

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

Acquisition Plan Action ID: VA256-18-AP-3532

1. **Contracting Activity:** Department of Veterans Affairs, NCO 16, Division II, Supply Team C, Veterans Healthcare System of the Ozarks Fayetteville, AR, Purchase Request Number 564-18-3-150-0160. This is a request for other than full and open competition.
2. **Nature and/or Description of the Action Being Processed:** New Procurement action IAW FAR 13.5 resulting in a Firm Fixed Priced Purchase Order with Base Year and Four 1-Year Options.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for Delivery of radiopharmaceutical isotopes to VHSO Fayetteville, AR in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Delivery of radiopharmaceutical isotopes. The estimated cost of this procurement is
See attached SOW

Base Year 1 April 2018 - 31 March 2019
Option 1 1 April 2019 - 31 March 2020
Option 2 1 April 2020 - 31 March 2021
Option 3 1 April 2021 - 31 March 2022
Option 4 1 April 2022 - 31 March 2023

Total Amount

4. **Statutory Authority Permitting Other than Full and Open Competition:**

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
() (2) Unusual and Compelling Urgency per FAR 6.302-2;
() (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
() (4) International Agreement per FAR 6.302-4
() (5) Authorized or Required by Statute FAR 6.302-5;
() (6) National Security per FAR 6.302-6;
() (7) Public Interest per FAR 6.302-7;

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

a. The radioactive isotopes are needed to perform diagnostic nuclear imaging procedures, some of which are also used for treatment of specific diseases. Diagnostic radioactive isotopes have a short shelf life and must be ordered on a daily basis. Due to the volatility of the nuclear isotopes it is necessary to administer required doses within 12 hours of manufacture to prevent degradation and/or mutation of the isotopes. Nuclear isotopes have the capability of splitting, in effect increasing the molecular content (strength) of a given dose beyond that which is necessary or safe for administration.

b. The use of a local vendor is essential with the short shelf life of the radioisotopes. It is imperative that the vendor has the delivery capabilities to provide a dose when needed. When procedures are added on during the day, whether it is an emergency or a patient being worked up with a new diagnosis, the Government needs to be able to provide that patient the ability to perform his/her scan as soon as possible. Due to the volatility of nuclear isotopes it is necessary to administer required doses within 12 hours of manufacture to prevent degradation and/or mutation of isotopes. Nuclear isotopes have the capability of splitting, in effect increasing the molecular content (strength) of a given dose beyond that which is necessary of safe for administration. The contractor must be capable of delivering the isotopes within one (1) hour of receipt of a request and on emergency basis.

c. Cardinal Health 144, LLC is the only known manufacturing facility in the tristate area of Arkansas, Missouri, and Oklahoma that can meet the Government's requirement. Cardinal Health is currently providing the nuclear isotopes to the Veterans Healthcare System of the Ozarks located in Fayetteville, AR. Cardinal Health 114, LLC has met the requirements of Purchase order VA256-17-P-0056 in an exceptional manner. No other vendor is located near enough to meet the delivery times required to provide timely and proper treatment of acutely ill veterans, and specified in the SOW.

(d)The contractor grants the VA nonexclusive, nontransferable license to possess and use the software package in machine-readable form only on a single personal computer located at the VHSD nuclear Medicine Dept. This software refers to the Syntac nuclear medicine software. This program is the record keeping workhorse of this department. Within it is stored eight years of record keeping to include but not limited to: Dosage to every patient, DOT, NRC, and NHPP approved records of all incoming and outgoing radiation. Records of all daily, weekly, quarterly, semiannual, and annual quality assurance testing on all hot lab equipment. Records of all daily and weekly radiation survey tests. This program is specific to Cardinal Health. Alternate companies could offer no software package that could accurately transfer this data to an alternate software package. Identification of another capable source would entail a lengthy process of getting another software program evaluated by the Nuclear Medicine Department.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: *The procurement of the incumbent contract produced only one responsive quote. Other vendors expressed interest, but were unable to conform to the delivery times specified in the SOW. The delivery times in the SOW are determined by physicians in accordance with best practices in providing patient care. Until another capable provider enters the geographic area, or technology provides better delivery methods, Cardinal is the only known capable source.*

7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** *The anticipated cost to the Government is determined to be fair and reasonable based on a comparison of the cost of similar items procured by other VA Medical Centers and the cost of these items on current purchase order.*
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** A review of the procurement of the current contract shows only one capable source. Capability of sources is limited by medically indicated delivery times and dearth of competition in the immediate geographical area. A Sources Sought – Sole Source Intent Notice will be published on FBO for this procurement to test our assumption that Cardinal is the sole capable source.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**
11. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:**
Government will seek full and open competition on subsequent acquisitions for required supplies or services when it is in the best interest of the Government and the Veterans.
12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

Eddie Landreth
Lead MRI Technologist (COR)
564-Veterans Healthcare System of the Ozarks

Date

13. **Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP](#):**

- a. **Contracting Officer or Designee's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

PAUL FILHIOL
Contracting Officer
NCO 16, Division II, Supply Team C

Date

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Sole Source Justification Format >\$150K

- b. **One Level Above the Contracting Officer (Required over\$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

RENATA OTT
Branch Chief
NCO 16, Division II, Supply Team C

Date

- c. **VHA SAO HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

RANDY L. HAYS
Deputy Director, Service Area Office (SAO) Central
VHA Head of Contracting Activity (HCA)

Date