

**SMG 1251.21a**

**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 Strategic Partnerships and Technology Innovation**

**Division of All Hazards Response, Science and Strategic Partnerships**

Effective Date: December 14, 2018

**1. Division of All Hazards Response, Science and Strategic Partnerships (DCCCA).**

- A. Advances national preparedness, response and coordination for all hazards threats, including but not limited to: chemical, biological, radiological, nuclear, explosive (CBRNE), emerging infectious diseases, natural disasters and cybersecurity incidents involving medical devices by enhancing collaborations, optimizing operational responsiveness and leveraging the Center for Devices and Radiological Health's (CDRH) regulatory science capabilities via an integrated approach.
- B. Leads and collaboratively advances the cybersecurity posture of the Healthcare and Public Health (HPH) critical infrastructure medical device ecosystem via a total product lifecycle (TPLC) approach, furthering the development and implementation of policy and strategic engagements.
- C. Expands the breadth and depth of regulatory science knowledge and expertise that will inform safety and effectiveness evaluation of medical countermeasure (MCM) assets critical for deployment before and during a public health incident, the All-hazards Readiness, Response and Cybersecurity (ARRC) program facilitates the timely review of all MCM medical devices and diagnostics in CDRH's MCM portfolio.
- D. Provides world-wide leadership in standards implementation and utilization for medical device innovation and manufacturing, and radiation-emitting product safety.
- E. Develops, fosters and advances partnerships with patient organizations, healthcare professional organizations, industry, science and other external

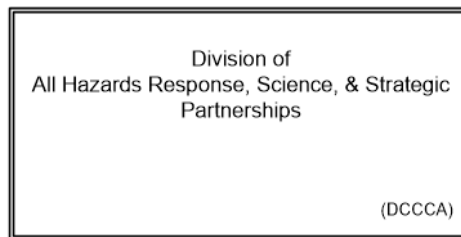
organizations to support broad national and international patient-focused and regulatory science programs and activities related to the safety, effectiveness, and quality of medical devices and radiation emitting products.

- F. Leads Center initiatives to advance patient engagement and input in regulatory decisions and actions. The Patient Engagement Patient Science (PEPS) Program advances the adoption and science of patient input in critical areas such as patient reporting outcomes (PRO) and patient preference information (PPI).
- G. Manages the Agency's Patient Engagement Advisory Committee (PEAC).
- H. Leads Center initiatives to advance the health and well-being of children and special populations by fostering innovative systems and collaborations that enhance the medical device ecosystem.
- I. Provides leadership and guidance for nationwide standards, as well as specific procedures and instruction, to guide the industry and government agencies with respect to the development, assessment, regulation and safe use of medical devices intended for use in the pediatric population.
- J. Provides leadership on medical device-related health of women (HoW) issues, including sex-specific evaluation in clinical studies, and sex/gender-specific questions in medical device related research.

## **2. Authority and Effective Date.**

The functional statements for the Division of All Hazards Response, Science and Strategic Partnerships 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 Strategic Partnerships and Technology Innovation  
Division of All Hazards Response, Science, and Strategic Partnerships**



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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 Strategic Partnerships and Technology Innovation, Division of All Hazards Response, Science and Strategic Partnerships organization structure depicting all the organizational structures reporting to the Director.

Division of All Hazards Response, Science & Strategic Partnerships (DCCCA)