

**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**

Effective Date: December 14, 2018

**1. Center for Devices and Radiological Health (DCC).**

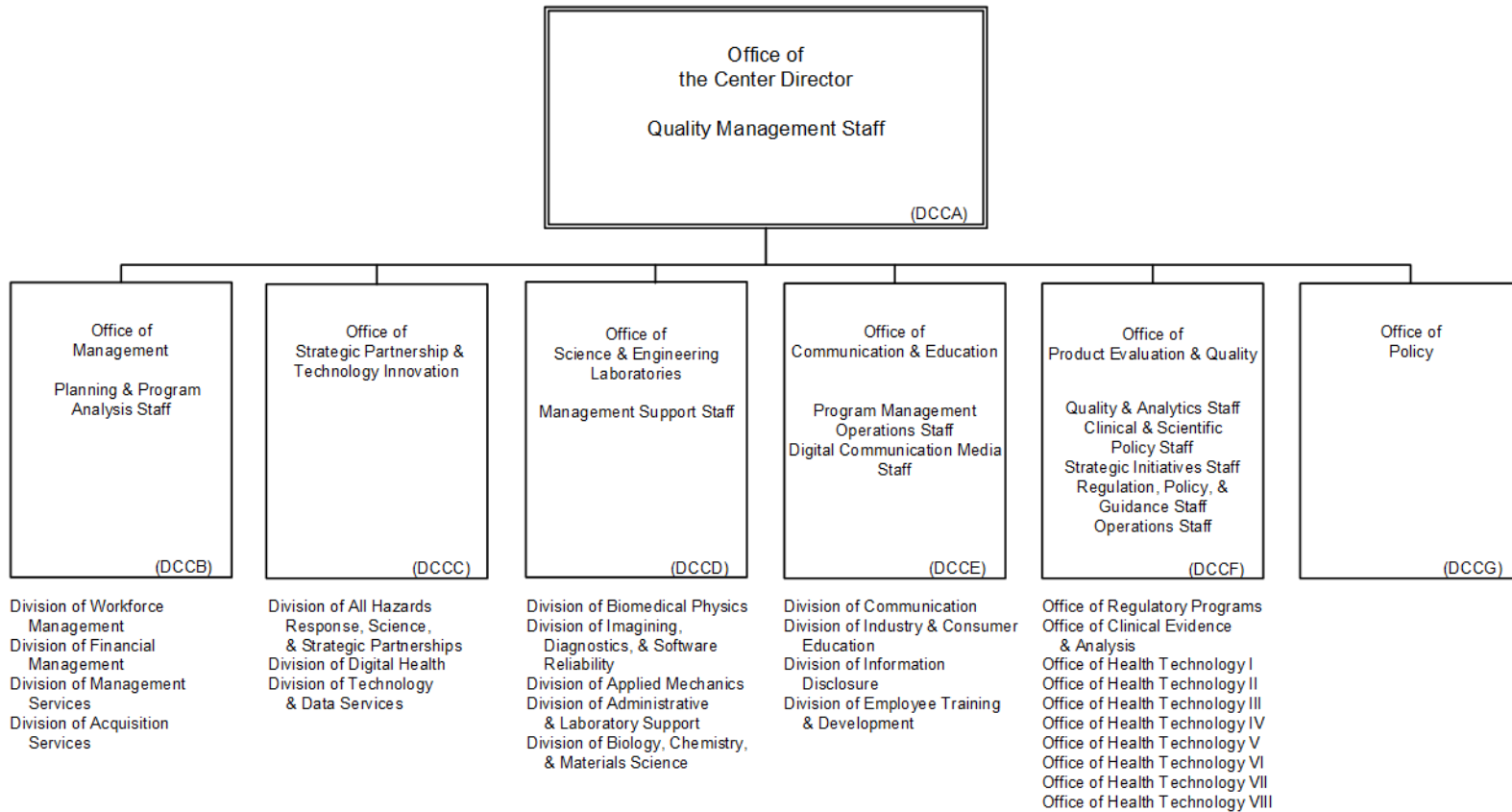
- A. Develops and carries out a national program designed to control unnecessary exposures of humans to, and assure the safe and efficacious use of, ionizing and nonionizing radiation-emitting electronic products.
- B. Develops and carries out a national program to assure the safety, effectiveness, and 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 the Center for Devices and Radiological Health 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**



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

Office of the Center Director (DCCA)

- Quality Management Staff

Office of Management (DCCB)

- Planning & Program Analysis Staff
- Division of Workforce Management
- Division of Division of Financial Management
- Division of Management Services
- Division of Acquisition Services

Office of Strategic Partnership & Technology Innovation (DCCC)

- Division of All Hazards Response, Science & Strategic Partnerships
- Division of Digital Health
- Division of Technology & Data Services

Office of Science & Engineering Laboratories (DCCD)

- Division of Biomedical Physics
- Division of Imaging, Diagnostics & Software Reliability
- Division of Applied Mechanics
- Division of Administrative & Laboratory Support
- Division of Biology, Chemistry, & Materials Science

Office of Communication & Education (DCCE)

- Program Management Operations Staff
- Digital Communication Media Staff
- Division of Communication
- Division of Industry & Consumer Education
- Division of Information Disclosure
- Division of Employee Training & Development

Office of Product Evaluation & Quality (DCCF)

- Quality & Analysis Staff
- Clinical & Scientific Policy Staff
- Strategic Initiatives Staff
- Regulation, Policy & Guidance Staff
- Operations Staff
- Office of Regulatory Programs

- Office of Clinical Evidence & Analysis
- Office of Health Technology I
- Office of Health Technology II
- Office of Health Technology III
- Office of Health Technology IV
- Office of Health Technology V
- Office of Health Technology VI
- Office of Health Technology VII
- Office of Health Technology VIII

Office of Policy (DCCG)