

**SMG 1121A.63**

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

**Department of Health and Human Services**

**Food and Drug Administration**

**Office of Inspections and Investigations**

**Office of Business Informatics and Solutions Management**

**Division of Solutions Planning, Management, and Governance**

Effective Date: May 13, 2024

**1. Division of Solutions Planning, Management, and Governance (DCSFD).**

- A. Manages the Investment Portfolio, acquisitions, budget, and governance for information technology (IT) related projects, business solutions, and initiatives supporting the Food and Drug Administration (FDA) Office of Inspections and Investigations (OII).
- B. Works in coordination and consultation with the FDA Office of Digital Transformation (ODT) to be consistent with enterprise-wide priorities.
- C. Manages OII's Information Technology Capital Planning and Investment Control Process and reporting requirements.
- D. Coordinates enterprise IT initiatives between OII and ODT and facilitates planning and acquisition of hardware and software in support of OII's business priorities.
- E. Interacts with the ODT to discuss IT and solutions needs, service agreements, management, and problem escalation.
- F. Research, reviews, and manages new and innovative business solutions to support processes and policies having the potential to materially affect OII capabilities, business models, or mission, in coordination with the Human Foods Program (HFP).
- G. Manages and coordinates solutions development and support across OII in coordination with the HFP.
- H. Develops and maintains a business and solution architecture, roadmaps, and business plans for OII, in coordination with the HFP.

- I. Complies with established guidelines for OII records management program and provides system administration for OII's quality management system.
- J. Manages administrative functions supporting OBISM operational activities.

**2. Integrated Management and Investments Branch (DCSFD1).**

- A. Manages OII IT and business solutions 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 OII's IT Investment Review Board. Manages OII's IT and business solutions portfolio and provides Capital Planning and Investment Control (CPIC) functions to ensure that all IT initiatives and business solutions are managed with sound life cycle management principles and practices consistent with FDA policies and procedures.
- C. Provides Investment Management services and certified Investment Managers all IT Investments for business solutions supporting OII.
- D. Reviews and/or formulates new program and project management standards. Provides business program and project Management support to new IT projects and business solutions.
- E. Provides guidance to assist in formulation of IT system and business solution policies and procedures and/or review of impact of operational or external policy and procedures to IT systems and business solutions.
- F. Provides human resource, property management, communications, and other administrative support functions to support the Office's operations and responsibilities.

**3. Program Solutions and Services Branch (DCSFD2).**

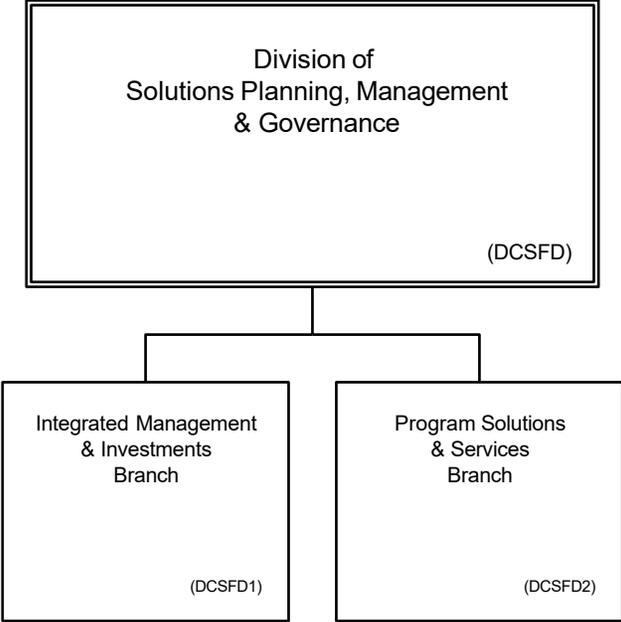
- A. Coordinates hardware and software purchases and OII Shared Services with ODT. Escalates and/or triages OII IT service requests and other reported issues.
- B. Collaborates with ODT on shared IT services, business solutions and security updates, advocating for all OII staff. Communicates HFP, Center, and office requirements to ensure staff are equipped with the tools and solutions needed to assist in conducting their work in support of Center and office missions.
- C. Maintains service agreements and manages changes dependent on trend analysis of usage and cost.

- D. Gathers OII customer-specific business needs, translates needs in requirements and communicates the needs to ODT.
- E. Manages and provides system administrative support for the internal OII Quality Management Information System.
- F. Manages system updates/upgrades, provides solutions for technical issues, and maintains timely system administrative support for the Quality Management Information System in support of OII's Quality Management program.
- G. Complies with established guidelines for the Records Management program for OII and provides information, tools, and solutions to Centers and offices ensuring compliance with records management Federal Regulations and National Archives and Records Management (NARA) mandate.

**4. Authority and Effective Date.**

The functional statements for the Division of Solutions Planning, Management and Governance were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

**Department of Health and Human Services  
Food and Drug Administration  
Office of Inspections and Investigations  
Office of Business Informatics' and Solutions Management  
Division of Solutions Planning, Management and Governance**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Inspections and Investigations, Office of Business Informatics' and Solutions Management, Division of Solutions Planning, Management and Governance organization structure depicting all the organizational structures reporting to the Director:

Integrated Management and Investments Branch (DCSFD1)

Program Solutions and Services Branch (DCSFD2)