

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Devices and Radiological Health

Office of the Center Director

Effective Date: December 14, 2018

1. Office of the Center Director (DCCA).

- A. Provides vision, leadership and strategic direction for all Center activities related to regulation of medical device and radiation-emitting products.
- B. Provides vision, leadership, and strategic direction for communicating Food and Drug Administration (FDA) initiatives and guidance to patients, consumers, providers, and industry in support of protecting and promoting the public health.
- C. Plans, oversees, and evaluates overall Center scientific, legal, policy, regulatory, compliance, public education, and management programs, policies, and plans.
- D. Provides leadership and direction for Center management, planning, and evaluation systems to ensure optimal utilization of personnel, budgetary and financial resources, information technology, and facilities.
- E. Provides Center-wide program and strategic planning, execution and support in the coordination, development, clearance and delivery of all Congressional mandated reports, studies and analyses, briefing materials, and background information for meetings and speeches.

2. Quality Management Staff (DCCA1).

- A. Establishes and develops resources to facilitate implementation of quality management systems for the Center.
- B. Integrates applicable quality management principles and best practices into key Center business processes.
- C. Establishes a foundation for quality, effectiveness, efficiency, and

improvement for all Center products, services and business processes.

- D. Supports the Center's mission to achieve operational efficiency and effectiveness while delivering continually improved products and services to provide the public access to safe, effective and high quality medical devices and safe radiation-emitting products.

3. Authority and Effective Date.

The functional statements for the Office of the Center Director were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of the Center Director**



Staff Manual Guide 1251.1
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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of the Center Director organization structure depicting all the organizational structures reporting to the Center Director.

The staff reports to the Office of the Center Director (DCCA)

- Quality Management Staff