

**FDA STAFF MANUAL GUIDES, VOLU ME I – ORGANIZATIONS AND  
FUNCTIONS**

**FOOD AND DRUG ADMINISTRATION**

**OFFICE OF OPERATIONS**

**OFFICE OF SECURITY AND EMERGENCY MANAGEMENT**

**OFFICE OF EMERGENCY MANAGEMENT**

Effective Date: September 30, 2016

**1. OFFICE OF EMERGENCY MANAGEMENT (DMMJB).**

- A. Serves as the first responder for the Agency in emergency and crisis situations involving Agency related products.
- B. Assists in the development and management of emergency crisis management security operations and safety policies and programs to ensure that a structure exists to respond rapidly to an emergency or crisis situation.
- C. Serves as Agency Emergency Coordinator and Department by providing situational awareness and compliance for emergencies and operational procedures.
- D. Participates in international initiatives to ensure capability and readiness with foreign counterparts in responding to international emergencies involving or impacting Agency-regulated products and sharing information with international counterparts during such emergencies.
- E. Manages the FDA Emergency Operations Network Incident Management System (EON IMS), to capture real time information about emergencies related to Agency-regulated products.
- F. Develops and updates Agency emergency operations plans and incident specific annexes, ensuring their alignment and compliance with the National Response Framework and its Emergency Support Functions (NRF) and the National Incident Management System (NIMS).
- G. Plans, coordinates, and executes the Agency's participation in intra- and inter-Agency exercises.

- H. Develops and implements Agency training goals and initiatives to ensure emergency response staff and senior officials are informed and comply with operational requirements.
- I. Oversees FDA Emergency Operations Call Center (EOC) to ensure responses to emergencies or events involving Agency-regulated products are in compliance.
- J. Oversees the EOC to provide after-hours service for responding to public inquiries and reports for Agency-regulated products.
- K. Coordinates Agency evaluation of emergency responses and crisis situations to determine appropriate internal and external referral for further action and recommended changes in Agency procedures.
- L. Oversees and tests the Agency's ability to communicate through the Government Electronic Telecommunications Service (GETS) which provides global telecommunications (secure voice, facsimile and data communications) capability for organizations that perform national security and emergency preparedness functions.

## **2. Emergency Planning, Exercises, and Evaluation Staff (DMMJB1)**

- A. Responds to emergencies which pose a significant risk to public health and which involve or impact Agency-regulated products.
- B. Develops and updates the FDA Emergency Operations Plan (EOP), incident-specific annexes to it and other agency emergency planning and preparedness documents.
- C. Plans and conducts Agency exercises to test emergency operations plans. Plans and coordinates in emergency exercises sponsored by HHS and other Departments and Agencies, including national and international level Plans, coordinates, and executes the Agency's participation in intra- and inter-Agency exercises.
- D. Develops and implements policies and procedures for evaluation and after action review of exercises and significant incidents.
- E. Conducts the evaluations of exercises and the Agency's response to actual events, areas for improvements, and recommendations to improve and strengthen the Agency's preparedness for future emergencies.
- F. Provides logistics, finance, and administrative support during Incident Management Groups established to respond to emergencies and events involving Agency-regulated products.

- G. Manages the EON IMS to capture information about emergencies related to Agency-regulated products.
- H. Provides budget execution and formulation, human resources, website management, project management, and other administrative support

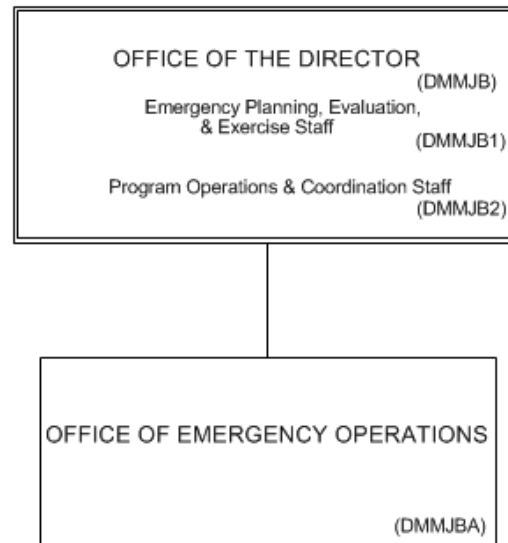
**3. Program Operations and Coordination Staff (DMMJB2).**

- A. Provides administrative, financial, project management, logistical, and Geographic Information Systems support in response to emergencies which pose a significant risk to public health and which involve or impact Agency-regulated products.
- B. Provides mapping capabilities that strengthen the Agency's overall immediate response efforts and its ability to analyze data effectively.
- C. Manages the EOC to monitor emergency situations, triage complaints and alerts, issue mission assignments to organizational components, coordinate overall Agency response operations, and communicate with external partners requesting technical and material support.
- D. Manages the EOC to ensure responses to emergencies or events involving Agency-regulated products are in compliance.
- E. Provides EOC support by serving as the central point for other Federal, tribal, state and local EOCs as appropriate.

**4. AUTHORITY AND EFFECTIVE DATE.**

The functional statements for this Office were approved by the Secretary, Human and Health Services and effective on September 30, 2016.

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ORGANIZATIONS AND FUNCTIONS  
EFFECTIVE DATE: September 30, 2016

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

OFFICE OF THE DIRECTOR (DMMJB):

- Emergency Planning, Exercises, and Evaluation Staff (DMMJB1)
- Program Operations and Coordination Staff (DMMJB2)
- OFFICE OF EMERGENCY OPERATIONS (DMMJBA)

[Back to Organizations and Functions, Volume I \(1000-1300\)](#)