

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

PROCUREMENT AND SUPPLY MANAGEMENT

PROCUREMENT

REQUEST FOR CONTRACT FOR ACTIONS LESS THAN OR EQUAL TO THE
SIMPLIFIED ACQUISITION THRESHOLD

Effective Date: August 11, 2017

Changed: September 12, 2019

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1. PURPOSE

Beginning with Fiscal Year 2018 (FY18) actions, this guide sets forth the FDA policy and procedures for completion, approval, and submittal of a Request for Contract (RFC) for actions with an estimated value (inclusive of all options) greater than the Micro-Purchase Threshold (MPT) and less than or equal to the Simplified Acquisition Threshold (SAT). The RFC, at a minimum, is comprised of: a Requisition document which cites type and amount of available funds to support a given action; clear identification of the overarching and previously approved Acquisition Strategy (AS); and, a **Stream-lined Acquisition Plan**, to include a Severability & Funding Determination and all other requisite attachments. This guide satisfies applicable *Federal Acquisition Regulation (FAR) Part 7 - Acquisition Planning requirements and implements Department of Health and Human Services*

¹ To access the Attachments 1, 2, and 3, please see the "Attachments" in the left window panel of the browser. The SMG Attachments are available via Microsoft Internet Explorer and Firefox Browsers only.

(HHS) Acquisition Alert 2015-01: New Acquisition Guides and Templates, dated March 26, 2015.

NOTE: This Guide does not address modification actions to pre-existing awards. For guidance and assistance executing award modifications, Program Personnel should contact the Office of Acquisitions and Grants Services (OAGS). The assigned OAGS Contracting Officer (CO)/Contract Specialist (CS) will provide all requisite guidance specific to each individual modification action.

2. DEFINITIONS

Preliminary Disclosure: *As a general rule, and unless indicated otherwise below, the FDA incorporates by reference, the definitions of words and terms adopted by HHS Policy and the FAR. Because HHS Policy may supplement the FAR and FDA Policy may further supplement HHS Policy, there may be some instances in which the definitions of words and terms may be more narrowly construed so as to accurately reflect the acquisition function at the Department or FDA levels. In those instances, FDA Policy shall take precedence over HHS Policy and HHS Policy shall take precedence over the FAR.*

- A. Acquisition Planning: The process by which the efforts of all personnel responsible for an acquisition are coordinated and integrated through a comprehensive plan for fulfilling an agency need in a timely manner and at a reasonable cost. It includes developing the overall strategy for managing the acquisition.
- B. Acquisition Strategy (AS): A top-level description of an agency program or project to procure the necessary resources to satisfy an agency need. It provides sufficient detail to allow senior leadership and other decision makers to assess whether the strategy makes good business sense. An AS is meant to effectively implement laws and policies, and accurately reflect management's priorities. An individual AS typically serves as the foundation for the development of multiple Acquisition Plans supporting a specific program/project.
- C. Advance Acquisition Plan (AAP): An acquisition planning and tracking tool that identifies all FDA anticipated acquisition actions over \$25,000 (inclusive of all options) for a given fiscal year. The AAP is captured in the Integrated Budget and Acquisition Planning System (IBAPS). It is a compilation of all individually submitted FDA Center acquisition planning items that is regularly updated to capture changes on an ongoing basis. The AAP must provide a sufficiently clear and detailed description of each requirement (e.g., planned contract with any options, modification, delivery order, task order, purchase order, grant, interagency agreement) having an estimated value anticipated to exceed \$25,000 (inclusive of all options).

Upon creation of an AAP item in IBAPS, a Center Item Number is generated to uniquely identify each requirement on the plan.

- D. Contracting Officer (CO): An acquisition professional residing within OAGS who has the authority to enter into, administer, and/or terminate contracts and make related determinations and findings.
- E. Contracting Officer's Representative (COR): An acquisition workforce member residing within a Program Center/Office designated and authorized in writing by the Contracting Officer to perform specific technical or administrative functions for a specific contract. A COR does not have authority to bind the Government by signing a contract or otherwise entering into a contractual arrangement.
- F. Contract Specialist (CS): An acquisition professional residing within OAGS who has the authority to negotiate, administer, and close-out contracts, subject to the review and approval of the Contracting Officer. The CS advises the COR and serves as the primary Point of Contact throughout the acquisition process.
- G. Integrated Budget and Acquisition Planning System (IBAPS): A suite of applications that support budget formulation, budget execution, acquisition planning (to include the AAP), and payroll planning.
- H. iProcurement: One component of the HHS Unified Financial Management System (UFMS) that is managed by the Office of Financial Management at the FDA. iProcurement is a web-based application where FDA requisitions are entered, approved, and tracked on a real time basis. Designated Requestors/Requisitioners identify the appropriate funding information (Common Account Number 'CAN' and Object Class) for each line item when entering requisitions into iProcurement. The requisition is then routed through predefined approval chains that may be modified, as needed. Upon final approval, the iProcurement requisition creates a commitment record within UFMS.
- I. Micro-Purchase Threshold (MPT): The threshold dollar amount, under which competition and formal contracting procedures are generally more relaxed. See *FAR 2.101* for the current threshold dollar amount and applicable exceptions. The Government Purchase Card is the preferred method of payment to execute new purchase transactions under the MPT. For guidance and assistance on the proper use and limitations of the FDA's Government Purchase Card Program, please see *Staff Manual Guide 2610.5*.
- J. Non-severable Performance Requirements: Performance requirements that comprise an entire or nonrecurring undertaking that cannot be

feasibly subdivided. They typically contemplate a specific outcome, product, or report. The agency does not receive the full value of a non-severable performance requirement until performance is fully completed. Full performance must have independent value (i.e., its value cannot depend upon the accomplishment of another activity). If full performance provides value only upon additional action, then the performance requirement is not non-severable and may represent only a portion of a non-severable performance requirement.

Non-severable performance requirements must be fully funded at time of award; however, they may take more than 12 months to complete (e.g., a study conducted over eighteen months that culminates in the delivery of a final report). Thus, non-severable performance requirements may not be incrementally funded. See *Incremental Funding of U.S. Fish and Wildlife Service Research Work Orders, B-240264, 1994*.

- K. Program: A group of assets planned and managed together to achieve an overall set of related outcomes. They are directed, funded acquisitions that provide new, improved, or continuing systems or services in response to an approved need. Programs are divided into levels established to facilitate decision-making, execution, and compliance with statutory and regulatory requirements and may be composed of multiple projects, services contracts, interagency agreements, and other types of acquisitions. With a systems or services capability focus, programs usually tie together an agency's higher-level programming and budgeting process with the agency strategic plan.
- L. Program Manager: An acquisition workforce member residing within a Program Center/Office who has the responsibility, and relevant discretionary authority, to make final scope-of-work, capital-investment, and performance acceptability decisions on assigned acquisition programs. The Program Manager is also responsible for meeting program objectives or production requirements through the acquisition of any mix of in-house, contract, or reimbursable support resources. Program Managers are responsible to stakeholders for management and oversight of subordinate projects within the scope of the overall program. The Program Manager is ultimately responsible for effectively managing all business and technical risks of the program to insure effective systems and services are delivered to the end user on schedule, within budget and at the required levels of performance. A Program Manager may also serve as a project manager and in this capacity will perform the responsibilities of the project manager.
- M. Project: An endeavor undertaken to accomplish a unique product or service with a defined start and end point and specific objectives that, when attained, signify completion. Projects are undertaken for development, modernization, enhancement, disposal, or maintenance.

Projects are composed of activities and are planned acquisition undertakings with a definite beginning and clear termination point which produces a defined capability. A project is an individually planned, approved and managed basic building block related to a program.

- N. Project Manager: An acquisition workforce member residing within a Program Center/Office who has responsibility for accomplishing a specifically designated work effort or group of closely related efforts established to achieve stated or designated objectives, defined tasks, or other units of related effort on a schedule, within cost constraints and in support of the program mission or objective. The Project Manager is responsible for the planning, controlling, and reporting of the project, and for the management of required functions, including acquisition strategy and planning, defining requirements, business case development, performance of the schedule, and formulation, justification, and execution of the budget. The Project Manager is responsible for effectively managing project risks to insure effective systems and services are delivered through a total life-cycle approach to the end user on schedule, within budget and at the required levels of performance. A Program Manager may also serve as Project Manager for projects within the scope of the program.
- O. Property Administrator: An FDA program official responsible for – in cooperation with the FDA Accountable Property Management Office – barcoding, recording, tracking, and managing all aspects of Government Furnished Property to be provided to contractor(s) and subcontractor(s) under a contract or other award instrument/agreement.
- P. Severable Performance Requirements: Requirements that can be separated into components that independently meet an ongoing need of the Government. They typically are continuing and recurring in nature. An agency receives the full value of the severable performance requirement every time it is performed (e.g., janitorial or security services).

The use of annual funds for severable performance requirements may cross fiscal years, but may not exceed twelve months. See *Funding of Maintenance Contract Extending Beyond Fiscal Year, B-259274, 1996*. On the other hand, the use of no-year funds (e.g., User Fees) for severable performance requirements, are not subject to the same twelve-month limitation. See *Severable Services Contracts, B-317636, 2009*.

- Q. Simplified Acquisition Threshold (SAT): The threshold dollar amount, under which simplified acquisition procedures are authorized. See *FAR 2.101* for the current threshold dollar amount and applicable exceptions.

- R. Sponsor: The Center/Office having the specific acquisition requirement and responsible for the commitment of funds for the proposed contract.
- S. Stream-lined Acquisition Plan: A plan derived from the Acquisition Strategy which documents all cost, schedule, technical, business, management, and other considerations that will govern a specific acquisition (inclusive of all options) greater than the Micro-Purchase Threshold and less than or equal to the Simplified Acquisition Threshold. It summarizes the acquisition planning discussions and identifies milestones in the acquisition process.
- T. Unified Financial Management System (UFMS): UFMS is an integrated system allowing purchasing functions to flow directly to Accounts Payable and the General Ledger modules.

3. POLICY AND RESPONSIBILITIES

A. PREPARATION OF THE REQUEST FOR CONTRACT (RFC)

The RFC serves as the official request for initiating a contract action in accordance with this guide. It should contain all preliminary documents, approvals, and authorizations for a planned contract action. It should also identify all administration details and provide funding commitment information. Absent a prior agreement to the contrary, a Program Representative must complete and submit a RFC to OAGS via iProcurement to formally initiate a specific contract action.

It is essential that Program Personnel proactively obtain all needed assistance from contributing members of the Greater FDA and HHS Acquisition Communities (e.g., acquisition, budget, finance, human resources, information technology, facilities, security, offices of legal counsel, and program subject matter experts) as early as possible for guidance and assistance in completing all components of the RFC to ensure that Agency needs are met in a timely, efficient, and effective manner.

The RFC includes, at a minimum: a Requisition document which cites type and amount of available funds to support a given action; clear identification of the overarching and previously approved Acquisition Strategy (AS); and, a Stream-lined Acquisition Plan, to include a Severability & Funding Determination and all other requisite attachments and approvals. AS and Stream-lined Acquisition Plan requirements are addressed below in Sections 3.B. and 3.C., respectively.

B. THE ACQUISITION STRATEGY (AS).

1. Use of the HHS AS Template Is Mandatory for all Programs/Projects.

An AS is required for all Programs/Projects (P/Ps) -- irrespective of estimated aggregate value or duration, if it is to be supported by one or more procurements. The AS must be completed using the prescribed HHS Template. The HHS AS Template and instructions for its completion, along with the overarching *Directive for Acquisition Strategy (DFAS)*, are currently available on the HHS/Office of Grants and Acquisition Policy and Accountability (OGAPA) Intranet Site. The current link is available at <http://sharepoint.fda.gov/orgs/OC-OO-OFBA/apob/SitePages/Details.aspx?&cid=129&list=ACQ>.

2. Program Personnel Are Responsible for Completion of the AS.

Program Personnel (ordinarily P/PMs) are responsible for completing the AS prior to the development of milestones to address the critical elements of the Program/Project (P/P). The AS includes information relevant to: management approach, business strategy, risks, technology, resources, requirements roadmap, procurement forecasting, testing, training, milestone schedules, implementation phases, and other logistics support over the entire P/P life cycle.

3. Assistance is Available to Help Program Personnel Complete the AS.

a. Contact OAGS for Help Completing an AS that is < \$20M.

In the event Program Personnel require any guidance or assistance in completing the HHS AS Template for a P/P with an estimated value less than \$20 Million (and not determined to be High Risk in accordance with the HHS DFAS), Program Personnel should contact OAGS at askOAGS@fda.hhs.gov. When e-mailing such requests, Program Personnel shall place in the e-mail subject line, "Request for BMT AS Support for (*insert name of AS Program/Project or other identifier*)."

b. Contact HHS for Help Completing an AS that is > \$20M or High Risk.

In the event Program Personnel require any guidance or assistance in completing the HHS AS Template for a P/P with an estimated value greater than or equal to \$20 Million (or, otherwise determined to be High Risk in accordance with the HHS DFAS), Program Personnel should contact HHS/Office of Grants and Acquisition Policy and Accountability (OGAPA)/Division of Acquisition

(DA)/Office of Acquisition Workforce and Strategic Initiatives
(OAWSI) at OGAPA@hhs.gov.

NOTE: After obtaining any requisite assistance from HHS, Program Personnel will still need to coordinate efforts with OAGS and all other requisite Agency-level signatories to obtain concurrence and approval of each individual AS prior to HHS submittal for final approval. It should be understood that FDA Approving Officials – to include the Head of the Contracting Activity (HCA) – are required to leverage independent experience, knowledge, and business judgment in their official capacities when reviewing an AS prior to approval. That being stated, there may be instances in which some signatories will require that some portions of the AS be enhanced prior to their approval even in those instances in which HHS-level guidance and support has already been provided.

4. HHS-level Approvals Are Required for an AS that is > \$20M or High Risk.

In addition to all Program/Center approvals, if the aggregate total estimated value of the AS is less than \$20 Million (and not otherwise determined to be High Risk in accordance with the HHS DFAS), it will require approval by the FDA/OAGS Head of the Contracting Activity.

And, if the aggregate total estimated value of the AS is greater than or equal to \$20 Million (or, otherwise determined to be High Risk in accordance with the HHS DFAS), it will require HHS-level approvals by the Director, Office of Small and Disadvantaged Business Utilization (OSDBU) and Senior Procurement Executive (SPE). Further, if any IT goods or services will be needed, then additional approval by the HHS Chief Information Officer (CIO) will be required.

Whenever HHS-level approvals are required for an AS, Program Personnel will also need to complete a PowerPoint Presentation. The completed draft PowerPoint shall accompany the AS at time of HHS AS submittal. See Chapter 4 of the HHS DFAS, the AS Template, and the clarifications provided below for a complete list of requirements and approvals.

5. HHS AS Template Signature Block Clarifications.

It should be understood that not all listed signatories on the HHS AS Template reflect mandatory approvals for each and every AS. For example, Division and HHS CIO approvals are only required when IT goods or services will be needed. In those instances where it is clear that a listed approval is not required, marking the signature block as “Not Applicable” is acceptable. It is also important to understand to whom the listed signatories refer at the FDA. For that reason, the

following clarifications are provided for each listed signatory block listed on Pages 3-5 of the HHS AS Template:

a. FDA Signatories

- (1) Program Manager: the cognizant Program or Center Certified P/PM
- (2) Division Chief Information Officer (Division CIO): the FDA CIO (required only if IT goods or services will be needed)
- (3) Division Head or Designee: the cognizant FDA Center/Office Senior Executive
- (4) Division Office of Small and Disadvantaged Business Utilization (OSDBU) Representative: the FDA OSDBU Representative located within OAGS
- (5) Head of Contracting Activity (HCA): the FDA HCA/Director, OAGS

b. HHS Signatories

- (1) Chief Information Officer (CIO): the HHS CIO
(required only if IT goods or services will be needed)
- (2) Director, Office of Small and Disadvantaged Business Utilization (OSDBU) Representative: the HHS OSDBU Director
- (3) Senior Procurement Executive (SPE): the HHS SPE/Associate Deputy Assistant Secretary, Division of Acquisition.

6. AS Review and Approvals Will Impact Standard Procurement Lead Times.

After the AS has been presumed complete, has all other requisite FDA-level approvals, and is ready for formal HCA submittal, Program Personnel shall upload the AS (along with a copy of the AS PowerPoint Presentation, if applicable) to the OAGS Acquisition Strategy SharePoint Site, located at <http://sharepoint.fda.gov/orgs/OC-OO-OFBA/oags/AdvanceAcquisitionPlanning/Acquisition%20Strategy%20Submission/Forms/AllItems.aspx>. Upon posting, the requisite OAGS Officials will automatically be notified that your submittal has been received.

The estimated turnaround time for OAGS to complete AS reviews is no more than 3-7 business days. In the event any changes are required, OAGS will contact the cognizant Program point of contact to provide any feedback and ensure that progress continues to move forward in a linear and timely manner. In the event that HHS-level approval is required (i.e., the AS has an estimated value greater than or equal to \$20M (inclusive of all options), or is otherwise determined to be High Risk), the HCA will forward any HCA-approved AS to HHS on behalf of the cognizant Program/Project point of contact.

HHS has recommended that FDA Officials plan for a 30-calendar-day turnaround time for HHS to complete a comprehensive review of an AS. While the standard time for HHS review and approval is ordinarily expected to take 3-7 business days, there are many factors (e.g., thoroughness and quality of the AS submittal; competing demands) that will impact the duration of such reviews. If HHS determines, upon initial review, that further information is required, or that corrections need be made, HHS will attempt to notify the Program Office point of contact within 3 business days. Should such action be necessary, the cycle will start over again; and, upon receipt of any ensuing resubmittal, HHS will require an additional 3-7 business days to complete a follow-on review.

Once preliminarily approved by the HHS Senior Procurement Executive (SPE), the SPE will schedule a Review Board Panel Meeting (with a Board comprised of Department-wide Executive-level subject matter experts) for the FDA Program Officials to present their AS PowerPoint Presentation. Upon successful completion of the subject presentation, the Board will grant final approval of the AS.

NOTE: No Waivers for HHS AS review and approval will be granted.

Program Personnel are highly encouraged to make every attempt to complete each AS completely and accurately prior to initial submittal for review and approval by required signatories (including, but not limited to those at HHS), well in advance of applicable standard procurement lead times for individual contract actions.

7. Major Revisions to an Approved AS May Result in Further Delays.

Each AS must be updated whenever there is a change to the approved strategy or as the approach and P/P elements are better defined. Major revisions to the AS shall be approved at the original approval levels. Once approved, the AS provides a basis for more detailed planning, to include the development, review and approval of individual

Acquisition Plans for new procurements anticipated to support program initiatives and activities within scope of the overarching AS.

C. THE STREAM-LINED ACQUISITION PLAN.

1. Use of the FDA Stream-lined Acquisition Plan Template Is Mandatory > MPT and < SAT.

A Stream-lined Acquisition Plan is required for all procurements with an estimated value (inclusive of all options) greater than the Micro-Purchase Threshold (MPT) and less than or equal to the Simplified Acquisition Threshold (SAT). The Stream-lined Acquisition Plan must be completed using the FDA Stream-lined Acquisition Plan Template, provided herein as Attachment 3.C.(1). The FDA Stream-lined Acquisition Plan Template is also available for download on the OAGS SharePoint Site, located at <http://sharepoint.fda.gov/orgs/OC-OO-OFBA/apob/Pages/OAGS-Active-Forms-and-Templates.aspx>.

a. Various IGCE formats are generally acceptable.

An Independent Government Cost Estimate (IGCE) is required for all contract actions with an estimated value greater than \$25,000 which require a Statement of Work (SOW) or Performance Work Statement (PWS); and, any other contract action, as determined by the Contracting Officer. See Section I.J. of the Stream-lined Acquisition Plan. Most any Independent Government Cost Estimate (IGCE) format is generally acceptable (to the extent that all estimated cost factors are completely addressed, documented, and supported). That being stated, pre-vetted IGCE templates are available for download on the OAGS SharePoint Site, located at <http://sharepoint.fda.gov/orgs/OC-OO-OFBA/apob/Pages/OAGS-Active-Forms-and-Templates.aspx>.

2. Program Personnel Are Responsible for Completion of the Stream-lined Acquisition Plan.

Program Personnel are responsible for completing the Stream-lined Acquisition Plan with input from the entire acquisition team. Every Stream-lined Acquisition Plan must relate back to and fall under an approved AS. Acquisition planning should ordinarily begin as soon as the AS is approved, preferably in advance of the fiscal year in which contract award or order placement is necessary. The Stream-lined Acquisition Plan should address the technical, business, management, and other significant considerations that will affect the acquisition lifecycle. The specific content of each plan will vary depending on the nature, circumstances, and complexity of the action.

3. Program Personnel Are to Contact OAGS to Obtain any Requisite Assistance.

Program Personnel are highly encouraged to seek OAGS assistance as early as possible during the acquisition planning process to obtain any requisite guidance or assistance in completing the Stream-lined Acquisition Plan to foster the successful execution of all actions in a timely, effective, and efficient manner. In order to request any such assistance, Program Personnel shall contact the OAGS Division Director with cognizance or purview over their specific acquisition. In the event Program Personnel do not know which OAGS Division Director to contact, Program Personnel shall send an e-mail request for assistance to askOAGS@fda.hhs.gov with "Request for Stream-lined Acquisition Plan Assistance for (insert name of the requirement or other identifier)" in the subject line.

4. Stream-lined Acquisition Plan Review and Approvals May Impact Standard Procurement Lead Times.

All Stream-lined Acquisition Plans require review and approval by the cognizant OAGS Contracting Officer responsible for executing the prospective contract action. Delays are to be expected in the event significant changes or improvements to an initial draft Stream-lined Acquisition Plan are required. For that reason, Program Personnel are highly encouraged to make every attempt to complete each Stream-lined Acquisition Plan completely and accurately prior to submittal, well in advance of applicable standard procurement lead times for individual contract actions.

NOTE: The Stream-lined Acquisition Plan does not ordinarily require any HHS-level approvals.

5. Major Revisions to an Approved Stream-lined Acquisition Plan May Result in Further Delays.

Each Stream-lined Acquisition Plan should be updated whenever there is a change to the approved plan. Major revisions to the Stream-lined Acquisition Plan shall be approved at the original approval levels. Once approved, the Stream-lined Acquisition Plan provides a basis to begin the development and eventual release of a solicitation for new procurements.

6. A Severability & Funding Determination Is Always Required.

The way in which a performance requirement is categorized (i.e., Severable or Non-Severable) is highly determinative of the way in which the corresponding award must be funded. Awards that are not properly funded may violate the Anti-Deficiency Act and result in serious repercussions for the FDA, as well as the individual employees who are held responsible. For that reason, a Determination – using the *Severability & Funding Determination Template* found at RFC Checklist Attachment 3.C.(2) – is always required.

4. REFERENCES

FDA Plan to Increase Access to Results of FDA-Funded Scientific Research, February 2015

FDA Staff Manual Guide 1440.1, December 24, 2009

FDA Staff Manual Guide 2610.1, revised February 2017

Federal Acquisition Regulation Parts 2; 3; 6; 7; 8; 9; 11; 22; 23; 27; 37; 45

Funding of Maintenance Contract Extending Beyond Fiscal Year, B-259274, 1996

HHS APM 2011-02, HHS' Prospective Service Acquisition Reviews, June 3, 2011

HHS APM 2011-03, Project Labor Agreements, July 25, 2011

HHS APM 2011-04, Appropriations Law Compliance Reviews, October 6, 2011

HHS APM 2011-05, Sustainable Green Acquisition, October 7, 2011

HHS Acquisition Regulation Parts 303; 304; 307; 315; 339; 370

HHS Acquisition Alert 2015-01: New Acquisition Guides and Templates, March 2015

HHS Directive for Acquisition Strategy, March 2015

HHS Directive for Acquisition Planning, updated April 2015

HHS Independent Government Cost Estimate, March 2015

HHS Policy on Promoting Efficient Spending, January 23, 2015

HHS Security and Privacy Language for Information and Information Technology

Acquisitions Guide (to be released circa March 2017)
Incremental Funding of U.S. Fish and Wildlife Service Research Work Orders, B-240264, 1994

Public Health Service Policy on Humane Care & Use of Laboratory Animals, revised 2015

5. EFFECTIVE DATE

The effective date of this guide is August 11, 2017 and is applicable for all FY18 submissions.

6. Document History - SMG 2610.7, Request for Contract for Actions Less than or Equal to the Simplified Acquisition Threshold

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/01/2009	N/a	OC/OO/OM/OSS/OAGS	Glenda Barfell, Director – OAGS
Change	06/04/2009	Document History	OC/OO/OM/OSS/OAGS	Glenda Barfell, Director – OAGS
Revision	10/01/2010	N/a	OC/OO/OM/OSS/OAGS	Glenda Barfell, Director – OAGS
Revision	07/28/2017	N/a	OC/OO/OM/OSS/OAGS	Leonard Grant, Acting Director – OAGS
Change	09/11/2019	Add footnote 1	OC/OO/OM/OSS/OAGS	Leonard Grant, Acting Director – OAGS

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Stream-lined Acquisition Plan Template For Actions Greater than the Micro-Purchase Threshold and Less Than or Equal to the Simplified Acquisition Threshold

Completion Instructions: *Complete all fill-ins; mark all applicable boxes; provide all requested information; attach a completed Severability and Funding Determination, along with all supporting documentation – to include a Statement of Work or other work/product description, market research, and an Independent Government Cost Estimate, as applicable.*

I. ACTION DESCRIPTION

A. CENTER ITEM NUMBER (REQUIRED IF OVER \$25K):

[Reference Item Number]

B. IDENTIFICATION OF OVERARCHING ACQUISITION STRATEGY BY NAME/NUMBER:

[Requisition Name/Number and Approval Date]

C. REQUIREMENT TITLE/DESCRIPTION:

[Title/Description]

D. BASE AWARD REFERENCE NUMBER*:

[Base Award Reference Number]

**REQUIRED FOR TASK/DELIVERY ORDERS OR CALLS PLACED AGAINST PRE-EXISTING ORDERING VEHICLES.*

E. REQUISITION NUMBER: *[Requisition Number]*

F. PROGRAM CENTER/OFFICE: *[Program Center/Office]*

G. PROGRAM POINT OF CONTACT (USUALLY THE PROSPECTIVE COR): *[Name]*

H. REQUIREMENT FULFILLMENT DEADLINE*: *[Date]*

**DISTINGUISH BETWEEN ABSOLUTE NEED-BY VS. PREFERRED AWARD DATES.*

I. PROCUREMENT CATEGORY: *Select all that apply*

- | | | |
|---|--|---|
| <input type="checkbox"/> Commercial (See FAR Part 12) | <input type="checkbox"/> Construction/A&E | <input type="checkbox"/> IT* |
| <input type="checkbox"/> R&D | <input type="checkbox"/> Services | <input type="checkbox"/> Supplies/Equipment |
| <input type="checkbox"/> States | <input type="checkbox"/> Other (describe): <i>[Description.]</i> | |

**See Section III.H.9. for additional approval requirements applicable to Acquisition Strategies and Acquisition Plans with an IT goods or services component.*

J. INDEPENDENT GOVERNMENT COST ESTIMATE (IGCE), including Base Period and all Options:
[Amount]

An IGCE is required for all contract actions with an estimated value greater than \$25,000 which require a Statement of Work (SOW) or Performance Work Statement (PWS); and, any other contract action, as determined by the Contracting Officer.

II. BACKGROUND

A. BRIEF DESCRIPTION OF REQUIREMENT/STATEMENT OF NEED:

[Summary]

B. CONDITIONS:

[Describe any known cost, schedule, environmental, capability or performance constraints.]

C. CONTRACTING HISTORY:

[Describe contracting history of the same or similar requirement, including previous contract type and dollar value.]

D. PERFORMANCE PERIOD:

[Describe the delivery or performance period requirements (e.g., contract will have a Base Period of 1 Year plus 2 Option Periods, each of which are 6 months each). See FAR Subpart 11.4.]

E. DELIVERY/PERFORMANCE REQUIREMENTS:

[Describe any required delivery/performance requirements. In the event there are multiple dates, provide a delivery/performance schedule that can be used for planning, cost estimation, and contract administration purposes. Be sure to distinguish between mandatory vs. optional line items for all delivery/performance requirements. See FAR Subpart 17.2 for further guidance regarding the use of options.]

**Note: Contractor support service requirement descriptions most often take the form of a Statement of Work (SOW) or Performance Work Statement (PWS). On the other end of the spectrum, equipment and product requirement descriptions most often entail the identification of functional compatibility and/or minimum specifications. In all cases, salient characteristics must be fully addressed so as to sufficiently define the Government's needs. Such documentation should ordinarily be submitted as a standalone attachment to the Stream-lined Acquisition Plan.*

F. SHIPMENT/DESTINATION:

[Describe any special shipping requirements (e.g., special packaging, labeling, care; end-user contact information and delivery address).]

III. PLAN OF ACTION

A. MARKET RESEARCH RESULTS/INTERESTED SOURCES:

[Discuss results of market research (e.g., potential sources of supplies/services; industry-specific commercial terms/conditions). Market Research documentation may be attached to the acquisition plan to fulfill the requirements of this paragraph.]

B. SMALL BUSINESS:

[Indicate any Small Business Designation Set-Aside Options/Preferences]

**Note: All actions above the MPT and less than or equal to the SAT are automatically reserved exclusively for small business concerns (SBCs) and shall be set aside for SBCs unless the Contracting Officer determines there is not a reasonable expectation of obtaining offers from two or more responsible SBCs that are competitive in terms of market prices, quality, and delivery. See FAR 19.502.*

- Small Business (SB)
- Small Disadvantaged Business
- Service-Disabled Veteran-Owned SB (SDVOSB)
- HUBZone SB
- 8(a)
- Woman-Owned SB (WOSB)

***Rationale:** *Please provide rationale, as supported by market research results.*

C. ACQUISITION APPROACH:

(1) Solicitation strategy contemplated. *Select all that apply.*

- FDA IDIQ/BPA
- GSA FSS
- Other (describe): *[Description.]*
- HHS IDIQ/BPA
- GWAC (describe): *[Description.]*

(2) Contract type. *Select all that apply.*

- Performance-Based
- Cost-Plus-Fixed-Fee
- Labor Hour
- Other (describe): *[Description.]*
- Fixed-Price
- Cost-Reimbursement
- Time-and-Materials

D. COMPETITION: (See FAR 7.105(b)(2) and 6.302): *Select all that apply.*

- Brand Name or Equal
- Brand Name*
- Competitive Small Business Set-Aside, Explain: *[Description.]*
- Other/Sole Source*, Explain: *[Description.]*
- Direct 8(a)
- Full-and-Open

[Describe how competition is to be fostered while supporting small business inclusion (e.g., small business set-asides) and known limitations thereof.]

**Note: Brand Name and Sole Source procurements require a formal Justification and Approval (J&A) document and will not be approved by the Contracting Officer unless shown to be necessary and appropriate in accordance with FAR Subparts 6.3 and 8.4.*

E. BASIS FOR EVALUATION:

[Describe how contractor proposals/quotations are to be evaluated. List preferred evaluation criteria, and describe how price is to be evaluated.]

F. CONTRACTING CONSIDERATIONS OR INCENTIVES:

[Identify any special clauses, provisions, deviations required, incentives to be used, and any other unique contracting considerations.]

G. GOVERNMENT-FURNISHED PROPERTY (GFP)/INFORMATION (GFI):

[Summarize extent and availability of any GFP/GFI.]

**Note: In the event GFP will be provided to a contractor, an individual need be identified in the contract to serve as the FDA Property Administrator. See FAR Part 45 and FDA-specific acquisition policy for more information.*

H. ACCEPTANCE/SURVEILLANCE:

[Describe the acceptance procedures for supply-type contracts; describe the surveillance method that will be used to ensure receipt of acceptable contract performance for service contracts.]

I. UNIQUE CONSIDERATIONS:

[Identify all unique clearances/approvals/considerations for the subject procurement by checking the appropriate block(s) and attaching all requisite analyses, determinations, approvals, and other supporting documentation. For further information and guidance concerning any of the listed items, please see SMG 2610.1.]

**Note: A Severability & Funding Determination is Always Applicable.*

- 1. Severability & Funding Determination -- Always Applicable.**
- 2. Advisory and Assistance Services for Evaluation of Proposals.**
- 3. Animal Welfare.**
- 4. Conferences and Meeting Space.**
- 5. Contracts with Federal Employees.**
- 6. Electronic and Information Technology – Section 508 Compliance.**
- 7. Food and Beverages.**
- 8. Information Security, Non-Disclosure Agreements, and Privacy.**
 - a. Security and Privacy Language for Information and IT Acquisitions.**
 - b. Privacy Office Reviews.**
 - c. Precision Medicine Initiative (PMI) Privacy and Security Plans.**
- 9. Information Technology (IT) – FITARA review and approval of the AS, AP and RFC by the FDA/HHS CIO, ADCIO (or equivalent).**

**Note: Any RFC with an IT-related goods or services component shall include the FDA CIO in the iProcurement approval chain for review prior to submittal to OAGS for processing. OAGS will not process any covered RFCs that do not demonstrate prior FDA CIO approval on the Requisition document or compliance with other Office of Information Management and Technology directives. Federal Information Technology Acquisition Reform Act (FITARA) Summary Approval Guidelines provided herein as Attachment 3.C.(3).*
- 10. Research Involving Human Subjects.**
- 11. Organizational and Consultant Conflicts of Interest (COI).**

- 12. Project Labor Agreements (PLAs) – Construction.
- 13. Promotional Items.
- 14. Printing and Publications.
- 15. Public Access to Results of FDA-Funded Scientific Research.
- 16. Rights in Data, Patents, Copyrights, and Royalties.
- 17. Sustainable Acquisition – Environmental Factors.
- 18. Other Known Clearance(s)/Approval(s): *[Description.]*

IV. PROGRAM REVIEW AND APPROVAL

(Insert Signature)

(Insert Date)

(Insert Printed Name of Program Official)

Date

(Insert Official Title and Center)

(Insert Signature)

(Insert Date)

(Insert Printed Name of ADCIO or equivalent)

Date

(Insert Official Title and Center)

(Insert Signature)

(Insert Date)

(Insert Printed Name of FDA CIO or equivalent)

Date

(Insert Official Title and Center)



Severability & Funding Determination

Purpose: *This document provides the template for completing a Severability Determination to ensure funded contract actions executed by the FDA meet applicable fiscal law and acquisition policy requirements.*

REFERENCE CENTER ITEM NUMBER: *[Reference Item Number]*

REQUIREMENT TITLE/DESCRIPTION: *[Title/Description]*

REQUISITION NUMBER: *[Requisition Number]*

The way in which a performance requirement is categorized (i.e., Severable or Non-Severable) is highly determinative of the way in which the corresponding award must be funded. Awards that are not properly funded may violate the Anti-Deficiency Act and result in serious repercussions for the FDA, as well as the individual employees who are held responsible.

Non-Severable Performance Requirements: Requirements that, from the time performance begins to the time it ends, constitutes a single, indivisible undertaking from which the requesting agency obtains no benefit until the entire undertaking has been completed. They typically require delivery of a specified end product (e.g., a final research report). Non-severable performance requirements must be fully funded at the time of award execution; however, they may take more than 12 months to complete. Thus, non-severable performance requirements may not be incrementally funded. See *Incremental Funding of U.S. Fish and Wildlife Service Research Work Orders, B-240264, 1994.*

Severable Performance Requirements: Requirements that are continuing and recurring in nature and can be separated into components that independently meet a need of the Government. The use of annual funds for severable performance requirements may cross fiscal years, but may not exceed twelve months. See *Funding of Maintenance Contract Extending Beyond Fiscal Year, B-259274, 1996.*

Section I: Severability Determination.

(To be completed by Program Personnel.)

- The subject performance requirements are Severable.
- The subject performance requirements are Non-Severable.

Rationale:

[Describe the characteristics of this requirement that support the severability determination.]

Section II: Proposed Funding Approach.

(To be completed by Program Personnel.)

- The prospective award will be funded in its entirety at time of award.
- The prospective award will leverage the use of options, each of which will be funded in its entirety at time of award.
- The prospective award will be incrementally funded within one or more periods of performance.

Details/Further Information:

[Provide any requisite details or information to explain the funding approach.]

Section III: Type and Source of Funds to Be Used.

(To be completed by Program Personnel.)

- The prospective award will be funded using one-year funds.
- The prospective award will be funded using multi-year funds.
- The prospective award will be funded using no-year funds.
- The prospective award will be funded using multiple types of funds.
- Fiscal Year of Funds to be used: _____.

Details/Further Information:

[Provide any requisite details or information to further explain the type and source of funds to be used – to include their fiscal year of origin.]

Section IV: Program Certification.

(To be completed by Program Personnel.)

- I hereby certify that, to the best of my knowledge and belief, the above information provided at Sections I – III is accurate and complete.
- I hereby certify that, to the best of my knowledge and belief, the subject funding approach complies with applicable fiscal law (e.g., Anti-Deficiency Act) and acquisition policy requirements.
- I understand and agree that, if any change in circumstances should take place that impact any of the determinations above, that I am required to complete a “New” Severability and Funding Determination.

COMPLETED BY:

(Insert Signature)

(Insert Date)

(Insert Printed Name of Program Official)
(Insert Official Title and Center)

Date

Section V: Funding Certification.

(To be completed by the cognizant Funding Official.)

Based upon my review of the information provided above at Sections I-IV, and in exercising my own professional judgment, I hereby certify that:

- I have no knowledge of or reason to believe that any of the above information provided at Sections I-IV is incorrect, incomplete, or otherwise requires revision.
- The subject funding approach complies with applicable fiscal law (e.g., Anti-Deficiency Act) and acquisition policy requirements.
- I understand that if I have any concerns regarding any of the information provided herein, I am required to fully address those concerns below.

Concerns/Comments/Further Information:

[Provide requisite details about any concerns or comments regarding the subject severability determination, proposed funding approach, type of funds to be used – to include the availability of such funding.]

COMPLETED BY:

(Insert Signature)

(Insert Date)

(Insert Printed Name of Funding Official)
(Insert Official Title and Office)

Date

Section VI: Contracting Officer Determination.

(To be completed by the cognizant Contracting Officer.)

Based upon my review of the information provided above at Sections I-V, and in exercising my own professional judgment, I hereby determine that:

- I have no knowledge of or reason to believe that any of the above information provided at Sections I-V is incorrect, incomplete, or otherwise requires revision.
- The subject severability determination, proposed funding approach, and type and source of funds to be used complies with applicable fiscal law (e.g., Anti-Deficiency Act) and acquisition policy requirements.
- The subject severability determination, proposed funding approach, and type and source of funds to be used does NOT comply with applicable fiscal law (e.g., Anti-Deficiency Act) and acquisition policy requirements. See comments below.

Concerns/Comments/Further Information:

[Provide requisite details about any concerns or comments regarding the subject severability determination, proposed funding approach, type of funds to be used – to include the availability of such funding.]

APPROVED BY:

(Insert Signature)

(Insert Date)

(Insert Printed Name of Contracting Officer)
(Insert Official Title and Office)

Date



**Federal Information Technology Acquisition Reform Act (FITARA)
Summary Approval Guidelines**

Purpose: *This document provides the FDA approval framework for Acquisition Strategies and Acquisition Plans with an IT Goods or Services Component under FITARA.*

FITARA Provides enhanced authorities to the HHS CIO and FDA CIO, through delegated authorities.

The FDA CIO is authorized to:

- Review and approve IT budgets, investments < \$20 Million annually or \$100 Million over 5 years, and acquisition strategies
- Approve the FDA IT budget request to the Department
- Conduct IT Portfolio Reviews for the IT budget

ACQUISITION STRATEGIES & PLANS WITH IT GOODS OR SERVICES

I. FDA Centers/Offices (includes OIMT and excludes OC)

Acquisition Strategy Threshold*	FDA Concurrence	FDA Approval	Requires HHS Approval
<\$20M	Center/Office ITIRB	FDACIO	No
>/\$20M, or high risk	Center/Office ITIRB	FDACIO	Yes
>/\$100M, over 5 years	Center/Office ITIRB	FDACIO	Yes

**Threshold applies to the aggregate total estimated value, unless otherwise noted.*

Acquisition Plan Threshold*	FDA Concurrence	FDA Approval	Requires HHS Approval
<\$5M	Center/Office ITIRB	ADCIO (or equivalent)	No
>/\$5M, but <\$50M	ADCIO (or equivalent)	FDACIO	No
>/\$50M	ADCIO (or equivalent)	FDACIO	Yes

**Threshold applies to the aggregate total estimated value, unless otherwise noted.*

II. Office of the Commissioner Only (excludes OIMT)

Acquisition Strategy Threshold*	FDA Concurrence	FDA Approval	Requires HHS Approval
<\$20M	Relevant Deputy Commissioner and OC Executive Officer	FDACIO	No
>/\$20M, or high risk	Relevant Deputy Commissioner and OC Executive Officer	FDACIO	Yes
>/\$100M, over 5 years	Relevant Deputy Commissioner and COO	FDACIO	Yes

**Threshold applies to the aggregate total estimated value, unless otherwise noted.*

Acquisition Plan Threshold*	FDA Concurrence	FDA Approval	Requires HHS Approval
<\$5M	Super Office POC or SMO	ADCIO	No
>/\$5M, but <\$50M	ADCIO (or equivalent)	FDACIO	No
>/\$50M	ADCIO (or equivalent)	FDACIO	Yes

**Threshold applies to the aggregate total estimated value, unless otherwise noted.*

NOTE:

- Center/Office without an ITIRB will leverage the Business Subcommittee for FDA IT Concurrence on Acquisition Strategies.
- All IT investments supported by one or more procurements must have an Acquisition Strategy.
 - An Acquisition Strategy can address multiple IT investments.
 - An IT investment can only be addressed in one Acquisition Strategy.
- FDA CIO will review and approve Acquisition Plans for contracts that vary from an approved Acquisition Strategy.