



DEPARTMENT OF VETERANS AFFAIRS
Office of Procurement, Acquisition and Logistics (OPAL)
Strategic Acquisition Center (SAC)
5202 Presidents Ct, Suite 103
Frederick, MD 21703

**SOLE SOURCE JUSTIFICATION UNDER SIMPLIFIED PROCEDURES FOR
CERTAIN COMMERCIAL ITEMS IN ACCORDANCE WITH FAR 13.5**

1. Contracting Activity:

Department of Veterans Affairs, Office of Healthcare Innovation and Learning (OHIL),
Office of Advanced Manufacturing (OAM)

2. Description of the Action Being Processed:

This procurement is for 3D printing support, equipment and supplies 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.

The Department of Veterans Affairs (VA), Office of Healthcare Innovation and Learning has a requirement for contract support to significantly expand advanced manufacturing technology and material offerings within VHA. Specifically, this contract will support the development, testing and manufacturing of soft goods out of a proprietary material known as Free Foam (DuraChain Resin XTR-50), which allows for volume production of goods such as custom wheelchair seat cushions, mattresses for spinal cord injury patients and patient positioning devices at the Point of Care. This material and the printers that utilize it will allow VA to explore a completely novel form of manufacturing through expandable resins that can make products at a fraction of their final size, minimizing storage and warehousing needs. When the product is needed, it is placed briefly in a thermal oven, which expands the part to its final size. This work will drive VHA innovations in both logistics and volume-based manufacturing at the point of care.

This is a new firm-fixed price contract.

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

Supplies: Xtreme 8K printer(s) and LightBar 6P printer(s), DuraChain Resin, and necessary support equipment including curing apparatus, drying oven and accessories, conveyor oven, thermal oven, and wash station. This effort is a sole source procurement to DESKTOP METAL OPERATING, INC. 63 3rd Ave Burlington, MA 01803. The proposed cost for a 12 month base plus two 12 month option years is

██████████

SOLE SOURCE JUSTIFICATION

The contractor shall provide:

- Printable formulations, including photopolymer resins that produce dimensionally accurate closed cell foam parts using 3D printing technology (digital light processing)
- Equipment, software, and maintenance service required to manufacture expandable 3D printed parts out of Free Foam materials
- Product development, technical, engineering, and scientific support related to point of care manufacturing using Free Foam
- Remote Technical support for manufacturing optimization within the hospital
- On site contractor support for product development and manufacturing using 3D printers at the point of care in VHA medical centers
- Processes to ensure reproducibility of all required activities to deliver safe and effective medical products meeting all regulatory VA quality requirements
- On-site technical training and guidance at VA campuses

Services: VHA requires onsite and remote extended contractor support and training on soft good product design, development, testing, as well as optimization of on-site manufacturing processes using DuraChain Resin.

The contractor shall provide:

- Product development, technical, engineering, and scientific support, though both on-site contractor operational support and remote technical support
- Support for VHA clinical implementation of the product, including manufacturing optimization within the hospital, though both on-site contractor operational support and remote technical support

4. Statutory Authority Permitting Restricted Competition:

FAR 13.5 Simplified Procedures for Certain Commercial Items. The statutory authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. § 1901 and is implemented by FAR 13.106-1(b)(2) for restricting competition on this procurement. **Competition is restricted on this procurement for the reason below:**

- (x) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements
- () Unusual and Compelling Urgency
- () Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services
- () International Agreement
- () Authorized or Required by Statute
- () National Security
- () Public Interest

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

OAM's vision is to provide personalized, safe, and equitable care for eligible Veterans by building advanced manufacturing (AM) capabilities across the enterprise. Point of care (PoC) manufacturing allows for health care solutions that are personalized to the Veteran. To date, personalized durable soft goods such as wheelchair cushions, mattresses, diabetic foot insoles and patient positioning devices have been difficult or impossible to make with AM, given limitations in materials and printers. However, recent technological advances from a 3D printing company, Desktop Metal Operating, Inc., has opened up this possibility. Desktop Metal Operating, Inc. recently announced a proprietary material referred to as "Free Foam" with the following salient characteristics:

- Closed cell foam
- Printed part can be expanded between 2- 7 times in an oven, maintaining tight tolerance
- Wide range of shore hardness values
- No tooling required
- Operating temperature -55 to 105 deg C
- Volumetric Expansion Factor 3.6 +/- 0.3 m³/m³

Desktop Metal Operating, Inc. has the only material of its kind on the market, and this material is essential to meeting OAM's mission of providing Veterans with customized solutions, particularly for health care issues that disproportionately affect Veterans, such as spinal cord injuries, wheelchair use, and diabetes. Through this contract, VHA will additionally receive a large format prototype printer for printing with FreeFoam materials. This printer is not available to the general public for purchase and is proprietary technology protected under an NDA between VHA and Desktop Metal Operating, Inc. VHA will also receive extensive, extended training through Desktop Metal Operating, Inc. employees on site for a total of 17 months, as well as through dedicated off-site training and support for a total of 17 months. Desktop Metal Operating, Inc. is the only vendor capable of providing the supplies and services described in Section III above to the VHA; without these supplies and services, VHA will experience significant delays in developing technologies essential to Veteran health, including women Veterans, amputees, and spinal cord injury patients.

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

VHA staff within the Office of Advanced Manufacturing have spent years looking for appropriate 3D printing materials that could be used for durable, patient-matched soft goods such as wheelchair cushions, mattresses, and diabetic foot insoles. This includes attendance to over 25 different conferences over the past five years, visits to General Electric, Covestro, 3D Systems, Materialise, Carbon, and other 3D vendors to discuss material offerings, and frequent internet searches for new patents, product releases, or news stories. Until the Desktop Metal Operating, Inc. material release, no material had sufficient properties and an appropriate price point to make these patient-matched soft goods feasible for manufacture within VA. VHA entered into a mutual Non-Disclosure

SOLE SOURCE JUSTIFICATION

Agreement NDA with Desktop Metal Operating, Inc. to confirm that the new material offering met the design needs for Veteran products, and subject matter experts confirmed that the material was viable for several priority VHA projects.

Based on the information obtained from the Vendor Information Page (VIP), the Government identified no additional sources. The select services/supplies are not readily available on an existing purchasing vehicle (such as a GWAC, Internal IDIQ, GSA FSS, etc.)

In accordance with VAAR 810.001-70, the Vendor Information Page (VIP) database was queried, and results are shown attached. Based on the information obtained from VIP above, the Government identified potential 0 Service-Disabled, Veteran-Owned Small Businesses. The services are not readily available on an existing purchasing vehicle (such as a GWAC, Internal IDIQ, GSA FSS, etc.).

The VIP was searched NAICs code "333249", yielding 49 companies. Those results were cross referenced for the term "expandable", which included 0 organizations, but those results are not relevant to this action. The GSA e-library was searched for "expandable", yielding 4 description matches, but none was appropriate.

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

No award shall be made until the Contracting Officer determines the cost to the Government to be fair and reasonable. This determination will be based on a comparison of current contract pricing, past proposal submissions (if available), other information made available, and an Independent Government Cost Estimate.

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

VHA staff within the Office of Advanced Manufacturing have spent years looking for appropriate 3D printing materials that could be used for durable, patient-matched soft goods such as wheelchair cushions, mattresses, and diabetic foot insoles. This includes attendance to over 25 different conferences over the past - five years, visits to General Electric, Covestro, 3D Systems, Materialise, Carbon, and other 3D vendors to discuss material offerings, and frequent internet searches for new patents, product releases, or news stories. Until the Desktop Metal Operating, Inc. material release, no material had sufficient properties and an appropriate price point to make these patient-matched soft goods feasible for manufacture within VA. VHA entered into a mutual NDA with Desktop Metal Operating, Inc. to confirm that the new material offering met the design needs for Veteran products, and subject matter experts confirmed that the material was viable for several priority VHA projects.

Through requests for information, we obtained the following information:

General Electric created a large facility dedicated to 3D printing and related technologies and outfitted it with 3D printers from a wide variety of manufacturers.

SOLE SOURCE JUSTIFICATION

At this facility, they service medical, aerospace, locomotive, industrial casting, and other applications. Though they have broad and deep experiences in 3D printing, their experience mirrored ours in that they had not yet found soft materials that are resilient, tough, and inexpensive.

Covestro manufactures a large variety of polymers and elastomers for many applications, including 3D printing. However, they did not offer any expandable materials for 3D printing.

3D Systems manufactures 3D printers across a range of process types. They do not offer expandable materials for 3D printing or a 3D printer capable of making objects at a very large scale.

Carbon manufactures SLA 3D printers and offer an excellent soft and tough EPU material that we have experience with. However, that material is prohibitively expensive for large prints. Additionally, they do not offer expandable 3D printed materials or a 3D printer capable of making objects at a very large scale.

VHA entered into a mutual NDA with Desktop Metal Operating, Inc. to confirm that the new material offering met the design needs for Veteran products, and subject matter experts confirmed that the material was viable for several priority VHA projects.

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

Currently, no other comparable product exists on the open market.

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

Desktop Metal Operating, Inc. has expressed in writing their 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:

We will continue to perform market research, including attending trade shows and conferences, reaching out to known manufacturers in the field, and continue searching for patents and press releases to ensure that if other materials come to market meeting OAM's needs, future contacts will be open to competition.

SOLE SOURCE JUSTIFICATION

[REDACTED]

[REDACTED]

[REDACTED]

A

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]