



Comptroller General  
of the United States

Washington, D.C. 20548

## Decision

**Matter of:** Roche Diagnostic Systems, Inc.

**File:** B-238965

**Date:** July 20, 1990

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Steven S. Diamond, Esq., Arnold and Porter, for the protester.

Timothy Sullivan, Esq., Dykema Gossett, for Abbott Diagnostics, an interested party.

Louise Hansen, Esq., Office of the General Counsel, Defense Logistics Agency, for the agency.

Scott H. Riback, Esq., and Michael R. Golden, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

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### DIGEST

Protest alleging that agency improperly made award to firm whose product does not conform to specifications is sustained where record shows that agency in fact relaxed material requirements of specification for awardee and such action was prejudicial to the other competitive range offerors.

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### DECISION

Roche Diagnostic Systems, Inc. protests the award of a contract to Abbott Diagnostics under request for proposals (RFP) No. DLA120-88-R-1138, issued by the Defense Logistics Agency (DLA) for the acquisition of a drug testing system including reagent kits. Roche argues that the agency erred in awarding the contract to Abbott because the firm's offered product failed to conform to mandatory technical requirements stated in the RFP and was improperly misbranded in violation of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 301 et seq. (1988). The protester also argues that the agency's source selection authority (SSA) erred in concluding that the proposals of Roche and Abbott were essentially technically equal for source selection purposes. We sustain the protest.

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The RFP contemplated the award of a fixed-price requirements-type contract for the acquisition of an automated drug testing system and reagent test kits to be employed by the Department of Defense (DOD) for initial drug screenings. Under the DOD program, urine samples are collected from military personnel from all three branches of the armed services and are subject to an initial screening procedure designed to detect six drugs of abuse. The six drugs are cannabinoid (marijuana), benzoylecgonine (cocaine), morphine, phencyclidine (PCP), amphetamines, and barbiturates. Where one or more of the specified drugs of abuse is detected in a personnel sample, that sample is given a more expensive and accurate gas chromatography mass spectrometry (GC/MS) screening for purposes of confirmation.

Prior to the current RFP, DLA fulfilled its drug screening system requirement using only radioimmunoassay (RIA) technology on grounds that this technology was the most accurate and reliable. In 1985, a protest was filed in our Office by a manufacturer of an enzyme immunoassay (EIA) drug testing system which alleged that the limitation to RIA technology was unduly restrictive of competition. While ultimately denying that protest we stated that DLA had an obligation to increase competition for its drug testing system so long as the agency was able to conclude that its requirements with respect to accuracy and reliability were maintained. See Syva Co., B-218359.2, Aug. 22, 1985, 85-2 CPD ¶ 210, aff'd, Syva Co.--Recon., E-218359.3, Jan. 22, 1986, 86-1 CPD ¶ 65.

The current RFP is the result of DLA's effort to broaden competition for this requirement and, rather than expressing the agency's needs on a brand-name or equal basis as was done previously, the solicitation contains only performance-type specifications which permit the use of any currently-developed drug screening technology.

The RFP requires that firms establish their ability to meet all specifications and provide enough information to show how they propose to comply with specifications. The specifications are broadly divided into "critical" and "non-critical" elements and provide that the failure of an offeror to satisfy one or more of the critical elements will result in the firm's elimination prior to the conduct of an on-site test contemplated by the RFP. Among other critical elements, firms were required to provide reagent test kits which were capable of reliably determining the presence of the designated drugs at specific "cut-off" concentrations. For example, a firm's barbiturate reagent test kit is

required to detect the presence of barbiturates at a concentration at or above 200 nanograms per milliliter (ng/ml) of urine. These "cut-off" values are of central importance for purposes of the kits' accuracy because they are the threshold at which and above which an individual is deemed to have initially tested positive for a given drug.

The specifications also provide, as a non-critical element, that accuracy of the testing device is to be ensured by one of two methods, arithmetic mean or calibration curve. If a calibration curve is used, it has to be established with a minimum of 5 data points, including the cut-off concentration and two different concentrations above and below the cut-off.<sup>1/</sup> In addition, the data points used to establish the calibration curve have to include one standard at 0.5 times the concentration of the cut-off concentration, and one standard at 1.5 times the cut-off concentration for amphetamines and cannabinoids and 2.0 times the cut-off concentration for the other drugs.

Roche, the incumbent contractor, offered the RIA test method, which involves the use of radioactivity to detect the level of drugs in a urine sample. The accuracy of the measuring equipment is established by arithmetic mean. Abbott's proposal uses fluorescence polarization immunoassay technology (FPIA) to detect the concentration of drugs in a urine sample. To ensure the accuracy of the testing equipment, Abbott uses a calibration curve consisting of 6 data points which are established by providing the measuring equipment with Abbott's standards at specified concentrations of a drug.

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<sup>1/</sup> A calibration curve is established by providing the measuring device with "data points" at certain specified levels above, below, and at the cut-off concentration. These "data points" are provided to the test mechanism by allowing the device to process "standards" at the various concentrations. "Standards" are urine samples prepared by the manufacturer which contain a known concentration of the drug and/or metabolite being tested. For example, where the testing device is required to test for barbiturates at a cut-off concentration of 200 ng/ml, the device may be provided standards at 0 ng/ml, 50 ng/ml, 100 ng/ml, 200 ng/ml, 300 ng/ml, and 500 ng/ml. Thus, the calibration curve is the data curve established by the standards and is compared to "control" samples (which are also prefabricated urine samples) during actual specimen processing to ensure that the device accuracy is maintained throughout the testing procedure.

Finally, a critical element requires that concentrations of the drug contained in the standards has to be within +/- 10 percent of the nominal value as determined by GC/MS. Thus, a standard containing 100 ng/ml of a given drug must be verified to that concentration to within 10 percent. Data is required regarding accuracy of standards with each test kit.

The RFP provides that technical proposals are point scored on the basis of a 100 point scale that assigned 75 points to the evaluation factor "technical capability and performance" (60 points of which were designed to reflect the firms' performance at the on-site test), 15 points to the evaluation factor "manufacturer's reagent quality program and system support services," 5 points to the evaluation factor "corporate experience," and 5 points to the evaluation factor "production capability." The RFP further states that award will be made to the offeror whose proposal is most advantageous to the government, cost or price, technical quality and other factors considered. Technical is more important than cost or price. The RFP also advises that as technical merit becomes more equal, cost or price become more important.

In response to the RFP, the agency received four offers. After evaluation, the technical evaluation panel (TEP) determined that three offers were within the competitive range, that is, these offerors had shown they did or could meet the critical specifications.

The three competitive range offerors were then requested to conduct an on-site test in accordance with the RFP, designed to provide the agency with actual test data from the firms' drug testing systems and reagent kits. This test data was part of the overall evaluation of the offerors and was used to assess the accuracy of each firm's various reagent kits. The tests were also designed to allow evaluation of the capability of the drug testing system to test a stated number of specimens for a specified number of drugs during a fixed period of time, referred to as the "throughput" requirement, and to evaluate the systems' and reagent kits' general conformity to the specifications.

After receiving the data from on-site tests, the TEP reviewed both the test results and initial offers. Point scores were given, and a cost realism analysis was conducted by the business evaluation panel (BEP). Both written and oral discussions were conducted. Subsequently, the agency solicited best and final offers (BAFO) which were timely submitted by all three competitive range offerors.

After receipt of BAFOs, the TEP and BEP reevaluated all three proposals. The TEP rescored the technical proposals in accordance with the evaluation scheme stated in the RFP. The TEP assigned a final point score of 70 to the Abbott proposal and a final score of 74.5 to the Roche proposal. In addition, the TEP also provided detailed narrative statements for each firm in each of the specified evaluation factors and subfactors.

The BEP and the TEP forwarded their respective reports to the source evaluation board (SEB) which produced a detailed report discussing the relative merits of the three proposals. The SEB's report concluded that the proposals of Roche and Abbott were "essentially equal" and that either firm would satisfy the government's needs. The SEB recommended to the source selection authority (SSA) that award be made to Abbott since its offer represented a savings of approximately \$3.5 million over the Roche proposal. On the basis of the SEB's recommendation, the SSA determined to award to Abbott as the firm submitting the most advantageous proposal. This protest followed.

Roche argues that Abbott's product fails to conform to the specifications relating to the establishment of the firm's calibration curves. The protester further argues that Abbott cannot conform its products to the specifications since, in order to do so, Abbott would be required to make adjustments to the standards it currently uses to establish its calibration curves, and such adjustments cannot be made without approval by the Food and Drug Administration (FDA). Such approval is required by the RFP no later than the time that BAFOs are submitted. Roche also argues that Abbott's product does not meet the specification that requires all standards to be within +/- 10 percent of the nominal values as verified by GC/MS procedures.

Roche also argues that Abbott's calibration curves are designed so that performance of the firm's reagent kits is optimized at cut-off concentrations higher than the cut-off concentrations specified in the RFP. According to Roche, the net effect of Abbott's failure to adhere to specifications will be that Abbott's kits will suffer accuracy problems near to, and at the specified cut-off concentrations, necessitating costly confirmatory GC/MS screening which would not otherwise be necessary. Roche asserts that, since Abbott's product was nonconforming to the specifications, the two offers could not be technically equal.

In an negotiated procurement, any proposal which does not conform to the material terms and conditions of the solicitation should be considered unacceptable and may not form the basis for an award. Instruments S.A., Inc.; V.G. Instruments, Inc., B-238452; B-238452.2, May 16, 1990, 90-1 CPD ¶ 132; Martin Marietta Corp., B-233742, Jan. 31, 1990 69 Comp. Gen. \_\_\_\_\_, 90-1 CPD ¶ 132. We conclude that the agency relaxed the specifications for Abbott and that the agency's actions in this respect resulted in the firm's receiving award on the basis of an offered product which was materially different from that called for by the RFP.

The RFP required that firms offering a calibration curve provide at least five standards with two data points below the designated cut-off, two above and one at the designated cut-off. Further, at a minimum the calibration curves had to include particular standards below, at and above the RFP designated cut-off concentrations. The record is clear that Abbott's calibration curves did not conform to this requirement. Specifically, two of Abbott's six reagent test kit calibration curves do not contain a calibration standard at the applicable cut-off concentration, four of the six calibration curves do not have standards at the applicable levels above the cut-off concentration (either 1.5 or 2 times the cut-off concentration depending upon the reagent kit in question) and none of the six had a standard at one-half the cut-off concentration as specified in the RFP. The record also shows that the evaluators raised concerns regarding compliance with this requirement in discussions and that the TEP saw this as a continual problem.

For example, the TEP records show that the TEP found that Abbott's calibration curves did not allow for the performance of its product to be optimized at the cut-off concentrations; rather, Abbott's reagent test kits were designed to perform optimally at higher cut-off concentrations and over a broader spectrum of cut-off concentrations, cut-offs not specified by the RFP. The prenegotiation memorandum prepared by DLA states "Abbott's kits were not all formulated to show maximum accuracy around the cut-off points." The TEP's report after performance of the on-site test and after written discussions provides in one portion that "Abbott's proposal was marginally acceptable with regards to meeting the specifications. Namely, several test kits do not have the required calibrations," and at another point that "the Abbott kits were not all formulated to show maximum accuracy around the cut-off points. . . ." The record also shows that, even after face-to-face negotiations, the TEP's concerns remained. In this regard, the agency's memorialization of the face-to-face negotiations with Abbott after receiving Abbott's proposal to provide

controls<sup>2/</sup> (as opposed to standards) at the RFP's specified levels states "The TEP feels that compliance [with the RFP's specifications regarding the placement of calibration standards] is essential. Firm must submit its plan to meet specifications. . . ." The TEP's final evaluation report also stated the exception to the specifications is significant and that it was a weakness to establish a calibration curve around the cut-off without using at least one standard that is below the cut-off. It further advised that standards proposed in several test kits indicated that the accuracy of these test kits may be around higher concentrations as opposed to around the cut-offs. Finally, in response to an inquiry from the SSA concerning this issue, the TEP stated that Abbott's kits were not, in contrast to Roche's kits, optimized around DOD cut-off and that generally a kit optimized around a given cut-off will give more consistent results around the cut-off. The TEP concluded that Abbott's kits were accurate over a much wider concentration range.

The agency argues that, while Abbott did not strictly comply with the RFP's specifications, the firm nonetheless met the "intent" of the requirements regarding calibration curves. The agency states that Roche is correct regarding the placement of Abbott's calibration standards; however, it states that Abbott's BAFO provides controls at the required concentrations. Consequently, the agency states that it was satisfied that the offered system was acceptable and would meet its needs. The agency also argues that, in any event, its relaxation of the specifications for Abbott was not prejudicial to the other competitive range offerors since neither of them uses calibration curves with its respective system, but instead employs an "arithmetic mean" methodology for calibration purposes. We disagree.

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<sup>2/</sup> Controls are prefabricated urine samples containing known concentrations of the drug or metabolite being tested which are run concurrently with the actual personnel samples being tested. Unlike standards, however, controls are not used to calibrate the testing mechanism but, rather, are used to ensure that the equipment retains its accuracy throughout the testing procedure.

It is a fundamental rule of federal procurement law that a contracting agency must treat all offerors equally and that they must be furnished with identical statements of the agency's requirements in order to provide a common basis for the preparation and submission of competitive proposals. When an agency's needs change so that a material discrepancy is created between an RFP's ground rules and the agency's actual needs, the RFP should be amended and all eligible offerors be given an opportunity to revise their proposals accordingly. See Dynalantic Corp., 68 Comp. Gen. 413 (1989), 89-1 CPD ¶ 421; Union Natural Gas Co.--Recon., B-224607.2, Apr. 9, 1987, 87-1 CPD ¶ 390.

In this case, the agency shifted its emphasis from a requirement which focused upon the accuracy of the reagent test kits at and around the cut-off concentrations by accepting a product which created the potential for less accuracy at the cut-off concentrations and a broader spectrum of accuracy at a variety of concentrations. In so doing, DLA relaxed a material provision of the RFP for standards at the cut-off and specified data points without providing all competitive range offerors an opportunity to compete for the agency's revised requirements. While Abbott's approach to provide increased controls at the cut-offs and data points is acceptable to DLA, Abbott's approach simply did not, as DLA admits, meet the specifications.

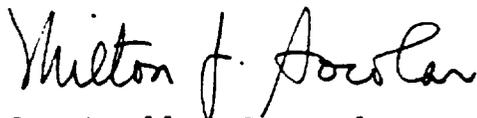
Contrary to the agency's assertion, we find its actions prejudicial to the other two competitive range offerors. While we are aware that the specification in question was inapplicable to the other two firms' products because of their proposed drug testing technology, we nonetheless conclude that the effect of the agency's relaxation of the specifications was to prevent the other two offerors from adapting their reagent test kits to the agency's revised requirements.<sup>3/</sup> The acceptance of Abbott's approach which did not involve significant alteration of its commercial product or additional FDA review presumably gave Abbott a cost advantage not available to other offerors.

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<sup>3/</sup> In this regard, we point out by way of example that Abbott apparently was able, during the conduct of the acquisition, to develop its cannabinoid reagent test kit and achieve FDA approval therefor prior to the time set for the submission of BAFOs. Similarly, we see no reason to conclude that the other competitive range offerors could not have reformulated their reagent test kits and achieve FDA approval prior to the time set for the submission of BAFOs in order to more competitively meet the agency's revised requirements for a "broad spectrum" drug testing system.

We therefore sustain Roche's protest.<sup>4/</sup>

In light of the foregoing we are by separate letter of today recommending to the Director of DLA that the agency review its actual requirements for a drug testing system. Since the agency accepted an approach which the record shows allowed the potential for less accurate results at the DOD cut-off and was not permitted under the RFP, the agency should reassess its minimum needs and, if appropriate, amend the RFP to afford all offerors in the competitive range an opportunity to submit revised proposals on the basis of those revised requirements. If, on the other hand, the agency concludes on the basis of its review that the RFP in fact accurately reflects its requirements, then DLA should terminate for the convenience of the government the contract awarded to Abbott and make award to Roche. We also find Roche entitled to its costs of pursuing this protest, including attorneys' fees. 4 C.F.R. § 21.6(6) (1990).

*for*   
Comptroller General  
of the United States

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<sup>4/</sup> Roche has also alleged that the Abbott barbiturate test kit is misbranded within the meaning of the FFDCA, 21 U.S.C. § 301 et seq. (1988). The FDA has informed us that the representations contained in Abbott's package insert for the barbiturate test kit provide adequate information for use, including appropriate performance and limitation information and that, to the extent that Abbott may have technically violated the FFDCA, such a technical violation would not by itself cause the FDA to engage in enforcement action. Roche further argues that Abbott's product does not meet the critical requirement that concentrations of standards be within +/-10% of the nominal value. While the record shows that the on-site test results revealed a problem with Abbott meeting this specification, Abbott's BAFO addressed its ability to meet this specification. The agency found Abbott's proposed solution to ensure compliance acceptable and we find its determination reasonable.