**SMG 1258.12**

**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 Regulatory Programs**

**Division of Regulatory Program II**

Effective Date: December 14, 2018

## 1. Division of Regulatory Programs II (DCCFAB).

A. Responsible for developing, interpreting and implementing policy and process for programs related to assessment of medical device and radiological health establishments.

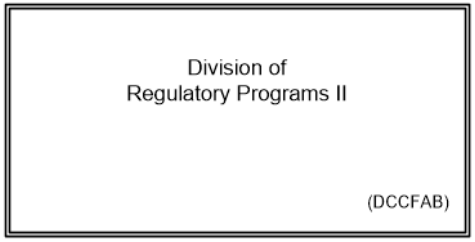
B. Provides programmatic expertise for Food and Drug Administration (FDA) inspections and Medical Device Single Audit Program (MDSAP) audits; from planning through evaluation of findings; firm registration and listing; as well as imports and exports, as well as potential enforcement actions associated with these programs.

C. Manages the Center's Export Certificate Program.

## 2. Authority and Effective Date.

The functional statements for the Division of Regulatory Programs 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 Regulatory Programs**
**Division of Regulatory Programs II**



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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 Regulatory Programs, Division of Regulatory Programs II organization structure depicting all the organizational structures reporting to the Director.

Division of Regulatory Programs II (DCCFAB)

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