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Decision

Matter of: ICU Medical, Inc.

File: B-422151; B-422151.2; B-422151.3

Date: January 4, 2024

Merle M. DeLancey, Esq., and Michael J. Slattery, Esq., Blank Rome LLP, for the protester.

William A. Shook, Esq., The Law Offices of William A. Shook PLLC, for CareFusion Solutions, LLC, the intervenor.

Erika Whelan Retta, Esq., Colonel Patricia S. Wiegman-Lenz, Major Ryan P. Payne, Major Craig M. Brunson, and Major Zachary T. Thurber, Department of the Air Force, for the agency.

Todd C. Culliton, Esq., and Tania Calhoun, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

1. Protest that the agency unreasonably described the services to be procured as part of a simplified acquisition conducted on a sole-source basis is denied where the record does not show that the agency inaccurately described the services.
 2. Protest that the agency improperly made the price reasonableness determination is denied where the record shows that the agency reasonably compared the quoted price against the independent government estimate and the historical price paid for the service.
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DECISION

ICU Medical, Inc., of San Clemente, California, protests the award of a contract issued on a sole-source basis to CareFusion Solutions, LLC, of San Diego, California, under request for quotations (RFQ) No. FA442723-Q-0076, issued by the Department of the Air Force for infusion pump software maintenance services. ICU argues that the Air Force unreasonably issued the contract on a sole-source basis because it erroneously concluded that only CareFusion can provide the requisite services and failed to determine that the awarded contract price was fair and reasonable.

We deny the protest.

BACKGROUND

On May 24, 2023, the Air Force posted a sources sought notice to SAM.gov, soliciting interest from vendors in providing software maintenance services for the agency's inventory of CareFusion Infusion Pump Systems (*i.e.*, the Alaris pump system) in use at the David Grant Medical Center (DGMC), Travis Air Force Base (AFB), California.¹ Contracting Officer's Statement (COS) at 3; Agency Report (AR), Tab 8, Justification and Approval (J&A) at 2-3. On June 13, the agency disseminated a request for information to industry vendors. COS at 3. Based on this market research, the agency determined that only CareFusion was authorized to provide software maintenance services for the Alaris pump systems. *Id.* The agency estimated the contract price to be \$254,150. AR, Tab 4, Market Research and Acquisition Report at 1.

On August 23, the Air Force finalized the RFQ, and sent it directly to CareFusion. COS at 3; AR, Tab 5, RFQ at 1.² The RFQ contemplates the issuance of a fixed-price purchase order to be performed over a 1-year base period and four 1-year option periods, under which the vendor will provide full-service software maintenance services to the agency's inventory of Alaris pump systems in use at Travis AFB, California. RFQ at 1, 8-9. The RFQ advises that the procurement was conducted under the commercial items and simplified acquisition procedures (*i.e.*, Federal Acquisition Regulation (FAR) parts 12 and 13). *Id.* at 1.

On September 12, the Air Force provided notice of its intent to issue the purchase order on a sole-source basis (*i.e.*, the sole-source notice (SSN)) in SAM.gov. The SSN communicated that the agency intended to procure software maintenance services for the Alaris pump systems from CareFusion. AR, Tab 6, SSN at 3. The SSN explained that CareFusion is the only authorized software maintenance provider for these pump systems. *Id.*

On September 22, ICU sent a letter to the Air Force, requesting that the agency issue a solicitation for contractors to provide entirely new pump systems. Protest, exh. B, Letter from ICU to Air Force at 1. ICU explained that CareFusion will not be able to provide software maintenance without replacing the existing pump systems. *Id.* According to ICU, any Alaris pump system that is six years or older must be replaced pursuant to a product recall, as those older systems are incompatible with required software updates. Protest at 7.

On October 2, the Air Force finalized its J&A for the sole-source award to CareFusion, and cited 10 U.S.C. § 3572 and Air Force Federal Acquisition Regulation Supplement

¹ CareFusion, a wholly owned subsidiary of Becton Dickinson and Company (BD), is the exclusive manufacturer of Alaris® products and software including Guardrails® Point-of-Care Software, Alaris® Pump Module, Alaris® Syringe Module, Alaris® PCA Module and Next Generation Alaris® PC Unit. AR, Tab 8, J&A at 2.

² Where available, citations to the report use the page numbers provided by the agency.

section 5313.501 as authority for the action. AR, Tab 8, J&A at 1. The J&A described the services to be procured as follows:

[DGMC] on Travis AFB, CA has a requirement for full service maintenance coverage of the Carefusion Systems Manager. The contractor shall provide all personnel, equipment, supplies, facilities, transportation, tools, materials, supervision, and other items and non-personal services necessary to perform Software Maintenance services for the Carefusion Infusion Pump System as defined in this Performance Work Statement (PWS) except for those items specified as government furnished property and services.

Id. at 2. The J&A explained that CareFusion's exclusive authority to provide software maintenance services to the Alaris pump systems supported the decision to procure the services on a sole-source basis. *Id.* Additionally, the J&A provides that the agency determined that the proposed price was fair and reasonable through comparison against historical prices paid. *Id.* at 3.

On October 11, the Air Force issued the purchase order to CareFusion in the amount of \$117,454. COS at 4. One day later, on October 12, the agency published the J&A. *Id.* On October 20, ICU filed this protest with our Office.

DISCUSSION

ICU raises multiple allegations challenging the agency's conduct of the acquisition. Principally, ICU argues that the agency unreasonably described the services to be procured as part of the J&A. Protest at 6. ICU also argues that the agency unreasonably determined that the contract price was fair. Protest at 7-8.

We have reviewed all the allegations and determine that none provide us with a basis to sustain the protest. We discuss the principal allegations in turn.³

Description of Services

ICU argues that the agency unreasonably awarded the contract on a sole-source basis to CareFusion because the Air Force improperly determined that only CareFusion could satisfy the government's needs. Protest at 6. In this regard, ICU contends that the Air Force cannot obtain only software maintenance services as contemplated by the J&A, but rather must procure new pumps and software due to product issues with the Alaris pump system. *Id.* at 6-7; First Supp. Protest at 9-10.

According to ICU, any Alaris pump system that is six-years or older must be replaced because those pumps are incompatible with software necessary to remedy issues

³ To the extent we do not discuss any allegation or argument, we have considered all the issues raised and conclude that none provide a basis to sustain the protest.

associated with a product recall. Protest at 7. As support, ICU points to a letter issued by CareFusion's parent company, BD, discussing the remediation efforts, and information set forth in a Department of Homeland Security, Cybersecurity and Infrastructure Security Agency (CISA) report describing cybersecurity vulnerabilities concerning the Alaris pump system. Protest at 7; First Supp. Protest at 9-10. Thus, because the agency must replace its existing Alaris pump systems with new pump systems to accommodate the necessary software, ICU contends that the J&A unreasonably described the services to be procured as only consisting of software maintenance services. Second Supp. Protest at 9.

The agency responds that ICU's allegation is factually incorrect because the Air Force obtained the pump systems in use at Travis AFB in June 2022, and therefore, these pumps are compatible with necessary software. Memorandum of Law (MOL) at 10.

As noted above, the agency conducted the acquisition using simplified procedures. These procedures, established under FAR part 13, are designed to promote efficiency and economy in contracting, and to avoid unnecessary burdens for agencies and contractors, where, as here, the value of the acquisition is less than \$250,000. See FAR 2.101 (simplified acquisition threshold); 13.002 (purpose of simplified acquisition procedures). When using them, agencies are only required to obtain competition to the maximum extent practicable. FAR 13.104. Under this standard, an agency may solicit from one source if the contracting officer determines that the circumstances of the contract action deem only one source reasonably available (e.g., an exclusive licensing agreement). FAR 13.106-1(b)(1). We review protests of sole-source determinations made in these procurements for reasonableness. *MCI Diagnostic Center, LLC*, B-418330, Mar. 11, 2020, 2020 CPD ¶ 103 at 5.

On this record, we find unobjectionable the agency's description of its need.⁴ Contrary to the premise of the protester's allegation, the record shows that the agency obtained 546 Alaris pump systems and PCU devices in June 2022, which means that these pump systems are only one-year old. AR, Tab 3, Material Inspection and Receiving Report, June 2022 at 1-4. Consistent with the product recall information, the agency explains that CareFusion will be able to remediate the pump systems since they are less than six-years old, and then will be able to provide software maintenance services for the duration of the issued purchased order. MOL at 10. In other words, the record shows that ICU's allegation is simply inaccurate, and that the agency's description of its need was valid since the pump systems do not need to be replaced and will require software maintenance as contemplated by the RFQ. See COS at 7. As a result, we

⁴ ICU also complains the J&A did not fully describe how the agency conducted the price reasonableness determination. See Comments at 26, n.10. While the agency acknowledges that the J&A was incomplete when posted, the record shows that the agency conducted the price reasonableness determination on September 30, which was before the finalization or issuance of the J&A. COS at 8-9. Thus, while the agency may have been remiss when drafting the J&A, the contract file nevertheless contained the requisite determination.

deny the protest allegation because the record shows that the J&A reasonably described the scope of the procurement as consisting of software maintenance services, and not for the purchase of new pump systems.⁵

Additionally, to the extent the protester argues that the agency should purchase new pump systems rather than maintain or remediate its existing inventory due to remediation costs or cybersecurity vulnerabilities, we view such challenge as arguing that the agency incorrectly determined its needs. See Comments at 16-19. Our decisions explain that the determination of an agency's minimum needs and the best method of accommodating them are primarily within the agency's discretion. See, e.g., *American Int'l Movers, Inc.*, B-419756, July 20, 2021, 2021 CPD ¶ 269 at 4; *A.B. Dick Co.*, B-219808, Oct. 10, 1985, 85-2 CPD ¶ 400 at 1-2. A protester's disagreement with the agency's judgment concerning the agency's needs and how to accommodate them does not show that such judgment is unreasonable. *American Int'l Movers, Inc.*, *supra*.

Here, the agency reasonably exercised its discretion in deciding to procure software maintenance services. While the pump systems may require some remediation via software updates and additional security measures, the agency explains that replacing the devices is not necessary, and that it needs only software maintenance to ensure the pump systems remain functional.⁶ See COS at 7. We view that explanation as

⁵ We are unpersuaded by ICU's argument that an affidavit submitted by CareFusion during the protest demonstrates that the agency plans to purchase new pump systems. CareFusion submitted an employee affidavit, which explained that the vendor would update the software to the latest version and provide other standard commercial services as part of the issued contract. Intervenor's Resp. to Req. for Dismissal, Employee Affidavit at 1-2. The Air Force explains that the employee's characterization of the contract duties is not attributable to the agency, and that any reference to "other standard commercial services" does not mean that the agency intends to receive services outside the RFQ's PWS. See MOL at 17. Further, we note that the employee specifically averred that the contract does not include or provide for the purchase of new pump systems. See Intervenor's Resp. to Req. for Dismissal, Employee Affidavit at 2

⁶ To the extent ICU argues that the agency unreasonably failed to consider vulnerabilities associated with the Alaris pump systems when defining its needs, we are unpersuaded. See Comments at 22. The record shows that the agency determined its needs as of July 10, 2023, and the CISA report was not issued until October 26, 2023. See AR, Tab 4, Market Research and Acquisition Report at 1; First Supp. Protest at 6. In any event, the agency explains that the vulnerabilities identified in the CISA report do not warrant replacing its entire inventory of nearly new Alaris pump systems because the identified vulnerabilities are not significant in the agency's estimation. MOL at 14 (explaining that identified vulnerabilities merely show that the pump systems are not "100 [percent] perfect"). Finally, the agency also explains that any course of action taken to address cybersecurity vulnerabilities are matters of contract administration because if the agency determines that the vulnerabilities compromise pump system performance, it will simply require CareFusion to mitigate such issues. *Id.* at 14, n.7.

reasonable because seeking to maintain existing useful inventory is perfectly sensible. Accordingly, we deny the protest allegation.

Determination of Fair and Reasonable Price

ICU argues that the Air Force failed to determine that the sole-source award would be made at a fair and reasonable price.⁷ Protest at 7-8; First Supp. Protest at 10-11. The agency responds that it reasonably found CareFusion's price fair and reasonable based on a comparison with the independent government estimate (IGE) as well as historical prices paid. MOL at 18-19.

Under FAR 13.106-3, before making award, the agency must determine that the proposed price is fair and reasonable. FAR 13.106-3(a). While price reasonableness should be determined based on comparing quoted prices, an agency may use alternate techniques when this comparison is not possible or practicable. FAR 13.106-1(a)(1-2). In such situations, the agency may use market research, comparison between proposed prices and historical prices or independent government estimates, current price lists, or any other reasonable basis. FAR 13.106-1(a)(2)(i-vii).

On this record, we have no basis to question the agency's determination that CareFusion's quoted price of \$117,454 was reasonable. The record shows that the agency compared the quoted price against the IGE and the price from the previous contract. AR, Tab 7, Fair and Reasonable Price Determination (FRPD) at 1-2. The agency noted that the quoted price, \$117,454, was lower than both the IGE, \$254,150, and the prior contract price of \$241,500. *Id.*

While the protester may assert that the figures of comparison are not reliable, the protester has not provided any data casting doubt on the reliability of those figures, such as contracts showing that software maintenance services are generally priced significantly lower. See Comments at 27. Additionally, to the extent ICU argues that the IGE and prior contract price are not valid comparisons because the agency recently determined that it needs maintenance for fewer pumps than originally anticipated, the record shows that CareFusion's quoted price per pump was consistent with the per pump prices of the IGE and prior contract. See AR, Tab 7, FRPD at 1-2. Accordingly, we deny the protest allegation.

The protest is denied.

Edda Emmanuelli Perez
General Counsel

⁷ The protester also argues that the price reasonableness analysis was flawed because the agency did not consider the cost of replacing the inventory of BD Alaris pumps. See Protest at 8. This allegation is without a basis because, as discussed above, the agency reasonably concluded that it only needs to procure software maintenance services, not replacement pumps.