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iThemba LABS
Laboratory for Accelerator Based Sciences

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RFQ Number: NRF/ILABS IOP1 /61/2025-26-01

Supply, Delivery, Installation, and Servicing of One Glove Box for Containment of an Astatine-211 Radiopharmaceutical Synthesis Module at iThemba LABS, Faure, Western Cape

Addendum One (1)

Closing date has been amended to: 1st December 2026, 11:00am.

Please find responses to questions received

Queriers Received	Responses from iThemba LABS
1. We kindly ask if you could extend the tender due date, if possible until Tuesday 1st December 2026	The closing date has been amended to **1st December 2026, 11:00am.**

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, Mr Mavuso Shabalala, Dr Angus Paterson *(Acting CEO)*

2. Could you please confirm whether it is acceptable to amend the sections of the bid documents relating to the contractual conditions, namely the "Special Conditions of Contract Management", "General Conditions of Contract", and "SBD 1", by submitting a separate document with our Bid Package on the due date, identifying the clauses we propose to amend and the specific amendments being requested? Furthermore, could you please confirm that any proposed contractual exceptions or amendments may be discussed and negotiated in good faith with the successful bidder prior to contract award? Kindly note that this request was accepted in the prior tender procedure.	• Please note that NRF iThemba LABS is an organ of state, the General Conditions of Contract (GCC) form part of all bid documents and may not be amended. • Bidders may submit a separate schedule identifying any proposed contractual qualifications or deviations from the tender conditions for consideration by the NRF iThemba LABS. However, submission of such proposed amendments does not imply acceptance thereof. NRF iThemba LABS reserves the right to determine whether any proposed deviation is acceptable and whether it affects the responsiveness of the bid. • Any discussions with a preferred bidder after evaluation will be conducted strictly in accordance with applicable procurement legislation, and the principles of fairness, transparency, competitiveness and equal treatment. No negotiations will be permitted that materially alter the scope, evaluation criteria, or terms and conditions of the tender.
3. Regarding the quotation, kindly confirm that we are allowed to submit it in Euros.	Yes.
4. On page 9 of 48 of the tender document, under the section "CONTRAC PERIOD", is mentioned a document "SBD 7.1", which we could not find, will it be provided later on? Is possible to have a draft copy?	Draft SBD 7.1 is attached as requested.

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5. **Radiation protection** 5.1. Is full lead shielding required, or would localized shielding be sufficient? Is there a minimum shielding thickness specified? 5.2. What is the maximum At-211 activity expected to be handled within the system?	**5.1** The proposal should include pricing for the following three options: • No Shielding (Perspex) • 25 mm lead equivalent shielding • 50 mm lead equivalent shielding **5.2** The production will reach up to 8 GBq of ^{211}At 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.
6. **GMP requirements and system configuration** 8.1. What GMP cleanliness classification is required for the main working chamber and the material transfer pass-box? 8.2. Is the installation of the synthesis module inside the main working chamber mandatory, or could a separate dedicated synthesis chamber, potentially classified as Grade C and equipped with appropriate ventilation and containment controls, be considered? 8.3. Is an integrated VHP biodecontamination system required?	**8.1** ^{211}At cannot be terminally heat sterilised and therefore must be aseptically handed in a grade A area with a B background. **8.2** Yes, it is mandatory. The synthesis module also performs radiolabeling in addition tot purification of the ^{211}At. **8.3 Please** provide separate quotation.

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7. **Process and material handling** 7.1. Could you provide further information on the operations to be performed inside the main working chamber, in addition to the synthesis process? 7.2. Is any manual or automated dispensing of the final product required? 7.3. Will the final product be collected in vials or syringes? Is a dedicated shielded extraction compartment or a transfer system using shielded pots required? 7.4. Should the glove box include dedicated collection systems for radioactive liquid waste, chemical waste and solid waste? 7.5. Is the dose calibrator to be included in the scope of supply or only accommodated within the glove box?	**7.1** Purification of ^{211}At and radiolabeling. Note that there will be a dose calibrator for activity measurements. **7.2** Please provide a quotation for both options. **7.3** The product will be collected in a bulk vial. Please provide a separate quotation for shielded extraction compartment or a transfer system using shielded pots required. **7.4** Please provide a separate quotation. **7.5** No, the dose calibrator is not included in the scope, by must be accommodated with in the glovebox. Please note that we have a Capintec dose calibrator - CRC-55tR
8. **Tender requirements** 8.1. Would references for GMP-compliant glove boxes or hot cells designed for other therapeutic radionuclides be considered acceptable, provided	**8.1** It must be a GMP compliant glove box suitable for containment of an Astatine-211 Atley C100 or similar Synthesis unit.

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that equivalent containment and technical requirements are demonstrated?	

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