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Comptroller General
of the United States

United States General Accounting Office
Washington, DC 20548



# Decision

**Matter of:** McKesson Automation Systems, Inc.

**File:** B-290969.2; B-290969.3

**Date:** January 14, 2003

John A. Burkholder, Esq., and Richard B. Oliver, Esq., McKenna Long & Aldridge, for the protester.
William A. Shook, Esq., Kelley P. Doran, Esq., and Michael F. Scanlon, Esq., Preston Gates Ellis & Rouvelas Meeds, for Innovation Associates, Inc., an intervenor.
Linda G. Sandoli, Esq., and Lynne E. Georges, Esq., Defense Logistics Agency, Defense Supply Center Philadelphia, for the agency.
Tania Calhoun, Esq., and Christine S. Melody, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

**DIGEST**

Protests that procuring agency improperly proposed award to a firm on a sole-source basis for the procurement and installation of a pharmacy robotic refill system is denied where the record shows that the agency's justification for concluding that only one responsible source could meet its needs is reasonable.

**DECISION**

McKesson Automation Systems, Inc. protests the proposed award on a sole-source basis to Innovation Associates, Inc. (IA) under request for proposals (RFP) No. SP0200-02-R-8022, issued by the Defense Logistics Agency, Defense Supply Center Philadelphia (DSCP), for the procurement and installation of IA's PharmASSIST robotic refill system at the United States Air Force Academy in Colorado Springs, Colorado. McKesson argues that the agency's use of a sole-source procurement to meet this requirement is improper.

We deny the protests.

In response to various reports and recommendations concerning the use of enhanced automation to improve patient safety, through the reduction of medication errors, and to improve the efficiency of pharmacy personnel, the Air Force Pharmacy and the Air Force Academy Pharmacy initiated market research into automated medication dispensing systems as early as 1999. This market research eventually extended to a detailed independent report that analyzed the automated pharmacy

systems sold by various firms, including IA and McKesson, as well as information gathered through trade shows, site visits, and meetings with pharmacy systems vendors. By March 2001, Air Force Academy representatives had developed a preference for the IA system based upon this market research and forwarded a set of draft salient characteristics to an Air Force consultant to the Surgeon General for Pharmacy (Air Force consultant). Transcript (Tr.) at 52, 58.[1] The Air Force consultant rejected the notion of a "preference"; conducted discussions with technical users and pharmacy professionals to ascertain the agency's minimum needs; engaged in additional market research which included site visits and meetings with pharmacy systems vendors, including IA and McKesson; and insisted that the salient characteristics be objective and reviewed them to ensure that they were related to human safety. Id. at 53, 58. The Air Force consultant ultimately agreed that IA was the only vendor that could meet the agency's minimum needs.

In February 2002, the Air Force forwarded drafts of its salient characteristics for a robotic refill system and its justification and approval for other than full and open competition (J&A)--prepared by the Air Force Consultant--to the DSCP, which was to conduct the procurement on behalf of the Air Force. On June 25, the DSCP posted a presolicitation notice for the procurement of a PharmASSIST robotic refill system, manufactured by IA, on the government's Federal Business Opportunities (FedBizOpps) web site. The notice inadvertently failed to include information on the sole-source nature of the procurement and was subsequently modified to advise that award would be made on a sole-source basis and that IA was the only known source that could supply the agency's requirements.

On July 17, McKesson requested copies of the J&A and the solicitation, and was told that copies would be forwarded when they were finalized.[2] On October 3, the agency issued the solicitation for the procurement and installation of the IA PharmASSIST robotic refill system. The system will be installed at the Air Force Academy and will process refill orders from the outpatient pharmacies at four Colorado locations: the Air Force Academy Hospital, the Air Force Academy Community Center, Peterson Air Force Base, and Evans Army Community Hospital. J&A at 3. The solicitation, issued pursuant to commercial item acquisition procedures,[3] listed 21 of what it

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[1] Cites to the hearing transcript refer to the transcript of the hearing that our Office conducted in connection with these protests.

[2] McKesson withdrew its July 19 protest of the sole-source award after the agency advised it had not yet approved the J&A or the solicitation.

[3] Since the propriety of the agency's use of the sole-source selection procedures at Federal Acquisition Regulation (FAR) subpart 6.3, not the commercial item acquisition procedures at FAR part 12, is the dispositive issue here, we need not address McKesson's allegation that the agency improperly utilized the latter procedures. See Johnson Controls World Servs., Inc., B-285144, July 6, 2000,

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referred to as "essential salient characteristics." RFP at 5. Award was to be made to the offeror that provided a technically acceptable proposal--one that met all the salient characteristics--at the lowest price. Id. at 28.

Prior to the October 15 closing date for receipt of proposals, McKesson filed this protest arguing that the DSCP is improperly using a sole-source procurement, challenging various aspects of the J&A, and alleging that certain of the RFP's salient characteristics are overly restrictive.[4] IA was the only firm that submitted a proposal; award has not yet been made. Along with its comments on the agency report, McKesson filed a supplemental protest in which it argued that IA's proposal did not meet certain of the RFP's requirements.[5]

Although the overriding mandate of the Competition in Contracting Act of 1984 (CICA) is for full and open competition in government procurements, obtained through the use of competitive procedures, 10 U.S.C. § 2304(a)(1)(A) (2000), CICA permits noncompetitive acquisitions in certain circumstances. 10 U.S.C. § 2304(c). One of those circumstances or exceptions to the mandate that competitive procedures be used--that only one responsible source and no other supplies or

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2000 CPD ¶ 108 at 3. We are of the view, however, that McKesson has not persuasively rebutted the agency's position that IA's system is a commercial item as defined by FAR § 2.1.

[4] McKesson also alleged that the agency failed to conduct adequate market research before proceeding with this sole-source procurement. However, our review of the record shows that the agency's market research, which included review of an extensive independent report comparing various firms' approaches to automated and robotic pharmacy systems, numerous meetings with these firms to obtain additional information, site visits to inspect various systems, and comparisons of the various features of each firms' systems, was appropriate to the circumstances present here. FAR § 10.001(a)(2). In any event, McKesson has not shown that the agency was unaware of its qualifications, given the firm's frequent contacts with the agency, the details of its products as set forth in the agency's market research, and the Air Force consultant's experience with its products. As a result, even if we were to assume, for purposes of analysis, that the agency had not conducted adequate market research, McKesson clearly was not prejudiced. Global Solutions Network, Inc., B-290107, June 11, 2002, 2002 CPD ¶ 98 at 7 n.5.

[5] McKesson also alleged in its comments that several more of the RFP's salient characteristics were overly restrictive. However, protests based upon alleged improprieties that are apparent in a solicitation must be filed prior to the time set for receipt of initial proposals. 4 C.F.R. § 21.2(a)(1) (2002). Since McKesson did not raise these allegations prior to the October 15 closing date for receipt of proposals, these allegations are untimely and will not be considered.

services will satisfy the agency's requirements--was cited by the DSCP as the authority for its proposed sole-source award to IA. J&A at 1; FAR § 6.302-1.

When an agency uses noncompetitive procedures under 10 U.S.C. § 2304(c)(1), it is required to execute a written J&A with sufficient facts and rationale to support the use of the cited authority, and publish a notice to permit potential competitors to challenge the agency's intent to procure without full and open competition. See 10 U.S.C. § 2304(f)(1)(A), (B); FAR §§ 6.302-1(d)(1), 6.303, 6.304; Marconi Dynamics, Inc., B-252318, June 21, 1993, 93-1 CPD ¶ 475 at 5. Our review of the agency's decision to conduct a sole-source procurement focuses on the adequacy of the rationale and conclusions set forth in the J&A. When the J&A sets forth a reasonable justification for the agency's actions, we will not object to the award. Global Solutions Network, Inc., supra, at 6; Diversified Tech. and Servs. of Virginia, Inc., B-282497, July 19, 1999, 99-2 CPD ¶ 16 at 3. Our review of the record shows that several of the agency's reasons for concluding that only IA's system can meet its needs constitute a reasonable justification for the agency's decision to procure this system on a sole-source basis.

The J&A lists four primary factors in the selection of a robotic refill system: (1) compliance with Air Force communications security requirements; (2) programmable dispensing units that eliminate the need to exchange/ship counting unit component(s); (3) availability of the optical original prescription image when checking the refilled prescription; and (4) no cross contamination between medications. J&A at 1. The Air Force consultant deemed these requirements to have an impact upon human safety, Tr. at 63-65, 67, 76-77, and concluded that IA's system was the only one that met all four of these requirements. J&A at 1. The J&A also states that only IA's PharmASSIST robotic refill system has all of certain other "essential features." According to the J&A, the robotic refill system to be procured must have these essential features due to the importance of minimizing medication errors and more efficiently using diminishing Air Force pharmacy resources. J&A at 3. These "primary factors" and "essential features" are expressed as the various salient characteristics set forth in the RFP.

One of the primary factors in the selection of the system was "compliance with Air Force Communications Security requirements." J&A at 1. As the J&A makes clear, this factor, and the corresponding RFP requirement that the system "provide evidence of certification meeting [Air Force] security requirements," RFP at 5, refers to the Air Force Communications Agency Certificate of Networthiness (AFCA CON) process. J&A at 2.

An AFCA CON is required before the fielding of systems that alter, reside, or require support from any part of the Air Force's enterprise network. Draft Air Force Certificate of Networthiness Guide (Draft Guide), Dec. 16, 2002, ¶¶ 1.3, 5.1.1; Draft Air Force Instruction No. 33-123, "Networthiness and System Certifications," Oct. 7,

2002, ¶¶ 1.1, 2 (implementing Air Force Policy Directive No. 33-1, "Command, Control, Communications, and Computer (C4) Systems"); Air Force Instruction No. 33-104, "Communications and Information: Base-Level Planning and Implementation," May 10, 2001, ¶ 4.2 (implementing Air Force Policy Directive 33-1, supra). The networthiness assessment process determines the impacts, risks, and vulnerabilities of fielding a system and considers such things as network security, network impact, and compatibility with the information technology infrastructure. Draft Guide ¶ 9.1.2. A system or application is "networthy" if it has been assessed and determined to be supportable from a communications and information perspective, and if any impacts, risks, and vulnerabilities it may present to the Air Force's enterprise network are deemed to be acceptable or manageable. Id. at ¶ 9.1.1. The networthiness process helps ensure that information technology systems and applications are secure, supportable, sustainable, and compatible with the Air Force enterprise network and information technology infrastructure.

McKesson does not dispute the agency's contention that the system required here must interface with Air Force communications and information infrastructures--the RFP requires the system to link and integrate with the Composite Health Care System, a DOD-wide hospital information system. RFP at 5. At the time the J&A was signed and the solicitation issued, IA was the only manufacturer of automated dispensing and robotic refill systems that had submitted a request for an AFCA CON. J&A at 2. According to the agency, the AFCA CON process takes 12-18 months to complete. IA began the process in November 2001, the Air Force Surgeon General's Information Management Branch completed the final inspection of IA's system by September 2002, and the final AFCA CON was signed on December 24.

McKesson's assertion that the agency is using this requirement as a competitive barrier against the firm, and that it has only "very recently been pointed in the right direction to begin to attain definitive answers" to questions about this process, Initial Protest at 5, is disingenuous. The Air Force consultant explains that, since these communication security requirements became strictly enforced after the terrorist attacks of September 11, 2001, the Air Force Pharmacy contacted most companies that have pharmacy equipment requiring interface with Air Force systems. On October 10, 2001, she told McKesson's representatives that the Air Force was "tightening up security requirements" and recommended that the firm start the AFCA CON security process. McKesson's representative stated that the firm saw no need to pursue this process. Air Force Consultant's Oct. 10, 2001 Memorandum for the Record; Air Force Consultant's Initial Declaration ¶ 15. On June 24, 2002, she asked McKesson's representatives if the firm had started the AFCA CON security process and was told that this process "did not apply to them" because their firm was "grandfathered." When the consultant tried to explain that "nothing was grandfathered when it was newly purchased or upgraded," she was told that McKesson "would not invest the time--they could get local approval if they needed it." Air Force Consultant's June 24, 2002 Memorandum for the Record; Air Force

Consultant's Initial Declaration ¶ 15. McKesson has not contradicted the Air Force Consultant's account of these events.

The record shows that this Air Force-wide requirement is, in fact, an expression of the agency's minimum needs. To the extent that it creates a "competitive barrier" to McKesson's participation in this procurement, the record also shows that McKesson resisted the agency's early attempts to assist the firm in overcoming this barrier. By failing to begin the AFCA CON process when it was advised to do so, McKesson accepted the risk that the Air Force would release a solicitation containing a requirement it would not be able to meet. Pilkington Aerospace, Inc., B-259173, Mar. 13, 1995, 95-1 CPD ¶ 180 at 10; recon. denied, B-259173.2, May 15, 1995, 95-1 CPD ¶ 242. McKesson has given us no basis to disagree with the agency's assertion that it cannot delay the project an additional 12-18 months simply because McKesson failed to initiate the AFCA CON process when it was advised to do so.[6]

We are unpersuaded by McKesson's argument that IA's proposal does not meet this requirement because it did not have a final AFCA CON at the time its proposal was submitted. Neither the J&A nor the RFP required the completion of the AFCA CON process at the time of proposal submission--the J&A merely required compliance with Air Force communications security requirements, and the RFP merely required evidence of certification meeting these requirements. See Container Prods. Corp., B-280603.2, Nov. 4, 1998, 98-2 CPD ¶ 106 at 3-4. Although offerors were instructed to include in their proposals evidence of certification meeting the requirements, this evidentiary requirement must be read in conjunction with the purpose behind the certification requirement--to ensure that a system could be certified prior to the time it must be fielded. As a result, we think that the evidentiary requirement was only meant to establish that the offeror would be able to meet the certification requirement at the time of delivery. Liebert Fed. Sys., Inc., B-274823, Jan. 8, 1997, 97-1 CPD ¶ 45 at 5. As IA's proposal made clear at the time of proposal submission, and as the J&A acknowledged, IA's PharmASSIST Enterprise System had passed its final inspection in this process and was merely awaiting interim and final certification. IA Proposal ¶¶ 4.11, 5.10; J&A at 2. In our view, this information was sufficient to meet the RFP's requirement.[7]

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[6] McKesson's assertion that it has obtained the same sort of network security approval from another federal agency and that the DSCP should consider this approval to meet the requirement is entirely unpersuasive, given the specific Air Force requirements outlined above and the dearth of detail provided by McKesson concerning this approval.

[7] McKesson argues that the AFCA CON applies to IA's PharmASSIST Enterprise System, and not to the PharmASSIST robotic refill system the firm has offered. As the Air Force consultant has explained, however, the IA robotic refill system can be viewed as merely the addition of the robotic component--an automated arm--to the PharmASSIST Enterprise System. Air Force Consultant Initial Declaration ¶ 8. IA's

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A second primary factor in the selection of a robotic refill system was that it have "programmable dispensing units that eliminate the need to exchange/ship counting unit component(s)."[8] J&A at 1. The J&A states that IA's system is fully programmable on-site to handle all tablet and capsule types, but that all similar systems require at least some shipping of the units for almost all product changes. J&A at 2. Medications must be hand-counted during the time units are being exchanged, and Air Force pharmacies typically have a significant number of generic product changes per month. Id.

As the agency explains, McKesson's dispensing units must be manually calibrated by the manufacturer for each product change. The exchange of McKesson's units has "always been a time-consuming process and requires hand-counting medication for high-volume prescriptions until the new unit is obtained." Air Force Consultant's Initial Declaration ¶ 10. The Air Force consultant states that experience contradicts McKesson's claim that its method simply involves the ordering and installation of new units on a next-day or maximum 48-hour delivery basis. Id. In any event, she adds, even if a 48-hour delivery were consistently obtained, 2 days of manually counting high-volume prescriptions is unacceptable when an alternative is available. Id. In this regard, giving such discretion to pharmacy personnel has a potential adverse impact on patient safety and efficiency. Id. ¶¶ 7, 10. In contrast with the McKesson system, IA's system does not require manual calibration either by the manufacturer or the customer. All of the calibration is software-driven--entering the National Drug Code number programs the cells. Id. at ¶ 8.

McKesson argues that IA's system does not comply with the requirement to eliminate the need to exchange/ship counting unit components because its units must be returned to the manufacturer for cleaning, repair, or replacement, which creates downtime requiring the hand-counting of medications, the issue of concern to the agency. As the agency points out, however, the requirement at issue is not linked to the cleaning, repair, or replacement of counting units, but to the programming of such units when products are changed. J&A at 2. Air Force pharmacies have a significant number of generically-equivalent product changes per month and IA's units can be calibrated on-site for such changes. Although a new cell must be requested from IA when a drug entity changes, each of the system's cabinets or banks comes with an additional programmable unit that minimizes downtime. In

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proposal indicates its plan to use the PharmASSIST Enterprise System, and there is no basis to conclude the AFCA CON does not apply to the system as offered.

[8] The related RFP salient characteristic required the system to be "fully programmable and handle all tablet and capsule types." RFP at 5. McKesson's allegation that this characteristic is overly restrictive was among its untimely allegations. See supra at 3 n.4.

contrast, the McKesson dispensing units must be calibrated off-site by the company when products are changed.

In any event, the agency also states that the time saved by IA's ability to electronically calibrate cells on-site is not offset by the maintenance requirement to return cells to the manufacturer for routine cleaning. The Air Force consultant explains that the Air Force has four pharmacies using the IA system. In the past year, only six counting units were returned from one site, and in the past 10 months only one counting unit was returned from another site.[9] In addition, when IA was told that a unit was being returned for disassembly and cleaning, a new unit was shipped immediately; in all cases, a clean unit was available at the site for use when the decision was made to change and the units were changed in only a few minutes. McKesson has not provided any rebuttal to the agency's explanation, which reasonably supports the agency's position that this is a minimum requirement for patient safety and that IA has the only system meeting this requirement. Where, as here, a requirement relates to human safety concerns, the agency has the discretion to set its minimum needs so as to achieve not just reasonable results, but the highest possible reliability and effectiveness. Harry Feuerberg & Steven Steinbaum, B-261333, Sept. 12, 1995, 95-2 CPD ¶ 109 at 3.

Since at least two of the primary factors set forth in the J&A reasonably support the agency's conclusion that only IA could meet its minimum needs, we need not decide whether the remainder of the J&A's rationale supports this conclusion or whether the RFP's challenged salient characteristics are overly restrictive.

Our Office will not sustain a protest unless the protester demonstrates a reasonable possibility of prejudice, that is, unless the protester demonstrates that, but for the agency's actions, it would have had a substantial chance of receiving the award. McDonald-Bradley, B-270126, Feb. 8, 1996, 96-1 CPD ¶ 54 at 3; Statistica, Inc. v. Christopher, 102 F.3d 1577, 1581 (Fed. Cir. 1996). Here, even if we were to conclude that the remainder of the J&A's rationale for this sole-source procurement were unreasonable, the portion of the rationale we have already discussed is sufficient to support the agency's decision that only IA could meet its minimum requirements. Likewise, even if we were to conclude that the three salient characteristics challenged by McKesson were overly restrictive of competition, since the firm cannot meet the two primary factors discussed above,[10] we would have no basis to

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[9] IA's proposal states that, for the average pharmacy, it would not be unusual for dispensers counting even the dustiest drugs to go almost a year between cleanings; most dispensers will never need to be cleaned. IA's Proposal at 21.

[10] It also appears that McKesson cannot meet, as written, the three salient characteristics that it untimely challenged in its comments on the initial agency report.

conclude that it has any chance of receiving the award. A protester is not an interested party where it would not be in line for contract award if its protest were sustained. See Four Winds Servs., Inc., B-280714, Aug. 28, 1998, 98-2 CPD ¶ 57 at 2.

Our review of the record also shows that McKesson's allegations that IA's proposal does not meet the agency's requirements are without basis.[11] McKesson argues that IA's system cannot meet the RFP's requirement that "[e]ach defined specification must have operational capability or operational experience/history in an existing pharmacy," RFP at 5, because it is not currently installed anywhere. As the agency explains, however, IA's pharmacy refill system is designed and produced using a variety of components, the basic component of which is an automated pharmacy that uses IA's PharmASSIST tablet and capsule dispensers that are used in a number of Air Force pharmacies. The robotics--an automated arm--is merely an additional component of the system and consists of a highly dependable and widely accepted unit that is sold in the United States. Other components used in IA's robotic system, such as conveyor belts, computer terminals, filling stations, counting unit cabinets, and checking stations, are used throughout the industry and are available in the marketplace from IA and its subcontractors and are customized to the customer's needs. As a result, the agency states, each defined specification of IA's system does have operational capability or operational experience/history in an existing pharmacy. McKesson has given us no basis to disagree with this conclusion.

McKesson also argues that IA's system does not permit out-of-cycle/sequence processing, an apparent reference to the RFP requirement that the system "have internal buffers to hold counted products until computer-controlled release allowing other items in queue to be processed out of cycle." RFP at 5. The agency explains that one reason for this requirement is that it is important to be able to fill and dispense prescriptions out of sequence. The Air Force consultant states that this requires more than one counting unit to contain medication at the same time when "stat" prescriptions--those with high priority--are processed. Internal buffers provide safety when processing out-of-sequence prescriptions because they do not allow an individual to choose the wrong counting unit and dispense the wrong medication, thereby eliminating human decision-making from the process and improving patient safety. Air Force Consultant's Initial Declaration ¶ 23.

IA's proposal states that its software supports a comprehensive set of priorities that allow sophisticated handling of the internal filling queue. Orders of standard priority

[11] McKesson's argument that IA's proposal does not indicate that its system can meet any of the RFP's salient characteristics because one page of its proposal merely indicates that it is compliant with each of these characteristics ignores the remaining contents of IA's proposal, and McKesson's argument that IA's proposal does not meet the agency's throughput requirements ignores the fact that there are no such requirements.

are counted in a first-in-first-out (FIFO) manner, and orders of high priority are counted before orders with standard priority. Within the group of orders with high priority, counting is performed in a FIFO manner. IA Proposal at 21. IA's software also supports two special priority designations, including the FillNext designation, which has the highest priority in the system. Orders with the FillNext designation are counted in a last-in-first-out manner. If the system cannot count a FillNext order with this priority because the required dispenser is in use, the software lets the user know what order must be filled so the FillNext order can be counted. Id. While McKesson points to hearing testimony that, in certain circumstances, the IA system may not allow immediate out-of-cycle processing (such as if both chutes for a medication are already filled), Tr. at 112-13, the RFP does not require immediate out-of-cycle processing at all times. We read the requirement as governing the rule, not the exceptions associated with the refilling process, and find no basis to conclude that IA's system cannot meet this requirement.

The protests are denied.

Anthony H. Gamboa
General Counsel