U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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

Comptroller General
of the United States

Decision

Matter of: Cue Health, Inc.

File: B-420528; B-420528.2

Date: May 23, 2022

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DIGEST

Protest that agency improperly excluded protester from the competitive range is denied where record shows that agency's evaluation was reasonable and consistent with the solicitation's evaluation criteria.

DECISION

Cue Health Inc. (Cue), a small business of San Diego, California, protests the exclusion of its proposal from the competitive range under request for proposals (RFP) No. SPE2DE-22-R-0007, issued by the Defense Logistics Agency (DLA) for SARS-CoV-2 (COVID), influenza (flu), and respiratory syncytial virus (RSV) rapid test kits and analyzers. The protester contends that the agency's decision to exclude its proposal was the result of an unreasonable and unequal evaluation.

We deny the protest.

BACKGROUND

Issued on December 23, 2021, under the procedures of Federal Acquisition Regulation (FAR) parts 12 and 15, the RFP contemplated award of multiple indefinite-delivery, indefinite-quantity (IDIQ) contracts for a period of 18 months from the date of award to meet the continuing need for rapid COVID, flu, and RSV test kits. Agency Report (AR), Tab 1, RFP at 4-5; Contracting Officer's Statement and

Memorandum of Law (COS/MOL) at 2.[1] The solicitation identified two different items to be delivered: (1) a single-plex Point-of-Care (POC) Nucleic Acid Amplification Test (NAAT) and analyzers for SARS-CoV-2 confirmatory testing (contract line item number (CLIN) 0001), and (2) a multi-plex POC NAAT and analyzers for Influenza A, Influenza B, RSV, and SARS-CoV-2 confirmatory testing (CLIN 0002).[2] RFP at 4-5, 8. Under CLIN 0001, the RFP required offerors to propose both test kits (subCLIN 0001a) and analyzers (subCLIN 0001b). *Id.* at 13.

For CLIN 0001, DLA sought to make multiple awards on a lowest-price, technically acceptable basis to provide the estimated requirement of 9 million tests and 2,250 analyzers. *Id.* at 7, 14. As relevant here, the RFP stated that the test kit must be self-contained. *Id.* at 4, 8-9. In this regard, the RFP required that the test kit must include positive and negative controls, and sterile sample swabs for use with the test.[3] RFP at 4, 8-9. The RFP directed firms to submit a technical description of the items being offered, which might include product literature. *Id.* at 44. The RFP also required that the test kits be U.S. Food and Drug Administration (FDA) -approved, 510(K)-cleared,[4] or emergency use authorization (EUA) -approved. *Id.* at 4, 8. The RFP required the FDA documentation, as well as the product instructions for use, in the proposal submission. *Id.* at 7. Additionally, the RFP instructed that offers from distributors must include a signed letter of commitment from the manufacturer. *Id.* at 5, 13.

To be eligible for award, a proposal had to be rated technically as acceptable. *Id.* at 15. The RFP advised that "[l]ack of adequate documentation in a proposal to support any portion of the [t]echnical [r]equirements" or "[t]aking exception to the terms and conditions of the solicitation" might result in a proposal being found technically

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[1] Citations to the record are to the pages of the Adobe PDF documents produced in the agency report. Furthermore, the RFP was amended four times, none of which are relevant here; therefore, all references to the RFP cite the original solicitation.

[2] Issues raised in this protest do not relate to CLIN 0002 and it is not discussed further.

[3] Positive and negative controls are used to show that the test is working properly. *See* AR, Tab 6H, Cue Instruction for Use (IFU) POC Test at 7. The RFP does not specify the form of the positive and negative control material.

[4] A 510(k) clearance is an FDA premarket document, which explains that before a medical device is marketed, the FDA finds the device to be substantially equivalent to, *i.e.*, as safe and effective as, another legally U.S. marketed device, and that clears the device for commercial distribution. *RCG of North Carolina, LLC*, B-418824, B-418824.3, Sept. 17, 2020, 2020 CPD ¶ 298 at 6 (citing https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k (last visited May 20, 2022)).

unacceptable.[5] *Id.* at 13, 15. The RFP contemplated award without discussions, but advised that if discussions were necessary offerors might "be permitted to provide revised/additional supporting documentation to support an 'acceptable' rating." *Id.* at 15, 16, 46.

The agency received a number of timely proposals, including one from the protester. AR, Tab 13, Competitive Range Determination at 6. The protester's proposal included a POC test cartridge and the "Cue Health Monitoring System" (analyzer). AR, Tab 6I, Cue Proposal at 1. Cue described its test kit as containing "one (1) single-use Cue COVID-19 Test Cartridge and one (1) single-use wrapped sterile Cue Sample Wand." AR, Tab 6H, Cue IFU POC Test at 3. Cue also submitted EUA-approved documentation in which the FDA identified Cue's test kit as containing a test cartridge and a sterile sample swab. AR, Tab 6F, FDA EUA Letter, Mar. 26, 2021, at 4. The positive and negative control material used with Cue's test kit are swabs; the control swabs may be purchased separately. AR, Tab 6H, Cue IFU POC Test at 4, 7.

The source selection evaluation board (SSEB) evaluated the non-price proposals in two parts--technical clinical and technical business. AR, Tab 13, Competitive Range Determination at 8. The technical clinical evaluation assessed whether the test kit offered met the RFP specifications, and the technical business evaluation confirmed that required contract clause certifications were completed and other submission requirements met. AR, Tab 11, Cue Evaluation at 6. The SSEB assigned all of the proposals overall technical ratings of unacceptable.[6] AR, Tab 13, Competitive Range Determination at 8.

After reviewing the evaluation results, the source selection authority (SSA) established a competitive range consisting of the proposals that were, in his view "susceptible to becoming technically acceptable" after discussions. *Id.* at 11. The SSA determined that Cue did not propose test kits that met the minimum requirements because the proposed kits did not include control swabs. The SSA further concluded that Cue's proposal was not susceptible of becoming technically acceptable because the protester's EUA-approved test kits could not be revised without further FDA approval. *Id.* at 10.

The contracting officer notified the protester that its proposal had been excluded from the competitive range and eliminated from consideration for award. AR, Tab 7, Notification of Exclusion from Competitive Range. After receiving DLA's debriefing letter, Cue timely protested its elimination from the competition with our Office.

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[5] Along the same lines, the RFP described a rating of acceptable as "[o]fferor takes no exception to the Statement of Work and/or Solicitation terms and conditions and provided all required documents." *Id.* at 15.

[6] The evaluation criteria in the solicitation did not specifically divide the technical evaluation into two parts. AR, Tab 10, Debriefing Letter at 6. The agency explained that it used the terms "technical clinical" and "technical business" for "administrative purposes." *Id.*

DISCUSSION

Cue protests the exclusion of its proposal from the competitive range, arguing that the agency unreasonably interpreted its proposal as indicating that Cue would not provide control swabs with its test kits. Protest at 9-11. Cue also contends that the agency unreasonably concluded the protester's proposal was not susceptible to being made technically acceptable and that the agency disparately evaluated proposals by applying a more exacting standard to the agency's evaluation of Cue's proposal. Comments & Supp. Protest at 2-7. For the reasons discussed below, we find no basis to sustain the protest.[7]

Where a protester challenges an agency's evaluation of an offeror's proposal, and its decision to exclude a proposal from a competitive range, we first review the propriety of the agency's evaluation of the proposal, and then turn to the competitive range determination. *Delta Risk, LLC*, B-416420, Aug. 24, 2018, 2018 CPD ¶ 305 at 9. Our Office will review an agency's evaluation and exclusion of a proposal from the competitive range for reasonableness and consistency with the solicitation criteria and applicable statutes and regulations. *Straughan Envtl., Inc.*, B-411650 *et al.*, Sept. 18, 2015, 2015 CPD ¶ 287 at 5. In this regard, a protester's disagreement with an agency's evaluation and competitive range judgment, without more, does not establish that the agency acted unreasonably. *CMC & Maint., Inc.*, B-290152, June 24, 2002, 2002 CPD ¶ 107 at 2.

Evaluation of Cue's Proposal

Cue first argues that the agency mistakenly believed that Cue's proposal indicated an intention not to provide control swabs with its test kits. Protest at 9-11. In this connection, the competitive range determination explains that "Cue offered a device that does not include positive and negative controls in the kit" and that the "control swabs are a separate part number that needs to be purchased separately." AR, Tab 13, Competitive Range Determination at 9. DLA thus concluded that Cue's test kit was not self-contained, which rendered Cue's proposal unacceptable because the minimum product requirements were not met. *Id.*; AR, Tab 7, Notification of Exclusion from Competitive Range at 1. In its protest, Cue contends that it submitted all the required documentation and expressly stated that it took no exception to the solicitation's terms, which thus required the agency to assign Cue's proposal a rating of acceptable. Protest at 9. Cue asserts that its proposal acknowledged that Cue would be contractually bound to provide control swabs for the test kits at no additional charge. *Id.*
Based upon our review of the record, we conclude that the agency's findings were consistent with the evaluation criteria and the specifications, and not unreasonable. As noted above, the RFP required test kits to be self-contained, which includes positive

[7] Cue also raises other collateral arguments. Although not addressed in this decision, we have considered the protester's various arguments and conclude that none provide a basis to sustain the protest.

and negative controls--control swabs for Cue's test kit--and sterile swabs for use with the test. RFP at 4, 8-9. Cue proposed a test kit that included one single-use test cartridge and one single-use sterile sample swab. AR, Tab 6H, Cue IFU at 3-4. Cue's test kit instructions, as included in its proposal, identified control swabs as materials required for use with the test kit, but not provided, and advised test kit users how to purchase the necessary control swabs from Cue. *Id.* at 4.

Additionally, Cue's proposal included EUA-approved documentation in which the FDA identified Cue's test kit as consisting of a test cartridge and a single-use sterile sample swab. AR, Tab 6F, FDA EUA Letter, Mar. 26, 2021, at 3-4. The FDA recognized that Cue's test kits do not include control swabs. *Id.* at 4 ("Your product also requires use of the Cue COVID-19 Test Positive Control Swab and Negative Control Swab. These swab controls that are required but not provided, or other authorized controls . . ., are to be [used] as outlined in the Instructions For Use, described below."). We find therefore that DLA reasonably concluded that the positive and negative controls were separate items that were not included in Cue's test kit and reasonably determined that Cue's proposal took exception to the product specifications warranting a rating of unacceptable.

Even though the protester asserts the agency unreasonably determined that its proposal was unacceptable because Cue certified that it took no exception to the contract terms, and thus, Cue acknowledged that it would be contractually obligated to provide control swabs at no additional charge, we are unpersuaded. As addressed above, Cue's proposed test kit requires, but does not include, positive and negative control swabs, and the agency required a self-contained test kit that included positive and negative controls. Even if Cue intended to provide its control swabs to DLA separately at no additional cost and for any quantity required, Cue did not propose a self-contained test kit that met the RFP's specifications. The agency reasonably determined that Cue's proposal was unacceptable, and therefore, we deny this protest ground.

Competitive Range Determination

Next, Cue challenges its exclusion from the competitive range. The protester contends that the agency unreasonably determined that its proposal was not susceptible to being made technically acceptable. Comments & Supp. Protest at 3-5. The protester also argues that DLA evaluated proposals unequally and applied a more exacting standard in evaluating Cue's proposal than the agency applied to its evaluation of the other proposals. *Id.* at 5-7.

Under FAR section 15.306(c)(1), the "contracting officer shall establish a competitive range comprised of all of the most highly rated proposals," based on "the ratings of each proposal against all evaluation criteria," unless the range is further reduced for purposes of efficiency. An agency is not required to include a proposal in the competitive range where the proposal is not among the most highly rated proposals or where the agency otherwise reasonably concludes that the proposal has no realistic prospect of award.

FAR 15.306(c)(1); *Wahkontah Servs., Inc.*, B-292768, Nov. 18, 2003, 2003 CPD ¶ 214 at 4. Where a proposal is technically unacceptable as submitted and would require major revisions to become acceptable, exclusion from the competitive range is generally permissible. *CMC & Maint., Inc.*, *supra*. Proposals with significant informational deficiencies may be excluded, whether the deficiencies are attributable to either omitted or merely inadequate information addressing fundamental factors. *American Med. Depot*, B-285060 *et al.*, July 12, 2000, 2002 CPD ¶ 7 at 6-7.

As noted above, the RFP advised that offerors submitting inadequate documentation in support of any technical requirements may be rated unacceptable; however, if discussions were held, the offeror may "provide revised/additional supporting documentation" which may merit a rating of acceptable. RFP at 15. None of the offerors submitted proposals that were rated technically acceptable overall. AR, Tab 13, Competitive Range Determination at 6. Consequently, the SSA established a competitive range of the proposals offering test kits that met the minimum clinical technical specifications, and were susceptible to being rated acceptable with the submission of revised or additional documentation. *Id.* at 10.

Based upon our review of the record, we conclude that DLA reasonably determined that Cue's proposal was not susceptible to being made acceptable without major proposal revisions and reasonably excluded it from the competitive range. As discussed above, DLA reasonably found that Cue's proposed test kit did not meet the minimum product requirements because the test kit did not include its required positive and negative control swabs. In this regard, the FDA's EUA and Cue's instructions described Cue's test kit as a test cartridge and a sterile single-use sample swab. Accordingly, the agency determined that Cue would need to offer a different item or revise the test kit contents in order to be compliant with the solicitation requirements, and that a revision to the test kit contents would require a revision to the EUA. Supp. COS/MOL at 6. The agency explained that "[t]he proposed medical items are FDA regulated, and the contents of the kits authorized under EUA cannot be revised without further approval." AR, Tab 13, Competitive Range Determination at 10.

The protester argues that its proposal could have been made acceptable with a simple clarification that it intended to include the control swabs with its proposed test kit. Supp. Comments at 4. The protester also argues that it does not need a revised EUA because the EUA makes clear that the FDA understood Cue provided positive and negative controls to purchasers of its test kits. Comments & Supp. Protest at 4-5; Supp. Comments at 4. We disagree. The RFP requires a self-contained test kit which includes positive and negative control swabs. The protester's proposed test kit does not include control swabs. The FDA provided an EUA for Cue's test kit without the swabs. It is irrelevant that the protester can provide control swabs separately or that the EUA contemplates the use of control swabs because the test kit as proposed does not meet the solicitation's requirements. Accordingly, we find that DLA reasonably determined Cue's proposal was not susceptible to becoming technically acceptable during discussions, and therefore, we conclude that DLA reasonably excluded Cue from the competitive range. Accordingly, this protest ground is denied.

Disparate Treatment

Turning to the protester's allegation of disparate treatment, it is a fundamental principle of government procurement that competition must be conducted on an equal basis; that is, the contracting agency must treat all offerors equally, and even-handedly evaluate proposals and quotations against common requirements and evaluation criteria. *Kingfisher Sys., Inc.; Blue Glacier Mgmt. Grp., Inc.*, B-417149 *et al.*, Apr. 1, 2019, 2019 CPD ¶ 118 at 8. Where a protester alleges disparate treatment in a technical evaluation, it must show that the differences in ratings did not stem from differences between proposals. *Battelle Memorial Inst.*, B-418047.5, B-418047.6, Nov. 18, 2020, 2020 CPD ¶ 369 at 6.

The protester argues that the agency's evaluation of the proposals included in the competitive range was less stringent than the agency's evaluation of Cue's proposal. Comments & Supp. Protest at 5-7. In particular, Cue argues that the agency unequally assumed that the other offerors could submit documentation during discussions that would render their proposals technically acceptable but did not make the same assumption about Cue's proposal. *Id.* at 6. Additionally, the protester contends that the proposals included in the competitive range are not susceptible to being made technically acceptable because the missing documentation may not resolve the issues with the proposals. *Id.* at 6-7.

Here, the record shows that the differing evaluation treatment of the proposals is reasonably explained by differences in proposals. DLA found that each proposal included in the competitive range offered a test kit that met the minimum product specifications but lacked documentation. *Id.* at 11; Supp. COS/MOL at 8-9. Examples of inadequate documentation included a failure to submit a signed copy of amendment 0004, a failure to submit a Berry Amendment disclosure, and a failure to provide a Distribution, Planning, and Tracking detailed summary. AR, Tab 13, Competitive Range Determination at 8, 9. Cue's proposed test kit, in contrast, failed to meet the solicitation requirements because the test kit did not include positive and negative control swabs. Cue could not simply submit documentation during discussions that would support an acceptable rating. Thus, Cue's proposal was not susceptible to being made acceptable without major revisions. We find the protester's allegation of disparate treatment to be unsupported.[8]

In sum, we find unobjectionable the agency's conclusion that Cue's test kit does not meet the solicitation requirements and is technically unacceptable. We also find reasonable DLA's determination that Cue's proposal is not susceptible to becoming technically acceptable, and therefore, Cue's exclusion from the competitive range was

[8] To be clear, we do not find that the proposals included in the competitive range will be made acceptable with the submission of additional documentation, but only that the agency concluded it is possible for the proposals to become acceptable with the submission of documentation.

also reasonable. Finally, because the record is clear that the different evaluations are the result of differences in proposals, and not disparate treatment, this protest ground also does not provide a basis to sustain Cue's protest.

The protest is denied.

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General Counsel