

**STATEMENT OF WORK:
NUCLEAR MEDICINE SERVICE – RADIUM-223 (XOFIGO) CONTRACT**

1. Contractor shall meet all Nuclear Regulatory Commission, National Health Physics Program (NHPP), Department of Transportation, FDA, OSHA, and all other agency rules and regulations (Federal and State), as well as any applicable Joint Commission Requirements.
2. Contractor must be licensed by the Nuclear Regulatory Commission and be regularly established in the business of providing radiopharmaceuticals. Offeror must provide copies of licenses and certifications along with proposal to the Contracting Officer.
3. Contractor must be able to provide service of Radium-223 (Xofigo) Nuclear Medicine radiopharmaceuticals to the following VA facilities:
 - a) VA North Texas Healthcare System
Dallas VA Medical Center
Attn Nuclear Medicine
4500 S Lancaster Rd
Dallas, TX 75216
 - b) VA South Texas Healthcare System
Audie L. Murphy VA Medical Center
Attn Nuclear Medicine
7400 Merton Minter Blvd
San Antonio, TX 78229
4. Radium Ra 223 (Xofigo)dichloride, an alpha particle-emitting pharmaceutical, is a radiotherapeutic drug. Xofigo is supplied as a clear, colorless, isotonic, and sterile solution to be administered intravenously with pH between 6 and 8. Each milliliter of solution contains 1,000 kBq radium-223 dichloride (27 microcurie), corresponding to 0.53 ng radium-223, at the reference date. Radium is present in the solution as a free divalent cation. Each vial contains 6 mL of solution (6,000 kBq (162 microcurie) radium-223 dichloride at the reference date). The active ingredients are 6.3 mg/mL sodium chloride USP (tonicity agent), 7.2 mg/mL sodium citrate USP (for pH adjustment), 0.2 mg/mL hydrochloric acid USP (for pH adjustment), and water for injection USP.
5. Contractor shall label all unit doses of delivered radiopharmaceutical with the amount, preparation time, expiration time, date, etc.
6. An additional label shall be affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

7. All packages containing radioactive material must be labeled and shipped in accordance with Title 49, Code of Federal Regulations Part 172 and 173.

8. Contractor shall perform all quality control procedures as required by Federal and State regulatory agencies. Quality Control results will be furnished upon request.

9. Contractor/supplier shall abide by Title 10, Code of Federal Regulation, which states: A Licensee may use for medical purposes only:

(a) By-product material or cyclotron produced materials manufactured, labeled, packaged and distributed in accordance with a license issued pursuant to the regulations in Title 10, Code of Federal Regulations, Part 35 and the equivalent regulations of an Agreement State.

(b) Reagent kit that has been manufactured, labeled, packed and distributed in accordance with approval by the Commission pursuant to Title 10 CFR 32.72 or an Agreement State under equivalent regulations for the preparation of radiopharmaceuticals for medical use.

10. Contractor shall have available an adequate supply of contract products to meet the requirements of the VA North Texas Healthcare System with proof of contingency supply chain to prevent disruption of clinical care. Pricing will be based on a tiered unit dose price per quantity of doses ordered with no other fees or surcharges.

11. Contractor will deliver radioisotope in amount greater than or equal to the activity ordered with calibration for the specified appointment time.

12. Radiopharmaceutical Returns for Credit: The Contractor shall accept returns for full credit toward future orders under the following conditions:

- a. Product(s) ordered or shipped in error.
- b. Product(s) damaged in shipment
- c. Concealed shipping damages
- d. Recalled product(s)
- e. Outdated products in unopened, original container.

Contractor shall invoice at least once per month showing period covered, billing date, name of preparation, quantity and amount and correct purchase order number.

13. Normal/ Routine Ordering: Orders shall be placed by authorized VA personnel during the normal workday, and placed at least 7 days prior to patient scheduled appointment.

14. Normal/ Routine Deliveries: Depending upon Medical Center patient care requirements, the contractor shall provide routine delivery. Delivery orders shall include the following information:

- Contract item (s) and quantity,
- Time(s) of delivery,

- Applicable VA purchase order number.

15. Ordering Contact Information: Contractor shall provide contact information for the placement of orders for items listed in the “Schedule of Supplies and Services” Section.

POC Name:

Address:

City/State/Zip Code:

Ordering Phone Number:

Ordering Fax Number:

Ordering E-Mail Address:

16. DELIVERY COMMITMENT: Time of delivery specified or mutually agreed to at the time of receipt of telephone orders shall become mandatory upon the Contractor's acceptance to commitment. Delivery of supplies by the scheduled time will be complete except as otherwise authorized by the Ordering Personnel. Failure to perform in accordance with the delivery commitment may be grounds for termination of contract in accordance with the provisions for default. The Government may terminate this contract in whole or in part if the contractor fails to meet the required delivery schedule. The contractor shall not be charged with damages when the delay in delivery arises out of causes beyond the control and without the fault or negligence of the contractor.

DELIVERY LOCATION:

Deliveries will be made to:

- a) VA North Texas Healthcare System
Dallas VA Medical Center
Attn Nuclear Medicine
4500 S Lancaster Rd
Dallas, TX 75216

- b) VA South Texas Healthcare System
Audie L. Murphy VA Medical Center
Attn Nuclear Medicine
7400 Merton Minter Blvd
San Antonio, TX 78229

Access to the radiopharmacy during non-business hours shall be obtained by contacting VA Police Service. Delivery personnel shall be escorted at all times within the Nuclear Medicine Service.

Contractor will sign in/sign out with Nuclear Medicine Service personnel upon each delivery of radiotracer and follow all policies and procedures in place at the facility Nuclear Medicine

Service. Compliance with all applicable regulatory bodies, including FDA and TX/US DOT is requisite.

Upon request by the facility Radiation Safety Officer, the Contractor shall provide a copy of reports of contractor’s RSO Safety Audits of Federal Compliance.

SCHEDULE OF SUPPLIES AND SERVICES

All quantities are estimates, contractor will only be paid for items and quantities ordered and delivered. Based on usage, quantities may be adjusted.

<u>DALLAS VA MEDICAL CENTER</u>				
	Period of Performance	Item Description	Estimated Minimum Quantity	Estimated Maximum Quantity
Base Year	Date of award – May 31, 2019	Ra-223 Radium Dichloride (Xofigo)	50 EA	4,500 EA
Option Year 1	June 1, 2019 – May 31, 2020	Ra-223 Radium Dichloride (Xofigo)	50 EA	4,500 EA
Option Year 2	June 1, 2020 – May 31, 2021	Ra-223 Radium Dichloride (Xofigo)	50 EA	4,500 EA
Option Year 3	June 1, 2021 – May 31, 2022	Ra-223 Radium Dichloride (Xofigo)	50 EA	4,500 EA
Option Year 4	June 1, 2022 – May 31, 2023	Ra-223 Radium Dichloride (Xofigo)	50 EA	4,500 EA

<u>AUDIE L. MURPHY VA MEDICAL CENTER</u>				
	Period of Performance	Item Description	Estimated Minimum Quantity	Estimated Maximum Quantity
Base Year	Date of award – May 31, 2019	Ra-223 Radium Dichloride (Xofigo)	50 EA	3,860 EA
Option Year 1	June 1, 2019 – May 31, 2020	Ra-223 Radium Dichloride (Xofigo)	50 EA	3,860 EA
Option Year 2	June 1, 2020 – May 31, 2021	Ra-223 Radium Dichloride (Xofigo)	50 EA	3,860 EA

Option Year 3	June 1, 2021 – May 31, 2022	Ra-223 Radium Dichloride (Xofigo)	50 EA	3,860 EA
Option Year 4	June 1, 2022 – May 31, 2023	Ra-223 Radium Dichloride (Xofigo)	50 EA	3,860 EA