

STATEMENT OF WORK

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 Veteran's Healthcare System of the Ozarks (VHSO) 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 the VHSO patients. When appropriate and with the approval of the VHSO Nuclear Medicine Service, the contractor may substitute a similar radiopharmaceutical for the one ordered. In the case of radiopharmaceutical, the VHSO will pay for the lower priced item.

1. Radiopharmaceuticals will be delivered strictly in accordance with the requirements of the VHSO Nuclear Medicine Service. Deliveries will be made directly to the Nuclear Medicine Service, commencing at 07:00 AM, Monday through Friday.
2. Emergency deliveries may be made on the following federal holidays on an as needed basis:
 - a. New Year's Day
 - b. Martin Luther King Day
 - c. President's Day
 - d. Memorial Day
 - e. Independence Day
 - f. Labor Day
 - g. Columbus Day
 - h. Veteran's Day
 - i. Thanksgiving
 - j. Christmas
 - k. Any other day specifically declared by the President of the United States to be a national holiday.
3. 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 federal and state regulations.
4. The only unused dose returned to the 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.
5. Contractor shall hold a current Arkansas Department of Environment 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 VHSO Nuclear Medicine Service, upon commencement of the contract. Contractor shall immediately notify the VHSO, upon any action by the USNRC agreement status and/or FDA to suspend or modify suppliers. Contractors shall provide radiopharmaceuticals, which have been prepared according to manufacturer's package insert.
6. The contractor shall remove all radioactive waste, including all syringes and vials, that are no longer required. All waste shall be returned (picked up) the next working day.

7. Contractor to supply VHSO Nuclear Medicine Service with the following:
 - a. Contractor's regular work hours
 - b. Contractor's telephone number for calling in orders, during normal work hours
 - c. Contractor's telephone number and instructions for placing emergency orders after contractor's normal work hours, weekends, and holidays
 - d. Contractor will furnish a statement that any radiopharmaceutical delivered as "ready to use" (individual syringe doses) will have quality control performed by the contractor, so the delivered product will comply with the requirements of The Joint Commission, and/or the United States Pharmacopeia
 - e. All radiopharmaceuticals shall be calibrated and labeled with concentration, calibration time, total volume, and total activity
 - f. Consultation service regarding radiopharmaceutical applications, problems, controls, etc.. shall be provided upon request at no additional charge
 - g. VHSO Nuclear Medicine Service shall be provided with copies of invoices
 - h. Supplies will be ordered by issuance of delivery order or telephone request

Should any changes occur in above information during contract performance period, contractor will provide updates in writing.

8. Current package inserts of all Radiopharmaceuticals supplied will be shipped to the VHSO Nuclear Medicine Service
9. Contractor will make quality control records available to the VHSO upon written request
10. The quantity of radioactivity for supplied radiopharmaceutical will not deviate more than +10% or - 5% at the time of calibration, from the quantity requested
11. The expiration date and time shall be indicated and affixed to each product as noted below:
 - a. Ready to use doses: Not shorter than six (6) hours
 - b. Tc-99m pertechnetate: Not shorter than twelve (12) hours
 - c. "Cold" kits intended for reconstitution by user: Not shorter than three (3) months
 - d. Unused cold 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 expiration not shorter than three (3) months
12. Procedure for labeling of patient's white blood cells (WBC) with Indium IN-111 Oxine or Tc-Ceretec for reinjection of same patient:
 - a. 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.
 - b. 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.

Delivery

Routine delivery orders placed prior to 16:00 will be delivered the next day between 07:00 AM – 08:00 AM to destination. Shipments classified as “call when needed” may be requested during regular work hours, or after regular work hours as “emergency”, including weekends, holidays, and nights.

Shipments requested as an “emergency” will be delivered as follows:

- a. Requests placed during regular work hours will be delivered within one (1) hour, or as specified.
- b. Requests placed after regular work hours (weekend, holiday, and night) will be delivered within one and one-half (1.5) hours, or as specified
- c. All shipments will be labeled as Radioactive Material in compliance with all pertinent regulations
- d. 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, federal, and state laws.
- e. All shipments will have a packing slip enclosed, giving product information and its identification
- f. All radionuclide scanning material shall be packaged in accordance with applicable Nuclear Regulatory Commission (NRC) regulations

Authorized employees of the VHSD 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 VHSD. Two (2) deliveries per day will be f.o.b. destination, additional deliveries during that period will be charged in accordance with the agreed upon fee schedule. The contractor shall supply two (2) phone numbers for ordering after normal hours. Orders shall be placed the afternoon before the required delivery date for exact quantities of each unit dose or quantity for bulk (vial) orders. Emergency orders can be placed anytime with delivery within one and one-half hours (1.5) hours of the order. Delivery of all items shall be to:

ATTN: Nuclear Medicine Service
Veterans Healthcare System of the Ozarks
1100 N College Avenue
Fayetteville, AR. 72703

Emergency Deliveries will be charged per emergency delivery fee, in accordance with the agreed upon fee schedule.

Additional deliveries, during normal business hours, will be billed as an additional delivery in accordance with the agreed upon fee schedule.

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.

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 VHSD. 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 VHSD at no charge.

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 the OSHA guidelines regarding bloodborne pathogens, DOT regulations, Board of Pharmacy regulations regarding radiopharmaceuticals, and the NRC requirements regarding radioactive materials.

Software

The contractor grants the VHSO a nonexclusive, nontransferable license to possess and use the software package in machine-readable form only on a single personal computer (PC) located in the VHSO Nuclear Medicine Service. 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 PC 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 the contract period, if the VHSO complies with the terms and conditions of this contract. Upon termination or expiration of the contract, for any reasons, the VHSO shall promptly return the software 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. The VHSO will not remove the copyright or any other proprietary notices from the licensed software. The software shall be compatible with the operating system currently used on VHSO PCs. This software is to be a stand-alone system that does not interface the VHSO's computer network.

Hardware

The VHSO will provide a PC for the use of the software. The PC 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 it, in accordance with the Privacy Act of 1974 and other 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 the Nuclear Medicine Service shall access this information for official use. This is a stand-alone system and will not connect to the VHSO's computer network.

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. Based upon the foregoing, the following paragraph shall not apply to this agreement. This statement is in direct regards to C14 VAAR 852.273-75 SECURITY REQUIREMENTS FOR UNCLASSIFIED INFORMATION TECHNOLOGY RESOURCES (Interim- October 20018) shall not apply unless contractor receives patient information. In the case that the information is received, the clause shall be enforced to its full extent.

Term of Order:

This order is effective one year from date of award plus four (4) one-year options that may be exercised by the VA. The exercising of each option year is at the sole discretion of the government. The contract is subject to the availability of funds.

END SOW

Estimated annual requirement:

Description/Part Number*	Qty	
Pharmacy Call Out, XCRG	6	
Regular Deliveries, (Monday-Friday), Days	500	
Additional Deliveries (Monday-Friday), Days	50	
STAT Delivery Fee	13	
DTPA Aerosol	25	
DTPA, Dose (Tc-99m Pentetate)	20	
MDP, Dose (Tc-99m Methylidiphosphonate)	12	
Sodium Iodine, 100uCi, Caps	6	
MAG3, Dose (Tc-99m Mertiatide_	25	
Choletec, Dose (Tc-99m Mebrofenin)	100	
HDP, Dose (Tc-99m Oxidronate)	300	
Sulfur Colloid, Dose (Tc-99m Sulfur Colloid)	40	
Filtered Sulfur Colloid Dose	6	
MAA, Dose (Tc-99m Macro Aggregated)	25	
Tc-99m Point Source, Dose (NATC04)	36	
Myoview, Dose (Tc-99m Tetrofosmin)	3090	
Sestamibi-Cardiolite, Dose (Tc-99m Cardiolite OR Sestamibi)	12	12
TI-201, mCi (Thallium)	12	
Sodium Pertechnetate, Dose	90	
Sodium Pertechnetate, MCI (NaTc04)	10	
in-111 WBC, Dose (in-111 Oxyquinoline (Oxine)	3	
Ceretec WBC, Dose (Tc-99m Exametazime)	3	
Ulratag Kit	85	
i-131 (1-6 mCi) Therapy CAP, CAPS	6	
i-131 Each Additional mCi Therapy	12	
i-131 Diagnostic Cap, Caps	3	
Ga-67, mCi Gallium	6	
Octreoscan Dose (in-111 Pentetreotide)	4	
Lexiscan (Regadenosen)	12	
Instavent Aerosol Numulizer	25	
in-111 WBC BID KIT (Heparin & Hetastarch)	8	
Sincalide (Kinevac)	100	
Co57 (Cobalt-57) E-VIAL	1	
Sodium Iodine, 200 uCi Caps (i-123)	40	
Syntrac Single Software License Fee	1	
C0-57, 24"x16.5", RFS 10 mCi, Product Number CO5951		1
Tc-99 NaTc04 UD mCi	16	
Tc-99m NaTc04	36	
Tc-99m NaTc04 UD Mci	8	
Radioaerosol Delivery Kit	1	
Venti-scan Tubing, Single Use	12	