

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FDA OFFICIAL COUNCILS AND COMMITTEES

FDA MANAGEMENT COUNCIL

Effective Date: August 10, 2015

Changed: February 22, 2018

1. Purpose
2. Ownership
3. Scope
4. Organizational Structure
5. Responsibilities
6. Procedures
7. Effective Date
8. History

1. PURPOSE

This charter describes the duties and responsibilities of the U.S. Food and Drug Administration (FDA or Agency) Management Council (MC), its membership, and its operating procedures. The Council was formed to coordinate the business processes and management operations across the FDA.

2. OWNERSHIP

Process and Document Owners

This document will be maintained by the following parties:

- Change Management Process Owners: Chairperson
- Document Owner: Chairperson
- Key Partners: Office of Operations, Executive Secretariat

Review Schedule and Sign-Off Procedure

Document will be reviewed for content and accuracy semi-annually by the Office of Operations Executive Secretariat and/or Chairperson.

Version Control

Initial approval of the Commissioner will result in 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	04/18/2014	E. Mitchell	Final draft - signed
1.1	09/12/2014	E. Mitchell	Draft – governance structure update
2.0	11/10/2014	E. Mitchell	Version 1.1 submitted for signature

3. SCOPE

The Management Council provides a forum to address the expanding and rapidly changing core functions of the Agency. In doing so, the Office of Operations will increasingly utilize this forum in a centralized oversight capacity. Most recently, in an effort to facilitate more dynamic and proactive management, and in response to feedback from senior leadership, the governance structure was updated to clarify roles and responsibilities of the MC as well as its subordinate bodies. The resulting structure ensures issues and concerns are addressed and resolved in a timely manner, optimizing the strength of the leadership and enhancing Agency interests.

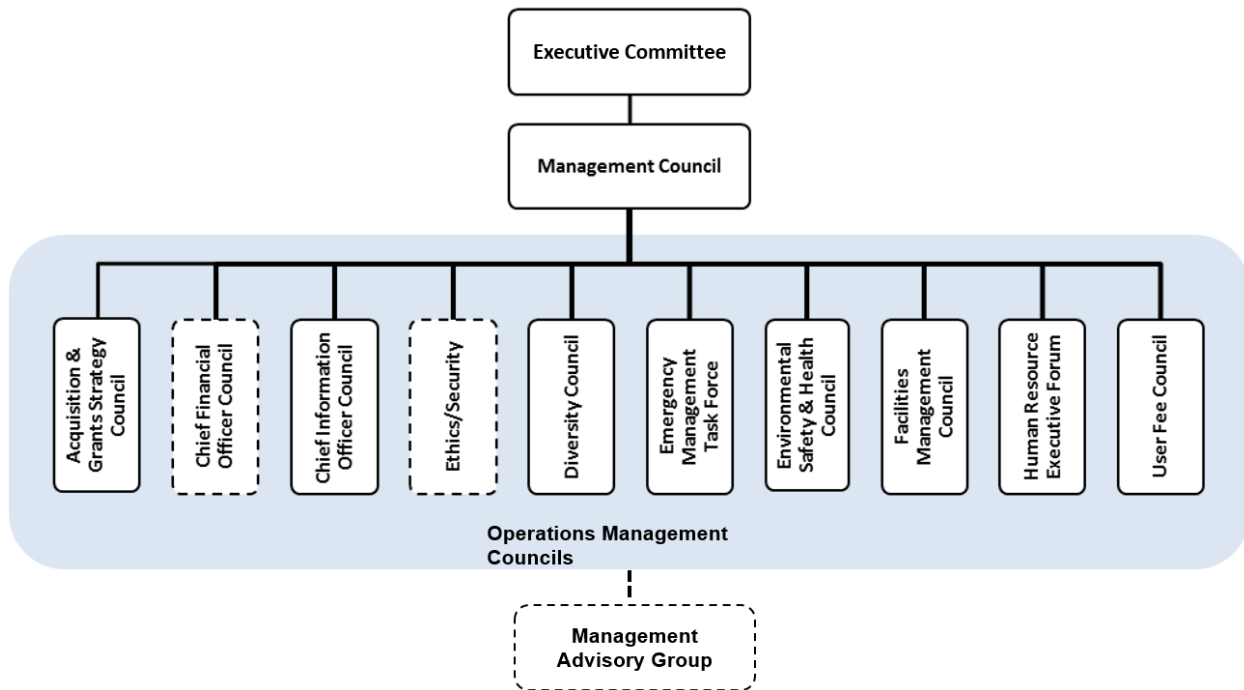
In partnership with the Executive Committee, the MC will provide the opportunity for a meaningful exchange of information and collaborative approaches to meeting common challenges. The MC will inform operational objectives, strategic management planning and shares best practices, in an effort to ensure Agency efficiency and effectiveness. Additionally, in conjunction with subordinate councils, the MC will address the following activities:

- Budget formulation and execution
- Human resources
- Information technology
- Management/administrative
- Property and acquisitions
- Long-range facility planning
- Safety and Security
- Ethics

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

4. ORGANIZATIONAL STRUCTURE

Subordinate to the Executive Committee, the organizational structure of the MC is consistent of two main parts: the Operations Management Councils and the Management Advisory Groups. A diagram of the organizational structure has been provided, with each part is detailed below.



Operations Management Councils

The Operations Management Councils (OMC) are a collective group of function-specific, core councils. Each OMC council will establish a charter to clarify specific roles and responsibilities. Additionally, each council will be subordinate to the MC, with any exceptions annotated in the perspective charter. The OMC councils are:

- Acquisition & Grants Strategy Council
- Chief Financial Officer Council*
- Chief Information Officer Council
- Ethics/Security*
- Diversity Council

- Emergency Management Task Force
- Environmental Safety & Health Council
- Facilities Management Council
- Human Resource Executive Forum
- User Fee Council

The Chief Financial Officer Council and Ethics/Security are ad hoc councils of the OMC, as they are not formal council and do not have charters. However, the leadership of these offices will serve as non-voting members of the MC, present to the MC on an ad hoc basis, and fulfill the OMC reporting requirements.

Management Advisory Group

Formerly the Management Operations Council, the Management Advisory Groups (MAG) will serve as an ad-hoc group, formed as needed to address cross-functional issues affecting one or more Councils. There may be multiple MAGs, i.e. MAG-Training or MAG-IT User Fees.

Each MAG will be chartered and subordinate to the OMC. Once formed, the MAG will include the following members:

- Representative from the initiating OMC
- Executive Officer
- Staff level Center/Office Representative
- Office of Operations, Program Effectiveness Office Representative (non-voting)

5. RESPONSIBILITIES

In fulfilling the requirements of the scope, the MC will:

- Identify, clarify, and prioritize the activities of the Council
- Approve, ratify and coordinate strategic management initiatives, as necessary
- Serve as a reporting body, providing oversight of the Operations Management Councils

- Facilitate the develop of mitigation strategies to address challenges in the Office of Operations Strategic Management Plan

In performing these responsibilities the Council will:

- Communicate recommendations, decisions, and actions on the Agency's policies, plans, and strategies, as necessary
- Maintain records of Council 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 MAGs for the purpose of fulfilling the Council's responsibilities, as necessary

Membership

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

Chairperson

The Deputy Commission for Operations/Chief Operations Officer will serve as the Chair of the MC. The Chairperson will be responsible for the following activities:

- Establish areas of priority for Council consideration, in alignment with the FDA Strategic Plan and resultant Office of Office Strategic Management Plan
- Arrange and organize meetings
- Distribute documents to Council members
- Maintain records of Council activities and actions/decisions
- Ensure accuracy of Council documents
- Gather details/additional information from appropriate staff across the agency to support ongoing Council activities, meetings, and initiatives
- Prepare and maintain minutes of Council meetings

Voting Members

The following voting members have been established:

- Deputy Commissioner for Operations/Chief Operations Officer, Chair
- Deputy Chief Operations Officer/OC Executive Officer
- Center/Office Executive Officers

Non-Voting Members

The following non-voting members have been established:

- Chief Financial Officer
- Chief Human Capital Officer
- Chief Information Officer
- Director, Office of Acquisition & Grant Services
- Director, Office of Crisis Management
- Director, Office of Equal Employment Opportunity
- Director, Office of Ethics
- Director, Office of Facilities, Engineering & Mission Support
- Director, Office of Security Operations
- Director, Employee Safety & Environmental Management
- Chair, User Fee Council
- Other members, as decided by the Council

Principals are expected to make every effort to personally attend Council meetings. The principal's primary deputy will be designated as an alternate.

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

The Office of Operations Executive Secretariat will maintain a listing of all members, to include alternates, observers, participants and consultants.

6. PROCEDURES

Council Meetings

- Will be held bi-weekly or as otherwise decided by the Chairperson or Council
- 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 Council member to the Chairperson and/or the Office of Operations Executive Secretariat
- The agenda items should be submitted and posted at least one week in advance
- Agendas, and all supporting documents, for the meeting will be distributed by the Office of Operations Executive Secretariat to all Council members a minimum of two days prior to the meeting
- Agenda items, and all supporting documents, requiring a Council vote will be distributed by the Office of Operations Executive Secretariat to all Council 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

- Decisions can only be made when quorum is achieved. In addition to the Chairperson, quorum requires the attendance of at least 6 voting members, with at least one voting member from each directorate. The listing of voting members by directorate is detailed below.

Office of the Commissioner	Office of Foods and Veterinary Medicine	Office of Global Regulatory Operations and Policy	Office of Medical Products and Tobacco
Deputy Commissioner for Operations/COO – Chair	Executive Officer, CFSAN	Executive Officer, ORA	Executive Officer, CDER
Deputy Chief Operations Officer/OC Executive Officer	Executive Officer, CVM		Executive Officer, CBER
Executive Officer, NCTR			Executive Officer, CDRH
			Executive Officer, CTP

- Designated alternates may proxy vote when the principal is absent. Additionally, designated senior executives or equivalents may proxy vote when the principal is absent; advance notice to the Chairperson will be required.
- Decisions of the Council will be reached through majority of the voting members. The Chairperson and/or Office of Operations Executive Secretariat will call the roll and the vote will be recorded.
- When majority vote cannot be reached, the Chairperson will make the final Council decision
- If a final decision cannot be reached by the Chairperson, the Commissioner will make the final decision
- The Deputy Commissioner for Operations/Chief Operating Officer as the Chairperson will keep the Commissioner and Executive Committee apprised of significant Council decisions. The Commissioner retains the right to change any decision.
- Agreements generally are reached through majority vote

Records and Reporting

- The Chairperson and/or Office of Operations Executive Secretariat will ensure Council activities including recommendations, decisions, issues, action items, meeting summaries and other pertinent materials attributable to the Council 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
- The Office of Operations Executive Secretariat will provide the Council a schedule/timeline of Council activities semi-annually
- Each OMC council will provide a quarterly report to the Office of Operations Executive Secretariat for distribution to the Council, to consist of accomplishments, issues and forecasts for the next quarter
- The Office of Operations Executive Secretariat will produce a quarterly report to the Chairperson for distribution to the Executive Committee

Management Advisory Groups

- The Council may establish MAGs to serve as subcommittees, as needed

- The MAG will be charted for a specific time period, outlining specific roles and requirements to be completed
- The MAG will produce a decision memo for the sponsoring OMC on their findings and recommendations

Charter Updates

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

7. EFFECTIVE DATE

The effective date of this guide is August 10, 2015.

8. Document History – SMG 2010, FDA Management Council

VERSION	STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
1.0	Initial	07/01/2004	N/a	Executive Secretary, FDA Management Council	Lester M. Crawford, FDA Commissioner
1.1	Change	10/03/2005	Section Heading 4, item 6	Executive Secretary, FDA Management Council	Janet Woodcock, FDA Deputy Commissioner
2.0	Revision	04/18/2014	N/a	Executive Secretary, FDA Management Council	Commissioner, Food and Drug Administration
3.0	Revision	08/04/2015	N/a	OO/PEO	Walter S. Harris, FDA Chief Operating Officer
3.1	Change	02/22/2018	Replace "Senior Leadership Council" with "Executive Committee"	FDA/OC/OES	Commissioner, Food and Drug Administration