SMG 3210.2

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

INFORMATION RESOURCES MANAGEMENT

INFORMATION TECHNOLOGY MANAGEMENT

IT INVESTMENT MANAGEMENT

Effective Date: 06/23/2016

1. Purpose
2. Background
3. Definitions
4. Policy
5. Responsibilities
6. References
7. Effective Date
8. History

1. PURPOSE

This Staff Manual Guide (SMG) establishes FDA Information Technology (IT) Investment Management (ITIM) policy. The purpose of this policy is to establish and maintain a partnership, common understanding, quality framework, and decision structure between FDA's business and IT communities that will be followed throughout the life cycle of all IT investments. This partnership begins at the executive level (i.e., Commissioner, Center Directors, Chief Financial Officer and Chief Information Officer (CIO)) with IT policies governing how IT investments are selected, controlled and evaluated. The partnership continues at the Center/ Office level with IT processes guiding how the IT community can best support business; and extends to the IT project and IT services level to ensure good management and legislative compliance.

This policy applies to all government and contractor staff supporting FDA in order to establish and sustain a common understanding of how IT investments are to be managed throughout the organization. Reference the SMG 3210.3 IT Project Management Policy for specific guidance on how FDA manages its IT investments at the project level.

2. BACKGROUND

The following IT Investment Management policy provides the basis for the management of IT investments:

- Clinger-Cohen Act (CCA) of 1996 - Requires agencies to use a disciplined capital planning and investment control (CPIC) process to acquire, use, maintain, and dispose of IT. The purpose of the CCA is to improve the productivity, efficiency, and effectiveness of federal programs through improved acquisition, use, and disposal of IT resources.

- OMB Circular A-11 - Preparation, Submission, and Execution of the Budget - Instructs agencies on the preparation and submission of budget estimates and budget execution; details the requirements of the budget process and preparation/submission of strategic plans and annual performance plans; addresses planning, budgeting, and acquisition of capital assets; and provides performance measures on management of physical and financial assets.

- Federal IT Acquisition Reform Act (FITARA) of 2014 - Requires the heads of the federal agencies to ensure that their respective Chief Information Officers (CIOs) have a significant role in information technology (IT) decisions, including annual and multi-year planning, programming, budgeting, execution, reporting, management, governance, and oversight functions.

3. DEFINITIONS

Definitions to be used for all IT policy are provided in the OMB Integrated Data Call (IDC) Common Definitions.

A. Information Technology (IT)

"The term "information technology" is defined as:

1. Any services or equipment, or interconnected system(s) or subsystem(s) of equipment, that are used in the automatic acquisition, storage, analysis, evaluation, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information by the agency; where

2. such services or equipment are 'used by an agency' if used by the agency directly or if used by a contractor under a contract with the agency that requires either use of the services or equipment, or requires either use of the services or equipment to a significant extent in the performance of a service or the furnishing of a product.

3. The term "information technology" includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment

designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including provisioned services such as cloud computing and support services that support any point of the lifecycle of the equipment or service), and related resources.

4. The term "information technology" does not include any equipment that is acquired by a contractor incidental to a contract that does not require use of the equipment."

B. IT Investment

"This term refers to the expenditure of IT resources to address mission delivery and management support. An IT investment may include a project or projects for the development, modernization, enhancement, or maintenance of a single IT asset or group of IT assets with related functionality, and the subsequent operation of those assets in a production environment. All IT investments should have a defined life cycle with start and end dates, with the end date representing the end of the currently estimated useful life of the investment, consistent with the investment's most current alternatives analysis if applicable.

1. When the asset(s) is essentially replaced by a new system or technology, the replacement should be reported as a new, distinct investment, with its own defined life cycle information."

C. Capital Planning and Investment Control (CPIC)

"This term refers to a decision-making process that ensures IT investments integrate strategic planning, budgeting, procurement, and management of IT in support of agency missions and business needs. The CPIC process has three distinct phases: Select, Control, and Evaluate. See 40 U.S.C 11302 for statutory requirements and the Clinger-Cohen Act of 1996."

4. POLICY

It is the policy of the FDA to enable the FDA Chief Information Officer (CIO) to implement IT investment management policies.

A. IT Investment Portfolio Organization and Accountability

Standard information for all FDA IT investments shall be collected and maintained in a single FDA level IT investment portfolio reported and managed using the Portfolio Management Tool (PMT) which is mandated for this purpose by HHS. The PMT is used by the FDA CIO to manage

and support IT decision making, FDA CIO Council, FDA CIO Subcommittees, other IT review board activities, OMB/HHS data calls and management reporting.

Centers and Offices shall collect and maintain detailed investment information for each IT investment and be able to demonstrate sound IT management practices as required by the FDA CIO. The level of detail needed to manage an investment should be commensurate with the size and complexity of the investment. Each Center/ Office is responsible for the performance of their Center/ Office IT portfolio and the establishment, facilitation of a Center/ Office level IT Investment Review Board (ITIRB) and to ensure adequate attention to strategic IT management.

B. Classifying IT Investments

IT investments are classified as Major or Non-Major. The funding thresholds for determining whether an IT investment is Major or Non-Major are determined by HHS and the FDA Chief Information Officer (CIO). A Major Investment is any IT investment requiring special management attention because of its importance to the mission or function to the government; significant program or policy implications; high executive visibility; high development, operating, or maintenance costs; unusual funding mechanism; or definition as major by HHS or FDA CIO regardless of the funding threshold.

C. IT Budget Request, Funding, and Acquisition Approval

The FDA CIO, in coordination with the Center/Office leadership, shall review and either approve or disapprove all IT budget requests, funding, and acquisitions (i.e., requisitions, Requests for Information/Proposal/Quote, Cooperative Research and Development Agreements, etc.) for their respective Center/Office. The FDA CIO shall present the approved FDA IT Portfolio budget request to the Management Council as part of the budgeting process.

D. IT Investment Governance

FDA CIO shall review the select, control, and evaluate process results of all IT investments, validate the results against FDA goals and priorities, and direct the adjustment of the FDA IT portfolio accordingly. The Centers/ Offices shall follow the processes set by the CIO Council.

5. RESPONSIBILITIES

The responsibilities for major roles and governance bodies include:

A. FDA Chief Information Officer (CIO)

It is the responsibility of the FDA CIO to provide leadership and oversight of IT policy, development, budget, operations and advise executive management on the strategic direction and management of FDA's IT programs. The CIO and his or her staff provide leadership for the implementation of technology to create the information foundation for the efficient and effective operation and management of FDA. The FDA CIO is responsible within FDA for IT long-term strategic planning, IT architecture management, IT budget review, IT security and privacy, IT performance and results-based management, CPIC, and, records management.

B. FDA CIO Council

The FDA CIO Council ensures that the IT CPIC process is properly executed.

6. REFERENCES

- The Clinger-Cohen Act (CCA) of 1996 (Federal Legislation)

- OMB IT Budget – Capital Planning Guidance (Directive)

- OMB Circular A-130 - Discussion of Clinger Cohen Act

- OMB Circular A-11: Capital Programming Guide

- GAO - Information Technology Investment Management (ITIM) Framework (Directive)

- Federal IT Acquisition Reform Act (FITARA) of 2014

- OMB Memorandum M-15-14 Management and Oversight of Federal Information Technology - implementation guidance for the Federal Information Technology Acquisition Reform Act (FITARA) and related information technology (IT) management practices.

- Department of Health and Human Services (HHS) Policy for Information Technology (IT) - Capital Planning and Investment Control (CPIC)

7. EFFECTIVE DATE

The effective date of this guide is June 23, 2016.

8. Document History – SMG 3210.2, IT Investment Management

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	03/31/2005	N/a	Strategy and Planning Staff, OCIO, HFA-83	Rod Bond, Director
Revision	06/22/2016	N/a	Office of Enterprise Portfolio Management (OEPM), Office of Information Management, OIMT/OO/OC	Chief Information Officer, Office of Information Management and Technology

Back to General Administration, Volume III (2000-3999)