

**SMG 1251.1**

**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**

**OFFICE OF THE CENTER DIRECTOR**

Effective Date: 07/08/2011

**1. OFFICE OF THE CENTER DIRECTOR (DKKWA)**

- A. Provides leadership and direction for the evaluation and coordination of the Center
- B. Provides advice and consultation to the Commissioner and other agency officials on policy matters concerning radiological health and medical device activities
- C. Recommends changes in legislative authority to the Office of the Commissioner
- D. Establishes policy in the areas of education and communications and formulates strategies for developing and disseminating educational and programmatic information to health professionals, consumers, and other government agencies
- E. Manages a tracking system for the control and monitoring of the Director's correspondence and provides management support for the coordination of meetings involving the Director and Deputy Director

**2. REGULATIONS STAFF (DKKWA1)**

- A. Advises the Center Director and appropriate Agency officials on FDA regulation development responsibilities relating to medical devices and radiological health activities. Serves as the Center focal point for liaison on regulations development activities with the Office of Chief Counsel
- B. Coordinates the development, review and submission of Federal Register publications for the Center. Prepares position statements for the Center on standards promulgated by other organizations

### 3. AUTHORITY AND EFFECTIVE DATE

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

<b>STATUS (I, R, C)</b>	<b>DATE APPROVED</b>	<b>LOCATION OF CHANGE HISTORY</b>	<b>CONTACT</b>	<b>APPROVING OFFICIAL</b>
Initial	07/15/2010	N/a	OC/OA/ OM/OMP	Director, Center for Devices and Radiological Health
Revision	06/10/2011	N/a	CDRH/OM	Director, Center for Devices and Radiological Health
Revision	07/08/2011	N/a	CDRH/OMS	Secretary of the Department of Health and Human Services

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

OFFICE OF THE CENTER DIRECTOR:

- Regulations Staff