

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

Appendix 5: Questions & Answers (Q&A) form

No.	Lot, Section and page no. or drawing to which the questions refers	Quote of the text to which the questions refers	Question	Answer
1.	Request for Tender, 2.4	Scope of Contract	It is unclear if the procurer accepts bids for the specified lots in part. Would the procurer please clarify if the tender is to be considered as one whole, and if submission of bids is conditional on submission of bids for all lots, or if the tenderer would accept bids for the individual lots in part.	As stated in the Contract Notice section II.1.6 "Information about lots" the tender is divided into 5 lots, and tenders may be submitted for all lots. This means that a tenderer has the possibility to submit tenders for all 5 lots but is not obligated to submit tenders for all 5 lots. A tenderer may therefore also decide to submit tenders for 1, 2, 3 or 4 lots.
2.	Request for Tender, 4	Inspection of the installation site.	Could you please clarify if the site visit is not mandatory and that there will be to	The site visit is not mandatory, - it is a possibility for the tenderers to visit the site but there is no obligation to participate and there will be no

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

			no disadvantage in the tender evaluation if we are not participating in the site visit.	consequences in terms of the tender evaluation.
3.	Lot 1, Appendix 1a, Section 4, page 1	Voluntary delivery options invited to be disclosed separately	Can additional items or options, not listed in this table, be proposed for consideration?	No additional options can be proposed by a tenderer.
4.	Appendix 4, Lot 1, General layout.pdf	Lot 1.	The general layout shows three bunkers, delineated by dotted lines, all inside the shaded area labelled Lot 1. Do these bunkers exist?	The three individual bunkers does not exist at the moment. However, the area indicated "Lot 1" is intended to house a total of three cyclotrons, meaning that only 1/3 of the area is available for installation of the supply in lot 1. At this time only the outer wall of 1800 mm concrete has been completed.
5.	Appendix 1a, Section 9.1	Installation in a bunker with maze entrance is the preferred solution, however access via a heavy door (plug) may also be accepted due to space limitations. Multiple installation proposals can be submitted, in which case pros and cons should be specified for each proposal.	Can you please specify what is the allocated space (m x m) for the cyclotron withing this area, with or without optional beam line?	The available space is 6.0 x 8.7 m2 including wall to the adjacent bunker.
6.	Lot 1, General layout.pdf	Lot 1.	What is the maximum ceiling height of the cyclotron bunker?	The free height from floor to ceiling is 3000 mm.

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

7.	Request for Tender, Section 3, page 5	Appendix 2	Can you please provide Appendix 2?	Appendix 2 is the tenderers own response. There is not a template for Appendix 2.
8.	Request for Tender, Section 3, page 6	Appendix 6	Does tenderer have to provide a draft of appendix 6 with the tender submission? Is there a specific format for Appendix 6?	The question concerns the Acceptance Test documents which according to the Request for Tender are to be prepared by the tenderer in accordance with the Contracting Authority based on the Contracting Authority's specifications and requirements. The document should not be provided with the tender submission.
9.	Appendix3a- quotation-sheet- lot1-cyclotron. Section Service and Spare Parts	Annual Cost. Excel: Cells E65 and E70	Is the price to be entered into these cells the total Annual Cost for Service agreement Level 2 and 3, or it is the incremental difference compared to the previous level? For example: If Annual Cost for Level 1 is DKK20 and Annual Cost for Level	It is the total annual cost for service agreement level 2 and 3. In the stated example, "50" should be entered in cell E65.

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

			2 is DKK50, Should DKK30 or DKK50 be entered in cell E65?	
10.	Lot 2- Appendix 1b Specification of requirements – pos. 5.11	The required minimum for individual lead shielded internal volume of the production hotcells shall be 65 x 70 x 80 cm (WxHxD).	May you clarify if the required minimum dimensions for individual lead shielded internal volume of the production hotcells are mandatory and if it is a difference in dimensions reason of exclusion from the tender?."	<p>Position 5.11 is a minimums requirement and shall be met by the tenderers solution.</p> <p>However the Contracting Authority has decided to adjust the specific position and make a corrigendum to Appendix 1b and uploaded at www.udbud.rm.dk :</p> <p>"The required minimum for individual lead shielded internal volume of the production hotcells shall be 65 x 70 x 80 cm (WxHxD)."</p> <p>Shall be replaced by the following:</p> <p>"The required minimum for individual lead shielded internal volume of the production hotcells shall be 60 x 65 x 70 cm (WxHxD)."</p>
11.	Request for tender – item 11. Variants	As stated in the contract notice variants will be accepted. Each tenderer may	To offer a variant, May you clarify if it is enough to send an additional envelope	To offer a variant a separate folder containing Appendix 1, Appendix 2 (the tender response) and Appendix 3 (the Quotation Sheet) shall be submitted. In

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

		submit up to two different variants. When offering variants the tenderer shall prepare separate tenders for each variant.	containing Appendix 1, Appendix 3 and Appendix 6 and related documentation to present the features of the offered item or we must send an additional envelope containg all documetation requested for the tender, including the administrative one?	terms of Appendix 6 Acceptance Test see the answer to Question 8.
12.	Request for tender – item 3 Tender and Contract Documents	Appendix 2: Tender Response (tenderers solution)	May you clarify what the Authority asks or if it is correct to interpret "tender response (tenderers solution)" as the additional documents related to the appendix 1 in order to present the offered items?	Appendix 2 is the tenderers offered solution /tender response. See the answer to question 7.
13.	Request for Tender, Section 13.1, page 10	<ul style="list-style-type: none"> – Requirements for functionality – Requirements for technical quality and service – Education and training – Working environment and safety 	There are five subjects that will be given an overall score from 0 to 8. How is the final quality score for each Lot	Yes the final score of "Quality of the system" (for each separate Lot) will be based on an average of the 5 individual scores (except for Lot 5 which will be based on an average of 4 individual

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

		<p>protection – Installation (except Lot 5)</p> <p>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.</p>	<p>calculated? Is it based on average of the five individual scores or is there another formula?</p> <p>As a result of the above calculation, can the Quality score for each Lot or the entire Tender Submission (in case if multiple Lots are offered), be a fraction or is it going to be an integer from 0 to 8?</p>	<p>scores).</p> <p><i>The tenderer is asked to please clarify the second question.</i></p>
14.	Lot 5 Shielded Laminar Air Flow workbench (LAF)for Tc-99m Generators / Appendix 4 - Drawing: Layout Tc99 LAF bench	N.A.	Following the site visit, we kindly ask you to clarify that the window 322.094 close to the hood for Tc99 will have vertical opening instead of horizontal as reported in the actual laboratory drawing.	Since the window 322.094 has not yet been produced, it can be constructed with an opening either horizontal or vertical according to the winning tenders specifications
15.	Lot 1, 3.5	Target, 11C, CO2/methane	Do you mean a combined target or two separate targets?	Two separate targets. One target designated for the production of C-11 CO2 and one target for the production C-11 CH4.
16.	Lot1, 5.21	It is preferred that recovery of 18O gas	Can you specify what	The tenderers are asked to disregard the

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

		from the 18F fluorine target after bombardment is efficient and automatic. Describe procedure for recovery, including molecular sieves and NaF traps.	you mean with NaF traps?	final sentence: " Describe procedure for recovery, including molecular sieves and NaF traps" Instead tenderers are simply asked to describe procedures for recovery of 18O gas.
17.	Lot 2, 4.1	Solid target, including transport system and chemical processings for several products e.g. Cu-64, Zr-89, I-124, Ga-68	In Lot 1 (3.7) you are asking for a mandatory delivery option on a solid target irradiation system. Is this a question for the same equipment or is it for a hotcell for the solid target system?	It is confirmed that this is a question for the same equipment.
18.	Lot 2, 5.11	The required minimum for individual lead shielded internal volume of the production hotcells shall be 65 x 70 x 80 cm (WxHxD).	We collaborate with leading Hotcell manufacturers. Can you confirm that WxHxD is correct?	See answer for question 10 The Contracting Authority has decided to adjust the specific position and make a corrigendum to Appendix 1b and uploaded at www.udbud.rm.dk : "The required minimum for individual lead shielded internal volume of the production hotcells shall be 65 x 70 x 80 cm (WxHxD)."

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

				<p>Shall be replaced by the following:</p> <p>"The required minimum for individual lead shielded internal volume of the production hotcells shall be 60 x 65 x 70 cm (WxHxD)."</p>
19.	Lot 2, 5.15	The tender shall include three development hot-cells (inner dimensions minimum: 111 cm (W) x 820 (D) cm (D) x 970 cm (H)).	We assume that min. dimensions are 1110mm (W)x820 mm (D)x 970 mm (H). Can you confirm? We are concerned about 5.11 and 5.15, that the WxDxH dimensions are switched around	It is confirmed that the minimum dimensions for the inner cell are: 1110mm (W) x 820mm (D) x 970 mm (H).
20.	Lot 3, 9 Installation	It is preferred that the supplied system is compact and designed to be housed in room 02.18.081, see attached drawing. Besides the switching system, room 02.18.081 is intended to house process cabinets serving a minimum of two cyclotrons. Describe possibilities.	Is it required to offer tubing? If yes, could you please specify requirements?	It is not required to offer tubing. The required tubing might be subject to cyclotron supplier specifications. The chosen supplier might be invited to offer tubing after a delivery contract is entered.
21.	Lot 1, Quotation sheet	Energy consumption	Can you confirm that for level (beam on) will last for 16 hours each day? Our experience is, that with modern	The quotation sheet for lot 1 contains a mistake regarding the use pattern. On working days it should be: Run level 1: 16 h Run level 2: 4 h Run level 3: 4 h

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

			cyclotrons you are able to run shorter runs with high production yields.	
22.	Answer for Question 13 (dated Oct.31)	Yes the final score of "Quality of the system" (for each separate Lot) will be based on an average of the 5 individual scores (except for Lot 5 which will be based on an average of 4 individual scores). The tenderer is asked to please clarify the second question.	Clarification: If, for example, 5 individual scores will be: 1, 2, 1, 2, and 2, according to the answer provided, the average score will be 1.4. Will this score be rounded to 1.0 or used as 1.4?	In the example where the 5 individual scores are 1, 2, 1, 2, and 2, the total score "Quality of the system" will be 1.6.
23.	Appendix 1a, Lines: 5.14, 5.15 and 5.16	Shaded cell in "Reply" column, G	These lines, specially line 5.15, require written answers. However cells in column G are shaded grey. Where should the answers be given, in the shaded cells?	The answer for B-requirement 5.15 should indeed be given in cell G55. Please ignore that this cell by mistake has been shaded.
24.	Appendix 1a Table 3. Mandatory delivery options. Line 3.6	Target, 68Ga (either liquid target or solid target based system)	If solid target is offered: Should this be a 2nd, complete solid target irradiation system, similar to the one requested in Line	This is a request for a target, capable for production of 68Ga. If a solid target is offered, this is an request for an individual 68Zn solid target, that can be used in the Solid target irradiation system (line 3.7)

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

			3.7? Or is this a request for an individual ⁶⁸ Zn solid target that can be used in the Solid target irradiation system (line 3.7)?	
25.	Request for Tender, Section 7.1.2 Technical capacity, page 8	ESPD part VI section C "Technical and professional capacity" must be completed.	The ESPD Part IV, Section C contains multiple tables. - Could you please confirm if the only table from this section that must be completed is the one titled: For supply contracts: performance of deliveries of the specified type. For supply contracts: performance of deliveries of the specified type For supply contracts: performance of deliveries of the specified type For supply contracts: performance of deliveries of the specified type	When we open the uploaded version of the ESPD-document, there is only one table, but we can confirm that the relevant table is for Supply Contract: "For supply contracts: performance of deliveries of the specified type For public supply contracts only: During the reference period, the economic operator has delivered the following principal deliveries of the type specified. Contracting authorities may require up to three years and allow experience dating from more than three years."

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

			performance of deliveries of the specified type	
26.	USB delivered during inspection of October, 27th /2016	N.A.	<p>Can you please send us the drawing named "detailed layout of site" in DWG format?</p> <p>In the USB we received during the inspection on site, only the structural drawing can be opened, the technical drawing 62.01-A-01-1-29-001 is in fault and can not be opened.</p> <p>Please, refer to the attached image.</p>	<p>The structural drawing is available at the tender website www.udbud.rm.dk</p> <p>The New University Hospital is working in the Revit file format. It is possible to convert Revit files to other technical file formats, eg. DWG through AutoDesk.</p> <p>http://www.autodesk.com/products/revit-family/free-trial</p>
27.		6.1 Access shall be granted to service software (including license keys/USB-dongle) needed for service and diagnostics of the system.	is it required to access to the control system to edit the parameters to do the service?	It is required to access to the control system to edit all parameters necessary for cyclotron service including verification and test of functionality.
28.			We understood that 02.18.080 is the room where the	If it is foreseen that the irradiation of the solid target will be in room 02.18.080. Chemical processing of solid target is

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

			cyclotron will be installed: In which room the solid target station is foreseen to be installed?	foreseen in room 02.18.037
29.	LOT 3 Switching system / Appendix 1c specification of requirements	Appendix 1c specification of requirements	<p>In order to provide a correct technical solution and due to the fact that the number of inlet lines listed in the technical requirements seems to be quite relevant (39?), we kindly request to clarify the following points if possible:</p> <ul style="list-style-type: none"> - What are the model name and brand of the two existing cyclotrons? - How many targets per each of the 3 cyclotrons? - What is the target configuration per 	<p>Cyclotron 1: PETtrace 800 6 targets (2 x F-18 liquid, 1 x F-18 F2 gas, 1 x N-13 liquid, 1 x O-15 gas, 1 x C-11 CO2 gas)</p> <p>Cyclotron 2: IBA Cyclone 18/18 8 targets: (1 x F-18 liquid 3,5 ml volume, 1 x F-18 liquid 2.0 ml volume, 1 x F-18 F2 gas, 1 x N-13 liquid, 1 x O-15 gas, 1 x C-11 CO2 gas, 1 x C-11 CH4 gas, 1 x solid target)</p> <p>Cyclotron 3: To be supplied within the tender. It is therefore referred to the specifications for lot 1</p> <p>However, the number of targets for cyclotron 3 might exceed 6 targets due to different possible cyclotron suppliers.</p> <p>Single vs. common lines From cyclotron to radioisotope</p>

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

			<p>each cyclotron, i.e. what are the mentioned targets per each cyclotron? Do you consider to have each single (separated) lines (39?) or common lines for groups of target?</p> <p>- line 5.1: into how many inlet lines do you prefer to have activity measurement system (dose calibrator)? Please confirm also that this system is requested only for liquid target.</p> <p>- line 5.11: could you better clarify this point? is it a liquid or gas circuit? Please confirm that we are talking about n.2 systems with 3 input and 5 output each.</p>	<p>distribution system (Switch): single line from each target. From radioisotope distribution system to individual receiving hotcell: common lines for identical isotopes.</p> <p>Line 5.1: The dose calibrator is intended to be used for target performance testing. It is not requested to measure the radioactivity "on-line" under transfer to the receiving hotcell. Therefore the dosecalibrator should be considered as receiving destination equivalent to a receiving hotcell. This output is requested for all cyclotron products with the exception of the solid target.</p> <p>Line 5.11: This is a gas circuit. For clarification The O-15+N2 gasmixture is either transferred as bolus after irradiation or continuously transferred under irradiation from the target to a processing system. Within the processing system hydrogen is added to the target gas. The O-15 O2/N2/H2 gasmixture is then directed to the switch and from here distributed to the receiving point. It is confirmed that there three inputs</p>
--	--	--	--	---

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

			- Liquid and gas steel tubings/capillaries from cyclotrons targets and distribution system, and/or from distribution system and new hotcells have to be included in scope of supply for LOT 3 or not?	and 5 outputs requested. Liquid and gas steel tubings: It is referred to the answer for question 20: It is not required to offer tubing. The required tubing might be subject to cyclotron supplier specifications. The chosen supplier might be invited to offer tubing after a delivery contract is entered.
30.	Request for Tender	Chapt. 7.1. European Single Procurement Document	In order to provide the document in the tender, is it correct to create the ESPD through the link stated at page 8, to fulfill part II, III and IV section C (and not part VI section C as stated in chapt. 7.1.2) and to download it? Please, provide some instruction.	ESPD has been prepared by the European Commission and can only be accessed via the Commission's website, https://ec.europa.eu/growth/tools-databases/espd/welcome ESPD should be opened as follows: Download the ESPD from the tender documents uploaded at www.udbud.rm.dk and store the document on your PC; Open the website https://ec.europa.eu/growth/tools-databases/espd/welcome

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

				<p>Click on "English" for ESPD shown in English;</p> <p>Click on "I'm an economic operator";</p> <p>Click on "Import ESPD"; Find the saved ESPD on your PC by clicking "Browse";</p> <p>Click the arrow in the box next to "Select a Country" and click on "Denmark"</p> <p>Click on "Next".</p> <p>The ESPD made by the Contracting Authority will then appear, and you shall complete the ESPD-document according to the instructions in Request for Tender and the ESPD document itself.</p> <p>You must then save the document on your PC again and upload it to an USB-stick and possibly also submit the document in PDF document in paper along with the rest of the tender documents.</p>
31.	Draft Contract		Do we have to accept the contract as it is or do we have the opportunity, at this	The Draft Contract is part of the tender documents and according to the tender regulations the contract is not negotiable. If during the tender process

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

			stage, to discuss some important points or do we have to wait for being awarded to discuss these points?	a potential tenderer wishes to raise any questions or to point out any inexpediencies regarding the contract this should be done according to the instructions stated in the Request for Tender, section 5 and section 6.
32.	Draft Contract Page 17 Point 12.2	Project Schedule	We would appreciate to have a more precise description of what does exactly correspond the term of "Acceptance Test Procedures" and "Approved Acceptance Test". Does the "Acceptance Test procedure" correspond to the acceptance tests issued and done by the Seller directly AFTER the installation of the equipment? Does the "Approved Acceptance Test" correspond to the tests to be performed at the end of the warranty period	<p>The term "The Acceptance test procedures" is an overall description of the acceptance procedures which ends with a final approval : "approved acceptance test".</p> <p>In Section 12.2 "Approved Acceptance Test" should be read as part of the overall acceptance procedure.</p> <p>The Acceptance Test Procedures are regulated in the Draft Contract, Section 15.2.</p>

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

			meaning one year after the "Acceptance Test Procedures"?	
33.	Draft Contract Page 21 Point 15.2	Acceptance Test Procedures	There are no "Approved clinical testing" for a cyclotron dedicated to the production of radiopharmaceuticals. Could you modify the text accordingly?	"Approved clinical testing" shall be changed to "approved testing" in the final contract.
34.	Draft Contract Page 22 Point 15.3	Pass of risk for loss and damage to the equipment : the risk for any loss or damage to the equipment shall pass to the Customer at the date of successful Acceptance Test	Does it correspond to the time of the "Acceptance Test Procedure" or to "the Approved Acceptance Test". The risk will pass to the customer after the installation or after the one-year warranty?	See the answer to Question 32. "Approved Acceptance Test" is the finalization of the Acceptance Procedures. It is stated in the Draft Contract Section 15.3: "Until the Acceptance Test Procedures are completed the Supplier shall maintain full responsibility for the Equipment." This means that when the Acceptance Test Procedures are completed with an Approved Acceptance Test, the responsibility of the equipment shall pass on to the Customer (and the 1-year warranty-period shall begin.)
35.	Draft Contract	1. Associated consumables: As part of	Do we have	Consumables listed in Appendix 3a-3e

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

	Page 12 Point 8.3	the scope, the Supplier is obligated to deliver associated consumables as listed in Appendix 3a-3e. The Supplier's obligation to deliver associated consumables applies until 10 years after approved Acceptance Test (see Clause 15).	<p>- to give and quote in advance, in the scope of supply, the total amount of associated consumables for the coming 10 years? In this case, this will be included in the price</p> <p>or</p> <p>- to agree on the fact that we will be able to deliver the same associated consumables as described in the scope of supply during the coming 10 years and that the related orders will be paid by the Customer.</p>	shall be priced and the submitted price for these consumables will be part of the tender evaluation.
36.	Lot 2 / 5.2	The hotcell shall be equipped with a system for observing and monitoring processes within the central working area of the hotcell.	What kind of monitoring systems or observing system are requested? Camera system or lead glass window?	The preferred solution is a lead glass window. In case a lead glass window cannot be supplied a camera system may be described.
37.	Lot 2 / 5.2	A pressure read-out for each gas within	Do you need an	Besides a regulation valve, an additional

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

		the operating panel is preferred. Describe possibilities.	additional valve to open/close each gas in the operating panel?	shut-off valve to open/close each gas in in the operating panel is preferred.
38.	Lot 2 / 5.4	The hot-cells shall be fitted with operating panel (for all technical functionalities such as gas and electricity supply, ventilation and ventilation surveillance) and space (e.g. a drawer or shelf), for a laptop computer.	How detailed shall the specification be?	<p>The specification shall contain</p> <ul style="list-style-type: none"> • On/off + indicator • Gas valves open/close • Ventillation on/off • Pressure read out for ventilation • Alarm indicators for pressure and radiation <p>The suppliers are encouraged to include more parameters if considered useful by the supplier.</p>
39.	Lot 2 / 5.4	It is preferred, that hotcell ventilation maintain underpressure to laboratory environment when open. Describe possibilities.	What is the strenghts (low pressure, air flow rate) of the on-site exhaust-air system?	<p>The air change rate for the laboratory is 20 x per hours. The differential pressure towards surrounding environment is 18 – 20 Pa overpressure.</p> <p>Within the preferred solution the hotcell ventilation ensures airflow from laboratory environment into the hotcell, when opened. It is not requested to maintain the same underpressure as under "closed hotcell" operations.</p>
40.	Lot 2 / 5.7	Documentation regarding compliance with structural air tightness requirements regarding contamination of laboratory space and air quality (class B	What kind of documentation in detail has to be provided with the	Documentation should be provided (e.g. FAT results and/or Site acceptance test results) from earlier installations of same or comparable installations,

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

		requirements), shall be included in the tender.	tender documents?	documenting air and radiation tightness.
41.	Lot 2 / 5.7	It is preferred, that the hotcells offer the possibility to connect to a particle measuring system. Describe possibilities.	What size of tube and funnel (diameter) should be provided? Connection point will be on top of the hot cells or on the front panel (according customer requirements)	Tubing for the particle measurement system is standard tubing for particle measurement systems with an inner diameter of 3/8" ID. Thus, funnel should be designed to be handle 3/8" ID tubing. Connection point on top is preferred. As integration of hotcells to a central particle measurement system is not decided yet, access to the connection point from e.g operating panel should be likewise possible.
42.	Lot 2 / 5.8	The tender shall include a detailed description of options for technical installations, including design characteristics (e.g. lighting, electricity, gases and feed-throughs).	What kind of documentation in detail has to be provided with the tender documents?	Type and location of light sources. Position of electrical sockets. Position of gas supplies. Position and path of feed throughs.
43.	Lot 2 / 5.10	Option IQ-OQ protocol: The IQ-OQ protocol should at least be equal to the Factory Acceptance test. Describe possibilities.	What kind of documentation regarding IQ/OQ in detail has to be provided with the tender documents?	The minimum documentation to be provided is a copy of the factory acceptance test.
44.	Lot 2 / 5.11	The required minimum for individual lead shielded internal volume of the production hotcells shall be 60 x 65 x 70 cm (WxHxD).	What are the specified minimum internal dimensions required for the sythesis module?	It is not decided yet, which synthesis platforms will be used. Currently GE Tracerlab MX, GE FASTlab and ORA Neptis are either in use or under consideration as synthesis platform. It is referred to the suppliers specifications for

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

				these platforms.
45.	Lot 2 / 5.13	It is preferred, that compartments for unspecified technical supporting equipment such as HPLC pump, controlling devices etc. are ventilated and have sufficient light. Describe possibilities.	What space is required for ventilated compartment for e.g. HPLC pump etc.?	It is acknowledged that the compartment space is dependent on hotcell design. Generally it is preferred to have as much space as possible and e.g. location of electrical boards and steering compartments should be designed accordingly.
46.	Lot 2 / 5.14	It is preferred, that two adjacent stackhotcells share the same side compartment housing two shielded compartments with sliding tray for finished products. Describe the possibilities.	In the drawing "layout dispenser and hot cells" are no stack hot cells adjacent to each other. Is the layout committing or can we offer alternativ layouts? What space is required for the shielded compartment?	Alternative layouts may be offered. These layouts should not compromise the installation of the dispenser with an opening towards room 02.18.040 for product shipment.
47.	Lot 2 / 5.16	The development hot-cells shall be fitted with a well for a dose-calibrator.	Which type of dose calibrator will you use in the hot cells? Should the well has shielding?	Currently it is intended to use Capintec CRC-15 dose calibrators. The well should be shielded.
48.	Lot 2 / 5.17	A sliding door for access is the preferred solution. Describe possibilities including the minimum time for complete opening.	What are the minimum dimensions of the opening of the	According to the dimensional specification of the inner cell, the opening should be as big as technical possible without

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

			hot cell?	compromising the air tightness of the inner cell when closed.
49.	Lot 2 / 5.18	A sluice for extracting the finished tracers shall be integrated in the offered solution.	Should this sluice be vantilated? What inner size should the sluice have? What shielding is required for the sluice? What kind of transport container you will prefer?	The sluice should be ventilated and designed to handle as minimum transport containers of type CF-18T supplied from Comecer. Shielding should be appropriate, taken the shielding capacity of CF-18T containers into account.
50.	Lot 2 / 5.19	It is preferred, that the hot-cells offer the possibility of placing equipment on a sliding tray/movable tray to facilitate servicing. Within the preferred solution it is possible to completely pull the sliding tray/movable tray out of the hot-cell with the possibility to rotate the equipment up to 90 degrees. Describe the possibilities including maximum workload for the tray for uncompromised working conditions.	What is the minimum required width of the sliding tray?	The required minimum is dependent on the opening of the hotcell, see answer to question 48, and should be not considerably less than the opening.
51.	Lot 4 / 5.4	The minimum number of possible connections to production hotcells shall be 6.	What is the max amount of connections and which kind?	The maximum amount is 12 (6 connections + 1 spare for each connection). The connection from the production hotcells is preferably made of 1/16" Tefzel tubing. Within the preferred solution the connections from the production hotcells end in a system with 12 inputs (2from each production cell and one output towards the dispenser.

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

52.	Lot 4 / 5.7	It is preferred that the dispenser ventilation keeps overpressure to laboratory environment when open. Describe possibilities.	Overpressure or low pressure to laboratory enviroment? What is the strenghts (low pressure, air flow rate) of the on-site exhaust-air system?	Under dispensing operation, the dispenser maintains underpressure towards laboratory environment. To avoid microbial contamination when opened for example during set-up operations underpressure conditions are critical due to the risk of microbial contaminations from laboratory. Measures should therefore be taken to avoid/minimize microbial contamination when open.
53.	Lot 4 / 5.8	An internal coating of the inner cell resistant towards corrosive materials without compromising cleaning and sterilization is preferred. Describe possibilities.	Which substances (towards corrosive materials) will you use?	The intended chemical processes involve the use of acids. For most processes, the strength of the acids equals 1 M hydrochloric acid. However, as some processes apply concentrated hydroiodic acid (57%) the coating should ideally be resistant to this strength.
54.	Lot 4 / 5.9	The dispenser shall release filled vials in a different packaging, not classified ,room behind the dispenser.	Please define max. dimension of "different packaging". Which transport containers will you use?	The packaging room is room 02.18.040. It is referred to the supplied drawings. Currently used vials are shipped in CF18-T shieldings supplied by Comecer. The dispenser should be able to handle these CF-18-T shielded containers.
55.	Lot 4 / 5.9	Internal light sources generating minimal heat are preferred. Describe possibilities.	Please define "minimal heat".	The heat generated by internal light sources should not exceed those from LED light sources.
56.	Lot 5 / 5.1.3	It is preferred, that the LAF bench is flexible with respect to installation and operation of different Tc-99m generator	Please define the "different generator" types.	By this we refer to the different size, shape and weight of Tc-99m generators from common manufacturers

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

		manufacturers.		
57.	Lot 5 / 5.1.7	It is preferred, that the supplied sensing systems is compliant with computerised surveillance and logging systems. Describe the possibilities.	Which parameters should be measured in detail?	At least particle measurements and air flow. Other parameters e.g. as temperature would be preferred.
58.	Lot 5 / 5.1.8	The LAF bench shall be lead shielded on the table and the walls above table level. Minimum 5 mm lead equivalent	Which thickness of lead shield do you need? Is 5 mm sufficient?	5 mm will be sufficient
59.	Lot 5 / 5.1.9	Continuous monitoring of particles according to EU GMP Class A environment shall be possible.	Please define the position of the particle counter in the working area.	The particle counting shall be placed nearby the critical operation, which is elution of the Tc-99m generator.
60.	Lot 2, 5.15	The tender shall include three development hot-cells (dimensions)	You have confirmed the minimum diameters, but just to be sure we want to ask again, if the minimum Width for the inner cell is: 111 cm? According to our understanding 110 cm, should be a more accurate minimum dimension.	It is confirmed that the width is 111 cm.
61.	ESPD form		As written and indicated on your website, we would like to know if now	See the answer to Question 30.

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

			<p>there is a new ESPD form available? The actual one on your website is .xml file that stays unreadable.</p>	
62.	Shielding and radioprotection responsibility (lot 1)		<p>Who is taking the responsibility for the radioprotection and shielding calculations?</p> <p>Who is responsible of the design for wall thickness, maze design, transfer line shielding and so on?</p> <p>Is it the tenderer or the local Radiation Safety Officer?</p> <p>We are assuming that we provide only a layout for implantation into the proposed shape of maze/vault (including precise target location) and that we</p>	<p>It is the responsibility of the Contracting Authority to undertake the necessary dialog with the Danish Radiation Protection Authority to ensure final approval of the installation.</p> <p>It is the tenderers responsibility that the proposed layout for the installation fulfills the limitations on dose rates (1 and 5 $\mu\text{Sv/h}$) as specified in the requirement specification, appendix 1a. The dose rate limit at the roof above the cyclotron bunker is 5 $\mu\text{Sv/h}$. The roof is expected to be constructed as 1800 mm normal concrete.</p>

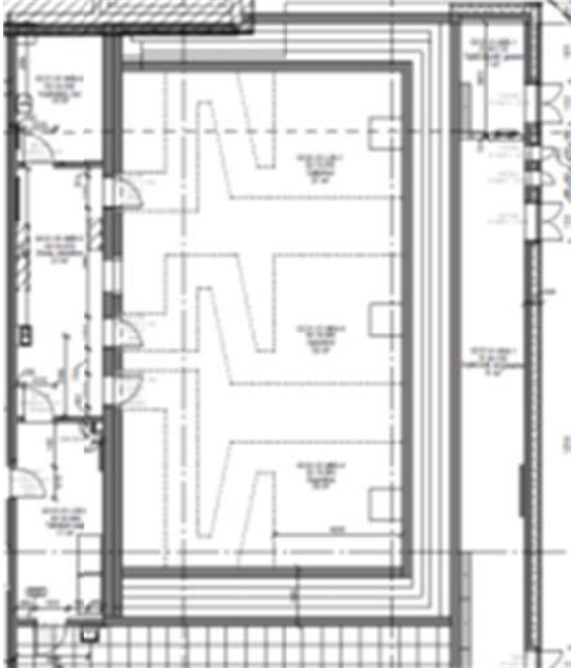
Open Procedure: Cyclotron, Hotcells, Switching system, Shielded Laminar Air Flow workbench (LAF)for Tc-99m Generators

			<p>provide the neutron and gamma source term of the cyclotron/target. Then shielding arrangements will be performed by the customer to take into consideration surrounding machines and other hypothesis, could you confirm?</p> <p>During the visit, it has been said that occupancy factors could be considered as low for a lot of surrounding areas (e.g. roof above the vaults, gas room,...). In any case, if tenderer is responsible for the shielding we should know these occupancy factors or the limit dose rate in each surrounding</p>	
--	--	--	---	--

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

			location and expected usage of the machine (amount of runs per day or week, activity produced, type of produced isotope, type of irradiation (Single/Dual); and we should know this information for the entire expected life time of the equipment (approx. 20years)) in order to work on the same hypothesis for all tenderers.	
--	--	--	--	--

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

63.	Drawing: detailed lay out of site	 A detailed architectural floor plan of a room, likely a cyclotron bunker. The plan shows three cyclotrons arranged in a row, each with its own shielding structure. There are also hotcells, a switching system, and a shielded laminar air flow (LAF) workbench for Tc-99m generators. The drawing includes various lines representing walls, doors, and equipment, as well as annotations and dimensions.	<p>On the proposed drawing, there is a provisional space to locate 3 cyclotrons. In this room there is a drawing for the shape of the walls drawn with dotted line: Is it the final shape for shielding? (for the vault assigned for tender but also for the other ones?)</p> <p>Again, we assume that the current shape proposal for maze is accepted from your side. We assume that it is under the responsibility of the customer regarding shielding efficiency and interface / impact with the other cyclotrons' vaults shielding. Could you confirm?</p>	<p>The dashed lines should not be considered as the final layout of the shielding between the three cyclotrons. Instead the dashed rectangle on the drawing "Layout-Cyclotron and Switch" in appendix 4 should be considered as the space limit for the cyclotron bunker in lot 1.</p> <p>Se also the answer for question no. five.</p>
-----	---	---	--	---

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

64.	Document 'Appendix1b-requirementspec-lot2-Hotcells' section 8, A requirements	The minimum height for the working space for the lower compartment of the stack production hotcells shall be at least 40 cm to ensure ergonomic working position.	Is there a maximum height for the working space for the upper compartment?	It is acknowledged that the height for the working space, ie. The height of the sliding tray, might be dependent on the supplied hot-cell. However, the maximum height is of course operator dependent. Due to this operator dependencies information of maximum height cannot be supplied and suppliers are encouraged to propose ergonomically acceptable solutions.
65.	Document 'Appendix1e-requirementspec-lot5-Tc-99m_etc' section 5.1, A requirements	The Tc-99m generators (up to 120GBq Mo-99 each) shall be placed in a shielded ventilated area (EU GMP Class A).	Does the generator safe to be class A or can the generators be lifted into the class area (LAF cabinet). And if yes, does the safe to be classified according to a certain GMP grade (for example C)	The generator safe can be class C, but the LAF-cabinet must be class A at all times. The class A environment should be maintained during lifting of the Tc-99m generator.
66.	General		Can we receive the drawing in another format than an .RVT file?	See answer to question 26.
67.	Appendix1b-requirementspec-lot2-Hotcells 5.3A	A minimum number of 4 different gas supplies shall be available for each hotcell.	5.3A what is the required purity of the gas? (e.g. 5.0, 6.0??)	The purity of the gases is equivalent to 6.0.

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

68.	Appendix1b-requirementspec-lot2-Hotcells 5.4A	The hot-cells shall be fitted with operating panel (for all technical functionalities such as gas and electricity supply, ventilation and ventilation surveillance) and space (e.g. a drawer or shelf), for a laptop computer.	5.4A unclear what is meant by ventilation and ventilation surveillance, could this be explained what is expected here?	Ventillation on/off Pressure Pressure alarm. It is referred to answer to question 38.
69.	Appendix1b-requirementspec-lot2-Hotcells 5.4B	It is preferred, that hotcell ventilation maintain underpressure to laboratory environment when open. Describe possibilities.	5.4B remark: very difficult to maintain a pressure differential with the door open. The required air exhaust must be very high. What is the maximum air exhaust?	See answer to question 39
70.	Appendix1b-requirementspec-lot2-Hotcells 5.5A	The hot-cells shall be installed with HEPA filters and the hotcell ventilation shall be sufficient to fulfil class B at rest conditions and constructed to prevent back-flush. Hotcells shall be compliant to all current EU GMP requirements for the production of radiopharmaceuticals.	5.5A what is exactly meant with backflush?	Backflush is the flow of air (and particles) from the hotcell exhaust into the hotcell.
71.	Appendix1b-requirementspec-lot2-Hotcells 5.5B	It is preferred, that internal coating of the inner cells is resistant towards strong acids and other corrosive materials without compromising cleaning and disinfection. Describe possibilities including the recommended cleaning and disinfection methods.	5.5B To which acids and in which concentrations the coating must be resistant to?	See answer for question 53.

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

72.	Appendix1b-requirementspec-lot2-Hotcells 5.7A	Documentation regarding compliance with structural air tightness requirements regarding contamination of laboratory space and air quality (class B requirements), shall be included in the tender.	5.7A To which norm must be tested (E.g. ISO or yellow pages), what is required leak rate and what is the required duration of the test?	Leak tightness test should be performed according to ISO 10648-2:1994. The leak tightness of the containment enclosure must comply with the rate of leakage of a class 2 containment enclosure in accordance with ISO 10648-2 ($Tf < 2,5 \times 10^{-3}$). Test length is a minimum of 30 minutes and a maximum of 60 minutes.
73.	Appendix1b-requirementspec-lot2-Hotcells 5.10B	Option IQ-OQ protocol: The IQ-OQ protocol should at least be equal to the Factory Acceptance test. Describe possibilities.	5.10B Which tests have to be performed?	See answer to question 43.
74.	Appendix1c-requirementspec-lot3-Switchingsystem 5.18A	The computer operating system shall be scalable, meaning additional valves can easily be integrated or removed.	5.18A Adding valves requires a hardware modification (adding valves and the required wiring) and a software update which can only be done by VG personnel. "easily" is not a smart requirement, can this be defined?	Easy: not hard or difficult; requiring no great labor or effort: The meaning of easily is adding extras or removal of features is without total redesign of the system.
75.	Appendix1d-requirementspec-lot4-Dispenser 4.1	A more simple movable dispensing system as back up, with possibility of placement in a different hot-cell.	Would this be in the direction of an automated pipetting unit? Please explain further details.	An automated pipetting unit might be a possibility. Proposals for different solutions are welcome.

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

76.	Appendix1d-requirementspec-lot4-Dispenser 5.2A	The dispensing system shall be equipped with a system for observing and monitoring processes within the central working area of the hotcell.	Which processes should be observed? And should monitoring of these processes be done with a LIMS system? (Lab Information Management Software).	See answer to question 36.
77.	Appendix1d-requirementspec-lot4-Dispenser 5.5A	The dispenser shall be fitted with operating panel (e.g. for all technical functionalities such as gas and electricity supply, ventilation and ventilation surveillance) and space (.e.g. a drawer or shelf), for a laptop computer.	A laptop is hard to clean (especially the keyboard), We would prefer to work with a medical keyboard and a separate monitor on a comfortable height. Are we allowed to offer this?	Yes, absolutely.
78.	Appendix1d-requirementspec-lot4-Dispenser 5.13B	An automated dispensing sequence is the preferred solution. Describe possibilities, including time requirement for complete filling inclusive vial dispatch to packaging for 1 vial and a production cycle of 20 vials, and the minimum time between two dispensing cycles. If a semiautomatic or manual dispenser procedure is offered, describe likewise.	What is the expected batch size?	<p>It is unclear what is meant by batch size.</p> <p>For radioactivity see user specific requirements 5.3. Maximum batch sizes of up to 400 GBq are possible. As batch sizes for different products might vary, the response should be linear as well for much lower activities.</p> <p>In terms volumes see user requirements 5.17.</p>

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

				In terms of vials see user requirements 5.13.
79.	Appendix1d-requirementspec-lot4-Dispenser 7.2A	Service engineers shall be trained at a sufficient level enabling them to perform all maintenance and repair on dispensing system.	Are we looking at preventive maintenance, or also on all corrective maintenance?	Both. Unless, if the corrective actions require external contractors, for example service on robotic arms.