

Performance Work Statement

MANUFACTURE AND DELIVERY OF UNIT DOSE INDIUM-111 PROSTRASCINT and F-18 AMYVID
RADIOPHARMACEUTICALS
C.W. Bill Young VAHCS, Bay Pines, FL. 33708
NUCLEAR MEDICINE

Contractor must provide deliveries as needed as well as emergent deliveries. Routine Weekday (M-F) delivery times; Bay Pines VAHCS, between 6:30AM and 7:30AM Monday through Friday, between 7:00AM and 8:00AM Monday through Friday and 10AM (2nd daily delivery) and 1PM (3rd daily delivery). There are no scheduled weekend deliveries. However, VA may require Emergency orders within two hours of receiving the order by phone or otherwise from VA.

Contractor must be able to provide emergency orders placed during regular work hours (Monday through Saturday 6:00 am to 4:30 pm) within 120 minutes after receipt of phoned or faxed orders from the C.W. Bill Young VAMC.

1) **DELIVERY/SCOPE:** Quantities expressed in the schedule are best estimated quantities. However, quantities of radiopharmaceuticals may vary based on patient demand.

- All radiopharmaceuticals and 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.
- Contractor/supplier shall abide by (CFR 10) Title Code of Federal Regulations, which states: A Licensee may use for medical use only:
 - i. By-product material 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.
- All radiopharmaceutical items shall be ordered as needed by the Nuclear Medicine staff and delivered with daily routine deliveries.
- The Contractor shall label all supplies as to the amount of radiopharmaceutical, preparation time, expiration time, date, etc., and provide a bar code label to facilitate scanning data into a nuclear medicine information management system. Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.
- The Contractor shall have available an adequate supply of the contract product to meet the requirements of the facility listed above at its distribution points.
- In an instance where an ordered radiopharmaceutical is not available and cannot be delivered to the VA when needed, the Contractor will notify the COR and then obtain the needed doses from another source, including other Radiopharmacies, at no additional cost to the government. Once the needed doses are identified and obtained the Contractor shall notify the COR of their estimated delivery time. The Contractor shall make every effort to deliver the doses as close to the requested delivery time in order to provide timely care to the Veteran patients. These delivery abnormalities are subject acceptable quality levels identified below.

- The Contractor may only substitute another radiopharmaceutical for the requested one with VA Nuclear Medicine and contracting office's approval. When this is done, the VA will pay for the lower priced radiopharmaceutical.
- No delivery charge shall be made for additional deliveries up to 5 per day during normal working hours, 6:00 AM-4:30 PM.
- The contractor shall deliver all radiopharmaceuticals with NO added fuel surcharge.
- Requests for emergency doses during regular work hours (Monday through Saturday 6:00 AM-4:30 PM) shall be delivered within 120 minutes of placing the order. Emergency and priority studies consist of 20%- 30% of the daily schedule and may include Saturday.
- The first daily delivery shall be made to Nuclear Medicine by 6:30 a.m. unless prior authorization arrangements have been made. Delivery shall be made directly to a Nuclear Medicine Technologist on duty. Subsequent deliveries will likewise be made as needed as described above. All packaging of radioactive materials SHALL BE clearly labeled RADIOACTIVE on the outside of the shipping carton and comply with all applicable regulating agencies. The Contractor shall perform all quality control procedures as required by Federal and State regulatory agencies.
- The Contractor shall meet all Nuclear Regulatory Commission, Department of Transportation, Food and Drug Administration (F.D.A), OSHA and all other Federal and State agency rules and regulations (Federal and State).
- Contractor shall accept returns for credit 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 (specifically authorized for return by manufacturer)
- Contractor shall offer some form of partial credit for unit doses that are not to be used or cancelled. Please describe partial credit process in Attachment C, CDRL 1.
- Ordering: Contractor will be furnished the name(s) of individuals authorized to purchase against the Contract. Bay Pines VAHCS will provide its own Contracting Officer's Representative (COR).

- DELIVERY SCHEDULE: DELIVERY SPECIFIED BY THE GOVERNMENT ON FOB DESTINATION WITHIN CONSIGNEE'S PREMISES CONTRACTS ARE THE DATES MATERIAL IS DUE IN, NOT THE SHIPPING DATES. DELIVERY WILL BE MADE, FOR THE TIMES INDICATED IN THIS CONTRACT TO THE FOLLOWING LOCATIONS UNDER THE FOLLOWING CONDITIONS:
 - a. BAY PINES VAHCS - DELIVER TO 10000 BAY PINES BLVD., BAY PINES, FL 33744, BLDG 100, NUCLEAR MEDICINE DEPARTMENT, SECOND FLOOR ROOM 2C110. THE FIRST DELIVERY IN THE MORNING SHALL BE NO EARLIER THAN 0630 AM, EST AND NO LATER THAN 0730EST, MONDAY – FRIDAY. IF A SECOND DELIVERY IS REQUIRED, IT SHALL ARRIVE BEFORE 10 AM, EST. IF A THIRD DELIVERY IS REQUIRED, IT SHALL ARRIVE BEFORE 1PM, EST. ADDITIONAL ON DEMAND DELIVERIES OCCURRING MONDAY-SATURDAY SHALL ARRIVE WITHIN TWO (2) HOURS FROM THE TIME THE PHONE REQUEST IS PLACED. THE CONTRACTOR SHALL BE REQUIRED, AS DEEMED NECESSARY BY THE BAY PINES VA HEALTHCARE SYSTEM, TO FURNISH SUCH SERVICES AS SPECIFIED, ON NATIONAL HOLIDAYS AND DURING NON-WORKING HOURS. ALL DELIVERIES SHALL BE MADE WITHIN TWO (2) HOURS AFTER RECEIPT OF ORDER. ALL CHARGES INCURRED FOR DELIVERY SHALL BE INCLUDED IN THE FEE SCHEDULE TO INCLUDE FUEL SURCHARGES. VENDOR SHALL SUBMIT A MONTHLY INVOICE WITHIN 15 DAYS AFTER THE END OF THE MONTH BEING BILLED. INVOICE SHALL BE ACCURATE AND PRICING MUST MATCH CONTRACT PRICE FOR EACH LINE ITEM.
- Contractor shall provide evidence of special driver's licenses required for transporting hazardous materials.
- Contractor must provide waste disposal at no additional charge of used radioactive dose syringes, vials, etc. All waste shall be picked up with the next delivery.
- All radiopharmaceuticals shall be delivered in properly shielded containers with disposable impenetrable biohazard liners. Shipping containers and their labeling must comply with all federal and state regulations.
- Any recalled/incorrectly delivered dose for any reason shall be credited for the full amount.
- It is the offeror's responsibility to provide the VA with recall notices on any product that has been delivered to the VA that may be defective. Notification shall be made to the Contracting Officer Representative via the most expedient method.
- Incorrectly delivered doses shall not exceed one per quarter.
- Any doses deemed below standard by the facility shall be credited toward the account and shall not exceed one per quarter, 4 per year, from date of award.

- Emergency call back fees shall not be charged for regular work hours (M-F 6:00 am-4:30 pm) on days not observed as a holiday by the VA, i.e. Christmas Eve, Good Friday, etc.

- Federal Holidays

January 1	New Year's Day
January 19	Birthday of Martin Luther King, Jr.
February 16	President's Day
May 25	Memorial Day
July 4	Independence Day
September 7	Labor Day
October 12	Columbus Day
November 11	Veterans Day
November 26	Thanksgiving Day
December 25	Christmas Day

-Any other day declared a Federal Holiday by the US President.

- Contractor shall provide any additional technical support deemed necessary for the technical staff, physicians, patient education, etc.
- All radiopharmaceuticals shall be calibrated and labeled with concentration, calibration time, total volume, total activity and expiration time and date.
- All technetium products shall be tested for molybdenum contamination and the amount of molybdenum present shall be stated.
- The Radiopharmacy shall be USP <797> compliant for sterile compounding and shall provide a statement to this effect.
- Product information including supplier's source of radiopharmaceuticals, package inserts, results of quality control testing performed by supplier and copies of supplier's license and procedures shall be provided upon request at no additional charge.
- Consultation service regarding radiopharmaceutical applications, problems, controls, etc., shall be provided upon request at no charge.

2) **PERSONNEL AUTHORIZED TO PLACE ORDERS:** The following personnel are authorized to telephone and/or fax radiopharmaceutical orders:

- Supervisory Nuclear Medicine Technologist
- Nuclear Medicine Technologists
- Other VA Medical Center Staff as designated
- Authorized User

3) INVOICING:

- Contracting Officer's Representative (COR) shall be provided with a copy of invoice at the end of each week for approval **before** submission to the Department of Veteran Affairs Financial Services Center for processing. Said invoices will be sent the COR via e-mail and then reviewed for accuracy. The contractor will correct any discrepancies identified within 48 hours. A new invoice will be generated and then sent to the COR before invoice is finalized.
- Contractor shall be paid monthly, in arrears, upon submission of a properly prepared invoice for services/supplies during the period. Contractor shall submit a monthly invoice within 15 days after the end of the month being billed. The invoice will be accurate and include the contract number, date of services, and an itemized listing of charges for each line item. Invoices shall be submitted electronically to: Sherry.DeRuzzo@va.gov for certification.
- Contractor shall submit certified invoices monthly. Invoices at a minimum shall show period covered, billing date, name of preparation, quantity and amount.

4) PERFORMANCE/QUALITY:

- a. Incorrectly delivered doses shall not exceed one per quarter.
- b. Any doses deemed below standard by the facility shall be credited toward the account and shall not exceed one per quarter, i.e. 4 per year.
- c. It is the offeror's responsibility to provide the VA with recall notices on any product that has been delivered to the VA that may be defective. Notification shall be made to the Contracting Officer Representative via the most expedient method.
- d. All technetium products shall be tested for molybdenum contamination and the amount of molybdenum present shall be stated.
- e. Contractor shall provide complete documentation of quality control results upon request. Product information including supplier's source of radiopharmaceuticals, package inserts, results of quality control testing performed by supplier and copies of supplier's license and procedures shall be provided at no additional charge.
- f. Contractor will perform quality control on each agent dispensed. Contractor shall perform all quality control procedures as required by Federal and State regulatory agencies. Only those products that pass Quality Control may be sent to the VA Nuclear Medicine Service. The supplier will demonstrate documentation of Quality Control performance of any item upon request of the VA Nuclear Medicine Service.
- g. All products are purchased subject to acceptance by the VA, Nuclear Medicine Service. Products that fail to meet Quality Control criteria of Nuclear Medicine will not be accepted. Products will be rejected and may be discarded if found unsatisfactory by the Nuclear Medicine's Quality Control when they are received, or later if deterioration of the product occurs before the expiration date. The VA will not be financially liable for unacceptable materials.

5) Services Summary

Task	Indicator	Standard	Acceptable Quality Level	Method of Surveillance	Incentive/ Disincentives
First Daily Delivery of Radiopharmaceuticals To Bay Pines VAHCS	Timeliness	Between 6:30AM and 7:30AM Monday through Friday	100%	Observation	Past Performance
Second Daily Delivery of Radiopharmaceuticals To Bay Pines VAHCS	Timeliness	10:00 AM Monday through Friday	100%	Observation	Past Performance
Third Daily Delivery of Radiopharmaceuticals To Bay Pines VAHCS	Timeliness	1:00 PM Monday through Friday	100%	Observation	Past Performance
STAT deliveries made to Bay Pines within 2 hours of order	Timeliness	Dose arrives with 2 hours of phone order	100%	Observation	Past Performance
Accurate Invoicing for Bay Pines	Vendor billing price matches contract price	No errors per monthly invoice	100%	100% Inspection	Past Performance

- 6) **QUALIFICATIONS:** Personnel assigned by the contractor to perform the services covered by this contract shall be licensed in a State, Territory, or Commonwealth of the United States or the District of Columbia. The qualifications of such personnel shall also be subject to review by the VA Chief of Staff and approval by VA Facility Director.
- 7) **PERSONNEL POLICY:** The contractor shall be responsible for protecting the personnel furnishing services under this contract. To carry out this responsibility, the contractor shall provide the following for these personnel: worker's compensation professional liability insurance health examinations, income tax withholding and Social Security payments. Such personnel shall not be considered VA employees for any purpose and shall be considered employees of the contractor.
- 8) **MODIFICATION:** In accordance with FAR 52.212-4(c), changes may only be made by a written modification which is formally executed by the contractor and the Contracting Officer.

1. HHS/OIG

To ensure that the individuals providing services under the contract have not engaged in fraud or abuse regarding Sections 1128 and 1128A of the Social Security Act regarding federal health care programs, the contractor is required to check the Health and Human Services - Office of Inspector General (HHS/OIG), List of Excluded Individuals/Entities on the OIG Website (www.hhs.gov/oig) for each person providing services under this contract. The listed parties and entities may not receive Federal Health Care program payments due to fraud and/or abuse of the Medicare and Medicaid programs. During the performance of this contract the contractor is prohibited from using any individual or business listed on the List of Excluded Individuals/Entities. Any healthcare provider or entity that employ or enter into contracts with excluded individuals or entities may have a Civil Monetary Penalty (CMP) imposed against them. By signing this offer, the Contractor certifies that all persons or entities listed in the contractor's proposal have been compared against the OIG list and are NOT listed as of the date the offer was signed.

2. DESIGNATION OF CONTRACT REPRESENTATIVE

COR will be designated in writing. COR will be furnishing technical guidance and advice regarding the work being performed under this contract. The foregoing is not to be construed as authorization to interpret or furnish advice and information to the Contractor relative to the financial or legal aspects of the contract. Enforcement of these segments is vested in and is the responsibility of the Contracting Officer.

3. CONTRACTOR RECALL AND SAFETY PLAN AND PROCESS NOTIFICATION TO FACILITIES

All contractors shall take immediate action to notify the Contracting Officers Representative (COR) whenever a product, piece of equipment or item is recalled or considered dangerous, hazardous or unsafe in order to remove such products, equipment or items from use. This notification process also applies to safety alerts. The contractor recall and safety notification plan and process is necessary so that proper notification to individuals who have received or individuals who may utilize such products, equipment or items can be made in as expedient and efficient manner as possible. The contractor shall provide to the COR their plan for this safety notification process and also maintain a record system in order to document any safety incident issues by their date, time, and description of the recall or safety alert issue provided to the COR.