

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)
For
Other Than Full and Open Competition (>SAT)

Acquisition Plan Action ID: VA257-18-AP-5324

1. **Contracting Activity:** Department of Veterans Affairs, SAO West, Network Contracting Office 17, on behalf of the Amarillo VA Health Care System (AVAHCS) intends to enter into a Blanket Purchase Agreement (BPA), on a sole source basis, with Panhandle Nuclear Rx, Ltd., for the purchase of Radiopharmaceuticals.
2. **Nature and/or Description of the Action Being Processed:** The AVAHCS, located in Amarillo, Texas, requires radiopharmaceuticals for dispensing to hospital patients. Radioactive Isotopes along with other substances are compounded to create various radiopharmaceuticals. The drugs must be compounded within close geographic proximity to the facility. This is because some radiopharmaceuticals require administration to patients within two (2) hours of compounding.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for radiopharmaceuticals and 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:** The AVAHCS, located in Amarillo, Texas, requires radiopharmaceuticals for dispensing to hospital patients. along with other substances are compounded to create various radiopharmaceuticals. The drugs must be compounded within close geographic proximity to the facility. This is because some radiopharmaceuticals require administration to patients within two (2) hours of compounding.

Exact radiopharmaceutical needs cannot be known prior to being prescribed by a Clinician for a specific patient; however, the facility can estimate the number of drugs required. Therefore, the government anticipates a BPA to be awarded pursuant to FAR Part 13.303.

The estimated value of the procurement, including options is \$387,036.00. Coverage is to begin on 10/01/2018 and will consist with one (1) base period of a year, and one (1) option period of a year.

The following items will be required:

Description

Sestamibi 10-30mCi

Sestamibi 25mCi

Thallium 6mCi

Thallium 4mCi

Tc99m MAA 5mCi

Tc99m MDP 25mCi

OFOC SOP Revision 08

Original Date: 03/22/11

Revision 08 Date: 04/18/2018

Tc99m Sulfur Colloid 1mCi
Tc99m Sulfur Colloid 5-8mCi
Tc99m Sulfur Colloid 10-15mCi
Tc99m Filtered Sulfur Colloid 1mCi
Tc99m DTPA
Tc99m 04 30mCi
Tc99m Choletec 5-8mCi
Tc99m MAG3 4mCi, 8mCi, 10mCi
Tc99m 04 1-5mCi
Tc99m 04 50mCi
I-123 100 uCi CAP
I-123 200 uCi CAP
Xenon 133 Gas 10-30 mCi
In-111 WBC Tags with .3-.5mCi In-111
In-111 Octreoscan
I123 Mibg
Tc99m Ceretec WBC
Gallium Citrate per 10mCi

Co57 Point Source Markers
Co57 Flood 10mCi Perflexion PF24R-057-10M
Co57 Flood 10mCi Featherlight 3713 AD 010M

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

FAR13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** The industry for radiopharmaceuticals is very specialized and regulated; in the remote location of Amarillo, Texas, within the panhandle area of the state, very few compounding pharmacies specializing in radioactive drugs are available. Due to the facility's remote location, and need for geographically close pharmacies, sources are limited. Panhandle Nuclear Rx, Ltd., located in Amarillo, Texas is the only supplier who can provide the needed radiopharmaceuticals within the required delivery times.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Market Research was conducted in accordance with FAR Part 10. A search of VetBiz.gov revealed fifty-eight (58) matches under NAICS code 325412. These fifty-eight (58) contractors were contacted on 04/04/2018 in reference to both the AVAHCS' and the West Texas VA Health Care System's (WTVAHCS) radiopharmaceutical needs. Two (2) negative responses were received from industry, and zero (0) positive responses were received.

A Sources Sought Notice was issued on 04/12/2018, under 36C25718Q9188, in an attempt to identify contractors capable and willing to provide items to either the AVAHCS, the WTVAHCS, or both. One (1) response was received from industry. This contractor is the incumbent, Panhandle

Nuclear Rx, Ltd., for the AVAHCS and stated they would like to continue to provide radiopharmaceuticals to the AVAHCS, but are out of the WTVAHCS service area being approximately four (4) hours away by car. IsoRx Texas, Ltd. was identified as having locations in Odessa, Texas, and Lubbock, Texas; however, after speaking with representative Alex Whyte, IsoRx Texas, Ltd. declined to provide coverage to the AVAHCS. The radiopharmaceutical compounding industry is very specialized, and the remote geographic location of the AVAHCS results in a shortage of viable sources. Despite all efforts, the Contracting Officer was unable to identify any other source capable of fulfilling the minimum requirements of the AVAHCS.

7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The radioactive pharmaceutical industry experiences volatile changes in market pricing. This is driven by laws and regulations restricting the production of radioactive isotopes necessary for pharmaceutical compounding, radioactive isotope sources, and market demand. Industry generally declines to provide pricing for more than one (1) or two (2) years due to the volatility of the market. Any request from the government for additional option years would result in unreasonable costs passed on to the government. The CO anticipates no added value in requesting pricing for more than two (2) years. In addition, there is no national formulary or price indexing for this industry. Pricing will be determined fair and reasonable based upon pricing offered to industry within the commercial marketplace.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market Research was conducted in accordance with FAR Part 10. A search of VetBiz.gov revealed fifty-eight (58) matches under NAICS code 325412. These fifty-eight (58) contractors were contacted on 04/04/2018 in reference to both the AVAHCS' and the West Texas VA Health Care System's (WTVAHCS) radiopharmaceutical needs. Two (2) negative responses were received from industry, and zero (0) positive responses were received.

A Sources Sought Notice was issued on 04/12/2018 in an attempt to identify contractors capable and willing to provide items to either the WTVAHCS, the AVAHCS, or both. One (1) response was received from industry. This contractor is the incumbent, Panhandle Nuclear Rx, Ltd., for the AVAHCS and stated they would like to continue to provide radiopharmaceuticals to the AVAHCS, but are out of the WTVAHCS service area being approximately four (4) hours away by car. IsoRx Texas, Ltd. was identified as having locations in Odessa, Texas, and Lubbock, Texas; however, after speaking with representative Alex Whyte, IsoRx Texas, Ltd. declined to provide coverage to the AVAHCS. The radiopharmaceutical compounding industry is very specialized, and the remote geographic location of the AVAHCS results in a shortage of viable sources.

The Contracting Officer (CO) does not have a reasonable expectation of receiving two (2) or more quotes from SDVOSB, VOSB, small business, or unrestricted.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The unique nature of compounding pharmacies specializing in radiopharmaceuticals, combined with the remote location of the AVAHCS, results in a scarcity of sources. In addition, many contractors within the marketplace are not willing to compete with previously established contractors. This has resulted in IsoRx Texas, Ltd.'s decision to decline to quote for the AVAHCS facility.

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

Panhandle Nuclear Rx, Ltd.

6700 W 9th St.
Amarillo, TX 79106
806-352-9561

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:** At this time the government has no recourse to remove or overcome barriers to competition.
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.

Alan Kinzer
Radiology PACS Administrator
AVAHCS

6/13/18
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.

Michael J. Tusinger
Contracting Officer
NCO 17

6/26/18
Date

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

Jeff Morris
NCO 17 Division Chief I

Date