

SMG 1254.5

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 APPLIED MECHANICS

Effective Date: 06/20/2014

1. DIVISION OF APPLIED MECHANICS (DKKWEF)

- A. Participates in the Center's mission in a variety of ways including conducting research, device review activities, developing consensus standards both domestic and international, developing regulatory guidance, testing forensic and regulatory samples, and providing educational programs in the area of applied mechanics.
- B. Core functions and responsibilities involve addressing issues for which mechanical interactions or transport are of primary concern, such as those involving motion; structural support, stabilization, or vibrations; device and material mechanical integrity; materials durability; and biologically relevant parameters of device and materials. The division provides expertise in the areas of fluid dynamics, solid mechanics and materials, acoustics and ultrasonics.
- C. Develops measurement methods, instrument calibration capabilities, and analytical procedures to characterize and evaluate devices, device materials, and products, and supports the Center's enforcement and product testing activities.
- D. Evaluates interactions of ultrasound energy with matter and the implications of these interactions on the safety and effectiveness of devices and products.

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.