

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

Effective Date: February 9, 2022

1. Office of Information Systems Management (DCIK).

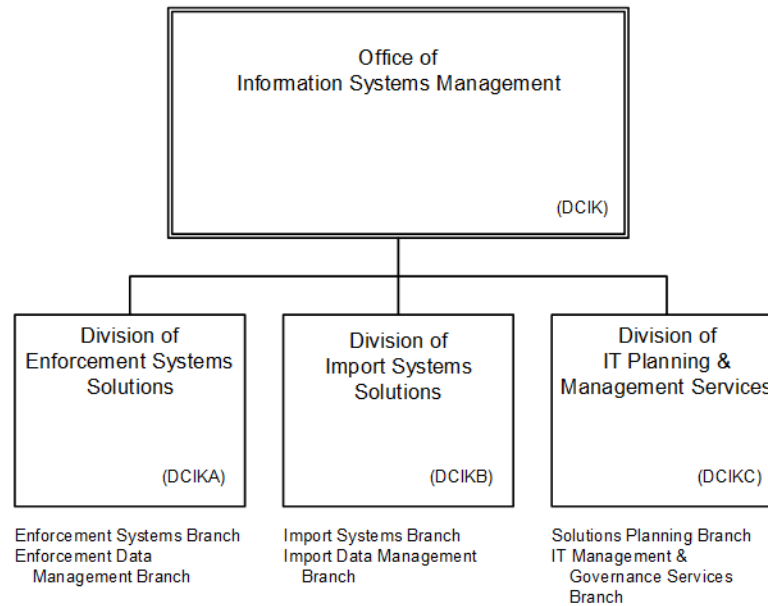
- A. Provides advice and counsel to the Associate Commissioner for Regulatory Affairs (ACRA), Deputy ACRA and other senior management officials on all matters related to ORA's information technology needs, systems development, and related budgetary issues.
- B. Leads and coordinates information system and technology management activities across ORA.
- C. Identifies, develops, evaluates and prioritizes business needs in relation to current and planned information technology systems, data standards, reporting and visualization functions in partnership with internal clients in ORA offices, field offices and laboratories as well as partners external to ORA.
- D. Serves as the focal point for data requests associated with ORA operational data emanating from ORA mission critical systems.
- E. Facilitates ORA IT-related hardware and software requests and interactions with the FDA Office of Information Management and Technology (OIMT).
- F. Translates business priorities into a single, organization-wide portfolio of information systems and technology initiatives that are delivered through strategic partnerships with OIMT.
- G. Provides IT portfolio spend planning and budget support services for all acquisitions and discretionary spending accounts for ORA IT Operations and OISM.
- H. Develops long-range strategic plans for ORA's information technology infrastructure and systems.

- I. Solicits feedback from end-users throughout ORA to achieve efficiencies within IT systems and to ensure customer needs are met.
- J. Evaluates new policies and regulations for impacts to ORA IT systems.
- K. Coordinates and manages ORA's IT Investment Review Board (ITIRB) and Change Control Boards (CCBs). 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.

2. Authority and Effective Date.

The functional statements for the Office of Information Systems Management were approved by the Deputy Secretary for 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**



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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 organization structure depicting all the organizational structures reporting to the Director:

Division of Enforcement Systems Solutions (DCIKA)

Division of Imports Systems Solutions (DCIKB)

Division of IT Planning and Management Services (DCIKC)

These organizations report to the Division of Enforcement Systems Solutions:

Enforcement Systems Branch (DCIKA1)

Enforcement Data Management Branch (DCIKA2)

These organizations report to the Division of Imports Systems Solutions:

Import Systems Branch (DCIKB1)

Import Data Management Branch (DCIKB2)

These organizations report to the Division of IT Planning and Management Services:

Solutions Planning Branch (DCIKC1)

IT Management and Governance Services Branch (DCIKC2)