

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Information Systems Management

Division of IT Planning and Management Services

Effective Date: February 9, 2022

1. Division of IT Planning and Management Services (DCIKC).

- A. Manages administrative functions supporting OISM operational activities.
- B. Coordinates enterprise IT initiatives between ORA and the OIMT and facilitates planning and acquisition of hardware and software in support of ORA's business priorities.
- C. Interacts with the Office of Information Management and Technology (OIMT) to discuss needs, service agreements, management and problem escalation.
- D. Researches, reviews, and manages new and innovative information technologies to support processes and policies having the potential to materially affect ORA capabilities, business models, or mission.
- E. Manages and coordinates enterprise-wide information technology development and support across ORA.
- F. Develops and maintains a business and IT solution architecture for ORA.
- G. Manages ORA's Information Technology Capital Planning and Investment Control Process.

2. Solutions Planning Branch (DCIKC1).

- A. Develops and maintains ORA's IT road maps and business plans for ORA.
- B. Manages design review activities across ORA IT Projects and programs ensuring proposed technical design solutions will effectively and efficiently meet the business needs of ORA.

- C. Gathers ORA customer-specific business needs, translates needs into requirements and communicates the needs to OIMT.
- D. Coordinates hardware and software purchases and ORA IT Portfolio with OIMT. Escalates ORA IT service requests and issues, and triages problems.
- E. Supports enterprise-wide and high priority ORA IT system development projects. Coordinates with other divisions and OIMT to ensure system development is aligned to regulatory and legislative authorities.
- F. Manages and provides system administrative support for the Quality Management Information System.

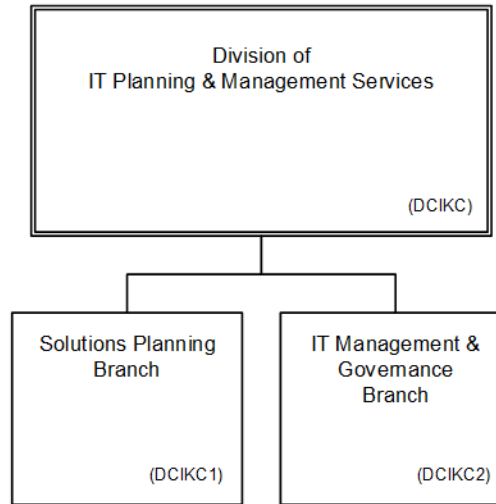
3. IT Management and Governance Branch (DCIKC2).

- A. Manages ORA IT Portfolio acquisition planning and provides office Contracting Officer Representatives information and best practices for proposed, existing and expiring contracts, interagency agreements and related financial responsibilities.
- B. Coordinates and manages ORA's IT Investment Review Board (ITIRB). Manages ORA's IT Portfolio and provides Capital Planning and Investment Control (CPIC) functions to ensure that all IT initiatives are managed with sound life cycle management principles and practices consistent with the agency policies and procedures.
- C. Provides Investment Management services for Administrative and Regulatory Business Information Services (RBIS) Investments supporting ORA.
- D. Reviews and/or formulates new program/project management standards. Provide additional Project/Program Management support to new IT projects.
- E. Provides guidance to assist in formulation of IT policies and procedures and/or review of impact of operational or external policy and procedures to IT systems.
- F. Provides human resource, communications and other administrative support functions to support OISM operations and responsibilities.

4. Authority and Effective Date.

The functional statements for the Division of IT Planning and Management Services were approved by the Deputy Secretary of Health and Human Services on December 22, 2021, and effective on February 9, 2022.

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Information Systems Management
Division of IT Planning and Management Services**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Information Systems Management, Division of IT Planning and Management Services organization structure depicting all the organizational structures reporting to the Director:

Solutions Planning Branch (DCIKC1)

IT Management and Governance Branch (DCIKC2)