#### TECHNICAL COMPLIANCE MATRIX

**IAEA RFQ 649604-AK – Lu-177 PSMA Doses for Brazil (BRA6032)**

**IMPORTANT INSTRUCTIONS**

1. Responses should not be direct copies (copy and paste) of the provided IAEA specifications. Bidders are required to provide a detailed response/explanation for each specification line item. This response must include specific technical details of the offered solution. Any proposed deviations shall be clearly defined and justified.
2. If a bidder references a technical proposal, please indicate where the relevant information can be found.
3. Generic statements such as “we shall customize to your needs/requirements” are **NOT** acceptable.

| **Ref.** | **Specification Requirements** | **Compliance Yes/No** | **Bidder’s technical details and explanations (Expand rows as needed)** |
| --- | --- | --- | --- |
| **1.** | **Requirements** |  |  |
|  | 78 patient doses of Lu-177-PSMA-I&T (each dose containing 7 400 MBq, 200 mCi on the calibration date). | Yes  No |  |
| **3** | **Packing** |  |  |
|  | Clear, colourless type I glass vial, closed with a bromobutyl rubber stopper and aluminium seal. Each vial contains an sterile pyrogen free injection solution that can range from 7.5 mL to 12.5 mL corresponding to a radioactivity of 7 400 MBq ±10% at the date and time of administration. The vial is enclosed within lead container with adequate protective shielding as per radiation protection regulation. | Yes  No |  |
| **4** | **Quality Requirements** |  |  |
|  | Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements, according to the Good Manufacturing Practices.  Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings. Preparation, receipt, storage, use, transfer and disposal of radiopharmaceutical are subject to the applicable regulations and/or appropriate licences from the competent regulatory agencies. | Yes  No |  |
| **5** | **Testing and Acceptance** |  |  |
|  | 5.1 Doses, prior to shipment, must be calibrated to the guaranteed delivery dates and marking quality requirements.  5.2 The dose calibration values and date will be documented by the Contractor in an acceptance protocol that will be signed by the End User.  5.3 All relevant quality testing reports of the radiopharmaceutical batch should be documented and supplied with the consignment. | Yes  No |  |
| **7** | **Delivery** |  |  |
|  | Delivery and internal transportation- batches-timeframe (18 months). Doses will be required in batches. The schedule is not fixed and depends on the patient studies.  The injection should not be frozen. Stored in the original package in order to protect from ionising radiation (lead shielding). Handling, transportation storage and disposal of radiopharmaceuticals should be in accordance with national regulations on radioactive materials. The doses will be delivered to the selected participating hospitals in different regions of Brazil for 1.5 years (18 months) starting from the first delivered batch. All training and support for use will be provided by SBMN. | Yes  No |  |
| **8** | **Deliverable Data Items** |  |  |
|  | The Contractor shall provide the technical documentation of the item in the Portuguese language. | ☐ Yes  ☐ No |  |