

ALL HANDS MESSAGE ON JANUARY 12, 2005 CDRH QUARTERLY STRATEGIC PLAN PROGRAM REVIEW

The purpose of this message is to give you a status report on our first quarterly FY 05 strategic planning program review held on January 12, and on our FY 05 project management plans. I want to thank you for your efforts supporting these important projects, and for your many other valuable contributions to how the Center does its job. The major purpose of the quarterly FY05 program reviews is to realistically assess where we are on the projects, whether we are accomplishing what was planned on schedule, and identify problems ahead. Future quarterly strategic planning program reviews are scheduled March 9, June 8 and September 14.

I'm going to outline the status of our FY 05 project management plans briefly below, then summarize the major action items from our January 12 meeting.

OCD

1. Medical Device Fellowship Program: Most of the MDFP FY 05 resources have already been allocated , with 42 participants as of 12/31/04.
2. Organizational Scorecards: Decisions have now been made on the FY 05 Office and Center scorecards.
3. Guidance development: Linda Kahan has developed a list of FY 05 high priority new guidances with Office input. A high priority list of existing guidances to update is being drafted.

OC

4. Contractor for design, development, and implementation of OC-wide tracking and workflow, integrated with ODE: This tracking system upgrade is intended to model on the recent DTS upgrade in ODE. OC has the lead.
5. Registration and listing requirements development: The purpose of this project is to do the current process electronically. There may be FDA registration and listing rulemaking in the future.

ODE

6. E-Consult Pilot: This project is intended to do review consults electronically, and to make sure that review consults are requested and timed to meet the MDUFMA review milestones of the applications in question.

7. Scanning ODE Documents: This project is intended to accelerate scanning time for PMAs and PMA panel track supplements from 2 weeks to 2 days. ODE has the lead to clarify what needs to be done to achieve this.

8. Division Tracking System upgrades needed to meet MDUFMA time-frames: The requirements for this project are clearly defined. For the Center's FY 05 IT contracts, Stu Carlow has the lead to identify possible solutions if barriers exist with the scheduling of IT contractor's time.

9. Pre-market database and tracking system improvements: This project looks at the long term future modernization of device review tracking.

10. Electronic Submissions and Review (new project to add to the list): This project has the long term goal of expanding the number of electronic device submissions and reviews. This will have a clear impact on projects like IMAGE 2000, Turbo-510(k), and device review tracking modernization.

OCER

11. Radiological health strategic plan implementation: The big issue for this project is how much to move from mandatory to voluntary standards.

12. New employee orientation program: This project is on schedule.

13. Core competencies: Supervisory core competencies have already been approved and are in FY 05 scorecards. OCER has the lead to identify core competencies for staff.

14. Continuing Science Education Program: The Montgomery College basic science training for support staff is on target. The Georgetown/VA Tech science leadership program is below critical mass. OCER will assess.

OIVD

15. Turbo-510(k) development: This project is on schedule. The next major step is installing "e-reviewer" software in March.

OSB

16. Conditions of Approval: This function transferred from ODE to OSB on schedule January 1. A guidance has been submitted to OCD.

17. e-MAUDE: This project is on schedule. OSB is responsible to see how far current funding will go toward web-based portals.

OSEL

18. Beowulf Cluster Research Network: This project is completed on schedule.

19. Science Infrastructure Priorities: This project is on schedule. The goal of this project is to get to a more reasonable level of laboratory support.

OMO

20. (OITCDRH) Cyclical replacement of PC/lap-tops: This project has several major issues, starting with confirming the inventory of current PC/lap-tops that need replacement. Stu Carlow has the lead to bring estimates on these issues in the March 9 program review.

At the end of the program review, we noted several projects had delays because of competing needs for IT contractor support. For the Center's FY 05 IT contracts, Stu Carlow has the lead to identify possible solutions if barriers exist with the scheduling of IT contractor's time. In addition, Donna-Bea Tillman has the lead to convene an IT Steering Council to discuss how the many major CDRH IT initiatives included in the project management plans relate to each other.

As you can see, these projects (like organizational scorecards) actively involve every Office in our efforts to effectively accomplish our mission throughout the Total Product Life Cycle. If you want more information on these projects, please contact OCD's Nancy Braier at 301-827-7967.

Thank you for your outstanding support of the Center and it's mission.

Dan Schultz