

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS**

**FOOD AND DRUG ADMINISTRATION**

**OFFICE OF MEDICAL PRODUCTS AND TOBACCO**

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**

**OFFICE OF SCIENCE AND ENGINEERING LABORATORIES**

**DIVISION OF BIOMEDICAL PHYSICS**

Effective Date: 06/20/2014

**1. DIVISION OF BIOMEDICAL PHYSICS (DKKWEC).**

- 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 this Division were approved by the Director, Center for Devices and Radiological Health on June 20, 2014.