Wolcott

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Comptroller General
of the United States
Washington, D.C. 20548

Decision

Matter of: Impact Instrumentation, Inc.

File: B-250968.2

Date: March 17, 1993

James M. McHale, Esq., and Daniel A. McNulty, Esq., Seyfarth, Shaw, Fairweather & Geraldson, for the protester.
Wilsie H. Adams, Jr., Esq., McKenna & Cuneo, for Bird Products Corporation, an interested party.
Frederick M. Quattrone, Esq., and Gale Furman, Esq., Defense Logistics Agency, for the agency.
Glenn G. Wolcott, Esq., and Paul Lieberman, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

1. Protest that awardee's proposal failed to comply with solicitation requirements is denied where record shows that, consistent with the solicitation, the awardee proposed modifications to its existing product in order to satisfy the specifications.

2. Protest challenging acceptability of awardee's proposal on the basis that awardee had not produced the item before submitting its proposal is denied where the solicitation does not call for a commercial item or otherwise require that the item proposed have been produced before proposals were submitted.

3. Agency's discussions with awardee did not constitute technical leveling where agency asked awardee only one set of questions which identified the solicitation requirements with which awardee's initial proposal failed to comply, and awardee responded with only one set of revisions to its technical proposal.

4. Solicitation clause that requires pre-marketing approval by the U.S. Food and Drug Administration of item offered constitutes a matter of responsibility compliance with which need only occur prior to contract performance.

DECISION

Impact Instrumentation, Inc. protests the Defense Logistics Agency's (DLA) award of a contract for portable ventilators to Bird Products Corporation under request for proposals (RFP) No. DLA120-92-R-0019. Impact asserts that Bird's proposal failed to comply with the solicitation requirements; that the agency engaged in technical leveling; and that Bird had not obtained pre-marketing approval for its proposed ventilators from the U.S. Food and Drug Administration (FDA) before submitting its proposal.

We deny the protest in part and dismiss it in part.

BACKGROUND

The solicitation, issued on January 28, 1992, sought firm, fixed-price proposals for 1,957 portable ventilators to provide and to assist patient respiration;[1] the ventilators are to be used in deployable medical systems (DEPMEDS), for example, "MASH" units and aeromedical evacuation in military aircraft. The solicitation listed over 50 "salient characteristics" as mandatory requirements for the ventilators. Section K of the solicitation also called for offerors to comply with section 510(k) of the Federal Food, Drug and Cosmetic Act (FFDCA) with regard to obtaining pre-marketing approval from the FDA, and advising the agency of the notification number assigned by the FDA and the date on which approval was granted. See 21 U.S.C. § 360(e) (1988).

Both Impact and Bird submitted initial proposals prior to the February 28 closing date. Impact proposed its Uni-Vent, model 750, for which it had previously obtained FDA pre-marketing approval, and which it had previously sold to DLA.[2] Bird proposed a modified version of its model

[1]The solicitation also contained a 100 percent quantity option which offerors were required to include.

[2]The ventilators sought under this RFP were first solicited under RFP No. DLA120-90-R-9305. Under that solicitation, Impact was awarded a contract for 1,000 ventilators at a price of $3,457 per unit. During Operation Desert Storm, another contract was noncompetitively awarded to Impact on the basis that it was the only known source.

6400ST, submitting manuals and descriptive literature for that model with its proposal. Bird had previously obtained FDA pre-marketing approval for the model 6400ST, and its proposal stated that FDA approval for the modified version of the model 6400ST would be obtained upon award of the contract.

The agency evaluated both proposals and determined that Impact's proposal was technically acceptable; Bird's proposal was found deficient in several areas, but susceptible of being made acceptable. The agency retained both proposals in the competitive range and initiated discussions with both offerors. By letter to Bird dated March 23, 1992, the agency identified the solicitation requirements which Bird's proposal failed to satisfy. On April 6, Bird submitted a detailed response to the agency's deficiency letter, enclosing revisions to the manuals and descriptive literature it had previously submitted.

The agency evaluated Bird's response and concluded that it addressed each of the identified proposal deficiencies, indicated what modifications would be made and, through references to its revised manuals and descriptive literature, demonstrated how the modifications would be accomplished. Based on this response, the agency determined that Bird's proposal was technically acceptable and requested that best and final offers (BAFOs) be submitted by September 4. Both Impact and Bird timely submitted BAFOs. Bird's BAFO offered a total price for both base and option quantities of $9,783,280; Impact's BAFO offered a total price of $15,239,900.

After BAFOs were submitted, the agency realized that it had failed to include procurement integrity certificates in the package of certifications provided to each offeror. Accordingly, on September 23, the agency sent such certificates to each offeror and asked that they be completed and telecopied to a specified telecopier number by September 24. Both offerors submitted the required certificates on September 24; neither offeror otherwise altered its proposal. On October 7, the agency awarded a contract to Bird on the basis of its low priced, technically acceptable proposal. This protest followed.[3]

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[3]On September 24, Impact telecopied its procurement integrity certificate to a different telecopying machine than the one which the agency had specified. Impact explains that the telecopier number specified was busy at the time transmission was attempted, so it sent the certificate to another number it had used earlier during this procurement and, after doing so, telephoned the

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DISCUSSION

Impact first protests that Bird's proposal should have been rejected for offering a ventilator that failed to comply with numerous solicitation requirements. This portion of Impact's protest was based on the assumption that Bird proposed its model 6400ST without modifications; accordingly, Impact's protest listed various solicitation requirements which the model 6400ST does not meet.

In its report responding to the protest, the agency provided conclusive evidence that Bird proposed modifications to its model 6400ST which made its proposal compliant with each of the solicitation requirements identified by Impact in its protest. In particular, as discussed above, in responding to the agency's discussions questions, Bird addressed each of the deficiencies contained in its initial proposal, indicated what modifications would be made and, through references to its revised manuals and descriptive literature, demonstrated how the modifications would be accomplished. Since Impact's assertion that Bird's proposal failed to comply with the solicitation requirements is factually contradicted by the record, this protest allegation is denied.

After learning of the questions posed to Bird during discussions, Impact amended its protest to assert that, by identifying the numerous deficiencies in Bird's initial proposal, the agency engaged in technical leveling. The agency responds that it provided only one set of technical questions to Bird during its discussions and permitted only one response; that the agency's questions simply listed the

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[3](...continued)
contracting officer to confirm his receipt of the certificate. After this protest was filed, the agency suggested that Impact's submission of its certificate via a telecopying machine other than the specified one rendered its proposal unacceptable. On that basis, the agency argued that Impact is not an interested party to file this protest, see 4 C.F.R. § 21.0(a) (1992), and requests that we dismiss the protest. The record is clear that the contracting officer did, in fact, receive Impact's procurement integrity certificate prior to the required closing time (albeit from a machine other than the one specified), and there is no indication that the agency considered Impact's proposal unacceptable before Impact filed this protest. On this record, we decline to dismiss the protest.

solicitation requirements with which Bird's initial proposal failed to comply; and that the agency provided no assistance to Bird in responding to the questions or preparing its BAFO.

Technical leveling arises only where, as the result of successive rounds of discussions, "the agency has helped to bring one proposal up to the level of other proposals by pointing out inherent weaknesses that remain in the proposal because of the offeror's own lack of diligence, competence, or inventiveness after having been given an opportunity to correct them." Price Waterhouse, B-222562, Aug. 18, 1986, 86-2 CPD ¶ 190; see also Columbia Research Corp., B-247631, June 22, 1992, 92-1 CPD ¶ 539. Here, since the agency gave Bird only a single opportunity to correct the deficiencies in its initial proposal and there is nothing in the record to suggest that it otherwise assisted Bird in revising its proposal, technical leveling did not occur. Id.

Impact also protests that the agency should have rejected Bird's proposal on the basis that Bird had not produced the modified version of its model 6400ST prior to submitting its proposal. This argument presumes that the solicitation required offerors to propose items that were in commercial production or that had been previously produced. In fact, the solicitation contained no such limitation; hence, there is no basis to object to the acceptance of Bird's proposal to modify an existing model.

Impact next protests that award to Bird was improper because Bird had not received pre-marketing approval from the FDA at the time it submitted its proposal. Referring to the section K clause of the RFP which incorporated the requirements of section 510(k) of the FFDCA and required offerors to provide the notification number and date of FDA approval, Impact asserts that this solicitation required a potential offeror to have obtained FDA approval prior to submitting a proposal. Since Impact's ventilator, which it has previously supplied to the agency, has FDA approval, the protester argues in effect that DLA may buy the item only from Impact.

Our Office has previously addressed the issue of the required timing for compliance with section 510(k) of the FFDCA. Impact itself raised the same issue in connection with earlier language used by DLA requiring compliance with section 510(k), Impact Instrumentation, Inc., B-217291, Feb. 26, 1985, 85-1 CPD ¶ 240, and, more recently, we considered application of the identical clause contained in this solicitation, requiring compliance with section 510(k) of the FFDCA and submission of information related to FDA's

approval. In Physio Control Corp; Medical Research Laboratories, Inc., B-231999.2; B-231999.3, Aug. 10, 1989, 89-2 CPD ¶ 123, the protester argued that because the solicitation clause referred to offerors' submission of information regarding FDA's pre-marketing approval, only proposals offering products which had received such approval prior to the time initial proposals were submitted were eligible for contract award. We rejected that argument, concluding that compliance with section 510(k) of the FFDCA was a matter of responsibility which could be determined in the affirmative if it appeared that the firm would be in compliance prior to contract performance. See also Astro-Med, Inc., B-232633, Dec. 22, 1988, 88-2 CPD ¶ 619; Chemical Compounding Corp., B-227333, June 15, 1987, 87-1 CPD ¶ 596; Hewlett-Packard Co., Medical Prods. Group, B-216125.2, May 24, 1985, 85-1 CPD ¶ 597.

This case is governed by our previous decisions regarding compliance with section 510(k) of the FFDCA; that is, that compliance with this FDA requirement constitutes a matter of responsibility, and such compliance need only occur prior to contract performance. As discussed in Physio Control Corp; Medical Research Laboratories, Inc., supra, the specific language of this solicitation created no exception to the general rule.[1] Here, before the award was made, the agency necessarily made an affirmative responsibility determination with regard to Bird; we have no basis to question that determination since Impact has not shown any possible fraud and the solicitation requirements do not constitute

[1]Subsequent to issuing this solicitation, DLA adopted a clause ("PREMARKET APPROVAL NOTIFICATION (MAR 1992) DPSC") that revised the solicitation language concerning the FDA pre-marketing approval requirements. The new clause explicitly requires rejection of offers of medical devices that do not have FDA approval 90 days prior to submission of the initial offer or the original closing date, whichever comes first. This decision addresses only the provision in the solicitation at issue here.

definitive responsibility criteria.[5] See Ace Van & Storage Co., B-210083, Dec. 28, 1982, 82-2 CPD ¶ 586. Accordingly, this portion of Impact's protest is denied.

Finally, in comments filed on December 8, Impact for the first time asserted that section 510(k) of the FFDCA required Bird to give the FDA notice of the proposed modifications to its model 6400ST 90 days before submitting its proposal. In its December 8 comments, Impact distinguishes between this new allegation regarding the alleged illegality of Bird's failure to notify FDA 90 days prior to submitting its proposal, and its initial protest allegation regarding Bird's failure to have obtained FDA approval at the time it submitted its proposal, stating:

> "While Impact still contends that Bird was required to receive 510(k) approval prior to the offer, whether Bird received this approval prior [to submitting its offer] is of no consequence to its failure to comply with its obligation under [the FFDCA] to submit its 510(k) notice 90 days prior to offer."

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[5]An agency's affirmative determination of a contractor's responsibility will not be reviewed by our Office absent a showing of possible fraud or bad faith by procurement officials, or that definitive responsibility criteria in the solicitation have been misapplied. Definitive responsibility criteria are special standards established by an agency to measure an offeror's ability to perform a particular contract and, in effect, represent the agency's judgment that an offeror's ability to meet the solicitation requirements must be measured not only against the traditional and subjectively evaluated responsibility factors, such as adequate facilities and financial resources, but also against more specific requirements, compliance with which at least in part can be objectively established. See Federal Acquisition Regulation (FAR) § 9.104-2; Nations, Inc., B-220935.2, Feb. 26, 1986, 86-1 CPD ¶ 203; Clausing Machine Tools, B-216113, May 13, 1985, 85-1 CPD ¶ 533. Where, as here, a solicitation requires licensing or other approval by a regulatory or governmental authority, but does not require that such approval must be obtained prior to contract award, the solicitation provision constitutes a general contract performance requirement--not a definitive responsibility criterion. See DOD Contracts, Inc., B-240590.3, Oct. 22, 1991, 91-2 CPD ¶ 354; Cumberland Sound Pilots Ass'n--Recon., B-229642.2, June 14, 1988, 88-1 CPD ¶ 567; Chemical Compounding Corp., B-227333, June 15, 1987, 87-1 CPD ¶ 596; S.A.F.E. Export Corp., B-213027, June 27, 1984, 84-1 CPD ¶ 675.

Impact learned on October 29 that Bird had not notified the FDA prior to submitting its proposal, but Impact first raised this issue with our Office on December 8. Our Bid Protest Regulations contain strict rules requiring timely submission of protests. Under these rules, a protest challenging another offeror's alleged failure to comply with a solicitation requirement must be filed no later than 10 working days after the protester knew, or should have known, of the basis for the protest, whichever is earlier. 4 C.F.R. § 21.2(a)(2) (1992). Where a protester initially files a timely protest and later supplements it with new and independent grounds of protest, the later-raised allegations must independently satisfy the timeliness requirements. Midwest Contractors, Inc.; R.E. Scherrer, Inc., B-231101; B-231101.2 Aug. 8, 1988, 88-2 CPD ¶ 118. Since Impact failed to raise the issue of Bird's alleged failure to properly notify FDA within 10 days after learning of this basis for protest, we will not now consider the matter. Id.

The protest is denied in part and dismissed in part.

James F. Hinchman
General Counsel