

Patients' Aid Foundation (PAF)

Jinnah Postgraduate Medical Centre (JPMC)
Karachi.

TENDER FOR

**Provision of Supply, Installation and Commissioning of Cyclotron
Synthesizer for production of 18F based multiple
Radiopharmaceutical for PET-CT facility at JPMC Karachi.**

For The Financial Year 2023-2024

Due on 7th August 2023 at 11:00 am

III- Class A Hot Cell/ Shielded Isolator.

Technical Evaluation Report:

1. Tender was advertised on 8th July 2023.
2. Following bidders participated in the tender:
 - a. M/s Allmed Solutions.
 - b. M/s BIOS.
3. Technical opening of the tender was held on 7th August 2023.
4. Technical evaluation was initiated with mandatory documents check list in which both above stated bidders complied on required documents.
5. Hence, Bidders were technically evaluated by Committee as:

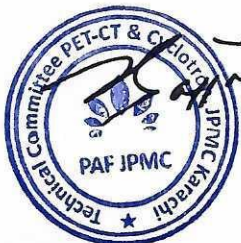
i. M/s Allmed Solutions	Technically Not approved
ii. M/s BIOS.	Technically Approved

Technical Compliance Sheet

S.No	III. Class A Hot Cell/ Shielded Isolator	M/s Allmed Solutions	M/s BIOS
	Brand	Radioprotech	Elsse
	Country of Origin	France	Italy
3.1	Class "A" Shielded Isolator Should Equipped with vertical laminar air flow over the entire work surface. It should ensure sterile conditions for labelling, dispensing and handling of kit preparations and extemporaneous preparations of high	Yes	Yes



	energy radiopharmaceuticals used in PET diagnostic exams.		
3.2	SHIELDINGS The isolator should have the following mm Pb shielding: Work Area 50 mm Hand Passages 50 mm Lead glass (mm 250 x 200) 50 mm eq.	Yes 325x210 mm 50mm 50mm	Yes
3.3	TECHNICAL FEATURES: Internal structure: AISI 316L stainless steel box with raised edges and mirror polishing. Class A work area. Touch-screen operator panel. G.M. probe.	Yes (Stainless Steel Structure) -NO Touch Screen but can be connected remotely on laptop. GM Probe: Yes	Yes
3.4	EXTERNAL DIMENSIONS: W x D x H: 1397 x 1058 x 2300 mm Internal dimensions: 1100 x 600 x 700 (w x d x h) mm Weight: 4,000 Kg	No External Dimensions: 1382x1070.5x1950mm Internal Dimensions: 750x585x600 mm Weight: 3485 Kg	Yes
3.5	CABLE CONNECTION For electrical connections, the isolator should have a seal passage that allows the passage of cables between the inside and outside of the isolator. The passage should allow the connection of 8 cables with a diameter of 10 mm or more cables with a smaller diameter.	Yes	Yes
3.6	GAS CONNECTION Connections for technical gases should be available inside the main chamber. The passage should include two 1/8" technical gas connections.	No	Yes
3.7	ISOLATOR OPERATOR PANEL The operator panel should have 7" or large touch screen operator panel for the managing commands and receiving notifications for any alarms. It should also support login password, allowing personalized access for authorized personnel.	No	Yes
3.8	INTERIOR LIGHTING To maintain the internal environment at a temperature close to the laboratory, the lighting system should consist of two 6000K lighting fixtures, waterproof with IP	No (300 LUX)	Yes



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	<p>67 protection rating and ultra-flat profile. Lighting should be controlled by the button on the external keyboard.</p> <p>The lighting in the work area should have > 500 lx.</p> <p>Each lighting fixture should design so that it can be easily replaced from the inside.</p> <p>The surface of the LEDs should cover with a layer of transparent acrylic material in order to make it possible to clean them completely.</p>		
3.9	<p>ELECTRICAL SOCKETS</p> <p>The equipment of the main chamber should comprise two electrical outlets for powering auxiliary devices such as a dry water bath or rotating shaker.</p> <p>The sockets should have IP65 protection and sealed on the wall of the isolator. These sockets should be covered by a plastic case with transparent front resalable in order to perform the cleaning operations with the use of spray products.</p> <p>The command of the sockets should available on the operator panel.</p>	Yes	Yes
3.10	<p>VENTILATION WORKING AREA VENTILATION</p> <p>The isolator should be equipped with laminar flow ventilation system with partial recirculation.</p> <p>The incoming air should be taken from the laboratory and after passing through a pre-filter. The extracted air should be recovered from new air taken from the laboratory.</p> <p>The ventilation system in the main chamber should provide the following performance:</p> <p>At rest < 3.520 particles/m3 (Ø 0.5 µm particles) < 20 particles/m3 (Ø 5.0 µm particles)</p> <p>In operation < 3.520 particles/m3 (Ø 0.5 µm particles) < 20 particles/m3 (Ø 5.0 µm particles)</p> <p>The ventilation system of the main chamber should be equipped with the following filters:</p>	Yes	Yes








3.11	SHOULD COMPLY WITH QUALITY CERTIFICATIONS: Directive 2006/42/CE : Machinery Directive UNI EN ISO 12100:2010 : Safety of machinery - General principles for design - Risk assessment and risk reduction UNI EN ISO 14644-1 : Cleanrooms and associated controlled environments UNI EN ISO 14644-3 : Laminar flow UNI EN ISO 10648-2:1994 – NSF 49 Metallic box - Part 2: Classification using data control methods of leaks and associated UNI EN ISO 11933 : Components for containment enclosures	(CE Marked) Yes	Yes
3.12	CONFORMITY WITH: GMP Good manufacturing Practice Annex 1: Manufacture of Sterile Medicinal Product Annex 2: Manufacture of Biological Medical Product Annex3: Manufacture of Radiopharmaceuticals Annex 11: Computerized System Annex 15: Qualification and Validation.	No	Yes
3.13	Warranty: 01 Year	Yes	Yes
3.14	Bidder shall possess agency/distribution certificate from manufacturer.	Yes (Offered Through Third party Best ABT)	Yes
3.15	Country of origin: USA/UK/ Europe/Japan.	Yes (France)	Yes (Italy)

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