U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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

Comptroller General
of the United States

Decision

Matter of: RCG of North Carolina, LLC

File: B-418824; B-418824.3

Date: September 17, 2020

Alan Grayson, Esq., Law Office of Alan Grayson, for the protester.
Allison Colsey Eck, Esq., Defense Logistics Agency, for the agency.
Lois Hanshaw, Esq., and Evan C. Williams, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

1. Protest challenging elimination from competition is denied where the protester's proposal failed to comply with a material term of the solicitation and the record shows that this issue was not a minor informality that could have been corrected through clarifications.

2. Challenge to domestic source restrictions identified in solicitation did not prejudice protester where its proposal was reasonably eliminated from the competition for failure to address a separate, material requirement.

DECISION

RCG of North Carolina, LLC (RCG), a service-disabled veteran-owned small business of Raeford, North Carolina, protests the terms of request for proposals (RFP) No. SPE1C1-20-R-0102,[1] issued by the Defense Logistics Agency (DLA) for disposable surgical masks. RCG contends that the domestic source restrictions identified in the RFP were improper. RCG also protests the agency's decision to eliminate its proposal from the competition.

[1] RCG also challenged the terms of RFP No. SPE1C1-20-R-0103 (RFP 0103) for isolation gowns. Prior to the submission of the agency report in B-418824, the agency notified our office that it had cancelled RFP 0103 due to a change in the government's requirements. Req. for Partial Dismissal at 1. The cancellation of a solicitation renders a protest academic. *Ferris Optical*, B-403012.2, B-403012.3, Oct. 21, 2010, 2010 CPD ¶ 265 at 2. We do not consider academic protests. *Id.* at 1-2. Therefore, we dismiss the protester's arguments regarding RFP 0103.

We deny the protests.

BACKGROUND

Issued on May 20, 2020, the RFP contemplated award of an indefinite-delivery, indefinite-quantity contract with a 1-year base term from the date of award through December 31, 2020. Agency Report (AR), RFP at 1, 6.[2] The solicitation identified an acquisition goal of promoting and supporting domestic manufacturing of personal protective equipment (PPE)[3] needed to help prevent the spread of Coronavirus Disease 2019 (COVID-19).[4] AR, RFP amend. 5 at 4.[5] In this regard, the agency sought to procure disposable surgical masks "cleared" by the U.S. Food and Drug Administration (FDA) as Class II medical devices.[6] AR, RFP amend. 4 at 2; RFP at 16.

As relevant here, the RFP identified FDA documentation requirements for the masks including, an FDA Premarket Document number, known as a 510(k) clearance number. RFP at 15, 77. The RFP stated that the FDA documentation was required for proposal submission. *Id.* at 15, 77; AR, RFP amend. 2 at 3. The RFP advised that failure to provide the specified documentation "may result in the offer being determined '[u]nacceptable' and may render an offer ineligible for award." RFP at 77. Additionally, the RFP stated that any proposal lacking the specified documentation would be removed from the competition. *Id.* at 16, 77, 82. The RFP contemplated making award without conducting discussions. RFP at 34.

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[2] The agency produced separate agency reports for each protest. Documents that relate to only one protest are specifically identified by protest, while documents common to both protests are identified generally as the agency report.

[3] The Occupational Safety and Health Administration defines PPE as being specialized clothing or equipment worn by an employee for protection against infectious materials. B-418824 Joint Memorandum of Law and Contracting Officer's Statement (MOL/COS) at 2.

[4] COVID-19 is the most recent outbreak of coronavirus, a virus that can spread rapidly and cause outbreaks with high mortality rates. Science & Tech. Spotlight: Coronaviruses, GAO-20-472SP at 1 (Mar. 2020).

[5] The agency produced the eight RFP amendments in one Adobe pdf document. AR, RFP amend. at 1-49. Our citations in this decision are to the page numbers in the specific amendment.

[6] The FDA reviews and clears surgical masks under 21 C.F.R. § 878.4040 as Class II medical devices, which may be labeled as surgical, isolation, dental, or medical procedure masks. RFP at 16.

DLA sought to make multiple awards on a best-value tradeoff basis to provide the minimum quantity (20 million each), estimated quantity (68 million each), and maximum quantity (140 million each) of masks. RFP at 7. The agency sought to procure the masks using three different and distinct lots. AR, RFP amend. 7 at 2. The solicitation advised that if the government was unable to make award for the complete requirement under Lot 1, the government would dissolve the balance of Lot 1 and seek to award the difference under Lot 2. AR, RFP amend. 5 at 4. Similarly, any unfulfilled requirements under Lot 2 would be awarded under Lot 3. *Id.*

Each lot was subject to differing domestic source restrictions, including the Berry Amendment and Buy American Act (BAA). For Lot 1, the solicitation included Defense Federal Acquisition Regulation Supplement (DFARS) clause 252.225-7012, Preference for Certain Domestic Commodities, which implements the Berry Amendment. *Id.* at 2. The Berry Amendment generally restricts the Department of Defense's (DOD) expenditure of funds for certain articles and items, including clothing, to domestically produced products. *See* 10 U.S.C. § 2533a. The RFP advised that the surgical masks being procured were considered an item of clothing for purposes of the Berry Amendment. AR, RFP amend. 5 at 4. In this regard, the RFP required that any product offered under Lot 1, including the materials and components thereof, must be grown, reprocessed, reused, or produced in the United States, except other items added to, and not normally associated with, clothing (and the materials and components thereof). AR, RFP amend. 7 at 2.

Lot 2 was subject to the BAA (DFARS clause 252.225-7000, Buy American - Balance of Payments Program Certificate, and DFARS clause 252.225-7001, Buy American and Balance of Payments Program), which restricts the purchase of supplies that are not domestic end products. AR, RFP amend. 5 at 4; *see* Federal Acquisition Regulation (FAR) 25.101. For DOD acquisitions subject to the BAA, offers of domestic or qualifying country end products are considered BAA-compliant. DFARS clauses 225.872-1 and 252.225-7000. Additionally, the RFP stated that for Lot 2 the Berry Amendment was inapplicable because the agency had approved a domestic non-availability determination (DNAD) based on the possibility that the urgent requirement would likely exceed domestic manufacturing capability.[7] AR, RFP amend. 5 at 2. Under Lot 2, the agency would consider an end product from a domestic source or qualifying country identified in the BAA, or an end item whose primary end item fabric was manufactured in the United States. *Id.*

Lot 3 was not subject to domestic source restrictions. The solicitation advised that the Berry Amendment was not applicable based on the DNAD. *Id.* at 3. Under Lot 3, the

[7] The DNAD was issued pursuant to DFARS clause 225.7002-2(b)(1)(v), which allows the Director of DLA to determine that an exception to the Berry Amendment applies to an acquisition because items grown, reprocessed, reused, or produced in the United States cannot be acquired in a satisfactory quality and sufficient quantities at U.S. market prices. B-418824, AR, Tab 4, DNAD at 1.

agency would consider an item that did not meet Berry Amendment restrictions, BAA requirements, or did not qualify as an end item whose primary end item fabric was manufactured in the United States. *Id.*

On June 12, RCG timely challenged the terms of the solicitation with our Office.[8] Several offerors, including RCG, submitted proposals by the June 1 closing date.[9] On June 29, the agency notified RCG that its proposal had been removed from the competition for failing to provide a 510(k) certification number.[10] On July 2, the agency awarded four contracts.[11] B-418824 MOL/COS at 5. On July 13, RCG timely protested its elimination from the competition to our Office.[12]

DISCUSSION

The protester contends that the domestic source restrictions and lot scheme applied to the solicitation are improper and overly restrictive. B-418824 Protest at 1-2. The gravamen of the protester's arguments is that the solicitation should contain only one lot for offers compliant with the Trade Agreements Act (TAA).[13] *Id.* at 15. In this regard, the protester raises various arguments asserting that the Berry Amendment should not apply to the solicitation and that the agency improperly classified the masks as

[8] RCG filed the B-418824 protest on behalf of itself and Organic Supply LLC, of Palm Beach, Florida. On June 15, our Office informed RCG, by registered email, that "GAO has opened the protest on behalf of RCG. A separate protest and filing fee needs to be filed on behalf of Organic Supply." Email from GAO to RCG, June 15, 2020 (11:54 a.m.). We did not receive a response to our email and decline to consider the B-418824 protest allegations raised by Organic Supply.

[9] On May 27, RCG filed a protest with the agency challenging the terms of the solicitation. On June 9, the agency denied the protest.

[10] On June 30, RCG filed a protest with the agency challenging RCG's elimination from the competition. On July 1, the agency denied that protest.

[11] On July 2, the agency made a determination pursuant to FAR 33.104(b), dealing with protests before award, that urgent and compelling circumstances which significantly affect the interest of the United States would not permit awaiting our decision on this matter. Letter of Override, July 2, 2020, at 1.

[12] On August 10, the agency also made a determination pursuant to FAR 33.104(c), dealing with protests after award, that urgent and compelling circumstances which significantly affect the interest of the United States would not permit awaiting our decision on this matter. Letter of Override, Aug. 10, 2020 at 1.

[13] The Trade Agreements Act allows the President to waive the BAA and other discriminatory provisions for eligible products from countries that have signed an international trade agreement with the United States. 19 U.S.C. §§ 2501-2582; FAR 25.402; DFARS clause 225.403.

"clothing" within the meaning of the Berry Amendment. *Id.* at 6. Additionally, RCG contends that reliance on the TAA, rather than the BAA, would open the procurement to a wider enumerated group of countries, including Mexico, the country where the protester's mask is manufactured. *Id*. at 10-11. The protester also challenges the elimination of its proposal from the competition and contends that if its proposal failed to comply with the requirement to provide certain FDA documentation, the agency should have considered the would-be discrepancy a minor informality that could be corrected through clarifications. B-418824.3 Protest at 1-2. For the reasons discussed below, we find no basis to sustain the protests.[14]

Here, our Office finds itself in the unique position of concurrently considering protests challenging the terms of the solicitation and the agency's evaluation for the same procurement. As explained below, we first conclude that the agency reasonably eliminated the protester's proposal from consideration for award. Additionally, under the unique circumstances presented here, we find that even if we accepted the protester's challenges to the terms of the solicitation, which we do not, RCG cannot establish that it was competitively prejudiced by the challenged terms where its proposal was reasonably found ineligible for award for failing to meet a separate, material requirement. We first address the protester's challenge to the agency's evaluation of its proposal.

Challenge to RCG's Elimination from the Competition

In reviewing protests challenging the rejection of a proposal for consideration for award, it is not our role to reevaluate proposals; rather our Office examines the record to determine whether the agency's judgment was reasonable and in accordance with the solicitation criteria and applicable procurement statutes and regulations. *Wolverine Servs. LLC*, B-409906.3, B-409906.5, Oct. 14, 2014, 2014 CPD ¶ 325 at 3. In a negotiated procurement, a proposal that fails to conform to the material terms and conditions of the solicitation is considered unacceptable and may not form the basis for award. *Id.* at 4. Further, it is the offeror's responsibility to submit a well-written proposal, with adequately detailed information which clearly demonstrates compliance with the solicitation and allows a meaningful review by the procuring agency. *Microwave Monolithics, Inc.*, B-413088, Aug. 11, 2016, 2016 CPD ¶ 220 at 6. A protester's disagreement with the agency's judgment does not establish that the evaluation was unreasonable. *LOGMET LLC*, B-405700, Dec. 14, 2011, 2011 CPD ¶ 278 at 3.

The protester argues that the agency's decision to exclude RCG's proposal from the competition because it did not identify a 510(k) certification number was unreasonable. B-418824.3 Protest at 1. In this regard, the protester contends its proposal met the

[14] RCG 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 either protest.

RFP requirement to identify a 510(k) certification number by providing a certificate of registration, which stated "FDA Registration No.: Active/Waiting for Registration Number Assignment." *Id.* Alternatively, the protester asserts that if its proposal failed to comply with the solicitation, the agency should have viewed any potential discrepancy as a minor informality that the agency should have remedied through clarifications. *Id.* at 1-2.

In response, the agency explains that it properly removed RCG's proposal because it failed to comply with a material solicitation requirement to identify a 510(k) clearance number in the submission of its proposal. B-418824.3 MOL/COS at 3. The agency asserts that the certificate of registration did not identify the same information as a 510(k) clearance number. In this regard, the agency cites to a page on the FDA website, entitled Premarket Notification 510(k), which explains that before marketing a medical device, a submitter must receive a letter from the FDA that 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. *Id.* at 10-11 (citing https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k) (last visited Sept. 9, 2020).

The agency also states that an FDA-issued 510(k) number starts with the letter "k." B-418824.3 MOL/COS at 11. In contrast, the agency contends that a certificate of registration, such as the one contained in RCG's proposal, merely shows evidence of registration with FDA, which was a separate and distinct solicitation requirement for proposal submission. *Id.* at 11 (citing RFP at 15, 77, requiring an offeror to provide FDA registration). Moreover, the agency notes that the certificate of registration stated that registering and listing a device or facility "does not, in any way[,] constitute FDA approval of your facility or your devices." *Id.* at 11 (citing B-418824.3, AR, Tab 4, RCG Proposal at 20).

Without rebutting either the agency's statements regarding how a 510(k) clearance number is obtained or identifying an actual 510(k) clearance number, the protester argues that its proposal does not say that RCG does not have a 510(k) number. B-418824.3 Comments at 2. The protester argues further that it could obtain a 510(k) number after contract award, even though the RFP required the number to be submitted with the proposal. *Id.* In addition, RCG contends that the agency should have engaged in clarifications to determine the status of RCG's 510(k) clearance number before rejecting its proposal. *Id.* at 4.

Here, the RFP required offerors to provide a 510(k) clearance number when submitting a proposal and advised offerors, in three separate places, including section M (Evaluation Criteria for Award), that the failure to provide such documentation would result in a proposal being removed from the competition. RFP at 15-16, 77, 82. The record shows that the certificate of registration provided in RCG's proposal does not identify a 510(k) clearance number, as required by the solicitation. *See* B-418824.3, AR, Tab 4, RCG Proposal at 19. Instead, the certificate shows that the protester's FDA

registration number, rather than a 510(k) number, was "Active/Waiting for Registration Number Assignment." *Id.*

Additionally, the certificate does not include information associated with obtaining a 510(k) number, such as an indication that the device was either cleared for commercial distribution or substantially equivalent to another legally U.S. marketed device. *Id.* On this record, we find no basis to object to the agency's conclusion that RCG failed to meet the RFP requirement to identify, by the time of proposal submission, a 510(k) clearance number; offering an FDA registration number does not satisfy the RFP's requirement. Given that the RFP advised that proposals lacking required FDA documentation could be found unacceptable and would be removed from the competition, we also find unobjectionable the agency's conclusion not to consider the protester's proposal for award where it failed to provide information required by the solicitation.[15]

Also, we find no merit to the protester's argument that the agency should have clarified RCG's FDA documentation information through clarifications. The RFP required the submission of 510(k) clearance numbers and advised that the failure to provide this information could render a proposal unacceptable and ineligible for award and any proposal lacking the specified documentation would be removed from the competition. RFP at 82. The RFP also stated that the agency intended to make award without conducting discussions. *Id.* at 34.

Here, by not providing the required 510(k) clearance number, RCG failed to respond to a material term of the solicitation. Clarifications are not appropriate to cure a material proposal deficiency at issue here. *See* FAR 15.306; *URS Grp., Inc.*, B-402820, July 30, 2010, 2010 CPD ¶ 175 at 5 n.3. As we have explained previously, clarifications cannot be used to cure proposal deficiencies or material omissions, materially alter the technical or cost elements of a proposal, or otherwise revise the proposal. *Alltech Eng'g Corp.*, B-414002.2, Feb. 6, 2017, 2017 CPD ¶ 49 at 6. Additionally, agencies

[15] The protester argues that its proposal was improperly eliminated because the RFP permitted, rather than required, the elimination of a proposal that failed to provide FDA documentation. B-418824.3 Comments at 6. In support of this argument, the protester cites the provision of the solicitation that failure to provide documentation "*may* result in the offer being determined '[u]nacceptable' and *may* render an offer ineligible for award." *Id.* (citing RFP at 77 (emphasis added)). We find this argument unavailing. In our view, the RFP language clearly placed offerors on notice that proposals could be found unacceptable and eliminated for failing to provide FDA documentation. An agency's subsequent decision to eliminate a proposal found to be unacceptable is not unreasonable. *See e.g.*, *Technology Mgmt. Co., Inc.*, B-409976, Sept. 26, 2014, 2014 CPD ¶ 294 at 3-4 (explaining that it is within the agency's discretion to reject a proposal as unacceptable where the RFP advised that an offeror "may have its proposal rejected" if its proposal lacks certain items).

have broad discretion as to whether to seek clarifications from offerors, and offerors have no automatic right to clarifications regarding proposals. *Valkyrie Enterprises, LLC*, B-414516, June 30, 2017, 2017 CPD ¶ 212 at 5. Thus, because RCG fails to establish that the agency's actions violated procurement law or regulation, we deny this protest ground.

Challenge to the Terms of Solicitation

In challenging the terms of the solicitation, the protester raises various arguments asserting that the solicitation should apply domestic source restrictions under the TAA, rather than the Berry Amendment or the BAA. B-418824 Protest at 2.

Competitive prejudice is an essential element of a viable protest; where the protester fails to demonstrate that, but for the agency's actions, it would have had a substantial chance of receiving the award, there is no basis for finding prejudice, and our Office will not sustain the protest, even if deficiencies in the procurement are found.[16] *Coulson Aviation (USA) Inc.*, B-414566, July 12, 2017, 2017 CPD ¶ 242 at 6.

As stated above, we are in the unique position of deciding the outcome of the protest to the agency's evaluation while we also consider RCG's challenges to the terms of the solicitation. Because the protester was reasonably eliminated from the competition on a matter unrelated to the challenges to the domestic source restrictions, we view the protest to the terms of the solicitation as effectively moot. In this regard, even if we accept the protester's argument that the solicitation should have identified only one lot subject to the TAA, we know here that RCG's proposal would still have been ineligible for award because it failed to meet a material term of the RFP, *i.e.*, the requirement to identify a 510(k) number that shows that the FDA certified its mask to be efficient, safe, and ready for commercial distribution.

Essentially, we find no basis to conclude that the protester's challenges to the terms of the solicitation would change the outcome of the agency's evaluation considering RCG did not also challenge the RFP requirement that formed the basis on which its proposal was found unacceptable. Accordingly, the protester has not adequately demonstrated

[16] Typically, in the context of a protest solely challenging the terms of a solicitation, competitive prejudice occurs where the challenged terms place the protester at a competitive disadvantage or otherwise affect the protester's ability to compete. *Global Sols. Network, Inc.*, B-298682, Nov. 27, 2006, 2006 CPD ¶ 179 at 3. Here, however, because we find ourselves considering both a protest to the terms of the solicitation and the agency's evaluation, we determine whether each argument demonstrates competitive prejudice based on the totality of the facts before us. *See e.g.*, *Foundation Health Fed. Servs., Inc.; Humana Military Healthcare Servs., Inc.*, B-278189.3; B-278189.4, Feb. 4, 1998, 98-2 CPD ¶ 51 at 14; *ActioNet, Inc.*, B-417173, B-417173.2, Mar. 5, 2019, 2019 CPD ¶ 100 at 13 (possibility of competitive prejudice determined based on consideration of totality of the record).

that it was prejudiced by the terms of domestic source restrictions.[17] *See e.g., Delta Chem. Corp.*, B-255543, Mar. 4, 1994, 94-1 CPD ¶ 175 at 4 (protester was not prejudiced by a solicitation defect unrelated to the basis upon which the protester's offer was found ineligible for award). Accordingly, we find no basis to sustain the protest.

The protests are denied.

Thomas H. Armstrong
General Counsel

[17] RCG argues that dismissing the challenge to the terms of the solicitation would encourage agencies concurrently considering protests challenging the solicitation terms and evaluation to ignore protests against the terms of the solicitation and seek to disqualify a protester on some other basis. RCG Resp. to GAO Req. for Additional Briefing at 5 n.2. We disagree. Our decisions have consistently explained that government officials are presumed to act in good faith and a contention that procurement officials are motivated by bias or bad faith must be supported by convincing proof. *Instrument Specialists, Inc.*, B-279714, July 14, 1998, 98-2 CPD ¶ 18 at 3 n.2. Where a protester alleges bias, it must not only provide credible evidence clearly demonstrating bias against the protester or in favor of the awardee, but must also show that this bias translated into action that unfairly affected the protester's competitive position. *Sterling Med. Assocs., Inc.*, B-418674, B-418674.2, July 23, 2020, 2020 CPD ¶ 255 at 12.