FDA Program Alignment
Medical Devices and Radiological Health
FY2016 Action Plan

The following Medical Devices and Radiological Health FY16 Action Plan (Action Plan) developed by the Office of Regulatory Affairs (ORA) and the Center for Medical Devices and Radiological Health (CDRH) 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.

This Action Plan is the agreed upon framework of mutually-shared strategic, policy and operational changes occurring during the second year of this multi-year change management initiative. Each year, starting with FY2015, ORA and CDRH will establish specific action items for implementation during that fiscal year. Where possible, Action Plans will include target implementation dates agreed on by CDRH and ORA. Defined roles and responsibilities for all parties, where appropriate, are incorporated into this plan for streamlined decision making. The annual plan is reviewed quarterly to assess progress and make any necessary adjustments. The existing governance process will be enhanced to ensure regular communication and coordination between senior leaders within ORA and CDRH for Program Alignment success.

The FY2016 Action Plan is largely based on the project summaries and timelines created by the workgroups in FY2015. The Medical Devices and Radiological Health Program Alignment Steering Committee (the Steering Committee) will continue to oversee the execution and progress of this plan.

A. Transition to Commodity-Based and Vertically Integrated Regulatory Program (Specialization)

The Devices Program will continue the following in FY2016:

- A.4 – Complete ORA Transition Timeline
- A.5.a and A.5.c– Implement plan to establish Devices Inspectorate and Compliance Group
- A.6.a - Establish Sub-Specialties, Resources and Support MDSAP

Devices A.4 ORA will refine and implement the overarching transition plan covering the transition from geographic management to program based management developed in FY2015 and provide regular progress updates.

- Lead Organization: ORA[1]

[1] The organization(s) designated in this Action Plan as "lead" for a commitment will be responsible for taking the lead in kicking off the work, organizing and scheduling workgroup meetings, tracking and reporting on workgroup progress, although any workgroup member may escalate an issue to the Steering Committee as needed. The lead

- Due Date: September 30, 2016
- Acceptance criteria: Implementation of the transition plan (would be evidenced by stand up plans for operations, new programmatic SOPs, alignment of ORA staff, etc.) & updates on the status of transition
- Deliverable Format: Updates to the Steering Committee

Devices A.5.a. CDRH and ORA will implement the FY2015 approved plan for establishing a medical device inspectorate, including a subspecialty in radiological health.

- Lead Organization: ORA
- Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates [2]
- Acceptance criteria: Complete defined FY2016 milestones

Devices A.5.c. CDRH and ORA will implement the FY2015 approved plan for establishing a medical device and radiological health compliance cadre.

- Lead Organization(s): CDRH; ORA
- Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
- Acceptance criteria: Complete defined FY2016 milestones

Devices A.6.a. CDRH and ORA will establish the sub-specialties for medical devices and radiological health identified in FY2015, including target resource levels based on inventory and other analysis. A process will be defined to periodically evaluate and assess specialization needs, and will specifically address MDSAP.

- Lead Organization(s): CDRH; ORA
- Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
- Acceptance criteria: Complete defined FY2016 milestones

B. Training and Certification

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organization will act as a facilitator and ensure that appropriate staff and managers from CDRH and ORA are involved, and that the deliverables are accomplished according to acceptance criteria and timeframes.

[2] FY2016 Devices action plan will be reviewed by charged workgroup leads to determine milestones for the commitment deliverable(s). Workgroups will establish due dates for commitment milestones and define final deliverable format for Devices Steering Committee approval by 1/31/2016.

The Devices Program with continue the following in FY2016:

- B.2 and B.3 - Competencies Review and Gap Analysis.

Devices B.3. The Medical Devices/Radiological Health Curriculum Committee will identify, prioritize and initiate those tasks that are supportive of the goals identified in the Medical Device and Radiological Health Multi-year Action Plan and will be completed in FY2016. Quarterly progress updates will be provided to the Steering Committee.

- Lead Organization: ORA
- Due Date: Define FY2016 Curriculum Committee Project Plan by 1/31/2016; quarterly progress updates
- Acceptance criteria: Complete defined FY2016 project plan approved by the Devices Steering Committee

C. Medical Devices and Radiological Health Program Work Planning

The Devices Program will continue the following in FY2016:

- C.1. – Implement process to ensure resources are allocated to shared priorities, enforcement strategies and program goals
- C.2. - Continue Registration and Inventory data improvement
- C.5 - Provide an annual update on program contracts, grants and cooperative agreements associated with work planning.
- C.7 – Establish the identified public health outcome metric and related performance-based metrics.

Devices C.1. CDRH and ORA will implement the FY2015 approved plan for establishing a process to ensure that resources are allocated to shared strategic priorities, enforcement strategies, and program goals. Specifically, in FY2016 CDRH and ORA will begin to establish a global work plan. Quarterly progress updates will be provided to the Steering Committee.

- Lead Organization(s): CDRH; ORA
- Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
- Acceptance Criteria: Complete FY2016 milestones approved by the Devices Steering Committee

Devices C.2. CDRH and ORA will continue collaboration with OIMT to automate data quality improvements to increase accuracy of registration and firm inventory. Quarterly progress updates will be provided to the Steering Committee.

- Lead Organization(s): CDRH; ORA
- Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
- Acceptance Criteria: Complete FY2016 milestones approved by the Devices Steering Committee

Devices C.5. ORA will provide an annual update to CDRH on current program contracts, grants, and cooperative agreements related to work planning. Annual reports for the previous year will be provided during the 1st quarter of the new fiscal year.

- Lead Organization: ORA
- Due Date: FY2015 report due by 12/31/2015
- Acceptance Criteria: Submission of detailed annual report

Devices C.7. CDRH and ORA will establish and implement a process to measure, document and report on the public health outcome metric and related performance based metrics identified in FY2015.

- Lead Organization(s): CDRH; ORA
- Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
- Acceptance Criteria: Complete FY2016 milestones approved by the Devices Steering Committee

D. Quality Policy and Strategy

The Devices Program will continue the following in FY2016:

- D.2 - Develop new inspection approach/strategy
- D.3 - Develop utilization of non-regulatory approach versus regulatory approach policy
- D.4 – Establish annual process to capture and exchange program priorities
- D.5 – Establish a process for assessing, prioritizing and updating device quality program and policy guides.
- D.6 – Develop the model for collaborative processing of quality-related actions
- D.7 – Develop the streamlined process for device and product related consumer complaints and Allegations of Regulatory Misconduct
- D.8 - Define and streamline the recall process and implementation strategy

Devices D.2. CDRH and ORA will develop at least one new inspection approach/strategy that considers early interaction, streamlined processes or focus on product quality.

- Lead Organization(s): CDRH; ORA
- Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
- Acceptance criteria: Complete FY2016 milestones approved by the Devices Steering Committee

Devices D.3. CDRH and ORA will build upon work done in FY2015 to develop additional decision making criteria in order to clarify when and how to use traditional regulatory tools or novel, non-regulatory approaches. These approaches should consider early evaluation of signals and include assessment of impact on product quality and patient safety – in order to proactively address issues before compliance or enforcement action is required. Incorporate these tools into new or existing compliance programs and policy documents.

- Lead Organization(s): CDRH; ORA
- Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
- Acceptance Criteria: Complete FY2016 milestones approved by the Devices Steering Committee

Devices D.4. CDRH and ORA will refine and establish a process and communication plan to exchange medical device and radiological health program priorities. The outcome of the exchange should be agreement on high-level common goals and areas each organization will pursue, which are then shared throughout all levels of the organization.

- Lead Organization(s): CDRH; ORA
- Due Date: Quarterly progress updates
- Acceptance Criteria: Complete FY2016 milestones approved by the Devices Steering Committee

Devices D.5. CDRH and ORA will continue establishing a process for assessing, prioritizing and updating device quality program and policy guides. Implement process for highest priority program and policy guides.

- Lead Organization(s): CDRH; ORA
- Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
- Acceptance Criteria: Complete FY2016 milestones approved by the Devices Steering Committee

Devices D.6. CDRH and ORA will develop a phased approach to define, pilot and implement the model for collaborative processing of traditional compliance and enforcement actions, including roles and responsibilities.

- Lead Organization(s): CDRH; ORA
- Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
- Acceptance Criteria: Complete FY2016 milestones approved by the Devices Steering Committee

Devices D.7. CDRH, ORA and the Office of Crisis Management (OCM) will define a streamlined process and implementation strategy for medical device and electronic product related consumer complaints and Allegations of Regulatory Misconduct (ARMs).

- Lead Organization(s): CDRH; ORA
- Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
- Acceptance Criteria: Complete FY2016 milestones approved by the Devices Steering Committee

Devices D.8. CDRH and ORA will define a streamlined process and implementation strategy for handling recalls.

- Lead Organization(s): CDRH; ORA
- Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
- Acceptance Criteria: Complete FY2016 milestones approved by the Devices Steering Committee

E. Imports

The Devices Program will continue the following in FY2016:

- E.2 - Finalize PREDICT rule making and implementation
- E.3 - Implement strategies for assessing device quality at point of entry
- E.4 – Implement plan to improve execution of current import screening strategies

Devices E.2. CDRH and ORA will finalize and implement PREDICT governance procedure so that the utilization of PREDICT rules and their implementation are handled in an efficient and effective manner.

- Lead Organization(s): CDRH; ORA

- Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
- Acceptance criteria: Complete FY2016 milestones approved by the Devices Steering Committee

Devices E.3. CDRH and ORA will implement the FY2015 approved strategies to assess device quality at the point of entry.

- Lead Organization(s): CDRH; ORA
- Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
- Acceptance criteria: Complete FY2016 milestones approved by the Devices Steering Committee

Devices E.4. CDRH and ORA will implement the FY2015 approved plan to improve execution of current import screening strategies.

- Lead Organization(s): CDRH; ORA
- Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
- Acceptance criteria: Complete FY2016 milestones approved by the Devices Steering Committee

F. Laboratory Optimization

The Devices Program will continue the following in FY2016:

- F.3 – Implement process to annually re-assess laboratory optimization and work planning

Devices F.3. ORA/CDRH Strategic Science and Compliance Committee will continue to share information annually regarding laboratory direction, investments and priorities.

- Lead Organization(s): CDRH; ORA
- Due Date: 9/30/2016
- Acceptance criteria: Quarterly progress updates; annual activity report

G.IT

The Devices Program will continue the following in FY2016:

- G.1 – Continue improvements to real-time visibility of data

- G.2 - Expand identified opportunities to improve information sharing with PREDICT and CenterViews

  Devices G.1. CDRH and ORA will continue to identify opportunities to improve real-time visibility of data. Workgroup will provide FY2016 milestones and quarterly updates.

  - Lead Organization(s): CDRH; ORA
  - Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
  - Acceptance criteria: Complete FY2016 milestones approved by the Devices Steering Committee

  Devices G.2. ORA and CDRH will continue information sharing improvements with CenterViews, PREDICT and CDRH IT systems integration to include implementation of: 1) CenterViews change to rad health tab user interface 2) PREDICT rule change to display radiation category

  - Lead Organization(s): CDRH; ORA
  - Due Date: Define FY2016 milestones by 1/31/2016; quarterly progress updates
  - Acceptance criteria: Complete FY2016 milestones approved by the Devices Steering Committee