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Comptroller General
of the United States

United States General Accounting Office
Washington, DC 20548

Decision

Matter of: Philips Medical Systems North America Company

File: B-293945.2

Date: June 17, 2004

Donna L. Yesner, Esq., McKenna Long & Aldridge, for the protester.
Maura C. Brown, Esq., Department of Veterans Affairs, for the agency.
Mary G. Curcio, Esq., and John M. Melody, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

Agency reasonably rejected protester's proposal for lack of a validation study where solicitation required that offers of other than one of several specified models of blood pressure monitor be accompanied by a validation study, and protester offered one of the listed models modified to include a radio for wireless transmission of results; agency reasonably determined that the modification changed the item sufficiently that the exception from the validation study requirement did not apply.

DECISION

Philips Medical Systems North America Company protests the rejection of the offer it submitted in response to request for proposals (RFP) No. 797-NC-04-0001, issued by the Department of Veterans Affairs (VA) for home telehealth equipment.

We deny the protest.

The solicitation requested proposals for, among other things, digital electronic blood pressure monitors, and provided that, "For DIGITAL ELECTRONIC blood pressure monitors THAT ARE DESIGNED FOR HOME USE, offerors must provide a validation study of the accuracy of the unit that has been published in a peer reviewed professional journal," unless one of several specified monitor models, including the A&D UA-767V, were offered. RFP at 23. The solicitation required the offered monitor to be capable of transmitting results to the applicable medical site by wired or wireless means.

Philips offered Philips Telemonitoring Blood Pressure Monitor (for home use) model number M3815A, which its proposal stated was based on the A&D UA-767V and outfitted with a radio. VA rejected the proposal on the basis that, by virtue of the

addition of the radio, Philips did not offer the UA-767V, and that its offer therefore was unacceptable for failure to include a validation study for the M3815A.

Philips argues that its proposal was improperly rejected because it did in fact offer the specified A&D model, merely with a radio attached internally to transmit data. Philips asserts that this did not constitute an alteration of the monitor, since the A&D circuit board contains five connection points for serial communications devices such as the radio it added. According to Philips, adding the radio required no changes to the circuit board or any other aspect of the monitor that could affect accuracy, but merely required the radio circuit board to be attached to the five connection points provided, using the exact method specified by A&D.

The VA responds that, while Philips does not believe that the addition of the radio affects performance of the monitor, the purpose of the validation study is to ensure that the monitor works accurately. VA explains that the study performed on the A&D model (which led to its being listed in the RFP in the first place) is only effective for the unit as presented for validation, in this case, without a radio. VA notes that Philips itself recognized that the addition of the radio could affect performance, as evidenced by the fact that Philips actually had a validation study performed by the manufacturer after it added the radio--the study did not meet the requirements of the solicitation because it was not published in a peer reviewed journal--in conjunction with a [DELETED] design test.

In reviewing a protest against an agency's proposal evaluation, our role is limited to ensuring that the evaluation was reasonable and consistent with the terms of the solicitation and applicable statutes and regulations. Urban-Meridian Joint Venture, B-287168, B-287168.2, May 7, 2001, 2001 CPD ¶ 91 at 2.

VA reasonably determined that a validation study was required. As noted above, the stated purpose of the validation requirement was to ensure the accuracy of the monitor. VA determined that modifying the offered A&D monitor internally to add a radio could affect the monitor's accuracy, and that there was no means of determining the effect other than a credible validation study. We think this was a reasonable conclusion. While the protester asserts that adding the monitor did not affect accuracy, it provides no definitive information supporting this claim, and it is not clear how the agency could receive the kind of assurance that it was seeking absent a validation study. Indeed, we agree with the agency that Philips's own actions in seeking validation of the effect of adding a radio support the agency's position that, absent such validation, there simply was no way to determine whether the change would affect the monitor's performance. Philips asserts that it only had the unit tested out of caution, not because there was a question as to whether the radio altered the monitor's performance. However, the agency's desire for a peer reviewed validation study reflects a similar degree of caution which, we believe, is consistent with the RFP. Therefore, since Philips did not provide a peer reviewed

validation study for its proposed A&D monitor, as modified, the agency properly rejected its proposal.

Philips argues that, at a minimum, the solicitation was ambiguous. Specifically, Philips asserts that, since the solicitation required data transmission by wired or wireless means, it reasonably interpreted the portion of the specification identifying the approved models to allow a communications device to be internally or externally connected to the blood pressure monitor for this purpose. This argument is not persuasive. Even if the protester is correct that the addition of communications devices was contemplated by the RFP, there is nothing in the RFP indicating--explicitly or implicitly--that adding such devices to a monitor not already so equipped would not constitute a modification that would necessitate a validation study. In this regard, we note that not all of the specified monitors required modification to meet the wired/wireless data transmission requirement. Supplemental Agency Report at 5.

The protest is denied.

Anthony H. Gamboa
General Counsel