

**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 BIOLOGY, CHEMISTRY, AND MATERIALS SCIENCE**

Effective Date: 06/20/2014

**1. DIVISION OF BIOLOGY, CHEMISTRY, AND MATERIALS SCIENCE (DKKWEL)**

- A. Participates in the Center's mission by conducting regulatory science research, participating in device review premarket activities, participating in postmarket activities, developing domestic and international consensus standards, developing regulatory guidance, testing forensic and regulatory samples, and providing training/educational programs in the area of biology, chemistry and materials science.
- B. Focus on the development of experimental data, test methods and protocols for regulatory and scientific activities involving biological risk assessment, biosensors, nanotechnology, immunology, genomic and genetic technologies, infection control and sterility, tissue-device interactions, toxicology, biocompatibility, biofilms, radiation bio-effects, multicomponent mass transfer, reaction kinetics, electrochemistry, materials characterization and processing, modeling of physiological processes, chemical contamination, and materials degradation.
- C. Performs research such as: 1. Evaluation of the potential adverse effects of medical devices on host biological systems, effects of host biological systems on implanted devices, and, identifying the source and impact of product degradation on organ systems both under acute and chronic conditions; 2. Development of measurements methods and analytical procedures to characterize and evaluate devices and products, studies molecular and cellular mechanisms and bioeffects of biomaterials, and supports the Center's enforcement and product testing activities; 3. Development of experimental data, test methods and protocols for multicomponent mass transfer, reaction kinetics, absorption and swelling of network polymers, polymer processing, modeling of physiological processes, and materials degradation; 4. Testing of the performance of chemical processes of importance to medical devices, such as mass transfer through membranes used

in dialysis and blood oxygenation, and manufacturing processes used to fabricate materials.

**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.