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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH'S PLAN OF ACTION

BASED ON BOOZ ALLEN HAMILTON MDUFA II/III EVALUATION PRIORITY RECOMMENDATIONS

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INTRODUCTION

As part of the 2012 Medical Device User Fee Amendments (MDUFA III), the Food and Drug Administration (FDA) agreed to participate with the medical device industry in a comprehensive assessment of the process for device submission review. A two-phase assessment, conducted under an FDA contract by a private, independent consulting firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to objectively assess FDA's premarket review processes is currently underway. The first phase of the analysis involves an assessment of the medical device submission review processes implemented by FDA as a result of the MDUFA III negotiations. The MDUFA III Commitment Letter specifies that the independent assessment will provide findings on a set of priority recommendations (i.e., those likely to have a significant impact on review times) within six months of contract award, and final recommendations for the full evaluation within one year. The Letter also specifies that FDA will publish an implementation plan for each set of recommendations within six months of the receipt of the recommendations.[1]

On December 11, 2013, Booz Allen Hamilton (BAH), the independent contractor, issued a report on the priority recommendations, "BAH MDUFA II/III Evaluation – Priority Recommendations." Section 3, "Key Findings and Priority Recommendations," of the report identifies four priority recommendations for FDA to improve the efficiency and review times of the medical device submission review process:

Recommendation: Develop criteria and establish mechanisms to improve consistency in decision making throughout the review process.

Recommendation: Provide mandatory full staff training for the three primary IT systems that support MDUFA III reviews.

Recommendation: Identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes.

Recommendation: Adopt a holistic, multi-pronged approach to address five quality component areas to standardize process lifecycle management activities and improve consistency of reviews.
Specifically:

- **Senior Management:** Document and communicate a mechanism for issue accountability and follow-up.
- **Corrective and Preventive Action (CAPA) and Continuous Process Improvement (CPI):** Develop a more formal method for logging, prioritizing, tracking, communicating and providing feedback on non-CAPA issues and improvement ideas.
- **Resource Management:** Deploy formal, regularly-scheduled training on new review processes to standardize awareness. Use quantitative methods to assess understanding and activation of behavioral changes.
- **Document Management:** Deploy planned document control system enhancements (e.g. CTS, DocMan, Image2000+, SharePoint) using a quality-oriented focus to optimize the utility of system changes to all review staff.
- **System Evaluation:** Identify and develop internal metrics to monitor the quality and effectiveness of review processes and facilitate continuous process improvement.

[1] MDUFA Performance Goals and Procedures Commitment Letter, http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf

This document outlines the actions the Center for Devices and Radiological Health (CDRH) intends to implement in response to the four priority recommendations. Recognizing that the recommendations can be expanded to further enhance the efficiency of our processes, we also outline additional long-term actions CDRH intends to implement to further enhance the review process. Actions we will take to address specific recommendations identified in the "MDUFA III Recommendation Preliminary Report" are listed under Stage 1. Actions that look beyond the report recommendations and describe longer-term actions to further improve our processes are listed under Stage 2. We intend to complete all Stage 1 actions by December 31, 2015. To the extent possible we intend to work on completing feasible Stage 2 actions while implementing Stage 1. These actions are consistent with the CDRH Quality Management Framework we issued and started to implement in January 2014.

RECOMMENDATION: DEVELOP CRITERIA AND ESTABLISH MECHANISMS TO IMPROVE CONSISTENCY IN DECISION MAKING THROUGHOUT THE REVIEW PROCESS.

STAGE 1

1. Inventory and, as needed, develop business process maps for 510(k) clearance decisions, PMA approval decisions, 510(k) requests for Additional Information, PMA Major Deficiencies, and IDE approval decisions.

2. Inventory existing documentation on processes, procedures, policies, information technology (IT), and metrics associated with 510(k) clearance decisions, PMA approval decisions, 510(k) requests for Additional Information, PMA Major Deficiencies, and IDE approval decisions. The inventory will include processes, procedures, and policies associated with cross-cutting review areas such as biocompatibility and software.
   - Map collected documentation to the business processes from step 1.
   - Determine usability of collected documents, including currency and relevance.
   - Where multiple processes exist for the same identified need, determine which process to follow.

3. Conduct a gap analysis to identify needed key processes, procedures, policies, IT, and metrics associated with 510(k) clearance decisions, PMA approval decisions, 510(k) requests for Additional Information, PMA Major Deficiencies, and IDE approval decisions, including processes, procedures, and policies associated with cross-cutting review areas.
   - Prioritize results and take steps to address priority findings, focusing on those sub-processes, procedures or policies that most impact the consistency of decision making.

STAGE 2

1. Identify Best Practices and Lessons Learned for assuring consistent decision making from other organizations.

2. Based on the results of the gap analysis conducted during Stage 1, as appropriate, develop new, streamline existing, and bring existing processes, procedures, policies, IT, and metrics associated with 510(k) clearance decisions, PMA approval decisions, 510(k) requests for Additional Information, PMA Major Deficiencies, and IDE approval decisions into the CDRH Quality Management Framework. Identify and address missing framework elements, including:
   - Training;
   - Documentation and document controls;
   - Measurement and evaluation tools, including metrics.

3. Develop measures and metrics to assess consistency of decision making for 510(k) clearance decisions, PMA approval decisions, 510(k) requests for Additional Information, PMA Major Deficiencies, and IDE approval decisions.

4. Establish mechanisms for knowledge sharing.

RECOMMENDATION: PROVIDE MANDATORY FULL STAFF TRAINING FOR THE THREE PRIMARY IT SYSTEMS THAT SUPPORT MDUFA III REVIEWS.

STAGE 1

1. Inventory existing Center Tracking System (CTS), Document Management (DocMan), and Image2000+ training available to CDRH staff.

2. Review existing CTS, DocMan, and Image2000+ training content and update, as needed.
   - Assess content for accuracy and currency.
   - Identify and incorporate best practices and lessons learned from existing CTS, DocMan, and Image2000+ training.

3. Identify CDRH staff requiring CTS, DocMan, and Image2000+ training and deploy training.
   - Track and monitor CTS, DocMan, and Image2000+ training participation to assure all appropriate staff receive training.
   - Evaluate CTS, DocMan, and Image2000+ training using the evaluation plan developed in response to Recommendation 3.3.

4. Incorporate CTS, DocMan, and Image2000+ training into the CDRH Reviewer Certification Program (RCP).

5. Establish a cadre of CTS, DocMan, and Image2000+ experts to further assist CDRH staff in the successful use of these IT systems and inform CDRH staff of the cadre members.

Stage 2

Develop a plan for continued process improvement of premarket training, including IT.

1. Research best practices for IT training in similar organizations.

2. Conduct a gap analysis to identify premarket training needs taking into account new and updated IT deployments (e.g., SharePoint, CARS). Develop a strategy to address identified gaps.
   - As needed, develop new or revise existing premarket IT training content.
   - Incorporate best practices and lessons learned in Stage 1.

3. Implement premarket IT training for identified premarket review staff.
   - Using the process developed in Stage 1, ensure that all required staff is trained.
   - Evaluate premarket IT training using the evaluation plan developed in response to Recommendation 3.3.

4. Incorporate premarket IT training beyond CTS, DocMan, and Image2000+ into the CDRH Reviewer Certification Program (RCP).

5. Establish a cadre of premarket IT training experts beyond CTS, DocMan, and Image2000+ and inform staff of the availability of cadre members.

CDRH intends to apply the process identified in Stage 2 to other aspects of premarket review training with the objective of improving this training program.

Recommendation: Identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes.

Stage 1

1. Research best practices for training evaluation in similar organizations.

2. Determine evaluation requirements for premarket review training.
   - Establish the evaluation criteria for each of the four levels of Kirkpatrick's model.
   - Outline the requirements for obtaining data at each of the four levels of Kirkpatrick's model.

3. Develop standardized metrics for each level.
   - Determine the assessment tools to obtain data for each of the four levels of Kirkpatrick's model (tests, surveys, focus groups of staff and supervisors, etc.).
   - Draft assessment questions to obtain data for each of the four levels of Kirkpatrick's model.

4. Develop a premarket review training evaluation plan (including Staff College, Offices, Divisions, etc.).

5. Apply the CDRH evaluation plan to all CDRH Premarket Review training.

RECOMMENDATION: ADOPT A HOLISTIC, MULTI-PRONGED APPROACH TO ADDRESS FIVE QUALITY COMPONENT AREAS TO STANDARDIZE PROCESS LIFECYCLE MANAGEMENT ACTIVITIES AND IMPROVE CONSISTENCY OF REVIEWS.

Senior Management: Document and communicate a mechanism for issue accountability and follow-up.

Corrective and Preventive Action (CAPA) and Continuous Process Improvement (CPI): Develop a more formal method for logging, prioritizing, tracking, communicating and providing feedback on non-CAPA issues and improvement ideas.

STAGE 1

1. Conduct a gap analysis to assess what is needed to improve current premarket CAPA and management review business processes.
   - Review existing premarket management review and CAPA documentation and business processes.
   - Determine what is needed to: (i) improve the current CAPA process; (ii) address non-CAPA issues and improvement ideas on premarket review processes, procedures, policies, IT, and metrics; and (iii) allow for staff and manager input at the Division and Branch levels during management reviews.

2. Based on the results of the gap analysis, as appropriate, develop new or revise existing documentation and business processes.
   - Determine a threshold for issues to be treated with a CAPA and for managing and assuring accountability and follow-up for significant, cross-cutting non-CAPA issues and improvements, including new processes.
   - Determine how to best manage those issues that require addressing, but do not merit a CAPA.
   - Determine how to include representation from different levels of the appropriate CDRH offices at CAPA meetings to promote discovery of common themes that may need to be addressed at the office level.

3. Implement changes to existing infrastructure to support the established procedures for logging, prioritizing, tracking, communicating and providing feedback on CAPA, non-CAPA issues, and improvement ideas for premarket review processes, including new processes.

STAGE 2

Develop and deploy a CDRH system to capture, prioritize and address quality issues and feedback, including process improvement and management oversight processes.

1. Inventory existing CDRH documentation and business processes addressing procedures, policies and IT for logging, prioritizing, tracking, communicating, and providing feedback on quality (CAPA and non-CAPA) issues and improvement ideas for CDRH processes, including procedures for senior management accountability, process improvement, and follow-up.

2. Conduct a gap analysis to assess documentation, business processes, procedures, policies, IT, and metrics for logging, prioritizing, tracking, communicating, and providing feedback on quality (CAPA and non-CAPA) issues and improvement ideas for processes(developing new or improving existing), including procedures for: senior management review, process improvement, and issue accountability and follow-up.

3. Based on the gap analysis results, develop a Center business process for addressing quality (CAPA and non-CAPA) issues and improvement ideas on processes, procedures, policies, IT, and metrics.
   - Allow for input at all levels and incorporate existing Office and Center systems (e.g., ODE CAPA and CDRH Suggestion System).
   - Incorporate CDRH Quality Management Framework principles and practices into existing processes.
   - Apply the CDRH Quality Framework to develop new processes.

4. Develop the infrastructure to support the established procedures for logging, prioritizing, tracking, communicating and providing feedback on CAPA, non-CAPA issues, and improvement ideas at all levels of CDRH. Include mechanisms to share information with staff.

5. Develop and execute a training program, support system, and communication strategies for staff to assure appropriate implementation and use of new or modified processes, procedures, policies, and IT, including points of contact for oversight.

Resource Management: Deploy formal, regularly-scheduled training on new review processes to standardize awareness. Use quantitative methods to assess understanding and activation of behavioral changes.

Implementation of the actions under 3.2 and 3.3 will lead to deployment of formal, regularly-scheduled training on new review processes, procedures, policies, and IT to standardize awareness that incorporates quantitative methods to assess understanding and activation of behavioral changes. Appropriate evaluation methods and metrics (see Recommendation 3.3) will enable CDRH to determine training effectiveness. Recommendation 3.2 outlines additional important components of a comprehensive, quality-managed reviewer training program. As noted in the BAH report, recommendation 3.4.2 encompasses the recommendations in 3.3. CDRH has determined that in addition to 3.3, the recommendation put forth under 3.2 addresses recommendation 3.4.2. In addition, the CDRH Quality Management Framework recognizes the importance of training to assure an "adequate level of understanding to carry out those processes and procedures [under the Quality Program]." The plans in this document are consistent with the CDRH Quality Management Framework. As the Center moves to implement the actions in this document, training will play a critical role in assuring understanding and effectuating needed behavioral changes.

Document Management: Deploy planned document control system enhancements (e.g., CTS, DocMan, Image2000+, SharePoint) using a quality-oriented focus to optimize the utility of system changes to all review staff.

STAGE 1

1. Inventory existing processes, policies, and documentation for the use of electronic document control systems to manage the premarket review, including the development of documents that are part of the administrative record (e.g., CTS, DocMan, Image2000+, and SharePoint). The inventory will include existing process, policies and documentation from all CDRH Offices that make use of CTS, DocMan, and Image2000+ when conducting premarket review activities.

2. Conduct a gap analysis to assess adequacy of existing processes, procedures, policies, and documentation for the use of document management systems (e.g., CTS, DocMan, Image2000+, and SharePoint).

3. Based on the gap analysis results, as appropriate, develop new or revise existing processes, procedures, policies, and documentation for the use of electronic document control systems to manage premarket review, including the development of documents that are part of the administrative record (e.g., CTS, DocMan, Image2000+, and SharePoint).
   - Include, for example, procedures for naming, version control, storage, and archiving.
   - As needed, revise existing or develop additional aids and training to address new or revised procedures.

STAGE 2

1. Inventory documentation on significant internal CDRH processes and procedures, and assess content for accuracy and currency.

2. Develop and implement a strategy to appropriately maintain and share process documentation.

3. Implement document control principles and practices identified in the CDRH Quality Management Framework.
   - Develop conventions and procedures for managing documents addressing internal processes and procedures. Include, for example, procedures for naming, version control, storage, and archiving.
   - Develop guidelines, including templates, to standardize the development of documentation related to internal processes and procedures.

System Evaluation: Identify and develop internal metrics to monitor the quality and effectiveness of review processes and facilitate continuous process improvement.

STAGE 1

1. Identity sub-processes related to the review of premarket notifications [510(k)s] and PMAs.
   - Review existing documentation, including process maps, "510(k) Review Milestone" spreadsheet, standard operating procedures, and performance goals.
   - Collect input from staff involved in the premarket review of 510(k)s and PMAs, including Document Control Center (DCC) staff, premarket review staff, and Program Operations Staff (POS).
   - Use information collected to prioritize and select sub-processes to monitor.

2. Conduct a gap analysis to assess what is needed to monitor review of selected sub-processes.
   - Inventory existing metrics.
   - As appropriate, develop new or streamline existing metrics.

3. Conduct post-review analyses of 510(k)s and PMAs that have reached a MDUFA decision to verify that the identified metrics facilitate sub-process monitoring and continuous process improvement. Use the analysis to revise metrics, as appropriate.

STAGE 2

1. Conduct a focused analysis to identify indicators that may be associated with a specific 510(k) decision.
   - Use a MDUFA dataset that includes sub-process data and variables to determine if the sub-process variables included in the analysis are indicators of performance-based NSE decisions.
   - Identify indicators that may improve monitoring the quality or effectiveness of sub-processes or outcomes of sub-processes.

2. Based on the results of the analysis, modify existing or develop new procedures to improve monitoring for consistency and quality using identified indicators.

3. Verify identified indicators yielded intended results.

4. Apply steps identified in Stage 2 to additional 510(k) and PMA decisions, as appropriate.