

SMG 1250.1

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: December 14, 2018

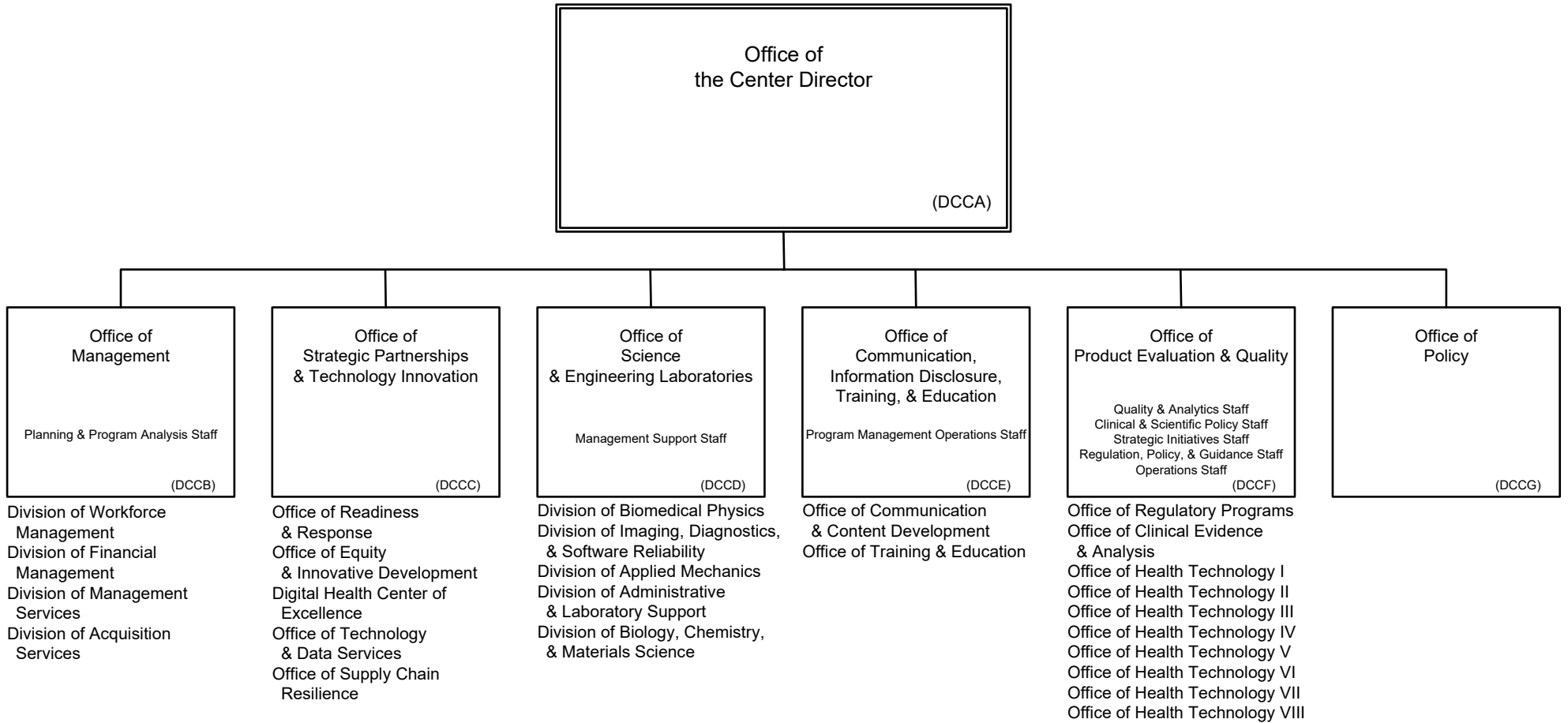
1. Center for Devices and Radiological Health (DCC).

- 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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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 Director:

These organizations report to the Office of the Center Director (DCCA):

- Office of Management (DCCB)
- Office of Strategic Partnerships and Technology Innovation (DCCC)
- Office of Science and Engineering Laboratories (DCCD)
- Office of Communication, Information Disclosure, Training, and Education (DCCE)
- Office of Product Evaluation and Quality (DCCF)
- Office of Policy (DCCG)

These organizations report to the Office of Management (DCCB):

- Planning and Program Analysis Staff
- Division of Workforce Management
- Division of Financial Management
- Division of Management Services
- Division of Acquisitions Services

These organizations report to the Office of Strategic Partnerships and Technology Innovation (DCCC):

- Office of Readiness and Response
- Office of Equity and Innovative Development
- Digital Health Center of Excellence
- Office of Technology and Data Services
- Office of Supply Chain Resilience

These organizations report to the Office of Science and Engineering Laboratories (DCCD):

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

These organizations report to the Communication, Information Disclosure, Training, and Education (DCCE):

Program Management Operations Staff

Office of Communication and Content Development

Office of Training and Education

These organizations report to the Office of Product Evaluation and Quality (DCCF):

Quality and Analytics Staff

Clinical and Scientific Policy Staff

Strategic Initiatives Staff

Regulation, Policy, and Guidance Staff

Operations Staff

Office of Regulatory Programs

Office of Clinical Evidence and 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