

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FDA OFFICIAL COUNCILS AND COMMITTEES

FDA CHIEF INFORMATION OFFICER COUNCIL

Effective Date: August 12, 2015

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) Chief Information Officer Council (CIOC), its membership, and its operating procedures. The Council will serve in an advisory capacity for the Office of Information Management and Technology (OIMT).

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: Chief Information Officer
- 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/or Chairperson.

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
1.1	01/09/2015	E. Mitchell	CFO added as voting member

3. SCOPE

The CIOC promotes FDA compliance with statutory provisions, presidential mandates, and Department of Health and Human Services policies regarding the governance and management of Information Technology. It operates on behalf of the FDA Commissioner and CIO, as the Agency governance board for information technology (IT) decision-making, in whole or part. Specifically, the Council will provide governance over all FDA IT, including but not limited to FDA-specific:

- IT strategic direction and prioritization
- IT policy and requirements development
- IT operations and security
- IT investment review and capital planning
- IT planning, programming, budgeting (including OIM resource utilization) and execution

4. ORGANIZATIONAL STRUCTURE

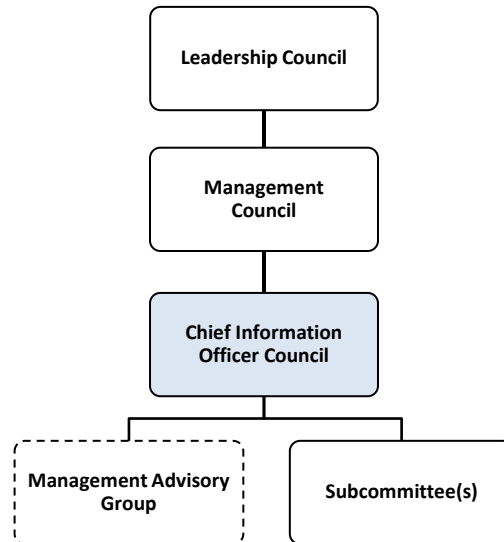
The CIOC is a component of the Operations Management Councils (OMC). Each OMC is subordinate to the MC.

Subordinate to the CIOC are any created subcommittees, in addition to the Management Advisory Group (MAG). The MAG is an ad-hoc group of the OMC, formed as needed to address cross-functional issues affecting one or more Councils. Additionally, the following standing subcommittees have been identified:

- Engineering Review Board
- Scientific Computing Board

- Center Information Technology Investment Review Boards

A diagram of the organizational structure is provided below.



5. RESPONSIBILITIES

The CIOC provides executive decision support to FDA senior leadership and CIO by providing advice and consent on all major IT investments, technical and operational activities. The objective of the CIOC is to synchronize the IT activities of the FDA Centers, Offices and Directorates, and maximize the return of all FDA IT investments in support of the FDA's mission of protecting and promoting public health. The CIOC will:

- Provide leadership over IT investment strategy and policy
- Integrate IT planning and collaboration across FDA
- Ensure the development and maintenance of the IT Strategic Plan
- Oversee the annual IT prioritization and budgeting process to ensure the most efficient and effective use of all FDA IT resources
- Ensure accountability and transparency for all IT cost across FDA
- Make, or oversee, all IT governance decisions

To support its activities, the CIOC may:

- Commission and decommission boards, councils, working groups, and committees, as well as assign the Chair
- Delegate specific governance authority to other boards
- Request the attendance of other executives and subject matter experts at CIOC meetings to act in an advisory or supporting capacity
- Set and ensure FDA IT policies and processes are followed
- Solicit and/or consider recommendations from other bodies
- Interview CIO candidates and advise the Chief Human Capital Officer regarding the best qualified CIO candidates
- Recommend the OIMT Operating budget to the Management Council for final approval

Membership

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

Chairpersons

The CIOC will be Co-Chaired by the Chief Information Officer, the Chief Health Information Officer and an Associate Deputy Chief Information Officer. The Chairpersons will be responsible for the following activities:

- Establishing areas of priority for CIOC consideration, in alignment with the FDA IT portfolio, strategic direction and priorities
- Arranging and organizing meetings
- Distributing documents to CIOC members
- Maintaining records of CIOC activities and actions/decisions
- Ensuring accuracy of CIOC documents
- Gathering details/additional information from appropriate staff across the agency to support ongoing CIOC activities, meetings, and initiatives
- Preparing and maintaining minutes of CIOC meetings

Voting Members

The following voting members have been established:

- Chief Information Officer, Co-Chair
- Chief Health Information Officer, Co-Chair
- Associate Deputy Chief Information Officer, Co-Chair: To serve one year, rotated among the willing Associate Deputy CIOs, and confirmed by the other Associate Deputy CIOs
- Associate Deputy Chief Information Officer from the following:
 - Center for Biologics Evaluation and Research (CBER)
 - Center for Drug Evaluation and Research (CDER)
 - Center for Devices and Radiological Health (CDRH)
 - Center for Food Safety and Applied Nutrition (CFSAN)
 - Center for Tobacco Products (CTP)
 - Center for Veterinary Medicine (CVM)
 - National Center for Toxicological Research (NCTR)
 - Office of the Commissioner (OC)
 - Office of International Programs (OIP)
 - Office of Regulatory Affairs (ORA)
 - Chief Financial Officer

Non-Voting Members

The following non-voting members have been established:

- Chief Human Capital Officer
- Director, Office of Acquisitions and Grants Services
- Office of Information Management and Technology Leadership as determined by the CIO

- Representative from HHS CIO
- Other members, as decided by the CIOC

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

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

6. PROCEDURES

CIOC Meetings

- Will be held monthly or as otherwise decided by the Chairpersons or CIOC
- 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 CIOC 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 CIOC members a minimum of two days prior to the meeting
- Agenda items and all supporting documents requiring a CIOC vote will be distributed by the Chairpersons to all CIOC 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. Quorum requires attendance of two-thirds of the voting members.
- Decisions are reached through consensus. If consensus cannot be reached, voting is conducted by roll call vote. In situations where there is a tie, CIO will serve as the tie-breaker.

- In cases of critical non-concurrence, the Management Council will decide.
- A synopsis of all CIOC decisions will be provided to the Management Council and are subject to ratification by the same

Records and Reporting

- Chairpersons will ensure CIOC activities including recommendations, decisions, issues, action items, meeting summaries and other pertinent materials attributable to the CIOC 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 CIOC accomplishments, issues and quarterly forecasts
- Chairpersons will provide the Office of Operations, Executive Secretariat a schedule/timeline of CIOC activities semi-annually.

Subcommittees

- CIOC may decide to establish subcommittees as needed
- CIOC 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 CIOC

Charter Updates

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

7. EFFECTIVE DATE

The effective date of this guide is August 12, 2015

8. Document History – SMG 2010.9, FDA Chief Information Officer Council

VERSION	STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
1.0	Initial	12/30/2014	N/a	OO/PEO	Walter S. Harris, FDA Chief Operating Officer