

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 Occupational Safety and Health

Effective Date: May 13, 2024

1. Office of Occupational Safety and Health (DCPG).

- A. Provides direction and oversees the Food and Drug Administration’s (FDA) occupational safety and health program activities and operations.
- B. Establishes, develops, implements, and evaluates occupational safety and health-related program plans, policies, and procedures, and provides training and outreach, designed to create and maintain a safe and healthful workplace for FDA employees, visitors, and guest workers.
- C. Manages operations for FDA occupational health units, including related records management functions.
- D. Promotes a culture of responsibility and safety to continuously improve and enhance the practice of good and safe workplace and laboratory practices.
- E. Determines the appropriate programmatic occupational safety and health improvements to facilitate compliance with relevant laws and regulations, Health and Human Services (HHS) policy, and FDA needs.
- F. Provides representation on intra- and inter-agency committees, workgroups, and task forces related to occupational safety and health program activities and environmental management programs.
- G. Funds appropriate applied research in support of program objectives (subject to funding availability).
- H. Provides leadership support during emergency situations, particularly with incidents originating in the laboratory, in coordination with other FDA components.

- I. Carries out these activities in collaboration with FDA Centers and Offices.

2. Occupational Safety Staff (DCPG1).

- A. Develops and implements occupational safety and health related manuals, plans, guides, and training, to include work in FDA laboratories, for FDA staff to leverage and use to ensure compliance and exercise best safety practices.
- B. Conducts and oversees inspections of laboratory work practices and workplaces, as per 29 Code of Federal Regulations (CFR) 1960.25(c).
- C. Provides guidance and assistance with FDA environmental compliance, audit, and management activities.
- D. Manages the Institutional Biosafety Committee to ensure compliance with the National Institutes of Health Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules, the Dual Use Research of Concern Review Entity to ensure compliance with United States Government policy, and Enhanced Potential Pandemic Pathogen Review to ensure compliance with HHS policy.
- E. Works with the Occupational Health Services Staff and other FDA components to develop and maintain inventory control and information management systems to enhance occupational safety and health operations.
- F. Coordinates and supports the implementation of laboratory quality management systems across the FDA, as needed.
- G. Supports laboratory-related security (not physical security), which is the protection, control of, and accountability for hazardous materials and information within laboratories to prevent unauthorized access, possession, loss, theft, misuse, diversion, manipulation, and/or intentional release.
- H. Supports the FDA's decommissioning efforts to close FDA laboratories and offices from an occupational safety and health perspective.
- I. Provides fire protection, safety engineering, and occupational health consultation to the FDA's program managers and engineering offices.

3. Occupational Health Services Staff (DCPG2).

- A. Manages operations for FDA occupational health units, ergonomics assessment program, and automated external defibrillator (AED) program, including related records management functions.
- B. Develops, manages, and maintains the occupational safety and health incident reporting portal and performs trend analysis of reported incidents.

- C. Works with the Occupational Safety Staff and other FDA components to develop and maintain inventory control and information management systems to enhance occupational safety and health operations.
- D. Provides guidance and assistance on a variety of FDA occupational safety and health program initiatives.
- E. Coordinates with FDA's Chief Medical Officer regarding clinical activities, as appropriate.

4. Authority and Effective Date.

The functional statements for the Office of Occupational Safety and Health 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 the Chief Scientist
Office of Occupational Safety and Health**

Office of
Occupational Safety and Health

Occupational Safety Staff
Occupational Health Services Staff

(DCPG)

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

Occupational Safety Staff (DCPG1)

Occupational Health Services Staff (DCPG2)