WILLIAMS

The Comptroller General
of the United States

Washington, D.C. 20548

Decision

Matter of: Physio Control Corporation; Medical Research Laboratories, Inc.

File: B-231999.2; B-231999.3

Date: August 10, 1989

DIGEST

1. Protest that agency failed to obtain full and open competition because agency relaxed material requirements of request for proposals (RFP) for the benefit of the awardee without advising protester is denied where record indicates that RFP's requirements were not relaxed and awardee's proposal complied with all material requirements of the solicitation.

2. Protest is denied where review of existing record consisting of protest and contracting agency's comprehensive response thereto does not indicate that agency had acted unreasonably in its conduct of the procurement.

DECISION

Physio Control Corporation and Medical Research Laboratories, Inc. (MRL), protest the award of a contract to Hewlett-Packard Company (H-P) under request for proposals (RFP) No. DLA120-87-R-0016 issued by the Defense Personnel Support Center, Defense Logistics Agency (DLA).

Physio contends that the award to H-P is improper because H-P's proposal did not comply with certain material requirements of the RFP and that, in making award to H-P, the agency improperly relaxed the RFP requirements without informing Physio and other offerors. MRL makes a variety of allegations in which it challenges the propriety and fairness of the agency's evaluation of technical proposals and its justification for requesting a second round of best and final offers (BAFOs).

The RFP, issued on June 9, 1987, was for the supply of military defibrillator and electrocardiograph equipment under the Deployable Medical Systems (DEPMEDS) acquisition program. The equipment is needed for use in military field ("MASH-type") hospitals and must therefore be portable and

capable of being activated in the event of an emergency. The amended RFP provided for the award of a firm, fixed-price requirements-type contract for a 1-year base period and three 1-year option periods. Evaluation of technical and business proposals would be based on three principal evaluation factors listed in the RFP using the "greatest value" procurement source selection method with technical quality more important than price.

Three firms submitted proposals. The initial technical evaluation showed that H-P's proposal was rated "superior"; Physio's proposal was rated "good"; and MRL's proposal was rated "adequate." Only H-P and Physio were initially included in the competitive range.1/ Following written and oral discussions two successive rounds of BAFOs were requested and received from all three firms.

After the evaluation of the first BAFO submissions, the technical ranking for H-P (91 out of 100 possible points) and Physio (78.5 points) remained unchanged and MRL's technical score increased slightly to a total of 66 points. A second round of BAFOs was requested following DLA's clarification of certain quantity and delivery requirements. No technical revisions were made and those scores remained unchanged. Physio offered the lowest maximum estimated price for the base plus 3 option years ($50,294,000); MRL the second highest ($51,9914,572); and H-P the highest evaluated price ($52,718,017). The Source Selection Authority considered the difference in technical quality among the competing proposals and agreed with the contracting officer and the Source Selection Evaluation Board that H-P's technical superiority justified its higher price. Award was made to H-P on March 29, 1989. By letter of the same date, Physio and MRL were notified of the award. Physio and MRL requested debriefings; received them on March 31 and April 5; and filed protests on April 5 and 7, respectively.

1/ MRL's proposal was initially excluded from the competitive range because its price was significantly higher than the other offerors. MRL filed protests with DLA and with our Office challenging its exclusion. The contracting officer reviewed the information furnished by MRL in its protests and included the firm in the competitive range, resulting in the withdrawal of MRL's protest.

PHYSIO'S PROTEST

Physio does not challenge the technical evaluation of H-P's proposal.2/ Rather, it argues that H-P did not meet an RFP requirement that the equipment to be supplied be a militarily modified version of a commercial modular defibrillator/electrocardiograph system, complete with commercial manuals and Food and Drug Administration (FDA) approval at the time of proposal submission.3/

Physio contends that under the solicitation, offerors were required to propose an existing, FDA-approved commercial modular system and not commercial components never before integrated into a modular system. The protester alleges that H-P did not propose a commercial modular system needing only minor military modification. Rather, Physio contends that H-P proposed to integrate two separate commercial products--a stand-alone defibrillator and a stand-alone electrocardiograph monitor/recorder--into a new (as opposed to existing) modular system. Physio bases its position on the language of the solicitation which includes, for example, the requirement for submission of commercial maintenance manuals and the requirement for FDA approval.

DLA and H-P take the opposite point of view. Initially, both parties argue that not only is Physio's position unsupported by the clear language of the RFP, but that, more importantly, it would unduly restrict competition in a manner that benefits Physio since only it and MRL had an existing, commercial modular system at the time proposals were due. These parties refer to recent decisions wherein we have declined to uphold challenges to specification

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2/ We also note that during the course of its protest Physio abandoned allegations that it was competitively prejudiced by the delays in the procurement process and the amendments to the RFP which changed the first article and production delivery schedules for the sole benefit of "an offeror [H-P] still developing [its] product."

3/ The equipment is considered a medical device and as such offerors/contractors are required to comply with section 510(k) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360(k) (1982) and regulations promulgated thereunder by the FDA which impose a premarket notification approval for manufacturers of this equipment. As evidence of compliance, offerors were to provide, for each product being acquired, the premarket notification number and the date of FDA approval.

requirements which have the purpose or effect, whether explicit or implicit, of reducing competition to the benefit of the protester. See Northrop Corp., Precision Prods. Div., B-234237, May 3, 1989, 89-1 CPD ¶ 423; Gould Elecs., B-233947.2, Mar. 27, 1989, 89-1 CPD ¶ 310. We need not address this latter argument since, as discussed herein, we find Physio's protest unsupported in the record. Simply stated, we find no requirement in the solicitation documents that offerors were restricted to an existing, FDA-approved, modular commercial system.

First, we note that the defibrillator/monitor-recorder is described in the RFP by Military Specification Sheet, Defibrillator/Monitor-Recorder, DPSC-DEPMEDS-AT/94D (DM), April 15, 1987, and the General Requirements for Deployable Medical Systems, MIL-D-42048, June 26, 1987. The latter contains general requirements intended to be used in conjunction with more detailed specifications for individual items, such as the Specification Sheet here. There is no question but that the Specification Sheet requires that the defibrillator/monitor-recorder system to be provided be of modular design, i.e., to consist of a defibrillator module and a monitor-recorder module capable of being separated and used independently.

Nevertheless, we read the Specification Sheet only to convey a requirement that the final configuration of the system be modular. The express language of the solicitation documents makes no mention that the system had to be "modular in design" prior to being modified to meet the military specifications of the RFP.

Second, we do not find persuasive Physio's argument that the RFP requirement for commercial manuals to be submitted for evaluation with the proposals is indicative of DLA's intent to purchase an existing commercial modular system, to be militarily modified. DLA points out that the manuals to be supplied under the contract will of necessity be different from their commercial versions in order to reflect the equipment modifications required by the military. The agency states that in DEPMEDS acquisitions, rather than waiting to review the manuals after the militarily modified equipment has been produced, it routinely chooses to evaluates offerors' existing commercial manuals, indicating (as it did in this RFP) that its intent is to use the existing manual "to the fullest extent possible." In fact, the record shows that all three offerors' manuals were reviewed and each offeror was provided with a list of deficiencies to be corrected. Under these circumstances, we do not think that the RFP's requirement for submission of

commercial manuals provides support for limiting offerors to those possessing an existing commercial modular system.

Finally, Physio contends that since the solicitation required "all offerors" to be in compliance with section 510(k) for "those medical device products intended to be delivered to the government," and since offerors were to provide the notification number and date of FDA approval, only those offerors which had such approval for an existing commercial modular system prior to the due date for receipt of initial proposals were eligible for consideration for award.

DLA responds that its solicitation clause was drafted in light of our decision in Impact Instrumentation, Inc., B-217291, Feb. 26, 1985, 85-1 CPD ¶ 240, in which we held that a solicitation requirement that the "offeror/contractor" comply with the FDA's premarket notification procedures concerned a matter of a firm's responsibility which could be determined in the affirmative if it appeared that the firm would be in compliance with the FDA's requirements prior to contract performance. In addition, DLA points out that FDA has concluded that the militarized items which all three offerors here have proposed to supply to DLA sufficiently differ from the commercial devices previously approved that any of the offers, if selected for award, would need to obtain FDA premarket notification approval.

We think this case is governed by previous decisions of our Office in which we have held that compliance with an FDA requirement such as this is a matter of responsibility, see, e.g., Astro-Med, Inc., B-232633, Dec. 22, 1988, 88-2 CPD ¶ 619 and cases cited therein, and have further held that actual compliance with such a requirement need only occur by the start of contract performance. See 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. Moreover, in this case, before award was made to H-P, the contracting officer necessarily determined that H-P was responsible. Accordingly, we deny Physio's protest of this award.

MRL'S PROTEST

MRL's protest raised various allegations, including that the technical evaluation of proposals was inconsistent with the criteria stated in the RFP; that the evaluation team included no users even though "user considerations" were among the evaluation criteria; that the evaluation was conducted in a manner prejudicial to small business concerns in that proposals were evaluated based on size and "glossy

'Madison Avenue' presentations" rather than substance; and that DPSC requested multiple BAFOs without adequate justification therefor.

DLA furnished a detailed report, including a 30-page contracting officer's statement, refuting MRL's allegations. In that response, DLA took exception to a number of factual assertions made by MRL and to its legal conclusions as well. The agency also explained that the second request for BAFOs was justified by the need to clarify the government's requirements concerning estimated quantities and delivery. It defended its evaluation of H-P's technical proposal as "superior" on the basis of the proposal's content and denied that it had put "gloss" over substance. It also noted that contrary to MRL's contention, a majority of the technical evaluation panel members were its military customers, including a cardiologist.

MRL subsequently participated in the protest conference held in connection with the protest filed by Physio at the conclusion of which MRL was invited to file conference comments. MRL did not substantively respond to DLA's position, however, but requested a decision on the existing record.

We have therefore thoroughly reviewed the record consisting of MRL's protest and the agency's response. Particularly in view of the fact that MRL's protest included a number of unsupported and speculative assertions, often phrased as rhetorical questions, and has been shown to rest on some incorrect factual assumptions, we conclude that it has not shown DLA's actions to be unreasonable. MRL's protest is therefore denied.

Accordingly, we deny both protests.

James F. Hinchman
General Counsel