### SMG 1111.511

## FDA Staff Manual Guides, Volume I – Organizations and Functions

Food and Drug Administration

Office of the Commissioner

Office of Digital Transformation

Office of Information Management and Technology

Office of Technology and Delivery

Effective: August 24, 2021

### 1. Office of Technology and Delivery (DCADAA).

- A. Coordinates and partners with the Chief Information Officer (CIO) and Chief Technology Officer (CTO) in development and maintenance of Food and Drug Administration (FDA) policies and procedures for independent verification and validation of Information Technology (IT) systems.
- B. Partners with the Department and other interagency groups to guide and align FDA to government-wide initiatives regarding information security, technologies and mandates.
- C. Manages Disaster Recovery and Continuity of Operations Plan (COOP) activities.
- D. Designs, deploys, monitors, and operates infrastructure hardware and software including servers, storage, network, and security devices and infrastructure management related software.
- E. Designs, develops, implements, and maintains FDA software applications, Commercial Off-The-Shelf (COTS) software, Information Technology (IT) systems, systems support and maintenance, and their integration by utilizing sanctioned plans such as cloud computing, incremental deliveries, and structured governance principles.
- F. Establishes and implements an Enterprise IT Common Component Framework containing modules/services to be shared across information systems and maintains enterprise applications to support FDA business processes and objectives.
- G. Manages, coordinates, and communicates changes for FDA's computing environment.
- H. Performs oversight and manages the master schedule.

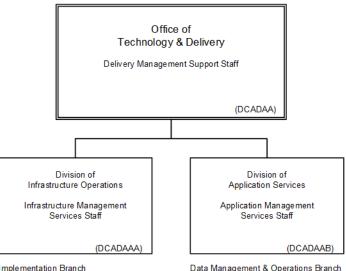
# 2. Delivery Management Support Staff (DCADAA1)

- A. Ensures transparency into IT Operations and ensures delivery of IT product and service needs.
- B. Provides, manages, coordinates and communicates changes to FDA's computing environments.
- C. Manages all infrastructure changes and configuration items and assets throughout the lifecycle of a system.
- D. Manages the information technology service request known as Intake.

# 3. Authority and Effective Date

The functional statements for the Office were approved by the Acting Commissioner of Food and Drugs on July 22, 2021 and effective on August 24, 2021.

# Department of Health and Human Services Food and Drug Administration Office of the Commissioner Office of Digital Transformation Office of Information Management & Technology Office of Technology & Delivery



Implementation Branch Infrastructure Engineering Branch Systems Monitoring & Response Branch Systems Operations Branch Network & Communications Operations Branch Data Management & Operations Branch Medical Products Branch OC, CVM, CTP Branch ORA, CFSAN Branch Enterprise Applications Branch Staff Manual Guide 1111.511 Organizations and Functions Effective Date: August 24, 2021

The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of Digital Transformation, Office of Information Management and Technology, Office of Technology and Delivery organization structure depicting all the organizational structures reporting to the Director:

Office of Technology and Delivery (DCADAA)

**Delivery Management Support Staff** 

The organizations below report to the Office of Technology and Delivery (DCADAA):

Division of Infrastructure Operations (DCADAAA)

Division of Application Services (DCADAAB)

The organizations below report to the Division of Infrastructure Operations (DCADAAA):

Infrastructure Management Services Staff

Implementation Branch

Infrastructure Engineering Branch

Systems Monitoring and Response Branch

**Systems Operations Branch** 

**Network and Communications Operations Branch** 

The organizations below report to the Division of Application Services (DCADAAB):

**Application Management Services Staff** 

Data Management and Operations Branch

Medical Products Branch

OC, CVM, CTP Branch

ORA, CFSAN Branch

**Enterprise Applications Branch**