

SMG 1121A.93

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Inspections and Investigations

Office of Training, Education and Development

Division of Instructional Systems and Technology

Effective Date: May 13, 2024

1. Division of Instructional Systems and Technology (DCSIC).

- A. Directs analyses, assessments, design plans, and summative and formative assessments.
- B. Evaluates intention and use of training products to determine efficiency and effectiveness.
- C. Collaborates with internal and external training experts to develop qualified assessment instruments.
- D. Collaborates with the Office of Training, Education and Development (OTED) Training Divisions to coordinate design and development training activities.
- E. Uses and applies audiovisual expertise to create media products in support of design and development of training products.
- F. Manages systems for the Office of Inspections and Investigations (OII) education, training, and certification records.
- G. Provides student and course completion data reports.
- H. Maintains functionality, access, and security for OII's official Learning Management System(s) (LMS).

2. Instructional Systems Branch (DCSIC1).

- A. Conducts analyses to identify training, education and developmental needs to support the design of training approaches.

- B. Creates design plans; develops and implements training products and evaluates training approach to match outcomes of learning objectives.
- C. Evaluates training products to determine efficiency and effectiveness.
- D. Conducts assessments to measure student achievement of learning outcomes and course effectiveness.
- E. Collaborates with experts to develop qualified assessment instruments.

3. Learning Management Technology and Multimedia Branch (DCSIC2).

- A. Provides audiovisual expertise to create media products in support of the design and development of training products.
- B. Integrates and maintains all audio-visual systems for OTED.
- C. Manages day to day operations (access, functionality, security) of Learning Management System(s) for OII, Food and Drug Administration (FDA), and State, local, tribal, and territorial regulatory partners who attend OTED courses.
- D. Provides student training completion report analysis.

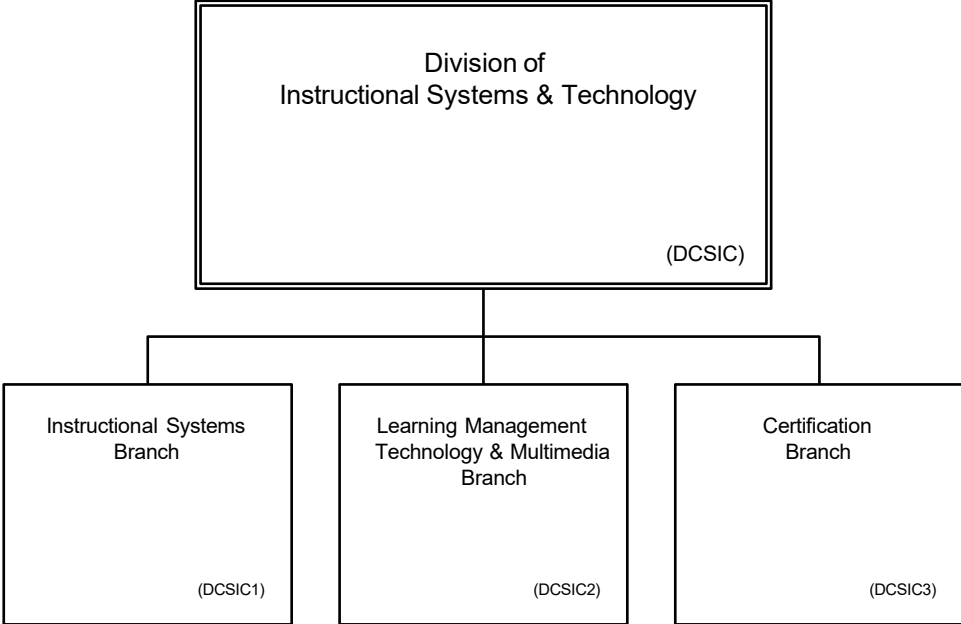
4. Certification Branch (DCSIC3).

- A. Administers the OII certification program.
- B. Determines and administers the eligibility criteria for certification.
- C. Implements the certification assessment strategy.
- D. Establishes and administers continuing education programs.
- E. Manages the office level quality system for analysis, design, development, delivery, and evaluation of training programs offered in conjunction with OII's Quality System directives.
- F. Manages Office level quality system for test measurement, evaluation, certification, and program analysis in compliance with OII's Quality System directives.
- G. Retains records consistent with National Archives and Records Administration (NARA), Health and Human Services (HHS) and FDA records management policy in support of training, education, development, and personnel certification.

5. Authority and Effective Date.

The functional statements for the Division of Instructional Systems and Technology 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
Office of Inspections and Investigations
Office of Training, Education, and Development
Division of Instructional Systems and Technology**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Inspections and Investigations, Office of Training, Education, and Development, Division of Instructional Systems and Technology organization structure depicting all the organizational structures reporting to the Director:

Instructional Systems Branch (DCSIC1)

Learning Management Technology and Multimedia Branch (DCSIC2)

Certification Branch (DCSIC3)