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LABS

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BID NUMBER: NRF/ILABS IOP1 /61/2025-26

BID DESCRIPTION: Supply, Delivery, Installation, and Servicing of Two Glove Boxes for Containment of an Astatine-211 Radiopharmaceutical Synthesis Module at iThemba LABS, Faure, Western Cape

Addendum six (6)

Please find below responses to questions received for this tender:

BOARD MEMBERS: Prof Ari Sitas (*Chairperson*), Mr Mark Brits, Prof Pumla Gobodo-Madikizela, Prof Glenda Gray, Ms Funeka Khumalo, Dr Len Konar, Ms Lahlane Malema, Prof Pamela Maseko, Prof Teboho Moja, Dr Mathetha Mokonyama, Dr Ntombi Mutshekwane, Prof Nadine Petersen, Prof Refilwe Phaswana-Mafuya, Mr Mavuso Shabalala, Dr Fulufhelo Nelwamondo (*CEO*)

Questions	Responses	Counter Response	Response from iThemba LABS
<p>1. How much shielding (mmPb) they need in the isolator? Or at least can they tell us how much activity of Astatine they would need to handle?</p>	<p>The production will reach up to 8 GBq of At-211. It is important to note that other metals will become activated during irradiation and contribute to additional gamma-ray emissions. This activation should be considered in shielding design.</p>	<p>To correctly dimension the additional shielding required for possible gamma emissions, the activity of the potentially present gamma emitters must also be specified by iTHEMBA.</p>	<p>Your proposal to include pricing for the following three options:</p> <ul style="list-style-type: none"> • No Shielding (Perspex) • 25 mm lead equivalent shielding • • 50 mm lead equivalent shielding

<p>2. On page 5 of 46 of the tender, section 2.6 "The surface of the glovebox chambers must be replaceable, non-flammable work floor material (e.g., tray) in case of physical damage or chemically induced corrosion of the workflow material over time", what do you mean by "replaceable"?</p>	<p>The floor/tray can be easily taken out without dismantling the entire glovebox. If it becomes damaged, contaminated, or corroded, it can be replaced with a spare.</p>	<p>From original URS, "Note: Dimensions of synthesis unit (W x D x H): 605 mm x 435 mm x 535 mm".</p> <p>A tray of 705 x 535 (L x D mm) with a perimeter wall of 20mm is proposed.</p> <p>To correctly select the material of construction for this tray, the aggressive chemical and their concentrations must be specified by iTHEMBA.</p> <p>Please note, no warranty of non-flammability may be offered until the material is selected based on its chemical resistance to aggressive agents.</p>	<p>Removable tray constructed of 316L stainless steel with a smooth, electropolished finish or equivalent</p>
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<p>3. The glovebox must provide a ventilated work compartment to contain vapor and/or particles containing 211At and other radionuclides for operator protection.</p> <p>4. Please confirm if the glovebox is required to maintain ISO Class 5, Unidirectional/Laminar Airflow.</p>	<p>The Glovebox is required to maintain GMP Grade A, Unidirectional/Laminar Airflow.</p> <p>The work compartment pressure shall be constantly kept below the surrounding laboratory environment pressure at -40 Pa to prevent radioactive release. The compartment shall be equipped with a differential pressure gauge to constantly assess and visualize that the differential pressure criteria are</p>	<p>According to IAEATECDOC-1430, terminally sterilized materials may be manipulated in Grade C spaces.</p> <p>The requirement to supply a GMP Grade A unidirectional airflow with 100% exhaust (no recirculation) and double stages of H14 filtration and single stage of active carbon filtration will impact on the project both economically and in terms of required installation space and installation infrastructure to handle the large volumes of exhaust air that will require treatment by client centralized air treatment plant.</p> <p>Please note, this requirement of GMP Grade A for the main chamber is in direct conflict with</p>	<p>6. Astatine 211 cannot be terminally heat sterilised and therefore must be aseptically handed in a grade A area with a B background.</p> <p>If a glovebox with Grade A is considered then a grade C background can be considered</p> <p>PICS Annex 3 and PIC Annex 1</p> <p>7. Yes Grade A for aseptic manipulations</p>
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	<p>maintained. The pressure gauges shall be equipped with an alarm in case the differential pressure is less than its specified value relative to the surrounding laboratory environment.</p> <p>An air exchange solution for the work compartment shall be proposed and supplied by the bidder and shall be verified for suitability by radiation safety division at iThemba LABS. The work compartment shall be connected to an air exchange system which facilitates a minimum ≥ 20 air</p>	<p>what is found in line 9 of this document.</p>	
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	changes per hour inside the compartment (e.g., IAEATECDOC-1430).		
5. <i>The material pass-through compartment must have a have a dedicated ventilation for radiation safety regulations.</i> Any ISO Class or airflow design requirements?	It must be GMP Grade B, Unidirectional/Laminar Airflow. It must maintain pressure hierarchy and prevent airflow short circuiting.	Same comment as line 7 concerning cost and client infrastructure support.	The pass box must meet iso class 5

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<p>6. An air exchange solution for the work compartment must be proposed and supplied by the bidder and must be verified for suitability by radiation safety division at iThemba LABS. Please confirm the requirements on below points:</p> <p>* Laminar or Turbulent Airflow * ISO Class 5 requirement? * Recirculating chamber or Total Exhaust?</p>	<p>It must be GMP Grade B, Unidirectional/Laminar Airflow, Total Exhaust.</p>	<p><i>Please note, this requirement of GMP Grade A for the main chamber is in direct conflict with what is found in line 7 of this document.</i></p>	<p>Laminar may not be required but unidirectional airflow essential, depending on the design</p> <p>Iso class 5</p> <p>Total exhaust 100% fresh air make up</p>

<p>7. Both air intake and exhaust for the glovebox must be equipped with manual shut-off valves to provide a means of validation for chamber pressure integrity testing (e.g., EN 12469) as well as isolation in case of emergency.</p> <p>Is fail-safe automated valves also acceptable? This type of valves automatically closes during power failure or emergency status. This is considered as a better solution but more expensive as the operators need not</p>	<p>Please quote according to specifications.</p>	<p>Considering the large air volumes to be handled with 100% expulsion of both glove boxes (pre-chamber and main chamber), the manual shut-off valves (butterfly) will be large and will require hand wheel assist for opening and closing requiring multiple revolutions (as opposed to valves that requires a simple 90° hand lever).</p> <p>For chamber validation, this may not be an issue.</p> <p><i>For rapid response in case of emergency, the use of hand-wheel assisted butterfly valves is less than ideal.</i></p>	<p>Automated or hand valves are acceptable.</p> <p>If diaphragm valves used then normally closed is usually used in case of fail safe.</p> <p>Diaphragm valves preferred to ball valves butterfly valves or angle seat valves</p>
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access the manual valves.			
8. <i>The compartment must be equipped with a differential pressure gauge to constantly assess and visualize that the differential pressure criteria are maintained.</i>	Please quote according to specifications. Transmitters are also acceptable – they enable remote monitoring, keep personnel away from radiation sources.	<p>The requirement in the original URS does not specify if a switch or a transmitter is required, it only mentions a <u>gauge</u>.</p> <p>The use of a transmitter (that presents the reading and alarm status on the HMI is considered the best and safest solution by this constructor.</p> <p><i>The transmitter solution will be quoted.</i></p>	<p>Yes, automated preferred that can be linked to an EMS</p> <p>Manual valves are not continuously monitored</p>

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9. Please confirm if Pressure Differential Transmitters are also accepted instead of the manual pressure gauges (analog)?		See counter response to line 11.	Yes, most definitely

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<p>10. The glovebox must comply with all radiation safety standards and certifications required for the operation of the GMP-compliant 211At Synthesis Module Synthesis model.</p> <p>11. Please confirm the shielding requirement for the entire unit and the compartments. Any specific testing or certification required?</p>	<p>Since At-211 is an alpha emitter, Glove box containment is critical. The standards and certifications must comply with GMP requirements.</p>	<p>Without the potential activity of extraneous gamma emitters, the shielding cannot be correctly specified.</p> <p>See counter response to line 1.</p>	<p>Your proposal to include pricing for the following three options:</p> <ul style="list-style-type: none"> • No Shielding (Perspex) • 25 mm lead equivalent shielding • 50 mm lead equivalent shielding

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<p>12. The requirements in points 2.17 and 2.19 are unclear to us. Alpha or gamma radiation monitors? They have very different characteristics and costs.</p>			<p>Both alpha and gamma radiation monitors are required, as astatine necessitates alpha monitoring, while gamma-emitting isotopes will be generated during the irradiation process</p>
<p>13. What type of dose calibrator do you need? Do you have a specific request of a brand type ?</p>			<p>We do not require a dose calibrator.</p>

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14. Please confirm the type of lead-shielding requirements range you would like us to offer on.			<p>Your proposal to include pricing for the following three options:</p> <ul style="list-style-type: none"> • No Shielding (Perspex) • 25 mm lead equivalent shielding • 50 mm lead equivalent shielding