BANK OF CYPRUS ONCOLOGY CENTER (BOCOC)

ΕΝΤΥΠΟ 8

Technical Specifications for the Purchase of a Negative Pressure Isolator and two Extract Fans for reconstitution of Cytotoxic drugs in the Clean Room of the Bank of Cyprus Oncology Center

Προσφορά για Αγορά ενός Κουβουκλίου Ασφαλείας και δύο εξαεριστήρων για Ανασύσταση Κυτταροστατικών Φαρμάκων στο Καθαρό Δωμάτιο του Ογκολογικού Κέντρου Τράπεζας Κύπρου.

Π 20011 / 008

TECHNICAL SPECIFICATIONS AND

STATEMENT OF CONFORMITY WITH SPECIFICATIONS

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BANK OF CYPRUS ONCOLOGY CENTRE
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I. Negative Pressure Isolator

Maintenance / Inspection Tasks

Frequency: Quarterly / every 4 months

Location: BOCOC

Task Description:

Supply, Installation, Commitioning, Inspection and Planned Maintenance of a new Negative Pressure Isolator and two new extract fans. Provide the cost of the above in Entypo 11. The second new extract fan must be connected by the successful tenderer to the existing isolator (supply and installation). The cost of all optional items must be given in Entypo 11A.

Safety requirements:

According to the Standards EU cGMP, BS EN ISO 14644, IEC 61010-1:2001 (Electric wiring), Pharmaceutical Isolators' Pharmaceutical Press 2004 and BS EN 1822-1:1998 (HEPA filters).

Safe working methods:

All works performed on the Negative Pressure Isolator must comply with the method and risk assessments described in relevant international standards for safe and proper working in a Clean Room.
A written report detailing the tasks performed, must be provided by the contracting company on completion of any Planned Preventive Maintenance (PPM) or any other Service visit, or when any work is undertaken in the Clean Room.

Planned Preventive Maintenance (PPM):

The tenderers must submit a table with detailed check-lists, which will include all Maintenance Tasks they are proposing to perform during PPM according to the instructions of the manufacturer.

The tenderers must also submit a list of at least two Service Engineers who will be the responsible persons to perform this PPM. Certificates regarding their qualifications must also be submitted, as indicated in Entypo 6 of this tender.

II. Outline Specifications

All installation works, acceptance testing, commissioning and quality control tests of all installed systems must be performed according to the Standards EU cGMP, BS EN ISO 14644, IEC 61010-1:2001 (Electric wiring), Pharmaceutical Isolators' Pharmaceutical
Press 2004 and BS EN 1822-1:1998 (HEPA filters).

1. The successful tenderer must submit the following:

a. The names of at least two institutions in Cyprus where the tenderer has done similar installations.
b. Provide documentation to verify the above (e.g. either copies of the contracts for relevant installations or Service Contracts for Maintenance or reference persons with telephone numbers from the relevant departments of the hospitals and/or the consulting engineers of the hospitals).

2. ***Installation and Commissioning of the Negative Pressure Isolator:***

After completion of installation, including connection of both new negative pressure exract fans to the new isolator and the existing A2-Amercare isolator, the systems will be subjected to **inspection and Quality Control under supervision of a manufacturer engineer specialized in such installations**. A file containing all measurements and results must be submitted to the Medical Physics Department of the BOCOC. The new isolator will be initially installed in the existing Clean Room of the Center. At some point during the planned construction of the new Clean Room, the existing clean room will have to be remodeled, and the successful tenderer will be responsible for de-installing all the isolators new and already existing, storing the already existing one (Amercare A2 isolator) and re-installing only the new isolator with its extract fan *in a temporary room, which will be used for the intermiddent period until the new clean room is completed.* The timetable to start the above works may last from one to three years from the date of the tender submission. When the new clean room is commitioned, the successful tender will be responsible for de-installing and re-installing and commitioning both the new isolator and the pre-existing isolator with their new extract fans in the new Clean Room. In case that the new isolator of the successful tenderer will not be made by the same manufacturer as the existing one (Amercare), then the successful tender will be responsible for the installation and commitioning of the isolator of its manufacturer only. In this case, Amercare's representative has to declare *separately* the costs just to re-install and commition the present Amercare A2-isolator in the new Clean Room after connecting it to the new extract fan. In any case, each isolator in the new Clean Room will be connected to one exctract fan installed on the roof of the building via a ductpipe. The time period to arrange above will be defined to the tenderer by BOCOC and must not in any way affect the scheduled program of other works in process of the BOCOC extension. All tenderers are invited to arrange a meeting either with Dr. Chris Constantinou, Head of Medical Physic Departmetn or Mr. Nestoras Georgiou, Biomedical Engineer, to clarify any questions regarding the above.

3. All Items offered (i.e. the Negative Pressure Isolator, the Extract Fans and all related accessories/controls etc) must be of the latest state-of-the-Art and compatible with each other. They must satisfy the needs of a modern medical oncology department.

III. Negative Pressure Isolator

Essential Information	***(To be completed by Tenderer)***
Name of Manufacturer	
Model	
Country of origin	
Year on which model was launched to the market	

Negative Pressure Isolator				***Weight Factor 60 %***
No.	***Specification Requirements***	***Statement of Conformity (To be completed by Tenderer)***	***Reference to Product Literature (Page & Paragraph)***	***Evaluation Points***
1	Tenderers must verify that the **Isolator** offered is appropriate for the safe aseptic reconstitution and dispensing of cytotoxics.			
2	**2.1** Verify that the Isolator offered functions with Negative Pressure and can be connected to an external Negative Pressure Extract Fan (externally ducted system). **2.2** Verify that all potentially contaminated airways and plenums are under negative pressure.			
3	Tenderers must provide description of the function of the whole unit with emphasis on the airflow and filtration parts and components.			

Negative Pressure Isolator (cont'd.)				*Weight Factor Cont'd (60 %)*
No.	*Specification Requirements*	*Statement of Conformity (To be completed by Tenderer)*	*Reference to Product Literature (Page & Paragraph)*	*Evaluation Points*
4	a) Verify that the HEPA filtered air will be exhausted to the atmosphere via a dedicated ducting system and an extract fan located on the roof of the hospital. b) The manufacturer must provide confirmation that the Extract Fan offered is suitable for proper operation when connected with the isolator offered, based on the required pipe lengths and pipe sizes. Note: Technical specifications of the Extract Fan must be provided separately (see relevant section on the extract fans below.)			
5	a) Verify that all HEPA filters and lighting systems can be safely removed and replaced from the upper site of the offered isolator ("dirty site"). b) Verify that the service engineer can seal the primary and all other HEPA filters into a plastic bag before removing it for safe disposal.			
6	a) The Tenderers must verify that the isolator offered provides an EC GMP Grade A (class 100) air environment in the Processing Chamber. b) Verify that the isolator is a three module one with a process chamber and two fully interlocked class E Transfer Chambers (Left and Right).			

	Weight

Negative Pressure Isolator (cont'd.)				Factor cont'd (60 %)
No.	**Specification Requirements**	**Statement of Conformity (To be completed by Tenderer)**	**Reference to Product Literature (Page & Paragraph)**	**Evaluation Points**
7	Verify that both transfer chambers operate with timed interlocks and high air change rates. Indicate the air change rates available.			
8	**8.1** The Tenderers must verify that the isolator is manufactured with high quality materials, and indicate what these materials are. More specifically, they must verify that all external and internal surfaces are durable, not rusting and allow easy cleaning and disinfecting. **8.2** Indicate what materials are used for the surfaces mentioned below: a) Interior surfaces of Processing Chamber b) Interior surfaces of Transfer Chambers (left & right) c) Doors d) Stand e) External panels. **8.3** For any coated surfaces, indicate the type of coating separately.			
9	**9.1** The offered isolator must allow performance of all operations in an easy, reliable and safe way. **9.2** Verify that the isolator offered has adjustable height and ergonomic design for all chambers, especially the Processing Chamber. (Wide clear openings of all doors for easy loading, inside surfaces easily reachable from the glove ports etc). **9.3** Indicate the Dimensions of all doors and of the two sleeve ports.			
10	The offered isolator must have ergonomically positioned DOP/particle counter test - ports in all chambers.			

Negative Pressure Isolator (cont'd.)				Weight Factor cont'd (60 %)
No.	**Specification Requirements**	**Statement of Conformity (To be completed by Tenderer)**	**Reference to Product Literature (Page & Paragraph)**	**Evaluation Points**
11	**11.1** The isolator design must allow easy maintenance. **11.2** The unit offered must allow service from a lockable front panel, which is preferable.			
12	Indicate the overall dimensions of the unit offered. The isolator approximate dimensions are given below: Length: 1800 - 2500 mm Depth: 750 mm Height: 2800 mm (maximum)			
13	**13.1** Verify that the isolator has adjustable height as required for this tender, for easier and more ergonomic use by the operators and for easier cleaning of all the external surfaces of the isolator. **13.2** Indicate if the base frame has: a) Lockable castors b) Adjustable height of the footrest c) At least 350mm unobstructed knee room.			
14	The offered unit must have good access to all potentially contaminated areas and all other equipment areas, to facilitate easy cleaning, sanitization and ergonomy of all operator movements.			
15	For each of the three working chambers, specify what the value of the air exchange rate is separately, and characterize the form of air flow.			

Negative Pressure Isolator (cont'd.)				Weight Factor cont'd (60) %
No.	**Specification Requirements**	**Statement of Conformity (To be completed by Tenderer)**	**Reference to Product Literature (Page & Paragraph)**	**Evaluation Points**
16	Indicate if and how, nursing or other personnel can continuously monitor important working parameters, like a) pressure b) condition of HEPA filters c) air-flow in all three working chambers.			
17	**17.1** Indicate if service engineers and users will be allowed to perform automated or semi-automated QA tests, like: a) Automated pressure decay seal/leak tests, b) glove leak test in an easy and quick way **17.2** List and shortly describe allavailable QA tests.			
18	Indicate availability of service mode password protection for use by service engineers.			
19	**19.1** Verify the availability of sealed fluorescent lighting inside the isolator cabinets, giving safe view at the whole work surface. State the resulting luminance in SI units (lux). **19.2** Indicate if Lighting systems have at least IP64 degree of protection against ingress of particles.			

Negative Pressure Isolator (cont'd.)				*Weight Factor cont'd (60) %*
No.	*Specification Requirements*	*Statement of Conformity (To be completed by Tenderer)*	*Reference to Product Literature (Page & Paragraph)*	*Evaluation Points*
20	**ALARMS** **20.1** Verify that the following are available: a) Latched audible and visible alarm for internal pressure b) Alarm for failure of downflow air exchange rate c) Alarm for transfer chamber door not closed. **20.2** Verify that Alarm mute option is available **20.3** Verify that battery back-up for alarms is available **20.4** Any additional visual and audible alarms available to be indicated			
21	Verify that Electrical supply is designed for 230VAC/50Hz, 1PH			
22	Verify that the Isolator is supported by Programmable Logic Controller (PLC) technology.			
23	The isolator offered must be supplied with UPS back-up to support the operation of key isolator functions, for at least 20 minutes. Specify what operations are possible with UPS back-up and indicate how this affects the safety of personnel and cytotoxics.			

Negative Pressure Isolator (cont'd.)				Weight Factor 60 %
No.	**Specification Requirements**	**Statement of Conformity (To be completed by Tenderer)**	**Reference to Product Literature (Page & Paragraph)**	**Evaluation Points**
24	The Tenderer must provide a price list with all accessories and consumables of the isolator (sleeves, gownlets, powder-free gloves suitable for cytotoxics, etc.).			
25	The following must be quoted separately as additional options in Entypo 11A: i. 13 amp single splash-proof socket ii. Cable gland for computer connection iii. CCTV monitoring and recording system.			
26	The Tenderer must provide two sets of manuals in English, one *Operation* and one *Service Manual*.			
27	The Tenderers must verify that the Isolator offered will comply with the following standards: • BS EN ISO 14644 • EU GMP Grade A (equivalent to ISO Class 5) air environment quality CE • BS EN 1822 (HEPA filters) • IEC 61010-1:2001 (Electric wiring) • 'Pharmaceutical Isolators' pharmaceutical, Press 2004 • AS 4273:1999 (when optional activated carbon filter is fitted). Compliance to additional relevant standards to be indicated			

Negative Pressure Isolator (cont'd.)				***Weight Factor cont'd (60%)***
No.	***Specification Requirements***	***Statement of Conformity (To be completed by Tenderer)***	***Reference to Product Literature (Page & Paragraph)***	***Evaluation Points***
28	The manufacturer must be established in the international market and be officially represented in Cyprus. At least two service engineers trained by the factory for servicing the offered isolator and extract fan are needed. If there are no factory trained engineers employed by the Tenderer, then two of the engineers employed by the Tenderer must be trained within three months from the date of signing a contract with the succesful Tenderer. In addition to technical problems, the service engineers will also be responsible for any periodical operation and technical training needed for the staff of the Oncology Center. The tenderers must provide Curriculum Vitae of the service engineers including experience related to the offered items.			
29	The Tenderers must provide a list of other public or private institutions in Cyprus where they have installed the same or similar equipment to that offered for this tender.			
30	The Tenderers must describe any additional advantages of the offered items that are not included above.			
31	The successful Tenderer must provide basic training on the isolator of an in-house engineer for emergencies.			

Extract Fans for Negative Pressure isolators				***Weight Factor 30 %***
No.	***Specification Requirements***	***Statement of Conformity (To be completed by Tenderer)***	***Reference to Product Literature (Page & Paragraph)***	***Evaluation Points***
1	**1.1** The Tenderer must provide a *declaration from the manufacturer of the Negative Pressure Isolator*, that the Extract Fans offered, are suitable for proper operation in connection with the offered isolator as well as the existing isolator of the Clean Room of the Oncology Center (Amercare Negative Pressure isolator, model A2). **1.2** The Tenderer must provide a declaration that the following will be performed: **a)** The new isolator will be connected via the existing pipe system of the present clean room to one of the new extract fans installed on the roof (present arrangement: "V"-connection of two isolators in the clean room and "V"-connection of two extract fans, duty & stand-by, on the roof). **b)** When the new clean room is commithioned, the second new extract fan must be <u>separately</u> connected via a new additional pipe to the existing Amercare A2 isolator, so that each isolator is functioning with its own fan. The second pipe line must be a S/S pipe of 160mm diameter and will be supplied and installed by the successful tenderer and according to the written instructions of the manufacturer of the isolator.			
2	The Tenderer must verify that the offered extract fans can be located on the roof of the BOCOC without any problems. Tenderers are invited to visit the areas of the Center after arrangement of a meeting, so that all installation works will be according to the needs of the BOCOC.			

Extract Fans for Negative Pressure isolators (cont'd.)				***Weight Factor 30 %***
No.	***Specification Requirements***	***Statement of Conformity (To be completed by Tenderer)***	***Reference to Product Literature (Page & Paragraph)***	***Evaluation Points***
3	The Tenderer must verify that the fan motors of the offered Extract Fan are supplied with sealed-for-life bearings and that no routine maintenance will be required for the bearings.			
4	a) The Tenderer must verify that the extract fans offered will function with a *3-Phase motor* designed for range of rated voltage 380-420 V ± 5%, 50Hz (IE1 Standard Efficiency Motors). *b)* The Tenderer must verify that each of the extract fans offered will function *with an Inverter* c) The Inverter must be a high-quality one, *with 3-phased inlet and outlet* d) The Inverter must be CE-marked, preferable made by a known european manufacturer e) The tender must provide the name of the inverters' manufacturer f) The tender must provide the model of the two inverters together with all technical data sheets and a copy of user and installation instructions.			
5	The Tenderer must verify that the duct connection of the Extract Fan offered is made with a flexible mount, in order to enable an easy visual check whenever needed.			

Extract Fans for Negative Pressure isolators (cont'd.)				***Weight Factor 30 %***
No.	***Specification Requirements***	***Statement of Conformity (To be completed by Tenderer)***	***Reference to Product Literature***	***Evaluation Points***
6	The Tenderer must verify that the offered Extract Fans have the following technical characteristics: i. Type: Negative Pressure Extract Fan. ii. Housing Material: Corrosion Resinstant Moulded Polypropylene, in order to handle corrosive substances that may be hazardous to health. iii. Inlet/Exhaust Spigot: 160mm Diameter iv. Impeller Type: Forward curved Centrifugal v. Impeller Drive: Direct vi. Volume: approx. 1000 m^3 per hour vii. Maximum Static Pressure: approx. 1300 Pa viii. Motor Type: Squirrel Cage Induction ix. Motor Speed: approx. 3000 r m^{-1} x. Motor Electrical Voltage: 415VAC/3PH/ 50Hz xi. Motor Rated Output: approx. 0.75 kW xii. Starting method: Variable Frequency Drive xiii. Waterproofing Classification: At least IP55.			
7	The Tenderer must verify that the offered Extract Fans have the following additional characteristics: i. Fans to be complete with anti-vibration mountings ii. Fans to have flexible connections with Quick Release Clips connected to the S/S pipe iii. The S/S pipe to have an individual Manual Damper near each Fan for manual flow regulation whenever necessary. iv. Fans appropriate for functioning without any problems under extreme high weather temperatures (over 60°C). v. The fan environmental conditions given by the fan manufacturer to be submitted with the tender. vi. Shadow/rain cover-protection to be provided for both extract fans. The cover-protection must not complicate the accessibility to the Fans for any maintenance or visual check.			

Extract Fans for Negative Pressure isolators (cont'd.)				***Weight Factor cont'd (30 %)***
No.	***Specification Requirements***	***Statement of Conformity (To be completed by Tenderer)***	***Reference to Product Literature (Page & Paragraph)***	***Evaluation Points***
8	The Tenderer must provide with the tender a detailed technical description of the Extract Fan offered with all accessories, including data sheets and diagrams showing basic dimensions of the unit that are important for the installation and for the connection with the Negative Pressure isolators.			
9	The Tenderer must provide a letter from the manufacturers of the isolator and the extract Fans guaranteeing the following: a) The manufacturer guarantees the availability of spare parts for at least 10 years after the purchase contract is signed. b) If the Tenderer (Representative of the manufacturer in Cyprus) becomes unable to continue offering maintenance for the equipment purchased by the Bank of Cyprus Oncology Center, then the Manuafacturers themselves undertake to send engineers for both the annual and the quarterly maintenance of the isolator and the extract fans. c) The manufacturer undertakes in addition, if the above unavailability becomes a reality, to train an in-house engineer for the maintenance of the isolator and the extract fan			
10	The successful Tenderer must provide basic training on the extract fan of an in-house engineer for emergencies.			

Warranty, Spare parts, Maintenance Contract, manufacturer support and Training of Service Engineers for the Negative Pressure Isolator and the extract fans offered				*Weight Factor cont'd (10 %)*
No.	*Specification Requirements*	*Statement of Conformity (To be completed by Tenderer)*	*Reference to Product Literature (Page & Paragraph)*	*Evaluation Points*
1	**1.1** Verify that the Isolator and the extract fans offered will have a two year full warranty, including service and all spare parts. **1.2** Verify that the Tenderer is willing to undertake and provide an eight year service contract following the two year warranty for the isolator and the extract fans offered. This service contract must cover all spare parts. It must also include an annual Preventive Maintenance and Quality Assurance session performed by a Service Engineer from the factory, as well as quarterly maintenance service provided by the local engineers trained at the factory. The cost of this service contract must be indicated in Entypo 11.			
2	The Tenderers must provide a list of the most important electronic/mechanic/ pneumatic and other spare parts that the manufacturer suggests having in stock and be available at the premises of their representative in Cyprus. Additionally the Tenderers must provide with their tender, an estimated *delivery time* for the other spare parts that may be needed one day, but are not available in the stock kept in Cyprus.			
3	The Tenderers must indicate the ability of the system to accept upgrades of the system's software. All upgrades and hardware releases during the warranty and service contract periods to be included and installed without any additional costs for the BOCOC, for at least ten years.			