

STATEMENT OF WORK
RADIOPHARMACEUTICAL ISOTOPES
(March 19, 2013)

1. GENERAL

The contractor shall provide all labor, tools, materials, equipment, facilities, transportation and supervision necessary to complete all work associated with furnishing, and delivering radiopharmaceutical isotopes to the VA medical center located at 1100 N. College Ave. in Fayetteville, AR in complete and strict accordance with this purchase order and all attachments hereto.

2. SCOPE

The Contractor is responsible for providing the requested radiopharmaceuticals at the requested time. If the ordered radiopharmaceuticals are not available and cannot be delivered to the VA when needed, the contractor will notify the VA Nuclear Medicine Department and obtain the needed doses from another source, including another nuclear pharmacy, to be delivered as close to the requested time in order to provide timely care to VA patients. When appropriate, the Contractor may substitute another radiopharmaceutical for the requested one but only with VHSO Nuclear Medicine Service approval. When this is done, the VA will pay for the lower priced radiopharmaceutical.

3. DELIVERY

3.1. Delivery times and dates will be provided when the order is placed. 1st shipment of a regular workday to be delivered between 7:00 AM and 8:00 A.M. Shipments “called when needed” may be requested during regular work hours, or after regular work hours, as “emergency”, including weekends, holidays and nights. Emergency deliveries may be made on an as needed basis on the following Federal Holidays (observed) and any other day specifically declared by the President of the United States to be a national holiday:

- 3.1.1. New Year’s Day
- 3.1.2. Martin Luther King Day
- 3.1.3. Presidents’ Day
- 3.1.4. Memorial Day
- 3.1.5. Independence Day
- 3.1.6. Labor Day
- 3.1.7. Columbus Day
- 3.1.8. Veterans Day
- 3.1.9. Thanksgiving Day
- 3.1.10. Christmas Day

3.2. Deliveries will incorporate sufficient lead or other high-density metal shielding to comply with all applicable federal and/or state standards relating to shipment of radioactive materials. Shipping containers must comply with all federal and state regulations.

3.3. The only unused doses returned to pharmacy that will be credited are doses dispensed as “per physician order” from pharmacy and sealed “shrink wrapped” technetium heart doses, both sestamibi and tetrofosmin. Returns will be accepted by the contractor to a maximum of 5% of total heart doses received.

- 3.4. The Contractor shall remove all radioactive waste, including all syringes and vials no longer required. All waste shall be returned (Picked-up) the next working day.

4. CERTIFICATION AND LICENSING

- 4.1. Contractor shall hold a current **Arkansas Department of Environmental Quality (DEQ) license** to produce and distribute radiopharmaceuticals for human administration, which permits Contractor to receive and dispose of radioactive waste. Contractor shall provide a copy of its radioactive material license to the Nuclear Medicine Service at the VHSO upon commencement of the contract. Contractor shall immediately notify the VHSO being supplied, upon any action by the USNRC agreement state and/or FDA to suspend or modify suppliers. Contractor shall provide radiopharmaceuticals, which have been prepared according to manufacturer's package, insert.
- 4.2. Contractor to supply VHSO Nuclear Medicine Service with the following:
 - 4.2.1. Contractor's regular work hours.
 - 4.2.2. Contractor's telephone number for **call-in-orders** during normal work hours.
 - 4.2.3. Contractor's telephone number and instructions for placing **"Emergency"** orders after contractor's regular work hours, including weekends.
 - 4.2.4. Contractor will furnish a statement that any radiopharmaceutical delivered as "ready-to-use" (individual doses in syringes) will have quality control performed by the Contractor, so that the delivered product will comply with the requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and/or with the United States Pharmacopeia.
 - 4.2.5. All radiopharmaceutical shall be calibrated and labeled with concentration, calibration time, total volume and total activity.
 - 4.2.6. Consultation service regarding radiopharmaceutical applications, problems, controls, etc, shall be provided upon request at no additional charge.
 - 4.2.7. VHSO Nuclear Medicine Service shall be provided with copies of invoices.
 - 4.2.8. Supplies will be ordered by issuance of delivery order or telephone request
- 4.3. Should any changes occur in above information during contract performance period, Contractor will provide updates in writing.

5. MARKING, LABELING AND RECORD KEEPING

- 5.1. Current package inserts of all Radiopharmaceuticals supplied will be shipped to the VHSO Nuclear Medicine Service.
- 5.2. Contractor will make quality control records available to the Veterans Affairs upon written request.
- 5.3. The quantity of radioactivity for supplied radiopharmaceutical **will not deviate more than +10% or -5%**, at the time of calibration, from the quantities specified.
- 5.4. The expiration date and time shall be indicated and affixed to each product as noted below; in general:
 - 5.4.1. Ready-to-use doses: **Not shorter than six (6) hours**
 - 5.4.2. Tc-99m pertechnetate: : **Not shorter than twelve (12) hours**
 - 5.4.3. Kits intended for reconstitution by user: **Not shorter than three (3) months from date of delivery.**

- 5.4.4. Unused kits having expiration time not less than two (2) weeks will be exchanged by the Contractor at no additional charge for a comparable kit having the three (3) months life span.
- 5.4.5. For labeling of patient's white blood cells (WBC) with Indium IN-111 Oxine or Tc-Ceretec for reinjection to the same patient:
- 5.4.6. The return by the Contractor, of the patient's radio-labeled white blood cells shall take place within five (5) hours from the time the specimen was submitted for labeling procedure.
- 5.4.7. VA Form 10-0130 "Administration of Radio-labeled Blood Products" will be submitted by the Nuclear Medicine Service for documentation purposes confirming the identification of the labeled blood specimen matches with the patient's blood specimen submitted for the labeling procedure.

6. DELIVERY

- 6.1. Delivery of Products: Delivery times and dates will be provided when the order is placed. 1st shipment of a regular workday to be delivered between 7:00 AM and 8:00 A.M. Shipments "called when needed" may be requested during regular work hours, or after regular work hours, as "emergency", including weekends, holidays and nights.
- 6.2. Shipments requested as an "Emergency" will be delivered as follows:
 - 6.2.1. Requests placed during regular work hours will be delivered within one (1) hours, or as specified
 - 6.2.2. Requests placed after regular work hours (weekend, holiday, and night) will be delivered within one and one-half (1.5) hours – or as specified.
 - 6.2.3. All shipments will be labeled as RADIOACTIVE MATERIAL in compliance with all pertinent regulations.
 - 6.2.4. All Radiopharmaceuticals, Radioassay Kits and/or Analytic Kits are to be furnished by the Contractor in strict accordance with the terms and conditions of the contract and all applicable Local, State and Federal Laws.
 - 6.2.5. All shipments will have a Packing Slip enclosed, giving information about the product and its identification.
 - 6.2.6. All radionuclide scanning material shall be packaged in accordance with applicable Nuclear Regulatory Commission (NRC) Regulations.

7. ORDERING

- 7.1. Authorized employees of the VHSO will place orders on an as needed basis. Individual radiopharmaceuticals will be provided in unit dose form and will be delivered at the request of the VHSO. Two (2) free deliveries during normal business hours defined as Monday-Friday 0700-1600 hours (excluding holidays). The contractor shall supply two (2) phone numbers for ordering after normal working hours. Orders shall be placed the afternoon before, or prior if known, the required delivery date for exact quantities of each unit dose or quantity for bulk (vial) orders. Emergency orders can be placed at anytime with delivery within one (1) hour of the order. Delivery of all items shall be to:
ATTN: Nuclear Medicine
Veterans Health Care System of the Ozarks
1100 N. College Avenue
Fayetteville, AR 72703

- 7.2. Emergency deliveries will be charged per emergency delivery in accordance with the fee schedule.
- 7.3. Additional deliveries during normal working hours will be billed per additional delivery in accordance with the fee schedule.
- 7.4. If needed, the contractor will be able to provide unit dose radiopharmaceuticals on weekends for emergency procedures. Radioactive shipments prepared in advance to anticipate emergency or routine studies **are not acceptable.**

8. QUALITY

The contractor shall guarantee the quality of the radiopharmaceuticals. Quality Control (QC) shall include pH testing, percent tag, alumina and 99Mo breakthrough as appropriate. QC shall be performed on each agent dispensed. Complete documentation of the QC results shall be provided upon request to the VHSO. All radiopharmaceuticals shall be calibrated and labeled with the concentration, time, total volume, and total activity. Consultation Service regarding radiopharmaceutical applications, problems, controls, etc, shall be provided upon request to the VHSO at no charge.

9. WASTE REMOVAL

The contractor shall remove all radioactive waste generated by the contractor (to include all syringes and vials). Safe transport of the waste is the responsibility of the contractor. The Contractor must adhere to OSHA guidelines regarding blood borne pathogens, DOT regulations, Board of Pharmacy regulations regarding radiopharmaceuticals, and NRC/Agreement State requirements regarding radioactive materials.

10. SOFTWARE

The contractor grants the VA a nonexclusive, nontransferable license to possess and use the software package in machine-readable form only on a single personal computer located at the VHSO Nuclear Medicine Dept. The VHSO shall not copy or transfer the software or license to any other party. "Use" means loading the software onto or transmitting to the personal computer and executing storing or displaying thereon. The contractor shall deliver to the VHSO the licensed program in a machine-readable object code form and support materials sufficient for the VHSO's exercise of its rights under this license, one (1) electronic copy and one (1) paper copy if possible. The software license shall remain in full force and effect at no charge for the term of this contract if the VHSO complies with the terms and conditions of this contract. Upon termination or expiration of this contract, for any reason, the VHSO shall promptly return the software together with all copies, modifications, and merged portions in any form to the contractor. The VHSO may not copy, reproduce, sublicense, assign or transfer this license or the software or remove any copyright or other proprietary notices from the licensed software. The software shall be compatible with Windows Vista Home Premium Edition.

11. HARDWARE

The VHSO will provide a laptop for the use of the software. The computer and all data stored remain the property of the VHSO at all times. The contractor shall not have access to this computer or the information stored on the computer in accordance with the Privacy Act of

1974 and VHSO guidelines on protecting patient information. At no time is the contractor authorized access to this computer for any means. If information is required from this computer, only the authorized individuals in Nuclear Medicine shall access this information for official use.

12. ELECTRONIC PATIENT INFORMATION

The parties agree and acknowledge that in performing its duties and obligations under the Agreement, the Contractor shall not have access to any patient information via the Contractor's electronic information systems.