SMG 1254.9

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

Division of Biomedical Physics

Effective Date: June 20, 2014

1. Division of Biomedical Physics (DCCDA).

A. Participates in the Center's mission in a variety of ways including conducting research, participating in device review activities, developing consensus standards both domestic and international, developing regulatory guidance, testing forensic and regulatory samples, and providing stakeholder outreach and educational programs in the area of biomedical physics.

B. Conducts focused scientific research (including laboratory science studies, engineering studies, laboratory science studies, and clinical studies) to support the Center's mission to assure the safety and effectiveness, and promote the innovation of medical devices and electronic products.

C. Provides scientific and technical specialties in the division include optical physics (as related to optical diagnostic and therapeutic medical devices), electromagnetics (as related to implant compatibility with MRI, electromagnetic compatibility and wireless medical device communications), electrical engineering (including electronic design and failure analysis), biophysics (including cardiac electrophysiology and clinical studies, neuroscience and functional MRI with clinical studies), and functional performance with medical devices (including physical medicine devices with related biomechanical problems, 3-DE device printing and human performance factor).

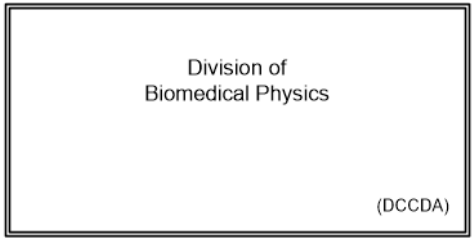
D. Develops and validates laboratory test platforms, measurement methods, instrument calibration capabilities, computational models, clinical endpoints and analytical procedures to characterize and evaluate devices and products, and supports the Center's enforcement and product testing activities.

E. Evaluates interactions of electromagnetic and optical energy with biological systems and medical devices, analyzes implications for the safety and effectiveness of devices and products and develops and evaluates procedures for minimizing or optimizing human exposure from such devices.

2. Authority and Effective Date.

The functional statements for the Division of Biomedical Physics 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 Science and Engineering Laboratories
Division of Biomedical Physics



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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, Division of Biomedical Physics organization structure depicting all the organizational structures reporting to the Director.

Division of Biomedical Physics (DCCDA)

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