DECISION

THE COMPTROLLER GENERAL
OF THE UNITED STATES
WASHINGTON, D.C. 20548

FILE: B-216125.2 DATE: May 24, 1985

MATTER OF: Hewlett-Packard Company, Medical Products Group

DIGEST:

1. Protest that post-bid opening performance test was not conducted as described in the solicitation need not be filed prior to bid opening in order to be timely under GAO's Bid Protest Procedures.

2. Benchmark tests should only be performed on a low bidder after bid opening on the second step of two-step formally advertised procurement in unusual case; such a test relates to that bidder's responsibility.

3. Benchmark test conducted after bid opening on the second step of two-step formally advertised procurement on the proposed system of the low bidder was not properly or fairly conducted so as to justify rejection of that bidder as not responsible where (1) neither the solicitation nor the agency adequately informed the bidder of the nature, details, ground rules or "pass-fail" nature of the benchmark and (2) the bidder was not adequately informed of the nature of or afforded a reasonable opportunity to correct the evaluated system deficiencies consistent with its acceptable technical proposal.

4. Low bidder, on second step of two-step formally advertised procurement, cannot be rejected for failing to comply with invitation for bid requirement that it furnish "current production model," where the term is not defined in the solicitation, and the bidder had produced 11 models by the time of award.

5. Bidder, which had submitted premarket notification of medical equipment to Food and Drug Administration (FDA) pursuant to 21 C.F.R. subchapter H, to which FDA had not responded as of the date of award, cannot be rejected as nonresponsible, where (1) solicitation does state such approval must be obtained by the time of award; (2) the bidder had certified and fully complied with FDA requirements at that time; (3) the agency had no basis to believe negative FDA action would occur or that bidder had any probable inability to meet contract requirements in this regard; (4) delivery of the equipment was to be made 6 months after award; and (5) FDA has since positively responded to the bidder's submission.

Hewlett-Packard Company, Medical Products Group (Hewlett-Packard), protests the rejection of its bid under the second step of a two-step formally advertised solicitation (No. M6-4-84) for automated electrocardiography interpretive systems (AECGIS), issued by the Veterans Administration (VA).

We sustain the protest.

BACKGROUND

This is a two-step formally advertised procurement. The protest only concerns the second step formally advertised portion. Two-step formally advertised procurements are intended to be conducted in the following manner. The first step is conducted as the technical evaluation of a negotiated procurement. Offerors submit technical proposals which are evaluated. Discussions may be held with offerors, and they may be permitted to correct weaknesses and deficiencies found by the contracting agency. Offerors' proposals are found to be technically acceptable or not. That is, all questions concerning an offeror's technical approach and capability should be decided in the first step. Step two is conducted as a formally advertised procurement, limited to those offerors whose step one proposals were found to be acceptable and only allowing those acceptable first-step proposals to be the basis of the second step bids. Award is to be made to the low responsible bidder, so long as the bidder does nothing in its bid to render the bid nonresponsive.

The VA received technical proposals from Hewlett-Packard and Marquette Electronics Inc., (Marquette) in response to the first step of the procurement. After discussions with both offerors, both technical proposals were found to be acceptable. The VA states that it did have questions about Hewlett-Packard's ability to provide equipment meeting the specifications, but that, in the interest of enhancing competition, the VA accepted Hewlett-Packard's written explanations and assurances to find its proposal acceptable.

The VA issued the step two invitation for bids on June 8, 1984, and bids were opened on July 16, 1984. Hewlett-Packard submitted the low bid of $3,489,500 while Marquette's bid was $3,592,565.

On August 6, 1984, Hewlett-Packard submitted its system to a "demonstration test" at a VA hospital. The VA believes that the Hewlett-Packard system failed this test. The VA reports that Marquette's system was similarly tested on August 16, 1984. The Marquette system test was successful, and the contract was awarded to Marquette on September 13, 1984. However, following Hewlett-Packard's protest to our Office, the VA issued a stop work order on the contract, which remains in effect.

On September 14, 1984, Hewlett-Packard was advised that its bid had been rejected for five basic reasons. VA has since conceded that two of the reasons were improper and it now grounds its rejection on three bases: (1) that Hewlett-Packard's system did not pass the performance test; (2) that Hewlett-Packard is not offering a "current production model" as required by the IFB; and (3) that Hewlett-Packard had not obtained the approval of the Food and Drug Administration (FDA) for its equipment when award had to be made.

PERFORMANCE TEST

The primary reason Hewlett-Packard was rejected was its failure to pass the August 6 demonstration test. The only indication in the IFB that such a test would be required is in the first paragraph of section A22 of the IFB which states:

> "no total system or component . . . will be awarded unless the offeror can demonstrate the operation of a production model of each piece of equipment by the date set for bid opening. . . ."

No demonstration test of Hewlett-Packard's proposed system was conducted prior to bid opening. The VA reports that this delay was caused by scheduling difficulties and because the VA believed Hewlett-Packard's equipment was not capable of being demonstrated at an earlier date.

Hewlett-Packard was apparently only first informed that its system had failed the performance test on September 14, 1984. At that time, the VA stated with regard to Hewlett-Packard's performance on the test:

> "4. The quality assurance function was not considered satisfactory on the electrocardiograph [ECG] cart. The system processed an ECG with bad lead connections without notifying the operator.
>
> "5. The remote edit terminal was considered too complicated to operate. The Hewlett-Packard representative operating the unit could not remember the codes to obtain information from the system."

Subsequently, in the agency report, the VA indicated that the Hewlett-Packard system failed to meet numerous other specification requirements, the most important of which was that "the normal processing time, input, analysis and output will be two minutes or less for each ECG."

Hewlett-Packard argues that the demonstration requirement, as worded in the solicitation, was not intended to be a full-blown benchmark-type test, but rather was to be a non-technical presentation. If it was intended to be a benchmark-type test, Hewlett-Packard contends that VA did not comply with the regulations applicable to benchmarks, such as providing a detailed statement concerning how the benchmark was to be conducted, and permitting bidders a second chance to pass the benchmark. Hewlett-Packard contends that the reasons cited for its failure of the demonstration are not valid, and that its equipment does meet the solicitation requirements. Also, Hewlett-Packard asserts that a member of VA's technical staff exhibited bias against Hewlett-Packard, which colored the conduct and evaluation of the test. Finally, since the test was conducted after bid opening, Hewlett-Packard contends that it involved a matter of bidder responsibility not bid responsiveness, and that the VA could not reject its bid based on the test results without further input from Hewlett-Packard.

Initially, the VA and Marquette argue that Hewlett-Packard's protest on the demonstration requirement is

untimely under our Bid Protest Procedures, 4 C.F.R. § 21.2(a)(1) (1984), because the demonstration requirement should have been protested prior to the bid opening if Hewlett-Packard thought the requirement was improper or unclear. We find that the protest is timely. Hewlett-Packard is arguing that the test that was conducted was not the test that was described in the solicitation. Hewlett-Packard could not have known this basis of protest from the solicitation and, therefore, was not required to protest prior to bid opening. See Modutech Marine, Inc., B-207601, Feb. 9, 1983, 83-1 C.P.D. ¶ 144.

We have expressly sanctioned tests or benchmarks conducted on proposed equipment after bid opening on a two-step formally advertised procurement to ascertain whether a bidder has the ability to comply with the contract requirements, where there is conflicting evidence whether the low bidder can actually comply with these requirements. United States Army Materiel Development and Readiness Command--Request for Advance Decision; Hitachi Denshi America Ltd., B-212925, Mar. 23, 1984, 84-1 C.P.D. ¶ 342. Nevertheless, such tests should only be performed after the second step in unusual cases because questions of product acceptability should have been resolved in the first step of the procurement. Cf. CompuServe Data Systems, Inc., 60 Comp. Gen. 468 (1981), 81-1 C.P.D. ¶ 374 (Benchmark tests should be conducted prior to receipt of best and final offers on a negotiated procurement so that system deficiencies which are likely to occur during the test can be pointed out and possibly remedied.)

The first step of two-step procurements is ordinarily where all questions concerning the acceptability of an offered product or system should be settled and any benchmark tests run. Since the VA apparently harbored grave doubts of Hewlett-Packard's system's acceptability, both before and after determining Hewlett-Packard's proposal was technically acceptable, it is apparent that a benchmark should have been part of the technical evaluation portion of the two-step formally advertised process. See, e.g., Exide Power Systems Division, ESB Inc., 57 Comp. Gen. 653 (1978), 78-2 C.P.D. ¶ 106.

The VA has now conceded that this test, as conducted, relates to Hewlett-Packard's responsibility, and not to the responsiveness of its bid, since this test was conducted after bid opening to verify whether Hewlett-Packard had the ability to provide a system in conformance with the specifications. We have consistently held that information relating to a bidder's responsibility may be furnished to an

agency any time prior to award. Urban Masonry Corp., B-213196, Jan. 3, 1984, 84-1 C.P.D. ¶ 48; Tomko Inc., 63 Comp. Gen. 218 (1984), 84-1 C.P.D. ¶ 202. On the other hand, we have also recognized that a procuring activity is not required to delay an award indefinitely while a bidder attempts to cure the causes for its nonresponsibility. Roarda Inc., B-204524.5, May 7, 1982, 82-1 C.P.D. ¶ 438. For a number of reasons as outlined below, we do not believe Hewlett-Packard was given an adequate opportunity to show that it was capable of meeting the specification requirements. See Tomko, Inc., 63 Comp. Gen., supra.

First, the IFB performance test provisions in this case fail to state that bidders would be required to demonstrate compliance with all specifications. In fact, they did not state what operations would be demonstrated or in any way indicate how the operations would be judged. We have held that the primary purpose of a benchmark, unless otherwise specified, is to show whether an offeror's equipment is capable of performing the desired functions; not to substitute for the contents of a technical proposal. See AT&T Information Systems, Inc., B-216306, Mar. 20, 1985, 85-1 C.P.D. ¶ 326. Moreover, in order to have a fully useful benchmark test, the firms should be apprised of the nature and details of the test prior to its running. See ADP Network Services, Inc., 59 Comp. Gen. 444 (1980), 80-1 C.P.D. ¶ 339.

Hewlett-Packard states that it believed the demonstration was to generally illustrate its system's performance and to demonstrate its Model 4760 ECG cart to reassure the VA that they had a device that had interpretative capability. Hewlett-Packard denies that it knew that a full-blown "pass-fail" benchmark test was going to be performed. Indeed, the VA does not indicate that it ever furnished Hewlett-Packard with a test plan for or otherwise apprised it of the details of the performance test prior to the test. Hewlett-Packard further states that its impression of this test was encouraged by the contracting officer, both before and after the test. Based on our review of the record, we find that Hewlett-Packard was not adequately apprised of the nature, degree, details or any ground rules of the performance test. Contrast United States Army Materiel Development and Readiness Command, et al., B-212925, supra, where the low bidder was apprised of the ground rules of a post-bid opening test to assure that its equipment complied with specification requirements.

Second, the record shows that Hewlett-Packard was not adequately informed of the deficiencies in its test

performance and given an opportunity to correct them before it was rejected. We have held that in most cases benchmark tests in negotiated procurements should not be conducted on a "pass-fail" basis, but rather offerors should be notified of the deficiencies in their performance and given an opportunity to correct their deficiencies. The Computer Company--A Reconsideration, 60 Comp. Gen. 151 (1981), 81-1 C.P.D. ¶ 1; NCR Corp. B-209671, Sept. 16, 1983, 83-2 C.P.D. ¶ 355. We believe this principle is equally applicable to the unusual post-bid opening benchmark test used in this case to evaluate Hewlett-Packard's responsibility. The system deficiencies that were found by the VA should have been discussed with Hewlett-Packard, which should then have been afforded a reasonable opportunity to correct these deficiencies to the degree it could consistent with its technical proposal. Cf. Tomko Inc., 63 Comp. Gen., supra (once an agency agrees to accept data concerning a bidder's responsibility, it cannot unreasonably cut off further discussions without giving the bidder a fair opportunity to present evidence supporting its ability to perform the contract).

While the VA claims that its representatives told Hewlett-Packard when it failed a specification at the test and gave it an opportunity to perform the test again, the record does not support that claim. Hewlett-Packard has provided affidavits to the effect that the VA representatives did not provide such information to it during the demonstration. Additionally, the VA admits that it did not determine until after the test whether Hewlett-Packard had passed or failed, and that immediately after the test the contracting officer informed Hewlett-Packard "not to worry yet and wait for the results." The record also indicates that Hewlett-Packard was only apprised of some (not all) of the evaluated deficiencies in its demonstration test on September 14, 1984, after award was made to Marquette. Prior to that time, the record indicates that Hewlett-Packard attempted to meet with the VA to discuss the matter but its efforts in this regard were not successful. Therefore, it appears that there was adequate time and opportunity to discuss this matter with Hewlett-Packard prior to award. Based upon our review, we conclude that Hewlett-Packard was not adequately informed during the test or prior to award of the deficiencies that caused its alleged failure, and was not given a reasonable chance to correct these evaluated deficiencies.

Third, written statements from the head of the VA technical team, prior to the test, make it clear that he did not want Hewlett-Packard to be awarded the contract because

he did not believe that its system was as good as Marquette's. Specifically, in a memorandum this individual wrote within a week before the test (discovered by Hewlett-Packard pursuant to a Freedom of Information Act request), he said that the technical evaluators:

> "consistently found the Hewlett-Packard AECGIS proposal wholly unsatisfactory. Nevertheless, we are now being forced to accept what none of the physicians in the field requests or wants. . . . To frustrate them would be a dreadful thing to do."

As indicated above, however, Hewlett-Packard's first step technical proposal was found technically acceptable, even though it appears that at least some VA technical evaluators did not believe the system actually was acceptable.

Further, Hewlett-Packard's affidavits concerning the conduct of the test indicate that the VA was generally uncommunicative and secretive during the test and that Hewlett-Packard's impression was that the VA evaluators intent was "to disqualify Hewlett-Packard as a legitimate supplier of this equipment."

There is considerable disagreement between the VA and Hewlett-Packard as to whether Hewlett-Packard actually passed the test. The reasons initially communicated to Hewlett-Packard in the September 14 letter regarding this test were its poor "quality assurance" and that it was "too complicated." These are obviously subjective conclusions, both of which are vigorously disputed and explained by Hewlett-Packard. Also, the record seemingly shows that Hewlett-Packard met the critical 2 minute processing time specification at least once during the test and Hewlett-Packard has made persuasive explanations as to why it did not meet it on other runs.

However, we need not resolve these technical disputes or whether the VA was biased because the record indicates that the test was not properly or fairly conducted. Under the circumstances, the test results cannot be used to reject Hewlett-Packard.

CURRENT PRODUCTION MODEL

Paragraph A-22, subparagraph 2, of the IFB, forms the second basis for the VA rejecting Hewlett-Packard's bid. This provision reads as follows:

"OFFEROR HEREBY CERTIFIES THAT EQUIPMENT AND SOFTWARE OFFERED IN RESPONSE TO THIS SOLICITATION ARE IN COMPLIANCE WITH EQUIPMENT OPERATIONS PROVISIONS AS STATED ABOVE AND ARE CURRENT PRODUCTION MODELS."

The VA found that the ECG cart, a critical component of the system which Hewlett-Packard demonstrated on August 6, 1984, was a prototype or preproduction model and therefore, Hewlett-Packard did not offer a "current production model."

Hewlett-Packard's compliance with its bid certification that it is offering a "current production model" concerns its responsibility. See Caelter Industries, Inc., B-203418, Mar. 22, 1982, 82-1 C.P.D. ¶ 265. Here, we note that the IFB did not specifically define the term "current production model." In these circumstances, the meaning of this term must be gleaned from its use in the context of the RFP. Id.

Hewlett-Packard argues that its ECG cart qualifies as a current production model under any reasonable definition of the phrase. Hewlett-Packard states that two initial preproduction models were completed by January 23, 1984, and nine more models were completed by May 1, 1984. According to Hewlett-Packard, a pilot production run of five units was completed on August 16, 1984. Hewlett-Packard states that corporate management announced the product commercially in September 1984.

We agree with Hewlett-Packard. Hewlett-Packard's demonstrated ECG cart was in fact one of the first eleven models produced. Production continued after the test. Therefore, Hewlett-Packard's bid cannot be rejected on this basis.

FDA PREMARKET REQUIREMENTS FOR MEDICAL EQUIPMENT

Finally, the VA argues that Hewlett-Packard failed to obtain approval from the Food and Drug Administration (FDA) under the FDA's pre-market requirements for the Hewlett-Packard ECG cart, Model 4760. The IFB, at paragraph A-3, contained the following requirement relating to FDA approval:

"MEDICAL DEVICE AMENDMENTS OF 1976: The bidder certifies that any facility listed under the "PRINCIPAL PLACE OF PERFORMANCE" provision is in compliance with 21 U.S.C. 360c et seq. (Public Law 94-295) and applicable provisions contained in

> 21 CFR Subchapter H - Medical Devices, including Current Good Manufacturing Practice Regulations (CGMPRS), as applicable. Food and Drug Administration (FDA), will be the single Agency charged with the Administrative interpretation and enforcement of the aforecited Law, including CGMPRS."

It is clear that the FDA requirement bears on the responsibility of the bidder, not the responsiveness of its bid. See Impact Instrumentation Inc., B-217291, Feb. 28, 1985, 85-1 C.P.D. ¶ 240.

Hewlett-Packard contends that the clause only required that its "facility" be certified and that its Andover, Massachusetts plant has had such FDA approval since 1976, the effective date of the cited FDA procedures. The VA states that it places a much broader meaning on the wording of the clause and the system being offered had to comply with the pre-market notification procedures in 21 C.F.R. Subchapter H. Even assuming that VA's broader interpretation of this clause is correct and the offered product must comply with the cited FDA procedures, we find for the following reasons that Hewlett-Packard had in fact complied with these procedures.

The FDA pre-market notification procedures, at 21 C.F.R. subchapter H, subpart E, § 807.81(a) (1984), requires:

> ". . . each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use. . . ."

On June 11, 1984, Hewlett-Packard submitted the above-referenced notification to the FDA that the ECG cart was substantially equivalent in terms of safety, effectiveness and intended use to existing product offerings. In this case, the FDA did not notify Hewlett-Packard that it determined that the device was substantially equivalent until November 20, 1984.

Under 21 C.F.R. subpart E, the FDA reviews a firm's premarket notification and makes a determination whether the device is substantially equivalent as represented. That is,

the FDA exercise of authority under these regulations is more limited than under its other authorities, inasmuch as it does not actually approve the device under these regulations where it determines substantial equivalency. 21 C.F.R. § 807.97. See generally Impact Instrumentation Inc., B-217291, supra.

The VA takes the position that since the FDA had not acted upon the Hewlett-Packard notification at the time it was prepared to make award, September 13, 1984, it was proper to reject Hewlett-Packard. We disagree.

Hewlett-Packard certified in its bid compliance with these FDA requirements and indeed had submitted the FDA notification more than 90 days before it planned to distribute or deliver the ECG cart as required by the FDA regulations. The IFB required delivery 180 days after the issuance of a delivery order. At the time of award, the FDA had taken no negative action on the Hewlett-Packard submission which would cause the VA to question the certification in Hewlett-Packard's bid. Moreover, the VA has indicated no reason why the FDA may have taken the position that the Hewlett-Packard device is not substantially equivalent, but instead only relies upon the fact that FDA had not acted as of the date of award. The VA does not attempt to relate FDA's failure to earlier respond to any probable inability of Hewlett-Packard to meet contract requirements. Also, the solicitation does not specifically require such an FDA determination by the date of award.

In Impact Instrumentation, Inc., B-217291, supra, we found that the contracting officer properly made an award to a low bidder which had filed as of the time of award with FDA pursuant to 21 C.F.R. § 807.81(a) a notice that its product was substantially similar to an existing product offered, but the FDA had not yet notified the awardee of its determination. In that case, as here, the requisite determination was obtained from FDA prior to delivery of the items under the contract. We found of particular significance in approving the agency's acceptance of the bid in Impact the fact that the solicitation did not require that this determination be made by FDA prior to award. In this regard, we have consistently held that such an approval or license can be obtained from the requisite authority as late as the time performance is required. See What-Mac Contractors, Inc., 58 Comp. Gen. 767 (1979), 79-2 C.P.D. ¶ 79; Propper Manufacturing Co., Inc., B-208035, Mar. 22, 1983, 83-1 C.P.D. ¶ 279 at 5. Contrast Noble Pine Products Co., B-189420, July 24, 1978, 78-2 C.P.D. ¶ 65, where an

offeror, which had not obtained FDA approval, pursuant to a different FDA regulation, of a drug component of the shampoo it was offering under a RFP, was properly rejected after 6 months of negotiations when the need for delivery of the product had become urgent. In the present case, performance was not to take place for 6 months after award.

Under the circumstances, we believe that this solicitation provision can be reasonably interpreted as only requiring that Hewlett-Packard fully comply with applicable law and FDA regulations to the degree possible when it submitted its bid. We find that Hewlett-Packard so certified in its bid and had in fact fully complied with applicable law. After award it would, of course, become a matter of contract administration. See Impact Instrumentation Inc., B-217291, supra. In any case, the solicitation provision in question read literally only requires compliance of a bidder's "facility" (not equipment) with FDA law and regulations and Hewlett-Packard has indicated without contravention that its facility does comply. Therefore, we do not believe that Hewlett-Packard can be rejected on this basis.

CONCLUSION

The protest is sustained. While the contract was awarded to Marquette in September 1984, a stop work order has been in effect since then. Consequently, we recommend that Hewlett-Packard be provided a detailed statement of the reasons that its system failed the test, and that it be permitted to retest the system offered in its first step technical proposal. If the system passes the test, then the Marquette contract should be terminated for the convenience of the government, and the contract awarded to Hewlett-Packard, if it is otherwise determined to be responsible.

This decision contains a recommendation for corrective action to be taken. Therefore, we are furnishing copies to the Senate Committees on Governmental Affairs and Appropriations and the House Committees on Government Operations and Appropriations in accordance with section 236 of the Legislative Reorganization Act of 1970, 31 U.S.C. § 720 (1982), which requires the submission of written statements by the agency to the committees concerning the action taken with respect to our recommendation.

for Milton J. Socolar
Comptroller General
of the United States