

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 Imaging, Diagnostics, and Software Reliability

Effective Date: December 14, 2018

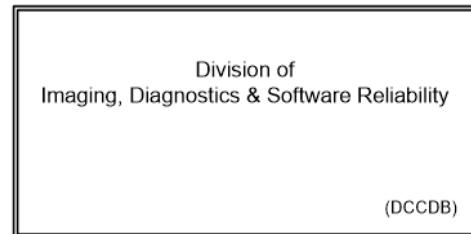
1. Division of Imaging, Diagnostics, and Software Reliability (DCCDB).

- 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 the Division of Imaging, Diagnostics, and Software Reliability were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

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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 Imaging, Diagnostics and Software Reliability organization structure depicting all the organizational structures reporting to the Director.

Division of Imaging, Diagnostics & Software Reliability (DCCDB)