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FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

PROCUREMENT AND SUPPLY MANAGEMENT

PROCUREMENT

FDA COST COMPARISON POLICIES AND PROCEDURES GUIDE

Effective Date: 06/01/2007

1. PURPOSE

This Staff Manual Guide provides specific guidelines for use by FDA staff in fulfilling requirements as set forth under OMB Circular A-76. If any information in this guide conflicts with information contained in OMB Circular A-76, the information in the Circular shall take precedence.

2. POLICY

The following policies and procedures are supplemental to those contained in the May 29, 2003, OMB Circular A-76, Attachments B through D. The format of this guide mirrors that of the Circular so that a reference can easily be made to the OMB policy and to the manner in which FDA has chosen to supplement that direction. Where paragraphs in this guide have been left blank. No Agency policy has been made to supplement that of the OMB Circular. These blank paragraphs were retained to preserve parallel formatting for cross-referencing purposes.

3. RESPONSIBILITIES

The Director of the Office of Management Programs is responsible for implementation and compliance of requirements delineated under OMB Circular A-76.

4. ACRONYMS AND DEFINITIONS

A. Acronyms.

1. PAG Project Advisory Group
2. OAGS Office of Acquisition and Grants Services
3. QAE Quality Assurance Evaluator
4. FDA Food and Drug Administration
5. DHHS Department of Health and Human Services
6. OFM Office of Financial Management
7. MOA Memorandum of Agreement
8. OPDIV Operational Division
9. CMIT Change Management Integration Team

B. Definitions.

5. PUBLIC AND PRIVATE COMPETITIONS

A. Preliminary Planning

1. Scope

a. Policy. FDA will conduct its studies in such a manner so that all occurrences of work meeting a functional description of the scope of the study will be included in the study. The objective of this policy is to make sure that, within a function or service area, all positions will be equally subject to the study and its impact. Also, all commercial contracts falling within the functional definition will be included within the scope of the study.

b. Procedures. The FDA A-76 Steering Committee (Executive Council) will develop and approve the scope of all FDA competitive

sourcing studies. The A-76 Steering Committee will consist of the following voting members:

(1) Voting Members*

(a) Associate Commissioner for Management or the Assistant

(b) Associate Commissioner for Management

(c) Executive Officers from each Center, the Office of Regulatory Affairs, and the Office of the Commissioner (OEO)

(d) Chief, Office of Shared Services

(e) Chief Information Officer

* Designated representatives may vote for their principles if they provide the Chair/Co-Chair with written authorization.

(2) Non-Voting members

(a) NTEU Representatives per the FDA MOU

(b) Program Manager for Competitive Sourcing

The scope of each study will clearly identify the specific organization or the function(s) that will be subject to the study. As this scope statement will be included in the public announcement, the description must be clearly understandable by both public and private parties. It is important to verify the boundaries of—or "business unit"—the function or scope of work under study. Where these boundaries are set and how they are defined is crucial to the organization's ability to efficiently perform the required work regardless of the outcome of the competition. In defining the scope of work, boundaries should be established in such a way that the Offerors are held responsible for a whole product or service and do not share responsibility with FDA

The Executive Officer assigned to a Commercial Activities Study will apply the approved scope of the study to all FDA positions and contracts in determining the number of FTEs and the studied population included within the scope. For larger studies, this responsibility may be accomplished by performing a functional assessment.

2. Grouping.

a. Policy. The FDA will group studied functions and organizations together to form logical business units rather than to meet arbitrary competition goals. This policy typically yields the greatest savings due to economies of scale in developing most effective organizations and also allows the contract administration of possible commercial contracts to be performed efficiently, i.e., administration of a large contract is more efficient than that of a multitude of smaller contracts totaling to the same size. The grouping will be consistent with the best interest of the FDA.

b. Procedures. The Executive Officer will establish a panel of subject matter experts (SME) and contracting officials whose charter will be to develop a recommendation on the best grouping of studied activities. To assist in development of the recommendations, the contracting officials may issue a request for information through the FedBizOpps website to research the manner in which commercial and other governmental organizations have grouped functions similar to those FDA is studying. The A-76 Steering Committee will review and approve the recommendations on the grouping of business units prior to public announcement of the study.

3. Workload Data and Systems

a. Policy. FDA is committed to performance-based service contracting and requires that functions and organizations studied for competitive sourcing have clearly defined output products or services. Each of these outputs must be of a nature where it is possible to determine performance standards to govern the acceptability of the output to FDA customers/users. If the candidate function or organization lacks such outputs and performance standards, the Executive Officer should carefully review the appropriateness of that function for an A-76 study.

The workload data that describes the quantity and character of the outputs must be collectible from reliable, validated and documented sources. To discover any seasonality in the outputs, historical workload data used to establish baseline volumes must cover a minimum of 6 months.

b. Procedures. The Executive Officer from each organization included in the scope of work will designate a representative to an A-76 workload pre-planning group. The group will determine if the key work components of the function or organization are compatible with a performance-based description and, if so, what those outputs and performance standards will be for FDA. The group will

determine if an organization merits having its own performance benchmark separate from that of the other Centers.

Having answered the question of “what” workload data to collect, the workload pre-planning group will establish “how” to collect the data This includes an evaluation of what data systems exist, how information is stored, and, finally, how to obtain and centralize workload data collected from the field units. These issues are resolved in the pre-planning phase in order to streamline the development of the Performance Work Statement (PWS) as much as possible after the study has been publicly announced and the time limit clock has started. As a final step in planning workload data collection, the workload pre-planning group will present PWS data collection methodology to supervisors, subject matter experts, and work leads for validation.

The Contracting Officer will lead the effort to draw information on performance levels from industry sources to assist the workload group in developing FDA’s own benchmark.

4. Baseline Costs

a. Policy. FDA will use COMPARE to develop the baseline cost of the FDA’s current operations. The cost will include all elements that would be included in the Agency Cost Estimate so that FDA will have an “apples to apples” comparison of the cost of the Current Organization to the MEO. This baseline cost will not be used as an Independent Government Estimate since this cost is based on current work methods and staff and not upon a “should” cost version of the function or organization. The Baseline Cost will not be published as part of the public announcement.

b. Procedures. Baseline costs will be developed by the A-76 support contractor or personnel from the Office of Financial Management. The Executive Officer will approve the baseline cost and forward to the A-76 Program Office for the record.

5. Types of Competition

a. Policy. FDA will primarily use standard competitions. Doing so provides the FDA workforce with the time needed to develop a competitive MEO and thus improve its chances of winning the competition. This policy applies to studies that are 65 FTEs or more unless, as a matter of expedience, the A-76 Steering Committee can elect to use the streamlined method which covers competitions

with an aggregate of 65 or fewer FTEs (OMB Circular A-76, Att B, paragraph A.b.).

b. Determine the use of a streamlined or standard competition.

(1) An agency shall use a standard competition if, on the start date, a commercial activity is performed by:

(a) The agency with an aggregate of more than 65 FTEs; or

(b) A private sector or public reimbursable source and the agency tender will include an aggregate of more than 65 FTEs.

(2) An agency shall use either a streamlined or standard competition if, on the start date, a commercial activity is performed by:

(a) The agency with an aggregate of 65 or fewer FTEs and/or any number of military personnel; or

(b) A private sector or public reimbursable source and the agency cost estimate (for a streamlined competition) or the agency tender (for a standard competition) will include an aggregate of 65 or fewer FTEs.

6. Schedule

FDA will allocate as much of the permitted time for the study to developing the MEO as possible. Accordingly, for a 12-month study, the second draft of the PWS will be initially scheduled for release and posted for information purposes on the FedBizOpps website within 3 months of the study start date. The final PWS will be briefed to the PWS Review Subcommittee within 4 months of public announcement. The Office of Acquisition and Grants and the Office of Field Finance & Acquisitions Services (OFFAS) will receive the completed and approved PWS (Section C of the Request for Proposal/Information) no later than 5 months after the start of the study. The solicitation period will typically be scheduled for 30 days. The Source Selection Evaluation Board (SSEB) referred to in the FDA as the Project Advisory Group, and the Source Selection Authority (SSA) will be allocated no less than 90 days from the end date of the schedule to receive and review all proposals and arrive at a performance decision.

7. Roles and Responsibilities of Participants

a. Executive Officer

(1) Each A-76 study will have an Executive Officer or Office of Management (OM) Director who is responsible for managing and coordinating the study with other Centers/Offices that have employees in the study. This person will be designated as the Executive Officer.

(2) The Executive Officer will generally be from the Center/Office that has the most employees in a given A-76 study.

(3) The Executive Officer is responsible for representing other participating Centers/Offices involved and for the timely completion of the study.

(4) The Executive Officer will chair the PWS final review committee.

b. MEO Team Leader

(1) The Agency Tender Officer will designate a MEO team leader and provide the name and contact information to the A-76 Program Office.

(2) The MEO Team Leader ensures that all MEO team members sign the Acknowledgement Letter concerning the Right of First Refusal, and those who want to retain their right are removed from the team at the appropriate time, i.e., may participate in Management Study analysis and make recommendations for the Management Study up to the time that the first draft of the Management Study is delivered to team members for review.

(3) Will coordinate MEO review meetings and encourage participation among team members to review the MEO and provide comments, critiques and/or ideas for increased competitiveness.

(4) A personnel specialist will be assigned by DHHS to each MEO team. The MEO team leader will work with the MEO team members and the personnel specialist to draft new position descriptions arising from the MEO. The assigned personnel specialist will classify the new position descriptions and provide a copy to the A76 support contractor and the MEO team leader.

(5) Works cooperatively with the supporting contractor to review and comment on the MEO.

(6) Assists in obtaining data needed to develop the MEO. Advises the Agency Tender Official of problems in obtaining data from the sponsoring Center and participating Centers/Offices.

c. Transition Team Leader

(1) The transition team leader implements the transition plan for the a-76 study and coordinates all activities required to transition from the in-house organization to the selected service provider either the MEO or a contractor. If the government wins, the transition team leader will be selected from the MEO Team. If the competition is won by an outside bid, the transition team leader will be chosen from the PWS team.

(2) Identifies responsible parties for tasks associated with the transition, such as human resources and facilities.

(3) Establishes the schedule and follows-up on the progress of assigned parties in meeting the schedule.

d. Competitive Sourcing Program Manager

(1) The Competitive Sourcing Program Manager is a full time inherently governmental employee assigned to the Office of Management Programs.

(2) Responsible for overall management and coordination of FDA's A-76 competitive sourcing studies, the Federal Activities Inventory Reform Act (FAIR), and independent audits of A-76 contracts.

(3) Leads staff that serve as the project officers for the A-76 support contract(s).

(4) Coordinates and prepares FDA's annual FAIR Act Inventory of commercial and inherently governmental activities.

(5) Chairs the A-76 Coordination Council.

(6) Prepares HHS reports for the competitive sourcing program:

(a) Annual competitive sourcing plan.

(b) Quarterly competitive sourcing reports.

(c) President's management scorecard competitive sourcing report.

(d) Ad hoc reports for A-76 studies.

(7) Represents FDA at HHS competitive sourcing and FAIR Act meetings and participates on the HHS competitive sourcing workgroup.

(8) Coordinates and participates in FDA competitive sourcing human resource workgroups.

(9) Coordinates A-76 study schedules between human resources, contracts, the contractor, the Executive Officer, and the Agency Tender Official.

(10) Serves on final PWS and MEO reviews within firewall limits.

(11) Answers questions from FDA employees, managers, and supervisors.

(12) Provides information to the Union related to the competitive inquires for the Commissioner and other FDA executives.

(13) Assists the FDA labor relations office. Prepares written responses to labor relations' officers in negotiation memoranda of understanding with Union regarding the competitive sourcing program.

(14) In conjunction with the A-76 support contract, provides A-76 and FAIR Act training and technical guidance.

(15) Chairs FDA's FAIR Act coordinator's workgroup.

(16) Writes responses to FAIR Act questions and challenges from the OMB, HHS, and the public on behalf of FDA.

(17) Provides management oversight and content for FDA's A-76 web site.

(18) Liaisons between HHS OPDIVs and other federal agencies on matters relating to the competitive sourcing program and the FAIR Act.

(19)Writes polices and procedures for FDA's competitive sourcing program.

(20)Leads competitive sourcing planning activities. Prepares recommendations for the A-76 Steering Committee and facilitates selection of activities to study.

e. A-76 Support Contractor.

(1) Performs and documents the overall A-76 study, including data analysis and collection for the PWS and the Management Study, which consists of the MEO, the technical performance plan and the in-house cost estimate. Provides draft source selection plan, and sections L, M and J of the solicitation to the contracting office. Provides technical advice and training for the study. Provides documents for the independent review.

(2) Each PWS and MEO team has a separate supporting contractor to maintain firewalls. An on-site supporting contractor manages and coordinates the activities of all supporting contractor staff and provides technical assistance to the project officer and the various A-76 committees.

8. PWS and MEO Review Subcommittees.

a. PWS Review Subcommittee

(1) This subcommittee is typically composed of five members of the Management Operations Council (MOC). The members are chosen so that Centers and staff divisions are evenly represented in reviewing the scope and performance standards of the final performance work statement (PWS). Thus, each major FDA organization can, through the review process, ensure the PWS meets its functional requirements.

(2) The PWS Review Subcommittee decides whether to accept/amend/reject the PWS by a majority vote. Designated members of the Subcommittee are not allowed to have an alternate stand in for them, and there must be a quorum of members present for a vote to be valid. A quorum is defined by at least fifty percent of committee membership. The Subcommittee must provide the PWS team with their approval before the PWS is posted on FedBizOpps for formal solicitation. The Review Subcommittee signifies its approval of the PWS by the Chair of the Subcommittee executing a memorandum of

need and providing the memorandum to the Contracting Officer as part of the contract file.

b. MEO Review Subcommittee

(1) This Subcommittee is typically composed of five members of the Management Operations Council (MOC). The members are chosen so that Centers and staff divisions are evenly represented in accepting the innovations and cost efficiencies that underlie the Most Efficient Organization (MEO) proposed for competition.

(2) The MEO Review Subcommittee decides whether to accept/amend/reject the MEO by a majority vote. Designated members of the subcommittee are not allowed to have an alternate stand in for them, and there must be a quorum of members present for a vote to be valid. A quorum is defined by at least fifty percent of committee membership. The subcommittee must provide the Agency Tender Official (ATO) with their approval before the MEO is submitted to the Contracting Officer as the final FDA technical and cost proposal for the competition.

9. Competition Officials.

a. Competition Sourcing Official (CSO)

(1) A Department level inherently governmental agency officer responsible for the implementation of the OMB Circular A-76.

(2) The CSO shall appoint competition officials for each standard competition, and, as appropriate, may appoint competition officials for streamlined competitions. The CSO shall appoint all competition officials, in writing, and shall hold these competition officials accountable for the timely and proper conduct of streamlined or standard competitions through the use of annual performance evaluations.

b. Agency Tender Official (ATO)

(1) The Associate Commissioner of Management will recommend FDA's ATO and forward the request for appointment to the DHHS CSO.

(2) The ATO will provide direction for and oversight of the MEO Team Leader on a recurring and regular basis.

c. Contracting Officer (CO)

(1) The Director of the Office of Acquisition and Grants Services OAGS) will appoint the Contracting Officer for each study. In turn, the DHHS Competitive Sourcing Official will appoint the approved Contracting Officer.

(2) The Contracting Officer is responsible for the pre-solicitation, solicitation, and source selection for the A-76 studies and for making all public announcements. The Contracting Officer is responsible for awarding the contract if the performance decision results in the selection of a contractor.

(3) The Contracting Officer will review the draft source selection plan provided by the MEO support contractor and develop the final source selection plan.

(4) Once the Contracting Officer receives the PWS, the quality assurance surveillance plan and the draft Sections L – Instructions, Conditions and Notices for Offerors, M –Evaluation Factor for Award, and J – Attachments, from the MEO support contractor, he/she is responsible for preparing the final solicitation.

(5) The Contracting Officer prepares the solicitation and works cooperatively with the PWS team leader to make revisions to the PWS, and sections L, M, and J of the solicitation as needed.

(6) The Contracting Officer will work cooperatively with the transition team coordinator.

(7) In addition to normal monitoring of commercial contracts, the assigned Contracting Officer will also be the official to issue letters of obligation to MEOs/Contractor for successive periods of performance.

d. PWS (Performance Work Statement) Team Leader

(1) The Executive Officer will identify a PWS team leader and provide the name and contact information to the competitive sourcing program manager.

(2) The PWS team leader forms and leads the PWS team with the assistance of the support contractor PWS analyst. Coordinates the team membership with other Centers/Offices participating in

the study and the Union's designated representative. Identifies the team members and provides the names and contact information in timely manner to the PWS supporting contractor, and the competitive sourcing program manager.

(3) Ensures that all PWS team members sign the Acknowledgement Letter concerning the Right of First Refusal, and those who want to retain their right are removed from the team at the appropriate time, i.e., after review and approval of the second draft of the PWS.

(4) Works cooperatively with the supporting contractor to coordinate PWS review meetings and encourage participation among team members.

(5) Works cooperatively with the FDA Contracting Officer to revise the PWS, and to write the evaluation criteria and instructions to Offerors for the solicitation document.

(6) Works cooperatively with the Contracting Officer to answer technical questions about the PWS during the solicitation phase.

(7) Assists the supporting contractor in obtaining data needed to develop the PWS. Advises Executive Officer of problems in obtaining data.

e. Human Resource Advisor (HRA)

The Department of Health and Human Services will identify personnel specialists to participate on each FDA competitive sourcing study. The requirements will be on two types. The first is to shepherd the directly affected workforce through the entire A-76 process, from announcement to full implementation of the performance decision. The responsibilities are primarily in the area of Employee and Labor Relations. The other set of human resources responsibilities are to support the ATO and the MEO team in developing the Agency Tender, classifying and writing MEO position descriptions and transition planning. The personnel specialist will provide guidance on MEO staffing recommendations, assist in writing new position descriptions, and will classify new position descriptions. The personnel specialist will provide existing position descriptions to the MEO support contractor for the employees in the A-76 study.

f. Source Selection Authority (SSA) The SSA shall

(1) be an inherently governmental agency official appointed in accordance with FAR Part 15.303

(2) comply with both the FAR and this circular when performing a streamlined and standard competition

(3) be independent of the ATO, HRA, and MEO team.

The SSA shall not appoint an SSEB until after public announcement. In cases where the Executive Officer wants a stronger role for functional representatives in Source Selection, a subject matter expert at a senior management level may be designated as the SSA. In all cases, the Executive Officer will form the Source Selection Evaluation Board (SSEB) referred to in the FDA as the Program Advisory Group (PAG) to provide a recommendation to the SSA on which commercial source would yield the best value to the FDA. Directly affected government personnel, their representatives, and any individual having knowledge of the Agency tender shall not participate on the PAG.

10. Incumbent Service Providers.

These are the FDA and contractor personnel currently performing the work to be studied. All FDA personnel will receive a notification letter at least 10 working days prior to public announcement of the study. The letter will inform each person of the fact that they will be subject to the study and what options are available to them should their position be retained by FDA or deleted in lieu of a commercial contractor position. The letter will include the date of the public announcement of the study and provide the contact information of points of contact for questions on the impact and process of the study.

11. Public Announcement

a. Start Date (Public Announcement Date). Public announcement of the study will not be made until all directly affected personnel and the managers and supervisors in their chain of command have been given prior internal announcement. The Contracting Officer will post the announcement as provided by the A-76 Competitive Sourcing Office. The Executive Officer will determine the date on which pre-planning is complete and the study is ready for public announcement and official start.

b. End Date (Performance Decision Date). The Contracting Officer and the SSA will jointly confirm the results of the competition as contained on the Standard Competition Form (SCF) or Streamlined Competition Form (SLCF). The resulting performance decision will be communicated to the Associate Commissioner of Management and the Executive Officer prior to its public release.

12. Streamlined Public Competition Procedures

a. Streamlined Competition Form

(1) Cost of Agency Performance

(2) Cost of Private Sector/Public Reimbursable Performance

(3) Adjusted Cost Estimate

(4) Cost Estimate Firewalls

b. Time Limit Refer to **OMB Circular A-76**

c. Performance Decision in Streamlined Competition

(1) SLCF Certification

(2) SCLF Review

(3) Public Announcement

(4) Implementing the Performance Decision

13. Standard Competition Procedures

a. Time Limit.

The FDA will use the maximum amount of time allowed to complete the competition, typically 12 months from the date of public announcement. This gives the MEO team the maximum amount of time to build a competitive MEO. As long as OMB and DHHS expect all studies scheduled for a fiscal year to be accomplished by the end of that same fiscal year, then the start date for the study must be on or about the first week in October of the fiscal year. Thus, all preliminary planning must be accomplished in the fiscal year prior to the year of the study. Example: for FY04, the studies must be completed by September 30, 2005, to get credit for timely execution of the study. Given a 12-month study, the study must

start no later than October 1, 2004. This means that all preliminary planning must be accomplished prior to October 1, 2004.

b. Team Designations, Responsibilities, and Restrictions.

(1) Performance Work Statement (PWS) Team

The workload data and systems preliminary planning team will reconstitute itself as the PWS team once the study is officially started. PWS team members will be selected by the Executive Officers of each Center directly affected by the study. Each Executive Officer will select two employees from his or her Center to represent the Center as a member of the PWS team: one person who is a subject matter expert and is also a directly affected employee. The other representative is outside the study and occupies a managerial position at least one level higher than that of the subject matter expert.

The Union will have the option of designating a Union representative from the list of names of PWS team members selected by the Executive Officers or selecting someone of their own choosing and having him or her also serve on the PWS team. The Union representative will serve on the team as in a manner agreed to by both FDA and Union.

Within a week after the first PWS team meeting, all members will have signed a PWS Team Member Acknowledgement Form and returned it to the PWS team leader. The form acknowledges that the PWS team member is aware that participation on the PWS team beyond a certain point would jeopardize his or her right of first refusal of employment with a commercial service provider (contractor).

(2) Most Efficient Organization (MEO) Team

Executive Officers of each Center directly affected by the study will nominate two representatives from its Center to serve on the MEO team. In the same manner as the for the PWS team, one person will be a subject matter expert and is also a directly affected employee. The other representative is outside the study and occupies a managerial position at least one level higher than that of the subject matter expert. Since the Agency Tender Official (ATO) is accountable to DHHS Competitive Sourcing Official for development of the MEO, the ATO will select the MEO team from among those nominated by the Executive Officers. If the ATO does not select one of the nominees, the

Executive Officer has the option of nominating a replacement representative.

The DHHS official responsible for FDA human resources management will select the Human Resources Advisor(s) (HRA) to serve on the MEO team. If the HRA is not supporting the MEO team according to the responsibilities outlined in the OMB Circular A-76, the ATO may request that the DHHS selecting official replace the HRA.

The Union will have the option of designating a Union representative from the list of names of MEO team members selected by the Executive Officers or selecting someone of their own choosing and having him or her also serve on the MEO team. Additionally, the Union has the option of forming its own "shadow" MEO team according to the Memorandum of Agreement (MOA). This adjunct MEO team must make its input into the official MEO team no later than the start of the review of the second draft of the Management Study. To make sure the appearance of a conflict of interest does not occur, members of the Union "shadow" MEO team cannot serve on the official PWS team for the same study.

Within a week after the first MEO team meeting, all members will have signed a MEO Team Member Acknowledgement Form and returned it to the MEO team leader. The form acknowledges that the MEO team member is aware that participation on the MEO team beyond a certain point would jeopardize his or her right of first refusal of employment with a commercial service provider (contractor).

(3) Source Selection Evaluation Board (SSEB)

After public announcement of a standard competition that will be a negotiated procurement, the SSA shall appoint an evaluation team (referred to as the SSEB) in accordance FAR Subpart 15.303. The SSA shall ensure that the SSEB complies with the source selection requirements of the FAR and this attachment. PWS team members who are not directly affected government personnel may participate on the SSEB. Directly affected personnel (and their representatives) and any individual (including, but not limited to, the ATO, HRA, MEO team members, advisors, and supporting contractors) with knowledge of the Agency tender (including the MEO and Agency cost estimate) shall not participate in any manner on the SSEB (e.g., as members or advisors).

c. The Solicitation and Quality Assurance Surveillance Plan

(1) Solicitation

(a) Review and Release of Information. The PWS team will give electronic copies of the first, second, and final drafts of the PWS and the solicitation to the Contracting Officer as they are delivered by the PWS team for FDA review. The Contracting Officer, in turn, will post these documents on the FedBizOpps website for public comments and suggestions. The Contracting Officer will provide the PWS team leader with copies of all communication received from all the respondents. The PWS team will give due consideration to all inputs thus received in order to attract potential qualified Offerors to join the competition.

(b) FAR Provisions. Solicitations issued for Competitive Sourcing studies must include the individual and corporate Conflict of Interest and Non-Disclosure of Public Information clauses due the regulatory nature of the FDA.

(c) Acquisition Processes and Source Selection Provisions. In order to stimulate creative proposals from bidders, FDA will, as a general rule, use the negotiated procedures in its source selection process. Until the use of tradeoff is expanded, FDA will use the phased evaluation process. Use of the process may result in issuing an amended solicitation with the concomitant effect of extending the total source selection process by two to four weeks. An allowance for this occurrence must be built into the study schedule so the performance decision is announced within the allotted timeframe.

(d) Solicitation Provisions Unique to the Agency Tender.

i. Solicitation Closing Date. **Refer to OMB Circular A-76**

ii. Compliance Matrix. **Refer to OMB Circular A-76**

iii. Performance Period. FDA solicitation will typically be for five years: one base year and four option years. Since the maximum allowable time for a service contract is five years, the five-year performance period for the A-76 solicitation includes any and all time allowed for phase-in.

iv. Government-Furnished Property (GFP). As a matter of policy, FDA will provide the service provider with all facilities and major equipment items (acquisition cost greater than $5000) necessary to perform the PWS as long as those facilities and equipment items do not have an efficient and effective alternate use for another FDA mission element.

v. Common Costs. **Refer to OMB Circular A-76**

vi. Performance Bond. **Refer to OMB Circular A-76**

vii. Incentive Fee. **Refer to OMB Circular A-76**

viii. Award Fee. **Refer to OMB Circular A-76**

ix. Phase-in Plan. The activities detailed in the FDA's Phase-In Plan will be only those that occur within the 30 to 90 days of the phase-in period listed in Section B of the RFP. Activities completed prior to the phase-in period are not included in the plan and or in the Agency Cost Estimate. These excluded activities will be addressed in the FDA's Transition Plan.

x. Quality Control Plan. The FDA's tender must include a Quality Control Plan that conforms to the specifications of the solicitation. Where appropriate, parts of the Quality Assurance Surveillance Plan (QASP) may be used in structuring and developing the Quality Control Plan.

(2) Quality Assurance Surveillance Plan (QASP).

The Quality Assurance Evaluators (QAEs) assigned to monitor service provider performance will complete the recurring evaluation reports described in the QASP. The QAEs will submit these reports to the A-76 Program Officer for FDA MEO performance and to the assigned Contract Specialist for evaluations of commercial contractors. These evaluations will be part of the competition file as used in the exercise of performance period options.

(3) Competition File.

The A-76 Program Office will be the office of record for all A-76 competition documentation. The A-76 Program Office will provide the Office of Acquisition and Grants Services (OAGS)

with a complete copy of the competition file for incorporation in the Government Contract File maintained separately by OAGS.

(4) The Agency Tender, Private Sector Offers, and Public Reimbursable Tenders

(a) Agency Tender.

i. Developing the Agency Tender. The MEO Team will develop the Agency Tender under the leadership of the MEO Team Leader. The MEO Team members will observe the “firewall” between themselves and the members of the PWS team and may obtain copies of the PWS only from public sources such as FedBizOpps. The Agency Tender Official (ATO) will provide executive level direction, guidance, review, and approval of the Agency Tender documents as they mature from draft to final. The ATO and the MEO team will present the Agency Tender to the FDA Executive Officers from each Center affected by the study for coordination in order to attest that the FDA, as an agency, approves of the MEO solution to the workload and performance requirements of the solicitation.

ii. Most Efficient Organization (MEO) **Refer to OMB Circular A-76**

iii. Agency Cost Estimate. The Agency Cost Estimate will be coordinated with the Office of Financial Management prior to being incorporated into the Agency Tender and briefed to the FDA Executives as part of the final approval process for the Agency Tender.

iv. Quality Control Plan. The Quality Control Plan will be coordinated with the A-76 Program Office prior to being incorporated into the Agency Tender and briefed to the FDA Executives.

v. Phase-in Plan **Refer to OMB Circular A-76**

vi. Submission of the Agency Tender. The sealed Agency Tender will not be submitted to the Contracting Officer until the designated FDA executives concur with both the technical and business elements of the proposal. The ATO has the responsibility to submit the Agency Tender on or before the solicitation closing date.

vii. Changes to the Agency Tender. If the Agency Tender is changed in such a manner that forces a change in the Agency Cost Estimate, the ATO must re-coordinate the revised Agency Tender with the FDA Executives.

viii. Procurement Sensitivity.

(b) Private Sector Offer.

(c) Public Reimbursable Tenders.

(d) No Satisfactory Private Sector or Public Reimbursable Source. The Source Selection Authority, with the technical assistance of the SSEB, or Program Advisory Group, will make the determination of technical responsibility. The Contracting Officer will make the determination of the responsiveness of the offers and tenders.

(5) The Source Selection Process and Performance Decision.

The FDA has maintained a commitment to using the Competitive Sourcing Program as an opportunity to bring innovation into the commercial activities of the Agency. Consequently, FDA will use negotiated acquisition procedures for all standard competitions. FDA recognizes that there may be some functions that do not lend themselves to negotiated selection procedures. The assigned Contracting Officer will conduct price analysis and cost realism as required by OMB Circular A-76 and shall enter the contract price and public reimbursable cost estimate, for each offer and tender determined to be technically acceptable, on Line 7 of the Standard Competition Form (SCF) and will sign the SCF.

(a) Sealed Bid Acquisition. Refer to OMB Circular A-76

(b) Negotiated Acquisition. Refer to OMB Circular A-76

(c) Special Considerations.

i. Price Analysis and Cost Realism of Private Sector Cost Proposals, Public Reimbursable Cost Estimates and Agency Cost Estimates. An Independent Government Cost Estimate will be made available to the CO to assist in performing price analysis and cost realism as part of the source selection process. This estimate is typically

prepared by the A-76 support contractor to maintain independency. The support contractor will maintain a firewall between the cost team and the MEO support team.

(6) Performance Decision in a Standard Competition

(a) Certification. Refer to OMB Circular A-76

(b) End Date. Refer to OMB Circular A-76

(c) Public Announcement of the Performance Decision. The CO will provide information required by FAR 15.503(b) to the A-76 Program Officer. The Competitive Sourcing Program Manager will, in turn, notify the Associate Commissioner for Management and the functional Executive Officer. The Executive Officer will, in turn, notify all affected employees of the outcome of the competition. The Executive Officer will tell the A-76 Program Officer when all affected employees have been properly notified so the Project Officer can direct public announcement via FedBizOpps.

(d) Debriefing. The FDA will debrief all directly affected personnel and their representatives prior to or at the same time as other Offerors are debriefed. Under no circumstances will the other Offerors be debriefed before the FDA's own employees.

(e) Release of the Certified SCF and Tender. Refer to OMB Circular A-76

(f) Implementing the Performance Decision.

i. Private Sector Provider.

ii. Public Reimbursable Provider.

iii. Agency Provider. If the results of the Quality Assurance Surveillance Plan evaluations so indicate, the Office of Acquisitions and Grant Services (OAGS), or the CO will issue the MEO letter of obligation to the Project Manager of the FDA MEO. The letter of obligation will be in accordance with the DHHS template.

14. Post-competition Accountability for Streamlined and Standard Competitions

a. Best Practices and Lessons Learned. The FDA Competitive Sourcing website will have a link on the Shared A-76 website. The website will contain accurate and current information in regards to the FDA's A-76 program results and status.

b. Execution Tracking of Streamlined and Standard Competitions

c. Competitive Sourcing Quarterly Report

d. Monitoring Performance. Quality Assurance Evaluators (QAEs), either full or part time will be assigned to monitor each service provider chosen under A-76 competitions. The QAEs will implement the Quality Assurance Surveillance Plan and provide evaluations to the functional Project Officer, the A-76 Program Office, and the authorized Contracting Specialist.

e. The A-76 Program Office will maintain the competition file while the CO will maintain the contract file of private sector service providers.

f. The A-76 Program Office will determine the actual cost of performance for each performance period for all competed functions and will compare these actual costs against the costs on the SLCF or the SCF for the corresponding performance period.

g. Option Years of Performance and Follow-on Competition. The CO will coordinate all option year exercise determinations with the A-76 Program Office.

h. Termination. For MEOs, the A-76 Program Office will determine when performance is so poor that cure notices or show cause notices are warranted. The A-76 Program Office will forward the list of discrepancies in the performance of the MEO to the cognizant Contracting Officer. If, after any remedy period has expired, the Office or Acquisition and Grants Services and the A-76 Program Office both agree that the continuation of poor performance warrants termination for default, the Office or Acquisition and Grants Services will issue a notice of termination, consistent with FAR Part 49. The activity is then scheduled for an immediate follow-up recompetition.

15. Contests.

a. Standard Competitions. A directly interested party may contest any of the following actions taken in connection with a standard competition:

(1) a solicitation;

(2) the cancellation of a solicitation;

(3) a determination to exclude a tender or offer from a standard competition;

(4) a performance decision, including, but not limited to, compliance with the costing provisions of this circular and other elements in an agency's evaluation of offers and tenders; or

(5) a termination or cancellation of a contract or letter of obligation if the challenge contains an allegation that the termination or cancellation is based in whole or in part on improprieties concerning the performance decision. The pursuit of a contest by a directly interested party and the resolution of such contest by the FDA shall be governed by the procedures of FAR Subpart 33.103.

b. Streamlined Competitions. No party may contest any aspect of a streamlined competition.

6. CALCULATING PUBLIC-PRIVATE COMPETITION COSTS

A. Overview

FDA will calculate public-private competition costs in strict conformity with the directions and policies contained in OMB Circular A-76. At this time, there are no supplemental policies to include in this Guide.

B. Cost of Agency Performance (SCF/SLCF Lines 1-6)/Cost of Public Reimbursable Performance (SCF/SLCF Lines 1a-6a)

C. Adjustable Cost of Private Sector or Public Reimbursable Performance (SCF/SLCF Lines 7-13)

D. Conversion Differential (SCF/SLCF Line 14)

E. Adjusted Total Cost of Agency Performance (SCF/SLCF Line 15)

F. Adjusted Total Cost of Private Sector or Public Reimbursable Performance (SCF/SLCF Line 16)

G. The Cost Difference (SCF/SLCF Line 17)

H. Low-Cost Provider (SCF/SLCF Line 18)

7. EFFECTIVE DATE

The effective date of this guide is June 1, 2007.

8. Document History -- SMG 2610.13, FDA Cost Comparison Policies and Procedures Guide

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Initial	06/26/2007	N/a	OC/OO/ OM/OMP	Irene Diehl, Director, OMP