



iThemba  
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 four (4)**

Please find below responses to questions received for this tender:

<b>Questions</b>	<b>Responses</b>
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?	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.
2. On page 9 of 46 of the tender, under "CONTRAC PERIOD" it is mentioned document SBD 7.1, which we could not find, will it be provided later on? Is possible to have a draft copy?	Please see attached draft

**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*)

<p>3. 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>4. Regarding the quotation, are we allowed to submit it in euros?</p>	<p>Yes</p>
<p>5. Is it possible to amend the part of the document referring to the Conditions (that is "Special Conditions of Contract Management", "General Conditions of Contract" and "SBD 1") using Word Track Change and submit the amended document together with our Bid Package on the due date? If so, could you please send the document on .doc format?</p>	<p>Please submit a separate document clearly identifying the clauses you propose to amend, along with the specific changes you are recommending.</p>
<p>6. The glovebox must <b>provide a ventilated work compartment</b> to contain <b>vapor and/or particles containing 211At</b> and other radionuclides for operator protection.</p> <p>7. 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</p>

	<p>differential pressure gauge to constantly assess and visualize that the differential pressure criteria are 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 <math>\geq 20</math> air changes per hour inside the compartment (e.g., IAEA-TECDOC-1430).</p>
<p>8. -The material pass-through compartment must have a have a <b>dedicated ventilation</b> for radiation safety regulations. Any ISO Class or airflow design requirements?</p>	<p>It must be GMP Grade B, Unidirectional/Laminar Airflow.</p> <p>It must maintain pressure hierarchy and prevent airflow short circuiting.</p>
<p>9. <b>An air exchange solution for the work compartment</b> must be proposed and supplied by the bidder and must be</p>	<p>It must be GMP Grade B, Unidirectional/Laminar Airflow, Total Exhaust.</p>

<p>verified for suitability by <b>radiation safety division at iThemba LABS.</b></p> <p>Please confirm the requirements on below points:</p> <ul style="list-style-type: none"> <li>* Laminar or Turbulent Airflow</li> <li>* ISO Class 5 requirement?</li> <li>* Recirculating chamber or Total Exhaust?</li> </ul>	
<p>10. Both air intake and exhaust for the glovebox must be equipped with <b>manual shut-off valves</b> 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 access the manual valves.</p>	<p>Please quote according to specifications.</p>
<p>11.-<i>The compartment must be equipped with a differential pressure gauge to <b>constantly assess and visualize</b> that the differential pressure criteria are maintained.</i></p>	<p>Please quote according to specifications. Transmitters are also acceptable – they enable remote monitoring, keep personnel away from radiation sources.</p>

<p>Please confirm if Pressure Differential Transmitters are also accepted instead of the manual pressure gauges (analog)?</p>	
<p>12. The glovebox must comply with <b>all radiation safety standards and certifications required</b> for the operation of the GMP-compliant 211At Synthesis Module Synthesis model.</p> <p>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>