

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Commissioner

Office of the Scientist

Office of Analytical Regulatory Laboratories

Tobacco Products Laboratory

Effective Date: May 13, 2024

1. Tobacco Products Laboratory (DCPJE).

- A. Plans, schedules, and controls laboratory operations; formulates, implements, and coordinates analytical workplans with the Food and Drug Administration (FDA) Centers and Offices being supported.
- B. Conducts laboratory analysis of samples to:
 - a. Assess each sample's compliance with applicable laws and regulations enforced by the FDA.
 - b. Determine the extent to which findings provide evidence of violative conditions and practices.
 - c. 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, validate, and refine methodology used in the analysis of samples and to explore new systems of analysis. Develops sample and sample preparation procedures, collaborative studies, and extensions of existing compendial methods to support the objectives of the program.
- E. Serves as the tobacco resource in scientific knowledge and provides expert advice and training regarding laboratory techniques and technological

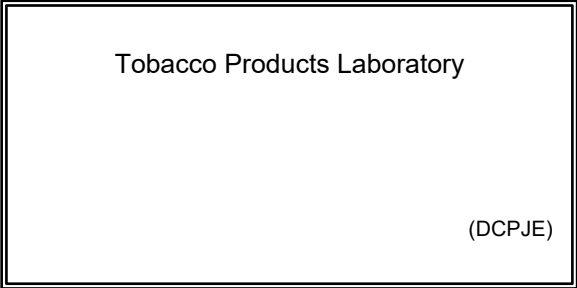
developments to FDA Centers and Offices, other federal agencies, state and local agencies, foreign counterpart agencies, industry, and academic institutions.

- F. Coordinates 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 FDA Centers and Offices, other federal agencies, state, local and foreign counterpart agencies, and to industry.
- I. Maintains liaison with scientists and scientific bodies with interests pertinent to laboratory activities.

2. Authority and Effective Date.

The functional statements for the Tobacco Products Laboratory 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 the Chief Scientist
Office of Analytical and Regulatory Laboratories
Tobacco Products Laboratory**



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of the Chief Scientist, Office of Analytical and Regulatory Laboratories, Tobacco Products Laboratory organization structure depicting all the organizational structures reporting to the Director: