

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Regulatory Affairs

Office of Regulatory Management Operations

Office of Training, Education and Management

Division of Testing, Measurement, Certification and Program Analysis

Effective Date: February 9, 2022

- 1. Division of Testing, Measurement, Certification and Program Analysis (DCIBFD).**
 - A. Directs planning, design, development, implementation and evaluation of assessment strategies and surveys.
 - B. Establishes Office of Regulatory Affairs (ORA) certification programs which determine competency standards that qualify regulatory staff through fair and reliable assessment practices.
 - C. Maintains compliance with accreditation standards.
 - D. Maintains separation between test and measurement functions and certification functions to prevent conflicts of interest with respect to certification.
 - E. Promotes use of the proper project management methodologies and best practice standards to ensure successful delivery and completion of training, education and developmental initiatives for branch, division, and office.
 - F. Provides recommendations to Director for direction of office or division level project management activities.
- 2. Test Measurement, and Certification Branch (DCIBFD1).**
 - A. Develops, and implements assessment strategies and plans.
 - B. Evaluates test performance to measure the achievement of its objectives.

- C. Creates and delivers survey instruments.
- D. Develops recommendations from study results.
- E. Administers the ORA certification program.
- F. Determines and administers the eligibility criteria for certification.
- G. Implements the certification assessment strategy.
- H. Establishes and administers continuing education programs.

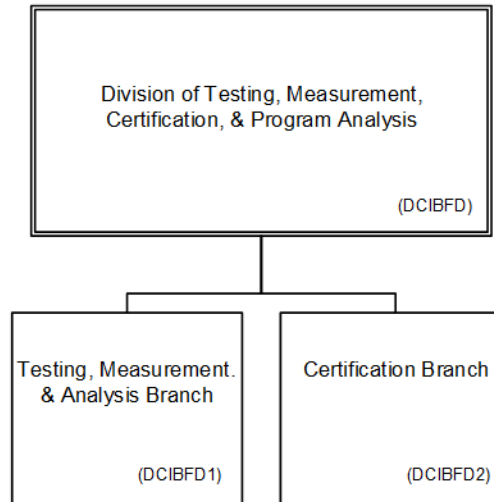
3. Certification Branch (DCIBFD2).

- A. Administers the ORA Certification program.
- B. Determines and administers the eligibility criteria for certification.
- C. Implements the certification assessment strategy.
- D. Establishes and administers continuing education programs.

4. Authority and Effective Date.

The functional statements for the Division of Testing, Measurement, Certification and Program Analysis 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
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Office of Training, Education, and Development
Division of Testing, Measurement, Certification and Program Analysis**



Staff Manual Guide 1121.184
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Effective Date: February 9, 2022

The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Regulatory Management Operations, Office of Training, Education, and Development, Division of Testing, Measurement, Certification, and Program Analysis organization structure depicting all the organizational structures reporting to the Director:

Testing, Measurement, and Analysis Branch (DCIBFD1)

Certification Branch (DCIBFD2)