

**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 Regulatory Science**

**Office of Medical Products, Tobacco and Specialty Laboratory Operations**

**Southeast Tobacco Laboratory**

Effective Date: December 14, 2018

**1. Southeast Tobacco Laboratory (DCIFBH).**

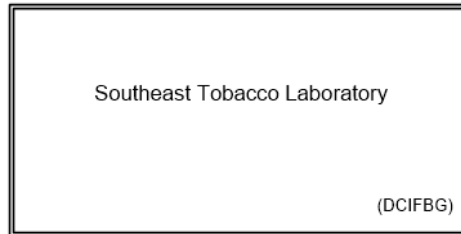
- A. Plans, schedules, and controls laboratory operations; formulates, implements, and coordinates analytical workplans for field offices being served.
- B. Performs laboratory analysis of samples for Office of Regulatory Affairs (ORA) field offices, as requested to:
  - 1. Assess each sample's compliance with applicable laws and regulations enforced by the Food and Drug Administration (FDA).
  - 2. Determine the extent to which findings provide evidence of violative conditions and practices.
  - 3. Obtain information through national surveillance programs for the purpose of identifying potential problems or trends.
- C. Provides evidence regarding analytical findings as requested.
- D. Conducts research to develop and refine methodology used in the analysis of samples and to explore new systems of analysis.
- E. Serves as the tobacco resource in scientific knowledge and provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies, State and local agencies, foreign counterpart agencies, and industry.

- F. Conducts the equal employment opportunity, internal security, safety and emergency preparedness programs.
- G. Implements an effective internal quality assurance program to assure the reliability of analytical results.
- H. Provides expert advice and training regarding laboratory techniques and technological developments to other Federal agencies; to State, local and foreign counterpart agencies, and to industry.
- I. Provides court testimony regarding analytical findings as requested.
- J. Assists investigational staff in the conduct of inspections and investigations involving complex testing procedures and production processes which may result in adulterated drug and medical device products.
- K. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.
- L. Conducts research on the analytical chemistry which includes developing analytical methodology, developing sample and sample preparation procedures, analytical methods validation and collaborative studies, extension of existing analytical methods to additional commodities and exploring new systems of analysis.

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

The functional statements for the Southeast Tobacco Laboratory 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 Regulatory Science  
Office of Medical Products, Tobacco and Specialty Laboratory Operations  
Southeast Tobacco Laboratory**



Staff Manual Guide 1121.928  
Organizations and Functions  
Effective Date: December 14, 2018

The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Regulatory Science, Office of Medical Products, Tobacco and Specialty Laboratory Operations, Southeast Tobacco Laboratory organization structure depicting all the organizational structures reporting to the Director:

Southeast Tobacco Laboratory (DCIFBH)