

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 Partnerships and Operational Policy

Office of Information Systems Management

Effective Date: December 14, 2018

1. Office of Information Systems Management (DCIHD).

- A. Provides direction and counsel to the Associate Commissioner for Regulatory Affairs (ACRA), Deputy ACRA and other senior management officials on all matters related to the Office of Regulatory Affairs (ORA) information technology (IT) needs, systems development, and related budgetary issues.
- B. Leads and coordinates information system and technology management activities across ORA.
- C. 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. Facilitates ORA IT-related hardware and software requests and interactions with the FDA Information Management and Technology (IMT) program.
- E. Translates business priorities into a single, organization-wide portfolio of information systems and technology initiatives that are delivered through strategic partnerships with FDA's IMT program.
- F. Develops long-range strategic plans for ORA's IT infrastructure and systems.
- G. Solicits feedback from end-users throughout ORA to achieve efficiencies within IT systems and to ensure customer needs are met.
- H. Evaluates new policies and regulations for impacts to ORA IT systems.

- I. 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.

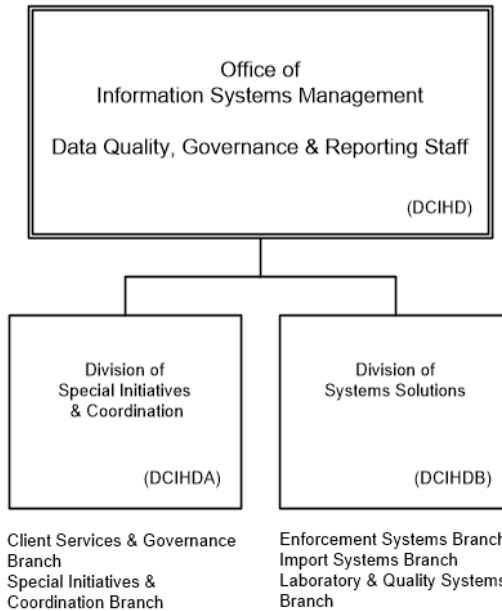
2. Data Quality, Governance and Reporting Staff (DCIHD1)

- A. Plans, develops and manages data management and governance functions.
- B. Plans and supports the development of systems to collect and disseminate ORA regulatory industry information via robust data warehouse, business intelligence and data mining technologies and data exchange platforms.
- C. Represents users in the development and enhancement of ORA's data warehouses, regulatory information databases and data exchange platforms.
- D. Provides expertise and knowledge in the development of queries and data extraction from enterprise systems and serves as subject matter experts and business analysts for integrating cross-program data.
- E. Determines quality assurance standards for accurate information collection and retrieval.
- F. Develops quality control checks on information entered in ORA's regulatory information databases.
- G. Provides training and guidance for regulatory information database users in collaboration with other ORA offices.
- H. Coordinates and collaborates with stakeholders to ensure data configuration and data sets optimize resources and reduce inaccuracies in a rational and repeatable way.
- I. Works with third party data providers to improve data quality and accuracy.

3. Authority and Effective Date.

The functional statements for the Office of Information Systems Management were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Partnerships and Operational Policy
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 Partnerships and Operational Policy, Office of Information Systems Management organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Office of Information Systems Management (DCIHD):

Data Quality, Governance & Reporting Staff

Division of Special Initiatives & Coordination (DCIHDA)

Division of Systems Solutions (DCIHDB)

These organizations report to the Division of Special Initiatives & Coordination (DCIHDA)

Client Services & Governance Branch

Special Initiatives & Coordination Branch

These organizations report to the Division of Systems Solutions (DCIHDB)

Enforcement Systems Branch

Import Systems Branch

Laboratory & Quality Systems Branch