

**STATEMENT OF WORK  
RADIOPHARMACEUTICAL SUPPLIES  
MONTANA VA HEALTHCARE SYSTEM  
FORT HARRISON, MONTANA**

The Montana VA Health Care System has a requirement for radiopharmaceuticals. These products will be used for human administration during diagnostic nuclear medicine studies.

**DESCRIPTION OF SERVICES / REQUIREMENTS**

1. Normally orders shall be placed mid to late work day and delivery shall be no later than 7:30 AM the following work day. Due to the demands of the Medical Center care requirements; there shall be no restriction to the number of orders which may be placed by VA or the number of deliveries which may be required per day. In the event that the requirements may be determined in advance, a longer delivery time will be scheduled accordingly.
2. Depending upon the availability of the product, the Contractor shall make deliveries within three (3) hours after orders are placed during business hours, 7:30 am to 4:30 pm Monday through Friday.
3. The Contractor will provide 24 hour on call service for emergent procedures, both within and outside of normal business hours. Times designated as outside of normal business hours are:
  - a. Monday through Friday from 4:30 pm to 7:30 am
  - b. Weekends from Friday at 4:30 pm until Monday at 7:30 am
  - c. Federal holidays
    - New Year's Day
    - Martin Luther King Day
    - President's Day
    - Memorial Day
    - Independence Day
    - Labor Day
    - Columbus Day
    - Veterans' Day
    - Thanksgiving Day
    - Christmas Day
  - d. In addition, any other day specifically declared by the President of the United States is considered to be a federal holiday. It should be noted, if a holiday falls on Saturday, it is observed on Friday. If a holiday falls on Sunday, it is observed on Monday.
4. Orders can be placed orally by telephone and/or facsimile transmission.

5. The Contractor will provide one (1) 20mCi Cobalt 57 sheet source every two years, as listed in the Schedule of Supplies section of this document. The used sheet sources will be removed from the Nuclear Medicine area and properly disposed of by the Contractor. The sheet source will measure approximately 16.4 inches by 24.2 inches, but is dependent upon the make and model of gamma camera in use at the time.
6. All products provided under this contract shall meet all requirements of the Nuclear Regulatory Commission (NRC). All products provided under this contract shall be packaged and shipped in accordance with the requirements of the NRC and Department of Transportation (DOT). All products returned will also be packaged in accordance with the requirements of the NRC and the DOT.
7. All packaging of radioactive material must be clearly labeled "RADIOACTIVE" on the outside of the shipping carton.
8. The Contractor will comply with all OSHA manufacturing, packaging and shipping regulations.
9. All shipping containers will be returned to the Contractor.

#### **QUALITY CONTROL**

1. The Contractor will perform all quality control procedures as required by Federal and State regulatory agencies.
2. The contractor shall guarantee the quality of all radiopharmaceuticals. Quality Control will include percent tag, Molybdenum 99 breakthrough, and Aluminum breakthrough testing as appropriate. The Contractor will provide Quality Control on each agent dispensed. The Contractor shall provide complete documentation on Quality Control results upon request.
3. The contractor shall provide a quarterly linearity source, as listed in the Schedule of Supplies section of this document. The activity requested can range from 25 to 100 mCi.
4. **RECALLED AND DEFECTIVE PRODUCTS:** The Contractor will immediately notify the Contracting Officer's Representative (COR) and/or the Imaging Service Supervisor of any product recalls or other important product safety issues. As appropriate, the Contractor will replace and/or reimburse recalled/defective products at no cost to the Government. The Contractor may be liable for the cost of processing recalls, i.e. administrative and clinical services to replace recalled/defective products.

**RECORD KEEPING**

1. The Contractor shall label all supplies with the amount of radiopharmaceutical, preparation time, expiration time, date, and provide a bar code label to allow scanning data into a nuclear medicine information management system.

**QUALIFICATIONS**

The Contractor must be licensed by the Nuclear Regulatory Commission (NRC) and be regularly established in the business of providing radiopharmaceuticals for medical use. The Contractor is required to meet USP 797 compounding standards and will furnish proof of compliance on demand.

**PLACE OF PERFORMANCE**

Montana VA Health Care System  
3687 Veterans Drive  
Fort Harrison, MT 59636