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BEFORE THE PUBLIC AUDITOR

PROCUREMENT APPEAL

IN THE APPEAL OF JMI - EDISON, Appellant.	DOCKET NO. OPA-PA-11-001 **APPELLANT'S COMMENTS ON AGENCY REPORT; CERTIFICATE OF SERVICE**

I. PROCEDURAL BACKGROUND

On July 9, 2010, the General Services Agency ("GSA" or the "Agency") issued Invitation for Bid (IFB) GSA 105-10 seeking a radiological Imaging System. Following the submission of two offers, the Agency issued award of the IFB to MedPharm. Because of defects in the winning offeror's response and the award process itself, JMI-Edison (the "Appellant") initiated a bid protest. On December 21, 2010, the Agency denied the appellants protest, and on January 4, 2011, the Appellant initiated the instant appeal before the OPA. On January 20, 2011, the Agency, through its counsel of record the office of the attorney general, submitted its mandated Agency report. These comments on that report are being timely provided in response.

II. COMMENTS ON AGENCY REPORT

A. THE AGENCY REPORT IS UNTIMELY

The Guam Procurement Regulations are unequivocal in their putting forth appeal timelines. The regulations state that "(t)he Agency Report ***shall*** be submitted within ten working days of receipt of by the Agency of the notice of Appeal of a Method, Solicitation, or Award; or notice of Appeal of a Suspension." 2 GAR §12104 (c)(3)(Emphasis added). The Appellant's appeal was submitted to the OPA on

January 4, 2010. Ten (10) working days following that submittal fell on Wednesday, January 19, 2011. The Agency failed to submit its comments on January 19, 2011. Though not directly addressing untimely agency submissions, the procurement regulations note that the failure to comply with the time limits stated in the protest provisions "may result in resolution of the appeal without consideration" of the untimely submission. 2 GAR §12104(c)(5). Appellant submits that the untimely agency report should be ignored and that, in and of itself, permits the OPA to set aside the award.

B. THE AGENCY REPORT IGNORES STATUTE AND DOES NOT ADDRESS THE GROUNDS RAISED IN THE APPEAL

The Guam Procurement Regulations require that the Agency provide "A statement answering the allegation of the Appeal and setting forth findings, actions, and recommendations in the matter together with any additional evidence or information deemed necessary in determining the validity of the Appeal." The regulations are clear in their command that the agency's statement "shall be fully responsive to the allegations of the appeal." 2 GAR §12105(g). Simply put, the Agency's untimely report fails to meet this standard.

The agency's report notes that, following the submission of bids, "an analysis by GSA ensued, resulting in a recommendation on 28 July 2010 to go with Medpharm as the lowest bidder; each bidder having met specs." Agency report, pg. 3. This simple recounting of the GSA's conclusion is coupled with an anemic conclusory statement that "GSA exercised due diligence in confirming with the Department of Health and Social Services that the bid received from Medpharm was responsive to, and in conformity with, the bid specifications." Agency report, pg. 4.

This conclusion is unsupported by the agency, and carries with it no reference to the procurement record, or even a simple citation to the purportedly responsive page of Medpharm's bid submission. Rather than attempt to "fully respond" to the Appellant's protest and conduct any independent review of the procurement file, the Agency instead applies circular logic and tells us that Medpharm's submission was responsive, because, as we are told, "the agency responsible for utilization (of the medical device).... has conclusively determined that the (medical device) meets the invitation for bid specifications." Agency report, pg. 4. The Agency Report has defended the

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procurement officer by merely stating, in effect, "Someone told us that the bid was responsive, so it must therefore be responsive."

The Agency's four and a half page report consists of a two page list of documents, a one page recitation of the bid protest history, a half page conclusion, and a one paragraph defense of the procurement decision at issue here. This anemic report fails to meet the regulatory requirement of a report that is "fully responsive to the allegations," and does nothing close to "setting forth findings, actions, and recommendations in the matter together with any additional evidence or information deemed necessary in determining the validity of the Appeal." The spartan agency report ignores the requirement to develop a defense of the agency action. Appellant filed its bid protest arguing that it was the only fully responsible bidder. This contention is at the heart of the protest and the Agency's Report ignores the issue by simply stating that an award to the lowest offeror was proper following the conclusion that "each bidder having met specs...." The failure of the GSA to support its actions with specific evidence and findings abrogates its responsibilities under the statute and places the OPA in the impossible and unfair position of having to guess why Appellant's protest was denied. The Agency also fails to meet two of the keys of Guam procurement law, which is to both "permit the continued development of procurement policies and practices" and to "provide for increased public confidence in the procedures followed in public procurement" 5 GCA 5001(b)(2); 5 GCA 5001(b)(3). Finally, the agency report's frail nature also heaps additional work upon the OPA and the hearing officer, who must wade through the procurement record themselves without the guidance of specific agency direction on the matter. *See generally*, Lamb v. Hoffman,2008 Guam 2(holding Court's can deny Motions outright which fail to announce standards and explain compliance).[1/]

C. THE AGENCY REPORT IGNORES THE FACT THAT THE FDA HAS PLENARY AUTHORITY OVER MEDICAL DEVICES

The GSA's response defends MedPharm's lack of FDA regulatory compliance in its submission by recognizing that proof of regulatory compliance was necessary for a responsive bid,

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[1/] The Agency's report is also error filled, and makes reference to a Purchase Order that does not appear in the documents received by Appellant as part of its Freedom of Information request, and incorrectly references the procurement of an MRI device.

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but that the "IFB did not specifically indicate a specific regulatory agency or agencies." GSA Response, pg. 3. This is a distinction of convenience, and a parsing of the bid solicitation that strains credulity. The Agency's failure to bolster— or even address— this defense of Medpharm's solicitation demonstrates just how weak the defense is.

It is uncontroverted that, in the United States, the Food and Drug Administration carries with it plenary power to regulate medical devices.[2/] *See generally,* Mark Herrmann & Geoggrey J. Ritts, Preemption and Medical Devices: A Response to Adler and Mann, 51 Food & Drug L.J. 1, 19 (1996) (describing how Congress, in the interests of public safety, expressed repeatedly in the legislative history of the FDA medical device act that its goal "was to create in the FDA plenary authority to regulate medical devices.) See also Webster v. Pacesetter, Inc., 171 F. Supp. 2d 1, 4 (D.D.C. 2001) ("noting how federal law "confers broad regulatory authority over medical devices on the FDA."); Gomez v. St. Jude Med. Daig Div. Inc., 442 F.3d 919, 931 (5th Cir. 2006) (stating that "the FDA has plenary authority to amend the regulations and requirements it imposed relating to (medical devices)" **In effect, there is only one regulatory standard that can exist in the United States : that which is imposed by the FDA.** The Agency's position that Medpharm's submission was responsive despite the lack of FDA regulation compliance ignores decades of applicable federal law, and seeks to have the OPA embrace a procurement standard for government of Guam that would be "any regulatory standard would do" if the IFB did not specify exactly what standard would be used.[3/]

The IFB was clear that the medical device was going to be used within the United States. The solicitation's requirement that offerors submit proof of regulatory compliance could only have

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[2/] The FDA is clear that, if a product is labeled, promoted or used "in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals" it qualifies as a medical device under section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act it will be regulated by the FDA as a medical device and is subject to regulatory controls.

[3/] The absurdity of the argument advanced by the agency carries significant impact for future procurements. The Guam airport, for instance, could put out a procurement seeking an instrument landing system that can show regulatory compliance. An offeror could, under the agency's standard, submit a fully responsive bid for an ILS system that was compliant with Zimbabwe aviation standards, since the solicitation failed to specify that Federal Aviation Administration standards would need to be adhered to. And again, the Guam police department could put out a procurement seeking police vehicles that can show regulatory compliance, and an offeror could submit, under the Agency's logic, a fully responsive bid for police vehicles that were compliant with Japanese police vehicle standards— right hand steering wheel included.

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been met, therefore, with proof of regulatory compliance within the United States. That compliance would have been in the form of FDA certification, and only the Appellant submitted such certification. The award to Medpharm, therefore, was in error and should be set aside.

D. THE AGENCY REPORT IGNORES THE FACT THAT MEDPHARM'S BID DID NOT RESPOND WITH THE REQUIRED "OPTIONAL STRETCHER."

The IFB clearly required, as part of responsive bids, a bid that would include "Standard or extended arm digital wall stand ONLY with single portable detector and optional stretcher." Bid Solicitation, Specifications (I)(A). The GSA's response was simply that "the brochure provided by MedPharm indicates that it does meet optional stretcher requirement." GSA Response, pg. 1. The agency report fails to address the issue, and provides no citation to the procurement record that shows Medpharm's compliance with the solicitation requirement even though it was clearly put at issue in the bid appeal.

The sole reference to compliance with the solicitation standard is Medpharm's response on the bid form, next to the requirement, that Medpharm would "comply." Unlike Appellant's bid response, Medpharm provided no support for its claim of willingness to "comply." If the OPA were to find Medpharm's submission in this regard responsive based upon a single word from the offeror, the need for comprehensive bid responses becomes obviated. Further, procurement officers become neutered under this standard and are rendered little more than government employees who can complete their tasks by looking for the only the most basic assurances from offerors that the submitted bids are indeed responsive to the solicitation. This minimalistic standard of bid compliance would lessen both the confidence the public has in the procurement process, and the quality of those who seek to respond to government solicitations.

E. THE AGENCY REPORT IGNORES THE FACT THAT MEDPHARM'S BID DID NOT RESPOND WITH THE REQUIRED "TWO... LCD COLOR MONITOR(S)."

The IFB clearly required, as part of responsive bids, a bid that would include "Two(2) 19 inch (48cm) LCD color Monitor (1280 x 1024 pixels)." Bid Solicitation, Specifications (I)(F). The GSA's response is that Medpharm confirmed "in their bid package that they will provide 2 LCD monitors." GSA Response, pg. 3. As with the optional stretcher requirement, the agency report fails to address the issue, and provides no citation to the procurement record that shows Medpharm's

compliance with the LCD display. And again like the stretcher requirement, the sole reference to compliance with the solicitation standard with Medpharm's response on the bid form next to the requirement with the single word "comply." Like the stretcher requirement response detailed above, the OPA should find the anemic support for compliance with the solicitation requirement unresponsive.

III. CONCLUSION

The Guam code dictates that the contract is to be awarded "to the lowest responsible bidder whose bid meets the requirements and criteria set forth in the" IFB. 5 GCA 5211(g). Here, the lowest bidder was awarded the project, but it remains clear that the bidder's response was neither responsible nor responsive to the solicitation. The Agency has sought to defend the selection through an untimely report that fails to address the issues raised in Appellant's appeal. The Agency report does not address the failure of Medpharm to respond with the optional stretcher and LCD monitors that met the solicitation's requirements. More egregiously, the Agency report does not address the Agency's decision to eschew controlling federal regulations, and the selection of an offeror despite the absence of regulatory compliance from the one federal agency with plenary control in this area. The Appellant renews its request that the OPA find the award of IFB GSA 105-10 to Medpharm to have been made in error, and conclude that Appellant, as the only responsive and responsible bidder be made the awardee under IFB GSA 105-10.

Respectfully submitted this 31st day of January 2011 at Hagatna, Guam.

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CERTIFICATE OF SERVICE

I, JOSHUA D. WALSH, do hereby certify that on the 31st day of January 2011, I will cause to be served a true and correct copy of the **APPELLANT'S COMMENTS ON AGENCY REPORT; CERTIFICATE OF SERVICE** upon the following Counsel of record:

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Executed at Hagåtña, Guam, on January 31, 2011.

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By _____
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