

SMG 1117A.9

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 Emergency Management

Effective Date: December 14, 2018

1. Office of Security and Emergency Management (DCNH).

- A. Provides leadership, oversight, and collaboration of the Food and Drug Administration's (FDA) security and emergency management programs by developing and implementing policies in coordination with internal Service Providers, Health and Human Service (HHS) Service Providers and other Federal Agency components.
- B. Provides oversight and leadership to the FDA for all aspects of physical and personnel security including the suitability and implementation of the National Security Information Program.
- C. Provides management oversight by developing and implementing FDA-wide security and emergency management policy, programs and initiatives and coordinates with Department and FDA components.
- D. Manages and administers the suitability and security program as required by the Office of Personnel Management as set forth in "Suitability" (5 CFR Part 731), and "National Security Positions" (5 CFR, Part 732).
- E. Provides oversight and leadership for coordination of response to emergencies involving FDA-regulated products, including natural and technological disasters.
- F. Provides oversight and leadership for the development and management of emergency preparedness and response policies, procedures, and programs needed to respond rapidly to emergency situations.
- G. Provides oversight and coordination to ensure security of classified and sensitive documents in Agency facilities and the management of transfer for documents.

- 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. Develops and provides oversight for strategic plans and the implementation of emergency management, security operations, and safety initiatives and requirements.
- J. Develops, implements, and provides oversight for Continuity of Operations Plans (COOP) Program.
- K. Serves as the focal point for the FDA and the final clearing authority for policies and procedures pertaining to international travel.

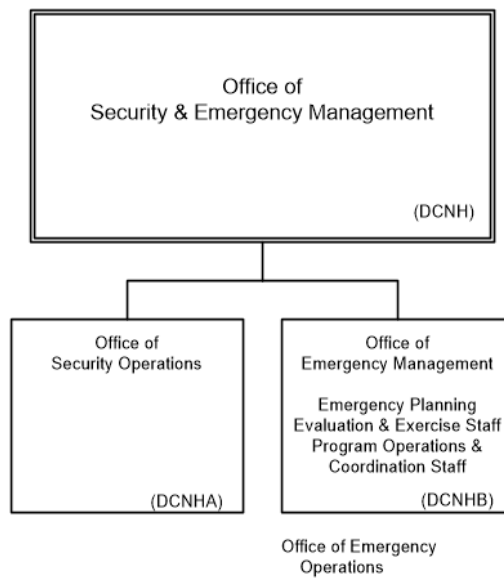
Administrative and Passport Program

- a. Provides direction and leadership for all internal Office of Security and Emergency Management (OSEM) administrative programs and initiatives.
- b. Manages the day-to-day operations for the Office administration programs such as human resources (HR) and personnel, budget, facilities, etc.
- c. Manages and initiates all FDA financial requirements for budget execution and formulation in the OSEM.
- d. Provides direction and implements international travel policies, initiatives, and training for the Passport and VISA program.
- e. Provides direction and acts as the focal point for the FDA and the final clearing authority for policies and procedures pertaining to international travel.
- f. Ensures compliance of all international requirements by FDA Travelers, as stated and, directed by the Department of State and other federal Agencies relating to international travel.
- g. Develops, manages, and implements the Continuity of Operations Plans (COOP) Program for the Office of the Commissioner.
- h. Provides directions, ensures compliance, and oversight for the COOP.

2. Authority and Effective Date.

The functional statements for the Office of Security and Emergency 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 Operations
Office of Security and Emergency Management**



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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 Emergency Management organization structure depicting all the organizational structures reporting to the Director.

These organizations below report to the Office of Security and Emergency Management (DCNH)

Office of Security Operations (DCNHA)

Office of Emergency Management (DCNHB)

These organizations below report to the Office of Emergency Management (DCNHB)

Emergency Planning Evaluation and Exercise Staff

Program Operations and Coordination Staff

Office of Emergency Operations