

**FDA STAFF MANUAL GUIDES, VOLUME I – ORGANIZATIONS AND
FUNCTIONS**

FOOD AND DRUG ADMINISTRATION

OFFICE OF THE COMMISSIONER

OFFICE OF LABORATORY SCIENCE AND SAFETY

Effective Date: September 30, 2016

1. OFFICE OF LABORATORY SCIENCE AND SAFETY (DAZ).

- A. Provides executive leadership in the area of laboratory science, laboratory security, 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 Agency.
- B. Provides oversight and monitoring for FDA's laboratory science, laboratory security, environmental, and occupational safety and health programs. These oversight and monitoring activities include:
 - 1. determining the appropriate measures the Agency must take to comply with federal, state, local, and Agency regulatory standards, policies, and other requirements;
 - 2. ensuring that the Agency is in compliance with federal, state, local, and Agency regulatory standards, policies, and other requirements;
 - 3. developing and implementing policy and guidance as needed to address federal, state, local, and Agency regulatory standards, policies, and other requirements;
 - 4. conducting and overseeing routine and ad-hoc inspections to evaluate compliance; and
 - 5. developing, implementing, and overseeing a robust laboratory quality management system for adoption across the Agency.
- C. Provides executive representation on intra- and interagency committees, work groups, and taskforces in support of FDA's laboratory science, laboratory security, environmental, and occupational safety and health programs.

- D. Identifies and addresses the training and education needs of Agency staff with respect to FDA's laboratory science, laboratory security, environmental, and occupational safety and health programs.
- E. Funds appropriate applied research to enhance the FDA's laboratory science, laboratory security, 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 Agency regulatory standards, policies, and other requirements, in coordination with the Office of External Affairs.

2. EMPLOYEE SAFETY AND ENVIRONMENTAL MANAGEMENT STAFF (DAZ1)

- A. Manages the Agency's environmental and occupational safety and health program, including the process to establish and implement a consolidated operational environmental and occupational safety and health program at White Oak.
- B. Provides guidance and assistance to the Agency operating activities on a variety of environmental and occupational safety and health program initiatives.
- C. Develops and implements program plans, policies, and procedures designed to create and maintain a safe and healthful environment for Agency employees, visitors, and guest workers, and to protect the environment.
- D. Develops Agency plans, policy, and procedures consistent with environmental and occupational safety and health regulatory requirements, HHS policy and Agency needs.
- E. Provides fire protection, safety engineering, and environmental health consultation to the Agency's program managers and engineering offices.
- F. Leads the Agency's decommissioning efforts to close Agency laboratories and offices from an environmental and occupational safety and health perspective.
- G. Provides consultative services on safety matters pertaining to changing and emerging research programs.

3. AUTHORITY AND EFFECTIVE DATE.

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

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STAFF MANUAL GUIDE 1115.1a
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: September 30, 2016

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

OFFICE OF THE DIRECTOR:

- EMPLOYEE SAFETY AND ENVIRONMENTAL MANAGEMENT STAFF (DAZ1)

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