

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Information Systems Management

Division of Enforcement System Solutions

Effective Date: February 9, 2022

1. Division of Enforcement System Solutions (DCIKA).

- A. Manages operational Information Technology (IT) systems supporting the ORA Program, Enforcement, Compliance, and Laboratory Systems operational activities of the Office of the Regulatory Affairs (ORA).
- B. Partners with the Office of Information Management and Technology (OIMT) to plan, implement, operate, and maintain systems that support the ORA Program, Enforcement, Compliance, and Laboratory operational activities for ORA as well as integrate such systems with other Food and Drug Administration (FDA) Centers and state regulatory and public health agency systems.
- C. Serves as a liaison to the Office of Information Management and Technology (OIMT) and the Department of Health and Human Services (DHHS) for the design, development, application, and implementation of operational business IT systems supporting the ORA Program, Enforcement, Compliance, and Laboratory operational activities; analyzes, reviews and makes recommendations for modifications to existing systems; and proposes new business systems to meet ORA and its customers' requirements.
- D. Provides a customer-oriented IT support center, technical assistance and business process re-engineering activities for ORA business systems supporting ORA Program, Enforcement, Compliance, and Laboratory operational activities.
- E. Develops scope of work and contractual mechanisms for execution of ORA IT projects supporting the ORA Program, Enforcement, Compliance, and

Laboratory operational activities working in conjunction with business sponsors, the Office of Acquisition and Grants (OAGS) and OIMT.

2. Enforcement Systems Branch (DCIKA1).

- A. Serves as business lead and subject matter experts for ORA IT systems supporting ORA program, compliance, laboratory and enforcement activities and processes.
- B. Conducts joint business planning with ORA and Center stakeholders to systematically assess and prioritize business needs for new functionality.
- C. Ensures processes and resources are in place to build, deploy, and support ORA program, compliance, laboratory and enforcement IT solutions.
- D. Supports adherence to policies and procedures for ORA Program, compliance, laboratory and enforcement through IT processes and development activities.

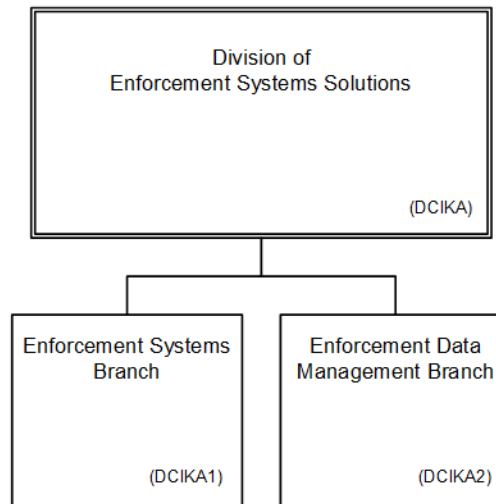
3. Enforcement Data Management Branch (DCIKA2).

- A. Provides official data responses and ad hoc reports in response to data requests associated with data stored in ORA Program, Enforcement, Compliance, and Laboratory Systems.
- B. Provides technical assistance and training to ORA staff associated with the generation of data and creation of reports associated with data stored in ORA Enforcement, Compliance, and Laboratory Systems.
- C. Assists business in managing data stored in ORA systems natively or received from other systems through analysis of data quality and recommending solutions to resolve or to improve data quality of data stored in Enforcement, Compliance, and Laboratory Systems.
- D. Engages with the development and enhancement of systems to be aware of policies that drive data collection, data exchange implementations, changes to data content, and changes to data modeling, and to advise on and have awareness of development to conduct data reporting and analysis.
- E. Facilitates implementation of best practices for data collection, data exchange, querying, and governance of data structures in ORA systems.

4. Authority and Effective Date.

The functional statements for the Division of Enforcement Systems Solutions were approved by the Deputy Secretary for Health and Human Services on December 22, 2021, and effective on February 9, 2022.

**Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Information Systems Management
Division of Enforcement Systems Solutions**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Information Systems Management, Division of Enforcement Systems Solutions organization structure depicting all the organizational structures reporting to the Director:

Enforcement Systems Branch (DCIKA1)

Enforcement Data Management Branch (DCIKA2)