

SMG 1121.30a

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 Training, Education and Development

Effective Date: December 14, 2018

1. Office of Training, Education and Development (DCIJ).

- A. Develops the strategic training, education and development plan for the Office of Regulatory Affairs (ORA) personnel and where appropriate, state and local regulatory partners, in line with ORA's mission, program priorities and core values.
- B. Provides direction and counsel to the Associate Commissioner for Regulatory Affairs (ACRA) and other ORA senior leaders on ORA national training, education and development policies, programs, and procedures.
- C. Provides and coordinates training and development programs for ORA employees in support of the ORA mission.
- D. Collaborates with internal and external stakeholders to leverage training, education and development programs.
- E. Manages and evaluates resources for the office.
- F. Maintains ORA and related State and local training data.
- G. Approves ORA certification programs and associated standards for regulatory staff.
- H. Develops and administers test and measurement systems to support training and certification needs.
- I. Provides oversight of the organization's accreditation commitments.
- J. Provides oversight and direction for office project management activities.

- K. Promotes use of the proper project management methodologies and best practice standards to ensure successful delivery and completion of training, education and developmental initiatives.
- L. Proves oversight and direction relative to the office's quality management system.
- M. Evaluates and reports on compliance with accreditation standards and leads accreditation compliance efforts.

2. Administrative, Logistics and Finance Staff (DCIJ1)

- A. Manages human resource functions, facility and property management activities, and printing and logistical services for the office.
- B. Retains records consistent with Food and Drug Administration (FDA) records management policy in support of accreditation standards and personnel certification.
- C. Maintains online resources in support of ORA training and certification programs.
- D. Advises on activities related to budget, finance and acquisitions for the office.
- E. Manages budget formulation, execution, tracking and reporting for the office.
- F. Manages acquisition planning and procurement for the office.
- G. Manages travel services for the office.

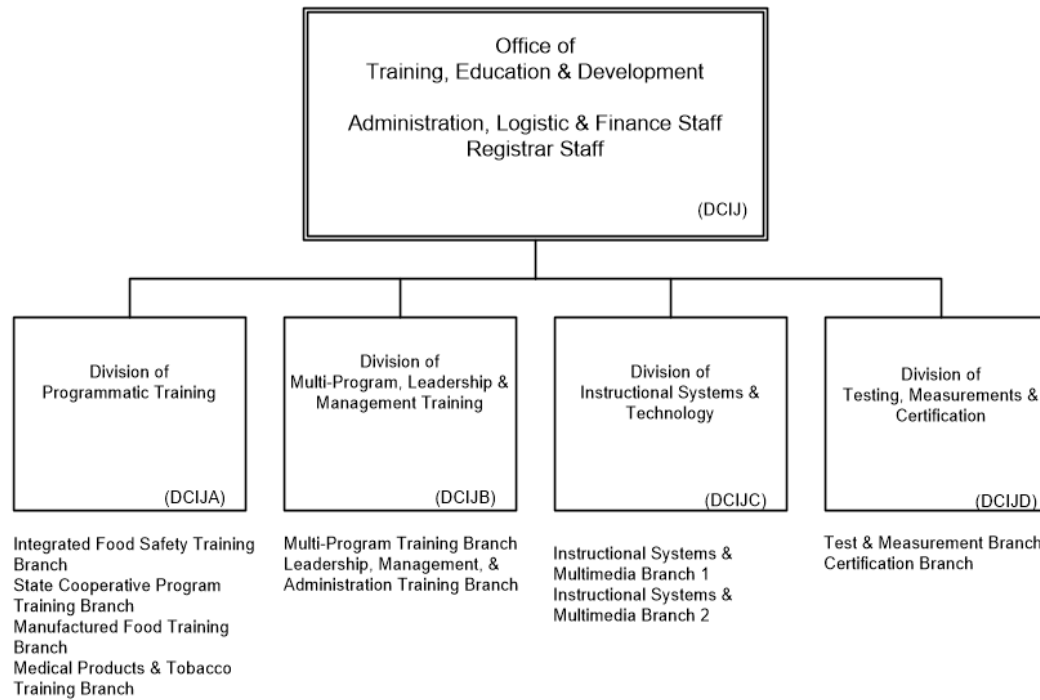
3. Registrar Staff (DCIJ2)

- A. Manages systems for ORA's education, training, and certification records.
- B. Provides student and course completion data reports.
- C. Provides Center guidance to OIMT on the approval and priority of helpdesk issues including hardware and software purchases and installation.

4. Authority and Effective Date.

The functional statements for the Office of Training, Education and Development 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
Office of Regulatory Affairs
Office of Training, Education and Development**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Training, Education and Development organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Office of Training, Education and Development (DCIJ):

Administration, Logistic & Finance Staff Registrar Staff

Division of Programmatic Training (DCIJA)

Division of Multi-Program, Leadership & Management Training (DCIJB)

Division of Instructional Systems & Technology (DCIJC)

Division of Testing, Measurements & Certification (DCIJD)

These organizations report to the Division of Programmatic Training (DCIJA)

Integrated Food Safety Training Branch

State Cooperative Program Training Branch

Manufactured Food Training Branch

Medical Products & Tobacco Training Branch

These organizations report to the Division of Multi-Program, Leadership & Management Training (DCIJB)

Multi-Program Training Branch

Leadership, Management, & Administration Training Branch

These organizations report to the Division of Instructional Systems & Technology (DCIJC)

Instructional Systems & Multimedia Branch 1

Instructional Systems & Multimedia Branch 2

These organizations report to the Division of Testing, Measurements & Certification (DCIJD)

Test & Measurement Branch (DCIJDA)

Certification Branch (DCIJDB)