features, including but not limited to, central server software and licenses, central database software and licenses, remote access software and licenses, and client software and licenses.

The clinical system must be available by a remote access system (ex. Citrix) and the scope includes central server software and licenses for remote access including for the required workstation farm.

The number of licenses for concurrent users must be made available in accordance with the Time Schedule set out in Appendix 1. Alternatively, site licenses fulfilling as a minimum the same number of concurrent users may be offered.

2.4.1.1 Licenses for differentiated functionality

The provided software licenses must make the PTPS available for a number of concurrent users with differentiated functionality. This will make it possible for the tenderer to offer licenses for a reduced price compared to the price for licenses for the full functionality. The differentiated functionalities are described below:

2.4.1.2 Clinical use, physicist

License for clinical physicist use of the system includes all functionalities of the PTPS in patient individual prospective clinical decision making. No limitation in the access to the functionalities described in the tender material or the tenderers response will be accepted, except possible research features clearly marked by the tenderer.

2.4.1.3 Clinical use, physician

License for clinical physician use is as described above for the "Clinical use, physicist". But, planning, dose calculation and optimization features related to Planning tools, Evaluation tools, Motion Management, Physics, Adaptive Radiotherapy, Automation and Workflow may be made unavailable for the user.

2.4.1.4 Non-clinical use, research

Research licenses must be provided with the same functionality as "Clinical use, physicist" and with potential additional research features. The use is non-clinical and does not include patient individual prospective clinical decision making. Research features can be made available without CE-making.

2.4.2 Server hardware, required by the tenderer to be delivered by the tenderer

If the tenderer insists on delivering parts of the hardware, ex. because of CE-marking or to ensure performance, this hardware must be included in the tender and it will be included in the scope of the contract.

2.4.3 Server hardware and workstations to be installed centrally for remote access (ex. Citrix farm)

For the sake of fair comparison of tender prices the tenderer must offer all hardware that is not part of the hardware required by the tenderer to be delivered by the tenderer. This includes both server hardware and workstations accessible by the offered remote access system (ex. Citrix). The number of workstation to be installed centrally for remote access (ex. Citrix farm) must be more than one third the number of concurrent users set out in appendix 1. The hardware must ensure high performance and meet all relevant Specifications of Requirements of the tender.

Each server-station and workstation must be priced separately, and the contracting authority can freely make use of the offer, parts thereof or nothing.

The offered hardware will be included in the evaluation price.

2.4.4 Service agreement

Service agreement is included in the scope of delivery as set out in Appendix 7. The service agreement will run from 1 year after the first delivery and for as long as requested by the contracting authority. The offered annual fee must be valid for ten years.

For further specifications of the Scope of Contract see Appendix 2, Specifications of requirements.

2.5 Organization of the procurement

The Contracting Authority has organized the DCPT Project Group to conduct the establishment of DCPT. This Project Group will approve the final selection of supplier. The DCPT Project Group has appointed a Working Group to both develop the Specifications and Requirements and to perform the evaluation of the tenders. The members of the Working Group have been selected based on their personal qualifications and do not represent authorities outside the Contracting Authority.

As part of the Working Group and also representing the Contracting Authority, legal advice in the tender phase will be conducted by Procurement Lawyer Sidsel Marcussen, Department of Procurement & Clinical Engineering, Central Denmark Region.

3 Tender and Contract documents

- Request for tender with the following appendix:

Appendix A: ESPD European Single Procurement Document

- K01 Standard Contract for Short-term IT Project with the following appendices:

- Appendix 1: Time schedule.
- Appendix 2: Specification of requirements.
- Appendix 3: Schedule of payments.
- Appendix 4: Specification of hardware, software and documentation, including prices.
- Appendix 5: Description of associated services, including prices.
- Appendix 6: The customer's participation.
- Appendix 7: Specification of maintenance, including prices.
- Appendix 8: Tests.
- Appendix 9: License terms.
- Appendix 10: Service levels
- Appendix 11: Project organization.
- Appendix 12: Procedure for changes.
- Appendix 13: Specification of options, including prices
- Appendix 14: Q&A Document, corrigendum etc.

4 Time schedule for the tender process

The contracting authority expects to complete the procedure in accordance with the time schedule set out below. Time is Danish local time.

August 5, 2016	Submission of Contract notice to the Official Journal of the European Union/TED (Tenders Electronic Daily).
August 25, 2016	Deadline for asking questions to the tender documents (answers will be published on www.udbud.rm.dk)
September 1, 2016 11.00 AM	Final deadline for the Contracting Authority to publish additional information on www.udbud.rm.dk .
September 8, 2016 12.00 noon	Deadline for the receipt of tenders.
September 2016	The Contracting Authority reserves the right to inspect reference sites to verify specific areas of the tenderers proposed solution. Evaluation of tenders finalized.
September / October	Documents confirming the information submitted by the tenderer in the European Single Procurement Document (ESDP) are to be provided by the winning tenderer.
October 2016	Announcement of award decision. Beginning of the standstill period.
November 2016	Contract signing.
February 28, 2017	Validity period of the tenderer's tender (6 months from the Deadline for the receipt of tenders).
August 5, 2016	Submission of Contract notice to the Official Journal of the European Union/TED (Tenders Electronic Daily).

5 Questions and Answers (Q&A)

The tenderers may ask clarifying questions to the Request for Tender and contract documents. Such questions should be sent by email to the appointed contact person in [section 2.3]. The Contracting Authority would appreciate the

questions to be presented in a listed format and specifying which document and to which section the question is referring.

The deadlines for receipt of questions or comments are in accordance with the time schedule in section 4.

Questions asked after deadline 2 may not be answered.

Q&A will be published in anonymous form on www.udbud.rm.dk.

If the contracting authority during the procedure find the need to disclose additional information later than 6 days before the deadline for the receipt of tenders the deadline will be extended.

Q&A will be part of the contract documents as Appendix 14.

6 Amendments to the tender and contract documents

During the tender procedure the Contracting Authority may make amendments to the previously published documents. The Contracting Authority will publish any revised documents regarding amendments in the tender and contract documents on www.udbud.rm.dk.

If a tenderer becomes aware of defects or significant discrepancies in the tender or the contract documents, the tenderer is requested to immediately inform the Contracting Authority thereof, so that the Contracting Authority if possible can rectify the situation through publication of revised documents.

Amendments will be included in the contract documents; corrigendum will be included as Appendix 14.

7 The tenderers suitability

7.1 European Single Procurement Document (ESPD)

Tenderers must complete and disclose the European Single Procurement Document (ESPD) as preliminary documentation for their suitability and to confirm that tenderer are not subject to grounds for exclusion.

Only the winner of the procurement procedure will be requested to submit the *original documentation* (section 7.1.3).

The ESPD is only accessible via the ESPD service provided by the European Commission:

<https://ec.europa.eu/growth/tools-databases/espdc/welcome>

As a standard the following parts must be completed:

- Part II: Information about the economic operator
- Part III: Exclusion grounds

If a tenderer is part of a temporary association of enterprises, such as a consortium, this must be stated in part II, section A of the ESPD and each of the participating economic operators must complete a separate ESPD with the information required.

7.1.1 Financial capacity

There are no specific requirements in terms of Financial Capacity. Therefore ESPD part VI section B: "Economic and financial standing" is not relevant and is not to be completed.

7.1.2 Technical capacity

ESPD part VI section C "Technical and professional capacity" must be completed.

In terms of technical capacity the tenderer must meet the following minimum requirements:

- The tenderer should provide references to similar completed or ongoing assignments for the installation of the PTPS.

- It is a minimum requirement that the tenderer can provide at least one reference site using the PTPS as the primary clinical installation for treatment planning with Pencil Beam Scanning. Information on references must be stated in the ESPD document and must include the following informations:
 - Contact information on customer
 - Description of the scope of the assignment
 - Description of the delivered services
 - Present status on the project

7.1.3 Declaration of support

The tenderer may rely on the financial and/or technical capacity of other entities (e.g. parent company or subcontractor) regardless of the legal nature of the connections between the tenderer and the entities on which the tenderer relies. The tenderer must then prove that the tenderer has at its disposal the resources necessary to fulfill the contract, e.g. by providing a declaration of support or other similar documentation of the legal commitment from these entities to make the required resources available in the contract period. Moreover, the entity/entities on which the tenderer relies must submit their own versions of the ESPD. If they fail to do so, the contracting authority will not be able to assess the financial and/or technical capacity of the other entities.

7.1.4 Documentation from the winning tenderer

Prior to the Contracting Authority's decision to enter into a contract the Contracting Authority requires the tenderer with which the Contracting Authority intends to enter into an agreement to present documentation for the information stated in the ESPD.

In this regard, tenderers should note that the tenderer with which the Contracting Authority intends to enter into the contract must submit final documentation as proof that there are no grounds for exclusion and that the minimum requirements for suitability have been met.

The following documentation regarding the tenderers situation must be presented if requested by the Contracting Authority:

- An extract from the relevant register or corresponding document issued by a competent legal or administrative authority which shows that the tenderer is not covered by the grounds for exclusion.
- A certificate issued by the competent authority in the relevant country as proof that the applicant is not covered by the grounds for exclusion.

For companies registered in Denmark, this documentation may be obtained in the form of an official certificate from the Danish Business Authority <https://erhvervsstyrelsen.dk/anmodning-om-serviceattest> .

In order to issue the official certificate, the Danish Business Authority requires a declaration of consent as well as solemn declarations from all Danish members of the executive board and board of directors in order to obtain their judicial records. Foreign members of the executive board and board of directors must obtain separate documentation pursuant to the information in this regard. The Danish Business Authority has stated that it takes about two weeks to draw up an official certificate from the date of reception of a correctly completed request.

7.2 Language

All correspondence or documentation submitted in response or in relation to this procurement procedure must be in the English language.

7.3 Form

The submission of the tender should be submitted in the following versions:

- 1 original signed paper version
- 1 USB-stick version

The tender must be received by the Contracting Authority in a sealed envelope stating "Tender: Proton Treatment Planning System, DCPT."

7.4 Deadline

The tender must be sent to or be delivered at:

Central Denmark Region
Department of Procurement & Clinical Engineering
Olof Palmes Allé 15, 1.
DK- 8200 Aarhus N
Att.: Mrs. Sidsel Marcussen

The deadline for submission of tender is: **September 8, 2016 12:00 noon (Danish local time)**.

For it to be submitted in time and be taken into consideration during the procedure, the tender must be received within the deadline. Tenders received after the deadline will be excluded from the further process. It is the tenderer's responsibility to ensure that the tender arrive within the deadline. There will be no access to the opening of tenders.

7.5 Validity period

Tenderers are bound by their tenders for the period specified in the time schedule in section 4. The purpose of the validity period is to allow the Contracting Authority to examine tenders, approve the contract award proposal, notify the successful and unsuccessful tenderers and conclude the contract.

7.6 Costs

Costs incurred during the preparation and submissions of tenders are to be borne by the tenderers and will not be reimbursed. A tenderer is not entitled to have the submitted tender returned from the contracting entity, which, in return, may not use such tender in other relations than those regarding this call for tender.

7.7 Presentation

The Contracting Authority reserves the right to require a presentation of the tenders from all tenderers. In this case, the presentation will be a part of the tender evaluation..

8 Pricing information

Prices must be specified in Appendix 3: Schedule of Payment. The prices are exclusive VAT but must include all customs duties, taxes, charges etc. It is the responsibility of the tenderer to take into account any issues relating to VAT, payroll and taxes, which could potentially be associated with delivery of equipment in Denmark. All costs related to this should be included in the final tender.

9 Variants

As stated in the contract notice variants will not be accepted.

10 Contract

Contract will be concluded on the basis of the attached "K01 Standard Contract for Short-term IT Project".

11 Award criterion

The award criterion will be the most economically advantageous tender in terms of the following criteria:

- Quality of the system (Weighing: 55 %)
- Price (Weighing: 45 %)

11.1 Quality of equipment

"Quality of the system" is evaluated based on an overall evaluation of the solution and answers to the evaluation criteria in Appendix 2: Specification of requirements, submitted by the tenderer under the following subjects:

- Segmentation tools
- Planning tools
- Evaluation tools
- Motion management

- Physics
- Adaptive Radiotherapy (ART)
- Automation, Workflow and Data Integrity
- Research, Education and training

For each of the above subjects there are a number of minimum requirements and evaluation criteria. The evaluation criteria are evaluated in terms of the quality of the functionality in question; or in terms of the added flexibility to the proposed solution by the feature in question. Each evaluation criteria is marked "Functionality" or "flexibility".

The eight subjects above are each given an individual quality score and the final quality score is the average of the eight scores.

11.2 Price

The evaluation of Price includes an evaluation of total contract sum including options and services.

The total Tender Price of the system and services includes the following elements:

- Total contract sum including options for the PTPS (appendix 3 and 13)
- Annual fees for the Service Agreement in 10 years (appendix 7)

Thus the Total Tender Price is calculated as [Total contract sum including options]+10x[Annual fee for service agreement].

Prices and fees must be given in Danish Kroners (DKK).

11.3 Tender evaluation

In terms of the tender evaluation the Contracting Authority will use a "Pricing model based on average prices".

The quality score of each tender will be converted into a price which added to the tender price forms *the Evaluation Price* (Both prices included by a factor equal to the weighting of the two sub-criteria).

The tender with the lowest evaluation price wins.

To find the price of the quality score, the individual quality score are multiplied by a Converted Amount (the price per quality score). The Converted Amount is found by calculating the average of the tender prices divided by the highest possible quality score (in this case 8 points). The quality score is then multiplied by the Converted Amount.

Each of the in section 11.1 mentioned subjects is given a score between 0 and 8, where 0 is given to the best possible solution and the score 8 is given when the proposed solution only fulfills mandatory requirements.

The scores are explained in the table below:

0 points Best possible solution or fulfillment of requirement
1 point Excellent solution or fulfillment of requirement
2 points Very satisfactory solution or fulfillment of requirement
3 points Above adequate solution or fulfillment of requirement
4 points Satisfactory, adequate solution or fulfillment of requirement
5 points Just below adequate solution or fulfillment of requirement
6 points Less than adequate solution or fulfillment of requirement
7 points Substantial below adequate solution or fulfillment of requirement
8 points Only fulfills mandatory requirements

Example:

Tender 1: Quality score 2 points and a Tender Price of 1.000.000 DKK.

Tender 2: Quality score 1 point and a Tender Price of 1.500.000 DKK.

Tender 3: Quality score 4 points and a Tender Price of 900.000 DKK.

Average of the tender prices: $3.400.000/3 = 1.133.333$ DKK
 Converted Amount (price per quality score): $1.133.333 / 8 = 141.666$

Weighting of the criteria: Price 40% and quality 60%

	Tender 1	Tender 2	Tender 3
Tender Price	1.000.000	1.500.000	900.000
Quality (141.666 dkk per each point)	283.332	141.666	566.664
Price(weghting 40%)	400.000	600.000	360.000
Quality (weghting 60%)	169.999	85.000	339.998
Evaluation price	559.999	685.000	699.998

Tender 1 which has the lowest evaluation price wins.

12 Reservations

The tenders must comply with the minimum requirements as stated in the Specification of Requirements (appendix 2) and Contract with appendices, unless otherwise stated in the instructions for each Appendix. Reservations against these elements cannot be made. The Contracting Authority will handle reservations in the tenders that are made intentionally or unintentionally in accordance with the public procurement regulations. The Contracting Authority is under obligation to reject tenders of which there is reservation against basic elements in the request for tender or other reservations that cannot be priced by the Contracting Authority. The tenderers are therefore requested not to make any reservations, in that a reservation implies a risk that the tender will not be taken into consideration, unless the reservation in question is evidently unimportant. Instead of considering reservations, a tenderer is requested, as early as possible to call the Contracting Authority's attention to unfit requirements, see Section 6.

13 Confidentiality

To the widest extent possible, a Contracting Authority must ensure confidentiality regarding information given by a tenderer during the procurement process and contained in a tenderer's tender and which is related to a tenderer's confidential business situations, see Article 6 of the Public Procurement Directive.

However the tenderers must be aware that documents concerning this procedure including the submitted tenders are subject to the Danish legislation on public access.

The contracting authority will not disclose any information without a prior dialogue with the tenderer and only to the extent that legislation imposes the Contracting Authority to disclose information to any third party such as the Danish Public Records Act. In the nature of things, undertaking of confidentiality is subordinated to such legislation.

14 Notification of the award

The Contracting Authority will by email notify the tenderers at the same time of the award decision. Notification of the award to the successful tenderer is not a guarantee that the contract awarded will be concluded with the tenderer. It is only a notification that, in the opinion of the Contracting Authority, the tenderer has submitted the successful tender and it is the intention of the Contracting Authority to conclude the contract with the awarded tenderer.

There is therefore no contract or guarantee until a contract, if any, has been signed by all parties. The signing of the awarded contract may not be concluded until the expiry of the stand still period of 10 days.

A Contracting Authority's notification of the award decision does not exempt unsuccessful tenderers from the obligations under the final tender which remain binding until the expiry of the specified period in the invitation during which the tenders must remain open for acceptance.

15 Minimum requirements and evaluation criteria

The specifications from the Contracting Authority contain minimum requirements and evaluation criteria. Minimum requirements and evaluation criteria, including their contents, clearly appear in Appendix 2, Specification of Requirements. By submitting the final tender the tenderer accepts all minimum requirements in the Contracting Authority's request for tender. For some of the minimum requirements specific documentation is requested from the tenderer, if this is the case it will be apparent in the text in Appendix 2. The evaluation criteria represent the Contracting Authority's requests for the offered solution and the tenderers solution to these requests will be part of the tender evaluation.

16 Law and Arbitration Procedures

Danish law is applicable to this procurement process. The Danish courts and the Complaints Board for Public Procurement will have exclusive jurisdiction in relation to any dispute(s) arising from this procurement process.

17 Reservations for cancellation

Until the call for tender is closed by concluding an awarded contract, the call for tender may be cancelled by the Contracting Authority if the Contracting Authority has factual grounds to do so.

18 Definition of terms

- 4DCT, Four-Dimensional Computed Tomography
- ART, Adaptive Radiotherapy
- CBCT, Cone Beam Computed Tomography
- DCE MRI, Dynamic Contrast Enhanced MRI
- DCPT, Danish Centre for Particle Therapy
- DECT, Dual-Energy CT
- DIR, Deformable Image Registration
- DRR, Digitally Reconstructed Radiograph
- DVF, Deformation Vector Field
- DVH, Dose Volume Histogram
- DWI MRI, Diffusion Weighted Imaging MRI
- ESPD, European Single Procurement Document
- EUD, Equivalent Uniform Dose
- HU, Hounsfield Unit
- IGRT, Image-Guided Radiation Therapy
- IMRT, Intensity-Modulated Radiation Therapy
- LET, Linear Energy Transfer
- MIP, Maximum Intensity Projection
- MRI, Magnetic Resonance Imaging
- MU, Monitor Units
- NTCP, Normal Tissue Complication Probability
- OIS, Oncology Information System
- PBS, Pencil Beam Scanning
- PET, Positron Emission Tomography
- ProBeam, Trademark name of the Varian proton therapy system
- PTPS, Proton Treatment Planning System
- PTV, Planning Target Volume
- RBE, Relative Biological Effectiveness
- ROI, Region of Interest

- SC, radiation-induced Secondary Cancer
- SECT, Single Energy CT
- SFUD, Single Field Uniform Dose.
- SPECT, Single Photon Emission Computed Tomography
- SPR, Stopping Power Ratio
- SUV, Standardized Uptake Value
- TCP, Tumor Control Probability
- TPS, Treatment Planning System
- VERT, a 3D virtual reality simulation system, trademark of Vertual Ltd.
- VMAT, Volumetric Modulated Arc Therapy