

SMG 1121.928

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND
FUNCTIONS**

FOOD AND DRUG ADMINISTRATION

OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY

OFFICE OF REGULATORY AFFAIRS

OFFICE OF REGULATORY SCIENCE

**OFFICE OF MEDICAL PRODUCTS, TOBACCO AND SPECIALTY
LABORATORY OPERATIONS**

SOUTHEAST TOBACCO LABORATORY

Effective Date: June 6, 2016

1. SOUTHEAST TOBACCO LABORATORY (DLLRKBH).

- A. Plans, schedules, and controls laboratory operations; formulates, implements, and coordinates analytical workplans for Districts being served.
- B. Performs laboratory analysis of samples for ORA Districts, as requested to:
 - 1. Assess each sample's compliance with applicable laws and regulations enforced by the Agency.
 - 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 this Laboratory were approved by the Secretary for Health and Human Services and effective on June 6, 2016.

**FOOD AND DRUG ADMINISTRATION
OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY
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OFFICE OF MEDICAL PRODUCTS,
TOBACCO AND SPECIALITY LABORATORY OPERATIONS
SOUTHEAST TOBACCO LABORATORY**

OFFICE OF THE DIRECTOR

(DLLRKBH)

STAFF MANUAL GUIDE 1121.928
ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: June 6, 2016

The following is the Food and Drug Administration, Office of Global Regulatory Operations and Policy, 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 Office Director.

OFFICE OF THE DIRECTOR (DLLRKBH)