

DEPARTMENT OF VETERANS AFFAIRS

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

1. Contracting Activity:

Department of Veterans Affairs (VA), VISN 21-VA Palo Alto Health Care System (VAPAHCS), Nuclear Medicine intends to enter into a sole source contract with Sirtex Medical Inc. The Purchase Request Number is 640-15-1-053-0020.

2. Nature and/or Description of the Action Being Processed:

This is a new action to purchase SIR-Spheres Yttrium-90 (Y-90) Selective Internal Radiation Therapy (SIRT) microspheres with associated materials on an as needed basis. This will be a commercial item, firm-fixed price supply, requirements contract.

3. Description of Supplies/Services Required to Meet the Agency's Needs:

The VA Palo Alto Health Care System (VAPAHCS) is requesting a sole source contract with Sirtex Medical Inc. The proposed contract action is for the purchase of SIR-Spheres Yttrium-90 (Y-90) Selective Internal Radiation Therapy (SIRT) microspheres with associated materials on an as needed basis.

SIR-Spheres Y-90 is used to treat select cancers affecting the liver including hepatocellular carcinoma and liver metastases from colorectal cancer. The therapy involves the direct instillation of small radioactive beads into tumors within the liver where they become trapped, killing tumor cells and sparing the surrounding healthy liver parenchyma.

SIR-Spheres Y-90 will be ordered for selected patients designated for treatment on an as needed basis.

Estimated Value: Base Year (04/01/15 – 09/30/15):
Option Year 1 (10/01/15 – 09/30/16):
Option Year 2 (10/01/16 – 09/30/17):
Option Year 3 (10/01/15 – 09/30/18):
Option Year 4 (10/01/15 – 09/30/19):
Total:

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

41 USC §3304(a)(1), as implemented by FAR 6.302-1. Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1.

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

Sirtex Medical Inc. is the sole supplier of SIR-Spheres Y-90, and they do not have any authorized distributors.

SIR-Spheres Y-90 is a critical tool to ensure VA patients are treated effectively for liver tumors. It consists of extremely small radioactive resin beads. Selected patients will be provided Y-90 treatments for liver cancer. Unlike conventional external beam radiation, Y-90 selectively irradiates a liver tumor which provides the ability to deliver more potent doses of radiation directly to the cancer cells over a longer period.

"Accordingly, Sirtex Medical Inc. is the only firm capable of providing the supplies and services described in Section 3 above without the Veteran's Health Administration experiencing unacceptable delays in fulfilling its requirements.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

A Presolicitation Notice (VA261-15-N-0230) was posted via FBO on 01-20-2015 and closed on 01-30-2015.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:

By signing this document the Contracting Officer is determining that the anticipated cost to the Government will be fair and reasonable. This requirement is for a commercial item and is therefore exempt from requiring certified cost or pricing data. However, data other than certified cost or pricing data will be requested to ensure that VA is receiving a fair and reasonable price consistent with a comparison of Sirtex Medical's proposed price with prices found reasonable on previous purchases. Additionally, the basis for determining fair and reasonable pricing will include confirming with the requiring activity that the anticipated cost is consistent with general industry practices and pricing. Also, pricing for Therasphere which is also a Y-90 based therapy to treat liver tumors will be reviewed and compared against the cost of a SIR-Sphere.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

A Presolicitation Notice (VA261-15-N-0230) was issued for the purpose of synopsisizing that the VAPAHCS intends to negotiate a sole source contract with Sirtex Medical Inc. to manufacture and deliver SIR-Spheres Y-90. Any firm that believed it could provide an equivalent product had the opportunity to provide written notification to the Contracting Officer for consideration.

One response was received from BTG International Group indicating that they could provide a Therasphere Y-90 product. The desired product requested by the VAPAHCS is a SIR-Sphere Y-90 provided by Sirtex Medical Inc. Y-90 is a catheter-based therapy that delivers internal radiation to hepatic tumor as either a constituent of a glass microsphere (Therasphere), or as a biocompatible resin-based microsphere (SIR-Sphere). Therasphere and SIR-Sphere are both Y-90 based therapies to treat liver tumors. However, the radioactive material is different and the products are used for

slightly different indications. SIR-Sphere is used to treat select cancers affecting the liver including hepatocellular carcinoma and liver metastases from colorectal cancer. Therasphere is used to treat primary liver cancer. Therefore, Therasphere Y-90 from BTG International Group cannot be considered an equivalent source to the SIR-Sphere Y-90 product provided by Sirtex Medical Inc. BTG International Group confirmed that their Therasphere Y-90 product could not meet the current intended indication treatment requested by the VAPAHCS.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

Specifications, engineering descriptions, statements of work, statements of objectives, or purchase descriptions suitable for full and open competition are not being used because VA has determined that only one supplier can supply and deliver this therapy dose which VA requires.

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

As stated above in Section 6, one source expressed interest. However, that source confirmed that their therapy dose was not an equal product to the SIR-Sphere product required by VA.

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:

No follow-on competitive acquisition is planned. However, VA will continue to monitor the commercial marketplace to determine if other sources have started to supply and deliver SIR-Sphere products.

