

Request for Tender

Cyclotron, Hotcells, Switching system, Dispenser, Shielded Laminar Air Flow workbench (LAF) for Tc-99m Generators

Open Procedure

Central Denmark Region

Reference Number: 1-23-4-70-1-16



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1 Introduction

The Central Denmark Region is currently reshaping and modernizing the structure of the regions hospitals. As part of this modernizing, Aarhus University Hospital, which is currently located at 5 different sites throughout Aarhus, will be relocated in new facilities at DNU, The New University Hospital in Aarhus.

The Department of Nuclear Medicine & PET-Center at Aarhus University Hospital is relocating to new facilities at DNU in the period 2018-2020 and is seeking partnerships with suppliers of equipment necessary for The Departments production of radiopharmaceuticals at the Departments new facilities at DNU.

2 Request for tender

2.1 Procedure

For the procurement of the Cyclotron, Hotcells etc., 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.

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.

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
Department of Procurement & Clinical Engineering
Olof Palmes Allé 15, 1.
DK-8200 Aarhus N

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
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 manufacture, delivery, installation, testing and potentially service and maintenance of the major parts involved in The Departments production of radioactive pharmaceuticals. The "rigging" of the Equipment (the moving of the Equipment into the Customer's installation site) is the responsibility of the Customer. The Customer shall take

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

the necessary measures and bear the cost of the rigging, unless the Supplier requests otherwise.

The scope is divided into the following lots:

- Lot 1: Cyclotron
- Lot 2: Hotcells
- Lot 3: Switching system
- Lot 4: Dispenser
- Lot 5: Shielded Laminar Air Flow workbench (LAF)for Tc-99m Generators

2.4.1 Lot 1: Cyclotron

Cyclotron for GMP-production of radiopharmaceuticals for use in connection with PET-scanning, consisting of a complete cyclotron system with 4 additional operating consoles, targets for ^{18}F , fluoride, ^{11}C , CO_2 and ^{11}C , methane and training of Buyers staff regarding operation and maintenance of the equipment included in the lot.

2.4.2 Lot 2: Hotcells

Hotcells for GMP-production of radiopharmaceuticals for use in connection with PET-scanning. The lot is divided into routine productions hotcells and development hotcells.

2.4.3 Lot 3: Switching system

Switching system for distribution of cyclotron produced isotopes for production of radiopharmaceutical for use in connection with PET-scanning including 4 operating consoles.

2.4.4 Lot 4: Dispenser (and associated consumables)

Dispensing system for GMP-production of radiopharmaceuticals, including but not limited to FDG, to be used for PET-scanning, including hotcell.

2.4.5 Lot 5: Shielded Laminar Air Flow workbench (LAF)for Tc-99m Generators

Fully shielded Laminar Air Flow workbench for handling Tc-99m Generators.

For further specifications of the Scope of Contract see Appendix 1a-1e, Specifications and Requirements for each of the lots.

2.5 Delivery options

The scope for each lot includes mandatory and voluntary delivery options, which the Contracting Authority may or may not choose to purchase. These options are listed in Appendix 1a-1e.

"Mandatory options" include delivery options that shall be part of the tender response and the tenderers solution. "Voluntary options" on the other hand include options that the tenderer is not obliged to include in the offered solution. Voluntary options will therefore not be part of the tender evaluation.

The mandatory delivery options for each lot are:

2.5.1 Lot 1: Cyclotron

Delivery options for lot 1 are additional targets (gas, liquid, and solid).

2.5.2 Lot 2: Hotcells

Delivery options for lot 2 are IQ-OQ protocol.

2.5.3 Lot 3: Switching system

A delivery option for lot 3 is delivery of lead shield housing and IQ/OQ protocol.

2.5.4 Lot 4: Dispenser

Delivery options for lot 4 are an automated sterilization of the hotcell, LAF bench for transfer into the dispenser, and IQ-OQ protocol.

2.5.5 Lot 5: Shielded Laminar Air Flow workbench (LAF)for Tc-99m Generators

Delivery options for lot 2 are IQ-OQ protocol.

For further specifications of the delivery options see Appendix 1a-1e, Specifications and Requirements for each of the lots.

2.6 Organization of the procurement

The management of The Department of Nuclear Medicine & PET-Center at Aarhus University Hospital is responsible for the relocation of the department to its new facilities at DNU, and as such also responsible for the procurement of equipment necessary for the relocation including the equipment described in this tender. The management has appointed a project group, who is responsible for describing the tender criteria, evaluation of the tender and the final selection of suppliers for each lot.

The project group has the following members:

Head Biomedical Laboratory Scientist Michael Werenberg Mikkelsen

Chief Chemist Dirk Bender

Senior medical physicist Søren Baarsgaard Hansen

Cyclotron technician Niels Nielsen

Chemist Helene Audrain

Chemist Marie Louise Olesen

Biomedical laboratory technician Gitte Munkebo Kodahl

Legal advice in the tender is conducted by procurement lawyer Sidsel Marcussen, Department of Procurement & Clinical Engineering, Central Region Denmark.

3 Tender and Contract documents

- Request for tender with the following appendix:

Appendix A: ESPD European Single Procurement Document

- Draft contract with the following appendices:

Appendix 1: Specifications and Requirements.

Appendix 1a Lot 1 Cyclotron Specifications and Requirements

Appendix 1b Lot 2 Hotcells Specifications and Requirements

Appendix 1c Lot 3 Switching system Specifications and Requirements

Appendix 1d Lot 4 Dispenser Specifications and Requirements

Appendix 1e Lot 5 Shielded Laminar Air Flow workbench (LAF)for Tc-99m
Generators Specifications and Requirements

Appendix 2: Tender Response (tenderers solution)

Appendix 3: Quotation sheet:

3.a Lot 1 Cyclotron Quotation Sheet

3.b Lot 2 Hotcells Quotation Sheet

- 3.c Lot 3 Switching system Quotation Sheet
- 3.d Lot 4 Dispenser Quotation Sheet
- 3.e Lot 5 Shielded Laminar Air Flow workbench (LAF)for Tc-99m Generators Quotation Sheet

Appendix 4: Plan for Delivery, delivery addresses, drawings, sitemaps etc. (drawings will be handed out on a USB stick at the inspection of the installation site or sent by post at the tenderers request.)

Appendix 5: Q&A, corrigendum etc.

Appendix 6: Acceptance Test documents *(to be prepared by the tenderer in accordance with the Contracting Authority based on the Contracting Authority's specifications and requirements).*

Appendix 7: Declaration on direct, unlimited and joint liability where the tender is submitted by a consortium/several joint tenderers. *(if relevant)*

Appendix 8: A declaration stating that the partner/subcontractor makes its economic or technical skills available to the Supplier in connection with the project. *(if relevant)*

Appendix 9: Service agreement

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.

October 4, 2016	Submission of Contract notice to the Official Journal of the European Union/TED (Tenders Electronic Daily).
October 27, 2016	Inspection of the installation site. (Registration no later than October 24 to Michael Werenberg Mikkelsen michmikk@rm.dk)
November 9, 2016	Deadline for asking questions to the tender documents (Questions and answers will be published in anonymous form on www.udbud.rm.dk)
November 16, 2016 11.00 AM	Final deadline for the Contracting Authority to publish additional information on www.udbud.rm.dk .
November 22, 2016 12.00 noon (local time)	Deadline for the receipt of tenders.
January 2017 (week 1, 2 and 3)	The Contracting Authority reserves the right to inspect reference sites to verify specific areas of the tenderers proposed solution.
February 2017	Evaluation of tenders finalized.

February 2017	Documents confirming the information submitted by the tenderer in the European Single Procurement Document (ESDP) are to be provided by the winning tenderer.
March 2017	Announcement of award decision. Beginning of the standstill period.
March 2017	Contract signing.
May 15, 2017	Validity period of the tenderer's tender (6 months from the Deadline for the receipt of tenders).

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 deadline for receipt of questions or comments is in accordance with the time schedule in section 4.

Questions asked after this deadline 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 5.

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 1.

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/espd/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 should provide references from similar assignments.

- It is a minimum requirement that the tenderer can provide at least one reference from a similar assignment with similar sites with a production of radiopharmaceuticals for use in clinical or preclinical scanning within the last 3 years (or ongoing). 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.

8 Language

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

9 Submission of tender

9.1 Form

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

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

The tender must be received by the Contracting Authority in a sealed envelope stating "Tender: Cyclotrone, hotcells, switching system, dispensing system and generator LAF-bench."

9.2 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: **November 22, 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.

9.3 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.

9.4 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.

9.5 Presentation

The Contracting Authority reserves the right to inspect reference sites for all tenderers to verify specific areas of the tenderers proposed solution. In this case, the inspection will be a part of the tender evaluation.

10 Pricing information

Prices must be specified in Appendix 3a-3e: Quotation sheet. 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.

11 Variants

As stated in the contract notice variants will be accepted. Each tenderer may submit up to two different variants. When offering variants the tenderer shall prepare separate tenders for each variant.

12 Contract

Contract will be concluded on the basis of the attached Draft contract.

13 Award criterion

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

- Quality of the system (Weighing: 70 %)
- Price (Weighing: 30 %)

13.1 Quality of equipment

For each of the 5 lots "Quality of the system" is evaluated based on an overall evaluation of the solution and answers to the evaluation criteria in Appendix 1a-1e: Specification and Requirements, submitted by the tenderer under the following subjects:

- Requirements for functionality
- Requirements for technical quality and service
- Education and training
- Working environment and safety protection
- Installation (except Lot 5)

For each of the above subjects there are a number of minimum requirements and evaluation criteria. The evaluation criteria consist of criteria which will be positively assessed with regards to the contract.

Each of the above subjects is given an overall score between 0 and 8, where 8 is given when the proposed solution only fulfills mandatory requirements and the score 0 is given to the best possible solution. The scores are explained in the table in section 11.3.

Evaluation criteria regarding mandatory options will be included in the evaluation by 50%. Voluntary options will not be included in the evaluation.

13.2 Price

The evaluation of price includes an evaluation of the total tender price.

The total tender price of the system and services includes the elements listed in Appendix 3a-3e Quotation Sheet. Mandatory options will be included in the evaluation of total cost by 50%. Voluntary options will not be included in the evaluation of total cost.

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

13.3 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 3 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)	424.998	141.666	566.664
Price(weghting 30%)	300.000	450.000	270.000
Quality (weghting 70%)	297.499	99.166	396.665
Evaluation price	597.499	549.166	666.665

Tender 2 wins.

14 Reservations

The tenders must comply with the minimum requirements as stated in the Specification of Requirements (appendix 1) 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.

15 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.

16 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.

17 Performance Security

By the signing of the contract the awarded tenderer (the contractor) must issue a performance security of 40% of the Contract Price. The security shall be provided in the form a bank guarantee issued by a reputable bank or other financial institution acceptable to the Contracting Authority.

The security provided will be reduced to 10 % of the contract price upon approved Acceptance Test.

18 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 1, 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 1. 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.

19 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.

20 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.