SMG 1258.40

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 Product Evaluation and Quality

Office of Health Technology II

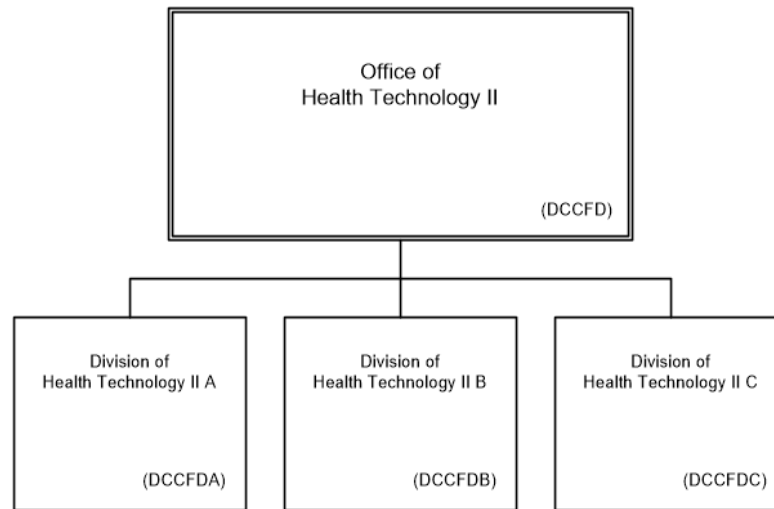Effective Date: December 14, 2018

1. **Office of Health Technology II (DCCFD).**

   A. Responsible for executing end-to-end device review programs and activities.

   B. Works closely with other offices on classification and reclassification activities, and the development of guidance documents.

   C. Provides initial support for questions related to regulatory programs in response to specific requests from medical device and health technology industries, trade associations, other Federal agencies, other countries, State agencies, and the general public.

   D. Advises, coordinates, and provides consultation to the Super Office Director and other Food and Drug Administration (FDA) officials on Office programs and policies concerning premarket review activities, postmarked market surveillance, and quality.

   E. Maintains and analyzes device-related compliance data, and uses this data to support Office and Center-level activities.

   F. Participates in the development of national and international consensus standards, and voluntary guidelines through interaction with appropriate national and international standards committees.

2. **Authority and Effective Date.**

   The functional statements for the Office of Health Technology II were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Product Evaluation and Quality
Office of Health Technology II

Office of
Health Technology II

(DCCFD)

Division of Health Technology II A	Division of Health Technology II B	Division of Health Technology II C
(DCCFDA)	(DCCFDB)	(DCCFDC)

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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 Product Evaluation and Quality, Office of Health Technology II organization structure depicting all the organizational structures reporting to the Director.

These divisions report to the Office of Health Technology II (DCCFD)
- Division of Health Technology II A (DCCFDA)
- Division of Health Technology II B (DCCFDB)
- Division of Health Technology II C (DCCFDC)