

STATEMENT OF WORK:
NUCLEAR MEDICINE SERVICE – PET/CT RADIOPHARMACEUTICALS

August 28, 2018

The radiopharmaceutical requirement is for the radiopharmaceuticals F¹⁸ FDG and F¹⁸ NaF, as well as any other necessary sources and ancillary supplies needed for the GE Discovery 690 PET/CT scanner.

Contractor must be licensed by the Nuclear Regulatory Commission or an Agreement State under equivalent regulations and be regularly established in the business of providing radiopharmaceuticals.

Contractor/supplier shall abide by Title 10, Code of Federal Regulation, which states:

A Licensee may use for medical purposes only:

- (a) By-product material or cyclotron produced materials 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.
- (b) Reagent kit that has been manufactured, labeled, packed and distributed in accordance with approval by the Commission pursuant to Title 10 CFR 32.72 or an Agreement State under equivalent regulations for the preparation of radiopharmaceuticals for medical use.

Contractor will deliver radioisotope in amount equal to or greater than the activity ordered with calibration for the specified appointment time.

Contractor shall have available an adequate supply of contract products to meet the requirements of the Oklahoma City Department of Veterans Affairs Medical Center with proof of contingency supply chain (where such contingency supply chain exists) to prevent disruption of clinical care.

Contractor shall be able to supply delivered PET radiopharmaceuticals as unit doses or in container compatible with MEDRAD Intego Pet Delivery System. Contractor is responsible for supplying container(s) compatible with MEDRAD Intego system.

All packages containing radioactive material must be labeled and shipped in accordance with Title 49, Code of Federal Regulations Part 172 and 173.

Contractor shall perform all quality control procedures as required by Federal and State regulatory agencies.

Contractor shall meet all Nuclear Regulatory Commission, National Health Physics Program (NHPP), Department of Transportation, FDA, OSHA, and all other agency rules and

regulations (Federal and State), as well as any applicable Joint Commission Requirements.

PET Radiopharmaceutical Returns for Credit:

The Contractor shall be responsible to accept returns for full credit toward future orders. Particularly 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.

Note: OKC-VAMC can return at least 5% of radioisotope due to patient cancellation or no show at no cost to the facility.

Normal/ Routine PET Radiopharmaceutical Ordering and Deliveries:

Orders shall be placed by authorized VA personnel during the normal workday, and first delivery shall be received no earlier than 06:30 am the following workday to the Oklahoma City VAMC Nuclear Medicine Service – PET Department (1G-114)

After award, the Contractor will be furnished the name(s) of VA personnel that are authorized to place orders against the Contract. Orders shall only be placed by authorized VA OKC Nuclear Medicine personnel via telephone, fax, e-mail or on-line.

Depending upon Medical Center patient care requirements, the contractor shall provide routine delivery and pick-up, as many times as required by the OKC VAMC.

Contractor agrees to accept unused radiopharmaceutical and provide reimbursement per unit dose applicable towards future orders.

On-time Delivery

Contractor is responsible for on time delivery of radiopharmaceutical and will have back-up facilities/production options available (where such contingency supply chain exists). All cancelled PET/CT scans due to contractor delayed delivery will be the responsibility of the contractor and the returned dose will not count towards the allotted 5% of available returns due to patient no show or cancellation.

The Contractor will be furnished with a copy of the user's license information as per Nuclear Regulatory Commission guidelines.

Same-Day Delivery

Contractor will be available for Emergency orders in accordance with the schedule of supplies.

Same-Day Delivery is required to be delivered and received at the OKC VAMC Nuclear Medicine PET/CT Service no later than 4 hours after order is placed during normal business hours. Nuclear Medicine PET/CT normal business hours are considered Monday through Friday: 7:00 am – 4:30 pm, except Federal Holidays.

The following are Federal Holidays:

New Year's Day

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

Washington's Birthday

Memorial Day

Independence Day

Labor Day

Columbus Day

Veteran's Day

Thanksgiving Day

Christmas Day

(Any other day designated as a National Holiday by the President of the United States.)

Ordering Contact Information: Contractor shall provide contact information for the placement of orders for items listed in the "Schedule of Supplies and Services" Section.

POC Name:

Address:

City/State/Zip Code:

Ordering Phone Number:

Ordering Fax Number:

Ordering E-Mail Address:

DELIVERY COMMITMENT: Time of delivery specified or mutually agreed to at the time of receipt of telephone /fax orders/ on-line order shall become mandatory upon the Contractor's acceptance to commitment.

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

DELIVERY LOCATION:

Deliveries will be made to:

OKC VA Medical Center
Attn: PET Center -1G-114
921 NE 13th St
OKC, OK 73104

Contract/Delivery personnel shall be escorted within the Radiation Oncology center to the PET/CT Hot lab by Nuclear Medicine personnel. The C&A requirements do not apply, and that a Security Accreditation Package is not required

Upon request by the COR, the Contractor shall provide miscellaneous supplies and/or services including, but not limited to the following:

A copy of reports of contractor's RSO Safety Audits of Federal compliance.