

ATTACHMENT 1 - STATEMENT OF WORK

A. GENERAL INFORMATION

1. Title of Project: **Statement of Work – PET Radiopharmaceutical Supplies**
2. Scope of Work: The contractor shall provide all resources necessary to accomplish the deliverables described in this statement of work, except as may otherwise be specified.
3. Background: Radiopharmaceuticals are used as a diagnostic tool in the evaluation of organ function and certain disease processes including but not limited to detection and/or staging of cancers, coronary artery disease, cardiac viability, facetogenic disease.
4. Performance Period:

For time period covering FY 2017 (Oct 1, 2016 through Sept 30, 2017)

Normal working hours for the Nuclear Medicine Service at VAPAHCS are Monday through Friday, 7:30 a.m. through 5:30 p.m. Services may be required for patient care after normal operating hours during the week and on Saturdays by prior arrangement. See Section F for list of observed Federal Holidays.

B. GENERAL REQUIREMENT

The contractor agrees to provide prepared single unit doses of pet-radiopharmaceuticals and associated materials to VAPAHCS as ordered and at the agreed upon price. Orders shall be placed each day (Monday through Friday by 4:30PM) for delivery the next business day (Monday through Friday) at least 30 minutes prior to 18F dose calibration times. For N13-Ammonia, the dose is to be delivered no less than 5 minutes prior to dose calibration time. Due to the demands of the Medical Center patient care requirements, contractor shall provide routine delivery and pick-up as many times as required by the VAPAHCS at no additional charge. For additional orders placed during normal business hours for same day delivery, deliveries must arrive within 30-45 minutes of order placement for 18F-FDG. Add-on orders for N13-Ammonia are to be received within 3 hours of receipt of order. In the event that the requirements may be determined in advance, a longer delivery time may be scheduled accordingly.

Required PET-Radiopharmaceuticals:

- 18F-FDG
- 18F-NaF
- N13 Ammonia
- Amyvid
- FluciclovineF18 (pending FDA approval)
- Delivery
- STAT fees for same day orders

HEALTH ENTERPRISE STRATEGY/HEALTH INFORMATICS STRATEGY

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Please reference “Attachment 2 – Price-Cost Schedule for Estimated Usage”.

Proposals will be considered only from Offerors who are regularly established in the business that is called for, and who in the judgment of the Contracting Officer are financially responsible and able to show evidence of the reliability, ability, experience, equipment, facilities and personnel directly employed or supervised by them to render prompt and satisfactory service.

C. SPECIFIC MANDATORY TASKS AND ASSOCIATED DELIVERABLES

1. 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 quote to the Contracting Officer.**
2. Contractor shall have available an adequate supply of contract products to meet the requirements of the VAPAHCS at its distribution points.
3. Contractor shall label all supplies as to the amount of radiopharmaceutical, preparation time, expiration time, date, etc. compliant with nuclear medicine information system.
4. All packaging of radioactive material **MUST BE** clearly labeled **RADIOACTIVE** on the outside of the shipping carton.
5. Contractor shall perform all quality control procedures as required by Federal and State regulatory agencies and Joint Commission.
6. Contractor shall meet all Nuclear Regulatory Commission, Department of Transportation, FDA, OSHA and all other agency rules and regulations (Federal and State).
7. 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).

D. SCHEDULE FOR DELIVERABLES

Orders can be placed by the VAPAHCS via telephone, fax, or e-mail.

The following Federal Holidays are observed:

New Year's Day

Birthday of Martin Luther King, Jr.(day of observance)

Washington's Birthday

Memorial Day

Independence Day

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Labor Day

Columbus Day

Veterans Day

Thanksgiving Day

Christmas Day

Delivery of supplies by the scheduled date will be complete except as otherwise authorized by the Ordering Personnel.

Radiopharmaceuticals shall be delivered to:

Bldg 100, Rm E1-340 located within the Nuclear Medicine Department

VAPAHCS

3801 Miranda Ave.

Palo Alto, CA 94304

If for any reason any deliverable cannot be delivered within the scheduled time frame, the contractor is required to notify the VAPAHCS Nuclear Medicine Service by phone or in writing as soon as is feasible.

E. CHANGES TO STATEMENT OF WORK

Any changes to this SOW shall be authorized and approved only through written correspondence from the CO. A copy of each change will be kept in a project folder along with all other products of the project. Costs incurred by the contractor through the actions of parties other than the CO shall be borne by the contractor.

F. GOVERNMENT RESPONSIBILITIES

The Nuclear Medicine Service of the VAPAHCS shall ensure that:

- The specification of the Product (radiopharmaceutical) is safe for the intended use
- The products are handled in a safe manner, and
- Any waste originating from the Products is disposed of in accordance with any relevant regulations.

G. CONTRACTOR PERSONNEL SECURITY REQUIREMENTS¹

The C&A requirements do not apply. A Security Accreditation Package is not required.