

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

OFFICE OF COMMUNICATION AND EDUCATION

Effective Date: 03/27/2014

1. OFFICE OF COMMUNICATION AND EDUCATION (DKKWG).

- A. Controls the resource management activities of the Office.
- B. Provides, maintains, and applies expertise in communications technology in support of Center and Food and Drug Administration (FDA) programs.
- C. Develops and implements strategies for obtaining, analyzing, and incorporating the views and needs of health professionals, lay device users, and industry into the Center policy and decision-making processes as well as in problem analysis, resolution strategy development, implementation, and evaluation processes.
- D. Develops and manages Center for Devices and Radiological Health (CDRH) internal communications, including the CDRH website and multimedia productions.
- E. Develops and manages CDRH external communications, including the CDRH website and multimedia productions.
- F. Provides educational programs for to Center employees to enhance their ability to support the CDRH mission.
- G. Coordinates Center activities pertaining to information disclosure including freedom of information requests, the Privacy Act and records management.
- H. Provides technical and non-financial assistance to small manufacturers of medical devices to facilitate compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, regarding medical devices and radiation-emitting products.
- I. Provides non-financial assistance to patients and consumers of medical devices and radiation-emitting products.

J. Provides education to domestic and foreign industry and governments about medical devices and radiation-emitting products.

K. Manages the Small Business Qualification and Certification Program for CDRH.

2. PROGRAM MANAGEMENT OPERATIONS STAFF (DKKWG1).

A. Directs, coordinates and controls the resource management activities of the Office. Coordinates and provides analysis, execution and evaluation of business operations; coordinates and carries out transactions needed to ensure the effective operation of business needs including human capital, performance management, budget formulation, procurement, facilities and information technology management.

B. Directs the CDRH Executive Secretariat function. Responsible for developing reports for FDA and Department of Health and Human Services (HHS) regarding Center activities and managing all incoming and outgoing congressional, HHS, FDA or Center tracked correspondence.

C. Directs CDRH's Meeting Management activities, including providing conference room scheduling and audio visual services for meetings and training events at the White Oak campus.

D. Coordinates and manages all public meetings hosted by CDRH including registration, procurement services and on-site support.

E. Coordinates all requests for CDRH speakers for external events.

3. DIGITAL COMMUNICATION MEDIA STAFF (DKKWG4).

A. Manages the CDRH video production studio facility.

B. Researches and evaluates suitable multimedia communications for client and stakeholder needs such as Public Service Announcements, internal and external training video programs, live and On-Demand webcasts, live remote telepresence for meetings, and satellite media tours.

C. Collaborates with Center and FDA staff to produce communication products that meet FDA objectives, contain sound medical and scientific standards, and are technically sound.

D. Provides design and execution of multimedia communication, including but not limited to videos, webcasts and podcasts and disseminates information and/or training to the FDA field, State health departments, other Federal agencies, health professionals and the medical device industry.

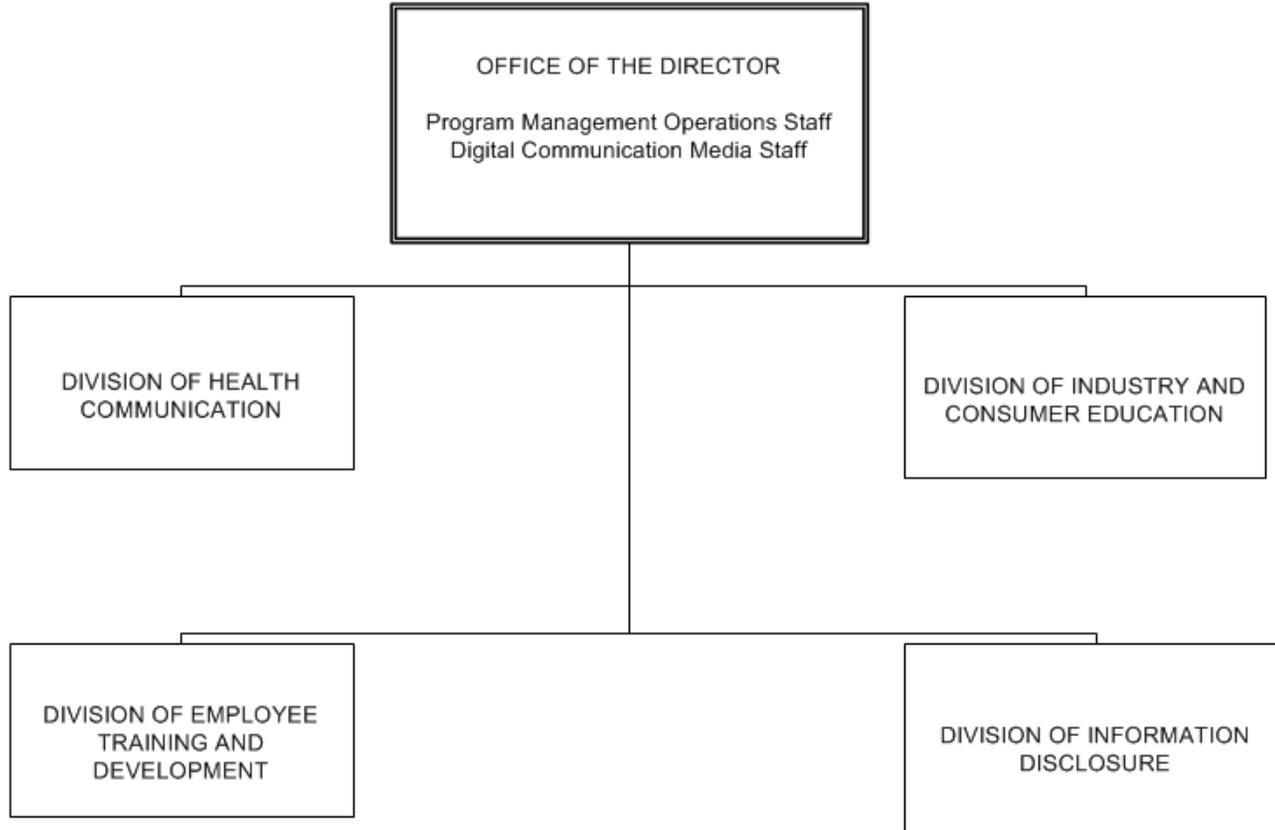
E. Provides digital media support to the agency including purchase, installation, inventory, maintenance and operation of equipment.

F. Provides video services to FDA and other federal agencies.

4. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Director, Center for Devices and Radiological Health on March 27, 2014.

**FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF COMMUNICATION AND EDUCATION**



Staff Manual Guide 1255.1
Organizations and Functions
Effective Date: March 27, 2014

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of Communication and Education organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF THE DIRECTOR:

- Program Management Operations Staff
- Digital Communication Media Staff
- DIVISION OF HEALTH COMMUNICATION
- DIVISION OF INDUSTRY AND CONSUMER EDUCATION
- DIVISION OF EMPLOYEE TRAINING AND DEVELOPMENT
- DIVISION OF INFORMATION DISCLOSURE