Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MANAGEMENT OF INFORMATION TECHNOLOGY CONTRACTS AT THE FOOD AND DRUG ADMINISTRATION'S CENTER FOR DRUG EVALUATION AND RESEARCH

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EXECUTIVE SUMMARY

OBJECTIVES

1. To assess the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) process for selecting information technology (IT) contractors from fiscal year (FY) 2004 to FY 2007.

2. To determine the extent to which CDER monitored the performance of its IT contractors from FY 2004 to FY 2007.

BACKGROUND

In FY 2006, the Department of Health and Human Services spent $5.4 billion on IT. Overall, Federal spending on IT has long been considered high risk for fraud, waste, and abuse because of the significant cost involved and insufficient planning on the part of Federal agencies.

The Office of Inspector General conducted a review of the IT contracting practices of FDA's CDER at the request of the Senate Committee on Finance. The request was in response to a draft consulting report that raised questions about the management of CDER's IT contracts. The Office of Information Technology was responsible for planning and managing many of the IT services for CDER. The Federal Acquisition Regulation (FAR) governs how all Federal agencies, including FDA, may acquire supplies and services with appropriated funds.

Agencies must establish procedures to select qualified contractors while protecting the Government from unnecessary financial risk. To ensure that contracted work is performed efficiently and funds are used effectively, agencies must perform acquisition planning, clearly define what they are buying in a statement of work, and select an appropriate contract type and method. Agencies may use several types of contracts to acquire supplies and services. One such type is time-and-materials, whereby the Government pays the contractor a fixed amount for hourly labor and generally reimburses it for any costs of materials. In addition, agencies must use performance-based contracting for a designated proportion of contracts to encourage contractors to focus on achieving specific outcomes. With limited exceptions, agencies must provide for full and open competition. Once contracted work begins, agencies must monitor contractors to ensure quality results.

We reviewed the contractor selection, performance measurement and quality assurance (QA) plans, and the performance monitoring for 28 CDER OIT contract actions. We also interviewed five current or former CDER contract project officers.

FINDINGS

CDER's contract actions demonstrated limited IT planning and increased risk for the Government. CDER used broad language to describe requirements in its statements of work, allowing it to specify its requirements over time. CDER relied primarily on acquisition methods that emphasize speed and flexibility over planning. CDER also relied on time-and-materials contract actions that increase risk for the Government. Because of these decisions, CDER may not achieve the benefits of performance-based acquisition.

CDER used quality assurance and monitoring plans inconsistently. Because CDER did not clearly define its requirements or performance measures, it also did not establish QA plans consistently. Twenty-one of twenty-eight contract actions reviewed did not have documented QA plans. Of the seven contract actions that included QA plans, three contained identical plans with generic language calling for 100-percent inspection of deliverables using the same checklist of qualitative measures.

RECOMMENDATIONS

Several areas of concern exist with CDER's IT planning process and its contract monitoring. Although the IT contract actions reviewed were generally compliant with the FAR, FDA could minimize its contract risk by making the following changes:

Define IT requirements more clearly. FDA should revise its planning processes to define IT requirements in greater detail. This step could lead to additional contracting options and create greater efficiencies in contractor selection and project management as well.

Convert ongoing time-and-materials contract actions to fixed-price contract actions when appropriate. Converting ongoing time-and-materials contract actions to fixed-price contract actions would reduce the financial risk borne by the Government and may allow FDA to obtain the same services at a reduced cost. Converting time-and-materials contract actions to

fixed-price contract actions would also reduce the amount of oversight needed to ensure labor efficiency.

Use performance incentive plans when appropriate. Use of performance incentives could allow FDA to reduce contract costs by tying the contractor's profit or award fees to quantifiable performance standards.

Use documented QA plans. Implementing documented QA plans in its contract actions would allow FDA to create a mechanism for contractor accountability by identifying services that do not meet defined requirements.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

FDA agreed with three of our four recommendations and identified steps it is taking to implement them. FDA neither agreed nor disagreed with our first recommendation to define its IT requirements more clearly. However, it did identify actions it is taking that support that recommendation. In addition, FDA agreed with our other recommendations to convert time-and-materials contracts to fixed-price contracts when appropriate and to use performance incentives and quality assurance plans when applicable. We ask that in its final management decision, FDA more clearly indicate whether it concurs with our first recommendation and what steps it will take to implement it.

TABLE OF CONTENTS

INTRODUCTION

OBJECTIVES

1. To assess the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) process for selecting information technology (IT) contractors from fiscal year (FY) 2004 to FY 2007.

2. To determine the extent to which CDER monitored the performance of its IT contractors from FY 2004 to FY 2007.

BACKGROUND

In FY 2006, the Department of Health and Human Services (HHS) spent $5.4 billion on IT.[1] Overall, Federal spending on IT has long been considered high risk for fraud, waste, and abuse because of the significant cost involved and insufficient planning on the part of Federal agencies. In 1996, Congress passed the Clinger-Cohen Act to improve the way Federal agencies acquire and manage IT services.[2] The Act requires agencies to develop best practices for the acquisition of commercial IT services and to monitor contracted IT services through performance measurement.[3] Despite these efforts, IT contracting remains a high-risk area for the Federal Government.[4]

The Office of Inspector General conducted a review of the IT contracting practices of FDA's CDER at the request of the Senate Committee on Finance. The request was in response to a draft consulting report that raised questions about the management of CDER's IT contracts. The draft report specifically addressed CDER's management of an IT project called the Adverse Event Reporting System II.[5] This system was intended to be a database for collecting adverse event information for prescription drugs. The draft report indicated that CDER's Office of Information Technology (OIT) mismanaged the project, resulting in cost overruns and decreased productivity. The draft report also questioned OIT's contractor selection and management processes.

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[1] Office of Management and Budget, "Report on Information Technology Spending for the Federal Government," May 2007.

[2] P.L. 104-106, Div. E (1996); 40 U.S.C. § 11101 et seq.

[3] 40 U.S.C. §§ 11302(f), 11313.

[4] For example, see United States Government Accountability Office (GAO), "High-Risk Series: Information Management and Technology," GAO/HR-97-9, February 1997. See also GAO, "Information Technology: Further Improvements Needed to Identify and Oversee Poorly Planned and Performing Projects," GAO-07-1211T, September 20, 2007.

[5] Breckenridge Institute, "Independent Verification and Validation of AERS II Requirements Process," November 2006.

CDER is responsible for ensuring that drugs marketed within the United States are safe and effective. This responsibility begins in the research and development stage of a potential drug and continues throughout the life of a marketed drug. In keeping with its mission, CDER receives large amounts of electronic information, such as clinical trial data and adverse event reports. It is critical that CDER procure IT systems and services that meet its needs in a cost-effective manner, while also complying with relevant acquisition regulations.

CDER IT Planning and Contracting Processes

OIT was responsible for planning and managing many of the IT services for CDER.[6] As of May 2008, OIT had 40 staff members across three branches: Enterprise Architecture, Application Development, and Quality Assurance. OIT and its counterparts from the other FDA centers were disbanded and absorbed at the end of FY 2008 into one agencywide Office of Information Management.

Prior to the reorganization, CDER components worked with OIT to develop and implement new IT systems. When CDER identified an IT need, such as new software, hardware, or support, it worked with OIT to develop a proposal for CDER's Information Management Steering Committee's Planning Subcommittee (the Planning Subcommittee).[7] OIT conducted various analyses to include with the proposal, and determined whether it had the expertise to meet each IT request with internal resources or whether it would need to hire a contractor.[8]

If the proposal was approved by the Planning Subcommittee and OIT decided to hire a contractor, OIT staff worked with FDA's Office of Acquisition and Grant Services (the Acquisition Office). The Acquisition Office administers contracts for all of FDA, including CDER.[9] Only contracting officers within the Acquisition Office have the authority to enter into, administer, or terminate a contract on behalf of FDA.[10] Project officers from OIT provide technical expertise to the Acquisition Office and monitor the contractor to ensure that CDER receives what it

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[6] FDA's Office of the Chief Information Officer plans and manages cross-center IT services. Some services used by CDER are not managed by OIT, such as data entry. This review will focus on IT services planned and managed by CDER's OIT exclusively.

[7] The planning subcommittee is also called the Information Management Advisory Board.

[8] HHS, FDA, CDER, "Manual of Policies and Procedures," MAPP 7600.9, Information Management Steering Committee Planning Subcommittee, March 4, 2005, p. 6.

[9] The Acquisition Office will continue this role after the reorganization.

[10] 48 CFR § 1.602-1(a).

has paid for, while also ensuring that it complies with the Federal Acquisition Regulation (FAR).[11]

Contracting Basics

In FY 2006, the Government bought over $400 billion worth of goods and services.[12] The FAR governs how all Federal agencies, including FDA, acquire supplies and services with appropriated funds.[13] Agencies also promulgate their own regulations as needed to supplement the FAR. In addition to the FAR, FDA acquisitions must conform to regulations set forth in the HHS Acquisition Regulation and the FDA Acquisition Operating Instructions.[14]

To comply with the FAR, agencies must establish procedures to select qualified contractors while protecting the Government from unnecessary financial risk. To ensure that contracted work is performed efficiently and funds are used effectively, agencies must perform acquisition planning,[15] clearly define what they are buying in the requirements section of a statement of work,[16] and select an appropriate contract type and method.[17] In addition, agencies must use performance-based contracting for a designated proportion of contracts to encourage contractors to focus on achieving specific outcomes.[18] With limited exceptions, agencies must provide for full and open competition when acquiring goods and services.[19] Once performance begins, agencies must monitor contractors to ensure quality results.[20]

For more information on contracting regulations and terminology, see the Contracting Primer starting on page 7. See Appendix A for abbreviations and acronyms used in this report and Appendix B for legal authorities governing Federal acquisitions.

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[11] 48 CFR § 302.1.

[12] Trending Analysis Report Since Fiscal Year 2000. Available online at: http://www.fpdsng.com/downloads/top_requests/FPDSNG/5YearViewOnTotals.xls. Accessed May 30, 2008.

[13] The FAR, located at 48 CFR ch.1, is authorized by the Office of Federal Procurement Policy Act of 1974, as amended. 41 U.S.C. § 405a.

[14] HHS Acquisition Regulation, 48 CFR ch. 3; FDA, "Acquisition Operating Instructions," on file at FDA.

[15] FAR § 7.102(a)–(b).

[16] Ibid., § 11.002(a).

[17] Ibid., § 16.104.

[18] Office of Management and Budget, "Fiscal Year 2008 Performance-Based Acquisition Performance Goal," December 5, 2007.

[19] FAR, § 6.101.

[20] Ibid., §§ 46.102, 46.103.

Acquisition Advisory Panel Report

The Services Acquisition Reform Act of 2003 created the Acquisition Advisory Panel (AAP) to review Federal acquisition laws and regulations and make recommendations to improve contracting practices.[21] Its January 2007 report highlighted problems within Federal contracting, including:

- the Government's failure to adequately define its service requirements, which leads to a reliance on time-and-materials contracts[22] and reduces the benefits of competition;[23]
- the importance of defining service requirements to obtain the maximum benefit of performance-based acquisitions concepts;[24] and
- the acquisition workforce's challenges in writing performance measures and metrics[25] and its insufficient surveillance of multiagency contracts.[26]

Recent United States Government Accountability Office Report

A recent GAO report demonstrates the same problems with Federal contracting that were highlighted in the AAP report. GAO's review of the Department of Defense's use of time-and-materials contracts found that the Department uses them because they can be awarded quickly and can be adjusted if requirements change. GAO also found that the Department's monitoring of time-and-materials contracts was not sufficient given the inherent risks of this contract type.[27]

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[21] National Defense Authorization Act for Fiscal Year 2004, P.L. No. 108-136, § 1423 (2003).

[22] AAP, "Report of the Acquisition Advisory Panel to the Office of Federal Procurement Policy and the United States Congress," January 2007, pp. 7 and 92.

[23] Ibid., pp. 7 and 92.

[24] Ibid., p. 8.

[25] Ibid., p. 178.

[26] Ibid., p. 93.

[27] GAO, "Defense Contracting: Improved Insight and Controls Needed over DoD's Time-and-Materials Contracts," GAO-07-273, June 2007.

METHODOLOGY

Scope

We reviewed CDER's contract actions for IT purchases valued at $250,000 or more issued from FY 2004 to FY 2007. The contract actions covered a range of IT services from upgrading and operating IT systems to migrating legacy IT systems into new ones. For each contract action, we included the value of all options and modifications. We used the Federal Procurement Data System to collect additional information and confirm the maximum dollar value.

Our final review consisted of 28 contract actions. Of these 28 actions, 19 were delivery orders generated from three blanket purchase agreements (BPAs).[28] We excluded contract actions that were not overseen by CDER OIT.

Data Sources and Analysis

Review of Office of Information Technology contract actions. For the 28 contract actions reviewed, we reviewed elements of the contract files to determine the extent to which CDER and the Acquisition Office used full and open competition as prescribed by the FAR. For those actions that were competed, we also examined the criteria that CDER used to evaluate prospective contractors and determined how these criteria were weighed during the selection process.

In determining the extent to which CDER monitored the performance of its IT contractors, we reviewed performance measurement and quality assurance (QA) plans that were written into the contract actions. We also reviewed evidence of CDER's monitoring activities and determined the extent to which CDER monitored contract actions after they were awarded.

Interviews with Center for Drug Evaluation and Research project officers. We interviewed five current or former CDER project officers to obtain additional background information on specific contract actions, the

[28] We note that the FAR defines "delivery order" to mean a contract action for products and "task order" to mean a contract action for services. FAR § 2.101. Although our sample contract actions included mostly task orders for services, we sometimes use the term "delivery order" to refer to these contract actions because FDA's Acquisition Office used this term and the documents are labeled as "delivery orders."

contract-monitoring process, and any challenges that they faced in carrying out their duties.

Limitations

We did not assess the qualifications of the contractors that CDER selected or the technology solutions that they provided.

Standards

We conducted this review in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

Overview

The FAR and applicable agency-specific supplements govern purchases of supplies or services using appropriated funds. Pursuant to these regulations and other applicable authorities, agencies must generally:

- provide for full and open competition when awarding contracts;
- select contractors based on objective evaluation factors; and
- conduct contract monitoring, including establishing a QA plan and ensuring that the contractors comply with the plans and any deadlines.

Additionally, legal authorities have established a preference for performance-based acquisition (PBA) of services. Although the Government previously dictated how contractors should perform their work, PBA requires Federal agencies to state their requirements in terms of desired outcomes or results and allows the contractors to perform the work in any manner they deem appropriate. To ensure that outcomes are achieved, PBA contracts must contain measurable performance standards by which to assess the contractors' work and performance incentives.

Acquisition Methods

Various acquisition methods are available to Federal agencies. Specifically, agencies may acquire supplies and services by:

1. Awarding a new stand-alone contract directly to a vendor and administering it. Generally, this method requires the greatest administrative burden because the agency must perform market research to, among other things, identify qualified contractors; to conduct a competition; and to evaluate proposals or quotes. Agencies are then obligated to administer the contract.
2. Ordering directly under an existing contract established by another agency. These contracts, called multiagency contracts or governmentwide acquisition contracts, often require the ordering agency to pay an additional fee for contract use. The main benefit of using this method is a decreased administrative burden associated with the contract award process.
3. Ordering from the General Services Administration's (GSA) Federal Supply Schedule (FSS) program. Under FSS, contractors do not compete directly against each other in obtaining the initial contract

award. Instead, GSA negotiates pricing and terms with FSS vendors that provide commercial goods and services based on the vendors' own pricing to their commercial customers. Agencies may then place orders under these FSS contracts. FSS orders are considered to be fully competed if agencies follow certain ordering procedures specified by regulation.

Contract Types

The contract type establishes the performance obligations of the contractor and the payment obligations of the Government. Agencies may use several types of contracts to acquire supplies or services, including:

- *Time-and-materials contracts*. Under this contract type, the Government pays the contractor a fixed amount for hourly labor (including wages, overhead, and profit) and generally reimburses for any costs of materials. These contracts, which specify a maximum dollar amount (ceiling price), may be used only when it is not possible to reasonably estimate the extent or duration of work or its costs. These contracts provide no incentive for the contractor to control costs or ensure labor efficiency and therefore require monitoring to ensure that efficient methods and effective cost controls are used.
- *Cost-reimbursement contracts*. Under a cost-reimbursement contract, the Government reimburses the contractor for its allowable costs, including labor and materials. The contractor has no incentive to control costs, and the Government assumes the financial risk that the service or supplies will be delivered in a cost-effective manner.
- *Fixed-price contracts*. Under a fixed-price contract, the contractor is paid a fixed amount for performing the work or producing deliverables regardless of the actual cost. The contractor, therefore, assumes all performance and financial risk and has an incentive to control costs while delivering the supplies or services.

Other Contracting Terms

Statement of work. A statement of work is a document that describes the contract's purpose and the goods or services required under the contract.

Full and open competition. With certain limited exceptions, agencies must acquire goods and services using full and open competition and

competitive procedures. For stand-alone contracts, competitive procedures often involve soliciting proposals or sealed bids. With respect to the FSS, task or delivery orders are considered competitive if they are placed using regulatory procedures. Further, an agency must provide written justification and approval before awarding a contract directly to a sole source under a stand-alone contract or an FSS order.

Blanket purchase agreement. BPAs are agreements, usually entered into under FSS contracts, that are intended for agencies that anticipate having recurring needs for supplies or services. Task and delivery orders may be placed under such BPAs.

CDER's contract actions demonstrated limited IT planning and increased risk for the Government

CDER's contract files contained basic documentation required under the FAR. However, the agency used broad language in its statements of work that failed to describe specific requirements, suggesting that it had not thoroughly planned its IT service acquisitions. In addition, CDER acquired IT services primarily through flexible acquisition methods and time-and-materials contract actions that reduce the agency's administrative burden but increase risk for the Government. The AAP report highlighted the importance of acquisition planning, which includes improved competition and innovative solutions at the best prices.[29]

CDER used broad language to describe requirements in its statements of work

Several FSS orders used identical language to describe requirements in the statements of work even when the orders were for different services. For example, six of nine orders under one BPA contained statements of work with identical lists of requirements that the contractor would provide. These lists included "IT project management support," "IT planning and other support," and "IT analysis and support." Broad requirements language provided CDER with the flexibility to specify its requirements over time.

Another FSS order contained broad language stating that the contractor "will assist with the analysis, development of plans, script writing, and documentation to be implemented immediately under the contract or at a later date by government employees." The project officer responsible for this order told us that CDER wrote this statement of work to match the contractor's expertise and that the actual tasks that the contractor performed were specifically defined only after award, when CDER identified its requirements.[30] Another project officer highlighted the difficulty in defining specific requirements because routine maintenance tasks were difficult to capture in a statement of work.

In addition, other statements of work contained lists of tasks that were never ultimately requested by CDER. For example, four of nine orders

[29] AAP, "Report of the Acquisition Advisory Panel to the Office of Federal Procurement Policy and the United States Congress," January 2007, p. 7.

[30] The FAR does provide authority for limiting sources under FSS orders. FAR § 8.405-6. For this contract action, CDER's contract file contained a justification document explaining why competition was limited.

under one BPA included statements of work listing emergency software releases and various administrative reports that CDER never requested. One project officer told us that CDER may write a statement of work broadly in case the contractor needs to perform tasks in those areas later.

Overall, using broad requirements in statements of work is prevalent throughout Government. AAP attributes the inability to clearly define requirements to the acquisition culture of "getting to award," budgetary time pressures, and an inexperienced contracting workforce.[31]

CDER relied primarily on acquisition methods that emphasize speed and flexibility over planning

In its contractor selection, CDER relied on acquisition methods that have streamlined procedures, including competition requirements. CDER used the FSS or governmentwide acquisition contracts for 27 of 28 contract actions reviewed.

Although the FAR provides for streamlined procedures, the AAP report raised concerns about FSS orders and governmentwide contracts that contain broad scopes of work and lack acquisition planning, stating that they may result in little meaningful competition.[32] CDER's reliance on FSS reflects a larger trend across Government, in which the use of FSS had grown to $35.1 billion by FY 2006.[33] One GSA study found that placing orders through FSS decreased the turnaround time for placing an order from 268 days to 15 days.[34]

Of the 27 contract actions that were FSS or governmentwide acquisition contract actions, 24 were FSS orders. Nineteen of those twenty-four contract actions were delivery orders placed against three BPAs, and the remaining five were single orders. Three of the twenty-seven contract actions were governmentwide acquisition contract actions awarded through interagency agreements.[35]

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[31] AAP, "Report of the Acquisition Advisory Panel to the Office of Federal Procurement Policy and the United States Congress," January 2007, p. 7.

[32] Ibid., pp. 91–92.

[33] GSA Data, "Contractors Report of Sales – Schedule Sales FY 2006 Final," October 2006 (on file with GSA).

[34] J.W. Chierichella and J.S. Aronie, "Multiple Award Schedule Contracting." Xlibris Corp., 2002, p. 41, cited in AAP, "Report of the Acquisition Advisory Panel to the Office of Federal Procurement Policy and the United States Congress," January 2007, p. 234.

[35] Multiple Award Schedule Contracts are awarded by GSA or the Department of Veterans Affairs for similar or comparable supplies or services, established with more than one supplier, at varying prices. The FSS program is also known as the GSA Schedules Program or the Multiple Award Schedule Program. See FAR 8.401–402(a).

CDER used the FSS primarily to procure IT support services, such as program management or technical writing. One project officer told us that CDER uses contractors to fill its ongoing need for IT personnel to perform a variety of tasks related to operations and maintenance. The project officer also stated that CDER previously performed these tasks with its own staff.

CDER also acquired IT services through three governmentwide acquisition orders placed through interagency agreements. CDER officials told us that they used interagency agreements primarily because the agency cannot perform contractor selection given its time and personnel constraints. In one instance, FDA received a congressional mandate to build a database. CDER relied on flexible acquisition methods to fill the need quickly. Under these circumstances, the agency had little time to solicit and review bids from contractors.

CDER relied on time-and-materials contract actions that increase risk for the Government

Twenty-six of twenty-eight contract actions reviewed were time-and-materials contract actions. The FAR states that time-and-materials contracts provide no incentive for the contractors to control costs or increase labor efficiency and, therefore, should be used only when no other contracting method is suitable.[36] CDER's reliance on time-and-materials contracts shifts financial risk onto the Government and places a greater burden on the agency to control costs.[37]

Furthermore, CDER extended 24 of 26 time-and-materials contract actions using contract options or modifications. The FAR states that "contracting officers should avoid protracted use of a cost-reimbursement or time-and-materials contract after experience provides a basis for firmer pricing."[38] We saw no examples in our review in which CDER negotiated firmer pricing for its contract actions over time.

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[36] FAR § 16.601(c).

[37] Ibid., § 16.601(c)(1). If the Government is not satisfied with the work performed by the contractor, the Government may ask the contractor to remedy the deficiencies but must pay the hourly rate (minus the portion that is profit) until the work is completed. FAR § 52.212-4(a)(4).

[38] Ibid., § 16.103(c).

CDER may not achieve the benefits of performance-based acquisitions

CDER characterized 20 of 28 contract actions as performance-based acquisitions, but most of these contract actions did not include measurable performance standards and only one included a performance incentive plan. The FAR requires that performance-based contracts contain a statement of work focused on the agency's desired outcomes, measurable performance standards, and a performance incentive plan.[39] Performance incentives provide additional funds to the contractor for achieving measurable goals.

In fact, 19 of the 20 performance-based contract actions identified were time-and-materials contract actions. Because they provide no incentive for the contractor to control costs or increase labor efficiency, time-and-materials contract actions may undermine the benefits of performance-based acquisition.

Even when contract actions included measurable performance standards, CDER used them inconsistently. In several contract actions, CDER included measurable performance standards, such as the amount of time needed to resolve help desk issues or hours of operation. However, the same actions included standards that were simply lists of deliverables with no measure of quality. One project officer stated that measurable performance standards do not always readily apply to IT services, such as project management and maintenance and operations. CDER's lack of clear performance measures may be related to the lack of clear work requirements that we referred to previously.

Furthermore, in the one contract action for which CDER used a performance incentive plan, it relied on largely subjective performance elements, such as the extent to which "contractor personnel are prepared for meetings and briefings" and whether work is "performed efficiently with the correct skill mix."

CDER used quality assurance and monitoring plans inconsistently

Because CDER did not clearly define its requirements or performance measures, it also did not consistently establish QA plans. QA plans state how and when an agency will evaluate the contractor's performance against established performance measures. When the agency monitors the contractor according to the QA plan, it

[39] Ibid., § 37.601(b).

protects taxpayer funds by holding the contractor accountable for its performance.

Twenty-one of twenty-eight contract actions reviewed did not have documented QA plans. Of the seven contract actions that included QA plans, three contained identical plans with generic language calling for 100-percent inspection of deliverables using the same checklist of qualitative measures. For two of these three contract actions, the project officers told us that they did not use the plans within their respective statements of work.

Without documented QA plans to guide contractor monitoring, CDER's monitoring appears to focus more on day-to-day tasks than on measuring the quality of the contractors' performance. For example, one contract action without a QA plan contained monitoring documentation consisting of status reports with a breakdown of the number of hours that the contractor worked on different IT systems. The project officer told us that he reviewed the status reports for billing purposes. Several project officers stated that because contractors often work in the same office as CDER staff, monitoring often consists of informal discussions, e-mails, and ad hoc meetings.

The FAR generally provides agencies with discretion when monitoring contracts. However, the FAR also considers time-and-materials contracts to be high-risk contracts that require monitoring commensurate with the risk. As noted earlier, the majority of the contract actions reviewed were time-and-materials.

CDER is responsible for ensuring that drugs marketed within the United States are safe and effective. In keeping with this mission, it is critical that CDER procure IT systems and services that meet its needs in a cost-effective manner while complying with relevant acquisition regulations. We acknowledge that Federal IT contracting presents unique challenges for acquisition personnel and project managers.

Although the IT contract actions reviewed were generally compliant with the FAR, several areas of concern exist with CDER's IT planning process and its contract monitoring. We found that CDER used broad language to describe requirements in its statements of work, relied primarily on acquisition methods that emphasize speed and flexibility over planning, relied on time-and-materials contract actions that increase financial risk to the Government, and may not achieve the benefits of performance-based acquisitions. We also found that CDER used QA and monitoring plans inconsistently. The AAP report of 2007 found the same problems throughout the Federal Government.

FDA's Office of Information Management absorbed CDER OIT at the end of FY 2008. Although CDER OIT no longer exists as a separate entity, we identified several steps that FDA should take to minimize its contract risk. FDA should:

Define IT Requirements More Clearly

FDA should revise its planning processes to define IT requirements in greater detail. Defining requirements more clearly may lead to additional contracting options, such as the use of fixed-price contracts with performance incentives. FDA could create greater efficiencies in contractor selection and project management as well.

Convert Ongoing Time-and-Materials Contract Actions to Fixed-Price Contract Actions When Appropriate

Although the flexibility of time-and-materials contract actions gives FDA access to a range of contractor expertise when designing a new IT system, this contract type shifts financial risk onto the Government and may not represent the best value for ongoing operations and maintenance functions. Converting ongoing time-and-materials contract actions to fixed-price contract actions would reduce the financial risk borne by the Government and may allow FDA to obtain the same services at a reduced cost. In addition, converting

time-and-materials contract actions to fixed-price contract actions would also reduce the amount of oversight needed to ensure labor efficiency.

Use Performance Incentive Plans When Appropriate

FDA could achieve many benefits from the proper use of performance-based acquisitions, such as competitive pricing, innovative solutions, quality services, and results that support agency missions. Use of performance incentives could allow FDA to reduce contract costs by tying the contractor's profit or award fees to quantifiable performance standards.

Use Documented QA Plans

QA plans state how and when an agency will evaluate the contractor's performance against established performance measures. Implementing formal QA plans in its contract actions would allow FDA to identify services that do not meet the defined requirements and create a mechanism for contractor accountability.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

FDA agreed with three of our four recommendations and identified steps it is taking to implement them. It also noted that its organizational restructuring in FY 2008 centralized IT resources and created new processes for acquisition planning.

FDA neither agreed nor disagreed with our first recommendation to define its IT requirements more clearly. However, it did identify actions it is taking that support that recommendation. Specifically, FDA reported that it is implementing new processes during the early stages of acquisition planning to better coordinate its IT systems and create efficiencies across FDA. These processes are intended to assist in defining requirements.

In addition, FDA agreed with our recommendations to convert time-and-materials contracts to fixed-price contracts when appropriate but noted that fixed-price contracts are most effective for acquisitions in which requirements are clear, such as those for hardware and commercial off-the-shelf software. Finally, FDA agreed with our recommendations to use performance incentive plans and quality assurance plans, stating that it will use these methods in future contracts when applicable.

We ask that in its final management decision, FDA more clearly indicate whether it concurs with our first recommendation and what steps it will take to implement it.

For the full text of FDA's comments, see Appendix C.

APPENDIX ~ A

Glossary of Abbreviations, Acronyms, and Contracting Terms

Acquisition Advisory Panel (AAP). The Services Acquisition Reform Act of 2003 created AAP to review Federal acquisition laws and regulations and make recommendations to improve contracting practices, particularly regarding commercial and performance-based acquisitions.

Blanket Purchase Agreement (BPA). Rather than issue new contracts, agencies may place delivery orders under a BPA to fill recurring needs for supplies or services.

Federal Acquisition Regulation (FAR). The FAR is the primary set of regulations governing Federal contracting.

Federal Procurement Data System (FPDS). The FPDS is an online database that captures basic information on Government contracts, such as the purchasing agency, contractor name, and contracted dollar amount, and indicates whether the contract was awarded competitively.

Federal Supply Schedule (FSS). The FSS is one type of Multiple Award Schedule operated by the General Services Administration. It is a list of prenegotiated Government contracts for commonly used commercial items and services that Federal agencies and other entities may use.

Government-Wide Acquisition Contract (GWAC). The Clinger-Cohen Act established GWACs for the streamlined acquisition of information technology (IT) services and products.

Performance-Based Acquisition (PBA). The PBA is the Government's preferred method of service contracting according to the FAR. PBA states the Government's desired outcomes and allows the contractor to decide how the work will be done to achieve those outcomes.

Options. An option is a unilateral right in a contract by which the Government may choose to purchase additional supplies or services or extend the term of the contract. Contracting officers may include options in contracts when they are in the Government's interest.

Risk. Risk refers to the possibility that a contract will not be fulfilled at the agreed-upon price. For example, if the Government agrees to pay a contractor a fixed price to build an IT system, the contractor earns additional profit only if it can build the IT system at a cost less than the fixed price. Thus, the contractor assumes the financial risk.

Small Business Contracting Goals. The FAR requires the Government to provide contracting opportunities to small businesses, those owned by

veterans and women, those in economically underutilized areas, and those owned by other groups that may be at a disadvantage when competing for contracts. The annual small business goal for all governmentwide prime contract dollars is 23 percent. Agencies must report their small business contract awards through the FPDS.

APPENDIX ~ B

Legal Authorities Governing Federal Acquisitions

Assisted Acquisition. 48 CFR § 4.601 (definition of assisted acquisition)

Blanket Purchase Agreements (BPA). 48 CFR § 8.405-3(a) (BPAs under Multiple Award Schedule (MAS)/Federal Supply Schedule (FSS) contracts); 48 CFR § 13.303 (stand-alone BPA)

Competition Requirements. 48 CFR ch. 1, Part 6; 48 CFR ch. 1, subpart 8.4 (FSS competition requirements); 48 CFR § 16.505 (multiagency contracts competition requirements)

Evaluation Factors. 48 CFR § 15.303(b)(94) (negotiated contracts); 48 CFR § 14.201-5(c) (sealed bid contracts); 48 CFR § 13.106-1 (simplified acquisitions)

Federal Acquisition Regulation Authority and Applicability. 41 U.S.C. § 405(a); 48 CFR § 1.104; 48 CFR § 2.101 (definition of acquisition)

Federal Procurement Data System (FPDS). 48 CFR ch. 1, subpart 4.6

***FSS Contracts** (also known as MAS contracts).* 41 U.S.C. § 259(b)(3); 48 CFR § 8.404(a); 48 CFR § 6.102(d)(3)

Multiagency Contracts (MAC) and Governmentwide Acquisition Contracts (GWAC). 41 U.S.C. §§ 253h and 253k (MAC); 41 U.S.C. § 11314(a)(2) (GWAC); 48 CFR § 2.101 (definition of MAC and GWAC)

Option. 48 CFR § 2.101 (definition of option); 48 CFR § 17.202 (option inclusion and exercise)

Performance-Based Acquisitions (PBA). Floyd Spence National Defense Authorization Act FY 01, P.L. No. 106-398, § 821 (Oct. 30, 2000); 48 CFR § 2.101 (definition of PBA); 48 CFR § 37.102(a); 48 CFR § 37.601

Quality Assurance Requirements. 48 CFR, subpart 46.4; 48 CFR § 16.601(b)(1) (time-and-materials contracts-related Government surveillance requirement)

Small Business Governmentwide Goal. 15 U.S.C. § 644(g)(1) (annual goal for prime contracts across Government)

APPENDIX C

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

November 14, 2008

To: Inspector General

From: Chief of Staff, FDA

Subject: Agency Comments to OIG Draft Report Entitled, "Management of Information Technology Contracts at the Food and Drug Administration's Center for Drug Evaluation and Research" OEI-01-07-00450

FDA is providing the attached general comments to the Office of the Inspector General Draft Report entitled, "Management of Information Technology Contracts at the Food and Drug Administration's Center for Drug Evaluation and Research" OEI-01-07-00450.

We appreciate the opportunity to review and comment on this draft correspondence before it is published.

Susan C. Winckler

Susan C. Winckler, R.Ph., Esq.

FDA Comments to Draft OIG Report on
Management of Information Technology Contracts at the Food and Drug Administration's Center for Drug Evaluation and Research

The organizational restructuring of the Office of Information Management (OIM) was officially approved in May of 2008, centralizing information technology (IT) personnel resources and budget that were once distributed throughout the Centers and Offices into one cohesive organization. The organizational change is a part of a larger IT modernization effort to enhance IT infrastructure and to create a robust foundation to enable interoperability across the FDA. As a result, the Office of Information Technology-Center for Drug Evaluation and Research (OIT-CDER) no longer exists and has been restructured into OIM.

Specific Comments in Response to OIG's Recommendations

In its report, OIG made the following recommendations to FDA. The Agency's response is provided under each recommendation:

1. Define information technology (IT) requirements more clearly

FDA should revise its planning processes to define IT requirements in greater detail. This step could lead to additional contracting options and create greater efficiencies in contractor selection and project management as well.

Agency Response

To improve identification and definition of IT requirements more clearly, FDA is implementing formal business process modeling to be used during the Pre-Development Phase of the System Development Life Cycle (SDLC). Incorporating the identification of a business need that requires an information technology solution with the SDLC process as the initial step facilitates coordination of business process with IT requirements. This formal adoption of business process modeling will enhance the Agency's understanding of its current business processes, assist in the analysis of these processes for standardization and efficiencies across the Agency, and enable the Agency to identify and develop an optimum future model. These business requirements are then utilized by the IT project teams as the foundation to identifying system requirements to address the business need that has been identified. This process is critical to ensuring the Centers work collaboratively on harmonizing their processes, which will ultimately enable the Agency to develop enterprise-wide IT systems.

2. Convert ongoing time-and-materials contract actions to fixed-price when appropriate

Converting ongoing time-and-materials contract actions to fixed-price contract actions would reduce the financial risk borne by the Government and may allow FDA to obtain the same services at a reduced cost. Converting time-and-materials contract actions to fixed-price contract actions would also reduce the amount of oversight needed to ensure labor efficiency.

Agency Response

The FDA agrees that it is appropriate for hardware and commercial off-the-shelf software to be procured using fixed-price contracts. When requirements are very solid, a development effort may be a firm fixed-price.

3. Use performance incentive plans when appropriate

Use of performance incentives could allow FDA to reduce contract costs by tying the contractor's profit or award fees to quantifiable performance standards.

Agency Response

The FDA agrees that profit tied to performance is desirable and plans to promote this whenever possible and appropriate in future contract actions.

4. Use documented Quality Assurance (QA) plans

Implementing documented QA plans in its contract actions would allow FDA to create a mechanism for contractor accountability by identifying services that do not meet defined requirements.

Agency Response

FDA agrees. The FDA will use documented QA plans for its development efforts in future contracts.

2

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Christopher Galvin served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Boston regional office who contributed to the report include Melissa Hafner and Rose Lichtenstein; central office staff who contributed include Mark Richardson and Matthew McMullen.