U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.
Washington, DC 20548

Comptroller General
of the United States

Decision

Matter of: Xenex Disinfection Services, LLC

File: B-415897; B-415898

Date: April 17, 2018

Joseph W. Whitehead, Esq., and Scott M. Heimberg, Esq., Akin Gump Strauss Hauer & Feld LLP, for the protester.
Donald C. Mobly, Esq., and Lindsay C. Roop, Esq., Department of Veterans Affairs, for the agency.
Michael Willems, Esq., Eric Ransom, Esq., and Edward Goldstein, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

1. Where the term effectiveness was not defined in the solicitation and no accepted industry standard definition existed, agency's application of a common sense definition of the term was reasonable.

2. In procurement of disinfection devices for use in a hospital setting, where evaluation was based on agency review of peer-reviewed journals by evaluators with substantial expertise, we will not question an agency's exercise of medical judgment in assessing whether medical information is reliable or significant.

DECISION

Xenex Disinfection Services, LLC, a small business of San Antonio, Texas, protests the award of two contracts to Steriliz, LLC, of Rochester, New York, under solicitation Nos. VA250-17-Q-0774 and VA250-17-Q-0746 by the Department of Veterans Affairs (VA) for ultraviolet (UV) disinfection devices to be used in VA hospitals. The protester alleges that the awardee's product fails to meet material requirements of the solicitations and that the agency should have found the awardee technically unacceptable.

We deny the protests.

BACKGROUND

On June 26, 2017, the agency issued VA250-17-Q-0746 for whole-room UV disinfection systems, as a brand name or equal procurement identifying one of Xenex's UV disinfection systems as the brand name. Agency Report (AR), Tab 1, Agency Memorandum of Law (MOL) at 2. Similarly, on July 7, the agency issued VA250-17-Q-0774 also for UV disinfection systems. Id. at 3-4. Both the solicitations[1] outlined technical features required for the relevant UV disinfection systems, and both provided, in relevant part, that the disinfection system should provide UV disinfection with proven effectiveness against Clostridium difficile (CD), methicillin-resistant Staphylococcus aureus (MRSA), and vancomycin-resistant enterococci (VRE). AR, Tab 4, Request for Quotations (RFQ) No. VA250-17-Q-0746 at 5; AR, Tab 14, RFQ No. VA250-17-Q-0774 at 3-4. Both solicitations additionally provided that "effectiveness" would be verified by reviewing peer-reviewed journals. RFQ No. VA250-17-Q-0746 at 5; AR, Tab 15, Amendments to RFQ No. VA250-17-Q-0774 at 4

Of particular relevance to this protest, the solicitations did not further define the term "effectiveness." Both solicitations provided that award would be made using a best-value tradeoff and that quotations would be evaluated for: (1) meeting technical requirements; (2) training/delivery schedule; and (3) price. RFQ No. VA250-17-Q-0746 at 6; RFQ No. VA250-17-Q-0774 at 4. The agency received several quotations in response to both solicitations, including, in both cases, quotations from Steriliz and Xenex. MOL at 3, 5. Of note, Steriliz submitted a peer-reviewed study that assessed Steriliz's UV disinfection system as well as a second UV disinfection system from another manufacturer not at issue in this protest. AR, Tab 7, Elizabeth Bryce, M.D., et al., Postdischarge Decontamination of MRSA, VRE, and Clostridium Difficile Isolation Rooms using 2 Commercially Available Ultraviolet-C-emitting Devices, 44 Am. J. of Infection Control 416, 2015, in Steriliz Quotation for RFQ VA250-17-Q-0746 at 45. The study concluded that the two tested UV disinfection systems "effectively reduce patient room contamination with MRSA, VRE, and CD over and above manual cleaning when used sequentially." AR, Tab 7 at 48-49.

In the case of both solicitations, the agency subsequently conducted a technical review of the quotations, and determined that Steriliz represented the best value to the agency. Memorandum of Law at 3, 5. In both cases, Xenex filed agency-level protests of the award, which were subsequently denied or dismissed. Id. These protests followed.

[1] The protest arguments advanced and the relevant provisions of the solicitations are largely identical. We cite to the respective documents jointly, unless otherwise noted. The agency filed a single consolidated agency report to both protests, and the protester likewise filed consolidated comments on the agency report.

DISCUSSION

The protester argues that the awardee's product does not meet the technical requirements of the solicitations and the awardee should therefore be ineligible for award. Protest B-415897 at 2-3. Specifically, the protester argues in the alternative that: (1) "effectiveness" in the medical context has a recognized meaning, and the reports from peer-reviewed studies provided by the awardee do not indicate that the awardee's product is effective in this technical sense; and (2) even using the ordinary sense of the word "effectiveness," the peer-reviewed studies provided by the awardee do not actually support the effectiveness of the awardee's product. Id.

First, the protester argues that the medical community distinguishes between "efficacy" and "effectiveness" of products, where "efficacy" describes the ability of a product to produce the expected result under ideal or laboratory conditions, while "effectiveness" instead refers to the ability of a product to produce an effect in "real world" clinical settings. Id. The awardee's peer-reviewed studies, the protester argues, only show, at best, results in a laboratory setting (i.e. the efficacy of the product), but do not show the effectiveness of the awardee's product as required by the solicitation. Id. Additionally, the protester contends that it was unreasonable for the agency to rely on a definition of the term other than the industry standard meaning, and argues that our Office has come to the same conclusion in our prior cases. Protester's Comments at 2 (citing Nautica Int'l, Inc., B-254428, Dec. 15, 1993, 93-2 CPD ¶ 321). Furthermore, the protester argues that, even if a lay definition of effectiveness is used, the peer-reviewed journal article provided by the awardee does not support the effectiveness of its product because, among other things: (1) the study did not separate data reported for the two UV disinfection systems tested; (2) the tested UV disinfection systems struggled to fully disinfect large concentrations of organisms in protein suspensions; and (3) the reported results do not show a statistically significant effect in reducing CD, one of the pathogens for which the solicitation required proof of effectiveness. Id. at 3-5.

The agency replies that it applied a reasonable, common-sense definition of the term "effectiveness," which was not otherwise defined in the solicitations. MOL at 6. Further, the agency contends that the study in question showed that the use of the awardee's product reduced the number of CD, MRSA, and VRE organisms. Id. The agency additionally argues that the study Steriliz provided showed effectiveness even in the technical sense advanced by the protester, and that the studies relied on by the protester do not use the terms efficacy and effectiveness in a manner consistent with the protester's suggested definition. Id. at 7-8

An agency's technical evaluation is primarily a matter within the contracting agency's discretion, since the agency is responsible for defining its needs and the best method of accommodating them. Computer Sciences Corp., B-409386.2, B-409386.3, Jan. 8, 2015, 2015 CPD ¶ 34 at 3-4; Highmark Medicare Servs., Inc., et al., B-401062.5 et al., Oct. 29, 2010, 2010 CPD ¶ 285 at 12. Where there is some uncertainty as to the precise meaning of a term used in stating the solicitation's requirements, the application by agency evaluators of a common sense definition, based upon the agency's general

needs as reflected in the solicitation, is reasonable. See Dennis Marceron, B-270253, Feb. 21, 1996, 96-1 CPD ¶ 107 at 2-3; Anadigicom Corp., B-235349, Aug. 18, 1989, 89-2 CPD ¶ 151 at 3.

In this case, the agency's application of the ordinary meaning of "effectiveness" is unobjectionable. In the absence of a definition in the solicitations, the agency's view that a product is effective when it reduces the numbers of CD, MRSA, and VRE organisms is reasonable. The instant case is clearly distinguishable from our cases concluding that the agency must use an industry-standard definition of a term, primarily because, as the protester concedes, the term "effectiveness" is not uniformly defined even within the specialist community.[2] Compare Nautica Int'l, Inc., supra at 2-3 (concluding agency erred when deviating from a generally understood, standard definition of "boat length," embodied in Coast Guard regulations and endorsed by National Marine Manufacturers' Association) with Anadigicom Corp., supra at 3 (concluding agency was reasonable in applying a common sense definition of a "standard" telephone handset where there was no accepted industry standard definition of the term). The protester has provided no authority which would compel the use of its proposed definition, and has not demonstrated that the agency's reading of the term is unreasonable or inconsistent with the solicitations. See Stinger Ghaffarian Techs., Inc., B-411041.2 et al., Apr. 29, 2015, 2015 CPD ¶ 266.

The protester's collateral argument that, even taking an ordinary reading of the term "effectiveness," the provided peer-reviewed study does not actually support the effectiveness of the protester's product is similarly without merit. The study provided by

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[2] Specifically, the protester's comments include a declaration prepared by a medical expert, which concedes that "currently, no one accepted definition of effectiveness exists," but goes on to note that any definition of the term must include certain elements, and that the peer-reviewed study provided by the awardee was, in his opinion, "to a scientific degree of certainty […] not able to clearly distinguish between the effectiveness and efficacy" of the two instruments it evaluated. Comments, Expert Declaration at 12-13. While the declaration does refer to suggested criteria for effectiveness issued as a reference by the Department of Health and Human Services, Agency for Healthcare Research and Quality, the proposed criteria reinforce that there is no single clear definition of effectiveness. Agency for Healthcare Research and Quality Publication No. 06-0046, Technical Review No. 12, Criteria for Distinguishing Effectiveness From Efficacy Trials in Systematic Reviews (April, 2006). Rather, the suggested criteria identify a variety of characteristics which contribute to effectiveness, noting that "efficacy and effectiveness exist on a continuum." Id. at 3. Even assuming for the sake of argument that the protester's expert is correct in his conclusions that the study lacks proof of effectiveness in the specialist sense, it would likely have been unreasonable for the agency to apply so amorphous a definition of effectiveness without providing notice to offerors by including that definition of effectiveness in the solicitations. See, e.g., Nautica Int'l, Inc., supra at 5 (agency has an obligation to describe its needs accurately, so that all vendors may compete on a common basis).

the awardee indicates that it evaluated two UV disinfection systems (including the awardee's UV disinfection device) for "effectiveness in reducing" MRSA, VRA, and CD. AR, Tab 7 at 45. The study concluded that the UVC-emitting machines it evaluated[3] "effectively reduce patient room contamination with MRSA, VRE, and CD over and above manual cleaning when used sequentially." Id. at 48-49.

Here, the solicitations indicated that effectiveness would be assessed through review of studies in peer-reviewed journals. RFQ VA250-17-Q-0746 at 5; Amendments to RFQ VA250-17-Q-0774 at 4. Accordingly, the agency believed that it could reasonably rely on the conclusions of published peer-reviewed studies in making procurement decisions, and the agency's technical reviewers, who possessed significant medical expertise,[4] exercised their medical judgment in choosing to rely on the study Steriliz provided. While the agency's reliance appears reasonable--the peer-reviewed study concluded that the Steriliz system was effective in reducing CD, MRSA, and VRE organisms--as we have previously explained, it is not the role of our Office to question an agency's medical judgment, and we decline to do so here. See GlaxoSmithKline, B-291822, Apr. 7, 2003, 2003 CPD ¶ 77 at 4-5 (concluding that, among other things, an agency's methods for evaluating medical information and the significance given by the agency to medical information involve the agency's medical judgment and policies, which are inappropriate for review under our bid protest function); Knit-Rite, Inc., B-293088.3. Aug. 5, 2004, 2004 CPD ¶ 159 (concluding that where an evaluation is based on medical judgments of evaluators with substantial expertise in the field, our Office will not question such medical judgments in the absence of a showing that the evaluation was unfairly administered).

The protests are denied.

Thomas H. Armstrong
General Counsel

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[3] While, as the protester argues, some of the data presented in the study was aggregated across the two UV disinfection systems, the study does include some breakout information about the two machines. AR, Tab 7 at 47-48, Tables 4 and 5. Contrary to the protester's assertions that the Steriliz system was less effective than the other system evaluated, the available breakout data provided in the study suggests that the Steriliz system (identified as "machine 1" in the study) was the more effective of the two systems evaluated. Compare Protest B-415897 at 2-3 with AR, Tab 7 at 47-48, Tables 4 and 5. Therefore, if anything, the available evidence suggests that the aggregation of data for the two systems made the Steriliz system appear less effective than it otherwise might have. Id.; see also AR, Tab 7, Slide Presentation on Bryce Study in Steriliz Quotation at 58, 59, and 62.

[4] For example, the technical reviewer for RFQ No. VA250-17-Q-0746 was a medical doctor and the [**DELETED**] at [**DELETED**] Medical Center. AR, Tab 8, Technical Review of Quotes at 11.