FDA Program Alignment
Medical Devices and Radiological Health
FY2015 Action Plan

The following Medical Devices and Radiological Health FY2015 Action Plan (the Action Plan), developed by the Center for Devices and Radiological Health (CDRH) and the Office of Regulatory Affairs (ORA) is intended to facilitate increased operational and program alignment as FDA transitions to distinct commodity-based and vertically-integrated regulatory programs with well-defined leads, coherent policy and strategy development, and well-designed and coordinated implementation. Core elements of the Action Plan include increased specialization and de-layered management structures and processes involving ORA and CDRH, jointly developed training programs, new work planning processes, strategic enforcement approaches with aligned and updated compliance programs and policy, strategic import approaches, laboratory optimization, and improved information technology systems. Coordination of internal and external communication on the Action Plan will ensure that FDA speaks with one voice on the policies and operations related to the medical device and radiological health program.[1] This Action Plan has been reviewed by CVM to ensure alignment with respect to veterinary devices and products.

Long Term Device and Radiological Health Program Alignment Goals

FDA is moving towards goals of enhanced device quality, supporting innovation, and increased consideration of patient benefit. CDRH and ORA agree that we must define a future state that supports these goals to best focus on the patients we serve.

One goal is to achieve a paradigm shift from reaction to problems after they occur to a model that focuses on the quality attributes of devices in order to prevent safety and efficacy issues before they occur. The public health and patient-focused proactive model we are striving to achieve will complement traditional regulatory inspection and enforcement approaches. CDRH and ORA will focus on promoting device quality and education of stakeholders, using non-regulatory and regulatory tools that are efficient and effective and increase public health and patient focus. Quality does not only relate to regulatory compliance; it relates to the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

Another goal is to support mechanisms to promote innovation and access to new technology. CDRH and ORA will facilitate development, approval of, and access to even safer and more effective devices as well as support promising new technologies. Examples of mechanisms to improve device quality include aligning our increasingly specialized inspection and enforcement activity with quality goals, educating firms and the healthcare industry about device aspects that are critical to the quality of the device, promoting practices that enhance quality, and incentivizing firms to increase device quality. Examples of mechanisms to ensure and encourage innovation include providing

[1] While the narrative in this document often specifies “devices” and “patients,” many goals and activities identified are also relevant to “radiation-emitting electronic products” and “consumers,” and should be considered as such.

clear and consistent guidance, sharing policy on emerging technology, and providing education and support to firms through various engagement opportunities.

It is essential that oversight strategies be carefully aligned with the medical and scientific understanding of device benefit and risk. Decisions and policies should consider both inspection and compliance history, as well as an overall assessment of the benefit versus risk to patients and consumers (e.g., the patient's use and need for the device, and ultimately the patient's access to medically important, and even lifesaving, devices).

Short Term (FY2015) Device and Radiological Health Program Alignment Goals

This Action Plan is the agreed framework of mutually-shared strategic, policy, and operational changes that will occur during the first year of this multi-year change initiative.

In addition, as part of this initiative, CDRH and ORA agree to establish a multi-year plan (projected to be a 5-year plan) that will describe long-range goals and the operational changes needed to implement the vision in the February 3, 2014, memorandum from the Commissioner as it relates to the Medical Device and Radiological Health program. This multi-year action plan will have specific performance efficiencies, goals, metrics, and procedures. The plan, which will be reviewed annually by CDRH and ORA and revised as necessary, will also be used to develop annual action plans for implementation. These annual plans and associated implementation efforts will be reviewed quarterly by the Center Director and the ACRA to assess progress and make any necessary adjustments to the broader multi-year plan. A steering committee comprised of senior executives from CDRH and ORA will be formed in order to monitor the progress of this action plan and will report to the CDRH Director and ACRA.

Development of the multi-year plan is anticipated in the second quarter of FY2015. CVM will review the multi-year plan to ensure alignment regarding veterinary devices and products.

Clear roles and responsibilities for all parties will be defined in these plans, where appropriate, including clarity on streamlined decision making and final decision rights. Where possible, both the multi-year and annual action plans will include milestones and target dates agreed to by CDRH and ORA. Senior managers in CDRH and ORA will be assigned responsibility for specified implementation activities and will be held accountable through their performance management plans.

A. Transition to Commodity-Based and Vertically-Integrated Regulatory Programs

CDRH and ORA agree to work together to establish ORA investigator cadres and ORA-CDRH cadres (compliance officers and managers) in the areas of medical

devices, including a sub-specialty in radiological health and the Mammography Quality Standards Act (MQSA), which will be responsible for inspections and audits. More areas of sub-specialty may be identified over time based on program needs. Inspectorates (investigators) will conduct inspections of medical device, MQSA and radiological health establishments; support third-party programs through the conduct of audits; and support new program initiatives moving forward (e.g., pilot programs). To that end:

1. ORA will establish the baseline of medical device and radiological health specialization of its current operational workforce through a survey during the 3rd quarter of FY2015.

2. CDRH will similarly establish a baseline of its staff involved in these activities during the 3rd quarter of FY2015.

3. ORA will establish the Senior Executive Program Directors and launch recruitment by October 1, 2014.

    a. ORA will work with CDRH on selection criteria that reflect Center interests and will include Center participation in the selection process of the Senior Executive for the Medical Device and Radiological Health Program.

4. In FY2015, ORA will develop and share a plan for transitioning operational resources within ORA to commodity-specific structures, including the pace and staging of the organizational change process. CDRH will have an opportunity to comment on this plan.

5. Staffing Actions, to be completed in FY2015:

    a. CDRH and ORA will develop a plan for establishing a Medical Device Inspectorate (investigators), including the necessary resource levels, and the pace and staging for stand-up.

    b. CDRH and ORA will develop a plan for establishing an MQSA Inspectorate (investigators), including the necessary resource levels, and the pace and staging for stand-up.

    c. CDRH and ORA will develop a plan for establishing a medical device and radiological health compliance group, including necessary resource levels, and the pace and staging for stand-up.

d. CDRH and ORA will analyze geographic distribution of firms and cadre resources and determine optimal resource structure to minimize logistical issues and cost impact.

6. Competency Requirements/Assessment Activities, to be completed in FY2015:

    a. To increase investigator knowledge, FDA will promote sub-specialties in device and product areas. Considerations could include:

        i. Determining what sub-specialties and associated resource levels are needed via inventory analysis and consideration of innovative or high-risk devices and products.
        ii. Determining CDRH and ORA staff competencies needed to support the Medical Device Single Audit (MDSAP) program.

B. Training

CDRH and ORA must jointly invest for training to be effective. As new infrastructure is developed, training will be modified to support long term goals. CDRH and ORA will train their cadres consistent with established curricula. Where appropriate, CDRH and ORA staff will be brought together for joint training and utilize instructors from both organizations.

1. In FY2015, CDRH and ORA will form a medical device and radiological health training steering committee, including a charter to define the role/responsibility of the steering committee.

2. CDRH will review recent ORA-developed competency requirements and provide input on any necessary changes to further develop device and radiological health based competency requirements.

3. CDRH and ORA will review existing Staff College and Division of Human Resource Development courses to identify which courses satisfy competency requirements for investigators, compliance officers, and other staff, and what gaps exist. Steps to resolve identified gaps will be included in the multi-year plan described earlier in this document. These steps will include assessing the use of qualification and training programs for private-sector auditors.

C. Work Planning

Over time, CDRH and ORA will establish a medical device and radiological health work planning process that improves FDA's targeting and utilization of program resources and that is based on risk factors, public health outcomes, patient focus, quality, and innovation, rather than geographic boundaries. The medical device and

radiological health work plan will include a multi-year outlook on future priorities and activities that allow CDRH and ORA to adjust their resources to meet future program needs. Program resource utilization will be evaluated through metrics clearly demonstrating compliance outcomes, product quality, and public health impact (including safety, timely patient access to medically necessary and/or innovative devices, and benefit/risk considerations). To that end, in FY2015:

1. CDRH and ORA will initiate a process to ensure that resources are allocated to shared strategic priorities, enforcement strategies, and program goals.

2. CDRH and ORA will continue to improve data quality to increase accuracy of registration and firm inventory and decrease wash-out inspections.

3. CDRH and ORA will expand the use of GIS data to better allow for efficient work planning.

4. CDRH and ORA will continue to expand international and alternative data (e.g., Dunn & Bradstreet) collection to inform site selection.

5. ORA will provide an annual update to CDRH on current program contracts, grants, and cooperative agreements related to work planning.

6. CDRH and ORA will track and report quarterly on establishments audited under MDSAP, starting in 1st quarter FY2015.

7. CDRH and ORA will collaborate on the development of one public health outcome metric and related performance-based metrics.

D. Device Quality Policy and Strategy

CDRH and ORA will improve access to high quality, innovative, safe and effective medical devices and products, which are in compliance with regulatory requirements. Clear, current, outcome-based and effectively communicated policies and strategies will be established for all aspects of device quality-related work (to include international, domestic, and imports). CDRH and ORA are shifting from reaction to problems after they occur to a model that focuses on the quality attributes of devices in order to prevent safety and efficacy issues before they occur. CDRH and ORA will develop strategies for proactive interactions with firms and create an effective and efficient process for the review of quality activities related to medical device and electronic product inspections.

CDRH and ORA will collaborate to improve consistency and establish clear guidance about the use of regulatory tools, including advisory and enforcement actions, to increase efficiency, reduce duplication of efforts, and provide clear accountability.

CDRH has the lead on establishing device quality-related policies and strategies, including compliance programs and enforcement strategies, with ORA participation. ORA has the lead in executing the policies and strategies through field activities, collaborating with CDRH.

In FY2015:

1. CDRH, with ORA participation, will review existing device and radiological health device quality programs, compliance policy guides, and guidance documents to identify necessary changes and evaluate the need to develop strategies that align with program goals.

2. CDRH and ORA will develop at least one new outreach or inspection approach/strategy in an area such as:
    a. Outreach, incorporating promotion of quality and innovation
    b. MDSAP audits performed by FDA staff

3. CDRH and ORA will develop and document a policy to clarify when to utilize a non-regulatory approach versus a regulatory approach based on factors such as benefit/risk principles.

4. CDRH will define and develop a process to annually capture medical device and radiological health program priorities to share with ORA for planning purposes.

5. CDRH will establish a process for assessing, updating, and implementing device quality programs and policy guides.

6. CDRH and ORA will determine the model for collaborative processing of device quality-related actions, including defined roles and responsibilities.

7. CDRH, ORA and the Office of Crisis Management (OCM) will evaluate and develop a streamlined process with defined roles and responsibilities for medical device and electronic product related consumer complaints and Allegations of Regulatory Misconduct (ARMs).

8. CDRH and ORA will jointly evaluate and develop a streamlined process with clear roles and responsibilities for handling recalls.

E. Imports

In FY2015:

1. ORA will share the PREDICT evaluation and collaborate with CDRH to adjust the risk scoring and establish commodity-specific thresholds for manual entry review, consistent with import program strategic goals and risk/benefit principles.

2. CDRH and ORA will evaluate current practices and develop a streamlined and efficient process with clear roles and responsibilities for PREDICT rule making and implementation.

3. ORA and CDRH will collaborate to identify and begin development of strategies for assessing device quality at the point of entry.

4. CDRH and ORA will develop a plan to improve the execution of current import screening strategies (e.g., better alignment with PREDICT scores; improved visibility of high risk lines).

F. Laboratory Optimization

In FY2015, CDRH and ORA will:

1. Establish a charter for the ORA/CDRH Strategic and Scientific Working Group that integrates lab work planning and execution and program alignment goals.

2. ORA will brief CDRH on the current lab optimization plan and work with CDRH to assess the need for further lab specialization.

3. Establish a process to meet annually to reassess laboratory optimization and work planning.

G. IT

CDRH and ORA will develop an IT-focused program to enhance information sharing and collaboration. CDRH and ORA will improve collaboration on IT requirements, change control requests, and modification of IT systems over time. To that end, in FY2015, CDRH and ORA will:

1. Evaluate ORA and CDRH databases including information on inventory, pre-market applications, facilities, adverse events, risk information, medical device or radiation emitting product information, recalls, field exams, labeling exams, lab testing, device labeling, inspection outcome, FDA-483 observations and device quality data for purposes of identifying at least one opportunity to improve real-time visibility of data.

2. Explore ways to better integrate Centerviews and PREDICT with CDRH IT systems and identify at least one strategy to implement that will improve information sharing.

H. BIMO

A separate Program Alignment Group has been designated to focus on the BIMO program; thus, it is not addressed within the scope of this Action Plan.