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Comptroller General
of the United States

United States Government Accountability Office
Washington, DC 20548



# Decision

**Matter of:** Smith and Nephew, Inc.

**File:** B-410453

**Date:** January 2, 2015

John G. Horan, Esq., McKenna Long & Aldridge LLP, for the protester.
Ashley D. Presley, Esq., Department of Veterans Affairs, for the agency.
Gary R. Allen, Esq., and Christina Sklarew, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

## DIGEST

Protest challenging a technical specification (set out as a "minimum technical requirement") in a solicitation for sterile wound dressing as unduly restrictive of competition is sustained where the record shows that the agency: (1) has not established its actual need for the requirement; (2) acknowledges that it has no data to support setting any specific requirement as its actual need; and (3) based its specification on an analysis of industry responses to inquiries about what products might be available, rather than first determining the agency's actual needs.

## DECISION

Smith & Nephew, Inc., of St. Petersburg, Florida, protests the terms of request for quotations (RFQ) No. VA119-14-Q-0158, issued by the Department of Veterans Affairs (VA) for sterile foam dressings for wound care. Smith & Nephew contends that the RFQ's minimum absorption requirement does not reasonably relate to the agency's needs and is therefore unduly restrictive of competition.

We sustain the protest.

BACKGROUND

In preparation for an attempt to standardize procurements for sterile foam dressings, the agency, on December 19, 2013, posted a request for information (RFI) to the General Services Administration's eBuy website seeking sources for three types of dressings. Contracting Officer's Statement (COS) at 1. Each dressing was designated with a contract line item number (CLIN), as follows:

(1) sterile bordered foam dressing (without contact layer) (CLIN 0001); (2) sterile bordered foam dressing (with contact layer) (CLIN 0002); and (3) sterile foam dressing (non-bordered) (CLIN 0003). Agency Report (AR), Tab 4a, RFI (Dec. 19, 2013), at 1-2. This protest relates only to CLIN 0002, the sterile bordered foam dressing with contact layer. See Protest at 4; Comments at 2.

As relevant here, before issuing the RFI, the agency determined that there were no clinical studies or industry standards for the "fluid handling capacity" of the types of dressings being sought under the RFI. AR, Tab 8, Wound Care Integrated Product Team Chair Decl., at 2; Tab 6b, E-Mails Related to Second RFI, at 7. For this reason, the RFI required vendors to submit documentation--including test result data--of the fluid handling capacity of their dressings.[1] AR, Tab 4a, RFI (Dec. 19, 2013), at 7-9. The RFI did not, however, specify any minimum fluid handling capacity requirement for the dressings. See id.

Eight vendors submitted responses to the RFI, including Smith & Nephew. AR at 1. Only three of these vendors [deleted], provided fluid handling capacity test result data for the dressing listed under CLIN 0002. The table below summarizes this data.

| Vendor | Product | Fluid Handling Capacity (g/10cm²/24hr) |
|---|---|---|
| deleted | deleted | deleted |
| deleted | deleted | deleted |
| deleted | deleted | deleted |

Protest, exh. E, Smith & Nephew Response to First RFI, at 4; Tab 5a, [deleted] Response to First RFI, at 36; Tab 5g, [deleted] Response to First RFI, at 43. As reflected in this table, [deleted] provided significantly different test results [deleted] grams of absorption versus [deleted] grams of absorption) for two different lots of the same product [deleted]. AR, Tab 5a, [deleted] Response to First RFI, at 36. [deleted] did not provide an explanation for this wide variance or represent that one of the test results was more accurate than the other. See id.

On March 9, 2014, the agency issued a second RFI. AR, Tab 4b, RFI (Mar. 9, 2014). This RFI was nearly identical to the first RFI, except that it included a minimum fluid handling capacity specification of 20 g/10cm²/24hr for the dressings listed under CLIN 0002. Id. at 7, 8, 9. After the RFI was issued, but before

[1] The RFI required that the fluid handling capacity test results be measured in grams per 10 square centimeters per 24 hours (g/10cm²/24 hrs). AR, Tab 4a, RFI (Dec. 19, 1013), at 7-9.

submitting a response to it, Smith & Nephew asked the agency about the rationale for this specification. AR, Tab 6b, E-Mails Related to Second RFI, at 7. The agency replied as follows:

> No market research was found for definite values. Values are based on published data from vendors. High fluid handling capacity in foam dressing is an essential component of efficacious use.

Id.

The agency received responses to the second RFI from all of the original eight vendors, as well as an additional respondent, [deleted]. AR, Tab 3b, Acquisition Plan, at 4. [Deleted] did not respond to the second RFI. AR, Tab 6c, Agency E-Mail dated Mar. 18, 2014, at 1. [Deleted] and [deleted] responses to the second RFI provided fluid handling capacity data for the dressing listed in CLIN 0002 as shown in the table below.[2]

| **Vendor** | **Product** | **Fluid Handling Capacity (g/10cm²/24hr)** |
|---|---|---|
| deleted | deleted | deleted |
| deleted | deleted | deleted |

AR, Tab 6b, [deleted] Response to Second RFI, at 20-21; Tab 6e, [deleted] Response to Second RFI at 30.

As the data in the table above shows, the fluid handling capacity values for the [deleted] and [deleted] products were below the 20 g/10cm²/24hr specification in the RFI. As such, both firms' responses to the RFI challenged the 20 g/10cm$^2$/24hr specification as being too high. For example, [deleted] pointed to clinical research showing a rate of 0.5 g/10cm²/24hr for moderate exuding wounds and a rate of 10 g/10cm²/24hr for high exuding wounds. AR, Tab 6b, [deleted] Response to Second RFI, at 11. Similarly, [deleted] pointed to clinical research showing a rate of 5-12 g/10cm$^2$/24hr for moderately exuding wounds. Tab, 6e, [deleted] Response to Second RFI, at 3, 24, 30. [Deleted] also pointed out that [deleted] claim of a 20 g/10cm$^2$/24hr capacity for one lot of its dressings was questionable because other test results for the same [deleted] products indicated a fluid handling capacity rate closer to 10 g/10cm$^2$/24hr. AR, Tab 6e, [deleted] Response to Second RFI, at 3.

[2] [Deleted] responded to the first RFI, but did not provide fluid handling capacity data in that response. AR, Tab 5c, [deleted] Response to RFI, at 14-18.

Because of the questions raised by vendors concerning the 20 g/10cm$^2$/24hr specification, the agency, on May 29, issued a third RFI to 11 vendors that had not responded to the first two RFIs. AR, Tab 3a, Market Research Summary, at 6. Three responses were received from this set of vendors. Id. However, the agency determined that none of these three vendors were capable of meeting the RFI's specifications for the dressing listed under CLIN 0002. Id.

On June 20, the agency issued a fourth RFI, this time posting it on the FedBizOpps website to allow the open market "to determine if there were contractors capable of meeting the fluid handling capabilities" specification. COS at 3. The agency received no responses to this RFI. Id.

On September 4, 2014, the agency publicized the RFQ at issue in this protest. The RFQ was restricted to vendors holding contracts under VA Federal Supply Schedule 65 II A, Medical Equipment & Supplies. RFQ at 1. The RFQ anticipated the establishment of a blanket purchase agreement (BPA) for the three types of dressings that were listed in the prior RFIs. Id. at 5. The RFQ stated that the BPA would be established "with one (1) vendor for all CLINS, one (1) vendor per CLIN, or any combination thereof." Id. The BPA was to have a 1-year base period and four 1-year option periods. Id. at 1. Its estimated total value was approximately $37 million. AR, Tab 3b, Acquisition Plan, at 8.

The RFQ provided that the BPA would be established on a lowest-priced, technically acceptable basis. RFQ at 38. Technical acceptability was defined as meeting all of the "minimum technical requirements" listed in the solicitation. Id. As with the final RFIs, one of the minimum technical requirements for the dressing listed under CLIN 0002 was a minimum fluid handling capacity of 20 g/10cm$^2$/24hr. Id. at 33.

The RFQ's closing date was September 24. RFQ at 1. Smith & Nephew filed this protest on September 23.

DISCUSSION

Smith & Nephew argues that the RFQ's requirement for a minimum fluid handling capacity of 20 g/10cm$^2$/24hr is unduly restrictive of competition. In this regard, Smith & Nephew asserts that this specification is not reasonably necessary to meet the agency's needs and that its inclusion in the RFQ prohibits Smith & Nephew and other firms from competing for a BPA under CLIN 0002. See Protest at 2, 8-9,

In response, the agency does not address how a minimum fluid handling capacity of 20 g/10cm$^2$/24 hr is necessary to meet any specific need. Instead, the agency states that its "goal is to procure the most absorbent and fluid-handling capable dressings available." AR at 3 (quoting AR, Tab 8, Wound Care Integrated Product Team Chair Decl., at 1). Therefore, the agency explains, it chose the "top tier" (i.e.,

highest) fluid handling capacity value that was identified in the responses to the RFIs; i.e., the agency chose the 20 g/10cm$^2$/24hr specification based on the value that was provided as one of [deleted] two test results. See AR at 3.

In preparing a solicitation, a contracting agency is generally required to specify its needs and solicit offers in a manner designed to achieve full and open competition, so that all responsible sources are permitted to compete. 41 U.S.C. § 3306(a)(1)(A) (2012). A solicitation may include restrictive provisions or conditions only to the extent necessary to satisfy the agency's needs or as authorized by law. Id. § 3306(a)(2)(B). To the extent a protester challenges a specification as unduly restrictive, that is, challenges both the restrictive nature of the requirement as well as the agency's need for the restriction, the procuring agency has the responsibility of establishing that the specification is reasonably necessary to meet its needs. The adequacy of the agency's justification is ascertained through examining whether the agency's explanation is reasonable, that is, whether the explanation can withstand logical scrutiny. Trident World Sys., Inc., B-400901, Feb. 23, 2009, 2009 CPD ¶ 43 at 3.

We find the RFQ here to be unduly restrictive because the agency has not explained how the challenged specification is reasonably necessary to meet an actual need of the agency. As an initial matter, we observe that the agency has failed to identify an absorbency threshold (or range) that actually is needed by the government, but has instead identified a general "goal" of attaining "top tier" absorbency. While we recognize that the VA is entitled to great discretion in establishing its medical needs, the agency has offered no support for limiting the competition to offerors whose products can meet the specific threshold of 20 g/10cm$^2$/24hr instead of any other number (lower or higher).

Beyond this issue, we also observe that the VA acknowledges it established the specification based only on information it received in response to the RFIs, and that it relied on this information because it knew of no supporting market research or industry standard for any specific fluid handling value. AR, Tab 6b, E-Mails Related to Second RFI, at 7. However, as shown above, only one response--[deleted] response to the first RFI--represented that a product could meet the 20 g/10cm$^2$/24hr specification, and that representation was contradicted by another test result from the same vendor, for the same product, showing a capacity of 10 g/10cm$^2$/24hr (half the required value).[3]

[3] The agency apparently never sought an explanation for the conflicting test results. Instead, it appears to have simply adopted [deleted] higher-referenced fluid handling capacity for use as its minimum technical requirement. Notably, [deleted] did not submit a response to any of the RFIs that the agency issued after it established the 20 g/cm$^2$/24hr specification as a minimum technical requirement.

Moreover, the agency made its decision in the face of considerable product data from other vendors indicating that the 20 g/10cm$^2$/24hr specification was higher than any known product could achieve. See, e.g., AR, Tab 6b, [deleted] Response to the Second RFI, at 11-16. Additionally, the agency seems to have ignored data provided by two of the vendors showing that the 20 g/10cm$^2$/24hr specification significantly deviated from standards derived from clinical studies and industry usage. See id. at 11; AR, Tab 6e, [deleted] Response to the Second RFI at 30. Given the nature and amount of contradictory information that was presented to the agency, and the agency's apparent failure to reasonably determine whether the 20 g/10cm$^2$/24hr specification was nonetheless necessary, we find that the agency's decision to rely on a single, internally inconsistent result from one vendor to establish its minimum requirement does not withstand logical scrutiny.[4]

We note that the agency has taken the position that responses to the RFIs indicated that at least two vendors could meet the 20 g/10cm$^2$/24hr specification. COS at 4. The agency apparently is relying upon the fact that [deleted], in its response to the second RFI, checked a box stating it could comply with the fluid handling capacity cited for CLIN 0002. AR, Tab 6e, [deleted] Response to the Second RFI, at 30. This indication, however, is located directly below a lengthy paragraph wherein [deleted] states that its products have a fluid handling capacity of 11-14 g/10cm$^2$/24hr, which "is in alignment with all leading manufacturers," and that the 20 g/10cm$^2$/24hr specification is "unfair" and "potentially eliminates all" but one manufacturer. Id. Given these statements, we do not find reasonable the agency's reliance on [deleted] apparently pro forma checked response.

The agency also argues that the determination of how much fluid a dressing must be able to absorb is directly related to its medical needs, and that our office should defer to the agency's judgment. In this regard, the agency quotes our decision in G.H. Harlow Co., Inc., B-254839, Jan. 21, 1994, 94-1 CPD ¶ 29, which stated "we will not question the contracting agency's determination of its minimum needs and the best method of accommodating those needs unless it has no reasonable basis." AR at 3. In G.H. Harlow, however, the agency provided a reasonable explanation for including a requirement--approval from an independent testing authority--that the agency acknowledged would significantly restrict the pool of competition. G.H. Harlow Co., Inc., supra, at 3. In contrast, the agency here has failed to provide any reasonable basis for its restrictive requirement, did not demonstrate that the 20 g/10cm$^2$/24 hr specification is related to its actual needs, and fails to

[4] To the extent that Smith & Nephew contends that the fluid handling capacity tests identified in the solicitation are flawed and are not proper methods for evaluating fluid handling capacity of dressings, Protest at 9-11, we think this determination is a matter within the agency's discretion, and not a matter for review by our bid protest forum. See Pfizer Inc., B-277733, Oct. 27, 1997, 97-2 CPD ¶ 119 at 2.

acknowledge that its specification appears to exceed the fluid handling capacity of any known product.

CONCLUSION AND RECOMMENDATION

In sum, we recognize that the VA is entitled to great discretion in establishing its medical needs. We also recognize that the VA is seeking "the most absorbent and fluid-handling capable dressings available." AR at 3. If, in responding to this protest, the VA had offered any reasonable explanation for why it has translated a need for the best dressing available to a minimum technical requirement for an absorption rate of 20 g/10cm²/24hr, the strong inclination of our Office would have been to accept the VA's judgment on the question.

However, no such explanation was provided during the course of this protest. Instead, the record reflects that the VA had no data to support a specific value for any particular absorbency capacity, and instead chose a 20 g/10cm²/24hr specification--now expressed as a minimum technical requirement--based on market research that repeatedly showed that value to be essentially unavailable within the confines of the commercial market where the procurement was being conducted. Where a protester challenges a specification as overly restrictive, we view it as incumbent on an agency to identify a specific government need and show how the specification in question is reasonably necessary to meet that need. In its response to this protest, the VA has failed to do so.[5]

Given that this protest challenges only the specification for the dressing listed under CLIN 0002, we have no basis to disturb the agency's procurement of the dressings listed under CLINs 0001 and 0003. Accordingly, we recommend that the agency make a documented determination of its need for the fluid handling capacity of the sterile dressing covered by CLIN 0002, to address whether a value of 20 g/10cm²/24hr (or some other value or range of values) is reasonably necessary to meet that need.[6] Once the agency identifies its need and the specification that is

[5] We note for the record that there is no concern that an inability to complete this procurement will interrupt the VA's ability to purchase sterile foam dressings generally. In this regard, the VA's acquisition plan states that there are a "host of sources and numerous corresponding contracts that currently provide Foam Dressings" that can be used to meet the VA's ongoing needs. AR, Tab 3b, Acquisition Plan, at 3.

[6] In the event that the agency determines that a specification of 20 g/10cm$^2$/24hr or greater is reasonably necessary to meet its need under CLIN 0002, we observe that the agency's market research to date suggests a product meeting that specification may not exist in the commercial sectors where the agency has conducted its market research. For this reason, if the agency continues to seek a product meeting this specification, it may be advisable to consider whether the type of procurement being (continued...)

reasonably necessary to meet that need, the agency should revise the RFQ accordingly.[7] Finally, we also recommend that Smith & Nephew be reimbursed the costs of filing and pursuing the protest, including reasonable attorneys' fees. 4 C.F.R. § 21.8(d)(1) (2014). Smith & Nephew should submit its certified claim for costs, detailing the time expended and costs incurred, directly to the contracting agency within 60 days after receipt of this decision. Id. § 21.8(f)(1).

The protest is sustained.

Susan A. Poling
General Counsel

(...continued)
conducted here--i.e., a competition among commercial vendors holding VA Federal Supply Schedule contracts for commercial products--is appropriate, or whether it is more appropriate for the agency to conduct the procurement using the procedures contained in FAR part 15.

[7] Alternatively, the VA may conclude that cancellation and revision of the RFQ in its entirety is in the agency's best interest, in order to fully leverage the quantity savings it sought to achieve with this BPA.