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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 Chief Scientist

Office of Specialty Laboratories and Enforcement Support

Winchester Engineering and Analytical Center

Effective Date: May 13, 2024

1. Winchester Engineering and Analytical Center (DCPKB).

A. Serves as a national resource for engineering and analytical chemistry associated with problems in compliance testing and methods development and required investigations and inspections.

B. Provides specialized engineering and analytical services for project activities relating to electronic product radiation, medical devices, radionuclides in food, and the biological and microbiological safety of radiopharmaceuticals.

C. Serves as the focal point for the Food and Drug Administration (FDA) activities related to Nuclear Regulatory Commission (NRC) licensing of FDA regulated products; for the purchase, servicing, use, storage, surveying, decommissioning and disposal of radioactive materials; and for the coordination of the FDA's Radiation Safety Program.

D. Provides chemical, physical, and microanalytical support for domestic and import program operations for which the FDA has authorized regulatory responsibility.

E. Provides training services in the operational aspects of medical devices, radiation emitting and electronic product testing, radiological safety, automated drug analysis, and other related compliance program areas.

F. Maintains liaison with national and international scientists and scientific bodies; other federal, state, and local government officials; and industry personnel having interests pertinent to Winchester Engineering and Analytical Center (WEAC) activities.

G. Develops and operates procedures for automated analyses of drugs, and radionuclides in foods and medical products.

H. Develops and operates engineering evaluation and compliance testing procedures for consumer and industrial products, medical devices, and other electronic, electro-mechanical, and mechanical products and devices.

I. Conducts research to develop and refine analytical methodology and to explore new systems of analysis.

J. Provides overall engineering services in design, operation, and maintenance of all environmental support systems, plants, buildings, grounds, and related equipment to support WEAC programs.

K. Monitors the operation of the facility to efficiently implement, operate, maintain, and conserve energy systems and resources at the WEAC.

L. Provides design specifications and cost data and fabricates and modifies prototype and unique or specialized scientific equipment that is usually not available from outside sources for WEAC research projects and for other FDA operational laboratories.

M. Maintains working liaison with other federal offices providing support services to the FDA.

N. Coordinates the Equal Employment Opportunity, internal security, safety, and emergency preparedness programs.

O. Provides FDA support in emergency response activities.

2. Analytical Branch (DCPKB1).

A. Plans, schedules, and manages analytical operations; and formulates, implements, and coordinates laboratory workplans with FDA Centers and Offices being supported.

B. Performs laboratory analysis of samples to:

   a. Assess compliance of each sample with laws and regulations enforced by the FDA.

   b. Obtain information through national surveillance programs for the purpose of identifying potential problems or trends.

C. Provides evidence and court testimony regarding analytical findings as required.

D. Conducts research to develop and refine methods used in the analysis of samples and to explore new systems of analysis. Develops and evaluates methods for the rapid and accurate analysis of large numbers of drugs, employing combinations of complex instruments in automated systems of original design.

E. Develops methods and carries out analysis of samples of foods to determine the level of radionuclide contamination.

F. Tests samples for radionuclide contaminations in foods per the FDA's Toxic Elements in Foods Program and Total Diet Study Program.

G. Assists investigators during inspections and investigations relating to manufacturing facilities to evaluate compliance with appropriate standards, Current Good Manufacturing Practice Regulations, and other regulations and requirements.

H. Operates a quality control program to assure the reliability of analytical results obtained in the FDA and other specific laboratories to whom delegated regulatory responsibility has been given.

I. Serves as a resource in scientific knowledge and provides expert advice and training regarding laboratory techniques and technological developments to scientific bodies and institutions; other federal, state, and local agencies; foreign counterpart agencies; and industry.

J. Serves as the technical advisor for the radiological branch of the FDA's Food Emergency Response Network (FERN), composed of laboratories from state, federal, and industry partners. Plans, prepares, and distributes samples for nuclear emergency preparedness exercises for FERN. Provides radiological proficiency testing materials and reference materials for FERN.

K. Plans, coordinates, and provides training courses for both the radiological and microbiological branches of FERN.

L. Collaborates with other federal, state, and local agencies to expand the nation's capacity of radiological and nuclear emergency response.

M. Serves as a resource for FDA activities related to NRC licensing of FDA regulated products. Provides expert advice on the licensing and regulatory requirements of all types of radioactive material. Provides technical support for the purchase, use, storage, and disposal of radioactive materials. Coordinates the decommissioning and decontamination of FDA laboratories. Provides training and coordinates the FDA's Radiation Safety Program.

N. Participates in nationwide training programs for investigators assigned to radiopharmaceutical compliance activities.

O. Performs microbiological analyses of medical products to assess compliance with applicable laws and regulations enforced by FDA.

P. Develops joint projects of regulatory significance with university faculty, federal and state governments, and industry.

Q. Serves as the lead laboratory in radiological FERN and technical advisor to the FERN National Program Office (NPO).

R. Provides court testimony in areas of expertise.

3. Engineering Branch (DCPKB2).

A. Plans, schedules, and controls branch operations; and formulates, implements, and coordinates workplans with FDA Center and Offices being supported.

B. Provides nationwide consultation on the operation, performance and compliance testing, and evaluation of consumer and industrial products, medical devices, and other electronic, electro-mechanical, and mechanical products and devices (e.g., pacemakers, defibrillators, x-ray machines, microwave ovens, etc.).

C. Serves as a national resource in scientific knowledge, biomedical engineering methodology, and techniques applicable to solving problems pertinent to consumer and industrial products, medical devices, and other products and devices.

D. Conducts research to develop and refine testing methodology used in the examination of products in its area of scientific specialty.

E. Plans, schedules, and controls branch operations in coordination with other FDA components to which services are provided.

F. Reviews proposed test and evaluation methods for appropriateness, ease of use, reproducibility, accuracy, etc., and recommends modifications or new methods, as required.

G. Conducts tests and evaluations of consumer and industrial products, medical devices, and other products and devices obtained in planned surveillance programs or submitted for examination by district offices, the Center for Devices and Radiological Health, or other agencies, to assure compliance with appropriate specifications and standards.

H. Cooperates with other appropriate agencies in collaborative study programs of consumer and industrial products, medical devices, and other products and devices.

I. Conducts research to determine the significance of defects in consumer and industrial products, medical devices, and other products and devices.

J. Prepares and conducts nationwide compliance workshops on electronic products, medical devices, and other standards for manufacturers, assemblers, and appropriate state and federal control agency personnel.

K. Participates in nationwide training programs for investigators assigned to electronic product and device compliance activities.

L. Provides expert advice and training regarding engineering techniques and technological developments to other federal, state, and local agencies, foreign counterpart agencies; and to industry.

M. Assists investigators during inspections and investigations relating to manufacturing facilities to evaluate compliance with appropriate standards, Current Good Manufacturing Practice Regulations, and other regulations and requirements.

N. Provides court testimony regarding engineering test results, as required.

O. Performs tests and evaluations of medical devices, radiation emitting products and suspected fraudulent devices obtained through the Office of Criminal Investigations (OCI) and other federal, state, local agencies, and regulatory entities.

P. Develops examination criteria and test kits for the FDA's inspection and investigation program for assessment of high risk/high priority imported medical devices and radiation emitting products at the point of entry in collaboration with FDA's inspection and investigation program and Center stakeholders.

Q. Implements an effective internal quality assurance program.

R. Provides expert advice, instrumentation evaluations and training to FDA staff and other federal and state partners in radiation safety and health for radiation emitting products such as lasers, X-rays and investigator tools.

S. Provides FDA support, representation, and technical expertise in emergency response activities.

4. Authority and Effective Date.

The functional statements for the Winchester Engineering and Analytical Center 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
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Office of the Chief Scientist
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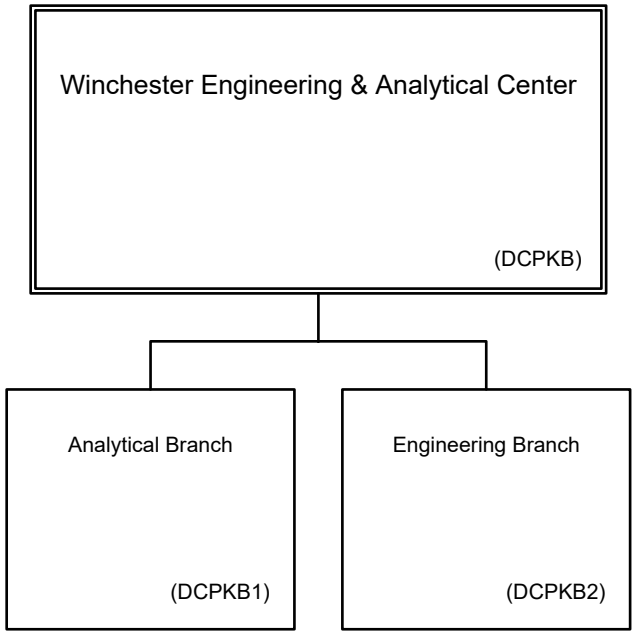

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of the Chief Scientist, Office of Specialty Laboratories and Enforcement Support, Winchester Engineering and Analytical Center organization structure depicting all the organizational structures reporting to the Director:

Analytical Branch (DCPKB1)

Engineering Branch (DCPKB2)