SMG 1258.30

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 I

Effective Date: May 13, 2024

1. Office of Health Technology I (DCCFC).

A. Responsible for executing end-to-end device review programs and activities; this includes premarket, investigational device exemption, compliance surveillance reviews.

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. Directs review of files, including applications for pre-market approval (PMAs), premarket notification of intent to market a product, product development protocols (PDPs), applications for investigational device exemptions (IDEs), De Novo, 513(g)s, inspection classification, allegations, recalls, Custom Device Reports, MDRs, import alerts, and information from other government agencies, and other product safety and compliance information.

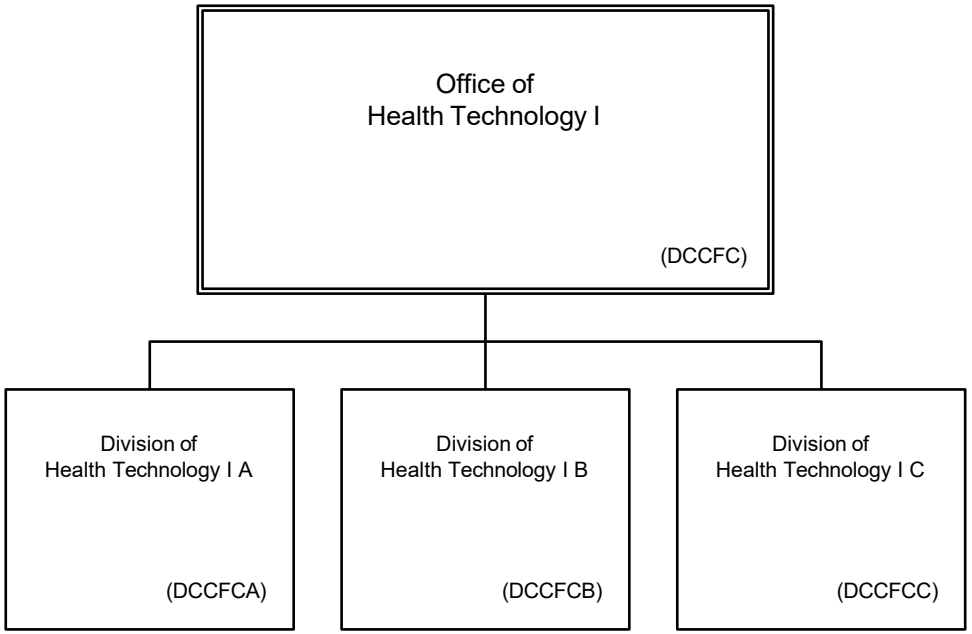
E. Maintains and analyzes device-related compliance data and uses this data to support Office and Center-level activities, makes determinations on enforcement actions, and determine follow-up activities.

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 I were approved by the Secretary of Health and Human Services on March 5, 2024, and effective on May 13, 2024.

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 I



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Organizations and Functions
Effective Date: December 14, 2018

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 I organization structure depicting all the organizational structures reporting to the Director:

Division of Health Technology I A (DCCFCA)

Division of Health Technology I B (DCCFCB)

Division of Health Technology I C (DCCFCC)