**SMG 1250.1**

# 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

Effective Date: 07/08/2011

## 1. CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (DW).

A. Develops and carries out a national program designed to control unnecessary exposures of humans to, and assure the safe and efficacious use of, ionizing and nonionizing radiation-emitting electronic products

B. Develops and carries out a national program to assure the safety, effectiveness, and labeling of medical devices for human use

C. Plans, conducts, and supports research and testing to provide the scientific and technological base required for risk assessment, evaluation, compliance, and performance standards development relating to medical devices and radiation-emitting electronic products

D. Collects information about inquiries and other experience in the use of medical devices and radiation-emitting electronic products and uses this information in Center activities

E. Reviews and evaluates medical device premarket approval applications (PMAAs), product development protocols (PDPs), exemption requests for investigational devices (IDEs), and premarket notifications (510(k)s)

F. Develops, promulgates, and enforces performance standards for radiation-emitting electronic products and medical devices, and Good Manufacturing Practice (GMP) regulations

G. Develops, directs, evaluates, and monitors compliance and surveillance programs for medical devices and radiation-emitting electronic products

H. Provides technical and other nonfinancial assistance to small manufacturers of medical devices

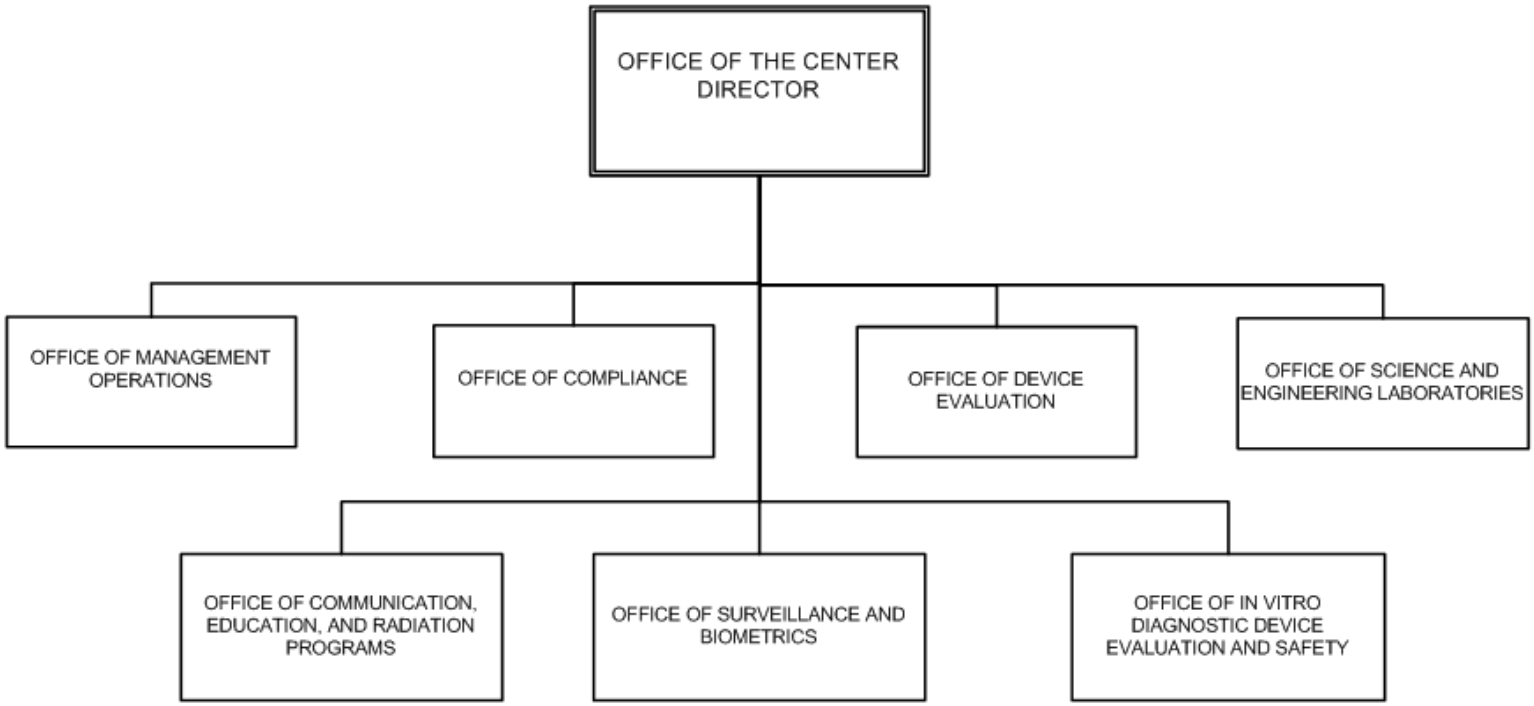
I. Develops and implements training and educational programs relating to radiological health and medical device issues for other Federal, State, and local agencies, the professional community, consumers, and the public

## 2. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Center were approved by the Secretary of the Department of Health and Human Services, effective July 8, 2011.

| STATUS (I, R, C) | DATE APPROVED | LOCATION OF CHANGE HISTORY | CONTACT | APPROVING OFFICIAL |
|---|---|---|---|---|
| Initial | 07/08/2011 | N/a | OO/OM | Secretary of the Department of Health and Human Services |

# FOOD AND DRUG ADMINISTRATION
# OFFICE OF MEDICAL PRODUCTS AND TOBACCO
# CENTER FOR DEVICES AND RADIOLOGICAL HEALTH



Staff Manual Guide 1250.1
Organizations and Functions
Effective Date: July 8, 2011

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

OFFICE OF THE CENTER DIRECTOR:

- OFFICE OF MANAGEMENT OPERATIONS
- OFFICE OF COMPLIANCE
- OFFICE OF DEVICE EVALUATION
- OFFICE SCIENCE & ENGINEERING LABORATORIES
- OFFICE OF COMMUNICATION, EDUCATION & RADIATION PROGRAMS
- OFFICE OF SURVEILLANCE BIOMETRICS
- OFFICE OF IN-VITRO DIAGNOSTIC DEVICE EVALUATION & SAFETY