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BEFORE THE OFFICE OF PUBLIC ACCOUNTABILITY
PROCUREMENT APPEAL

IN THE APPEAL OF	)	DOCKET NO. OPA-PA-11-001
	)	
JMI – EDISON,	)	
	)	
Appellant.	)	**MEMORANDUM ON REMEDIES**
	)	
	)	
	)	

Memorandum on Remedies

I.

This appeal should be dismissed. There has been no violation of Guam procurement law by the General Services Agency ("GSA"). The basic complaint is that GSA awarded a contract to purchase a modern radiological device to a bidder, MedPharm, but the radiological device offered by MedPharm did not meet the specifications set out in the Invitation For Bids. The assertion by the Appellant, JMI-Edison, is incorrect and without merit. There are three claims. First, the Appellant claims that MedPharm's offer is nonresponsive as it fails to provide for an optional stretcher. The specification at Section I. A. states "Standard or extended arm digital wall stand ONLY with single portable detector and optional stretcher." In MedPharm's Bid response to this specification, under the column of the Bid document titled BIDDING ON OR

REMARKS MedPharm stated "Comply". See MedPharm Bid at Tab 4 of the Procurement Record. In fact the specification requires that the radiological device be capable of use when the patient is on a stretcher. The specification does not require a stretcher, but rather use of the device with a stretcher. See MedPharm video, provided with the bid and available at Tab 4 - RadSpeed Demo Video. In this regard MedPharm's bid is responsive.

It is important to note that the Department of Public Health and Social Services ("DPHSS"), the actual purchaser of the radiological device, joined in the assessment of the bid by MedPharm, finding that in this aspect of their bid, it met specifications. See DPHSS' confirmation at Procurement Record Tab 13.

Second, Appellant claims that MedPharm's offer is nonresponsive as it fails to provide for two LCD monitors. The specification at Section I, F, states "Two (2) – 19 in. (48 cm) LCD color monitor (1280 x 1024 pixels)." In MedPharm's bid response to this specification, under the column of the bid document titled BIDDING ON OR REMARKS Medpharm stated "Two (2) - 19 in. LCD monitor (1280x1024 pixels)." See MedPharm Bid at Tab 4 of the Procurement Record. The only conclusion to draw from this response by MedPharm is that it is in compliance with the bid specification and provide a device with two LCD Monitors as described in the bid specification. It is impossible to understand how this could be considered a non-responsive bid.

Significantly, DPHSS, the actual purchaser of the radiological device, confirmed this assessment of the MedPharm bid, finding that it met specifications. See DPHSS' ratification of same at Procurement Record Tab 13.

Third, Appellant asserts that the MedPharm bid provides no documents to show compliance with necessary federal and local regulatory agencies. In this respect, GSA sought a review by the purchasing agency, DPHSS, of the bid submitted by MedPharm. In the process of this review, MedPharm submitted to DPHSS documentation proving that the device offered by MedPharm in

its bid. (actually, a series of related devices, comprising a complete radiological imaging system), is either compliant with FDA regulations (for example, the CANON CXDI-40EC imaging device), or is exempt (having received a 510(k) medical device exemption) from FDA compliance as a medical device, specifically exempting its high voltage regulator, diagnostic x-ray tube mount, radiologic table and its wall-mounted radiographic cassette holder. See Exhibit 5, Interested Party MedPharm's Comments On Agency Report, which provides additional documentation in support of MedPharm's initial response to the request for documentation from DPHSS.

Finally, the assertion by Appellant that the FDA Quality System Regulation at Part 820 (21 CFR part 820) is incompatible with the International Standards Organization ISO standards is inaccurate. Although in some ways the quality manufacturing standards being measured by the FDA and the ISO are different, as they highlight different values and require different record keeping, in fact, the FDA and ISO organizations do work together in an ongoing effort to make monitoring and quality assurance standards compatible. See, for example, the FDA website at http:www.fda.gov/MedicalDevices/ DeviceRegulationandGuidance/PostmarketRequirements, and, specifically, the article on the relationship between the FDA's Quality System Regulation for Devices, Part 820 and ISO:2000 at http:www.fda.gov/downloads/MedicalDevices/Device Regulations and Guidance/ Postmarket Requirements/ QualitySystems Regulations UCM134625.pdf

It is the respectful assertion by GSA that the MedPharm bid to provide the Shimadzu RADSpeed DR Auto digital radiological system for the Department of Public Health and Social Services is in all respects compliant with the specifications set out in the IFB found at Tab 5, the Original Bid Specification. The appeal should be dismissed.

II.

This is an appeal taken from a post-award protest. The protest is dated August 6, 2010. The Purchase Order for the acquisition of the Radiology Imaging System from MedPharm was issued on July 28, 2010 to MedPharm by GSA. Therefore any analysis of the proper remedy, even if it were somehow determined that the appeal had merit and that a violation of the Procurement Act had been committed, should be analyzed pursuant to 5 GCA §5452.

> "If after an award it is determined that a solicitation or award of a contract is in violation of the law, then:
> (1) If the person awarded the contract has not acted fraudulently or in bad faith:
>
> (i) The contract may be ratified and affirmed, provided it is determined that doing so is in the best interest of the Territory, or
>
> (ii) The contract may be terminated and the person awarded the contract shall be compensated for the actual expenses reasonably incurred under the contract, plus a reasonable profit, prior to termination."

There has been no assertion that MedPharm has acted fraudulently or in bad faith. No party has acted fraudulently or in bad faith. During every step of this process GSA has sought information and clarification from its customer, the Department of Public Health and Social Services, in the effort to acquire a badly-needed Radiology Imaging System to include a clarification and clearance that the system being offered by MedPharm is consistent with the specifications. MedPharm readily provided detailed information about the system offered and the companies, Shimadzu Medical Systems USA, and Canon USA, Inc., that manufactured the medical devices that make up the system.

It is respectfully suggested that it is in the interests of the Territory to affirm the contract that has been executed. It is worth noting that this radiology imaging system has received the No.1 rating in 2010 from the KLAS, a medical equipment monitoring and grading organization. KLAS has the mission to improve healthcare technology delivery by honestly, accurately and impartially

measuring and reporting vendor performance. The equipment being provided by MedPharm and Shimadzu Medical Systems USA is not a second class medical device. In fact, health care providers have independently accorded it the highest honor as the No. 1 Digital X-Ray device in its class for 2010. A visit to the KLAS website at www.klasresearch.com will assist in understanding what this may mean for the Territory of Guam.

III. Conclusion.

There is no evidence to indicate that the bid by MedPharm is non-responsive. There is every indication in the bid submitted by MedPharm and in the documentation provided during GSA's review of the bid, that the radiology imaging system offered by MedPharm meets all of the specifications and all of the requirements of law. Further, there is considerable competent evidence to show that it is in the interests of the Territory to affirm this award. Further, there is absolutely no evidence provided to show that it is in the interests of the Territory to terminate the contract that has been awarded.

Dated this 8th day of March, 2011

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