SMG 1254.1

# 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

## Office of Science and Engineering Laboratories

Effective Date: December 14, 2018

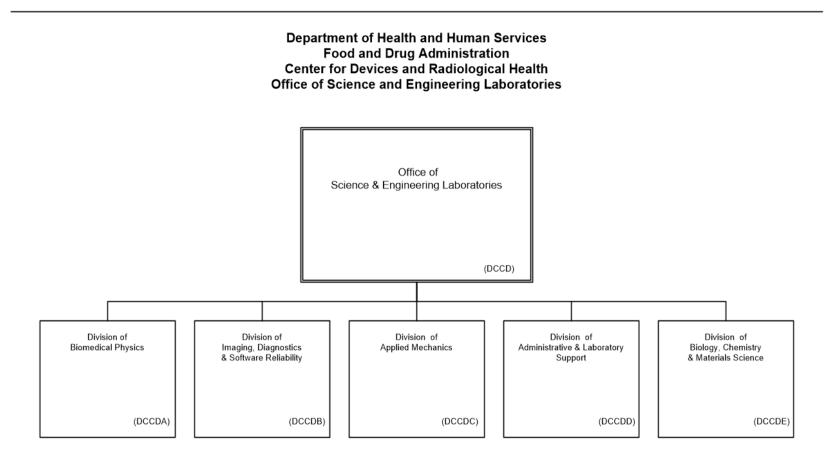
## 1. Office of Science and Engineering Laboratories (DCCD).

- A. Provides scientific support and laboratory analyses in response to the program needs of other Center and the Food and Drug Administration (FDA) components.
- B. Plans, develops, and implements an intramural science program covering key areas of engineering, physics, and biology; develops, modifies, and validates test methods and measurement techniques, risk assessments and hazard analyses, and generic techniques to enhance product safety and usefulness.
- C. Provides scientific and engineering support in the review of regulatory documents, the development of regulatory decisions, and the analysis of postmarket surveillance issues.
- D. Plans, conducts, or stimulates research on the human health effects of radiation and medical devices.
- E. Participates in the development of national and international consensus standards and voluntary guidelines through interaction with appropriate standards committees; coordinates with other standards-setting groups representing national and international standards-setting organizations; conducts the review and analysis of performance standards, guides and documents related to the Center's mission.

#### 2. Authority and Effective Date.

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

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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 Science and Engineering Laboratories organization structure depicting all the organizational structures reporting to the Director.

These divisions report to the Office of Science & Engineering Laboratories (DCCD)

- Division of Biomedical Physics (DCCDA)
- Division of Imaging, Diagnostics & Software Reliability (DCCDB)
- Division of Applied Mechanics (DCCDC)
- Division of Administrative & Laboratory Support (DCCDD)
- Division of Biology, Chemistry, & Materials Science (DCCDE)