

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FDA OFFICIAL COUNCILS AND COMMITTEES

FDA ACQUISITION AND GRANTS STRATEGY COUNCIL

Effective Date: August 11, 2015

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1. PURPOSE

This charter describes the duties and responsibilities of the U.S. Food and Drug Administration (FDA or Agency) Acquisition and Grants Strategy Council (ASC), its membership, and its operating procedures. The ASC will serve in an advisory capacity for the Office of Acquisitions and Grant Services (OAGS) within the Office of Finance, Budget and Acquisitions.

2. OWNERSHIP

Process and Document Owners

This document will be maintained by the following parties:

- Change Management Process Owners: Chairpersons, as described in Membership below
- Document Owner: Director, Office of Acquisitions and Grant Services
- Key Partners: Office of Operations, Executive Secretariat

Review Schedule and Sign-Off Procedure

This document will be reviewed for content and accuracy semi-annually by the Office of Operations, Executive Secretariat and Chairpersons.

Version Control

Initial approval by the Commissioner will result in the creation of version 1.0. Future approvals will always be whole numbers (version 2.0, 3.0, etc.). Any changes will result in a change of version number as well. For example, should a new objective/process be added after initial approval, this would result in draft version 1.1. Once this change is approved by the Commissioner, the document would become version 2.0.

Version #	Date	Modified by	Description of Modification
1.0	12/22/2014	E. Mitchell	Version 0.2 submitted for signature

3. SCOPE

In partnership with the Management Council (MC), the ASC facilitates a forum for FDA-wide representation in the acquisitions planning, development and implementation processes. As such, each member provides vital counsel to the Director, OAGS as well as to the senior leadership of his/her organization regarding these issues. The ASC ensures issues and policies are addressed and resolved in a manner that enhances the best interests of the Agency.

The ASC will provide its members the opportunity for a meaningful exchange of information and collaborative approaches to meeting common acquisition-related challenges. The ASC informs strategic acquisition and grants planning and shares Departmental best practices, in an effort to ensure Agency efficiency and effectiveness. Additionally, the ASC serve as a forum to support the initiatives and

outreach efforts of OAGS. For example, ASC could support the following OAGS programs: seminars, conferences, workshops, or other meetings. Specifically, the ASC will:

- Review and discuss FDA-wide acquisition and grants programmatic policies and procedures prior to establishment, to include both new policies and/or updates, except for policies or procedures promulgated by law or federal regulations
- Resolve overarching acquisition and grants issues/concerns not limited to one Center/Office
- Advise and make recommendations on Federal and Departmental acquisition and grants regulations, policies, and other decisions, statutes, and issuances that affect the acquisition and grants community
- Strategize future acquisition plans, analyzing common requirements for the FDA

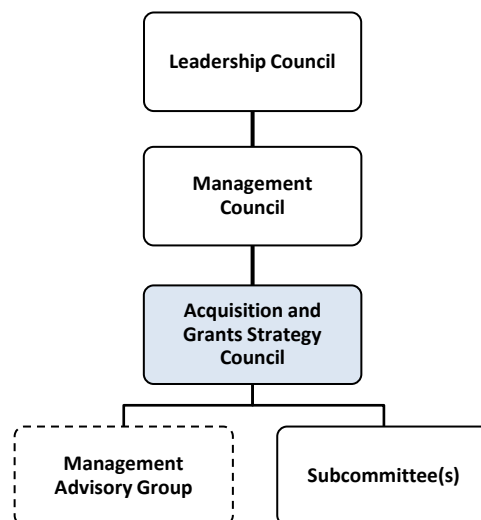
The scope of the activities may be expanded by ASC decision, with the concurrence of the Commissioner.

4. ORGANIZATIONAL STRUCTURE

The ASC is a component of the Operations Management Councils (OMC). Each OMC is subordinate to the MC. However, the ASC will be subordinate to the Leadership Council while the Deputy Commissioner for Operations/Chief Operations Officer serves as the Co-Chair; the Chief Financial Officer will serve as Co-Chair in the future state.

The MAG is an ad-hoc group of the OMC, formed as needed to address cross-functional issues affecting one or more Councils. Any subcommittees will be subordinate to the ASC.

A diagram of the organizational structure is provided below.



5. RESPONSIBILITIES

In fulfilling the requirements of its scope, the ASC will:

- Identify, clarify, and prioritize the activities of the ASC
- Provide advice and assistance in the coordination of overall Agency acquisition and grants initiatives
- Provide Agency-wide governance and oversight of FDA acquisition and grants management strategic goals, priorities and performance/accountability measures

- Develop mitigation strategies to address challenges in the Office of Operations Strategic Management Plan
- Serve as a reporting body for designated subcommittees of the ASC
- Review the FDA advanced acquisition plan, in order to identify opportunities for strategic sourcing

In performing these responsibilities the ASC will:

- Communicate recommendations, decisions, and actions on the Agency's policies, plans, and strategies as appropriate
- Maintain records of ASC recommendations, decision, and actions
- Provide input to and work with other Agency components as necessary to achieve FDA goals and missions
- Provide an opportunity to exchange best practices across the Department for mission implementation
- Establish and oversee subcommittees and MAGs for the purpose of fulfilling the ASC's responsibilities
- Review work products of the subcommittees and MAGs appointed by the ASC to develop recommendations/options for cross-Agency implementation

Membership

Members of the ASC will serve as long as they are in the below-mentioned positions.

Chairperson

The ASC will be Co-Chaired by the Deputy Commission for Operations/Chief Operations Officer and the Director, Office of Acquisitions and Grant Services. The Chief Financial Officer will serve as Co-Chair in the future state.

The Chairpersons will be responsible for the following activities:

- Establishing areas of priority for ASC consideration, in alignment with the FDA strategic acquisition planning
- Arranging and organizing meetings

- Ensuring accuracy of ASC documents
- Distributing documents to ASC members
- Maintaining records of ASC activities and actions/decisions
- Gathering details/additional information from appropriate staff across the Agency to support ongoing ASC activities, meetings, and initiatives
- Preparing and maintaining minutes of ASC meetings

Voting Members

The following voting members have been established:

- Deputy Commissioner for Operations/Chief Operations Officer, Co-Chair
- Director, Office of Acquisitions and Grant Services, Co-Chair
- Deputy Chief Operations Officer/OC Executive Officer
- Center/Office Executive Officers
- Chief Financial Officer

Non-Voting Members

The following non-voting members have been established:

- Chief Information Officer
- Chief Human Capital Officer
- Chief Counsel, FDA Legal Advisor
- OAGS Senior Leadership
 - Division Director of Acquisition Support and Grants
 - Division Director of Acquisition Programs
 - Division Director of Acquisition Operations
 - Division Director of Information Technology and Acquisitions
 - Branch Chief for Acquisition Policy and Oversight

- Other members, as decided by the ASC

Principals are expected to make every effort to personally attend ASC meetings.

Other participants, observers, and consultants from within the Agency and from other federal government organizations may participate and attend as decided by the ASC.

6. PROCEDURES

ASC Meetings

- Will be held monthly or as otherwise decided by the Chairpersons or ASC
- Will have minutes prepared in writing within one week after they are held
- At a minimum, meeting minutes should record attendees, issues presented, decisions made, and any outstanding action items

Meeting Agenda

- Proposed agenda items may be submitted by any ASC member to the Chairpersons
- Agenda items should be submitted and posted at least one week in advance
- Agenda items and all supporting documents will be distributed by the Chairpersons to all ASC members a minimum of two days prior to the meeting
- Agenda items and all supporting documents requiring an ASC vote will be distributed by the Chairpersons to all ASC members with a minimum of five calendar days review time. Items that do not meet this threshold will be postponed to the following meeting.

Decision Making

- Agreements are reached through majority vote
- When a vote is required, the Chair will call the roll and the vote will be recorded
- Once approved by the ASC, decisions will be referred to the MC for final approval, as appropriate

Records and Reporting

- Chairpersons will ensure ASC activities including recommendations, decisions, issues, action items, meeting summaries and other pertinent materials attributable to the ASC are documented and communicated to senior management and affected staff, as appropriate, in a timely manner
- Meeting summaries will generally be made available to Agency staff on the FDA intranet
- Chairpersons will provide an operations report to the MC quarterly, consisting of Office of Operations Strategic Management Plan updates/mitigation strategies, as well as ASC accomplishments, issues and quarterly forecasts
- Chairpersons will provide the Office of Operations, Executive Secretariat a schedule/timeline of ASC activities semi-annually

Subcommittees

- ASC may decide to establish subcommittees as needed
- ASC shall decide on and record in writing the specific responsibilities and operating procedures for each subcommittee
- Subcommittees will consist of appropriate FDA personnel, as decided by the ASC

Charter Updates

- Amendments to the ASC Charter can be proposed by any ASC member at any time. Adoption of amendments to the ASC Charter will be by decision of the ASC, with the concurrence of the Commissioner.

7. EFFECTIVE DATE

The effective date of this guide is August 11, 2015.

8. Document History – SMG 2010.8, FDA Acquisition and Grants Strategy Council

VERSION	STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
1.0	Initial	05/14/2015	N/a	OO/PEO	Walter S. Harris, FDA Chief Operating Officer