Food and Drug Administration

Independent Assessment of FDA Device Review Process Management – Phase 2

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Deliverable 6: Final Implementation Evaluation Report

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Booz | Allen | Hamilton

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1. EXECUTIVE SUMMARY

The Medical Device User Fee Amendments of 2012 (MDUFA III) included a provision for a two-phased independent assessment of the Food and Drug Administration's (FDA) medical device review process. The first phase of the assessment, conducted by the consulting firm Booz Allen Hamilton, focused on the identification of best practices and process improvements to promote predictable, efficient, and consistent premarket reviews that meet FDA's regulatory standards. In December 2013, a preliminary report was published on the FDA website, which featured four priority recommendations from Booz Allen deemed likely to have a significant impact on review times. This was followed by a final report released to the public in June 2014 that detailed an additional seven recommendations for improvements in the submission review process, Information Technology (IT) infrastructure, training and retention policies and practices, and quality management (QM) systems. In December 2014, FDA's Center for Devices and Radiological Health (CDRH) published its final *Plan of Action* to address each of the final Phase 1 recommendations. This report presents the findings of the Phase 2 assessment, which evaluates FDA's implementation of the 11 recommendations from the Phase 1 assessment.

The Phase 2 assessment of FDA's implementation was performed using a five-stage framework, which evaluates each improvement project based on its planned objectives, measurability, execution of project plans, initial results, and impact. The time required to fully implement some of the plans, and collect data to measure results and outcomes, did not allow a sufficient period to complete the latter stages of the assessment framework. However, CDRH successfully completed each project in its *Plan of Action* to address Booz Allen's recommendations, which represents a significant accomplishment by the Center across a broad range of areas in its medical device review program, and satisfies FDA's commitment to fulfill the recommendations from the Independent Assessment. A brief summary of the implementation projects outlined in the *Plan of Action*, and their associated results is provided below:

- QM: Corrective and Preventive Action (CAPA) and Continuous Process Improvement (CPI) (Priority Recommendation) – CDRH conducted a gap analysis to identify necessary documentation for CAPA and non-CAPA issue management, and revised a QM Program website to promote their quality initiatives and policies. CDRH also developed new processes and an online feedback tool that was incorporated into the QM Program site. The result of this project was the creation of a *Management Review Standard Operating Procedures (SOP)*, a *FEEDBACK✓CDRH SOP* and quality feedback tracking and reviewing tool, located together with other quality-related documents on a QM Program website. The use of the new quality feedback tool was measured over the course of this assessment, and demonstrates that the products of this project are being put to use by the Center.
- QM: Document Control System Enhancements (Priority Recommendation) – CDRH conducted an inventory of all existing processes, policies and documentation for the use of electronic document control systems to manage the premarket review. Based on this inventory, CDRH conducted gap analyses of premarket administrative records and IT systems enhancements to identify needed revisions or enhancements. The project yielded a new *Document Management SOP* and *IT System Enhancement Request SOP*, as well as revised aids and training on both.
- QM: Review Process Quality Metrics (Priority Recommendation) – CDRH assessed the complete Traditional 510(k) process map and other documents to identify critical review

process steps to monitor for CPI. This resulted in a set of priority metrics that aligned to the identified steps. CDRH conducted post-review analyses to select a set of short-term and long-term review process metrics to track and monitor for quality.

- Decision-Making Consistency (Priority Recommendation) – CDRH developed a *Management Oversight of Critical Control Points SOP*, and rolled out a guided review tool to facilitate consistent reviews. In addition, many of the activities undertaken to address the other recommendations impact this recommendation as well.
- Refuse-to-Accept (RTA) Process Improvement – CDRH conducted an audit of the RTA program to identify criteria that had the greatest impact on reviews, and analyzed the audit data to find opportunities for improving the RTA review process. Industry feedback was also incorporated into these internal analyses, resulting in a revised RTA guidance and re-designed applicant checklist.
- Withdrawn Submission Analysis – CDRH conducted an analysis of withdrawn submissions to identify trends, correlations, or patterns across the 510(k) review cycle that may lead to Withdrawal decisions. Additional root cause analyses into the findings helped FDA determine reasons for the identified trends or correlations. As a result, CDRH created a new *Work Instructions* document for Withdrawal decisions, which included mitigation actions.
- Sponsor Communications – FDA assessed the existing communications practices through review staff interviews and identified best practices for early and frequent communication during the 510(k) review process. This project resulted in the release of a new *Work Instructions* document for Interactive Review during the submission review process, as well as training staff on the new communications practices.
- IT Systems Training (Priority Recommendation) – CDRH conducted an inventory and gap analysis of existing IT systems training, resulting in updating training content to address staff needs. CDRH identified staff required to take the training and released mandatory training on its primary premarket review IT systems for all premarket review staff. Additionally, CDRH created a Cadre of IT Experts to provide IT support and guidance on the use of Center-specific premarket review IT systems in each review division. The compliance with the new mandatory training measured during this assessment was very strong, with 93% of required staff completing the course as of December 15, 2015.
- eCopy Guidance – CDRH identified structural issues encountered in eCopy use by review staff and industry through an online survey. Issues were prioritized based on benefit, risk, and cost, and CDRH addressed the highest priority issues. This project culminated with the release of revised eCopy Guidance to emphasize the importance of the use of features that facilitate navigation.
- Workload Management Tool Review – CDRH convened a working group of experienced staff to inventory and analyze the existing and evolving workload management landscape at the Center. After evaluating existing tools, such as canned reports in the IT systems, CDRH identified gaps to address. In response, CDRH developed a best practices document for workload management, IT requirements for a workload management system, and a prototype workload management tool.
- Training Program Evaluation and Metrics (Priority Recommendation) – CDRH researched and documented training best practices in comparable organizations to develop a strategic approach to meeting training evaluation needs and requirements. Based on their findings, CDRH developed standard processes and procedures for collecting training metrics. This project resulted in an overall training evaluation SOP, as well as SOPs for the collection of Kirkpatrick Level 1-4 metrics. The initial results of this

implementation included the collection of Levels 1 and 2 metrics for participants in the mandatory IT Systems Training (see above) and 11 cohorts of Reviewer Certification Program (RCP) training, consisting of 315 trainees.

- Promote Informal Training – CDRH convened a focus group to identify and assess existing practices for promoting and tracking informal training across CDRH, as well as benchmarking training best practices, to develop a comprehensive view of the training landscape in the Center. This yielded an *Informal Training SOP* and a new form to request transcript credit for informal training. The initial results indicate a successful early rollout, with nearly half of surveyed staff claiming awareness of the new informal training procedures. CDRH can build on this with additional directed messages as well as word-of-mouth communication among staff.
- Staff Turnover and Transition Plans – CDRH conducted gap analyses for both succession planning and transition planning processes to identify gaps and best practices, which led to revising existing succession planning processes and metrics, and developing new transition planning processes. CDRH produced a Center-wide *Transition Planning SOP* and *Succession Planning SOP*.

The initial results for a subset of the projects provide a positive indication that CDRH has promoted and begun using the products of their implementation projects. Similar analyses could be conducted to assess the initial results of implementation of the nine remaining projects, after sufficient time has elapsed to allow for adoption and data collection. There was insufficient time to assess the outcome and impact of any of the implementation projects. Measuring outcomes represents the most critical and meaningful assessment in the framework, to determine if the projects are having the intended impact of the original recommendation. Booz Allen recommends that CDRH complete the assessments of initial results and outcomes in the evaluation framework, after sufficient time to allow for full adoption and for the intended benefits of the original recommendation to be measurable (e.g., beginning in January 2017). This assessment could confirm that the recommendations are working as planned, and also allow for course correction to avoid further investment in a project that needs to be modified.

2. PROJECT BACKGROUND AND OBJECTIVES

The Medical Device User Fee Amendments of 2012 (MDUFA III) reaffirms the original intentions of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) to utilize fees from medical device manufacturers to support enhancements in the device approval process. The MDUFA III legislation also broadens the scope of the legislation to include expanded risk management, post-marketing systems, complete lifecycle tracking, and information technology (IT) improvements. The MDUFA III Commitment Letter specifies new processes for managing Pre-Submissions, includes guidance development on premarket review processes, provides updates to review performance goals, and calls for improvements in staffing ratios and training programs. Pursuant to the performance Goals and Procedures adopted under MDUFA III, the FDA also agreed to participate with the medical device industry in a comprehensive assessment of the process for the review of medical device submissions. The Commitment Letter specified a two-phased assessment for performing technical analysis, a management assessment, and program evaluation required to objectively assess FDA's premarket review processes.

In July 2013, Booz Allen Hamilton was selected as the management consulting firm to perform the independent assessment. The first phase of the assessment focused on the identification of best practices and process improvements to promote predictable, efficient, and consistent premarket reviews that meet FDA's regulatory standards. The assessment centered on the medical device submission review processes, in addition to evaluating the Center for Devices and Radiological Health's (CDRH) quality management (QM) systems, IT infrastructure, and training and retention policies and practices. On December 11, 2013, FDA published four priority recommendations[1] developed by Booz Allen for addressing key areas of concern identified by industry and FDA. The recommendations were intended to optimize and enhance existing systems and processes to resolve issues that would otherwise impede the success of the MDUFA III review processes going forward, and were deemed likely to have a significant impact on review times. On June 11, 2014, Booz Allen's final report[2] was published, which included the findings, analysis, and final recommendations for Phase 1 of the independent assessment. While Booz Allen considered resource requirements to a limited degree in developing these recommendations, it was understood that certain recommendations may have resource implications that could impact FDA's ability to fully implement them. The 11 final recommendations for FDA to improve the efficiency and review times of the medical device submission review process are summarized in Exhibit 1.

FDA subsequently developed a *Plan of Action*[3] in response to the priority recommendations on June 11, 2014, and a final *Plan of Action*[4] published on December 11, 2014 to address each of the final Phase 1 recommendations. FDA structured this plan by outlining actions aligned to each recommendation in two stages. Actions described under Stage 1 were designed specifically to fully address each recommendation in the independent assessment Phase 1 final report. Actions listed under Stage 2 were intended to build upon the advancements of the Stage 1 activities, and represent additional long-term actions planned by FDA to further enhance the review process. FDA's stated intention was to try, where possible, to complete certain Stage 2

[1] MDUFA III Evaluation – Priority Recommendations—December 2013.
[2] MDUFA III Evaluation Final Report on Findings and Recommendations—June 2014.
[3] CDRH's *Plan of Action* – Priority Recommendations. June 2014.
[4] CDRH's *Plan of Action* – Final Recommendations December 2014.

actions while implementing Stage 1, but only Stage 1 activities were planned for completion by December 31, 2015.

Exhibit 1. Recommendations from Phase 1 of the Independent Assessment

Number	Recommendation
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
1a*	Senior Management: Document and communicate a mechanism for issue accountability and follow-up
1b*	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
1c*	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
1d*	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
1e*	System Evaluation: Identify and develop internal metrics to monitor the quality and effectiveness of review processes and facilitate CPI
Review Process	
2*	Develop criteria and establish mechanisms to improve consistency in decision-making throughout the review process
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 (SR) phase to address and resolve potential issues prior to Substantive Interaction
IT Infrastructure and Workload Management Tools	
6*	Provide mandatory training for the three primary IT systems that support MDUFA III reviews
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
Training Programs and Staff Turnover	
9*	FDA should identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes
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
11	Develop CDRH-wide staff transition and succession plans to mitigate the impact of turnover on submission reviews

Note: Priority recommendations designated with an asterisk (*)

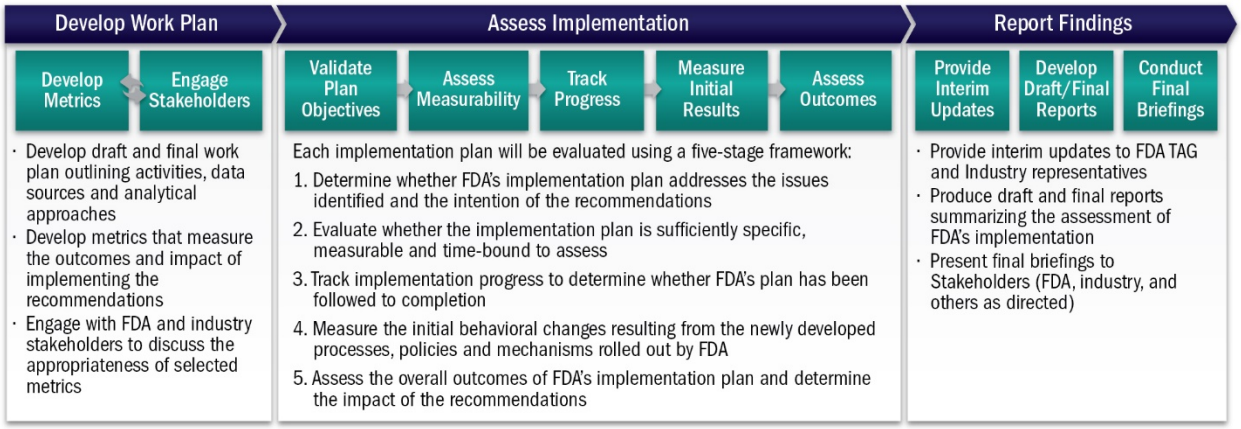
The key objectives for Phase 2 of the independent assessment were to evaluate the implementation of the recommendations identified during Phase 1 of the study, and to publish a written assessment. Because the Stage 1 activities were intended to completely address each recommendation from the independent assessment, only those activities, and not those described under Stage 2, are the focus of this report. This report describes the methodologies

employed by Booz Allen, and provides a structured assessment of FDA's implementation of each of their action plans.

3. METHODOLOGY

The Phase 2 Independent Assessment consisted of three major tasks, as illustrated in Exhibit 2: Develop Work Plan, Assess Implementation and Report Findings.

Exhibit 2. Independent Assessment Phase 2 Approach



3.1 Develop Work Plan

Booz Allen developed a work plan that outlined project activities, described the data collection approach, identified data sources and detailed the evaluation framework. The work plan also described the process for developing and refining evaluation metrics for assessing implementation, and discussed the approach for engaging stakeholders from both FDA and the medical device industry.[5] An initial draft work plan was developed and subsequently revised after the release of *CDRH's Final Plan of Action* in December 2014.

To develop the evaluation metrics, Booz Allen analyzed the outputs of each of FDA's implementation plans to identify a set of quantitative or qualitative measures to assess the initial results and overall outcomes resulting from the plan. We identified the measurable output from each detailed implementation plan, which included newly-developed or revised processes, policies and/or tools that address the recommendation. A preliminary list of potential metrics was refined to specify those that were deemed most likely attainable and accurate for assessing initial results and overall outcomes. These potential metrics were discussed with key stakeholders from both FDA and industry to iteratively revise and validate the selected metrics. In addition, metrics were updated as FDA progressively identified additional specific implementation activities to accomplish the goals listed in the *Plan of Action*. Specifically, some projects in *CDRH's Plan of Action* involved interim steps to assess CDRH's current state and conduct gap analyses to identify areas requiring additional processes, documentation or training needed to address a recommendation (e.g., review process, training and QM

[5] Industry stakeholders consisted of representatives from the Medical Device Manufacturer's Association (MDMA), Advanced Medical Technology Association (AdvaMed), and the Medical Imaging & Technology Alliance (MITA).

recommendations). Because the results of the gap analyses were not known at the time the initial work plan was developed, the complete set of metrics could not be finalized initially, and were revised and finalized with consultation and feedback with the key project stakeholders as more information on the implementation projects became available. Final evaluation metrics were only documented for those implementation projects that left a sufficient observation period to collect data and perform an analysis of initial results.

3.2 Assess Implementation

The assessment of FDA's implementation was performed using the five-stage framework outlined in Exhibit 3. Each stage of the framework consists of a different type of evaluation, characterized by a set of key questions, and all implementation plans were to be assessed in each stage of the framework sequentially (e.g., the Stage 1 assessment will be completed prior to beginning the Stage 2 assessment). Each stage of the framework required a progressively more thorough evaluation than the prior stage, and focused increasingly on the impact of the implementation on CDRH's operations and performance. Consequently, these more thorough evaluation stages require more substantial data collection and analysis. In addition, a sufficient timeframe was required for the latter evaluation stages, to account not only for the analysis, but also for the measurable impact of the implementation to take effect. Therefore, Booz Allen's ability to complete the latter stages of the evaluation framework was dependent on the implementation timeframe and the nature of the evaluation metrics for each implementation plan. Each implementation plan was evaluated through as many stages as possible within the project timeframe. While each implementation plan in FDA's *Plan of Action* consists of two stages, this evaluation of the implementation was intended to only assess activities up to the point that they achieve the objectives underlying the original recommendation.[6]

Exhibit 3. Phase 2 Evaluation Framework

1. Validate Implementation Plan Objectives	· What are the issues and associated recommendations identified for further improvement? · Does FDA have a plan in place to address each recommended area for improvement?
2. Assess Measurability of Implementation Plan	· Is the planned implementation of each recommendation sufficiently specific, measurable, and time-bound to be able to effectively assess? · If not, what changes would enable FDA's plan to be assessed?
3. Track Implementation Progress	· Are activities being executed according to planned schedules? · If not, are there plans and points of contact in place for course correction, oversight, and activity completion?
4. Measure Initial Results	· What metrics may be used to assess whether activities were performed as intended by the implementation plan? · What initial results are feasible to measure during the Phase 2 study timeframe?
5. Assess Outcomes	· What measures may be used to assess FDA achievement of desired outcomes? · What are the actual outcomes of FDA implementation? · What outcomes are feasible to assess during the Phase 2 study timeframe?

[6] In its *Plan of Action*, CDRH indicates that the recommendations will be addressed in Stage 1 of its implementation plans. Stage 2 plans are intended to go above and beyond the recommendations, and are outside the scope of this assessment.

3.2.1 Validate Objectives

The initial stage of the evaluation framework is to determine whether the proposed implementation plan addresses the issues identified and the intention of the recommendation. Booz Allen analyzed the implementation plan and its associated outputs, and where necessary, met with FDA stakeholders to clarify the details of the plans, and compared this with the observations and rationale that led to the original recommendation. In cases where the implementation was not found to clearly address the recommendation, Booz Allen provided this feedback to FDA to facilitate modifications to the plan that would satisfy the intent of the recommendation. After the plan was modified, Booz Allen repeated this evaluation stage to ensure that the plan was relevant and attainable to address the recommendation.

3.2.2 Assess Measurability

The purpose of the second stage of the evaluation is to ensure that the implementation plan is designed in a way that it could be objectively evaluated for successful implementation. Specifically, Booz Allen made a determination about whether each implementation project had goals that were sufficiently specific, measurable, and time-bound, because those criteria would ensure that each implementation plan could be objectively assessed through defined metrics. Any issues or questions about the implementation plan satisfying these criteria were documented and shared with FDA stakeholders to clarify and resolve.

3.2.3 Track Progress

The third stage of the evaluation framework is an assessment to determine that the implementation plan was followed to completion. Booz Allen leveraged detailed project plans provided by FDA, including interim dates and milestones, to track the ongoing progress of each implementation plan using Microsoft Project and Excel spreadsheets with project milestones and actual completion dates. Booz Allen tracked progress against each recommendation by engaging in regularly scheduled meetings with each project implementation team to discuss progress and track against interim milestones. Booz Allen reviewed periodic updates from CDRH via an internal project timeline, written progress reports, documentation supporting implementation activities provided by FDA project teams, and in-person meetings. Booz Allen reviewed all CDRH documents that described results from interim products, such as gap analyses. We also examined newly-created and revised documents that served as the final outputs for the implementation projects, such as guidance documents, training materials, and standard operating procedures (SOPs).

3.2.4 Measure Initial Results

The fourth stage of the evaluation framework is designed to ascertain whether the end products of the implementation plans that have been deployed by FDA are being put into action by reviewers and management in CDRH as intended. Metrics for each implementation plan that was completed with a sufficient observation period were developed as described in Section 3.1, corresponding to the measurable output of the implementation plans. Specific processes for data collection and analysis varied, depending on the nature of the metric. Due to the timing of the completion of the various implementation plans, this stage of the evaluation framework was only applied to four of the projects, listed below along with the data collected for the assessment:

- Recommendation 1a: Corrective and Preventive Action (CAPA) and CPI – The Stage 1 output for this recommendation was a revised Quality Management (QM) Program site

that aggregated SOPs and QM documents, as well as a link to a newly-developed quality feedback system. The initial results for this plan were measured by collecting and analyzing system usage data generated by the feedback system, as a measure of use of the portal, which was provided by FDA.

- Recommendation 6: IT Systems Training – The Stage 1 output for this recommendation was full staff training on the primary IT system use, and the creation of a cadre of IT experts to provide informal support. The initial results for this project were evaluated by analyzing training completion rate data provided by FDA, and the results of an online survey distributed by Booz Allen to Office of Device Evaluation (ODE) and Office of In Vitro Diagnostics and Radiological Health (OIR) reviewers assessing their awareness of the cadre of IT experts.
- Recommendation 9: Training Program Evaluation and Metrics – The Stage 1 output for this recommendation included the development of Kirkpatrick Level 1 and Level 2 metrics for FDA's reviewer training programs. Initial results were assessed by analyzing data collected on the Level 1 and Level 2 metrics for the Reviewer Certification Program (RCP) training.
- Recommendation 10: Promote Informal Training – The Stage 1 output for this project included a new SOP for informal training and a form to request transcript credit for engaging in informal training. Initial results were evaluated by analyzing data from an online survey distributed by Booz Allen to ODE and OIR reviewers to assess awareness of the new SOP and transcript credit request form.

3.2.5 Assess Outcomes

The purpose of the fifth and final stage of the evaluation framework is to assess whether the ultimate intent of the original recommendation has been met through the implementation of FDA's *Plan of Action*. This evaluation is intended to determine whether the use of these outputs has had the desired impact that addresses the issues identified in the original recommendation. None of the implementation projects had a sufficient observation period after completion to be able to apply this stage of the framework. Booz Allen developed potential metrics for this evaluation stage, as described in Section 3.1, which are discussed in the corresponding section for each implementation project.

3.3 Report Findings

The results of all analyses and assessments were compiled and documented in this draft evaluation report. Each implementation project is discussed according to each stage of the evaluation framework that was performed. For those projects that were not completed in time to allow for a sufficient observation period to evaluate initial results, Booz Allen has recommended next steps and metrics for possible future assessment.

4. EVALUATION FINDINGS

This section of the report discusses the findings of the evaluation for each implementation project from CDRH's *Plan of Action*. The order in which the recommendations appear is based on the numbering of the recommendations from Booz Allen's Phase 1 final report.[7] The findings

[7] Some of the QM recommendations were consolidated and addressed in a single project, which affected the numbering. Recommendations 1a (Senior Management) and 1d (CAPA and CPI) from the Phase 1 Final Report were

for each implementation project are described for each stage of the evaluation framework (Exhibit 3). The first two stages of the framework (Validate Objectives and Assess Measurability) are discussed in the Appendix of this report. The remaining stages of the assessment framework for each implementation project are discussed in this section. The time required to fully implement some of the plans, and collect data to measure results and outcomes, did not allow a sufficient period to complete the latter stages of the assessment framework. In these cases, those sections of the report discuss potential next steps and metrics for conducting the evaluation of those stages.

A summary overview of the evaluation of each project is depicted in Exhibit 4, which highlights which stages of the evaluation framework could be completed for each implementation project, and outlines the key project results. These are discussed in more detail in the remainder of this section.

Exhibit 4. Progress of Implementation Plans against Booz Allen Evaluation Framework

Recommendation	ASSESSMENT FRAMEWORK STAGE COMPLETED 1	2	3	4	5	Project Results
1a. CAPA and CPI*	●	●	●	●		· Management Review SOP · Addressed Quality Feedback through FEEDBACK✓CDRH system
1b. Document Control System Enhancements*	●	●	●			· Document Management SOP · IT System Enhancement Request SOP
1c. Review Process Quality Metrics*	●	●	●			· Review process metrics to monitor for quality
2. Decision Making Consistency*	●	●	●			· Management Oversight of Critical Control Points SOP · Guided "SMART" Review Tool to facilitate consistent reviews
3. RTA Process Improvement	●	●	●			· Revised RTA Guidance and applicant checklist
4. Withdrawn Submissions Analysis	●	●	●			· Work Instructions for Withdrawn Submissions
5. Sponsor Communications	●	●	●			· Work Instructions for Interactive Review
6. IT Systems Training*	●	●	●	●		· Mandatory Premarket Review IT Systems training modules · Cadre of IT Experts
7. eCopy Guidance	●	●	●			· Revised eCopy Guidance
8. Workload Management Tool Review	●	●	●			· Best Practices SOP/IT Requirements for Workload Management · Prototype workload management tool
9. Training Program Evaluation & Metrics*	●	●	●	●		· Overall Evaluation SOP for training · Kirkpatrick Levels 1-4 metrics SOPs · Collected Levels 1-2 training metrics
10. Promote Informal Training	●	●	●	●		· Informal Training SOP · Training for Transcript Credit form
11. Staff Turnover & Transition Plans	●	●	●			· Transition Planning SOP · Succession Planning SOP

*** Priority Recommendation**

addressed in one project, designated 1a (CAPA and CPI) in this report. Recommendation 1c (Document Management) from the Phase 1 Final Report is designated 1b (Document Control System Enhancements) in this report. Recommendation 1e (System Evaluation) from the Phase 1 Final Report is designated 1c (Review Process Quality Metrics) in this report.

4.1 **Recommendation 1a:** Develop a more formal method for logging, prioritizing, tracking, communicating and providing feedback on non-CAPA issues and improvement ideas

In performing a QM assessment of the Senior Management component during the Phase 1 assessment, Booz Allen concluded that the feedback loop linking management at all levels, from the Branch to the Center, was not formally documented. Booz Allen recommended that CDRH formally document the issue resolution pathway and communicate this process to review staff to promote accountability and facilitate follow-up on raised issues. Additionally, in the assessment of the CAPA and CPI element, Booz Allen found that while ODE uses a CAPA database to track and resolve issues impacting multiple Divisions, no formal method to log, track, prioritize, or communicate issues existed for non-CAPA (i.e., Division-specific) issues. Similarly, ODE did not use a database or employ other systematic methods to manage and record non-CAPA issue resolution. Booz Allen therefore recommended development of a formal method, to be applied consistently across Divisions, for tracking issues that do not rise to the level of a CAPA, to ensure that they are properly attended to and resolved.

4.1.1 Implementation Progress

The key milestones in CDRH's implementation plan for developing a more formal method for logging, prioritizing, tracking, communicating, and providing feedback on non-CAPA issues and improvement ideas are shown in Exhibit 5.

Exhibit 5. Implementation Plan for CAPA and CPI

Key Milestones	Description
1. Conduct a gap analysis	• Reviewed existing premarket CAPA documentation and business processes • Determined what is needed to improve current CAPA process; addressed non-CAPA issues and improvement ideas on premarket review processes, procedures, policies, and IT; and allowed for staff and manager input at the Division and Branch level
2. Develop new and/or revise existing documentation and business processes	• Determined how to best manage those issues that require resolution but do not merit a CAPA • Determined 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	• Promoted a revised QM Program site that houses quality-related documents, SOPs, and an issue logging and tracking system

CDRH leveraged previous gap analyses[8] using existing premarket CAPA documentation and business processes to determine areas to improve the premarket CAPA business and review processes, policies, and IT infrastructure. Based on the gap analysis, CDRH developed a new CAPA SOP for identifying, entering, and tracking premarket CAPAs. Additionally, CDRH began updating and restructuring their QM Program SharePoint site, which contains QM documents and SOPs available to all Center staff. As part of this initiative and the gap analyses, CDRH identified the need to develop a more formal, integrated approach for logging, prioritizing,

[8] CDRH completed these gap analyses as part of an ongoing quality management program improvement effort prior to Booz Allen publishing the Phase 1 final report.

tracking, communicating, and providing feedback on CAPA and non-CAPA issues to facilitate CPI.

As a result, CDRH initiated work on the Stage 2 task from this action plan to develop and deploy a Center-wide system to capture, prioritize and address quality issues and feedback, including process improvement and management oversight processes. This system, called FEEDBACK✓CDRH, was housed within the QM Program site and provides a mechanism to collect information to assist CDRH in applying its QM principles outlined in the CDRH QM Framework. Developing the CDRH-wide process and system for capturing CAPAs, non-CAPAs, and suggestions for improvements was one of the many enhancements CDRH made to the existing QM infrastructure to provide staff access to QM resources. The implementation of this new feedback system necessitated developing policies and procedures for its use, which resulted in the creation of the *FEEDBACK✓CDRH SOP,* which superseded the *ODE CAPA SOP*. This SOP describes the process for collecting and addressing information gathered from CDRH data sources.

Management Review, a principle and practice described in the CDRH QM Framework under "Senior Management Responsibility," is another initiative CDRH addressed through this implementation given its importance to the success of a quality management program. To facilitate the establishment of the CDRH QM program and management of the Agency's business processes, CDRH developed a *Management Review SOP* which established the method and level by which management reviews are performed, and following its approval, communicated and launched this SOP to CDRH senior management. This SOP also defined the process for CDRH senior management to systematically review the QM program to ensure its suitability, adequacy and effectiveness. The *Management Review SOP* indicates that annually, CDRH senior management will review and analyze data that pertain to quality issues, strategic priorities, performance goals and the continuous improvement of CDRH products, services and systems. The review shall also include an assessment of the quality policy and quality objectives for the entire Center.

4.1.2 Initial Results

Booz Allen's assessment of initial results demonstrate that CDRH is currently using FEEDBACK✓CDRH to collect and respond to feedback, which serves as an indication that staff are accessing resources on the newly revised QM Program site. Initial findings show 187 cases reported to FEEDBACK✓CDRH from its implementation in March 2015 through data collection in December 2015, and 44% of these cases were closed.[9] These data demonstrate that CDRH staff are not only leveraging this system, but they are also accessing the updated QM Program site. Further, the closed cases demonstrate that CDRH is following the entire feedback process through to completion, by collecting, triaging, addressing and resolving feedback they receive. Additional time is needed for further adoption in order to evaluate results and see downstream impacts of the use of this system. Initial results of FEEDBACK✓CDRH implementation on management of CAPA and non-CAPA issues could be assessed through a survey to determine user awareness and use of the system, as well as ease of use and usefulness. Additionally, the implementation of the *Management Review SOP* could be assessed by tracking when CDRH management review meetings and Office management review meetings occur.

[9] The closed cases are reported here only to indicate that the full process is being carried out. Booz Allen did not analyze the nature of the issues, and no conclusions should be drawn regarding the time required to close an issue.

4.1.3 Assess Outcomes and Next Steps

Although the project team addressed the Booz Allen recommendation and Booz Allen collected early data on initial results of the implementation, there was not a sufficient observation period to assess outcomes. Once the revised processes and the new feedback system have been in place for a sufficient period of time, awareness and use of the system for logging, prioritizing, tracking, communicating and providing feedback on issues could be assessed. In particular, outcomes could be measured by monitoring how effectively the established SOPs guide discovery, reporting and resolution of CAPA, non-CAPA and CPI issues. Once they do occur, assessing the impact of recommended changes from management review meetings on improving issue resolution could be useful as well.

4.2 **Recommendation 1b:** Deploy planned document control system enhancements using a quality-oriented focus to optimize the utility of system changes to all review staff

During the Phase 1 assessment, Booz Allen found that CDRH employs various mechanisms for introducing quality into its document control and document management processes, but also identified inconsistencies within document control elements that ultimately detracted from review performance. For example, folders in DocMan, the document management system that provides central location for managing ongoing reviews, often contained many duplicative and/or outdated documents, which resulted in errors and inefficiencies when performing document searches. FDA staff survey results also indicated inconsistent practices among review staff to use and store documents in DocMan. To address these issues, Booz Allen recommended the provision of mandatory staff training on the appropriate use of document control IT systems (see Recommendation 6; Section 4.8), and that CDRH incorporate quality management components into its roll-out strategy for document control and data system transitions or upgrades, to ensure that these upgrades are positioned for successful use. This second, quality management-focused recommendation, is the subject of this section.

4.2.1 Implementation Progress

The key milestones in CDRH's implementation plan for deploying planned document control system enhancements using a quality-oriented focus are shown in Exhibit 6.

Exhibit 6. Implementation Plan for Document Control System Enhancements

Key Milestones	Description
1. Inventory existing processes, policies, and documents	• Inventoried documentation for premarket administrative records and IT systems enhancements
2. Conduct gap analyses	• Completed analyses of premarket administrative records and IT systems enhancements to identify needed revisions or enhancements
3. Develop new or revise existing processes, procedures, policies, and documentation	• Revised an SOP for the use of IT systems to create premarket administrative records • Revised existing aids and developed additional aids and training for administrative records and IT systems enhancement • Developed a new SOP for premarket IT systems enhancement • Released CDRH's new and revised document control systems SOPs

CDRH conducted an inventory of all 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.[10] The inventory covered documentation related to the Center Tracking System (CTS), DocMan and Image2000+ platforms, and included SOPs that support senior management oversight of new IT development and enhancements. CDRH concluded that the CTS, DocMan and Image2000+ technical documentation was limited and outdated, with no formal training available for either one. Training programs for these primary IT systems were developed and deployed under Recommendation 6 (IT Systems Training; see Section 4.8).

Additionally, an inventory of the SOPs related to the IT systems in managing and controlling CDRH's pre-market documentation was updated and completed. For Pre-market IT system enhancement, CDRH inventoried existing charters and SOPs used in planning and tracking IT, prioritizing IT operations, and managing changes and investments within CDRH. The inventory also covered policies and procedures governing planning and tracking of major IT or Information Management (IM) activities and investments; reviewing, approving, and prioritizing operations and management (O&M) changes, such as corrections and minor enhancements to existing systems; and managing IT programs, priorities, and investments within the FDA's Office of Compliance (OC). This inventory provided a baseline for comparison in the subsequent gap analysis.

CDRH completed a gap analysis of document control systems for administrative records, covering control procedures including those for file naming, version control, storage and archiving. The results, documented in a gap analysis report, identified gaps in the following six areas:

- Technical Documentation
- High-level Document Management SOP
- Compiling the Administrative File for Premarket Submission Decisions
- What to Sign and What to Print
- Digital Signatures
- Substantial Equivalence (SE) Packaging, DocMan Archiving, and SE Document Corrections

From this analysis, CDRH concluded that several SOPs required revisions in these areas, and that a formal training system would facilitate implementation and adherence to these policies.

CDRH conducted an additional gap analysis to examine how effectively its roll-out strategies for document control system transitions and/or upgrades incorporated quality management components when new development, enhancements and upgrades are deployed. CDRH completed the gap analysis by comparing the existing charters and SOPs to the actual processes that were being followed by CDRH staff, and this comparison revealed that CDRH staff involved in the IT Project Request (ITPR)/Program Priority Needs (PPN) were following the process to submit new IT project requests for senior management review. The project team also found that charters and SOPs for the IT Steering Committees (ITSCs) and other groups were maintained as required based on the maturity of each IT steering committee. The SOPs covered all steps and provided the required processes for senior management oversight. During the gap

[10] The FDA Retentions Policy includes SOPs and administrative documentation.

analysis, CDRH determined that the addition of overarching process flow diagrams along with an SOP, tools and aids would improve use of the tools and processes that support document control IT system enhancements. The Business Information Systems (BIS) team, working in collaboration with the system owners, also identified, evaluated and addressed other gaps that might hinder CDRH personnel from effectively utilizing the technical documentation.

In the final implementation step, four SOPs for managing and controlling pre-market administrative records were updated and revised. As part of the document control system enhancements, CDRH created the *CDRH IT System Requests SOP* and *CDRH IT Request Work Instructions* to direct how requests should be submitted, planned, analyzed, prioritized and implemented for continuous improvement of the CDRH IT systems. The *CDRH IT System Request SOP* includes all the processes that together facilitate deployment of planned document control system enhancements supporting ODE and OIR staff. CDRH also developed additional work instructions that support the implementation of new IT request processes. The *CDRH IT Request Work Instructions* was developed to assist users in identifying information to enter into each field when submitting a change request via the application "Help/Support" link.

4.2.2 Initial Results

Staff training was completed in September 2015 to roll out SOPs[11] for pre-market administrative document management that were effective October 2015. For IT systems enhancement, *CDRH IT System Requests SOP* was rolled out to CDRH staff in August 2015 and training of Pre-Market Approval (PMA) employees directly involved with IT systems was completed in September 2015. Due to the recent deployment of these SOPs for new or updated procedures, there was insufficient time to evaluate the initial impact of CDRH's implementation activities. Initial results may be obtained by assessing staff awareness of the revised SOPs, implementation of the SOPs, and completion of additional staff training. CDRH staff use and awareness of training materials could be assessed by survey several months after the new SOP has been deployed to allow for sufficient dissemination of the information. Additionally, awareness and use of the administrative record SOPs could be assessed by monitoring adherence to document management processes (e.g., where staff store files, naming conventions) in the IT systems.

4.2.3 Assess Outcomes and Next Steps

There was insufficient time to measure the impact and outcomes of the document control system enhancements on the review process after CDRH implemented the SOPs. This could be assessed by a survey of user satisfaction with respect to how changes to IT document control systems are deployed. The team could assess the effectiveness of the new SOP or updated instructions by deploying a survey to CDRH staff impacted by the release, focusing on whether their needs are met and the processes are improved.

[11] *Compiling the Administrative File for Premarket Submission Decisions* SOP and *High-level Premarket Document Management* SOP

4.3 **Recommendation 1c:** Identify and develop internal metrics to monitor the quality and effectiveness of review processes and facilitate continuous process improvement

During the Phase 1 assessment, Booz Allen found that CDRH senior management diligently monitors and reports on submission status, and relies heavily on MDUFA goal milestones for evaluating progress and success. CDRH also performed periodic *ad hoc* audits on certain processes (e.g., RTA audit). Through these audits, Program Operations Staff (POS) identified certain trends for submissions that did not meet their MDUFA goal dates, such as missing milestones earlier in the review process. POS are now more aware of these gaps and pay more attention to such indicators and send reminders to Lead Reviewers of upcoming due dates based on workload reports from CDRH Ad Hoc Reporting System (CARS) and CTS. As a result, Booz Allen recommended that CDRH identify and develop more granular internal metrics to monitor the quality and effectiveness of sub-processes (e.g., RTA or IR) and facilitate CPI within the larger submission review process.

4.3.1 Implementation Progress

The key milestones in CDRH's implementation plan for developing internal metrics to monitor the quality and effectiveness of review processes and facilitate continuous improvement are shown in Exhibit 7.

Exhibit 7. Implementation Plan for Review Process Quality Metrics

Key Milestones	Description
1. Identify sub-processes related to the review of 510(k)s and PMAs	• Reviewed existing documentation to identify sub-processes related to 510(k) and PMA reviews • Collected input from staff involved in the review of 510(k)s and PMAs • Used information collected to prioritize and select sub-processes to monitor for CPI
2. Conduct a gap analysis to assess what is needed to monitor review of selected sub-processes	• Conducted gap analysis using documentation and staff input • Identified existing metrics across the review process • Developed new metrics and streamlined existing metrics
3. Conduct post-review validation analyses of 510(k)s and PMAs that have reached a MDUFA decision	• Conducted analysis to confirm validity of metrics, and revised and refined a final set of metrics
4. Revised Metrics Selected to Facilitate Sub-Process Monitoring and Continuous Process Improvement	• Used final set of metrics from post-review analyses to prioritize sub-processes for monitoring and CPI • Developed proposed short-term and long-term measures for each sub-process

CDRH began implementing this recommendation by reviewing existing documentation, including process maps, SOPs, MDUFA performance goals, and input they gathered from premarket review staff. Through the review of this documentation, CDRH identified the sub-processes related to the review of 510(k) and PMA submissions. CDRH took an inventory of the different tools (e.g. checklists, templates, SOPs, etc.) used by each Branch/Division to aid in the conduct of PMA and 510(k) reviews. The implementation team surveyed ODE review staff, 510(k) staff and PMA staff to ensure that they had a complete listing of the resources currently

available. After taking an inventory of existing tools, CDRH began two parallel tasks. First, CDRH established the consistency and predictability working groups to review and assess the inventory of tools. These working groups also reviewed the process maps, "MDUFA III 510(k)/PMA Review Milestone" spreadsheets and MDUFA III performance goals. Next, CDRH convened working groups to review and assess the inventoried tools for 510(k)s and PMAs. Based on relevance and importance for task completion, the working groups created a generic review process map that describes common sub-processes and Critical Control Points (CCPs) across the following review process steps: Lead Reviewer Assignment, RTA review, Consult Review, Substantive Review (including Interactive Review (IR) and Interim Decision), Advisory Panel, and Final Decision. The identification of these sub-processes assisted in CDRH's understanding of the current review process to prioritize them for monitoring and process improvement.

After the implementation team completed the assessment of 510(k) sub-processes and currently tracked metrics, they identified gaps and addressed these through developing an initial set of metrics that could be collected for monitoring to improve oversight of CCPs and the identified sub-processes. FDA conducted additional deep dive analyses of these gaps under Recommendation 2 (Decision-Making Consistency) to refine and identify new metrics for each of the seven sub-processes.

Upon selecting the initial set of metrics, CDRH conducted post-review analyses of traditional 510(k) submissions that had reached a MDUFA decision over a 2-year time period to verify the ability of these metrics to facilitate sub-process monitoring and CPI. These analyses, which focused on RTA Review, Substantive Review, and Consult Review, led to the identification of potential critical control points across the sub-processes. The implementation team refined them and finalized a set of priority metrics that would have the greatest impact on these steps, which would result in improving the overall review process. From the post-review analyses, CDRH also identified several CCPs (e.g., RTA and SI) which would require additional management oversight to ensure consistency and quality, as described in more detail under Recommendation 2 (Decision-Making Consistency). The post-review analyses helped CDRH verify that the selected sub-processes and metrics would facilitate managing these CCPs and monitoring review processes for consistency, quality and CPI.

CDRH finalized the implementation by selecting five premarket areas across the review process for monitoring and CPI: RTA decisions, Advisory Panel, Consult Review, SI Review, and Final Decision, as shown in Exhibit 8. For each of the areas, CDRH proposed short-term measures,[12] flags,[13] long–term measures,[14] and validation measures.[15] Short-term measures include acceptance rates,[16] rates of withdrawn submissions, average timing of Advisory Panel milestones, consult review metrics, AI and major deficiencies (MAJR) rates, as well as long-term metrics correlating CCPs to total time to market (TTM). Specific information on each selected sub-process can be seen in Exhibit 8. CDRH is currently exploring ways to collect the data in real-time efficiently and effectively for the five sub-process areas identified. Now that

[12] The proposed short-term measures are intended to collect data feasible with the current CDRH IT systems.
[13] The proposed flags are items that will require IT changes.
[14] The proposed long-term measures are items that are pending validation analysis and will need IT updates and/or new policies or procedures to implement.
[15] The proposed validation measures mark the verification stage.
[16] Refuse to Accept – Decline Decision (RTA1); Refuse to Accept – Approve Decision (RTAA)

CDRH has inventoried, analyzed, prioritized and selected the five sub-processes, they can begin the process of monitoring and CPI for review process quality.

Exhibit 8. Revised Pre-Market Metrics Selected for Monitoring and CPI

Process Phase	Short Term Measures	Possible Long-Term Measures
RTA Decisions	• Pre-RTAA rate of Withdrawal/Deletion • RTA1 rate = 1st cycle & 2nd cycle • % without acceptance after 2 cycles • Average/Median total days to acceptance	• Relationship between total days to RTAA and downstream outcomes/measures • Relationship between RTA cycles to RTAA and downstream outcomes/measures
Advisory Panel	• Rate of submissions that go to panel • Average time from decision to go to panel to panel meeting date • Average time from filing date to panel meeting date • Average time from panel meeting date to FDA decision date • Rate of decisions by "Day-90/SI Due Date	• Average time from filing date to decision to go to panel
Consult Review	• Rate of consults per submission • Rate per type of submission • Time from request to closure	• None
Substantive Interaction Review	• Pre-SI Withdrawal/Deletion rate • PI rate (% of SI decisions) • SE rate (% of SI decisions) • AI/MAJR Rate (% of SI decisions for 510k)	• % Pre-SI review with IR • Days to 1st interaction (post acceptance) • Relationship between existence of or timing of IR and submitter days • Relationship between timing of IR or SI and downstream outcomes
Final Decision	• SE/Approved rate • Average/Median TTM; SE/Approved decisions only • Post-SI Withdrawal/Deletion rate • Post-SI Not Substantially Equivalent (NSE) rate	• Relationship between submitter days and final outcome • Relationship between submitter days and TTM

4.3.2 Initial Results

CDRH completed the assessment, gap analysis and identification of selected metrics for monitoring and process improvement. CDRH has selected a group of metrics for monitoring the quality and effectiveness of the review process, as well as CPI. While Booz Allen was unable to assess initial results due to insufficient time following implementation, the initial results of this implementation could be assessed through CDRH's proposed short-term measures described in Exhibit 8. This would require additional data collection using the selected metrics across the RTA, Advisory Panel, SI Review, Consult Review, and Final Decision review processes. The data collection using these metrics could continue to validate the use of these metrics to assess review process quality and help FDA identify any problems in the review process that they could mitigate.

4.3.3 Assess Outcomes and Next Steps

Booz Allen was unable to assess outcomes due to insufficient observation period following implementation of this recommendation. CDRH plans on implementing proposed long-term measures across the RTA Decision, Advisory Panel, Consult Review, SI Review and Final MDUFA decision phases of the review process after validation analyses of the processes and in some cases, changes to IT systems, procedures and policies. These validation measures may be assessed through audits of submissions and surveys for both FDA staff and sponsors to determine whether the selected metrics improve the review process. Measuring the relationships between the proposed metrics for each process phase outlined in Exhibit 8 and anticipated outcomes could result in overall process improvement such as:

- Decreased total time to market
- Decreased rates in RTA1, AI, and NSE[17]
- Decreased FDA Days to RTA, SI[18], and MDUFA
- Decreased industry days to RTA1, AI and IR responses

4.4 Recommendation 2: Develop criteria and establish mechanisms to improve consistency in decision-making throughout the review process

An analysis of pre-MDUFA III issues during Phase 1 revealed that inconsistent decision-making among FDA review staff throughout various stages of the review process remained a concern and an outstanding issue to be addressed in the MDUFA III timeframe. One key issue Booz Allen identified was a lack of transparency to sponsors regarding thresholds or requirements used to trigger additional information (AI) requests. In addition, industry stakeholders reported inconsistencies between reviewers referencing outdated guidance during submission reviews, as well as reviewers referencing new standards that were not yet finalized at the time of original submission. The objective of Booz Allen's recommendation was for FDA to develop criteria and establish mechanisms to improve consistency in decision-making throughout the review process.

4.4.1 Implementation Progress

The key milestones in CDRH's implementation plan for developing criteria and establishing mechanisms to improve consistency in decision-making throughout the review process are shown in Exhibit 9.

Exhibit 9. Implementation Plan for Decision-Making Consistency

Key Milestones	Description
1. Inventory existing documentation on processes, procedures, and policies	• Inventoried existing documents and determine usability for 510(k) clearance, PMA approval, 510(k) Request for AI, PMA Major Deficiencies, Investigational Device Exemption (IDE) approval, and biocompatibility
2. Develop or revise needed business process maps	• Developed or revised business process maps for 510(k) clearance, PMA approval, 510(k) Request for AI, PMA Major Deficiencies, IDE approval, and biocompatibility

[17] Refuse to Accept – Decline Decision (RTA1); Additional Information Request (AI); Not Substantially Equivalent (NSE)
[18] Refuse to Accept – Approve Decision (RTAA); Substantive Interaction (SI)

Key Milestones	Description
3. Identify best practices and lessons learned from other organizations	• Determined organizations to evaluate for best practices in creating, assuring, and maintaining consistency across their organization's critical products or services • Researched and identified best practices and the infrastructure from chosen organizations
4. Conduct a gap analysis	• Aligned documentation with business process maps • Identified critical and consistent steps and activities that did not have sufficient documentation for each pre-market process • Identified critical needs to be developed for decision-making consistency
5. Identify and address highest priority processes of gap analysis incorporating Best Practices	• Prioritized actions based on criticality and available resources • Identified and addressed missing framework elements • Developed a guided premarket review tool (the SMART template) to ensure consistent steps will be followed by reviewers • Incorporated processes into CDRH QM Framework and created a review process flow map that depicted the management oversight of critical controls

At the onset of this project, business process maps existed for managing the IDE, PMA and 510(k) submissions. Working groups for each of these program areas evaluated the existing process maps and revised them as necessary. Through this exercise, FDA found that there was no business process map to guide biocompatibility review, leading the working group to develop a new biocompatibility process map that could be applied to cross-cutting areas. These new or updated business process maps accurately represented the review process in each program area and were made available to CDRH review staff to promote consistency in the review process.

CDRH contacted the following four organizations that are engaged in risk-based decision-making, and might therefore have similar processes and practices: United States Patent and Trademark Office (USPTO), National Aeronautics and Space Administration (NASA), Nuclear Regulatory Commission (NRC), and Federal Aviation Administration (FAA). CDRH investigated these organizations' best practices for creating, ensuring and maintaining consistency across their critical products or services, and studied the infrastructure (e.g., processes, procedures, policies, IT, training, and metrics) they had in place to support their practices. The project team documented their findings on best practices and lessons learned in a summary document, which supported the final deliverables for this project.

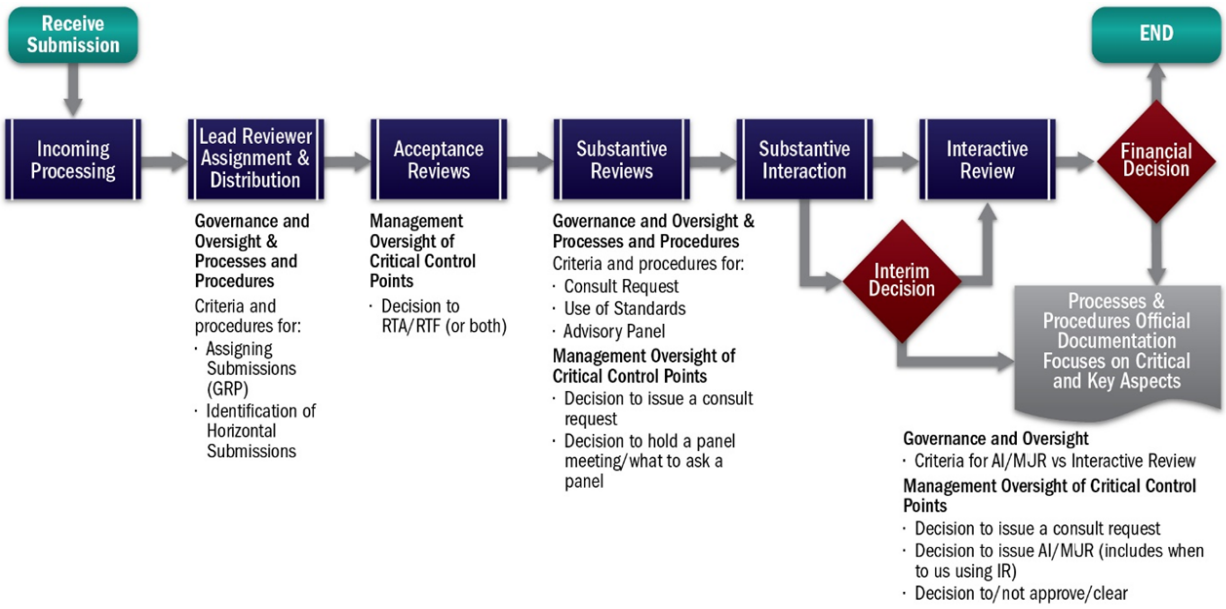
The working groups next conducted a gap analysis using the newly-revised process maps, to identify any procedures or steps (general issues or program-specific) that were not previously recognized as standard procedures. They also assessed whether development of new processes, procedures, policies or IT was necessary to ensure consistency in the review process. Lastly, using the business process maps, the working groups evaluated significant review steps (e.g., RTA/Refuse to File (RTF) decision, consult request) for gaps and documented their findings. These steps were then prioritized by potential impact on fostering more consistent and predictable decision-making, and grouped into four categories: resources and knowledge management, quality of review process, staff training and policy development.

Based on findings in the gap analysis, CDRH's working groups and QM team recommended a list of activities in each quality category and, considering urgency and available resources, the working groups proposed the following priority actions:

- Adopt a guided premarket review tool (SMART template) initially for 510(k) submissions and then expand to other submission types
- Develop enhanced reviewer training in all aspects of performing a review for all submission types
- Develop reviewers' competencies, specifically for specialty/cross-cutting/horizontal areas (sterility, biocompatibility, MRI, software, clinical trials) requiring a minimum body of knowledge for all staff conducting or providing managerial oversight
- Establish and implement clear management responsibilities and oversight for interim and final decisions
- Develop criteria for requesting subject matter expert consults for each specialty area (e.g. biocompatibility), including determination of when a consult is needed and the parameters of the consult request
- Develop criteria for assigning submissions to reviewers
- Increase utilization of CDRH established standard processes in premarket review

Based on findings from the gap analysis and the working groups' recommendations, CDRH identified standardized procedures across the review process to improve consistency in decision-making. CDRH's QM Program has laid the groundwork for the adoption of quality within CDRH and incorporated with the pre-market review program to establish a framework for the adoption of quality management of pre-market review processes as shown in Exhibit 10.

Exhibit 10. Management Oversight of Critical Controls in the Review Process



CDRH also created the *Management Oversight of Critical Control Points SOP* establishing minimum requirements for CCPs of RTA, deficiencies communicated as a part of Substantial Interaction (SI), decision to convene a panel meeting, and final decision for pre-market submissions based on least burdensome approach provisions and benefit-risk principles, which will apply to all of CDRH's premarket submissions. This SOP delineates roles and

responsibilities for Lead Reviewers, Branch Chiefs, Deputy Division Directors and Division Directors, as well as the procedures to follow. To implement new comprehensive quality management procedures, CDRH created the *Quality Management Board Charter* and the guided premarket review tool in the SMART template to support deployment of the *Management Oversight of Critical Control Points SOP* and ensure the steps are followed by reviewers. The SMART template is a self-guided tool for reviewers based on standardized operating procedures to handle similar issues encountered on different submissions. As a reviewer fills out the template, it will autofill specific fields and provide suggested language and relevant regulations based upon the submission information. This is intended to improve consistency in decision-making while maintaining flexibility based on current FDA policy. CDRH staff directly involved in 510(k) reviews first completed training in October 2015 to implement the SMART template in their review.

4.4.2 Initial Results

The initial results of CDRH's implementation on the current recommendation were planned to be assessed by evaluating the use of the SMART template, as well as interviews, focus groups and surveys with managers and reviewers about the implementation of critical control points. Due to insufficient observation period within the phase 2 evaluation timeframe, however, initial results of CDRH's implementation activities were not measured. Initial results could be measured by conducting an audit of completed submission reviews to determine how consistently the SMART template was used in accordance with the guidelines in the *Management Oversight of Critical Control Points SOP*.

4.4.3 Assess Outcomes and Next Steps

The outcome intended from the original recommendation is greater consistency in decision-making across the review process. Once the new processes and control points have been fully implemented and adopted, submissions could be audited to look for specific types of inconsistency and evaluated by how that has improved after implementation. For example, consistent application of review criteria across divisions and reviewers, consistent criteria within different stages of the same review, or use of current guidance referenced in decision-making. In addition, surveys of managers and reviewers on the impact of the new processes and controls, as well as feedback from industry representatives, could also be used to assess the outcome of this project.

4.5 **Recommendation 3:** Optimize RTA process by improving awareness of and clarity around administrative requirements for 510(k) submissions

The MDUFA III implementation introduced several new processes to improve the efficiency and timeliness of reviews for 510(k) submissions, including Refuse to Accept (RTA). During Phase 1, Booz Allen determined that more than half the closed Traditional 510(k) submissions received during calendar year (CY) 2013 received an RTA1 decision during the first cycle, indicating that the submission was deemed not acceptable for review. These submissions were associated with overall longer review times. Furthermore, elements within the Administrative category of the RTA Checklist (i.e., 510(k) summary, identification of prior submissions, inclusion of Standards Data Reports) were the most frequently identified as missing or deficient elements during RTA review. These observations indicated a need for increased sponsor awareness of administrative requirements for 510(k) submissions to mitigate RTA1 decisions due to Administrative

deficiencies. As a result, Booz Allen recommended increasing awareness and clarity of administrative requirements for 510(k) submissions.

4.5.1 Implementation Progress

The key milestones in CDRH's implementation plan for optimizing the RTA process by improving awareness of and clarity around administrative requirements are shown in Exhibit 11.

Exhibit 11. Implementation Plan for RTA Process Improvement

Key Milestones	Description
1. Conduct an audit of the RTA program	• Identified top missed criteria in RTA applications • Identified criteria with the greatest amount of SR
2. Conduct an analysis of RTA audit data to identify trends, correlations, or patterns	• Identified characteristics or patterns for sponsors with RTA1 (e.g., eCopy hold, User Fee hold, checklist inclusion prior MDUFA III submission, etc.) • Evaluated the differences in RTA rates within the various sponsor segments (e.g. small manufacturers vs. large manufacturers, or foreign vs. domestic submitters, ODE vs. OIR)
3. Conduct an analysis of feedback from industry on their experience with the RTA policy and checklist	• Received feedback from industry on the RTA process • Identified areas for improvements using sponsor feedback
4. Conduct root-cause analyses	• CDRH concluded that enough information was provided from the RTA audit and subsequent analyses that a specific root-cause analysis was not necessary
5. Revise the RTA policy to increase clarity and further promote awareness	• Clarified boundaries around the use of interactive review and reviewer discretion in the application of the RTA policy; used this information to modify the RTA Checklist • Modified criteria phrasing and/or explanatory text in the *RTA Guidance* to improve understanding and clarity of the RTA policy

Prior to the Phase 2 evaluation, CDRH conducted a trend assessment of the RTA program. The assessment started with an audit of the RTA process on files received over a three-month time period. This included an analysis of 731 submissions, including a sample cohort of 80 randomly selected RTA1 files, and focused on four elements: general RTA information (basic statistics on RTA1 files), checklist criteria most frequently unanswered or incorrectly answered by sponsors, frequency of SR during RTA review, and criteria in RTA1 applications that auditors flagged but reviewers felt were not in error (i.e., auditor discrepancies).

From this audit, CDRH learned that the examined files averaged 8 missed criteria, 75% had ≥4 missing elements, and 66% did not include an industry-completed checklist. CDRH identified the top four most frequently unanswered or incorrectly answered criteria as: Element 28 (shelf-life methods, 41%), Element 9 (prior submissions, 34%), and Element 16 (SE rationale, 33%), and Element 36 (performance data- full test reports provided, 33%). CDRH concluded that Administrative and Biocompatibility sections of the checklist were problematic as three Administrative elements and two Biocompatibility elements were present in the top 10 most frequently missed elements.

The audit showed a low occurrence of substantive review during RTA (11%) and no strong patterns of substantive review. The audit also showed that substantive review was not the sole

cause for the RTA1 decision, although substantive review in the Device Description Section was noted in 55% of files with substantive review. SR during the RTA review has the potential to slow completion of the administrative review.

The audit revealed differences between ODE and OIR that may impact the rate of RTA1 decisions. For example, ODE reviewers were trained not to interact with submitters during RTA to obtain missing information, while OIR worked interactively with submitters during RTA review. CDRH subsequently concluded that IR during RTA may reduce the rate of RTA elements requiring clarification and modified RTA policy to allow use of IR during RTA review.

CDRH used the audit data to conduct an analysis to identify trends, correlations or patterns in the audit results that may lead to developing relevant RTA metrics and indicators. CDRH's analysis included an evaluation of the differences in RTA rates within the various sponsor segments (e.g., small manufacturers vs. large manufacturers, or foreign vs. domestic submitters, ODE vs. OIR). CDRH found that prior 510(k) submission experience does not impact the likelihood of RTAA, submissions with eCopy/User fee holds may be more likely to receive an RTA1 decision, and sponsors who include the checklist may improve the likelihood of an RTAA decision.

CDRH also analyzed "limited comment" feedback from industry stakeholders on their experience with the RTA policy and checklist. Industry suggested providing fillable RTA Checklists to sponsors, providing advisory comments on issues for the SI review if the basis for RTA1 decisions is not clear, and allowing premarket reviewers to use discretion when requesting missing elements.

After analyzing the audit data and industry feedback, CDRH determined that an additional root-cause analysis was not necessary, because sufficient information was captured during the audit. Factors related to the RTA process that impacted quality or consistency were addressed as part of the responses to Recommendations 1c (Review Process Quality Metrics; see Section 4.3) and 2 (Decision-Making Consistency; see Section 4.4), respectively.

CDRH conducted a pilot study assessing IR/RTA Reviewer Discretion Policies (RRD) using existing RTA Checklists from 510(k) submissions received over a two month time period. The pilot study examined use of these processes during the RTA review and analyzed RTA rates before and after implementation of IR/RRD. The findings included feedback from review staff, which were used to develop policies for when IR and RRD should be considered during the RTA review process.

CDRH revised and updated the RTA policy to clarify processes and reflect current review practices, streamline RTA Checklists, and encourage IR where useful and appropriate. RRD will be performed on a file-by-file basis, but it will be incorporated into review practice, reflecting input from industry representatives. The *RTA Policy for 510(k)s: Guidance for Industry and FDA Staff* was distributed to staff and industry on August 4, 2015 and in effect as of October 1, 2015. The changes CDRH made to the new RTA guidance and Checklist published on October 1, 2015 are listed in Exhibit 12. A key goal of these changes was to further reduce the number of submissions that are considered administratively incomplete upon initial receipt. One of the key changes that went into effect with the new *RTA Guidance* included updated language to reflect checklist and RTA process modifications, and removed language that had the potential to lead to SR.

Exhibit 12. Revisions to RTA Guidance and Checklist

Document	Purpose	Modification
Guidance Document	Clarify 510(k) submission requirements	• Clarified text to reflect checklist and RTA process modifications • Removed language that had the potential to lead to SR (e.g., removal of assessment of 510(k) Summary contents) • Updated references, guidance, and links changed since the prior checklist version
Checklists	Streamline checklists to reflect practical review practice	• Removed criteria non-critical to initiate review (e.g., 510(k) Summary and 510(k) Statement contents, Standards Data Report Forms) • Added options to promote use of reviewer discretion if missing information deemed non-critical to make submission administratively complete (e.g., software) • Separated elements better reviewed independently (e.g., electrical safety and electromagnetic compatibility (EMC)) • Modified text to reflect changes in review policy (e.g., sterility section modified to reflect new reprocessing guidance)
	Modify checklist elements to improve clarity	• Clarified text throughout checklist to improve understanding of information needed to address elements (e.g., information on prior submissions) • Clarified text to remove language/elements that had the potential to lead to SR • Combined elements asking for similar information (e.g., SE determination) • Clarified and updated elements per comments from FDA review staff and sponsors (e.g., addition of “N/A” boxes in Preliminary Questions section) • Updated references, guidance, links changed since the prior checklist version
	Improve usability for sponsors	• Included page number column in checklist for sponsors to identify location of elements in submission

4.5.2 Initial Results

The revisions to the RTA Checklist and RTA Guidance document took effect near the end of the Phase 2 Booz Allen evaluation, which did not provide a sufficient observation period to measure initial results. The initial results of this implementation could be assessed through impact studies such as assessing sponsor adherence to the new guidance policies in a sample cohort of 510(k) submissions. Analyzing the rate of submissions that used the new RTA Checklist could serve as initial results for this recommendation. Additionally, measuring FDA staff and sponsor awareness of the new RTA policies through surveys could provide insights into the usefulness of the updated Checklist and Guidance documents.

4.5.3 Assess Outcomes and Next Steps

Due to an insufficient observation period, Booz Allen was unable to assess outcomes of the implementation. Outcomes could be measured by assessing the impact of the revised Checklist on the percentage of RTAA vs. RTA1 decisions. In addition, a follow-up survey of sponsors may be useful to assess improvements in clarity and ease of use of the revised RTA Checklist and

Guidance document on users (sponsors and CDRH staff). Combined with annual audits of RTAA and RTA1 applications, these can inform future iterations of the inventory-audit-revise cycle to identify pain points in the RTA process and suggest possible solutions.

4.6 **Recommendation 4:** Perform a retrospective root cause analysis of withdrawn submissions and develop a mechanism to minimize their occurrence

During the Phase I assessment, Booz Allen detected that rates of withdrawn submissions increased by 50% between MDUFA II to MDUFA III timeframes. Analysis of withdrawn submissions from a MDUFA III cohort revealed that two-thirds were withdrawn during the MDUFA/IR phase, of which nearly 30% were withdrawn with fewer than 10 days remaining on the review clock. Analysis of our limited sample signaled a potential issue that warranted further investigation through another study. Booz Allen recommended that FDA conduct a larger-scale retrospective root cause analysis of withdrawn submissions to identify submissions with characteristics that might benefit from additional review time. The recommendation also suggested that FDA should communicate study findings with public stakeholders and develop mitigation strategies as necessary to minimize their occurrence.

4.6.1 Implementation Progress

The key milestones in CDRH's implementation plan for performing a retrospective root cause analysis of withdrawn submissions are shown in Exhibit 13.

Exhibit 13. Implementation Plan for Withdrawn Submissions Analysis

Key Milestones	Description
1. Conduct an analysis of withdrawn submissions to identify trends, correlations, or patterns	• Conducted several analyses on 510(k) submission cohorts that had received withdrawn decisions throughout the review cycle, including those withdrawn during RTA, SI, and FDA days 81-90 (end of the review cycle) to assess the reasons for withdrawals
2. Conduct root-cause analyses to determine cause of identified trends, correlations or patterns	• Conducted deep dive root-cause analyses to determine the cause of trends, correlations or patterns identified in step 1, focused on Divisions with the highest withdrawal rates • Reviewed the degree and timing of supervisory input regarding withdrawal requests
3. Develop mitigation actions for these findings, if necessary	• Developed necessary mitigation actions as part of the implementation of Recommendation 2 (Decision-Making Consistency) *Management Oversight of Critical Control Points for Pre-Market Review SOP* • Developed a *Work Instructions for Withdrawn Submissions* document • Developed CCPs for withdrawals/deletion tracking with implementation of Recommendation 1c (Review Process Quality Metrics)

CDRH conducted an initial analysis of withdrawn 510(k) submissions and found that 33% (67 of 204) of Withdrawal decisions occurred between FDA review days 81-90 (the final phase of the review cycle). FDA then used this cohort of 67 submissions to determine the cause of withdrawal and to develop mitigation actions for these findings as necessary. Further analyses showed Withdrawal decisions represented only a small proportion (2.3%) of all final decisions,

with no documentation of the reason for withdrawal, and an increase in withdrawals during the RTA phase.[19] Based on these findings, CDRH conducted a deeper dive analysis into withdrawn submissions across different phases of the review cycle and considered potential methods to provide greater oversight of Withdrawal decisions. CDRH's withdrawn submissions analysis helped identify where and when withdrawals were occurring in the review cycle, as well as new ways to improve monitoring and tracking withdrawals.

FDA continued conducting root cause analyses by taking a deeper dive into 20 of the 510(k) submissions from the original 67 submission cohort. The implementation team reviewed submission data and FDA correspondence through the primary premarket review IT systems. The analysis looked at specific timeline information for RTA, AI and SI, and overall reasons as to why withdrawal occurred. CDRH's analysis reviewed RTA completeness, days to RTAA and whether RTA questions were appropriate. Review of AI requests looked at the types and degree of complexity of AI requests communicated during IR or at SI and the time between the AI request and receipt of supplement containing responses. IR review examined when IR occurred, the request type and who initiated the IR. CDRH found through the analyses that time to RTA may be an indicator of withdrawal, and the majority of AI requests tend to be complex in nature and require additional time to respond. CDRH also determined that a majority of submissions contained IR from both the sponsor and FDA with an average of three communications per submission. Thus, FDA determined that IR was not a contributing factor to withdrawn submissions.

Based on these findings, the implementation team developed considerations and recommendations to address the trends and issues correlated with withdrawn submissions across the RTA, AI and SI phases of the review cycle. FDA developed two overarching mitigation actions to implement as part of this recommendation: management oversight through the degree and timing of supervisory input regarding withdrawal requests throughout the review cycle,[20] and continued analysis and tracking of withdrawals.[21] FDA incorporated guidelines in the *Management Oversight of Critical Control Points for Pre-Market Review SOP* under Recommendation 2 (see Section 4.4) for staff to consider when any final decision is made (including a Withdrawal decision). These critical control points (CCPs) will require senior leadership approved memorandums of acceptable review quality that include Appropriate Scientific/Regulatory Review Recommendations. FDA also developed a set of *Work Instructions for Withdrawn Submissions* to guide reviewers on how to appropriately document Withdrawal requests in order for CDRH to track the rates of withdrawn and deleted submissions.

CDRH completed root cause analyses to identify trends, correlations, and patterns that may lead to Withdrawal decisions. As a result, CDRH developed two mitigation actions for management oversight and continued analysis of Withdrawal decisions in concert with the implementation of Recommendations 1c (Review Process Quality Metrics; see Section 4.3) and

[19] The RTA Phase did not exist under MDUFA II. MDUFA III introduced legislation that granted user fee refunds for 510(k)s withdrawn by the sponsor before RTA acceptance, and FDA observed an increase in withdrawn submissions after a sponsor received an RTA1 that refunded the sponsor their fee.
[20] An ongoing effort to address management oversight of CCPs across the review cycle (including Withdrawal decisions) was simultaneously underway in response to Booz Allen's recommendation on Decision-Making Consistency. The issues identified with withdrawn submissions will be addressed as described in Section 4.4 of the Management Oversight SOP under that recommendation.
[21] Withdrawn submissions was identified as a metric to monitor and track at specific points across the review in response to Booz Allen's recommendation on Review Process Quality Metrics (Section 0).

2 (Decision-making Consistency; see Section 4.4)). Management oversight actions will be implemented through the *Work Instructions: Documenting and Processing Withdrawal Requests* document and the *CDRH Management Oversight of Critical Control Points for Pre-Market Review* SOP. Providing management oversight, withdrawal documentation guidelines, and continued analysis of withdrawals throughout the review process will help FDA monitor and track withdrawals at a more granular level to provide a better understanding of when and why withdrawal decisions occur.

4.6.2 Initial Results

Booz Allen did not have a sufficient observation period to collect data and assess the initial results for this recommendation. However, initial results of the implementation could be assessed by measuring the level of awareness and use of the *Work Instruction*s guidelines and the practices identified in the *Management Oversight SOP*. Continued analysis of withdrawn submission actions will be implemented through the metrics found under Recommendation 1c (see Section 4.3), and initial results may include an analysis of future 510(k) submissions designated a Withdrawal decision or Deletion and tracking these metrics. Possible metrics to measure successful implementation of mitigation actions may include collecting and reviewing acceptable review quality memos to ensure senior leadership approval; measuring withdrawal rates across critical phases of the review cycle; surveying reviewers to assess if their knowledge around the RTA phase correlates with lower withdrawal rates; and tracking and measuring the communications during the SI phase, specifically where IR is recommended and AI communications.

4.6.3 Assess Outcomes and Next Steps

Booz Allen expects that the increased tracking and analysis of withdrawn submissions through adherence to policy documents (i.e., the *Work Instructions* and *Management Oversight SOP*) and the metrics identified under Recommendation 1c will lead to a better understanding of the reasons why withdrawals may occur. Analysis and measurement of the rates of withdrawal at the RTA, SI and Final Decision phases of the review cycle can determine effectiveness of the oversight procedures. The impact of this implementation (e.g., implementing the *Work Instructions*) could be assessed by monitoring whether reviewers are properly documenting withdrawal requests as they occur. By continuing to monitor and analyze the outcomes and impact of the *Work Instructions* and *Management Oversight of Critical Control Points for Pre-Market Review SOP*, FDA will be able to look at more discrete metrics regarding withdrawal decisions and why they occur.

4.7 **Recommendation 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

Booz Allen's Phase 1 evaluation of communication practices for both ODE and OIR submissions revealed that OIR reviewers held more frequent communications with sponsors throughout the course of the review. This increase in overall communications among OIR submissions was also associated with shorter Total Time to Decision[22] (TTD). Further analysis

[22] TTD is an established measure used by FDA and industry to assess MDUFA III review times, and reflects the time from when the review clock begins for an accepted submission to final decision.

within specific phases of the review process revealed that the average number of communications between FDA and sponsors was significantly greater during the SR phase in OIR than in ODE, while the average number of communications for all other review phases was comparable between OIR and ODE, consistent with recognized communication practices between Offices. As the primary goal of SR is to identify major and minor deficiencies/issues within the submission, Booz Allen also observed that OIR submissions were associated with fewer deficiencies/issues identified within the Substantive Interaction (SI). Given that the number of SI deficiencies is positively associated with TTD, Booz Allen recommended that FDA implement consistent practices for early and frequent communication during SR with the goal of ultimately contributing to shorter review times.

4.7.1 Implementation Progress

The key milestones in CDRH's plan for implementing a consistent practice for early and frequent sponsor communication during the SR phase are shown in Exhibit 14.

Exhibit 14. Implementation Plan for Sponsor Communications

Key Milestones	Description
1. Conduct an assessment of current practices and identify best practices	• Conducted an assessment of existing practices and identified best practices for early and frequent sponsor communication during 510(k) review • Interviewed reviewers and management to collect feedback on what does and does not work in IR
2. Use results of the assessment to develop policy, standard procedures, and metrics for communication during early 510(k) review.	• Developed *Work Instructions* document that provides information on when to use different types of communication during all review phases of a submission
3. Finalize and implement *Work Instructions* policy document and train staff on new philosophy	• Distributed *Work Instructions* document to obtain feedback at managers meeting • Trained managers on new philosophy • Finalized *Work Instructions* document, incorporating feedback from managers and senior management • Trained all ODE staff at All-Hands meeting on *Work Instructions* • Implemented *Work Instructions* document Center-wide for all staff

CDRH conducted an assessment of existing practices in sponsor communications during the 510(k) review process. Some of the key best practices they identified include establishing friendly contact with sponsors, requesting elements that were already suggested, and asking simple and general clarification questions. CDRH also identified that complex issues and premature questions prior to management input were places where communications did not work. CDRH analyzed the types of frequently asked SI Deficiencies across ODE and OIR, including label, device description, performance, administrative, indication for use, and other non-categorized issues. CDRH found that a majority of the submissions in ODE had label (75%), device description (70%) and performance (50%) questions. Similarly, OIR reported the majority of submissions having questions pertaining to performance (100%). CDRH's assessment also identified several communications best practices, such as establishing friendly contact with sponsors, requesting elements that were already suggested in the guidance

communication, and providing simple clarification questions around device descriptions, administrative elements, labeling and indication for use. These findings led CDRH to identify best practices for early and frequent communications during 510(k) review. CDRH's assessment helped to identify communication practices that are already working, and focused on addressing areas where improved guidance, policy and procedures could help both FDA staff and sponsors.

After CDRH conducted interviews and assessments, FDA developed a *Work Instructions* document as a guide for reviewers in implementing a consistent practice of communicating early and frequently with sponsors during the 510(k) SR phase. These practices provided a framework to help reviewers request and obtain all the information they need for a complete SR, resolve potential issues prior to SI, as well as help provide valuable customer service to sponsors. The *Work Instructions* document includes guidance on the appropriate type of information and timing to ask for AI interactively, tips on how to request interactive information effectively, helpful language for reviewers to use when communicating in different situations and documenting the information received via IR.

After these new policy documents were established, CDRH had proposed in their original *Plan of Action* to conduct a pilot of the SOP to assess whether the policy impacted communications. However, through the course of the implementation, CDRH concluded that after receiving feedback through their assessment and developing best practices, that the best policy to implement was a *Work Instructions* document in lieu of an SOP. FDA determined that changes in communication were fundamentally philosophical[23] in nature and were part of valued customer service, rather than a formalized set of procedures to be followed in an SOP.

After CDRH collected senior leadership feedback, the *Work Instructions* were finalized and went into effect Center-wide to address how and when to communicate with sponsors at different points in the review cycle (with a focus on the RTA review, pre-SI review and post-SI review phases). Sections outlined in the *Work Instructions* provide guidance and recommendations for communication timing and in some cases suggested language for each review phase. Exhibit 15 provides an overview of the practices detailed in the *Work Instructions.*

Exhibit 15. *Work Instructions* Communication Guideline Overview

Work Instruction Communication	Description
Guidelines for Interactive Review	IR is an opportunity to promote communication and information exchange during device reviews. Effective communication with sponsors throughout the process will allow staff to raise and resolve issues throughout the review process as they are identified.
During RTA Review	While communication during the RTA review is at the discretion of the reviewer, FDA has now provided guidelines recommending that for five or fewer missing elements in the RTA Checklist, the best method to request information is through interactive communication with the sponsor.

[23] CDRH's philosophy takes into account that each reviewer has their own discretion as to when and how often communications work for each review.

Work Instruction Communication	Description
During Pre-SI Review	The pre-SI phase is an important time in the review cycle for the reviewer to ask questions of the sponsor prior to the SI decision point, thus reducing the number and time of requests during and following SI. The *Work Instructions* includes examples of the types of communication that will assist the reviewer in determining what to request for a complete review.
While the File is on Hold	IR while the file is on hold is intended to help clarify deficiencies and proposed responses.
During Post-SI Review	Practices to follow for post-SI review communication, provides examples of issues that may occur and best practices for interactive deficiencies being communicated early in the review cycle.
Documentation of Interactive Review	Guidance for the documentation of all communications that occurred during the interactive review which is linked to Recommendation 1b's *Compiling the Administrative File for Premarket Submission Decisions* provides steps for how to properly document communications.

CDRH trained review staff on this new philosophy during an All Hands meeting in which they introduced the *Work Instructions* as a resource for reviewers. Through establishing the *Work Instructions* document, FDA has put into place procedures for reviewers to follow when communicating with sponsors that will help to improve review time.

4.7.2 Initial Results

There was not a sufficient observation period to properly assess the initial results for CDRH's implementation of this recommendation. Initial results may be measured through an assessment of the level of awareness CDRH staff have of the new *Work Instructions* document. Additional measures may include tracking whether the guidelines outlined in this document are being implemented by reviewing 510(k) submissions to determine how and when review staff facilitate and document sponsor communications.

4.7.3 Assess Outcomes and Next Steps

There was not a sufficient observation period to assess outcomes for this recommendation. Booz Allen expects that after CDRH assesses the level of awareness and implementation of the sponsor communication policies, FDA may continue to refine these policies to address the needs of CDRH reviewers in an effort to enhance the efficiency and effectiveness of sponsor communications, ultimately reducing TTD. Some potential metrics to assess the impact of the *Work Instructions* and training on improving sponsor communications practices and TTD during IR would include:

- How reviewers interact with sponsors during acceptance review (e.g. number of times and mode of IR communication)
- If reviewers engage in IR while a submission is on hold or after substantive interaction
- If reviewers document their communications in accordance with the *Administrative File SOP* described in Recommendation 1b

Additionally, the impact of this implementation could be measured by assessing types of IR communication. Potential metrics to assess across the review cycle could include the number of minor requests sent, number of significant issues or deficiencies sent, and if reviewers seek supervisory approval prior to sending alerts for future significant deficiencies.

4.8 **Recommendation 6:** Provide mandatory training for the three primary IT systems that support MDUFA III reviews

FDA developed new IT infrastructure systems and system upgrades to support MDUFA III process changes for streamlining reviews. While reviewers were offered training prior to October 1, 2012, focus groups and CDRH staff interviews conducted during Phase 1 of the assessment indicated a need for consistent training of review staff on the three primary IT systems (CTS, DocMan and Image2000+) that support MDUFA reviews. Focus group results had suggested that training documents did not provide sufficient explanation for using IT tools. CDRH staff survey results suggested that training on IT systems positively impacted the effectiveness of the review process. Our survey data indicated that many staff did not report participation in the system training, which led Booz Allen to recommend that CDRH ensure all reviewers complete the appropriate system training courses.

4.8.1 Implementation Progress

The key milestones in CDRH's implementation plan for providing mandatory training for the three primary IT systems that support MDUFA III reviews are shown in Exhibit 16.

Exhibit 16. Implementation Plan for Mandatory IT Systems Training

Key Milestones	Description
1. Inventory existing CTS, DocMan and Image2000+ IT training available to CDRH staff.	• Collected and inventoried available materials on IT training • Interviewed Office staff working on the Premarket IT Systems development and staff training
2. Review existing CTS, DocMan and Image2000+ training content and update, as needed	• Reviewed collected materials for content to ensure they were up-to-date and relevant • Identified and incorporated best practices and lessons learned from existing CTS, DocMan and Image2000+ training • Developed new training modules incorporating Kirkpatrick Level 1 and 2 measures • Piloted new training with SMEs
3. Identify CDRH staff requiring CTS, DocMan and Image2000+ training and deploy training	• Worked with CDRH Offices to identify staff requiring training • Deployed, tracked and monitored CTS, DocMan, and Image2000+ training participation to ensure all appropriate staff received training
4. Incorporate CTS, DocMan and Image2000+ training into the CDRH Reviewer Certification Program (RCP)	• Conducted a quality control review of the module • Added "Using IT Systems in Premarket Review: CTS, DocMan and Image2000+" module to RCP Curriculum
5. Establish a Cadre of Experts of CTS, DocMan and Image2000+ experts to further assist CDRH staff in the successful use of these IT systems	• Worked with Office Directors and Deputies to identify IT experts in each review Division to join Premarket IT Cadre of Experts • Communicated to Center availability of Cadre to assist reviewers with use of Premarket IT systems

CDRH began the project by conducting an inventory of existing CTS, DocMan and Image2000+ training materials available to ODE and OIR for the purpose of assessing whether available training content was up-to-date and met review staff needs. As part of this inventory, CDRH also

conducted focus groups and informal interviews with ODE and OIR reviewers who were considered subject matter experts (SMEs) on the premarket IT systems development to collect feedback on their training experience and identify their training needs. The premarket Offices (ODE and OIR) both wanted an online tool that could be used to establish a training framework for ongoing future training needs. The data and findings from the inventory, focus groups and interviews were used to develop a training plan, which will serve as the basis for developing new training and deploying it to premarket review staff once it has been finalized and reviewed for concurrence by the Premarket Offices.

After assessing the collected materials, CDRH identified and incorporated best practices and lessons learned from their research on existing CTS, DocMan and Image2000+ training, resulting in the development of a new training module for these systems. CDRH used the 510(k) process map to develop the training model, which related the IT systems training to the 510(k) review processes and incorporated Kirkpatrick Level 1 and 2 measures of training effectiveness. CDRH developed the initial training as a classroom based course and piloted this training with senior premarket review SMEs who were involved in training development. After incorporating feedback from focus groups and the pilot, CDRH revised the training and developed an online eLearning module that covers all three primary IT systems in one course. The course materials include:

- Pre- and post-training evaluations and answer key to collect Level 1 data
- Student and instructor guides
- Quick reference guide for each system
- Hints and tips guide for each system

Although this training is specific to the 510(k) review process, CDRH designed it to focus on the functionality of the IT systems and how they could be used to facilitate the review process. As a result, this 510(k) training model could serve as a framework for developing other review process training in the future, which would address the needs of ODE and OIR identified earlier in implementation.

Once CDRH finalized the online training module, they worked with the Program Management Offices (PMOs) to identify staff requiring training, which resulted in the identification of 749 CDRH staff (514 ODE staff, 235 OIR staff), including both RCP participants and non-RCP premarket reviewers. With this information, CDRH prepared communications via multiple modalities[24] announcing that the mandatory online training would be available in an eLearning format as of June 2015 and established training completion deadlines for identified staff. Once CDRH deployed the training, they monitored and tracked participation, and sent reminder emails to Office management with weekly completion reports as completion deadlines approached. To evaluate the effectiveness of the training, CDRH also collected data on Kirkpatrick Level 1 and 2 metrics using the Level 1 and 2 SOPs developed in response to Recommendation 9 (Training Program Evaluation and Metrics; see Section 4.11), which included tracking and evaluating metrics using CDRH's Pathlore Learning Management System (LMS). CDRH completed the Stage 1 plan by incorporating the module into the RCP, beginning with the fall 2015 RCP cohort. CDRH added the training module to the RCP curriculum and

[24] Including email communications for Premarket Office Directors to share with management and staff, communications during senior staff meetings, weekly training announcements, The Weekly Pulse, and posting on Monitor slides.

communicated its availability to ensure that RCP participants were aware of the training requirement.

As a further means of ensuring that the new training module would be effective in improving reviewer confidence with use of the primary premarket IT systems, CDRH worked with the Offices to establish the "Premarket IT Cadre of Experts". The Offices identified 1-2 individuals in each Division from ODE, OIR, Office of Surveillance and Biometrics (OSB), and Office of Science and Engineering Laboratories (OSEL) who were IT SMEs and could serve as a resource for staff involved in the premarket review process. The purpose of the Cadre is to provide IT support and guidance on the use of CDRH-specific premarket review IT systems, and CDRH plans to add additional experts for all other IT systems in the future. Upon establishing the Cadre, CDRH communicated their availability to ODE and OIR staff.

4.8.2 Initial Results

CDRH also tracked participation rates for their online training program on an ongoing basis to ensure all 749 identified staff (including RCP participants and non-RCP premarket reviewers) had completed the mandatory training. As of December 15, 2015, ODE had achieved 96% completion and OIR reached 89% completion (averaging 93% completion across CDRH). CDRH intends to monitor and track participation until they reach 100% completion. The results of the training indicate that CDRH has effectively developed, deployed and communicated the requirements for training to premarket review staff. Additionally, CDRH collected metrics to evaluate participant satisfaction with the training, the results of which will be discussed under Recommendation 9 (see Section 4.11.2). Booz Allen also distributed a survey to CDRH premarket review staff in ODE and OIR to assess their awareness of and experiences with the Premarket IT Cadre of Experts. As previously noted, FDA designated this Cadre beyond the requirements of Booz Allen's recommendation as a means of providing continued support and assistance to premarket review staff in the use of CDRH IT systems. Awareness of the Cadre simply indicates that staff are being made aware of the Cadre and does not indicate how effectively CDRH has communicated their availability and purpose to CDRH staff. Survey results indicated that a sufficient number of respondents (47%; n = 173) knew who their Office/Division IT experts were. Among this group, a large majority (80%; n = 82) indicated they were at least somewhat familiar with the types of support services available through the experts, and nearly half (44%, n = 82) of those had reached out to their IT experts at least once since CDRH communicated the availability of the Cadre in June 2015. The Cadre is available for use by those who may need assistance after completing IT systems training; therefore, use of this resource may occur on a case-by-case basis and does not reflect the effectiveness of implementation.

Measuring awareness of the Cadre and their available support services provides an initial view of how effectively DETD communicated the availability of this new resource to premarket review staff. Continued communication to staff on the availability of the Cadre could raise awareness and promote the use of the Cadre to those staff who may experience issues following mandatory IT systems training. Findings on the use of the Cadre do not reflect upon how well DETD implemented their training program. Instead, DETD may use these early survey results as a measure of identifying staff who may need additional assistance with use of the premarket IT systems in addition to the existing online training resources available to them. Additionally, awareness of the Cadre and their services is likely to increase by word-of-mouth as more time is allowed for adoption.

4.8.3 Assess Outcomes and Next Steps

Although the project team fulfilled the Booz Allen recommendation and Booz Allen collected data on initial results of the implementation, there was not a sufficient observation period to assess outcomes. Booz Allen's recommended next steps align with CDRH's plans to continue monitoring and tracking IT systems training participation rates to achieve the goal of 100% completion. The impact of this implementation could be assessed through collecting data on Kirkpatrick Levels 1 through 4 metrics as part of CDRH's plan under Recommendation 9 to determine whether participants are satisfied with the updated IT training module and additional resources (e.g. Frequently Asked Questions guide) and if these resources result in improved use of the IT systems to facilitate premarket reviews.

4.9 **Recommendation 7:** Provide increased clarity to applicants beyond existing eCopy guidance to enhance organized submission structure

Booz Allen's Phase 1 analyses revealed inconsistencies within the structure and quality of eCopy submissions from sponsors, which often rendered them unsearchable or difficult to read. FDA focus group participants indicated that consistent sponsor submission of searchable PDFs would enable more efficient reviews. Additionally, reviewers noted that sponsor inclusion of bookmarks were beneficial for identifying important submission content, a practice not strongly emphasized in guidance for CDRH submissions. Booz Allen recommended that CDRH take steps to provide greater clarity to sponsors, to emphasize the rationale for applying navigation support (e.g., scanning, bookmarking, hyperlinking) and provide greater specificity to existing application submission instructions to ease FDA reviewer navigation of submission reviews.

4.9.1 Implementation Progress

The key milestones in CDRH's implementation plan for providing increased clarity to sponsors beyond existing eCopy guidance are shown in Exhibit 17.

Exhibit 17. Implementation Plan for Enhanced eCopy Guidance

Key Milestones	Description
1. **Collect feedback from staff and industry**	• Identified eCopy structural issues encountered by CDRH review staff and sponsors • Identified top structural issues by type, including IT, training, and policy
2. **Determine which structural issues to address and implement**	• Prioritized issues taking into consideration of benefit, risk, and cost (return-on-investment) • Addressed highest priority issues including revision of existing eCopy Program Guidance

To understand the extent of structural issues encountered in reviewing eCopy submissions, CDRH collected feedback on eCopy through a survey, which was sent to all review staff. CDRH also distributed a survey to industry to collect feedback on the structural issues in submitting eCopies to FDA. The CDRH review staff survey asked about eCopy issues that were identified by Booz Allen during Phase 1 of the independent assessment, including navigation support

issues, such as searchable text, bookmarks, and hyperlinks. Key findings from the CDRH survey included the following:[25]

- Nearly 80% of reviewers responded that they were reviewing non-searchable eCopy submissions without optical character recognition (OCR), and that this led to an increase of review time.
- Almost 90% of reviewers indicated that they were reviewing submissions without bookmarks or hyperlinks, and that this added time to the review.

CDRH also requested and received feedback on industry's eCopy pain points, which included submissions exceeding the maximum allowed file size limit of 50MB and corruption of submitted zip files that could not be opened by the reviewers.

CDRH stratified the staff and industry input by type, including IT, training and policy and then prioritized the issues to address based on benefit, risk and cost (return-on-investment) analysis as shown in Exhibit 18. The findings resulted in the creation of a Level 2 revised eCopy program guidance. CDRH analyzed the anticipated benefit, risk and cost of proposed solutions to the issues identified by Booz Allen and by review staff and industry from survey responses. Additionally, CDRH conducted an analysis considering the expected benefit, risk and cost to add SOLR functionality to eCopy loader, which would allow the program to create a searchable PDF from non-OCR'd PDFs submitted by sponsors.

Exhibit 18. Prioritized Issues for eCopy

Issue Type	Issue Description	Solutions Proposed or in Progress
Policy	(Navigation support) Bookmarks were identified as helpful for quickly identifying important submission content. Many submissions contain no bookmarks.	• Strengthen *eCopy Program Guidance* to include suggested headings that should be bookmarked for each submission type; the suggested headings can be created from RTA Checklists • A brief description of how to create bookmarks and links has been added to the eCopy guidance
IT/Policy	(Navigation support) Focus group participants and survey respondents reported difficulties searching documents that have no OCR.	• Strengthen guidance to include stronger suggestions regarding searchable PDFs • Add functionality to SOLR so that the program can create a searchable PDF from non-OCR'd PDFs submitted by sponsors
	PDF security settings requiring passwords or authorization to open the file - one of the top reasons that eCopies fail and are placed on hold.	• The Validation Module would identify this issue so that the sponsors can correct the problem before submitting
	Non-compliant naming conventions - one of the top reasons that eCopies fail and are placed on hold.	• The Validation Module would identify this issue so that the sponsors can correct the problem before submitting
IT	Industry (particularly small companies) has reported insufficient function of the submission and validation tool.	• Developed the eCopies Validation Module, which is a tool that sponsors can use to verify the format of an eCopy (deployed November 2014)

[25] CDRH received 125 responses from 360 review staff on the eCopy structural issues they encountered.

Issue Type	Issue Description	Solutions Proposed or in Progress
	Ghost files (hidden files that do not appear in the storage drive when uploading eCopy) - one of the top reasons that eCopies fail and are placed on hold.	• The Validation Module would identify this issue so that the sponsors can correct the problem before submitting

CDRH developed the eCopies Validation Module, which is a tool that sponsors can use to verify the format of an eCopy. CDRH reviewed and improved tools and instructions to help facilitate the eCopy submission and review processes. The language in the eCopy guidance was strengthened to emphasize the need for and utility of searchable text and to describe how to create bookmarks and what should be bookmarked in submissions as Level 2 guidance. Further description of the eCopy validation tool was added to help sponsors identify and resolve the most common issues leading to eCopy failure before submitting to FDA. CDRH staff have been trained on how to OCR a document in Adobe for documents without an OCR search function as a short-term fix to the OCR issue. CDRH's activities under the current recommendation were implemented to achieve increased clarity to applications beyond existing eCopy guidance. As a result of CDRH's implementation activities, CDRH developed and issued *eCopy Program for Medical Device Submissions Guidance* on December 3, 2015, containing all necessary language and elements implemented in the current project.

4.9.2 Initial Results

Due to insufficient time of the current evaluation timeframe, initial results, including change in rate of submissions with bookmarks and hyperlinks and the rate of "Fail-to-submit" submissions, could not be measured.

4.9.3 Assess Outcomes and Next Steps

As a long-term solution to the OCR issue, CDRH intends to add SOLR functionality to the program that creates searchable PDF documents from non-OCR'd PDFs submitted by sponsors and continue to train review staff. To assess the impact of current implementations, multiple potential metrics can be considered such as rate of eCopy hold, change in review time, and awareness of program improvement and satisfaction from review staff and sponsors.

4.10 **Recommendation 8:** Evaluate tools for providing a comprehensive view of staff workload

At the time of Booz Allen's Phase 1 assessment, CDRH supervisors did not have a robust tool or system for providing a comprehensive view of staff workload. CARS and CTS are the two primary IT systems available to managers for making workload management decisions; however, managers primarily relied on only CTS because it contains real-time information and neither system has all the critical data for informing workload decisions. While CTS contains information on current submission assignments, the system does not have critical data for informing workload decisions, such as the number of Inter-Center Consults a reviewer may have or the number of submissions a reviewer has on hold. As a result, managers would develop their own custom support tools to piece together information from multiple sources for a comprehensive view of current and pending workload of their staff. Therefore, Booz Allen recommended that FDA perform an assessment to identify methods of providing a more comprehensive view of each reviewer's current and evolving workload to help managers

efficiently use staff resources and provide better insight on reviewer performance and areas of review difficulty.

4.10.1 Implementation Progress

The key milestones in CDRH's implementation plan for evaluating tools for providing a comprehensive view of staff workload are shown in Exhibit 19.

Exhibit 19. Implementation Plan for Workload Management Tool Review

Key Milestones	Description
1. Analyze existing tools and identify gaps	• Identified existing tools and data available for assessing staff workload • Determined advantages and disadvantages of each tool, and the type of workload data each tool provides • Used data to identify gaps in existing tools and data and determined how to address gaps
2. Develop an IT requirements document for improved workload management tool	• Convened a work group to use the data gathered during Phase 1 assessment and gap analysis to develop an IT requirements document for an improved electronic workload management tool that would incorporate real-time data • Developed a prototype for a new workload reporting tool
3. Develop a general best practices document for workload management	• Identified general best practices for workload management through gathering information from staff with successful workload management experience • Developed a best practices document for workload management, including best practices for reviewers and supervisors in meeting MDUFA goals

The project team began the gap analysis phase of the implementation by performing an inventory of the existing workload management tools at CDRH. They analyzed existing tools in CTS and CARS, including CTS dashboards (for Division Directors and Branch Chiefs), "canned" CTS reports,[26] and standardized CARS reports (available to all users). CDRH also conducted targeted stakeholder interviews with power users to evaluate the custom CTS and CARS reports they had created or used. For each tool, the team gathered information on the type of data it provided, whether it contained unique or redundant information, its advantages and disadvantages, as well as recurring themes to develop a comprehensive view of existing and evolving workload management tools in use across the Center.

For the stakeholder interviews, CDRH targeted eight individuals who were considered "power users" of workload management tools, such as Branch Chiefs and savvy CARS users. Each of these stakeholders had developed their own strategies for workload management or had experience in developing tools to address issues with existing capabilities. In each individual interview, CDRH discussed stakeholder needs (either their own experiences or those of others), tools they had developed to address those needs, data those tools provided, advantages and disadvantages of each tool, and ideal alternatives. CDRH used this information to identify recurring themes to document stakeholder needs, build upon work they had already done and incorporate best practices.

[26] Canned reports have pre-defined data fields and parameters.

The analyses showed that each Branch/Division had unique needs as stakeholders tailored the tool they used for workload management based on the type of work they performed.[27] In addition to identifying the advantages and disadvantages of each tool and stakeholder needs, CDRH also identified gaps for assessing and managing current and evolving reviewer workload (e.g., number of submissions a reviewer has on hold, date-related data for each submission on hold, number of inter-Center consults, indicator of submission complexity, branch due dates, individual performance, and additional considerations that may inform the submission assignment process[28]).

To inform the key deliverable of this project, the implementation team convened a small work group to develop the IT Requirements document and a prototype (Version 1) for a new workload report that would incorporate real-time data. The work group included policy analysts and an IT contractor who had experience as a Lead Reviewer and Branch Chief, as well as experience in developing custom reports.[29] Based on the information gathered from the gap analyses, the work group concluded that an effective new workload tool must meet the following primary goals:

- Efficient and cost-effective to develop and maintain
- Easy for all Branch Chiefs (including new and acting branch chiefs) to access and use
- Combine all relevant data in one place in an organized, easy-to-use format
- Include both standard and customizable features
- Provide data in multiple different ways
- Incorporate both pre- and post-market work

The work group focused the requirements for developing Version 1 on these criteria. The work group discussed the feasibility of various features, determined and refined the prototype's requirements, identified five Branch Chiefs from ODE and OIR for the focus group, and solicited feedback from the focus group on Version 1. The key changes the focus group suggested included incorporating real-time data, different ways to convey submission complexity and customizable calendars into Version 2. The team will continue to work on refining the prototype tool based on iterative feedback from the focus group, and translating this feedback into requirements through an evolving process. Given the agile nature of the development process, the implementation team provided a summary overview of the IT requirements along with demos of the new prototype report. They continue to refine and develop the formal IT requirements as they solicit feedback on and finalize the prototype tool.

During the final phase of implementation, FDA identified and developed best practices for managing workload through collecting information from staff with Branch Chief experience regarding their approaches to successful workload management. They used this information to develop a *Best Practices* document[30] intended to serve as a quick guide for staff (e.g. Branch Chiefs) to use in managing workloads. The *Best Practices* document focused on assigning

[27] This was confirmed by a review of CTS dashboards for different Branch and Division leaders, which showed that there is a spectrum of numbers and types of submissions in a particular organizational unit.
[28] For example: submission type, upcoming deadlines, reviewer expertise, pre-existing relationship with submission, or use of electronic tools to assist in managing deadlines.
[29] The work group included 2 Policy Analysts with Lead Reviewer and Branch Chief experience, 1 Policy Analyst with Lead Reviewer and internal IT development experience, 1 Policy Analyst with extensive experience developing custom CARS reports, and 1 IT contractor with experience developing standardized CARS reports.
[30] *CDRH Quick Guide: Generally-accepted Practices for Assigning Premarket Submissions*

premarket submissions and included practices such as assigning responses to deficiency letters to the same Lead Reviewer who previously worked on the submission, managers identifying a single reviewer to manage submissions that are rarely reviewed in their Branch/Division, and conducting one-on-one meetings between managers and staff prior to assigning new submissions or adjusting due dates where necessary.

4.10.2 Initial Results

There was not a sufficient observation period to properly assess initial results for implementation of the *Best Practices* guide and completion of the IT Requirements document since these were deployed to internal stakeholders at the end of Booz Allen's evaluation timeframe. Given sufficient time, the initial results of this implementation could be assessed through a staff survey that would measure review staff use and awareness of the identified best practices.

The project team did satisfy the recommendation of identifying methods to improve workload management as evidenced by the IT Requirements document, development of a prototype reporting tool and collection of ongoing feedback from the focus group. Preliminary results indicated that CDRH has implemented the primary IT requirements that the work group identified into the prototype workload management report they developed. However, these initial results provide limited value due to the agile and iterative nature of collecting feedback to define the IT requirements while simultaneously developing new versions of the prototype tool. As a result of CDRH's ongoing implementation activities (to continue incorporating focus group feedback to refine the reporting tool), the project team may not have a final set of formal IT requirements available for evaluation until a later stage in the implementation. The initial results of this implementation could then be assessed through measurements such as the development of a formal IT requirements document, observing the requirements being incorporated into new versions of the prototype, and a survey of the work group and focus group on their satisfaction with the identified requirements.

4.10.3 Assess Outcomes and Next Steps

Although the project team fulfilled the Booz Allen recommendation and completed the *Plan of Action* deliverables, Booz Allen did not have a sufficient observation period to assess outcomes. The usefulness of the *Best Practices* guide could be assessed by conducting targeted stakeholder interviews to determine whether the tools meet their needs and collecting data on their implementation of identified best practices (e.g., conducting one-on-one meetings between Managers and Reviewers prior to assigning new submissions). The impact of this project could be assessed through evaluating reviewer and management satisfaction with the requirements incorporated into a new workload management tool, as well as observing improvements in workload assignments and management.

4.11 **Recommendation 9:** Identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes

During phase 1 of the independent assessment, Booz Allen analyzed the four CDRH training programs (RCP, Leadership Enhancement and Development Program (LEAD), Experiential Learning Program (ELP), and Ad Hoc Training) using the Kirkpatrick Model, and uncovered gaps in FDA's ability to fully take into account staff needs, evaluate improvements in knowledge,

and objectively assess the impact of learning and the extent to which participants' behaviors changed as a result of training. To address this, Booz Allen recommended that FDA identify metrics and incorporate methods to better assess review process training satisfaction, learning and staff behavior changes. We derived a specific set of sub-recommendations based on recognized industry and government best practices to enable CDRH to ensure the quality and effectiveness of its training programs.

4.11.1 Implementation Progress

The key milestones in CDRH's implementation plan for training program evaluation are shown in Exhibit 20.

Exhibit 20. Implementation Plan for Training Program Evaluation and Metrics

Key Milestones	Description
1. Research Best Practices	• Met with training leaders in comparable organizations to research best practices • Developed a summary of best practices findings around training evaluation
2. Determine Training Evaluation Requirements	• Developed a strategic metrics plan and approach for designing and deploying Levels 1-4 metrics to evaluate CDRH's training programs
3. Develop SOPs and Questions for Level 1-4 Metrics	• Developed standard processes for collecting metrics for Levels 1-4 • Developed questions to assess Levels 1 and 2 metrics for RCP • Developed Level 3 feedback forms for trainee and supervisor • Drafted a standard process for conducting a periodic training needs assessment
4. Implement Use of Metrics in RCP	• Deployed surveys to collect Level 1 metrics • Deployed pre- and post-training tests to collect Level 2 metrics • Developed framework and plan for collecting Levels 3 and 4 metrics • Drafted an SOP for annual training needs assessment

CDRH first identified a set of comparable organizations to research and interview, for the purpose of identifying specific best practices in developing and deploying metrics for training program evaluation and continuous improvement. For this research, CDRH conducted interviews with representatives from the training programs at CDER, USPTO, FAA, and General Electric (GE) Healthcare to understand their training program and objectives, as well as mechanisms for assessing effectiveness and promoting continuous improvement. The data and findings from these interviews were compiled into a best practices summary of findings, which enabled a direct comparison between the benchmark organizations, and served as a key driver in developing the strategy and framework for training metric development.

Based on the findings from the best practices summary, CDRH developed a strategic metrics plan, which documented the specific needs, approaches and frameworks for the training program evaluation. The document outlined the strategy for identifying metrics and incorporating new methods to assess effectiveness, including establishing evaluation criteria for each Kirkpatrick Level, determining the appropriate assessment tools (e.g., surveys, interviews), and drafting assessment questions. It also defined the goals for a 12- and 24-month period for deploying the various Kirkpatrick Level metrics and evaluations across the different training programs. This strategy document provided the basis for subsequent steps to develop the specific frameworks and processes for metric collection and analysis.

Once the metrics strategy was in place, CDRH developed a series of frameworks and SOPs, first for the overall training evaluation approach, and then for each individual Kirkpatrick Level. The overall SOP defined CDRH's responsibilities and objectives in rolling out training evaluation across CDRH. The document describes the approach to using Kirkpatrick Levels 1-4, defining each Level and specifying the various mechanisms that should be used to collect and analyze data for each one. The document also established roles and responsibilities for CDRH's Division of Employee Training and Development (DETD), CDRH management, and CDRH staff in ensuring a successful training evaluation program.

CDRH also developed SOPs for implementing the evaluation and metrics for each Kirkpatrick Level. These Level-specific SOPs defined the following items:

- Objectives of the particular Level (e.g., Level 1 Reaction measures participant reaction to and satisfaction with received training)
- Roles and responsibilities for carrying out activities in each Level
- Administration methods (e.g., survey, interview, test)
- Data collection, analysis and reporting procedures

CDRH developed and distributed a survey tool template for collecting Level 1 metrics, which are similar across all courses. Additionally, CDRH developed Level 2 questions to use as a pre- and post-training assessment of knowledge for the different modules within RCP, and structured feedback forms to capture Levels 3 and 4 data. CDRH also developed a draft SOP for an annual training needs assessment. This document, when finalized, will describe the roles, responsibilities and procedures for conducting a systematic needs assessment on an annual basis to ensure the adequacy and relevance of reviewer training.

CDRH completed its Stage 1 plan by deploying tools to collect and analyze training metrics in RCP and the premarket review IT systems training. The project team collected Level 1 metrics through an online survey within 5 days after the completion of a course. Level 2 metrics were captured through a set of pre- and post-test questions to participants prior to and after training, as a means of determining the effectiveness of knowledge transfer. CDRH developed frameworks for the deployment of tools (e.g., questionnaires) to capture Level 3 and Level 4 metrics. These metrics can only be captured after trainees have had sufficient time to put the processes they learned into practice, which could be 6-9 months after completion of training. Due to the timing of the project completion and the constraints of the independent assessment schedule, Level 3 and 4 tools were not deployed, but the framework establishes the appropriate processes and approaches to developing tailored questionnaires to accurately capture the necessary information 6, 9, and 12 months after completion of training.

4.11.2 Initial Results

Booz Allen evaluated the initial results of the implementation project by reviewing the data on Level 1 and Level 2 metrics collected in RCP training cohorts, as well as the Premarket IT Systems Training that was provided in response to Recommendation 6 (IT Systems Training; see Section 4.8). DETD first collected Level 1 metrics through a survey distributed in the Premarket IT Systems Training online course, beginning June 2015. Through September 23, 2015, 310[31] trainees who had taken the course completed the Level 1 metrics survey. As of

[31] As of December 9, 2015, 475 trainees had completed the IT Systems training; however, updated data on the Level 1 metrics survey is pending.

December 9, 2015, 195 trainees (158 from ODE and 37 from OIR) met the 90% threshold for testing out of the IT Systems training course. The remaining 469 who took the IT Systems training were also required to take the post-training knowledge assessment for Level 2 metrics.

This IT training course has been incorporated into the RCP training for new reviewers, and Level 1 and Level 2 metrics have been collected since January 2015. Through December 9, 2015, 11 cohorts consisting of 315 trainees completed the RCP training and provided Levels 1 and 2 metrics through survey responses and post-training tests, respectively. Based on this early data collected, FDA is effectively putting the new training metrics tools into practice. Level 3 and Level 4 metrics could not be collected because they have not yet been deployed due to the recent completion of the project, but the framework and SOP for collecting them is in place.

4.11.3 Assess Outcomes and Next Steps

While FDA successfully rolled out the collection of Level 1 and Level 2 training metrics, more time is required to demonstrate and measure the outcomes of this implementation. FDA intends to collect Level 3 and 4 metrics in the latter half of 2016, after which data could begin to be collected to determine outcomes. This recommendation was made during the phase 1 assessment, based on best practices and benchmark analysis, to facilitate FDA accounting for staff training needs, evaluating gains in knowledge and skills, and assessing the impact of learning through behavior changes and improved performance. Additionally, there should be feedback mechanisms based on an analysis of Levels 1-4 metrics, to augment, modify, and improve training as needed. Metrics to assess the outcomes of this implementation may include trainee survey feedback on the effectiveness and responsiveness of the training program, as well as updates and revisions made to training based on metrics analyzed.

4.12 **Recommendation 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

Due to the complexity of scientific reviews of product submissions, formal training programs are limited in the extent to which they can impart knowledge and skills to participants. CDRH review staff received mandatory formal MDUFA III training on premarket medical device submission reviews and milestones. However, FDA survey findings during the Phase 1 assessment revealed that only 55% of OIR staff and 57% of ODE staff rated their understanding of MDUFA III processes with confidence at the time of training; staff confidence increased substantially during the course of their work (to 90% and 92%, respectively). Additionally, FDA survey findings illustrated that newer ODE review staff were least likely to be aware of a Master Reviewer in their Division, and much less likely than newer review staff in OIR or staff with longer tenures in both Offices to solicit Master Reviewers for help and support on the job. Management interviews indicated that on-the-job training such as staff rounds, Division meetings and Master Reviewers were potential sources for informal training and knowledge sharing. FDA survey findings indicated a strong interest among CDRH review staff to participate in informal training opportunities. Therefore, Booz Allen recommended that FDA promote informal training and knowledge sharing by seasoned staff and management for review staff.

4.12.1 Implementation Progress

The key milestones in CDRH's implementation plan for promoting informal training and knowledge sharing are shown in Exhibit 21.

Exhibit 21. Implementation Plan for Promote Informal Training

Key Milestones	Description
1. Assess existing practices for promoting and tracking informal training improvements	• Convened five focus groups and appointed a detail to OCE to 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	• Benchmarked training in similar organizations • Developed and implemented guidelines and procedures for conducting and evaluating informal training, including best practices for trainers and best practices for promoting and tracking training using CDRH LMS
3. Develop procedures for tracking and evaluating informal training	• Developed an SOP with the framework for informal training as well as a process for tracking and evaluating the training using CDRH's LMS and standardized metrics • Developed a form to track informal training with a follow-up survey to collect user feedback • Automated the informal training tracking form and made it available to staff via the DETD website
4. Train all Premarket Offices on the new procedures	• Developed informal training presentation for Program Management Offices (PMO) • Presented Draft Informal Training SOP to PMOs and finalized the SOP in December

CDRH began the implementation of this recommendation by forming premarket reviewer training focus groups consisting of new (< 2 years), seasoned (> 2 years), and consulting premarket reviewers to develop a full understanding of what the existing training landscape looked like at CDRH. Over the course of the implementation, CDRH conducted five focus groups to identify and asses existing practices for promoting and tracking informal training. The focus groups also helped identify opportunities for improving the informal training and knowledge sharing processes. The first task that CDRH completed was gathering data on existing training in the Center, including both formal programs and informal procedures. The primary objectives of this data collection effort were to identify the as-is premarket Offices informal training environment, and to bridge the gap between official and unofficial training. CDRH was tasked with identifying the landscape of existing training in the context of the premarket review process and the key findings from this analysis included:

- The tracking, storage and dissemination of training materials and announcements varied widely by program and by workgroup
- Training resources were stored across multiple systems (e.g. POS SharePoint site, CDRH Offices SharePoint sites, etc.) with varied access restrictions to individual sites; therefore, all material may not be accessible by those who need it or may not be the most current version
- OIR had a dedicated SharePoint site for storing informal training materials; however, this system does not track who accesses the materials

As a result, the implementation team developed a Center-level SOP that established consistent guidelines for conducting and tracking informal training.

In addition to evaluating the as-is state of informal training, these focus groups also prioritized methods to track informal training. The implementation team drafted and piloted a form to track and request credit for informal training entitled *CDRH Training for Transcript Credit*, and developed a survey to track user feedback on completed forms. CDRH collected data during the

pilot on types of informal training, issues with the form, and suggestions for improvement. CDRH incorporated this feedback into a revised request form and refined the guidelines on its use. CDRH automated the *CDRH Training for Transcript Credit* form and prepared a one-page summary document regarding the process, with examples of informal training for which staff might request credit via the form. CDRH staff can submit this form before or after training for LMS[32] credit. During the final activity in this phase of implementation, CDRH distributed this form and the associated usage guidelines to staff.

Once the guidelines for informal training and knowledge sharing were finalized along with the tracking form, CDRH finalized the *Informal Training SOP*, which presented a cohesive view on the development, delivery, tracking and evaluation of informal training. The SOP established a framework for informal training as well as procedures for tracking and evaluating training that is mission-critical and not offered by CDRH. CDRH's OCE provided training to the POS Offices following the completion of the SOP, which CDRH cleared in the late stage of the implementation timeframe. CDRH has also developed an ongoing training plan and next steps, which are described in Sections 4.12.2 and 4.12.3, respectively.

4.12.2 Initial Results

Booz Allen distributed a survey to CDRH managers to assess their awareness of and experiences with the *Informal Training SOP*[33] and *Training for Transcript Credit* form. Results showed that 48% of the managers who responded to the survey were becoming familiar with the Center's informal training procedures and most had learned about the SOP via meetings (55%) or email (27%) communications. These results indicate that CDRH management is becoming familiar with the updated informal training procedures and how to promote informal training and knowledge sharing amongst staff.

Understanding that awareness of new policies and tools is the initial step towards implementing and using these resources, Booz Allen also surveyed managers on their awareness of the new tracking tool. When managers were asked about their familiarity with the *CDRH Training for Transcript Credit*, 37% responded that they were aware of this form as a means of tracking informal training, which indicates managers are starting to become aware of this new process to track informal training.

These results are preliminary due to the limited observation period between the time CDRH implemented the *Informal Training SOP* and *Transcript Credit Request* form and the distribution of the survey. Nevertheless, these results suggest that staff are becoming aware of the Center's new policies around informal training and that the most effective forms of communicating and promoting informal training appear to be through meetings or email. Use of this form will ensure proper documentation of training and adherence to the guidelines set forth by this recommendation and the newly developed policies around informal training.

The finalization, clearance and communication of availability of these informal training resources to the Center coincided with Booz Allen's data collection phase. Booz Allen distributed the staff survey within a short timeframe after CDRH management received the final versions and communications regarding these resources. Consequently, the data represent only initial

[32] The Center's official resource for maintaining staff training records.
[33] The survey question asked specifically about awareness of CDRH informal training *procedures* rather than the SOP itself since the SOP had only been implemented at the time of survey distribution.

insights into the use and implementation of these new procedures and tools. Awareness and use of policies and tools can serve as a marker of successful implementation – in this case, that management has effectively promoted informal training and knowledge sharing of best practices amongst review staff. Further assessments of staff awareness and use of these resources would be valuable to ensure staff are consistently promoting informal training and knowledge sharing across the Center using the guidelines specified in the *Informal Training SOP*. Additionally, continued collection of data on the usage of the tracking form (e.g. through LMS, completed *CDRH Training for Transcript Credit* forms, feedback from completed survey forms following submission of the tracking credit request form) would serve as an indicator of staff awareness of informal training opportunities, as well as their familiarity with and knowledge of MDUFA III processes.

4.12.3 Assess Outcomes and Next Steps

Although the project team addressed the Booz Allen recommendation and Booz Allen collected preliminary data on initial results of the implementation, there was not a sufficient observation period to assess outcomes. Booz Allen's recommended next steps align with CDRH's plans to continue working on promoting informal training. CDRH plans to continue formalizing the new guidelines around informal training, and training staff on the SOP and training tracking procedures. The impact of this implementation could be assessed by conducting targeted stakeholder interviews to determine whether the tools meet their needs and collecting data on the success of increased informal training via surveys (e.g. conducting surveys before and after informal training has occurred to assess the outcomes on reviewer satisfaction and confidence in their ability to conduct their reviews). Additional measures to determine effectiveness of these policies include evaluating types of informal training for which staff request LMS credit and its correlation to reviewer confidence in understanding MDUFA III processes and conducting reviews after receiving informal training.

4.13 **Recommendation 11:** Develop CDRH-wide staff transition and succession plans to mitigate the impact of turnover on submission reviews

Booz Allen's Phase 1 analysis indicated that overall attrition had decreased since fiscal year (FY) 2011 at a rate not significantly different from that at USPTO, a benchmark organization selected for this study. Yet this turnover appeared to impact performance continuity at CDRH. More specifically, ODE staff reviewers perceived staff turnover as having a more significant impact on their ability to perform timely reviews than did OIR staff reviewers. Similarly, ODE staff reviewers believed their Divisions were not as well prepared as OIR to successfully manage through attrition. While SOPs existed for management of review staff changes during the review of a premarket submission, neither the Center nor Office levels employed formal transition and succession plans, potentially leading to disruption of consistent and timely reviews. Only informal CDRH or Office-wide transition processes existed (e.g., leveraging Master Reviewers, reassigning submissions when turnover occurs, identifying and training potential future leaders). Therefore, Booz Allen recommended the development and implementation of a CDRH management succession plan and review staff transition plan to promote more seamless transitions when turnover occurs and help reduce disruption to timely and consistent reviews.

4.13.1 Implementation Progress

The key milestones in CDRH's implementation plan for developing CDRH-wide staff transition and succession plans to mitigate the impact of turnover are shown in Exhibit 22.

Exhibit 22. Implementation Plan for Staff Turnover and Transition Plans

Key Milestones	Description
1. Conduct a gap analysis to assess CDRH's existing succession and transition planning process, procedures, and metrics	• For succession planning: o Evaluated effectiveness in identifying soon-to-be vacated critical leadership and technical positions o Evaluated effectiveness in identifying/implementing mitigation strategies to ensure continuity of knowledge, expertise, and operations o Identified opportunities for improvements • For transition planning: o Reviewed existing documentation (e.g., SOPs) and metrics o Collected information from CDRH Offices to identify existing best practices to promote seamless premarket review staff transitions • Identified a need for a guidance document to facilitate transition of activities across CDRH, including mechanisms to share knowledge between review staff
2. Revise CDRH succession planning processes, procedures, and metrics	• Revised existing *Succession Planning SOP*
3. Based on gap analysis, develop new or revise existing transition planning processes, procedures and metrics	• Created *Transition Planning SOP*
4. Implement the revised succession planning and transition planning process, procedures and metrics. Develop training and outreach tools for staff.	• Succession Planning and Transition Planning SOPs were finalized and released • Began implementation of Succession Planning SOP by developing Center workforce data and information in support of annual process • Developed and planned training and outreach for transition planning process

CDRH performed a gap analysis of existing transition planning activities and resources within ODE and OIR with respect to six key elements that Booz Allen identified as a successful organizational transition plan.[34] OMO developed a draft overview of the activities and resources within ODE and OIR related to each of the six key elements, which ultimately supported and facilitated the transition of premarket workload and responsibilities and helped to mitigate the impact of turnover on the review process. As a result, CDRH developed a Center-wide *Transition Planning SOP* to establish procedures to facilitate the transition of workload, responsibilities, and knowledge in an effort to mitigate the impact of staff turnover on program operations. Key provisions of this SOP are shown in Exhibit 23. The SOP includes steps to take when documenting workload and responsibilities, management review of documentation, and use of a *Transition Planning Template* to guide staff and help identify strategies to streamline and strengthen transition planning activities and resources within ODE and OIR. Furthermore,

[34] The six elements are: Redundancy of responsibilities, Knowledge sharing and documentation, Training, Shadowing, Exit surveys or checklists, and Flexible policies for retiring employees.

the SOP aids in the use of system-generated workload reports and any other documentation intended to help plan for the transition of workload and responsibilities.

Exhibit 23. Overview of *Transition Planning SOP*

Procedures	Description
Document Workload and Responsibilities	• The *Transition Planning Template* may be used to facilitate documentation of a departing employee's workload and responsibilities
Documentation Review	• The supervisor will meet with the departing employee to ensure a thorough understanding of the duties and responsibilities to be transitioned
Transition Planning	• The supervisor will use the *Transition Planning Template*, system-generated workload reports, and/or other relevant documentation prepared to plan for the transition of workload and responsibilities
Transitioning Workload and Responsibilities	• The supervisor will ensure that plans for the transition of the departing employee's workload and responsibilities are clearly communicated to affected staff and stakeholders, as appropriate
Transition Monitoring	• Once the transitions begin, the supervisor will regularly monitor and evaluate the status of the transitions to ensure their effective and efficient completion and to provide support and assistance to staff, as necessary

Following its gap analysis, OMO developed a revised *Succession Planning SOP* which describes CDRH's annual succession planning process. The SOP also serves to promote employee engagement, training, and retention by investing in the focused development of the knowledge, skills and abilities needed to assume future leadership positions. The key procedural steps in the SOP are outlined in Exhibit 24.

Exhibit 24. Overview of *Succession Planning SOP*

Procedures	Description
Align Strategic Direction with Succession Planning Objectives	• CDRH will align its strategic direction with overall succession planning objectives • To assess the factors impacting short- and long-term leadership needs, Offices will review and consider the following: o CDRH's mission, vision, and strategic priorities o Workforce profile o Environmental scan for other factors
Identify Succession Targets and Assess Bench Strength	• Offices will identify succession targets and assess relevant bench strength • Offices will use the *CDRH Succession Planning Template* to document the following key characteristics of each succession target: o Organizational component o Position title, series, and pay scale o Duties and responsibilities o Required competencies, expertise, and other credentials o Anticipated timeframe of when qualified successors are needed for the position

Procedures	Description
Develop and Implement Succession Management Strategies	• Offices will develop and implement succession management strategies, including: o Recruitment Strategies: The use of recruitment practices, policies, and resources to effectively and efficiently recruit highly qualified successors for succession targets o Retention Strategies: The use of retention practices, policies, and resources to retain highly-qualified potential successors for targeted positions o Development Strategies: Employee training and development programs, activities, and resources to build overall bench strength, close competency gaps, and develop and prepare potential successors to fill targeted positions
Evaluate and Monitor Succession Management Strategies	• Offices will evaluate and monitor the effectiveness of their strategies to adequately prepare for succession management

It is noteworthy that CDRH plans to include metrics to assess the effectiveness of the transition and succession SOPs, and this exceeded Booz Allen's recommendation.

4.13.2 Initial Results

Booz Allen was unable to measure initial results of this implementation due to an insufficient observation period. The initial results of this implementation could be assessed through a survey of review staff awareness of formal succession and transition plans, and evaluating use of the proposed documentation (e.g., release of *Succession Planning Template*, written communication of transition plans to staff and stakeholders, developed lists of retirement-eligible staff, documentation of succession management strategies).

4.13.3 Assess Outcomes and Next Steps

Due to an insufficient observation period, Booz Allen was unable to measure the impact of the transition and succession plans on the 510(k) review process since CDRH implemented the SOPs. The outcomes of this implementation could be assessed through measurements such as a survey that addresses ODE and OIR awareness and understanding of SOPs; the impact on transitioning responsibilities by departing employees who followed the appropriate SOP and its guidelines; proper application of *Transition Planning Template*; and usefulness of the *Transition Planning Template* for Office management and immediate supervisors.

5. SUMMARY AND DISCUSSION

The purpose of Phase 2 of the Independent Assessment is to evaluate CDRH's progress in implementing Booz Allen's recommendations for improving the review of medical device premarket submissions, resulting from the Phase 1 assessment of the Agency's premarket review processes, infrastructure and quality systems. Booz Allen's assessment was conducted following a five-stage evaluation framework (see Exhibit 3) that was used to assess each implementation project based on FDA's completion of the project as well as the initial results and impact, where possible. This evaluation report represents the final deliverable of the Independent Assessment of FDA's Medical Device Review Program, as agreed upon by FDA and the medical device industry in the MDUFA III Commitment Letter.

As detailed in this report, CDRH successfully completed Stage 1 for each project in its *Plan of Action* to address Booz Allen's recommendations. This marks a significant accomplishment by the Center across a broad range of areas in its medical device review program, and satisfies FDA's commitment to fulfill the recommendations from the Independent Assessment. If supported and sustained, these improvements implemented are expected to yield meaningful progress toward the shared goals of greater consistency, transparency and predictability in the review process, as well as shorter review times to get products into the hands of patients sooner.

Due to time constraints of this assessment, there was an insufficient observation period after implementation to assess the initial results of most of the projects. This stage of the evaluation framework is an important component of the assessment because it demonstrates that not only were new processes, tools and systems developed and released, but that they are also being actively put into practice. The four projects that were completed in time to allow for data collection and analysis of their initial implementation results were:

- 1a. CAPA and CPI (assessed the use of a new online issue reporting and tracking system on QM program site)
- 6. IT Systems Training (assessed the completion of mandatory training on premarket review systems, and awareness of newly designated Cadre of IT Experts)
- 9. Training Program Evaluation and Metrics (assessed the deployment and collection of Levels 1 and 2 Kirkpatrick metrics)
- 10. Promote Informal Training (assessed awareness of new informal training policies and procedures, as well as training for transcript credit request)

Initial results for this subset of the projects provide a positive indication that CDRH has promoted and begun using the products of their implementation projects. Similar analyses could be conducted to assess the initial results of implementation of the nine remaining projects, after sufficient time has elapsed to allow for adoption and data collection.

There was also insufficient time to assess the long-term outcomes of any of the implementation projects. Measuring outcomes represents the most critical and meaningful assessment in the framework, to determine if the projects are having the intended impact of the original recommendation. However, this type of evaluation also requires a relatively long lead time for the impacts to be revealed and involves complex approaches to measure them. This was not feasible given the time available for CDRH to fully implement the recommendations after they were published in June 2014 (December 2013 for the priority recommendations).

Booz Allen recommends that CDRH complete the assessments of initial results and outcomes in the evaluation framework, after sufficient time to allow for adoption and for the intended benefits of the original recommendation to be measurable (e.g., beginning in January 2017). This assessment could confirm that the recommendations are working as planned, and would allow for course correction, avoiding further investment in a project that may not be working as intended. CDRH has established a QM program and developed a framework[35] for the adoption of quality management, which they are in the process of implementing. CDRH committed in the *Plan of Action* to undertake actions that align with the principles and practices detailed in its

[35] CDRH Quality Management Framework, Jan 24, 2014 - http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHQualityManagementProgram/UCM384569.pdf

Quality Management Framework, and has demonstrated a commitment to further enhance its review processes by taking the initiative in outlining additional long-term actions on all but one of Booz Allen's Phase 1 recommendations. These actions, designated by CDRH as Stage 2, look beyond the recommendations and stand outside the scope of the Independent Assessment. Regardless of performing Stage 2 activities, a full evaluation to ensure the impact of the Stage 1 recommendations is being realized could help facilitate a successful rollout of the Stage 2 projects.

APPENDICES

Appendix A: Acronym Glossary

Abbreviation	Definition
AdvaMed	Advanced Medical Technology Association
AI	Additional Information Request
BIS	Business Information System
CAPA	Corrective and Preventive Action
CARS	CDRH Ad Hoc Reporting System
CCP	Critical Control Point
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CPI	Continuous Process Improvement
CR	Consult Reviewer
CTS	Center Tracking System
CY	Calendar Year
DCC	Document Control Center
DELE	Deletion
DETD	Division of Employee Training and Development
ELP	Experiential Learning Program
EMC	Electromagnetic Compatibility
FAA	Federal Aviation Administration
FDA	United States Food and Drug Administration
FY	Fiscal Year
GE	General Electric
IDE	Investigational Device Exemption
IMSC	Information Management Steering Committee
IR	Interactive Review
IT	Information Technology
ITPR	Information Technology Project Request
ITSC	Information Technology Steering Committee
LEAD	Leadership Enhancement and Development
LMS	Learning Management System
MAJR	Major Deficiency
MaPP	Manual of Policies and Procedures
MDMA	Medical Device Manufacturers Association
MDUFA	Medical Device User Fee Act
MITA	Medical Imaging and Technology Alliance
NASA	National Aeronautics and Space Administration
NRC	Nuclear Regulatory Commission
NSE	Not Substantially Equivalent
OCE	Office of Communications and Education
OCR	Optical Character Recognition
ODE	Office of Device Evaluation
OIR	Office of In Vitro Diagnostics and Radiological Health
OMO	Office of Management Operations
OSB	Office of Surveillance Biometrics
OSEL	Office of Science and Engineering Laboratories
OSMA	Orthopedic Surgical Manufacturers Association
PMA	Pre-Market Approval

Abbreviation	Definition
POS	Program Operations Staff
QM	Quality Management
RCP	Reviewer Certification Program
RRD	RTA Reviewer Discretion
RTA	Refuse to Accept
RTA1	Refuse to Accept – Decline Decision
RTAA	Refuse to Accept - Approve Decision
RTF	Refuse to File
SE	Substantial Equivalence
SME	Subject Matter Expert
SOP	Standard Operating Procedures
SR	Substantive Review
TTD	Total Time to Decision
TTM	Time to Market
USPTO	United States Patent and Trademark Office
WTDR	Withdrawal

Appendix B: Analyses for Recommendation 1a: CAPA and CPI

Validate Objective

These two recommendations within different components of the QM framework were closely related, and CDRH outlined a *Plan of Action* in Stage 1 to address both of them in a single project. This includes logical steps to identify specific quality management issues, develop and/or modify procedures to address these issues, and implement the procedures to improve the management of the review process and resolve communication issues. Booz Allen deems this plan relevant to addressing the intent of the recommendations, and it appears attainable based on CDRH's schedule and plan to meet the objective with current resources.

SMART Analysis

Booz Allen conducted a SMART analysis of CDRH's Stage 1 *Plan of Action* to assess the alignment between Booz Allen's recommendation and CDRH's response. An overview of the SMART analysis for this action plan is provided in Exhibit 25.

Exhibit 25. SMART Analysis for CAPA and CPI

Criteria	Evidence
Specific	• CDRH proposed conducting gap analyses to: o Determine areas to improve premarket CAPA business processes o Assess processes for logging, tracking, prioritizing and communicating CAPA, non-CAPA and CPI issues • Based on the gap analyses, CDRH was proposing to update a Quality Management Program site on SharePoint which would contain QM documents, SOPs available to all FDA staff, and a direct link to an issue reporting and tracking system • CDRH was also planning to develop SOPs to address the management review process and use of the new feedback system they would be developing
Measurable	• The revision of a QM Program site on SharePoint and use of the issue reporting and tracking system can be objectively measured • Reviewing finalized SOPs would serve as a measure of completion
Attainable	• The action plan and schedule proposed were considered reasonable with the identified resources
Relevant	• The proposed changes in documents and procedures, and development of an issue reporting and tracking system, directly address the intent of the recommendation
Time-Bound	• Proposed activities included a schedule of interim milestones and final completion within the Stage 1 timeframe

CDRH's QM Framework provided the foundation for the response to this recommendation. This framework, as well as Booz Allen feedback, provided the motivation for conducting a gap analysis to assess the strengths and weaknesses of the communications concerning CAPA and non-CAPA issues during device reviews. The provisions in this document and focus of the gap analysis are sufficiently detailed to meet the standards for specificity, measurability, and relevance. Because this effort included realistic interim milestones and can be performed with the identified resources, Booz Allen determined that it is both attainable and time-bound.

Appendix C: Analyses for Recommendation 1b: QM Document Control System Enhancements

Validate Objective

To address this recommendation, CDRH planned to initially develop a baseline inventory of the existing document management and control system processes and policies, followed by a gap analysis to identify new processes for improvement in use of electronic document management systems. Finally, CDRH intended to develop new or revise existing processes, including IT system enhancements to manage administrative documents. The project team also identified the need to update documents that are part of the administrative record, which would be accessed through document control systems and used during premarket review activities. These planned activities were consistent with the objectives of Booz Allen's recommendation on document control system enhancements, and planned for completion with existing resources.

SMART Analysis

Booz Allen performed a SMART analysis of CDRH's Stage 1 *Plan of Action* for this recommendation. An overview of the analysis is provided in Exhibit 4.

Exhibit 26. SMART Analysis for Document Control System Enhancements

Criteria	Evidence
Specific	• CDRH planned to assess existing processes, policies, and documentation to inventory across all CDRH Offices that make use of document control systems for conducting premarket reviews • CDHR planned to conduct gap analyses of these existing processes for the use of document control system to identify areas of potential improvement • CDRH intended develop and revise necessary elements of electronic document control system based on the gap analysis
Measurable	• CDRH proposed to create an inventory of existing processes, policies, and documentation pre-market administrative records • New or revised SOPs, work instructions, and staff training will be created, as necessary
Attainable	• CDRH planned to inventory existing processes, policies, and documentation, conduct gap analyses, and develop or revise processes to enhance CDRH's document control systems with existing staff and resources
Relevant	• CDRH's planned activities focused on identifying improvements and developing new or revised processes for its document control system, which meets the intent of the recommendation
Time-Bound	• CDRH's *Plan of Action* for document control system enhancements was planned to be completed within the Stage 1 timeframe

CDRH established specific plans to perform an inventory of existing processes, policies, SOPs, and documentation for the use of electronic document control systems to manage premarket review activities, including the development of necessary documents in the administrative record (e.g., CTS, DocMan, Image2000+, SharePoint, eCopy). This was to be followed by conducting a gap analysis focused on premarket review document management systems, and subsequent revision of existing documentation and polices as well as creation of new documents as needed, including IT system enhancements. The result would be a more refined, streamlined set of policies, processes and documents dedicated to fully documenting premarket review document management, including records of all communication between FDA and

sponsors, internal FDA discussions, 510(k) submissions, and 510(k) summaries. Finally, CDRH planned to initiate a three-phase training program to roll out the new or revised document control system. These activities were measurable as the inventory of existing processes, policies, SOPs, and documentation would be created and areas of potential improvement would be identified following CDRH's gap analyses. Additionally, SOPs, work instructions, and a staff training plan would be developed or revised as a result of CDRH's implementation. CDRH's planned activities were attainable as sufficient staff were available to complete the planned project. CDRH's planned activities were aligned to address the recommendation, and therefore relevant to improve CDRH's document control systems. CDRH planned to complete these activities by October 2015.

Appendix D: Analyses for Recommendation 1c: Review Process Quality Metrics

Validate Objective

CDRH's initial implementation plan addressed Booz Allen's recommendation on system evaluation, including the development and refinement of metrics to monitor the quality and effectiveness of review processes and ensure CPI. CDRH's *Plan of Action* includes three main objectives: 1) Review existing documentation[36] in an effort to identity sub-processes related to the review of premarket notifications for 510(k) and PMA submissions and use this information to prioritize and select sub-processes to monitor; 2) inventory existing metrics and conduct a gap analysis to assess what is needed to monitor the review of selected sub-processes, which would result in developing of new or streamlining existing metrics ; and 3) conduct post-review analyses of submissions that have reached a MDUFA decision in order to verify that the identified metrics facilitate sub-process monitoring and CPI. The identification of sub-processes for the 510(k) and PMA review cycle and a further gap analysis were relevant to the recommendation in order to identify missing processes or existing processes that could impact the quality or effectiveness of review processes. Based on these planned activities, CDRH was planning to select a targeted set of metrics to monitor across the review process.

SMART Analysis

Booz Allen conducted a SMART analysis of CDRH's Stage 1 *Plan of Action* to assess the alignment between Booz Allen's recommendation and CDRH's response. The specific activities and interim milestones in FDA's *Plan of Action* evolved over the course of Phase 2 and Booz Allen worked with FDA on an ongoing basis to ensure these updates continued to satisfy the SMART criteria. An overview of the analysis is provided in Exhibit 27.

Exhibit 27. SMART Analysis for Review Process Quality Metrics

Criteria	Evidence
Specific	• CDRH's plan included an inventory of SOPs, Manual of Policies and Procedures (MaPPs) and other guidance documents around the 510(k) and PMA review processes to identify sub-processes related to the review of these premarket notifications • CDRH planned to conduct a gap analysis to assess what FDA would need to monitor the review of the selected sub-processes and conduct a post-review analysis of 510(k)s and PMAs that will have reached a MDUFA decision to verify that the identified metrics would facilitate sub-process monitoring and CPI • CDRH would revise and finalize metrics for the 510(k) processes that they validated through post-review analyses
Measurable	• Evaluated the selected sub-processes and the selection and/or development of metrics that could be used to measure the quality of the review processes • CDRH will identify existing metrics and develop additional metrics to assess the 510(k) review process as a result of the gap analysis findings
Attainable	• CDRH had identified staff who would be able to identify sub-processes, conduct a gap analysis, and revise and finalize metrics for the 510(k) found through post-review analyses

[36] E.g., Process maps, SOPs, performance goals and collection of input from staff involved in premarket reviews of 510(k)s and PMAs.

Criteria	Evidence
Relevant	• CDRH's activities are relevant to achieving the objective of the recommendation to identify internal metrics to support the monitoring process and facilitate CPI
Time-Bound	• CDRH's *Plan of Action* for document control system enhancements is planned to be completed within the Stage 1 timeframe

Throughout the implementation process, Booz Allen assessed each activity against interim milestone dates and final project completion dates to ensure they satisfied the SMART criteria described in Exhibit 27. Booz Allen evaluated CDRH's *Plan of Action* and found the proposed implementation plan to be specific, measurable, relevant and attainable within the timeframe FDA developed. Booz Allen found that CDRH had developed specific time-bound goals and activities to address the recommendation, including an inventory of existing SOPs, MaPPs and other guidance documents around the 510(k) and PMA review processes to identify sub-processes related to the review of these premarket notifications, which would result in the identification of sub-processes related to the review process. The inventory of existing metrics and documents would help the team prioritize and select sub-processes to monitor. In addition, CDRH planned to conduct a gap analysis and identify existing metrics to assess what was needed to monitor the review of the selected sub-processes. In cases where CDRH identified gaps, the implementation team was planning to develop new metrics to monitor and evaluate the selected review sub-processes. CDRH's plan also included conducting post-review analyses of 510(k) and PMAs that would have reached a MDUFA decision to verify that the identified metrics would facilitate sub-process monitoring and CPI. The implementation would culminate in revising and finalizing metrics for the 510(k) processes that the project team will have validated through the post-review analyses.

Through continuous meetings and discussions with CDRH staff, Booz Allen determined that FDA's finalization of metrics selection for the 510(k) review process would be attainable based on FDA's proposed timelines of their implementation plan. Booz Allen also determined FDA's plan to identify sub-processes with associated metrics for monitoring was relevant to the objectives set forth by Booz Allen's recommendation.

Appendix E: Analyses for Recommendation 2: Decision-Making Consistency

Validate Objective

To address Booz Allen's recommendation, CDRH intended to inventory existing and, as needed, develop new business process maps for 510(k) clearance decisions, PMA approval decisions, 510(k) requests for AI, PMA MAJR, and IDE approval decisions in cross-cutting review areas such as biocompatibility and software. Additionally, CDRH planned to inventory documentation on processes, procedures, policies, IT, and metrics associated with 510(k) clearance and PMA approval decisions. A gap analysis was planned to identify necessary key processes, procedures, policies, IT, and metrics associated with premarket reviews, as well as best practices and lessons learned from other organizations for ensuring consistent decision-making. CDRH's working group then planned to determine the highest priority issues that most impact the consistency of decision-making and incorporate them into the CDRH QM Framework. The final outcome of this plan was the creation of an SOP for management oversight of CCPs in premarket review processes and a standardized process map throughout the review cycle to ensure consistency in decision making and improve CDRH's QM System. This plan was consistent with the objectives of the original Booz Allen recommendation, and planned to complete with existing CDRH resources.

SMART Analysis

Booz Allen conducted an analysis of CDRH's Stage 1 *Plan of Action* to assess the measurability of the plan. An overview of the analysis is provided in Exhibit 28.

Exhibit 28. SMART Analysis for Decision-Making Consistency

Criteria	Evidence
Specific	• CDRH planned to conduct an inventory of business processes, SOPs, guidance and policy documents • CDRH planned to identify best practices and lessons learned from similar organizations • CDRH planned to conduct a gap analysis for each premarket process • CDRH planned to identify findings and recommendations from the gap analysis • CDRH planned to address identified gaps and incorporate best practices into the CDRH Quality Management Framework and Program • CDRH intended to develop a tool or aid supporting standardized and predictable view processes
Measurable	• Documents following research and analyses including a best practice report, a gap analysis report, working groups' findings and recommendations report would be created • A new *Management Oversight of Critical Control Points SOP* guiding procedures at CCPs throughout review process would be created • A new Improving Consistency in Decision Making throughout the Review Process Map incorporated into CDRH's QM System would be developed • A new review-guiding tool in the SMART template would be developed
Attainable	• CDRH planned to conduct analyses, create reports, develop a tool, and incorporate findings into its Quality Management Framework and Program with existing resources
Relevant	• CDRH's activities were consistent with the objective of achieving improvement of consistency in decision-making throughout the review process
Time-Bound	• CDRH's *Plan of Action* for document control system enhancements was planned to be completed within the Stage 1 timeframe

CDRH established specific plans for conducting an inventory of business processes, SOPs, and guidance and policy documents for AI and biocompatibility. CDRH intended to identify best practices and lessons learned from leading organizations that were similar in size and organizational structure, such as the USPTO, NASA, NRC, and FAA followed by creating a best practices report. In parallel, CDRH planned to conduct a gap analysis for each premarket process and working groups would develop a findings and recommendations report as a result. CDRH also planned to address the findings of its gap analysis results and incorporate the identified best practices into the CDRH Quality Management Framework and program. CDRH intended to establish requirements and criteria for management oversight of interim and final decisions throughout the review process and develop enhanced reviewer training in all aspects of performing a review. CDRH's proposed activities were intended to create measurable products including a best practices report, a gap analysis report, working groups' findings and recommendations report, *Management Oversight of Critical Control Points* SOP in premarket review processes, and improving consistency in decision-making throughout the review process. Additionally, CDRH planned to develop and implement a review tool (the SMART tool) designed to guide reviewers through the end-to-end review process to help address common mistakes and questions and help reviewers follow standardized steps to make consistent decisions during a review. CDRH planned to complete these activities within the Stage 1 timeframe.

Appendix F: Analyses for Recommendation 3: RTA Process Improvement

Validate Objective

Booz Allen's recommendation was primarily based on the finding that administrative elements were marked as missing in over 80% of RTA1 decisions. Therefore, CDRH's Stage 1 *Plan of Action* included five steps to assess the RTA program and identify actions to improve the RTA process: (1) assessment of the RTA program, specifically identifying missed criteria and criteria with the greatest amount of SR; (2) audit of RTA data with the goal of examining trends, correlations and patterns leading to the development of appropriate metrics and indicators; (3) analysis of industry stakeholders' experiences with the *RTA Guidance Policy* and checklist; (4) root-cause analysis to identify underlying causes and appropriate mitigation action for the priority findings of the RTA assessment; and (5) revision of the *RTA Guidance Policy* to increase clarity and further promote awareness of RTA requirements.

SMART Analysis

Booz Allen conducted a SMART analysis of CDRH's Stage 1 *Plan of Action* to assess the alignment between Booz Allen's recommendation and CDRH's response. The organization and structure of the response evolved over the course of Phase 2, based on input from biweekly meetings with Booz Allen. An overview of the analysis is provided in Exhibit 29.

Exhibit 29. SMART Analysis for RTA Process Improvement

Criteria	Evidence
Specific	• CDRH proposed performing an assessment and audit of the RTA program to identify specific criteria for, and trends associated with, RTA decisions that would suggest relevant RTA metrics and indicators • FDA proposed to conduct a pilot study to assess IR and RRD using existing RTA Checklists, which would aid in developing IR and RTA RRD polices during RTA review • Following the audit and pilot study, FDA's plan included revisions to the RTA policy and Checklist to increase clarity and further promote awareness of requirements
Measurable	• Proposed revisions to RTA policy documents could provide evidence of fulfilling the recommendation
Attainable	• Any changes to the *RTA Guidance Policy* and RTA Checklist must go through a lengthy FDA approval process; therefore, the Booz Allen recommendation to improve clarity around the Administrative requirements may not be attainable within the timeframe specified • Attainability is also dependent on the time necessary to assess whether modifications actually improve the clarity of the RTA process
Relevant	• The proposed revisions to the RTA policy could directly address the recommendation
Time-Bound	• CDRH's *Plan of Action* included specific target dates for revising the RTA policy • The pilot study was scheduled for a specific time period within the Stage 1 timeframe

CDRH proposed conducting an assessment and audit of the RTA process to identify trends associated with RTA designations that would possibly lead to developing relevant RTA metrics and indicators. CDRH's plan also included an analysis of feedback they collected from industry representatives during the assessment of the premarket review process on their experience with the RTA policy and checklist. This solicitation from industry representatives could maintain focus

on the impact of RTA revisions on 510(k) review, thereby maintaining specificity of the CDRH response to the Booz Allen recommendation. In addition, CDRH proposed a pilot study to assess use of IR and RRD using existing RTA Checklists and 510(k)s received between March 2 and April 30, 2015. The findings could aid in the development of IR/RRD polices during RTA review. The proposed pilot study would specifically examine RTA rates before and after implementation of IR/RRD as well as any problematic elements for IR. Finally, CDRH was planning to use the audit results and data from industry feedback to revise the *RTA Policy for 510(k)s* guidance to increase clarity and further promote awareness of 510(k) submission requirements. These actions confirm that CDRH's response to Booz Allen's recommendation is specific, measureable, relevant, and time-bound.

It is important to note that CDRH's changes to the RTA guidance and RTA Checklist had to undergo formal FDA approval, which did not include a specified timeframe for completion due to the regulatory requirements and variable timelines associated with approving Guidance documents. Therefore, while the Booz Allen recommendation to improve clarity around the Administrative requirements was attainable, the RTA guidance would likely not go into effect before the current Booz Allen assessment was in its final stages.

Appendix G: Analyses for Recommendation 4: Withdrawn Submissions Analysis

Validate Objective

The CDRH *Plan of Action* provided two main objectives to be met for this implementation: to identify trends, correlations, or patterns that may lead to withdrawn data, including reasons for withdrawal through an analysis of withdrawn submissions; and to determine the cause of identified trends, correlations or patterns through root cause analyses, and subsequently develop and implement mitigation actions for these findings, as appropriate. The analyses conducted by CDRH into the root cause and subsequent further investigation into the withdrawn submissions met the objective of the original recommendation to perform a retrospective root cause analysis of withdrawn submissions and develop a mechanism to minimize their occurrence.

SMART Analysis

Booz Allen conducted a SMART analysis of CDRH's Stage 1 *Plan of Action* to assess the alignment between Booz Allen's recommendation and CDRH's response. The specific activities and interim milestones in FDA's *Plan of Action* evolved over the course of Phase 2 and Booz Allen worked with FDA on an ongoing basis to ensure these updates continued to satisfy the SMART criteria. An overview of the analysis is provided in Exhibit 30.

Exhibit 30. SMART Analysis for Withdrawn Submissions Analysis

Criteria	Evidence
Specific	• FDA plans to conduct an analysis of withdrawn submissions across the review cycle, focusing on the RTA phase, SI phase and final ten days before action, to identify trends and/or correlations to identify reasons for withdrawal • FDA also states that they will develop mitigation actions upon the results of the root cause analyses
Measurable	• CDRH's activities will be measurable by reviewing: o The analysis of withdrawn submission data and any trends, correlations or patterns CDRH identifies related to reasons for withdrawal o Evaluating the documented findings from the analysis and any mitigation actions CDRH identifies o Evaluating the implementation of mitigation actions addressing withdrawn submissions
Attainable	• CDRH had identified staff and a submission cohort they would analyze to facilitate the root cause analyses
Relevant	• CDRH's activities are relevant to achieving the objective of the recommendation to identify trends related to withdrawal and develop mitigation actions
Time-Bound	• CDRH's *Plan of Action* was planned to be completed within the Stage 1 timeframe

Throughout the implementation process, Booz Allen assessed each activity against interim milestone dates and final project completion dates. Booz Allen evaluated CDRH's *Plan of Action* and found their proposed implementation plan to be specific and measurable as CDRH refined the implementation process. CDRH specified areas to evaluate through their review of the documentation related to withdrawn submissions. CDRH had developed a plan that met all the SMART criteria that would include a deep dive analysis to specifically evaluate withdrawals during the RTA and SI review phases. This analysis was relevant to determine what actions

were needed during those specific review phases to mitigate withdrawal rates. CDRH's *Plan of Action* also included an analysis of factors that lead to increased withdrawals during FDA review days 81-90, which correlates to Booz Allen's Phase 1 findings. CDRH's initial plan to develop mitigation actions was not specific, as it would rely upon the results of the root cause analyses. However, CDRH refined this plan over the implementation timeframe to develop mitigation actions that were relevant and specific to the root cause findings. Booz Allen evaluated CDRH's *Plan of Action* against the SMART criteria in Exhibit 30 and determined that CDRH would be able to complete their planned analyses and implement mitigation actions with the available resources in the timeframe described. CDRH's *Plan of Action* for conducting root cause analyses was relevant to the recommendation to identify trends or correlations associated with reasons for withdrawal and subsequent mitigation actions.

Appendix H: Analyses for Recommendation 5: Sponsor Communications

Validate Objective

The CDRH *Plan of Action* identified the following six objectives to fulfill this recommendation: (1) conduct an assessment of current practices and identify best practices for early and frequent communication during 510(k) review, (2) use the results of the assessment to develop policy, standard procedures, and metrics for communication during early 510(k) review, (3) pilot the policy and procedures in one premarket review branch, (4) evaluate results of pilot study and collect feedback to determine if frequency of communications increased, (5) revise policy, procedures, and metrics to incorporate results from pilot study; and (6) implement new policy and internal procedures. While implementing the original *Plan of Action*, senior leadership determined that implementing a consistent practice for communicating early and frequently was a philosophical exercise. Thus, CDRH's *Plan of Action* shifted from developing and piloting a formal SOP to drafting a *Work Instructions* document that would provide reviewers guidelines on communications for different phases of the review cycle, as well as train staff on the new *Work Instructions* document. The assessment of existing practices and best practices is relevant to understand the nature of communications within CDRH. While the planned implementation activities shifted during the course of this phase of the assessment, the objective of the *Work Instructions* is relevant as it still meets the original recommendation of developing a policy and internal procedures for sponsor communications.

SMART Analysis

Booz Allen conducted a SMART analysis of CDRH's Stage 1 *Plan of Action* to assess the alignment between Booz Allen's recommendation and CDRH's response. The specific activities and interim milestones in FDA's *Plan of Action* evolved over the course of Phase 2 and Booz Allen worked with FDA on an ongoing basis to ensure these updates continued to satisfy the SMART criteria. An overview of the analysis is provided in Exhibit 31.

Exhibit 31. SMART Analysis for Sponsor Communication

Criteria	Evidence
Specific	• FDA will assess their current communications practices during 510(k) review processes. • FDA will develop and implement a *Work Instructions* document specifying the guidelines for sponsor communications
Measurable	• CDRH's implementation can be measured by: o Reviewing documented assessments of interviews and summarized feedback in the *Best Practices* document o Evaluating the revised communication policy documents o Tracking implementation and training on the new policy
Attainable	• CDRH had identified available resources to conduct the assessment of current communication practices and develop and implement a *Work Instructions* document
Relevant	• The *Work Instructions* document was intended to assist premarket staff by clarifying IR expectations and providing practical recommendations for implementation of IR during review of a 510(k) submission
Time-Bound	• CDRH's *Plan of Action* for finalizing the Work instruction is planned to be completed within the Stage 1 timeframe

Booz Allen evaluated FDA's *Plan of Action* and found their proposed implementation plan to be specific and measurable as FDA refined the implementation process. FDA's *Plan of Action* proposed to assess reviewer communication practices specifically during 510(k) reviews through interviews with review staff and managers from ODE and OIR. Through these interviews, CDRH was planning to identify metrics associated with communication patterns which could be used to inform revisions to policy and procedures. This would ensure a consistent set of guidelines would be followed when communicating with sponsors. In lieu of a formalized SOP, the implementation team decided to develop a *Work Instruction*s: *Interactive Review During the Review of 510(k) Submissions* document as a means of achieving this objective. The implementation plan was specific and measurable, as it included the development of a document that would provide guidelines around sponsor communications policies and a review staff training plan that could be evaluated. The training plan would target staff on the communications practices identified in the *Work Instructions* document during Division meetings over a specified timeframe that was attainable during the implementation. Additionally, the *Work Instructions* would be added to the RCP, the training curriculum for new review staff.

Booz Allen determined that CDRH's plan to complete the *Work Instructions* with the available resources was attainable within the specified project timelines. CDRH's implementation plan to develop and implement a policy for communication during early 510(k) review was relevant to the recommendation to implement a consistent practice for communicating early and frequently with sponsors.

Appendix I: Analyses for Recommendation 6: Mandatory IT System Training

Validate Objective

The intent of this recommendation was for CDRH to provide training to all review staff on the primary IT systems. FDA's response was to not only provide Center-wide training to reviewers, but to also update existing training content and resources to ensure they would meet staff needs. In order to accomplish this goal, CDRH was planning to inventory existing training available to staff on CTS, DocMan and Image2000+ and update this content once they had identified best practices for training. Upon updating the training content, the implementation team would identify all CDRH staff requiring training on these systems, deploy the training, and track participation rates to ensure all identified staff will have completed it, which would fulfill Booz Allen's recommendation. In parallel with Recommendation 9 (see Section 0), CDRH would be developing metrics to evaluate training satisfaction, learning and staff behavior changes. Following this activity, the project team was planning to incorporate the updated IT systems training into the CDRH RCP. In addition, CDRH's implementation activities surpassed the objective of the recommendation to include a plan for establishing a cadre of IT system experts whose purpose would be to assist CDRH staff in effectively using these systems.

SMART Analysis

Booz Allen conducted a SMART analysis of CDRH's *Plan of Action* to assess the alignment between Booz Allen's Phase 1 recommendation and CDRH's response. The organization and structure of the response evolved over the course of the implementation, based on input from biweekly meetings with Booz Allen. An overview of the analysis is provided in Exhibit 32.

Exhibit 32. SMART Analysis for Mandatory IT Systems Training

Criteria	Evidence
Specific	• CDRH's plan to inventory existing training and identify necessary updates was specific to the primary IT systems (CTS, DocMan and Image2000+) used to support MDUFA III reviews • CDRH was planning to identify all staff involved in MDUFA III reviews whom they would enroll in mandatory training • CDRH would be tracking participation rates to ensure all required staff completed the mandatory training • The *Plan of Action* included developing procedures and standardized metrics for evaluating training, including specific metrics for user satisfaction, learning and staff behavior changes • CDRH planned to provide additional resources beyond online training in the form of a cadre of IT experts who would provide continued assistance to staff on the use of IT systems that support MDUFA III reviews
Measurable	• CDRH's implementation activities would be measurable by: • Collecting data on participation and completion rates of the IT Systems Training • Assessing staff use and awareness of the cadre of IT experts
Attainable	• CDRH had identified staff and resources available to join review existing training and develop updated training modules • CDRH would be identifying the target population for taking the training so they would be able to incorporate necessary elements into the training modules based on staff needs and communicate the training requirement prior to deployment

Criteria	Evidence
Relevant	• CDRH's planned activities would ensure that all required staff complete IT systems training relevant to MDUFA III reviews
Time-Bound	• CDRH's *Plan of Action* for updating IT systems training and deploying it to identified staff was planned to be completed within the Stage 1 timeframe

The implementation team specified a phased approach in response to Booz Allen's recommendation. The first planned activity was to inventory existing training on the three primary IT systems related to MDUFA III reviews (CTS, DocMan and Image2000+). CDRH would accomplish this through identifying best practices for training in similar organizations, convening focus groups to learn about reviewers' experience with existing training to understand the advantages and gaps, and then incorporate lessons learned into updated training modules. Once CDRH would have updated the training, they would identify all staff who are required to take the training and ensure the new training modules met their needs. The key activity in their *Plan of Action* to address Booz Allen's recommendation was to deploy training across CDRH and develop a mechanism to track participation and completion. Tracking training is relevant to the initial recommendation as it would ensure the mandatory training requirements are met, as well as provide a means for directly measuring the effectiveness of IT systems training. The final phase of implementation was to create a cadre of CTS, DocMan and Image2000+ experts within each premarket review Division at CDRH and communicate their availability to staff. Once implemented, the cadre would serve as an additional resource beyond training modules to assist staff with effectively using the IT systems to perform their reviews.

Appendix J: Analyses for Recommendation 7: Enhanced eCopy Guidance

Validate Objective

FDA's Initial *Plan of Action* was consistent with the objectives of Booz Allen's recommendation. CDRH planned to initially conduct an assessment of the eCopy program. First, a survey was planned to collect feedback on eCopy structural issues encountered by CDRH review staff and industry. CDRH then intended to identify top structural issues by type, including IT, training, and policy, and determine which of these structural issues to prioritize, taking into consideration the likely benefit, risk, and cost of implementation.

SMART Analysis

Booz Allen analyzed CDRH's Stage 1 *Plan of Action* to assess the measurability of the project goals. An overview of the analysis is provided in Exhibit 33.

Exhibit 33. SMART Analysis for Enhanced eCopy Guidance

Criteria	Evidence
Specific	• CDRH planned to collect feedback from CDRH review staff and industry for structural issues in eCopy submission • CDRH planned to identify top structural issues encountered by CDRH review staff and industry and stratify the results by type, including IT, training, and policy • CDRH planned to determine which structural issues to address and prioritize issues based on benefit /risk and return-on-investment
Measurable	• Survey results would be created from feedback from review staff and industry • A list of issues and potential solutions would be created after identification and prioritization of the structural issues for eCopy submissions • Improved tools and revised *eCopy Program Guidance* would be published on the FDA website
Attainable	• CDRH had staff available to conduct survey and analysis on the identified structural issues and address priority issues including IT systems
Relevant	• CDRH's planned activities were consistent with the objectives of the recommendation to clarify eCopy submission process and enhance submission structure
Time-Bound	• CDRH's *Plan of Action* for document control system enhancements was planned to be completed within the Stage 1 timeframe

CDRH established specific plans to identify and address high priority structural issues of eCopy Program Guidance. To collect feedback, CDRH planned to create and send a survey to CDRH review staff and three main medical device industry groups (AdvaMed, MITA and MDMA). Then, structural issues identified from the survey results were planned to be stratified by type, including IT, training, and policy for further analyses to create a list of structural issues to address. Next, CDRH intended to prioritize the structural issues considering benefit, risk, and cost (return-on-investment) and address the highest priority issues. These activities were measurable as the survey results on eCopy submission structural issues would be collected and a list of identified and prioritized issues to address would be created after CDRH' analysis. FDA's implementation activities on improving eCopy submission tools and publishing a revised eCopy Program Guidance would be available on the FDA's website. CDRH planned to complete these activities within the Stage 1 timeframe.

Appendix K: Analyses for Recommendation 8: Workload Management Tool Review

Validate Objective

FDA's *Plan of Action* provided a clear response to Booz Allen's recommendation on workload management tool review, including a provision for developing best practices and an IT requirements document outlining the necessary criteria for a comprehensive workload management tool. CDRH planned to convene a work group who would identify existing methods, tools and data available to staff for assessing and managing workload. First, the work group would review the existing workload management capabilities to determine what type of data they provide, and then assess the advantages and disadvantages of each. Next, the working group had planned to use this information to identify gaps in existing reviewer workload capabilities and develop solutions on addressing any gaps identified. CDRH then intended to leverage this information to develop an IT requirements document identifying key criteria for an improved electronic workload management system, and a best practices document that would provide guidelines to reviewers and supervisors on managing workload and meeting MDUFA performance goals. Booz Allen's recommendation required CDRH to *evaluate* approaches to improve workload management capabilities. CDRH's plan addressed this recommendation and included supplemental activities that would result in the development of a prototype workload report that would meet the criteria to be identified by the analyses.

SMART Analysis

Booz Allen conducted a SMART analysis of CDRH's *Plan of Action*[37] to assess the alignment between Booz Allen's Phase 1 recommendation and CDRH's response. The organization and structure of the response evolved over the course of the implementation, based on input from biweekly meetings with Booz Allen. An overview of the analysis is provided in Exhibit 34.

Exhibit 34. SMART Analysis for Workload Management Tool Review

Criteria	Evidence
Specific	• CDRH proposed to convene a working group that would identify and develop methods for providing a more comprehensive view of current and evolving reviewer workload through an assessment of existing tools and data available to assess staff workload • CDRH planned to use the working group data to identify gaps in existing workload management capabilities and develop approaches for addressing identified gaps • Following the gap analysis, CDRH will develop an IT requirements document for an improved electronic workload management tool that incorporates real-time data, and identify general best practices for workload management
Measurable	• CDRH's implementation activities would be measurable by reviewing: o The summary results that would be created from the gap analysis on existing tools o The IT requirements document and the Best Practices guide to ensure specific plans were developed to address identified gaps o The criteria for inclusion and feasibility that will have been selected and defined in the IT requirements document

[37] FDA's published *Plan of Action* included only Stage 1 activities for this recommendation.

Criteria	Evidence
Attainable	• CDRH had identified staff and resources available to join the working group • CDRH had also identified staff with IT development and requirements gathering experience who would be able to facilitate the creation of the IT requirements document given their working knowledge with the existing systems at CDRH
Relevant	• CDRH's activities are relevant to the recommendation to assess and identify methods to improve workload management and provide managers better insight to review performance
Time-Bound	• CDRH's *Plan of Action* for document control system enhancements is planned to be completed within the Stage 1 timeframe

The CDRH team specified a three-phased approach to implementation. In the first phase, CDRH proposed to convene a work group that would identify and develop methods for providing a more comprehensive view of current and evolving reviewer workload. Specifically, the work group would plan to:

- Identify existing tools and data available to assess staff workload
- Determine the advantages and disadvantages of each tool
- Identify the workload data each tool provides and determine its usefulness
- Determine the comprehensiveness of existing tools

The work group data would serve to identify gaps in existing workload management capabilities and develop approaches for addressing any identified gaps through the use of data, indicators, and tools that would help managers more efficiently use staff resources. The group will have identified specific individuals to interview for data collection who have their own strategies for workload management and/or significant experience in developing tools to address these issues. Following the gap analysis, CDRH planned to develop an IT requirements document along with a prototype tool to pilot with a defined group of experienced stakeholders. The plan was attainable as CDRH had identified staff with IT development and requirements gathering experience who would be able to facilitate the creation of the IT requirements document and prototype tool given their working knowledge of the existing systems at CDRH. The final outcome would be a Best Practices document for workload management that would include best practices for reviewers and supervisors in meeting MDUFA goals.

FDA's plan demonstrated specificity in the gap analysis and requirements gathering approach within a reasonable timeframe as specified in their detailed *Plan of Action* that would enable Booz Allen to evaluate this implementation. Booz Allen had recommended that FDA evaluate tools for providing a comprehensive view of staff workload. The CDRH team developed a detailed *Plan of Action* that would not only satisfy this recommendation through the creation of IT Requirements and Best Practices documents, but also address the gaps they would be identifying in the IT Requirements document through their plan for developing and piloting a prototype workload management tool.

Appendix L: Analyses for Recommendation 9: Training Program Evaluation and Metrics

Validate Objective

FDA's *Plan of Action* provided a comprehensive response to Booz Allen's recommendation. FDA planned to research best practice for training evaluation in similar organizations followed by determining evaluation requirements for premarket review training. FDA established the evaluation criteria for each of the Kirkpatrick Level and outlined the premarket review requirements for obtaining data at each Level. Then CDRH planned to develop standardized procedures and metrics for each Level 1 -4 of training assessment in Kirkpatrick's model through tests, surveys and focus groups. FDA then developed metrics to assess CDRH's review process training and procedures and aids incorporating to CDRH's review training program. The final step in their implementation plan was to implement the use of standardized Kirkpatrick's model Level 1-4 metrics into the CDRH RCP. Booz Allen's recommendation asked FDA to identify metrics and incorporate methods into the RCP. FDA's plan addressed the recommendation to ensure quality and effectiveness of FDA's training program.

SMART Analysis

Booz Allen conducted a SMART analysis of CDRH's *Plan of Action* to assess the alignment between Booz Allen's Phase 1 recommendation and CDRH's response. The organization and structure of the response evolved over the course of the implementation, based on input from biweekly meetings with Booz Allen. An overview of the analysis is provided in Exhibit 35.

Exhibit 35. SMART Analysis for Training Program Evaluation and Metrics

Criteria	Evidence
Specific	• CDRH planned to conduct a study for training evaluation in similar organizations by researching best practices and interviewing organization representatives • CDRH planned to determine evaluation requirements and establish criteria for premarket review training for four Levels of Kirkpatrick's model • CDRH planned to identify standardized metrics for Level 1 to 4 of Kirkpatrick's model applied to its review process training • CDRH planned to implement Kirkpatrick's model Level 1 to 4 into CDRH's RCP program
Measurable	• A best practices report would be created • Training evaluation criteria and outlined metrics would be listed in CDRH's project summary • Survey questions to CDRH staff and the survey result summary would be created to initially assess CDRH's review training for each Level of Kirkpatrick's mode
Attainable	• CDRH had staff available to identify metrics and incorporate methods to assess its review process training program
Relevant	• CDRH's planned activities were relevant to identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes
Time-Bound	• CDRH's *Plan of Action* for review training program evaluation and metrics was planned to be completed within the Stage 1 timeframe

CDRH established specific plans to benchmark best practices of four organizations to include CDER, USPTO, FAA, and GE Healthcare and identify metrics to assess its training program. CDRH adopted four Levels of Kirkpatrick's model (Level 1-4) to determine evaluation

requirements and establish criteria for premarket review training. This then lead to identification of standardized metrics to assess CDRH's review process training. Eventually, CDRH intended to implement Kirkpatrick's model Level 1 to 4 into CDRH's RCP program. These activities were measurable as a best practices report on training program would be created at completion of the best practices study. Based on the findings identified, CDRH will create a summary report on determination of training evaluation criteria and metrics. Identified metrics will be evaluated by collecting feedback from survey questions created to initially assess CDRH's review process training program. Booz Allen assessed that CDRH's planned activities were attainable to implement activities including conducting the best practices study, identifying metrics and incorporating methods, and finally assessing CDRH's review training program. CDRH's planned activities were aligned to address the current recommendation, "Identify metrics an incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes", and therefore relevant to achieve an objective of implementation. CDRH planned to complete these activities by July 2015.

Appendix M: Analyses for Recommendation 10: Promote Informal Training

Validate Objective

FDA's implementation plan provided a clear response to Booz Allen's recommendation to promote informal training[38] and knowledge sharing, and included provisions for tracking informal training and formalizing the process. CDRH's plan included a three-pronged implementation approach, starting with an assessment of existing practices for promoting and tracking informal training to identify opportunities for improvement. CDRH would use the results of this analysis to develop and implement guidelines for conducting informal training, including best practices for trainers and best practices for promoting and tracking training. As part of this approach, the DETD within the OCE would also develop procedures to track and evaluate informal training using CDRH's LMS and standardized metrics. The implementation team planned to address the issue of tracking training by creating a *CDRH Training for Transcript Credit* form to track internal training that would occur within the Center not affiliated with DETD. The goal of this form would be to provide participants of informal training with credit that would appear on their learning transcript. As the final phase of the implementation, CDRH would promote informal training by training all pre-market Offices on the procedures they would be developing.

SMART Analysis

Booz Allen conducted a SMART analysis of CDRH's *Plan of Action* to assess the alignment between Booz Allen's Phase 1 recommendation and CDRH's response. The organization and structure of the response evolved over the course of the implementation, based on input from biweekly meetings with Booz Allen. An overview of the analysis is provided in Exhibit 36.

[38] DETD defines informal training as: training conducted that is not provided by DETD; specific to review practices, institutional knowledge, or current scientific findings within a small group setting of 3 or more people; and/or conducted in-person via informal discussion, slide show, or webcast, or via electronic methods such as a stored database of information accessible to everyone.

Exhibit 36. SMART Analysis for Promote Informal Training

Criteria	Evidence
Specific	• CDRH's plan to identify and assess existing practices for promoting and tracking informal training and identify opportunities for improvements would include convening a premarket reviewer experience focus group to prioritize informal training tracking • CDRH was planning to develop and implement guidelines for conducting informal training, including best practices for trainers and best practices for promoting and tracking training. o CDRH would research best practices in similar organizations and work on developing an informal training tracking/credit request form to promote the use of training. • The final *Plan of Action* was to develop procedures for tracking and evaluating informal training using CDRH's LMS and standardized metrics, and then to train all Premarket Offices on the new procedures. o CDRH was planning to develop focus groups to help implement these activities. o CDRH had identified the target population (Center premarket review staff) for this implementation.
Measurable	• CDRH's implementation activities would be measurable by: o Collecting data on the use of the Informal Training Tracking for Credit Request form by review staff[39] o Reviewing the Best Practices and SOP CDRH will have developed o Assessing staff use and awareness of the guidelines outlined in the SOP o Tracking participation rates of training across Premarket Offices in CDRH
Attainable	• CDRH had identified staff and resources available to join the focus group, as well as a detail to OCE to conduct informal training landscape assessment • CDRH had also identified existing resources (SharePoint sites and LMS) where they could embed the Informal Training Transcript Credit Request form • CDRH had identified a target population for conducting training
Relevant	• CDRH's activities were relevant to the recommendation to promote informal training
Time-Bound	• CDRH's *Plan of Action* for developing informal training procedures and providing training to identified staff was planned to be completed within the Stage 1 timeframe

The CDRH team specified a phased approach to implementation in response to Booz Allen's recommendation. The first planned activity was to convene a focus group comprised of premarket reviewers with various levels of experience and tenure at CDRH. The focus group was intended to identify and evaluate existing practices for promoting informal training and identify areas for improvement. Upon completing this assessment, the focus group would work to prioritize the gaps and the approaches to conducting and tracking informal training. This effort would include identifying best practices for promoting and tracking training and knowledge sharing through benchmarking in similar organizations. In parallel, the implementation team would work. The next phase of implementation would result in developing Center-wide procedures to track and evaluate informal training using CDRH's LMS. Along with these guidelines and procedures, CDRH would develop a transcript credit request form to facilitate tracking informal training use. Tracking informal training is relevant to the initial recommendation as it would help promote informal training opportunities as well as provide a means for directly measuring the use of informal training resources across the Center. The implementation team had identified potential IT resources (e.g., LMS, SharePoint) to host this training request form. The final phase of implementation was to train all Pre-market Offices on the new procedures, which would help promote awareness of the available resources and opportunities for informal training across the Center.

[39] Use of this form will ensure proper documentation of the training and adherence to the new procedures and best practices.

Appendix N: Analyses for Recommendation 11: Staff Turnover and Transition Plans

Validate Objective

Based on Booz Allen's recommendation, CDRH's *Plan of Action* for succession planning included four steps: (1) a gap analysis to assess its existing succession planning process, procedures, and metrics; (2) revision of these elements; (3) implementation of the revised process, procedures, and metrics; and (4) development of training and outreach tools for staff. The *Plan of Action* for addressing staff transition followed the same four steps. As a result, CDRH developed a *Succession Planning SOP*, which outlines the annual succession planning process for CDRH, and a *Transition Planning SOP*, which facilitates the transition of workload, responsibilities, and knowledge to mitigate the impact of staff turnover on program operations.

SMART Analysis

Booz Allen conducted a SMART analysis of CDRH's Stage 1 *Plan of Action* to assess the alignment between Booz Allen's recommendation and CDRH's response. An overview of the analysis is provided in Exhibit 37.

Exhibit 37. SMART Analysis for Staff Turnover and Transition Plans

Criteria	Evidence
Specific	• CDRH's plan included an evaluation of existing succession planning processes, procedures, and previous outcomes that would address succession planning • CDRH's plan was to conduct a pre-assessment information review and gather data to document and assess existing transition planning activities and resources within ODE and OIR to address transition planning • The *Plan of Action* included the development of a *Succession Planning SOP* and a *Transition Planning SOP*
Measurable	• CDRH's implementation activities would be measurable by reviewing the *Succession Planning* and *Transition Planning SOPs* they will have developed • The impact of transition and succession plans on the review process will be difficult to measure in the time allotted
Attainable	• CDRH had identified staff who would be able to implement the *Plan of Action*
Relevant	• The proposed products of CDRH's *Plan of Action* are two SOPs directly addressing the recommendation
Time-Bound	• A release date was defined for the SOPs within the Stage 1 timeframe

CDRH developed a detailed *Plan of Action* that targeted transition and succession issues by assessing the mechanisms that govern staff turnover. This plan focused on the development of SOPs that would provide Center staff with guidelines on how to effectively manage staff turnover, transitions and succession. Although FDA's plan was attainable and measurable under the initial project timelines FDA proposed, the final products of the implementation would not be available until the end of Booz Allen's evaluation. As a result, there would not be a sufficient observation period for Booz Allen to evaluate the impact of the SOPs. However, the activities FDA had outlined to implement this plan confirm that CDRH's response to Booz Allen's recommendation was specific, relevant, and time-bound.