

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Operations

Office of Security and Passport Operations

Effective Date: May 13, 2024

1. Office of Security and Passport Operations (DCNH).

- A. Provides leadership, oversight and collaboration of the Food and Drug Administration (FDA) security, passport and visa and Continuity of Operations programs by developing and implementing policies in coordination with Internal Service Providers, Health and Human Service (HHS) providers and other Federal Agency components.
- B. Leads and provides guidance to the FDA in managing and administering the suitability and security program as required by the Office of Personnel Management (OPM) as set forth in “Suitability” Code of Federal Regulation (5 CFR Part 731) “National Security Positions” (5 CFR, Part 732), Defense Counterintelligence and Security Agency (DCSA) and HHS policies and procedures.
- C. Provides oversight and leadership for coordination of response to emergencies involving FDA-regulated products to include natural, technological, continuity and security related disasters.
- D. Responsible for developing and implementing FDA-wide security, passport operations, and international travel policies, programs initiatives in coordination with HHS and FDA product Centers and Offices.
- E. Provides oversight and coordination to ensure security of classified and sensitive documents in FDA facilities and the management of transfer for documents.
- F. Provides leadership and oversight to the FDA Continuity of Operations Program (COOP) in accordance with Executive Order 12656, Assignment of Emergency Preparedness Responsibilities; Presidential Policy Directive-40, National Continuity Policy; Federal Continuity Directive 1, Federal Executive

Branch National Continuity Program and Requirements, January 2017, and HHS Continuity of Operations Policy, April 2018.

- G. Provides oversight and manages the Food and Drug Administration's nationwide Communications Security (COMSEC) program that safeguards classified information over telecommunication systems and equipment in accordance with National Security Directives.
- H. Provides security policies and procedures for the non-disclosure of national Security Information (NSI), Personally Identifiable Information (PII), and Confidential Business Information (CBI) in the possession of the FDA.
- I. Manages FDA's Drug-Free Workplace Program and coordinates drug testing activities, in collaboration with FDA human resources component and HHS security and drug testing officials.

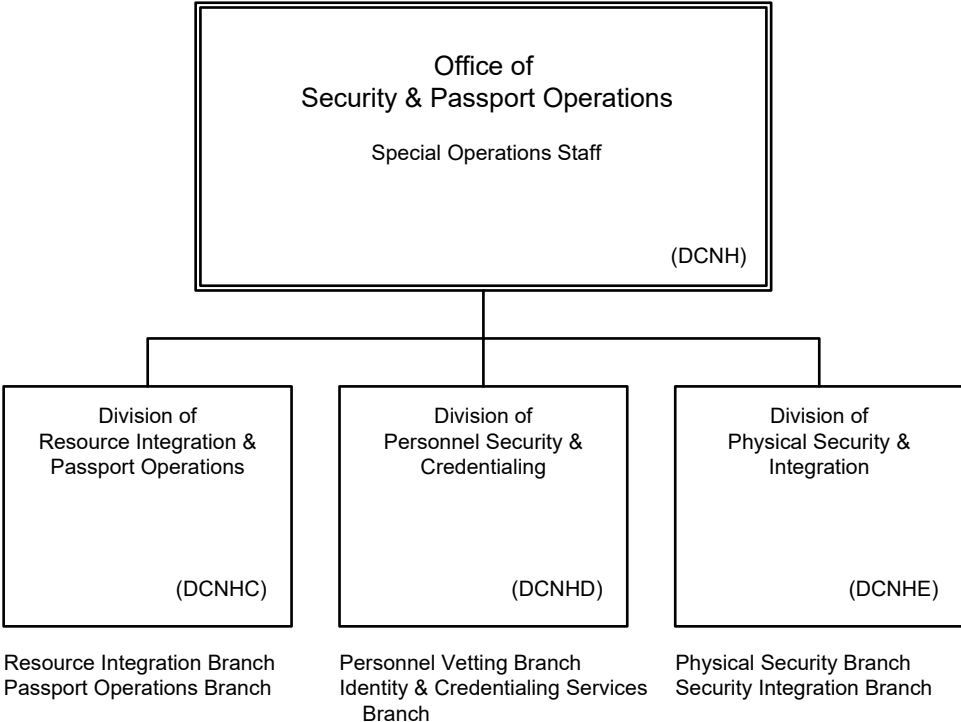
2. Special Operations Staff (DCNH1).

- A. Protects classified government information; manages sensitive compartmented information facilities (SCIF); and investigates and reports security violations and incident reports.
- B. Develops, implements, and monitors the Office of the Director of National Intelligence sensitive compartmented information, special security policies and procedures; ensures compliance with all aspects of the classified information/national security program.
- C. Promote a "whole of FDA" approach to Continuity and integrate a mission continuity mindset into daily activities and ensure the continuous performance of FDA's Mission Essential Functions (MEFS).
- D. Coordinates security review of all visitors requesting access to FDA facilities utilizing Visitor Management System.
- E. Manages and administers FDA's Emergency Notification System, AlertFDA.
- F. Responsible for maintaining accountability and safeguarding FDA's secured telecommunication systems and equipment.

3. Authority and Effective Date.

The functional statements for the Office of Security and Passport Operations 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 Operations
Office of Security and Passport Operations**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Operations, Office of Security and Passport Operations organization structure depicting all the organizational structures reporting to the Director:

Special Operations Staff

Division of Resource Integration and Passport Operations (DCNHC)

Division of Personnel Security and Credentialing (DCNHD)

Division of Physical Security and Integration (DCNHE)

These organizations report to the Division of Resource Integration and Passport Operations (DCNHC):

Resource Integration Branch

Passport Operations Branch

These organizations report to the of Division of Personnel Security and Credentialing (DCNHD):

Personnel Vetting Branch

Identity and Credentialing Services Branch

These organizations report to the of Division of Physical Security and Integration (DCNHE):

Physical Security Branch

Security Integration Branch