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**Comptroller General
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Washington, DC 20548**

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Decision

Matter of: Triad Isotopes, Inc.

File: B-411360

Date: July 16, 2015

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DIGEST

Protest is sustained where the agency's market research was insufficient to conclude that the agency would likely receive quotations from at least two responsible small business concerns that could meet the requirements in the RFQ at a fair market price, and therefore, the agency's decision to restrict the solicitation to small business concerns was unreasonable.

DECISION

Triad Isotopes, Inc., of Orlando, Florida, protests the decision of the Department of Veterans Affairs (VA) to issue request for quotations (RFQ) No. VA247-15-Q-0330, for the acquisition of radiopharmaceuticals, as a small business set-aside. Triad contends that the agency's market research did not provide a reasonable basis to conclude that the agency would receive proposals from two or more small business concerns, and therefore, argues that the requirement should be competed on an unrestricted basis.

We sustain the protest.

BACKGROUND

On April 2, 2015, the VA issued the current RFQ for the manufacture and delivery of radiopharmaceutical¹ and non-radiopharmaceutical items, as a small business set-aside, and designated North American Industry Classification System (NAICS) code 325412, Pharmaceutical Preparation Manufacturing, which has a corresponding size standard of 750 employees, as the size standard for small business participation in the procurement. RFQ at 2. The solicitation also states that the acquisition is to be conducted under the commercial item and simplified acquisition procedures of Federal Acquisition Regulation (FAR) subparts 12.6 and 13.5. Id. at 2.

The RFQ anticipates the issuance of a fixed-price contract, for a base year and four 1-year options. RFQ at 2-6. The solicitation states that the award will be made on a lowest-priced, technically-acceptable basis.² Id. To be considered technically acceptable, the RFQ requires, as relevant here, that a vendor provide a copy of the company's business license and insurance, as well as a "written description in sufficient detail to allow the Government to ascertain the Offeror[']s capability to meet the requirements indicated in the [statement of work (SOW)]." Id. at 7. The solicitation further states that this description should demonstrate the vendor's ability to meet . . . the required delivery timeframes, including the ability to respond to a medical emergency requirement, and that vendors should show "demonstrated ability to produce non-HEU (High Enriched Uranium) radioisotopes." Id. at 7-8. In addition, the RFQ provides: "If the offeror is not a manufacturer of a required item, the offeror must provide evidence they are an authorized distributor or reseller of the proposed items." Id. at 7.

The Market Research Supporting the Set-Aside Decision

The decision to set-aside this procurement for small businesses resulted from market research conducted in November 2014. AR, Tab 1, Market Research Report (Nov. 13, 2014), at 1. Specifically, the stated objective of the market research was "[t]o award a . . . contract to a contractor who can provide the required radioisotopes³ for the Ralph H. Johnson VA Medical Center." Id. The market

¹ The terms radiopharmaceuticals and radioisotopes are used interchangeably in this decision.

² The estimated value of the procurement is approximately \$4 million. Agency Report (AR), Tab 1, VA Form 2268, at 1.

³ Radiopharmaceuticals are used in the field of nuclear medicine as radioactive tracers in medical imaging and in therapy for many diseases. AR at 1. The shelf-life (expiry period) of a radiopharmaceutical preparation depends primarily on the physical half-life of the radioisotope, the radiochemical stability and the content

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research report stated that “[t]he Contractor must have the appropriate permits and licenses⁴ to manufacture Radioisotopes and must be able to deliver them in a timely manner.” Id. The report also stated: “Contractor must have insurance and have proven past performance and experience for the production and delivery needs of the [VA Medical Center].” Id.

The market research included “[a] search of vetbiz.gov on November 14th, 2014, for NAICS code 325412 (Pharmaceutical Preparation Manufacturing (size standard 750) . . . with no state restrictions,” the result of which, “netted 14 companies.” Id. The market research also involved “[a] search of the SBA Dynamic Small Business Database (DSBD) with NAICS 325412[, which] produced six hundred and seventy-six (676) vendors.” Id. The report explained that the “Market Research was not limited by state or location, as it is common for Pharmaceutical companies which produce Radioisotopes to have facilities in other locations with their headquarters locations which show in DSBD.” Id. at 2.

The market research report also noted the results of prior attempts to procure these items. Id. Specifically, the report stated that a solicitation for the same requirement was posted on September 9, 2014, for isotope manufacture and delivery, with a performance period of 4 months. Id. The report explained that the previous solicitation was for a shorter term contract (October 1, 2014 – January 31, 2015) until a longer term contract could be awarded. Id. The report noted that the solicitation was not restricted to small business concerns, and that the agency received three proposals in response to the solicitation. Id. at 2. The report also stated: “While only one small business responded to the recent solicitation, it was only for 120 days. A five year long contract should result in more interest.” Id. at 2. The overall recommendation of the contracting officer, based on the market research report, was that “this requirement should be set aside for Small Business,

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of longer-lived radionuclidic impurities included during the preparation. Id. at 2. The agency explains that “[m]any radiopharmaceutical preparations contain radioisotopes with very short half-lives and such preparations therefore have very short shelf-lives,” which require indication of the expiry date and time. Id.

⁴ Because of the potentially hazardous properties of radioisotopes, their use is closely regulated to ensure that public health and safety are protected. See NUREG/BR-0217, Revision 1, The Regulation and Use of Radioisotopes in Today’s World, at 6, available at: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0217/r1/br0217r1.pdf> (last visited July 16, 2015). The U.S. Nuclear Regulatory Commission (NRC), and certain States that have entered into agreements to assume regulatory authority from the NRC, coordinate the licensing and regulation of the production of radioisotopes through machines (called linear accelerators or cyclotrons). Id. at 7-8.

as there are a number of small businesses under this NAICS who could submit a proposal for the Ralph H. Johnson VA Medical Center.” Id. at 2. There is no evidence in the record, however, that this requirement has previously been set aside for small businesses.

Triad filed this protest challenging the agency’s decision to issue the RFQ as a small business set-aside, prior to the RFQ’s closing date of April 8. In response to the protest, the agency advised that it received only one quotation by the April 8 closing date. Contracting Officer (CO) Statement at 1. During the course of this protest, the agency has also advised that it received a quotation from a second small business vendor, but noted that the quotation was received after the closing date. Id. The VA has not advised our Office of the name of the second vendor, or provided any information about the company.

DISCUSSION

Triad challenges the VA’s decision to set aside this acquisition for exclusive small business participation. Specifically, Triad protests the adequacy of the agency’s market research, arguing that the agency’s market research was flawed and inconsistent with the terms of the RFQ.⁵ As discussed in greater detail below, Triad contends that: (1) the agency’s search of two databases for small businesses operating under NAICS Code 325412 could not properly support a conclusion that there are small businesses manufacturing radiopharmaceuticals that can meet the delivery requirements of the RFQ because the applicable NAICS code includes a large array of different types of businesses manufacturing all types of pharmaceuticals, including cold medicines and lip balms; and (2) the agency’s previous award to an ostensible small business should not be viewed as evidence that a small business has the capability to manufacture these products because the

⁵ Triad also asserts that the RFQ’s delivery terms are ambiguous because they do not adequately define the delivery requirements for emergency situations. In support of this argument, the protester notes that, although the previous solicitation specified a 45 minute time frame for responding to emergencies, the instant solicitation states only: “There may be requests placed during other than normal working hours, possibly to be delivered quickly for an emergency.” RFQ at 5. In response, the agency states that it removed the 45 minute requirement because the agency “requires offerors [to] provide acceptable emergent procedures, but they do not constrain them to a specific 45 minute time limit.” AR at 9. Because we sustain the protest based on the inadequacy of the agency’s market research, we need not address the protester’s allegations challenging the terms of the RFQ at this time. We note, however, that in light of the agency’s statements regarding the “very short half-lives” of “many radiopharmaceutical preparations,” AR at 2, the agency may want to consider these allegations, and clarify the agency’s requirements, when taking the corrective action recommended below.

agency never considered whether the putative small business can meet the manufacturing requirement that applies to the selected NAICS code. In short, Triad contends that the VA has not reasonably shown that there is even one small business that can both meet the requirement that it manufacture its own radiopharmaceuticals and meet the brief delivery requirements set out in the solicitation.

For the reasons discussed below, we conclude that the agency's market research was insufficient to support the agency's conclusion that it would receive viable quotations from at least two responsible small business concerns. We therefore find that the agency's reliance on the market research in deciding to restrict the RFQ to small businesses was unreasonable.

Under Federal Acquisition Regulation (FAR) § 19.502-2(b), a procurement with an anticipated dollar value of more than \$150,000, must be set aside for exclusive small business participation when there is a reasonable expectation that offers will be received from at least two responsible small business concerns, and award will be made at a fair market price. No particular method of assessing the availability of capable small businesses is required; rather, the assessment must be based on sufficient facts so as to establish its reasonableness. Mountain W. Helicopters, LLC; Trans Aero, Ltd., B-408150, B-408150.2, July 1, 2013, CPD ¶ 152 at 2, 3. The decision whether to set aside a procurement may be based on an analysis of factors such as the prior procurement history, the recommendations of appropriate small business specialists, and market surveys that include responses to sources sought announcements. Commonwealth Home Health Care, Inc., B-400163, July 24, 2008, 2008 CPD ¶ 140 at 3.

A contracting agency's investigation to determine the availability of responsible small business concerns for set-aside purposes, however, must address not only the existence of small businesses that might submit proposals, but also their capability to perform the contract; the fact that multiple small businesses are identified in the course of market research is not necessarily determinative. See The Protective Grp., Inc., B-310018, Nov. 13, 2007, 2007 CPD ¶ 208 at 3. In this regard, we have held that the contracting officer must make reasonable efforts to ascertain whether it is likely that offers will be received from at least two small businesses capable of performing the work. DNO Inc., B-406256, B-406256.2, Mar. 22, 2012, 2012 CPD ¶ 136 at 4; Information Ventures, Inc., B-279924, Aug. 7, 1998, 98-2 CPD ¶ 37 at 3 (stating that the contracting agency's investigation goes not only to the existence of the businesses, but also to their capability to perform the contract).

As relevant here, in order to qualify as a small business concern to provide manufactured products or other supply items, an offeror must either be the manufacturer or producer of the end item being procured, or if it does not manufacture the item being purchased, the offeror must comply with what is known

as the nonmanufacturer rule. 13 C.F.R. § 121.406(a). The nonmanufacturer rule provides that the offer of a nonmanufacturer small business concern can be considered, provided, among other things, that the small business concern represents that it will supply the product of a domestic small business manufacturer or processor, or that a waiver of this requirement is granted by the SBA. 15 U.S.C. § 637(a)(17); see also 13 C.F.R. § 121.406.

Whether the nonmanufacturer rule should be included in a procurement set aside for small businesses primarily depends on the NAICS code assigned to the procurement by the procuring agency.⁶ See BlueStar Energy Solutions, B-405690, Dec. 12, 2011, 2011 CPD ¶ 275 at 3. In this regard, “[t]he nonmanufacturer rule applies only to procurements that have been assigned a manufacturing or supply NAICS code.” 13 C.F.R. § 121.406(b)(2)(C)(ii)(3); see FAR § 19.303(a)(2) (“A concern that submits an offer or [quotation] for a contract where the NAICS code assigned to the contract is one for supplies, and furnishes a product it did not itself manufacture or produce, is categorized as a nonmanufacturer and deemed small if it meets the requirements of [the nonmanufacturer rule].”). The contracting officer is tasked with “determin[ing] the appropriate [NAICS] code and related small business size standard and includ[ing] them in solicitations.” Id. § 19.303(a)(1); see 13 C.F.R. § 121.402(b). In this regard, the contracting officer “shall select the NAICS code which best describes the principal purpose of the product or service being acquired.” FAR § 19.303(a)(2).

Triad argues that the VA’s market research failed to assess whether any of the businesses identified by researching the two databases actually manufactured radioisotopes, or was otherwise able to qualify as a small business concern under the NAICS code for this procurement. In this regard, the RFQ here provides that, “[i]f the offeror is not a manufacturer of a required item, the offeror must provide evidence they are an authorized distributor or reseller of the proposed items.” See RFQ at 7. Triad contends that without considering whether any of the identified businesses, or the incumbent contractor for the requirement, could provide the radioisotopes or otherwise meet the nonmanufacturer rule, the contracting officer could not have known, based on the market research, whether any of the identified businesses qualify as small for this procurement.

Triad also notes that the relevant NAICS code covers a broad swath of pharmaceutical manufacturing—from the manufacturing of cold medicines and lip balms, to the manufacturing of radiopharmaceuticals.⁷ The protester argues that

⁶ The NAICS code scheme is used by the federal government to identify and classify specific categories of business activity that represent the lines of business a firm conducts. See FAR § 19.102; BlueStar Energy Solutions, supra, at 3 n.2.

⁷ The protester points out that there appear to be 72 different pharmaceutical preparation manufacturing industries included within NAICS code 325412. These
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the contracting officer's conclusion that there would be small businesses available in the field of radiopharmaceuticals could not reasonably be based on the number of small businesses included under such a broad NAICS code.

In defending the adequacy of the conclusions set forth in its market research report, the VA, in its initial response to this protest, acknowledged that the nonmanufacturer rule applies to this procurement. The report stated: "[T]here is no indication that the incumbent contractor cannot comply with the nonmanufacturer rule." AR at 8. The agency also noted that, under the nonmanufacturing rule, the small business must be "capable of providing the end item" or "supply the end item manufactured by a small business manufacturer, process or producer made in the United States." Id.

In its supplemental agency report, the VA changed its view, and asserts that the nonmanufacturer rule does not apply to the procurement. Specifically, the contracting officer asserts that she viewed the solicitation as a service contract, rather than a manufacturing contract, and therefore, states that she did not consider as part of her market research whether the identified businesses, or the incumbent contractor, were a manufacturer of radioisotopes. CO Statement (June 16, 2015), at 2 ("The agency did not consider the cyclotron in the evaluation of Market Research. . . . [W]e viewed this as a Service, and did not consider the manufacture of the underlying base pharmaceutical."); Supp. AR (June 16, 2015), at 3.

In short, and as developed further below, we agree with the protester on the basic underpinning of its challenge. If the VA did not consider the issue of whether the companies it identified manufacture radiopharmaceuticals, or could comply with the solicitation's delivery requirements, the agency could not reasonably assess whether there are eligible small business concerns capable of performing the requirements of the RFQ.

As an initial matter, despite the CO's representation that she "did not consider the manufacture of the underlying base pharmaceutical," id., there is little basis for dispute that the NAICS code here was a manufacturing code. As discussed above, this solicitation is for the provision of and delivery of radiopharmaceutical and non-

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separate pharmaceutical industries include, for example: adrenal medicinal preparations manufacturing, antacid preparations manufacturing, belladonna preparations manufacturing, cough drops (medicated) manufacturing, effervescent salts manufacturing, lip balms manufacturing, mouthwashes (medicated) manufacturing, nuclear medicine (e.g., radioactive isotopes) preparations manufacturing, tranquilizer preparations manufacturing, vitamin preparations manufacturing, and zinc oxide medicinal preparations manufacturing. Protester's Comments (May 22, 2015), exh. 4, NAICS Definition, at 1-3.

radiopharmaceutical items. RFQ at 5. The NAICS code assigned by the contracting officer to this procurement is 325412, Pharmaceutical Preparation Manufacturing. RFQ at 1. This code, on its face, is a manufacturing code.⁸

In addition, at no point during this protest has the agency contended that the NAICS code it selected was not appropriate for this procurement.⁹ Rather, the contracting officer explains that, “[b]ased on the unit dose¹⁰ nature of this requirement, [she] viewed this as a Service [contract].” Supplemental CO Statement (June 16, 2015), at 2. There is an inconsistency between the statement above, and the NAICS code incorporated into this procurement. As stated above, application of the nonmanufacturer rule depends primarily on the NAICS code assigned to the procurement, and it is the contracting officer who is responsible for designating the proper NAICS code. See FAR § 19.303(a)(2); BlueStar Energy Solutions, supra, at 2.

We conclude that the contracting officer’s market research failed to support an assessment as to whether the identified companies were radiopharmaceutical providers, or otherwise capable of performing the contract requirements. See Information Ventures, Inc., supra (stating that the required inquiry for the contracting officer goes not only to the existence of small businesses that might submit proposals, but also to small businesses’ capabilities to perform the contract requirements). Specifically, the agency’s database searches were based solely on the RFQ’s NAICS code, which as mentioned above, covers a wide range of pharmaceutical manufacturing—from the manufacturing of lip balms, to the manufacturing of nuclear medicine (e.g., radioisotopes). There is no indication in the market research report, or otherwise, that any of the identified companies are radiopharmaceutical providers or have the required nuclear pharmacy licenses to perform under the contract. AR, Tab 1, Market Research Report, at 1-4; see also

⁸ In addition, the RFQ includes a supply classification code, rather than a service code, further reflecting the contemporaneous intent of the agency to categorize the solicitation as one for supplies, not services. RFQ at 1 (stating that the Federal Supply Classification Code is 65 (medical, dental & veterinary equipment & supplies)).

⁹ The Small Business Administration (SBA) regulations discussing the applicable size standards for government procurements state that “[a] procurement is usually classified according to the component which accounts for the greatest percentage of contract value,” and that “[a]cquisitions for supplies must be classified under the appropriate manufacturing or supply NAICS code.” 13 C.F.R. § 121.402(b)(2).

¹⁰ The agency states that “unit dose(s)” are “prepared by the vendor off site and delivered at specific times throughout the day such that the . . . technician combines the radioactive specific isotopes with the appropriate medications to ensure that the dosage is patient specific.” AR at 2.

Protester's Comments (May 22, 2015), at 6-7, exh. 5, Pharmacy License Registration Information for Small Business References. Accordingly, we find the contracting officer's determination that there was a reasonable expectation of receiving offers from at least two responsible small business concerns was not based on sufficient facts or market research to establish its reasonableness. We sustain the protest on this basis.

The agency also argues that its assessment of the availability of small business concerns was reasonable--despite the failure to consider the capability of the identified businesses to provide or manufacture the radiopharmaceuticals--because it also considered the performance of the incumbent contractor for this requirement.¹¹ As discussed above, the market research report stated that, "[w]hile only one small business responded to the recent [unrestricted] solicitation, it was only for 120 days," and "[a] five year long contract should result in more interest." Id. at 2. Accordingly, the contracting officer concluded that "this requirement should be set aside for Small Business, as there are a number of small businesses under this NAICS code [that] could submit a proposal for the . . . VA Medical Center." Id.

During the course of this protest, the contracting officer conceded that she did not assess whether the incumbent contractor met the eligibility requirements under the RFQ's NAICS code to qualify as a small business concern for this procurement. Supplemental CO Statement (June 16, 2015), at 2. In addition, the protester has raised concerns, at this point unrebutted, that the incumbent may not be able to meet the nonmanufacturer rule (which incidentally, would not have applied in the previous procurement because the procurement was not conducted as a small business set-aside).¹² Any conclusion about whether the incumbent contractor can, or cannot, comply with the nonmanufacturer rule is a matter for the Small Business Administration, not our Office; thus, we reach no conclusion on this issue. Bid Protest Regulations, 4 C.F.R. § 21.5(b)(1). That said, the contracting officer has acknowledged that, at this point, the issue has not been considered. Accordingly, we find that the contracting officer's reliance on the assumption that the incumbent contractor qualified as small in determining that there was a reasonable expectation

¹¹ Specifically, the contracting officer states that "[t]he incumbent Small Business had adequately performed on [its] contract, and the customer had indicated their satisfaction of [the incumbent's] performance in the delivery of unit dose radiopharmaceuticals." CO Statement (June 16, 2015), at 2.

¹² Triad also contends that the incumbent contractor is not able to manufacture the radiopharmaceuticals required by the RFQ because it does not possess a cyclotron, which the protester explains, is a particular type of particle accelerator required to produce certain of the radioisotopes required by the RFQ. Protest at 9.

of receiving offers from at least two responsible small business concerns was not based on sufficient facts to establish its reasonableness.¹³

Finally, the VA contends that it received offers from two small businesses in response to the solicitation (although the second offer was received after the solicitation's closing date), and that the receipt of these offers reflects the reasonableness of the contracting officer's determination to restrict the procurement to small business concerns. While our case law has found in certain circumstances that the receipt of offers from two or more apparently responsible small businesses in response to the RFQ may support an agency's decision to set aside a procurement for small business concerns, see York Int'l Corp., B-244748, Sept. 30, 1991, 91-2 CPD ¶ 282 at 7, the receipt of the offers here does not remedy the flawed market research or failure of the contracting officer to evaluate the market research in accordance with the RFQ. The one timely quotation received by the agency prior to the solicitation's closing date was submitted by the incumbent contractor. AR at 6. As discussed above, however, the contracting officer admittedly failed to consider whether the incumbent manufactures or provides radioisotopes, or otherwise qualifies as small under the pertinent NAICS code. Instead, the contracting officer states that the incumbent's delivery services under the prior contract adequately support the incumbent's capability to perform a service contract. In these circumstances, where the contracting officer is not assessing small business eligibility in accordance with the agency's actual requirements, we find that the agency's receipt of one timely offer (from an ostensible small business), and one late one (from a business the VA represents is small) does not support the contracting officer's determination that there was a reasonable expectation of receiving offers from at least two responsible small business concerns that could meet the RFQ's requirements.

On this record, we find no support for the contracting officer's assumption that any of the companies identified in the market research report fall within the radiopharmaceuticals industry, or were capable of performing the contract requirements. We further conclude that it was not reasonable for the agency to base its assessment of the availability of small business concerns on search results

¹³ The agency also argues that the VA small business liaison's concurrence with the contracting officer's recommendation to restrict the procurement to small business concerns demonstrates that the contracting officer's decision was reasonable. Supplemental AR (June 16, 2015), at 2. The small business liaison, however, based her concurrence on the same database search results in the market research report, as the contracting officer. As discussed previously, we conclude that the search results, without more, are insufficient for assessing the availability of small business concerns for this procurement. Accordingly, the small business liaison's reliance on the same insufficient market research results is no more persuasive than the contracting officer's conclusion.

that merely identified the existence of small businesses under the pertinent NAICS code. While we express no view on whether the agency might be able to support a reasonable decision to set aside this requirement for small businesses, we find that the agency offered no reasonable basis to do so here. As a result, we sustain the protest.

SUMMARY AND RECOMMENDATION

We find that the VA's market research was insufficient to conclude that the agency would receive quotations from at least two responsible small business concerns that could meet the requirements in the RFQ at a fair market price. For this reason, the agency's decision to restrict the solicitation to small business concerns was unreasonable. We recommend that the contracting officer conduct a proper market survey, in accordance with the agency's requirements for this procurement and this decision, to ascertain whether there is a reasonable expectation that at least two or more responsible small business concerns will submit quotations at fair market prices. We also recommend that Triad be reimbursed the reasonable costs of filing and pursuing the protest, including reasonable attorneys' fees. The protester should submit its certified claims for costs directly to the contracting agency within 60 days after receipt of this decision. Bid Protest Regulations, 4 C.F.R. § 21.8(f)(1).

The protest is sustained.

Susan A. Poling
General Counsel