

## **SMG 1119A.3**

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

#### **Department of Health and Human Services**

##### **Food and Drug Administration**

###### **Office of the Commissioner**

###### **Office of the Chief Scientist**

###### **Office of Laboratory Safety**

Effective Date: December 14, 2018

#### **1. Office of Laboratory Safety (DCPB).**

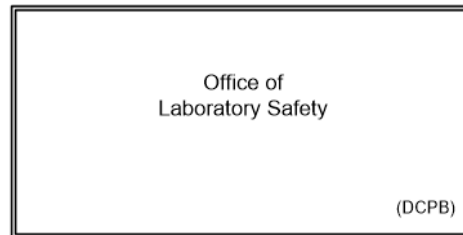
- A. Provides executive leadership in the area of laboratory science, laboratory security, laboratory related environmental and occupational safety and health programs. This includes: developing, centralizing, standardizing, and implementing policies, planning, directing, managing and evaluating activities for these programs, and implementing best practices across the Food and Drug Administration (FDA).
- B. Provides oversight and monitoring for FDA's laboratory science, laboratory security, laboratory related environmental and occupational safety and health programs. This includes:
  - a. Determining the appropriate measures the FDA must take to comply with Federal, State, local and FDA regulatory standards, policies, and other requirements.
  - b. Ensuring that FDA is in compliance with Federal, State, local and FDA regulatory standards, policies, and other requirements.
  - c. Developing and implementing policy and guidance as needed to address Federal, State, local and FDA regulatory standards, policies, and other requirements.
  - d. Conducting and overseeing risk based assessments/audits of laboratory safety issues and activities to evaluate compliance; and
  - e. Developing, implementing, and coordinating a robust laboratory quality management system for adoption across the FDA.

- C. Provides executive representation on intra and interagency committees, workgroups, and taskforces in support of FDA's laboratory science, laboratory security, laboratory related environmental and occupational safety and health programs.
- D. Identifies and addresses the training and education needs of FDA staff with respect to FDA's laboratory science, laboratory security, laboratory related environmental and occupational safety and health programs.
- E. Funds appropriate applied research to enhance the FDA's laboratory science, laboratory security, laboratory related environmental and occupational safety and health programs.
- F. Provides executive leadership during emergency situations, particularly with incidents originating in the laboratory to ensure adherence to Federal, State, local and FDA regulatory standards, policies, and other requirements, in coordination with the External Affairs program.

**2. Authority and Effective Date.**

The functional statements for the Office of Laboratory Safety 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 the Commissioner  
Office of the Chief Scientist  
Office of Laboratory Safety**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Chief Scientist, Office of Laboratory Safety organization structure depicting all the organizational structures reporting to the Director.

Office of Laboratory Safety (DCPB)