

SMG 1254.10

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 IMAGING, DIAGNOSTICS, AND SOFTWARE RELIABILITY

Effective Date: 06/20/2014

**1. DIVISION OF IMAGING, DIAGNOSTICS, AND SOFTWARE RELIABILITY
(DKKWED)**

- 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 educational programs in the areas of imaging, diagnostics, and software reliability.
- B. Provides scientific expertise and carries out a program of applied research in support of CDRH regulation of radiation-emitting products, medical imaging systems, other devices utilizing computer-assisted diagnostic technologies, and medical device software. Medical imaging research encompasses ionizing and nonionizing radiation from data capture through image display and observer performance.
- C. Performs computer-assisted diagnostics work focused on the appropriate mathematical evaluation methodologies to evaluate the stand-alone performance of sophisticated computational algorithms and their performance when used to aid medical practitioners interpret diagnostic device results.
- D. Develops and disseminating performance assessment methodology appropriate to these modalities.

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.