DECEMBER 2014

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH'S PLAN OF ACTION

BASED ON BOOZ ALLEN HAMILTON MDUFA II/III EVALUATION DELIVERABLE 10: FINAL REPORT ON FINDINGS AND RECOMMENDATION

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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." The report identified four priority recommendations for FDA to improve the efficiency and review times of the medical device submission review process:

- Develop criteria and establish mechanisms to improve consistency in decision making throughout the review process.
- Provide mandatory full staff training for the three primary IT systems that support MDUFA III reviews.
- Identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes.
- Adopt a holistic, multi-pronged approach to address five quality component areas to standardize process lifecycle management activities and improve consistency of reviews.

Six months later, on June 11, 2014, FDA issued a Plan of Action outlining the actions the Center for Devices and Radiological Health (CDRH) intends to implement in response to the four priority recommendations.

On June 11, 2014, BAH issued the final report on findings and recommendations, "Deliverable 10: Final Report on Findings and Recommendations." Including the four priority recommendations from the December 2013 BAH report, Section 1.9, "Recommendations" of the final report identifies eleven recommendations in four categories for FDA to improve the efficiency and review times of the medical device submission review process:

Quality Management

1. Adopt a holistic, multi-pronged approach to address five quality component areas to standardize process lifecycle management activities and improve consistency of reviews. (**Priority Recommendation**)
   - **Senior Management:** Document and communicate a mechanism for issue accountability and follow-up.
   - **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, eCopy) using a quality-oriented focus to optimize the utility of system changes to all review staff.
   - **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.
   - **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

Evaluation of Review Process

2. Develop criteria and establish mechanisms to improve consistency in decision-making throughout the review process. (**Priority Recommendation**)
3. Optimize RTA process by improving awareness of and clarity around Administrative requirements for 510(k) submissions.
4. Perform a retrospective root cause analysis of withdrawn submissions and develop a mechanism to minimize their occurrence.
5. Implement a consistent practice for communicating early and frequently with Sponsors during the Substantive Review phase to address and resolve potential issues prior to Substantive Interaction.

Evaluation of IT Infrastructure and Workload Management Tools

6. Provide mandatory training for the three primary IT systems that support MDUFA III reviews. (**Priority Recommendation**)
7. Provide increased clarity to applicants beyond existing eCopy guidance to enhance organized submission structure.
8. Evaluate tools for providing a comprehensive view of staff workload.

Evaluation of Training Programs

9. Identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes. **(Priority Recommendation)**
    - Level 1: Perform annual training needs assessments to fully consider and identify changes in reviewers' and management's training needs in both Offices to improve review process efficacy and efficiency.
    - Level 1: Periodically re-assess training program material and objectives to ensure they continue to support reviewer needs.
    - Level 2: Perform pre- and post-course test assessments to gauge knowledge transfer and course metrics for learning. (**Priority Recommendation**)
    - Level 2: Develop internal SOPs on the timing of evaluations and training processes.
    - Levels 3-4: Collect, record, and analyze feedback from trainers to improve reviewer training curriculum.
    - Levels 3-4: Establish a refresher program for RCP (Tier II) to improve core review skills of RCP-ineligible review staff and re-certify RCP graduates.
    - Levels 3-4: Deploy post-course completion surveys and/or interviews to assess staff behavioral changes based on knowledge gained during training courses.
    - Levels 3-4: Assess program results by developing course outcome metrics.
10. Promote informal training and knowledge sharing by seasoned staff for review staff and management to share Division or science-specific review processes, lessons learned, and best practices.

Assessment of Staff Turnover

11. Develop CDRH-wide staff transition and succession plans to mitigate the impact of turnover on submission reviews.

This document, the December 2014 Plan of Action, supersedes our June 2014 Plan of Action. It includes revisions to address additional information on the December 2014 priority recommendations included in the contractor's June 2014 final report and outlines the actions CDRH plans to implement in response to the additional seven recommendations identified in the final report.

CDRH's approach to addressing the recommendations remains the same. 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 "Deliverable 10: Final Report on Findings and Recommendations," 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. All actions in this document are consistent with the CDRH Quality Management Framework we issued and started to implement in January 2014.

QUALITY MANAGEMENT

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

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 ensure 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 the "Evaluation of Training Programs" and "Evaluation of IT Infrastructure and Workload Management Tool" Sections of this Plan of Action (see recommendations 6, 9 and 10) 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 will enable CDRH to determine training effectiveness. In addition, the CDRH Quality Management Framework recognizes the importance of training to ensure an "adequate level of understanding to carry out those processes and procedures [under the Quality Program]." This Plan of Action is in alignment with the CDRH Quality Management Framework. Therefore, as the Center moves to implement the actions in this document, training will play a critical role in ensuring understanding and effectuating needed behavioral changes.

Document Management: Deploy planned document control system enhancements (e.g., CTS, DocMan, Image2000+, SharePoint, eCopy) 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+, SharePoint, eCopy). The inventory will include existing process, policies and documentation from all CDRH Offices that make use of document control systems 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+, SharePoint, eCopy).
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+, SharePoint, eCopy).
   - 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 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 and incorporate the guidelines into staff training, 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.

EVALUATION OF REVIEW PROCESS

2. 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.
4. Identify Best Practices and Lessons Learned for ensuring consistent decision making from other organizations and incorporate best practices findings into premarket processes.
5. Use the results of the gap analysis to identify highest priority processes, procedures, policies, IT, and metrics to address those that most impact the consistency of decision making. As appropriate, develop new, streamline existing, and bring highest priority processes, procedures, policies, IT, and metrics into the CDRH Quality Management Framework. Identify and address missing framework elements, including: training, documentation and document controls, and measurement and evaluation tools, including metrics.

STAGE 2

1. Address additional priority findings. As appropriate, develop new, streamline existing, and bring processes, procedures, policies, IT, and metrics into the CDRH Quality Management Framework. Identify and address missing framework elements, including: training, documentation and document controls, and measurement and evaluation tools, including metrics. 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.
2. Establish mechanisms for knowledge sharing.

3. Optimize the RTA process by improving awareness of and clarity around Administrative requirements for 510(k) submissions.

STAGE 1

Conduct an assessment of the RTA program.

1. Conduct an audit of the RTA program.
   - Identify top missed criteria.
   - Identify criteria with the greatest amount of substantive review.
2. Conduct an analysis of RTA audit data to identify trends, correlations, or patterns in audit results that may lead to developing relevant RTA metrics and indicators.
   - Identify characteristics or patterns for sponsors with 1st round rejection (e.g., eCopy hold, User Fee hold, checklist inclusion, prior MDUFA III submission, etc.).
   - Evaluate the differences in RTA rates within the various segments (e.g. small manufacturers vs. large manufacturers, or foreign vs. domestic submitters, ODE vs. OIR).
3. Conduct an analysis of feedback from industry collected during the assessment of the premarket review process on their experience with the RTA policy and checklist.
4. Conduct root-cause analyses to determine the underlying causes and appropriate mitigation action for the priority findings of the RTA assessment (Steps 1 through 3, above).
5. Revise the RTA policy to increase clarity and further promote awareness of requirements.
   - Clarify boundaries around the use of discretion in the application of the RTA policy.
   - Modify criteria phrasing and/or explanatory text to improve understanding and clarity of the RTA policy.

STAGE 2

1. Update the RTA checklist to incorporate new policy and assessment results. Develop frequently asked questions (FAQ) to clarify best practices and tips for industry.
2. Update RTA guidance document, including modified checklist and FAQs.
3. Develop and make available training (online and in person) and use outreach tools to communicate RTA policy and program developments to staff and industry (e.g., CDRH LEARN modules, webinars for industry, and conferences or workshops)

4. Perform a retrospective root cause analysis of withdrawn submissions and develop a mechanism to minimize their occurrence.

STAGE 1

1. Conduct an analysis of withdrawn submissions to identify trends, correlations, or patterns that may lead to withdrawn data, including reason for withdrawal.
   - Identify characteristics or patterns during the acceptance review.
   - Identify characteristics or patterns during the substantive interaction phase of the review, including the end of the review cycle.
2. Conduct root-cause analyses to determine cause of identified trends, correlations or patterns, and develop mitigation actions for these findings. As appropriate, implement mitigation actions.

5. Implement a consistent practice for communicating early and frequently with sponsors during the substantive review phase to address and resolve potential issues prior to substantive interaction.

STAGE 1

1. Conduct an assessment of current practices and identify best practices for early and frequent communication during 510(k) review.
   - Interview ODE and OIR reviewers and management.
   - Collect feedback on what does and what does not work in interactive review.
2. Use the results of the assessment to develop policy, standard procedures, and metrics for communication during early 510(k) review. Use focus groups to inform development of policy, procedures, and metrics.
3. Pilot the policy and procedures in one premarket review branch.
4. Evaluate results of pilot study.
   - Determine if frequency of communications increased (e.g., DocMan audit).
   - Collect feedback, including recommendations for improvement and lessons learned, from pilot branch.
5. Revise policy, procedures, and metrics to incorporate results from pilot study.
6. Implement new policy and internal procedures.

STAGE 2

1. Develop frequently asked questions (FAQ) to clarify best practices and tips for industry.
2. Develop and make available training (online and in person) and use outreach tools to communicate policy and procedures to staff and industry, e.g., CDRH LEARN modules, "Crucial Conversations" Staff College Training (Vital Smarts), webinars for industry, conferences and workshops.

EVALUATION OF IT INFRASTRUCTURE AND WORKLOAD MANAGEMENT TOOLS

6. 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 ensure all appropriate staff received training.
   - Evaluate CTS, DocMan, and Image2000+ training using the evaluation plan developed in response to recommendation 9, "Identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes," which is addressed in this Plan.
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 for new primary premarket IT systems.

1. Research best practices for IT training in similar organizations.
2. Conduct a gap analysis to identify premarket training needs for new primary IT systems (e.g., SharePoint, CARS).
   - Identify existing training.
   - Assess training for accuracy and currency.
3. Develop a strategy to address identified gaps. As needed, develop new or revise existing training content for new primary IT systems.
   - Incorporate best practices and lessons learned in Stage 1.
   - Incorporate lessons learned from existing training.
4. Deploy training to premarket review staff.
   - Ensure that required staff receives the training.
   - Evaluate training using metrics to assess satisfaction, learning, and staff behavior changes.
5. Incorporate premarket IT training into the CDRH Reviewer Certification Program (RCP).
6. Establish a cadre of premarket IT training experts for new primary IT systems and inform staff of the availability of cadre members.

7. Provide increased clarity to applicants beyond existing eCopy guidance to enhance organized submission structure.

Conduct an assessment of the eCopy program.

1. Collect feedback from staff and industry, including:
   - Identify eCopy structural issues encountered by review staff.
   - Identify eCopy structural issues encountered by industry.
2. Identify top structural issues encountered by industry and staff. Stratify the results by type, including IT, training, and policy.
3. Determine which structural issues to address.
   - Prioritize issues taking into consideration benefit, risk, and cost (return-on-investment).
   - Address highest priority issues.

8. Evaluate tools for providing a comprehensive view of staff workload

1. Convene a work group to identify and develop methods for providing a more comprehensive view of current and evolving reviewer workload.
2. Identify tools and data available to assess staff workload.
   - Determine advantages and disadvantages of each tool.
   - Identify the workload data each tool provides and determine if the data is unique or redundant.
   - Determine comprehensiveness of existing tools.
3. Identify gaps for assessing and managing current and evolving reviewer workload. Determine how to address gaps, including specific data, indicators, and tools that will help managers more efficiently use staff resources (e.g., number of submissions that a reviewer has on hold and date-related data for each submission, number of inter-Center consults, additional premarket review milestones, indicator of submission complexity, branch due dates, individual performance, additional considerations that may inform the submission assignment process (e.g., submission type, upcoming deadlines, reviewer expertise, pre-existing relationship with submission, or use of electronic tools to assist in managing deadlines.
4. Develop an IT requirements document for an improved electronic workload management tool that incorporates real-time data.
5. Identify general best practices for workload management (e.g., setting no more than two significant goals in one-week for a reviewer, incorporating time for management review in the review timeline, and using one on one meetings for further assessment of workload).
6. Develop a best practices document for workload management, including best practices for reviewers and supervisors in meeting MDUFA goals

EVALUATION OF TRAINING PROGRAMS

9. 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 levels 1 through 4 of Kirkpatrick's model.
   - Identify assessment tools for obtaining data on levels 1 through 4 of Kirkpatrick's model (e.g., tests, surveys, focus groups of staff, supervisors, and trainers).
4. Develop procedures (including evaluation methods and timing of evaluations) and aids (including draft assessment questions) for obtaining data for levels 1 through 4 of Kirkpatrick's model.
5. Implement the use of standardized Kirkpatrick's model level 1 through 4 metrics into the CDRH RCP Training Program.

STAGE 2

Develop and implement a process for continued evaluation and improvement of premarket training programs.

1. Conduct a gap analysis to identify premarket training needs and objectives for staff and management.
   - Collect input from staff, managers, subject matter experts, and training instructors.
   - Assess existing training for accuracy and currency.
2. As needed, develop new or revise existing premarket training content.
   - Incorporate standardized Kirkpatrick's model level 1 through 4 metrics to assess training satisfaction, learning, and staff behavior changes.
3. Incorporate documentation and aids developed in Stage 1 into the new processes and procedures.
4. Deploy training to all premarket review staff.
5. Evaluate training using metrics to assess satisfaction, learning, and staff behavior changes using established evaluation methods and guidelines.

10. Promote informal training and knowledge sharing by seasoned staff for review staff and management to share Division or science-specific review processes, lessons learned, and best practices

1. Identify and assess existing practices for promoting and tracking informal training and identify opportunities for improvements.
2. Develop and implement guidelines for conducting informal training, including best practices for trainers and best practices for promoting and tracking training.
3. Develop procedures for tracking and evaluating informal training using CDRH's Learning Management system and standardized metrics. Train all Premarket Offices on the new procedures.

ASSESSMENT OF STAFF TURNOVER

11. Develop CDRH-wide staff transition and succession plans to mitigate the impact of turnover on submission reviews.

STAGE 1

SUCCESSION PLANNING

1. Conduct a gap analysis to assess CDRH's existing succession planning process, procedures, and metrics. Include in the analysis an assessment of past years' implementation.
   - Evaluate effectiveness in identifying soon-to-be vacated critical leadership and technical positions.
   - Evaluate effectiveness in identifying/implementing mitigation strategies to ensure continuity of knowledge, expertise, and operations.
   - Identify opportunities for improvements.
2. Revise CDRH succession planning processes, procedures, and metrics to incorporate analysis findings.
3. Implement the revised succession planning process, procedures and metrics. Develop training and outreach tools for staff.

TRANSITION PLANNING

1. Conduct a GAP analysis to assess CDRH's transition planning process, procedures, metrics and resources. Review existing transition planning-related process and practices/activities
   - Review existing documentation (e.g. standard operating procedures) and metrics.
   - Collect information from CDRH Offices to identify existing best practices to promote seamless premarket review staff transitions.
2. Based on gap analysis, develop new or revise existing transition planning processes, procedures and metrics to help mitigate the impact(s) of review staff turnover on the review process.
3. Implement enhanced transition planning process, procedures and metrics. Develop training and outreach tools for staff.