SMG 1252.4

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

OFFICE OF COMPLIANCE

DIVISION OF ANALYSIS AND PROGRAM OPERATIONS

Effective Date: 09/03/2013

1. DIVISION OF ANALYSIS AND PROGRAM OPERATIONS (DKKWBB).

A. Advises and supports Office officials and staff regarding statutes, regulations, policies and procedures relating to enforcement activities as requested.

B. Provide analysis activities for Office, Center and Agency senior management in the development and implementation of risk-based regulatory and enforcement activities.

C. Provide analyses of enforcement data to inform activity throughout the Center (e.g. pre-market review) and for external stakeholders (e.g. device industry)

D. Advise Office officials and staff regarding management information systems initiatives and serves as the Office liaison to other Center and Agency components on such matters. Plan, coordinate, and implement an Office Information Technology strategic plan. Lead the Office of Compliance Information Technology Steering Committee.

E. Draft and track Medical Device Tracking orders. Provide industry support.

F. Provide information for requests from external as well as internal sources. Coordinates and processes Freedom of Information requests and issues certificates for requests to export approved medical devices and non-approved medical devices under 801(e) of the Federal Food, Drug, and Cosmetic Act.

G. Facilitate the office strategic planning and prioritization process.

H. Develop and maintain an office strategic framework and competencies alignment.

I. Coordinate with the Quality Management System (QMS) staff on development and tracking of metrics for strategic plan.

J. Provide project management support for high-level collaboration projects.

K. Development and planning of organization and staff development activities.

L. Assess cultural competencies and behaviors. Develop and implement action plan to address gaps.

M. Consult on organizational needs, assessment tools, project management tools, and operation practices.

2. FIELD INSPECTIONS SUPPORT BRANCH (DKKWBB1)

A. Coordinate the Centers inspection assignments with field offices as well as internal regulatory actions. Provide information to Office and Center senior Staff in order to guide and direct field management in inspectional priorities.

B. Develop, coordinate, and/or conduct medical devices training programs for field personnel and state and local agencies in coordination with other Center and Agency components.

C. Provide coordination and inspection support for the Pre-Market Approval Program.

D. Develop analysis and strategy for the Post-market Quality System Compliance Program.

E. Provide logistical support for the 30-Day Notice Pre-Market Approval program.

F. Provide logistical support for the domestic directed inspection program.

G. Provide operational support and management of the Office of Compliance foreign inspection program.

H. Coordinate and provide logistical support for the Division of Bioresearch Monitoring inspection program.

I. Manage responses and documentation for Office of Compliance Warning Letters, Injunctions, or additional compliance actions.

J. Track and manage legal action cases received in Office of Compliance.

K. Provide logistical support and coordination for the inspection training of Office of Compliance personnel.

L. Manage the Establishment Inspection Report Information Technology support for Office of Compliance personnel including providing Field Accomplishments and Compliance Tracking System (FACTS) and Operational and Administrative System for Import Support (OASIS) User Accounts for Office of Compliance staff.

M. Provides information and support for the development of the Office of Compliance Risk Based Work Plan.

3. RECALL BRANCH (DKKWBB3)

A. Develop, implement and communicate policy and procedures to support Center for Devices and Radiological Health (CDRH)'s recall information intake, evaluation, publication and sharing of information in transparent manner. Develop and present training for CDRH personnel. Provide logistical support for recall program to Office of Compliance and Office of In Vitro Diagnostics and Radiological Health.

B. Serve as a liaison between CDRH Compliance, Office of Device Evaluation, and Communication entities, Office of Regulatory Affairs, and Food and Drug Administration (FDA) District Compliance and Recall personnel on matters pertaining to device corrections and removals.

C. Develop and implement programs to ensure uniform interpretation and application of the recall regulations to ensure that medical devices will be safe and effective and in compliance with the Food, Drug, and Cosmetic Act.

D. Draft and support development of recall regulation and guidance.

E. Develops and integrates recall Information Technology (IT) systems.

F. Guide CDRH personnel on requests for information which can be satisfied during a recall evaluation, to reduce inspection requests and assignments, while aiding agency effectiveness.

G. Identify gaps and set regulatory expectations for industry in the area of recall strategy and communication quality and develops proactive strategies to reduce risk. Prepare presentations on these topics.

H. Analyze recall data. Communicate analysis results to Office of Compliance, CDRH, and Office of Regulatory Affairs for program support such as risk-based work planning. Support Office of Device Evaluation and its reorganization with recall analyses and root cause information.

I. Identify potential recalls through analysis of signals, MedWatch reports, and complaints.

J. Manage the termination of recalls, including evaluating corrective actions and monitoring for lapses in communication.

K. Develop, interpret, and issue recall policy guidance in response to specific requests from the foreign medical device industry, trade associations, other Federal agencies, other countries, State agencies, domestic medical device industry, other FDA entities, and the general public.

L. Review inspection reports to determine manufacturers' compliance with Correction and Removal reporting requirements. Enforce the Reports of Corrections and Removals regulation as it applies to manufacturers and importers of medical devices.

M. Develop, coordinate, and implement new submission procedures for Reports of Corrections and Removals for manufacturers and importers of medical devices.

N. Collaborate with other CDRH Offices, Centers, and FDA Offices in developing and implementing cooperation agreements with foreign governments regarding information sharing and publishing recall information.

4. REGISTRATION AND RISK BRANCH (DKKWBB4)

A. Develop, processes information for, and maintain the medical device registration and product listing system; develop and monitor contracts for data processing; ensures industry compliance with reporting requirements through a certification program; and develop and maintain a document tracking system.

B. Develop new risk analysis methods for measuring the public health impact of compliance actions and identifying emerging risk areas.

C. Develop a "one-stop shop" for data identification, integration and analysis.

D. Perform data gathering and analysis and business process analysis to support risk analysis and improve operations and communication.

E. Develop and implement new and improved processes, both business and IT.

F. Integrate and analyze data and work products to drive quality improvements.

G. Develop and implement approaches to increasing transparency and sharing CDRH data and work products.

H. Develop improved risk-based approaches for improved inspection plan.

I. Develop and maintain expertise in Information Technology systems, including those owned by CDRH, other FDA, other government agencies and public entities.

J. Develop and conduct training as well as publishing of work products within the Center and publicly, as appropriate.

K. Manage the Registration and Listing program.

L. Work with other offices to identify ways that Registration and Listing can support Center operations and programs.

M. Identify reports and products that can be generated from Registration and Listing.

N. Identify and implement changes to the Registration and Listing system to improve data received by CDRH and support new laws and regulations as they become effective.

O. Work with other CDRH offices and Office of Chief Counsel to revise implementing Registration and Listing regulation (21CFR807) as necessary to support new legislation and initiatives.

P. Develop training materials and outreach products (newsletter, web pages, etc.) to disseminate Registration and Listing information to internal and external stakeholders.

Q. Work with Office of Regulatory Affairs and other FDA offices to improve data collection, sharing and analysis.

R. Develop, interpret, and issue policy guidance in response to specific requests from the medical device industry, trade associations, other Federal agencies, other countries, State agencies, and the general public.

S. Support Office of Regulatory Affairs import initiatives and related Information Technology framework (e.g., PREDICT)

5. ALLEGATIONS OF REGULATORY MISCONDUCT BRANCH (DKKWBB5)

A. Develop, implement and communicate procedures to support CDRH compliant information intake, evaluation, and publication. Standardize the intake and support of Complaints. Develop and present training for CDRH personal and provides logistical support for the compliant program to CDRH.

B. Coordinate regulation, policy and best practices to support Center’s Complaints Program.

C. Draft and support development of regulation and guidance for complaints.

D. Communicate Complaint policy and best practices within CDRH, to Office of Regulatory Affairs, and to industry.

E. Analyze Compliant Data and Communicates analysis results to Office of Compliance, CDRH, and Office of Regulatory Affairs for program support such as risk-based work planning.

F. Triage complaints based on Center IT systems and utilizing a standardized risk based assessment tool.

G. Incorporate analytics designed to track Complaint handling, precedence in Complaint actions and trends predictive of signals originating from Complaints.

H. Collaborate with other CDRH Offices, Centers, and FDA Offices in developing and sharing compliant relevant information in transparent manner.

I. Utilize complaint information as an independent source to evaluate recall notification effectiveness, scope of the recall device, root cause analysis, corrective and preventative actions taken, and criteria used to terminate a recall.

J. Assess complaint information as a signal that a silent recall occurred or that a recall is needed (support Health Risk Analysis).

K. Use recall information to aid in triage of complaints.

6. QUALITY MANAGEMENT SYSTEM AND EXECUTIVE SECRETARY STAFF (DKKWBB6)

A. Retrieve and consolidate data call to office divisions in preparation of accomplishment exhibits and updates

B. Coordinate and monitor the development of new processes and procedures. Oversee the periodic review of standard operating processes and procedures.

C. Monitor and track Senior Executive Service (SES) performance goals within the Office of Compliance.

D. Advise on the development and monitoring of metrics for success. Ensure that metric development conforms to Center and Agency criteria. Track metrics and alert office leadership if performance goals are slipping.

E. Communicate Office goals across the Office of Compliance.

F. Research root causes of target slips and develop “mid-course” correction recommendations.

G. Oversee monthly, quarterly, and yearly progress reports.

H. Act as office lead on FDA Track monthly updates. Respond to FDA Track inquiries received from the Office of the Commissioner (Office of Legislative Affairs).

I. Coordinate and facilitate the Quality System Executive Board activities.

J. Oversee the office Corrective and Preventative Action program.

K. Prepare and coordinate Quality Management System training, auditing, and process improvements. Oversee Quality Management System quality control assurance activities.

L. Ensure the formation of guidance document teams in accordance with leadership decisions. Monitor and report on guidance document progress. Prepare documents for Office Clearance and Briefings with Center level staff.

M. Disseminate and monitor all data calls and inquiries. Act as investigations gatekeeper and results tracking for Office of Inspector General, Government Accountability Office, and internal investigations. Address Office of Legislation inquiries, congressional inquiries, and press inquiries.

N. Respond to calls from public/industry and triage calls to appropriate subject matter experts.

O. Presentation clearance and posting

7. AUTHORITY AND EFFECTIVE DATE.

The functional statements for this Division were approved by the Director, Center for Devices and Radiological Heath on September 3, 2013.

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OFFICE OF MEDICAL PRODUCTS AND TOBACCO
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OFFICE OF THE DIRECTOR

Field Inspections Support Branch
Recall Branch
Registration and Risk Branch
Allegations of Regulatory Misconduct Branch
Quality Management System and Executive Secretary Staff

Staff Manual Guide 1252.4
Organizations and Functions
Effective Date: September 3, 2013

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Devices and Radiological Health, Office of Compliance, Division of Analysis and Program Operations organization chart depicting its organizational structure.

OFFICE OF THE DIRECTOR:

- Field Inspections Support Branch
- Recall Branch
- Registration and Risk Branch
- Allegations of Regulatory Misconduct Branch
- Quality Management System and Executive Secretary Staff