بسم الله الرحمن الرحيم

القيادة العامة للقوات المسلحة الأردنية – الجيش العربي
مديرية الخدمات الطبية الملكية
شعبة المشتريات المركزية

الرقم : ش٥٠٠/٢٠٢٠/٢٧
التاريخ : ٧/ رجب / ١٤٤٦
: ٧/ كانون الثاني / ٢٠٢٥

السادة : المناقصون
الموضوع : استفسارات

تحية وبعد ،،،

الاشارة الى : العطاء رقم ش٥٠٠/٢٠٢٠/٢٧

- مرفق طيه التعديلات على مواصفات وشروط العطاء.

- للعلم لطفا.

وتفضلوا بقبول فائق الاحترام

ع / العميد الطبيب
مدير عام الخدمات الطبية الملكية
عقيد صيدلاني طارق محمد الجبوري

جهاز رقم (٢)

بسم الله الرحمن الرحيم

محضر اجتماع

الموضوع : العطاء رقم ش٥٠٠/٢٠٢٠/٢٧
(شراء جهازي (Cyclotron) و (Hot lab) والمبنى الخاص بهما في مدينة الحسين الطبية)

بتاريخ ٢٠٢٥/١/٥ اجتمعت لجنة المواصفات المشكلة بموجب كتب عطوفة مديرعام الخدمات الطبية الملكية رقم(ش٥٠٠/٢٠٢٠/٢٧/١٠٤٢٢) تاريخ ٢٠٢٠/٥/١١ و رقم (ش٥٠٠/٢٠٢٠/٢٧/٣٠٢٦٦) تاريخ ٢٠٢٤/٩/٢٥ و رقم (ش٥٠٠/٢٠٢٠/٢٧/١٢) تاريخ ٢٠٢٥/١/١
وذلك لدراسه الاستفسارات التاليه الوارده بموجب مذكرة شعبه المشتريات المركزيه رقم ش٥٠٠/٢٠٢٠/٢٧/٦٦٥٧
تاريخ ٢٠٢٤/١٢/٣٠ :

- كتاب الساده الشركة الوطنيه الاولى لتجاره الاجهزه الطبيه رقم (628/7672-02) تاريخ ٢٠٢٤/١٢/٢٩.
- كتاب الساده شركه سنديان للانظمه الطبيه رقم (EXPERIA/L/1024739/SAK) تاريخ ٢٠٢٤/١٢/٣٠.

حيث اوصت اللجنه ما يلي :

١. بخصوص الشهادات التي سيتم تقديمها لجهاز (Cyclotron) و الاجهزه التابعه للمختبر الحار (Hot lab)
قبول شهادات (Declaration Of Conformity) كونها تعتبر (CLASS I) .

٢. بخصوص توضيح المواصفه رقم (A.26) :
Automated cassette-based synthesis module according to GMP requirements to produce wide range of (Ga^{68}), ($^{18}F^-$) as well as capable of labeling Lu^{177} based radiotracer including but not limited the following: FDG, F-DOPA, F-MISO, F-CHOLINE, Ga-PSMA, Ga-DOTATOC, Lu^{177} DOTATATE, Lu^{177} PSMA

ان يكون الجهاز المقدم جاهز لتحضير مستحضرات (Lu^{177}) في هذه المرحله بالاضافه لكافه المواد المذكوره بالمواصفه اعلاه

٣. بخصوص توضيح المطلوب من البند رقم (C. Building Facilities):
- يتم تقديم الموافقات والمتطلبات المدرجه تحت هذا القسم ومن الجهات المذكوره مطلوبه من المناقص الفائز في مرحله تقديم العروض
- المطلوب موافقة هيئه الطاقه الذريه و هيئه تنظيم قطاع الطاقه والمعادن / تنظيم العمل الاشعاعي (كلتيهما معا) .
- يتم تقديم كافه متطلبات الـ GMP المطلوب تقديمه من المناقص في مرحلة تقديم العروض وحسب ما ورد بموجب البند (E)
ويلتزم المناقص الفائز بالمسؤوليات الفنيه والماليه التي ترتب عليه .

٤. بخصوص عقود الصيانه وفتره الكفاله المجانية :
- كفاله الصيانه المجانية لمدة عامين تشمل كافه الاجهزة والمباني .
- عقود الصيانه لمدة (١٥) عام ما بعد كفاله الصيانه المجانية تشمل جهاز (Cyclotron) و جميع اجهزة (Hot lab)
والغرف الخاصة بهذة الاجهزة وجميع الانظمة المرتبطة بها .

٥. بخصوص الشرط رقم (7) فتره التوريد : يتم دراسه مده انجاز المشروع والتوريد (Time Frame) عند دراسه العروض المقدمه عن طريق لجنه الشراء المعنيه .

٦. فيما يخص الشرط رقم (8) فتره الاصلاح والاستبدال :
- الشرط رقم (8/C) : لا تعديل
- الشرط رقم (8/D) : لا تعديل

٧. فيما يخص الشرط رقم (٢٣) مسؤوليه التخليص على قطع الغيار :
لا مانع من التخليص على قطع الغيار خلال فتره الصيانه المجانية وخلال فتره عقود الصيانه لتكون من مسؤولية الخدمات الطبية الملكية - القوات المسلحة الاردنية والنقل من مسؤوليه الشركة.

بسم الله الرحمن الرحيم .

محضر اجتماع

٨. الملحق رقم (و) الائتلاف :
يتم الرد على الاستفسارات الوارده فيما يخص الائتلاف عن طريق شعبة المشتريات المركزيه .

٩. زياره الموقع : يتم التنسيق مع شعبه المشتريات المركزيه والتخطيط والتطوير بخصوص تحديد موعد لزياره الموقع .

١٠. تثبيت سعر الدولار : لا تعديل

١١. بخصوص توضيح الاعفاءات الضريبية على المبنى وانظمته : الاعفاءات الضريبه حسب التعليمات والانظمة السارية وحسب ما ورد في دعوه العطاء .

١٢. بخصوص توضيح طريقة الدفع : يتم دراسة الدفعات وطريقه الدفع عن طريق لجنه الشراء المعنية عند الاحاله

١٣. بخصوص موعد اغلاق العطاء : يعدل موعد اغلاق العطاء ليصبح لغايه تاريخ ٢٠٢٥/٢/٢٠.

- لا تعديل على باقي المواصفات والشروط وتبقى كما هي .

JORDAN ARMED FORCES

The DIRCETROATE OF ROYAL MEDICAL SERVICES

THE INSTITUE OF BIOMEDICAL TECHNOLOGY

٤٧ / ٠٠٠ / ٥٠٠

ملحق رقم ١

الشروط والمتطلبات الخاصة بتنفيذ المبنى المخصص للأجهزة(cyclotron &hot lab)

تلتزم الشركة الفائزة بالعطاء بمايلي:

١- ان يتم تنفيذ المبنى من خلال شركة مقاولات مصنفة (مقاول لايقل تصنيفه عن الدرجة الثانية) وان يتم اعتماده والموافقة عليه من قبل مديرية مؤسسة الاسكان والأشغال العسكرية

٢- ان يتم تقديم المخططات والمواصفات وجداول الكميات وجميع الوثائق لكافة التخصصات الهندسية (معماري, مدني, كهرباء ,ميكانيك ,غازات طبية ,اجهزة طبية .....الخ) للمبنى المطلوب وان تكون مصدقة من جميع الجهات الرسمية ذات الصلة على ان تتحمل الشركة الفائزة بالعطاء كافة الامور المالية المترتبة على ذلك.

٣- يجب ان تكون جميع المخططات والتصاميم متوافقة مع المعايير العالمية لل GMP

٤- الحصول على موافقة هيئة الطاقة الذرية الاردنية على المخططات والتصاميم حسب المعايير العالمية المعتمدة من قبلهم.

٥- الحصول موافقة مديرية مؤسسة الإسكان والأشغال العسكرية على كافة المخططات والمواصفات وجداول الكميات وجميع الوثائق لكافة التخصصات الهندسية (معماري, مدني ,كهرباء, ميكانيك ,غازات طبية ,اجهزة طبية .....الخ) للمبنى المطلوب

٦- موافقة الخدمات الطبية الملكية على التصاميم و المخططات من حيث المساحة والتقسيم الداخلي والوظيفي.

٧- يتم اعتماد موقع المبنى من خلال مديرية مؤسسة الاسكان والأشغال العسكرية وبالتنسيق مع مديرية الخدمات الطبية الملكية وتكون من مسؤولية الشركة الفائزة بالعطاء عمل واعداد المخططات المساحية والطبوغرافية واعداد الفحوصات والتقارير اللازمة لفحص التربة لموقع المبنى حيث تتحمل الشركة كافة الكلف واي امور مالية مترتبة على ذلك.

٨- تزويد المبنى بخدمات المياه والكهرباء والصرف الصحي من خلال المصادر الحالية في الموقع المحدد ان توفرت الامكانية وبخلاف ذلك ان تقوم الشركة الفائزة بالعطاء بتزويد المشروع بهذه الخدمات من مصادر جديدة ومستقلة حيث تتحمل الشركة كافة الكلف واي امور مالية مترتبة على ذلك على ان يتم الحصول على موافقة مديرية الاسكان العسكري بهذا الخصوص.

٩- تشرف مديرية مؤسسة الإسكان والأشغال العسكرية على تنفيذ المشروع مع التزام الجهه المحال عليها العطاء بتوفير كافة المرافق والتسهيلات اللازمة لفريق الاشراف وبالتنسيق مع مديرية مؤسسة الإسكان والاشغال العسكرية دون ان تتحمل الخدمات الطبية الملكية أي تبعات مادية بهذا الخصوص.

١٠-يتم استلام المشروع من قبل مديرية الخدمات الطبية الملكية و مديرية مؤسسة الإسكان والإشغال العسكرية

الملحق (و)

*** الملحق (و) : ملحق خاص بالعطاءات الممولة كمنحة من صندوق أبو ظبي للتنمية.**

- على الرغم مما ورد في الملاحق (أ, ب) تطبق الشروط التالية الصادرة عن الجهة المانحة (صندوق أبو ظبي للتنمية) :

١. السماح للشركات المرخصة والمؤهلة ذات الخبرة في تنفيذ المشاريع سواء في المملكة الأردنية الهاشمية، دولة الإمارات المتحدة، و/أو دول الخليج العربي بالدخول للمنافسة بحيث تكون إما :

أ- شركة إماراتية تتمتع بالخبرة والمؤهلات المناسبة والمسجلة لدى الجهات المعنية الجهات الحكومية في دولة الإمارات المتحدة.

ب- ائتلاف بين شركات إماراتية كما هو منصوص عليه في البند (أ) .

ج- ائتلاف بين شركات إماراتية كما هو منصوص عليه في البند (أ) أعلاه وشركة أردنية مسجلة ومؤهلة وذات خبرة.

د- ائتلاف بين شركة إماراتية كما هو منصوص عليه في البند (أ) أعلاه وشركة غير أردنية طبقاً للمعايير المعمول بها في المملكة الأردنية الهاشمية .

هـ - شركة اردنية مسجلة ومؤهله وذات خبرة مناسبة.

و- ائتلاف بين شركة أردنية وأخرى أردنية أو غير أردنية طبقاً للمعايير المعمول بها في المملكة الأردنية الهاشمية.

٢. عند التقييم الفني والمالي لعروض الشركات المتقدمة للمشروع تُعطى الشركات الإماراتية أو الائتلافات بين شركة إماراتية وأي شركة أخرى والتي تكون فيها حصة الشركة الإماراتية ٥١% أو أكثر أفضلية بنسبة ١٠% مقارنة بالشركات والائتلافات الأخرى.

٣. تبقى الشروط المرجعية في مناقصة المشروع مدار البحث أعلاه وفي المناقصات القادمة لمشاريع الخدمات الطبية الملكية الممولة من صندوق أبو ظبي للتنمية كما هي بدون تعديل، وإنما يتم إضافة التعديلات المذكورة أعلاه كبنود إليها.

٤. يُسمح بتقديم المناقصات على شكل ائتلاف على أن يتم تطبيق ما يلي :

أ- تقديم اتفاقية الائتلاف مصدّقة أصولياً أو رسالة نوايا من أعضاء الائتلاف جميعهم كجزء من العرض المقدم أو طلب التأهيل المسبق أو التعبير عن الاهتمام، للدخول رسمياً في الائتلاف عند إحالة العطاء على الائتلاف .

ب- الطلب من أعضاء الائتلاف تسمية رئيس الائتلاف ليكون مسؤولاً عن متابعة إجراءات العملية الشرائية .

ج- يُعتبر أعضاء الائتلاف جميعهم مسؤولين بالتكافل والتضامن عن تنفيذ العقد .

بسم الله الرحمن الرحيم

G.H.Q. JORDAN ARMED FORCES
DIRECTORATE
ROYAL MEDICAL SERVICES
CENTRAL PROCUREMENT BRANCH

القيادة العامة للقوات المسلحة
مديرية الخدمات الطبية الملكية
شعبة المشتريـــــات المركزية

هــــــام جـــــــداً

ش ٥٠٠/٢٠٢٠/٢٧

السادة : المناقصون
الموضوع : دعوة العطاء

تحية طيبة وبعد ،،،

١. يرجى الالتزام بتقديم COMPLIANCE SHEET لجميع الاجهزة والعدد المقدمة من قبلكم يتضمن وجود المواصفة المطلوبة (YES,NO) و بيان موقعها برقم صفحة الكتالوج و العرض الفني (محددة بلون فسفوري) و بالشكل التالي **وبغير ذلك سيتم اهمال العرض المقدم وغير ملتزم بالجدول**:-

ITEM NO.( ) NAME ( ) MODEL NO.( )

ملاحظات	رقم صفحة الكتالوج (تحديدها بلون فسفوري)	YES OR NO	المواصفة المطلوبة
	(مهم جداً)		

٢. يرجى الالتزام بتقديم عرضين منفصلين مالي و فني **على ان تكون كفالة دخول العطاء مرفقة بالعرض المالي او بمغلف منفصل.**

٣ . يرجى تقديم اي استفسار لديكم على المواصفه خلال (اسبوعين) من تاريخ الطرح ولن ينظر في اي استفسار يصل بعد ذلك التاريخ.

و تفضلوا بقبول فائق الاحترام،،،

A. FULL CYCLOTRON SYSTEM

General Description: Royal Medical Service/Jordan Army Forces is intended to establish turnkey project of cyclotron/Nuclear Medicine Department Facility to fulfill local needs of several radiopharmaceuticals that meet GMP most recent released of IAEA/WHO specifications and comply with JDFA & JAEC regulations.

IMPORTANT NOTE:

Vendors are required to fill out the product details, compliance information, and brochure reference page number in the columns below

TECHNICAL SPECIFICATIONS:

The unit must meet or exceed the requirements listed in the table below.

Product Details	
Name of manufacturer	
Model/catalogue number	
Country of origin for the offered model	
Country where the manufacturer is based	
Delivery time	
Full warranty period	
FDA clearance or CE or ISO certificate	

	Minimum Requirements	Compliance (Y/N) Notes	Brochure Page No.
1	Full cyclotron system with all laboratory equipment required to produce PET radioisotopes ($^{18}F^-$ and Ga^{68}) and upgradable to produce other radioisotopes as listed below and should meet all GMP requirements.		
2	Cyclotron system must include all power supplies, power distribution system, electronic devices, and primary cyclotron chiller with heat exchanger, Magnet system, Radio Frequency system, Ion sources, Beam extraction system, Vacuum system, UPS for cyclotron, and all other required subsystems to meet all GMP requirements.		
3	Self-shielding cyclotron system.		

4	The system should be capable of delivering proton and deuteron. However, system using proton technology only should be capable of producing all required radioisotopes and comparable with other system delivering proton and deuteron without affecting its performance and efficiency.		
5	The cyclotron energy must be not less 16 MeV The cyclotron shall be capable of producing and accelerating protons to an energy **≥16MeV** The cyclotron shall be capable of producing and accelerating deuteron to an energy **≥8MeV** **(for systems accelerating deuterons).**		
6	Maximum extracted proton beam current not less than **150 µA**		
7	Fully automated radiochemical production system to produce the following radioisotopes:		
	☐ $^{18}F^-$		
	☐ Ga^{68}		
8	The system should be fully upgradable with needed infrastructures (replace and upgrade components at site) to produce the following radioisotopes:		
	☐ ^{11}C		
	☐ ^{13}N		
	☐ ^{123}I		
	☐ ^{64}CU		
	☐ ^{89}Zr		
	☐ ^{15}O		
9	Yield of cyclotron produced radioisotopes:		
	☐ Minimum yield for (^{18}F-): not less than 6000 mCi@120 minutes per single beam irradiation of one target.		
	☐ Minimum yield for (Ga^{68}): not less than 100 mCi@60 minutes per single beam irradiation of one target.		
	Targets		
10	Cyclotron system should be capable to adapt:		
	☐ Gas target		

	□ Liquid target		
	• Solid target		
11	Number of Targets ports not less than 6		
12	Dual bombardment, (Dual simultaneous Irradiation for two florid (^{18}F-) targets, and capable of irradiation florid (^{18}F-) and Gallium (Ga^{68}) targets at same time.		
13	^{18}F- Complete target, ready to be connected to a cyclotron:		
	□ Target Material/Media: (please specify)		
	□ Target Reaction: (please specify)		
	□ Target chamber material/ Insert Material: (please specify)		
	□ Foil material/Window Material: (please specify)		
14	Ga^{68} complete target, ready to be connected to a cyclotron:		
	□ Target Material/Media : (please specify)		
	□ Target Reaction: (please specify)		
	□ Target chamber material/ Insert Material: (please specify)		
	□ Foil material/ Window Material: (please specify)		
	Ion Source:		
15	**Ion source** type internal or external (please specify)		
16	**Source type**: PIG internal or CUSP external (please specify)		
17	RF system, (please specify full details)		
18	Vacuum System, (please specify details)		
19	Main Magnet, (please specify details)		
	Cyclotron Control System		
20	Suitable computers shall be supplied for computer-controlled operation of the cyclotron. Any additional computers or workstations and software required for full maintenance of the cyclotron and for problem diagnosis of the cyclotron shall be provided according to GMP requirements.		

21	The cyclotron control system shall allow fully automated operation of the cyclotron, including but not limited to the following:		
	A. Loading of target with target material		
	B. Selection of target to be irradiated		
	C. Selection of beam current		
	D. Irradiation of target		
	E. Transfer of radioisotope to the selected delivery point (synthesizer module).		
22	Continuous monitoring display and record cyclotron operational parameters and provide alerts when abnormal conditions are detected		
23	Manual cyclotron control should be applicable when needed.		
	Synthesis Modules		
24	Automated cassette-based synthesis module according to GMP requirements to produce ($^{18}F^-$ FDG)		
25	Automated cassette-based synthesis module according to GMP requirements to produce (Ga^{68}) radiotracers		
26	Automated cassette-based synthesis module according to GMP requirements to produce wide range of (Ga^{68}). (^{18}F-) as well as capable of labelling Lu^{177} based radiotracer including but not limited the following: FDG, F-DOPA, F-MISO, F-CHOLINE. Ga-PSMA. Ga-DOTATOC, Lu^{177} DOTATATE, Lu^{177} PSMA.		
	B. CYCLOTRON HOT LAB EQUIPMENT		
1	All hot lab equipment should meet the requirements of GMP to produce ($^{18}F^-$) and (Ga^{68}) radiopharmaceuticals.		
2	Radioactive Gas Compressing station. QTY(1)		
3	Lead containers to store targets for isotopes decay before maintenance. QTY(5)		
4	Dual hot cell for automated modules to host most commercially available synthesis units meeting GMP		

	guidelines Qty (2) Dual hot cell can host two synthesizers		
5	Automated Dispensing System for Vials and Syringes. QTY(2)		
6	Dispensing hot cell for aseptic dispensing of radiopharmaceuticals solutions under the GMP guidelines Qty (3). • Each hot cell is equipped with two dose calibrators, one of them should be integrated with the offered automated dispensing system. • Each hot cell is equipped with two master slave manipulators (Not teletong /Not teleplier), the slave hand of the desired manipulators should follow the master hands in complete synchronism.		
7	Tungsten/Lead shielded containers for vials. QTY (10)		
8	Laminar flow hood for preparation under aseptic conditions, for non-radioactive materials. QTY(1)		
9	Dose calibrator for PET radiotracers. QTY(2)		
10	High pressure liquid chromatograph (HPLC), System in configuration for ($^{18}F^-$) and Gallium radiotracers, Gradient type including all types of detectors needed for above mentioned radiopharmaceuticals. QTY(1)		
11	Lead shield for radioactivity detector. QTY(1)		
12	Gas Chromatograph (GC) with auto-injector. QTY(1)		
13	Radio Thin Layer Chromatograph (TLC). QTY(1)		
14	Automated LAL Tester. QTY(1)		
15	PH Meter. QTY(1)		
16	Integrity Tester. QTY(1)		
17	Multi-channel Analyser for Gamma Spectroscope (MCA), QTY(1)		
18	Dose Calibrator and Chamber Shield. QTY(1)		
19	Water purifier. QTY(1)		
20	PC Computer for hot lab workflow. QTY(3)		
21	Electronic balance with Printer. QTY(1)		
22	Vibration Damper. QTY(1)		

23	Digital Thermometers. QTY(2)		
24	Mercury Thermometers. QTY(6)		
25	Timer/stopwatch. QTY(6)		
26	Compact anemometer. QTY(1)		
27	Flow meter. QTY(1)		
28	Refrigerator not less than 500 liters, stand type with digital thermometer display. QTY(1)		
29	Freezer, not less than 500 liters, stand type with digital thermometer display. QTY(1)		
30	Incubator. QTY(2)		
31	Hot plate/stirrer. QTY(1)		
32	Heat gun. QTY(1)		
33	Vacuum/pressure pump. QTY(1)		
34	Mixer. QTY(1)		
35	Pipettes, different sizes. QTY(10)		
36	Vial crimper, different sizes including 20 mm. QTY(5)		
37	Vial decapper, different sizes including 20 mm. QTY(5)		
38	Colored labels lasers jet printer. QTY(2)		
39	Hand-feet clothe monitor. QTY(1)		
40	Personal dosimeters. QTY(10)		
41	Tabletop block shield for PET. QTY(1)		
42	Ultrasonic Bath. QTY(1)		
43	Bench top lab oven. QTY(1)		
44	Integrated Radiation Monitoring System with set of Sensors and Control Workstation.		
45	Start-up kit for all consumables needed to operate the system must be provided.		
46	All consumables needed to run and produce FDG for 120 runs must be delivered free of charge upon request with four weeks from formal written request and should keep 2/3 rds of its shelf life.		
47	All consumables needed to run and produce Ga^{68} for 30 runs must be delivered free of charge upon request with four weeks from formal written request		

	and should keep 2/3 rds of its shelf life The required consumables include precursor for the cyclotron to produce Ga, in addition to raw materials and reagents needed to produce • Ga-dotatate (15 runs). • Ga PSMA (15 runs).		
48	Other available standard and optional features, packages, instruments and accessories needed for production and quality control must be listed and priced separately.		
	C. BUILDING FACILITIES		
	C.1 CYCLOTRON BUILDING FACILITIES		
1	Facility layout planning and implementation should meet the primary requirements of GMP, radiation protection requirement associated with product manufacturing and handling, enhance the flow of materials and people, and integrate the structural elements necessary to achieve these objectives.		
2	Facility layout planning should be divided into controlled and non-controlled areas. • The controlled areas encompass provisions for product protection (GMP) and meet radiation protection requirements concerning controlled and radiation area according to GMP and Jordan atomic energy commission (JAEC) regulations. • The non-controlled areas, on the other hands, encompass non-production areas from a GMP perspective and public areas with reference to radiation protection. These include administrative offices, strong rooms, restrooms, technical rooms, and heating ventilation and air-conditioning (HVAC)		
3	Facility layout planning should be approved by Jordan Atomic Energy Commission (JAEC)		
4	The bidders should provide comprehensive architectural design, structural design, electrical design, and mechanical design according to GMP requirements to meet full operational capacity of cyclotron and hot lab building facilities with area not		

	less than 500 m^2, all above mentioned design should be approved by: • Jordan Atomic Energy Commission (JAEC) • Directorate of Housing Establishment and Military Works • Directorate of Royal Medical Services		
	D. Payment: the vendor should submit financial offer as following:		
1	Cash with two years' warranty, the offer must include the price of: • Full cyclotron system • Cyclotron Hot Lab Equipment • Cyclotron and hot lab Building Facilities with area not less than 500m^2 • Service contract valid for a period of (15) years starting at the end of the 24-month warranty period.		
	E. Validation, Start-up, Training and Daily Operation		
1	The awarded bidder should guarantee that their design, products, installation and implementation of the project will be complied with GMP requirements.		
2	Certified operating and training team for Cyclotron and hot lab system, the certified team should perform at least the following: • Implementation and Start-up of cyclotron and Hot lab equipment. • Validation and Qualification. • Writing, approval and execution of all protocols required for all required radiopharmaceuticals production. • Quality management and quality assurance for all equipment according to GMP guidelines. • On site training for local operators for at least 50 successful runs (single successful run per day) after full system operation: (Cyclotron operation, hot lab operation, Synthesis and dispensing operation, quality control equipment and any required training according to GMP). • Apply and prepare all necessary documents required to obtain GMP certificates.		

SPECIAL TERMS

- ***Offers not complying with any of the special terms or the technical specifications shall be considered non-conforming with tender requirements.***
- ***Any vendor providing FORGED documents shall be disqualified from the current tender and banned from participating in any future RMS tenders.***

1. ***All equipment must be the most recently released model/version which is equal to or higher than the range of the specifications of the required system (low, mid or high) and equal to or higher than the level of technology and required options mentioned in the technical specifications.***
2. ***Required certificates (must be submitted with the technical offer):***

2.1 ***FDA approval & the relevant 510K clearance for equipment of USA origin (Country where the manufacturer is based).***

2.2 ***CE certificate with the relevant CE number (Medical directive) for equipment of EU (European Union) origin (Country where the manufacturer is based).***

2.3 ***UKCA certificate for Equipment of Great Britain origin (England, Scotland, Northern Ireland, and Wales) (Country where the manufacturer is based).***

2.4 ***ENTID (Enterprise Identification) with the relevant ARTG (Australian Register of Therapeutic Goods) number issued by the Therapeutic Goods Administration for Equipment of Australian origin (Country where the manufacturer is based).***

2.5 ***Establishment License with the relevant Device License issued by the Therapeutic Products Directorate for Equipment of Canadian origin (Country where the manufacturer is based).***

2.6 ***Japanese Pharmaceutical Affairs Law (JPAL) certification or approval for equipment of Japanese origin (Country where the manufacturer is based).***

2.7 ***Swissmedic (Swiss agency for therapeutic products) certification or approval for equipment of Swiss origin (Country where the manufacturer is based).***

2.8 ***Norwegian Medicines Agency certification or approval for equipment of Norwegian origin (Country where the manufacturer is based).***

2.9 ***The vendor is responsible to ensure through official documents that classified medical devices are manufactured in conformity with applicable quality system standards (ISO, IEC); (the international quality systems standard for medical device manufacturing ISO 13485) or ISO9001.***

2.10 ***Only for class I medical equipment, submission of a copy of Declaration of Conformity certificate for the offered model shall be accepted.***

2.11 ***In all of the above cases certificates must be formally endorsed by JFDA.***

2.12 ***Any vendor not submitting all required certificates will be eliminated.***

3. ***Offered items should be from reputable well known manufacturers and excellent experience in the field which have multiple installations of the same offered model and/ or previous models or previously evaluated in Main Hospitals in Royal Medical Services, Otherwise The purchasing committee has the right to request one or all of the following:***

   a- ***A sample of the same offered model at any time during the purchasing process, the sample unit shall be delivered within three weeks from the date of a written notification; any vendor rejects to deliver a sample unit will be eliminated. Evaluation duration will be determined by the purchasing committee.***

   The purchasing committee has the right to require a sample for any equipment previously installed in RMS Hospitals.

   Any offered item fail in the evaluation/assessment process will be rejected

   b- ***A list of installation basis of the same offered model and/ or previous models in reputable local hospitals.***

   List should include: Name of hospital, Model Installed, Quantity, and Year of installation.

   The purchasing committee has the right to contact or visit any of the sites where the offered model and/ or previous models were installed and get feedback of these models at these sites from the physicians, operators as well as service engineers.

   c- ***Official website of the manufacturer must be provided. The website must clearly demonstrate the history profile and manufacturing features of the company including the same offered model and its brochure.***

   In case of inconsistency between the information on the website with the provided information of the local agent regarding any offered product, the committee has the right to eliminate that product from the awarding process.

4. *Country of origin:*
   - 4.1. *The country of origin of the main part (s) of the system must be one of the following:*

     USA, Canada, Japan, UK, Sweden, Finland, Denmark, Switzerland, Belgium, Germany, France, Netherlands, Spain, Norway, Italy, Ireland, Austria, New Zealand, Australia, Czech Republic, Luxembourg & Poland.
   - 4.2. *Accessories and consumables may be manufactured in other countries and/or by different manufacturers and should be approved by the manufacturer.*
   - 4.3. *All offered items must be approved for sale in the same country of origin. An original and officially endorsed free-sale certificate from an authorised body must be included in the offer.*
   - 4.4. *Vendors must specify the origin of all offered items and accessories in the technical offer.*
   - 4.5. *Except for X-ray based equipment, MRI, and nuclear medicine systems, equipment manufactured by reputable companies based in any of the countries mentioned in (4.1) will be taken into consideration regardless of the manufacturing site only:*
     - a. *If they are approved for sale in the same county of origin (an original and officially endorsed free-sale certificate from an authorised body must be included in the offer.*

     OR
     - b. *If they are approved for sale in at least three of the countries mentioned in (4.1) (an original and officially endorsed free-sale certificate from an authorised body in those countries must be included in the offer).*

5. *Bidders must submit their reservations/queries regarding tender specifications and/or special terms within the first half of the tender closing period starting from the tender announcement date. Reservations/queries submitted after the end of this period shall be rejected.*
6. *Goods are to be brand new; manufacturing date of the delivered products should not exceed 18 months from the date of the final award.*
7. *Delivery period should be mentioned clearly; the purchasing committee has the right to reject any offer with delivery time exceeding 4 months.*
8. *Warranty:*
   - a- *Offers must include a full warranty for a period of a minimum of 24 months from the date of installation or 30 months from the date of receiving the items at the agreed location mentioned in the final order (whichever comes first).*

     Warranty must include corrective & preventive maintenance activities as per manufacturer recommendations including:
     - *Required spare parts (free of charge)*
     - *Labour*
     - *Hardware*
     - *Software*
     - *Rechargeable batteries*

At the end of the warranty period, the supplier commits to implement final inspection of the submitted goods and submit the reports signed by the site chief engineer stating that the equipment are working properly as well as all preventive maintenance reports during the warranty period.

Warranty & installation are excluded for items mentioned in Attachment no.1 the purchasing committee has the right to exclude any other item not listed in the attachment and does not required installation and warranty.

b- In the case where a delay in installation has occurred as a result of the supplier's dereliction and has exceeded a period of one month from the date of receiving the items, the approved warranty period will automatically be considered as 24 months from the date of installation.

c- If at any time during the warranty period the item becomes inoperative due to a technical fault the item must then be repaired by the supplier /local agent within a period of 5 working days from written notification, warranty will be extended according to downtime period.

d- If the delay exceeds 30 days, the supplier must replace the item with a new identical functioning one (within the same delivery period mentioned in the final offer). In case the item was replaced by a new one, the warranty period mentioned in 8.a) above will start from the installation and commissioning date of the new item.

e- Local agent/ supplier is committed to transport and install any awarded item during the warranty period on free of charge basis to any location inside the country whenever required by Royal Medical Services, this should not include pre-installation requirements in the new site.

9. *One set of operation manual(s) and one set of service manual(s) including schematics and a spare-part list must be delivered with each unit, CD/DVD is acceptable. For large tenders, a certain agreed percentage of manuals per item may be agreed upon.*
10. *Where applicable, pre-installation shall be the sole responsibility of the supplier. Pre-installation shall include removal of old system(s), any civil work, electrical work or site modification(s) necessary to accommodate the new system(s) according to manufacturers' specifications and safety standards in addition to the work required for bringing back the site to the same working conditions as before installing the new system(s).*
11. *Power requirements: where applicable either single phase 220V, 50Hz or 3-phase 380V. Systems with external transformers are considered conforming only if clearly stated in the technical specifications.*
12. *Technical offers must include clear original technical brochures/catalogues for all offered items.*
13. *Offers must include fully detailed technical offers and compliance sheets as a soft copy (either Microsoft office or Microsoft excel format) in addition to a hard copy, mentioning the exact model/catalogue number and country of origin of the offered item(s), full technical description/specifications and any accessories or options included in the offer.*

    Offer must clearly indicate the origin of the offered item and the country where the manufacturer of the offered items is based
14. *Compliance sheets must be as per the tabular format of the technical specifications in the tender documents, listing the required specifications on one column and a Yes or NO response to each point in*

the adjacent column, with reference to page and line numbers in the relevant technical brochure. Offers not complying with this term shall be rejected.

15. *Qualifications and after sales service: The technical bid should contain all the necessary documents (training certificates) to prove the capability of the bidders for supplying and installing a trouble free equipment meeting the quality standards and technical specifications of the manufacturer and the ability of the bidders for providing efficient after sales service conducted by authorized certified biomedical service engineers with minimum 2 years' experience in the same field.*
16. *Accessories and consumables:*
    - *16.1 Any accessories and consumable items necessary to operate the offered system must be clearly identified and priced separately.*

      All offered accessories and consumables must be approved by the manufacturer.
    - *16.2 Technical offers must include a priced list for all accessories and consumables related to the required equipment as a hard copy in addition to a soft copy (either Microsoft office or Microsoft excel format) with prices fixed for a period of five years from the date of installation and commissioning with a maximum annual increase of 2%, any essential item not listed will be considered free of charge.*
    - *16.3 Accessories and consumables must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.*
    - *16.4 Where applicable, a start-up kit of accessories and consumable items must be provided with each system on a free-of-charge basis.*
17. *Spare Parts:*
    - *17.1. Technical offers must include a comprehensive and priced list of all spare parts related to the awarded equipment (including rechargeable batteries) as a hard copy in addition to a soft copy (either Microsoft office or Microsoft excel format) valid for a minimum period of five years with a maximum annual increase of 2%, commencing at the end date of the warranty period, any essential item not listed will be considered free of charge.*
    - *17.2. Spare parts must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.*
    - *17.3. Prices of spare parts should be reasonable and will be taken into consideration during the purchasing process; the purchasing committee has the right to eliminate any offered item with unreasonable high prices of spare parts.*
    - *17.4. Delivery period of required spare parts should not exceed 2 months from the date of the final order.*
18. *Spare parts, consumables and accessories availability must be guaranteed for a minimum period of ten years starting from the date of installation and commissioning.*
19. *Local agent is committed to sign a service contract with Royal Medical Services to perform all relevant maintenance for the awarded equipment (whenever required by DRMS within a period that does not exceed one year from the end date of the warranty period and if mentioned clearly in the specifications)*

without exceeding the original mentioned cost and as per mentioned terms within minimum required period.

20. *Tender Awards:*

20.1. *For the final list of offers having a chance of winning the award, the awarding process shall be based on the accumulative value of both the offered item and its' running cost (Total Cost of Ownership) over a period of seven years from the date of installation and commissioning. Only offers with the lowest total cost of ownership over a period of seven years from the date of installation and commissioning shall qualify for the award.*

20.2. *Running cost includes the value of consumables, accessories needed to operate the system over the same period as well as the cost of any service contract (where applicable).*

21. *For PC/Laptop based systems:*

21.1. *Complete restoration medium (CD/DVD/etc.) of the operating system and the application software must be supplied.*

21.2. *Purchased licenses, software keys & dongles must be provided at any time during and after the warranty period on free of charge basis whenever required by DRMS for a minimum period of ten years starting from the date of installation and commissioning.*

21.3. *Where locally supplied computers or laptops are offered, only computers/laptops from Apple, hp/Compaq, Lenovo, Dell, fujtisu or Toshiba will be accepted, offered models must be the latest available version upon delivery.*

21.4. *Where locally supplied printers are offered only the following types and brands are accepted: HP, SAMSUNG, OKI, CANON, EPSON.*

22. *Pricing must include services of sale, shipment, transportation, delivery from port to site or to Main Medical Stores, installation, pre-installation (if needed), training, commissioning, warranty and bringing the equipment into service.*

23. *Custom clearance of goods shall be the responsibility of the Jordanian Armed Forces (JAF), however, suppliers shall bear all costs incurred by handling charges and any demurrage charges or extra expenses incurred by the port's corporation (including expenses caused by delay in presenting the necessary shipment documents for either clearing or transporting the goods to the required location mentioned in the final order, delivery note issuing charges, unloading charges, local shipping charges etc.). The supplier is also responsible for providing of all relevant shipping documents, together with the delivery order(s).*

24. *a. DRMS has the right to increase the awarded quantities by a percentage not exceeding 35% after the final order notification with the same prices, terms and conditions of the original contract upon DRMS request and approval of the awarded party.*

b. DRMS has the right to decrease the awarded quantities by a percentage not exceeding 50% after the final order notification with the same prices, terms and conditions of the original contract upon DRMS request and approval of the awarded party.

25. *a. Bidder is not allowed to submit more than one offer for the same item whether that's solely or in coalition or partnership with other bidders.*

    b. Bidder is allowed to include within their offer optional alternatives for the same offered item from the same manufacturer.

26. *The supplier must furnish DRMS with a guarantee stamped and legalized by the Notary Public equals to (115%) of the total value of the awarded equipment valid for twelve months from the date of final acceptance of the equipment by DRMS.*

27. *Training:*

    27.1 For items where abroad service training courses are required in technical specifications, offers must include a certified service training program at a reputable center abroad recognized by the manufacturer for at least one biomedical engineer or biomedical technician; all costs inclusive, air tickets, , boarding, commuting, accommodation (minimum 3 star hotel on full board basis) and any extra costs.

    27.2 For items where abroad user training courses are required in technical specifications, offers must include a certified operator training program at a reputable center abroad recognized by the manufacturer for at least one operator; all costs inclusive, air tickets, boarding, commuting, accommodation (minimum 3-star hotel on full board basis) and any extra costs.

    27.3 The period of the training courses must be according to the manufacturer's program excluding traveling days and must be stated clearly in the technical offer.

    27.4 Training Programs must conform to the following standards:

    - *User training must comprise understanding and use of operation manual(s), correct and safe operation of the equipment, as well as user preventive maintenance and calibration.*
    - *Service training must comprise: theory, understanding and use of service manual(s), calibration, preventive maintenance procedure, and practical troubleshooting and repair exercises, and must be conducted by professional instructors employed or authorized by the system manufacturer.*
    - *Service training must be conducted on a system of identical make, model, and configuration to that purchased by DRMS, and designated by the manufacturer or the local agent for training purposes.*
    - *Certificates must be endorsed and officially sealed by the system manufacturer, legally empowering trainees to engage in user and service activities according to operation and service manual(s).*
    - *Where applicable, offers must include an on-site user and service training.*

Attachment 1

#	Equipment
1	*Adjustable Auto Pipettes*
2	*Resuscitation Bag*
3	*Laryngoscope Set*
4	*Oxygen Flow meter wall type/ single*
5	*Regulator Suction with canister, wall vacuum outlet*
6	*Oxygen Regulator for Oxygen Cylinders*
7	*Pulse Oximeter, Finger type*
8	*Oxygen Cylinder*
9	*Doppler, portable*
10	*Diagnostic set, Portable*
11	*Direct Ophthalmoscope, Portable*
12	*Otoscope, Portable*
13	*Air Mattress System, homecare*
14	*Stethoscope*
15	*Aneroid Sphygmomanometer*
16	*Video Assisted Laryngoscope, portable*
17	*Scale, Manual*
18	*Wood's Light*
19	*Cough Pressure, Normal Saline*
20	*Rehabilitation Walking Parallel Bars, non-powered*
21	*Therapy Mat*
22	*Medical Ball All Size*
23	*Dumbbells Rack with complete set of dumbbells*
24	*Crutches*
25	*Shoulder wheel*
26	*Mobile Mirror*
27	*Cuff Weights*
28	*Walker, different sizes*

29	*Patient Elbow Stick*
30	*Rehabilitation Training Ladder*
31	*Rehabilitation Suspension Frame*
32	*Exercise Band All Size (Theraband)*
33	*Lens trial set*
34	*Wheel Chair*
35	*Commode Chair*
36	*Bassinet (Baby Cot)*
37	*Resuscitation Cart (Crash Cart)*
38	*Medication Cart*
39	*Cart, Drawers*
40	*Examination Couch, Manual*
41	*Gynaecology Examination Table, Manual*
42	*Examination Table, Neonates, Manual*
43	*Intravenous Pole, Mobile Stand*
44	*DDA Cabinet*
45	*Stainless steel Multipurpose Trolley*
46	*Cabinet, Instrument, Operation Theatres*
47	*Dressing Cart*
48	*Stainless steel wire shelving unit*
49	*Paper Trolley*
50	*Stainless Steel Sink (Clean up counter)*
51	*Scopes Cabinet*
52	*Mayo Table*
53	*Table, Instrument*
54	*Stool, Adjustable, Doctor*
55	*Stool, Adjustable, Operation Theatres*
56	*Carts, linen/laundry, soiled, Double*
57	*Closed distribution trolley*
58	*Step Ladder, Conductive, Double*

59	*Step, Surgeon, Single*
60	*Kick Bucket*
61	*Mobile Stand for Oxygen Cylinder*
62	*Stainless Steel Wire Basket, 1 STU*
63	*Cart, Plaster*