

**ALL HANDS MESSAGE ON MARCH 9, 2005 CDRH
SECOND QUARTER STRATEGIC PLAN PROGRAM
REVIEW**

The purpose of this message is to give you a status report on our second quarterly FY 05 strategic planning program review held on March 9, 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 June 8 and September 14.

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

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

Dan Schultz, M.D.

OCD

1. Medical Device Fellowship Program

All of the MDFP FY 05 resources have been allocated, meeting all Office priorities. As of March, there were over 55 participants in this important program.

2. Organizational Scorecards

A draft FY 05 Center scorecard glossary was presented, incorporating senior staff input. A second quarter scorecard report is due, and Bob Navazio has the lead.

3. Guidance Development

Linda Kahan presented lists of FY 05 high priority new guidances to write, and Nancy Braier distributed sample guidance tracking forms. Linda Kahan has the lead to develop a priority list of existing guidances to update.

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 recent Division Tracking System upgrades in ODE. The contract has started and OC has the lead to clarify what will be accomplished.

5. Registration and Listing Requirements Development

The purpose of this project is to perform the current process electronically. OC has the lead to clarify scope of the project getting input from AHRQ.

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 two weeks to two days. In the long run, if CDRH can increase its capacity to receive and review applications electronically, then less scanning money will be needed. ODE has the lead to clarify what needs to be done to meet the project goals. Stu Carlow and Paul Fisher have the lead to clarify what additional IT support is needed so CDRH has the computer ability to receive and review applications electronically so reviewers can use electronic files in their reviews.

8. Division Tracking System upgrades needed to meet MDUFMA time -frames

The DTS task order was issued in February, and it will take place in a series of DTS “releases” intended to increase its tracking capabilities. Conditions of approval will be included in the next release.

9. Pre-market database and tracking system improvements

This project is looking at the long term future modernization of device review tracking. The goal is to integrate with Compliance tracking and Conditions of Approval so they will all have a TPLC look and feel. ODE has the lead to develop and get agreement on a concept of operations.

OCER

10. Radiological Health Strategic Plan Implementation

OCER has developed a future strategy for the radiological health program and briefed CDRH senior staff, ORA, and FDA stakeholders including a CRCPD meeting the end of April. Implementation will begin in the third quarter.

11. New employee orientation program

The purpose of this project is to hold TPLC orientation for new CDRH employees. This project is “On Target”.

12. Core Competencies

Supervisory core competencies are included and are being included in FY 05 scorecards. OCER has the lead to survey managers about core competencies for staff, and brief the Executive Committee.

13. Continuing Science Education Program

The Science Leadership (SLEP) program is “On Target”, but the Georgetown/VA Tech science leadership program is below critical mass. OCER has the lead to evaluate the Georgetown/VA Tech program.

OIVD

14. Turbo-510(k) Development

The purpose of this project is to develop and use a standard electronic template, starting with OIVD 510(k)s, for electronic 510(k)s, for electronic receipt and review. The installation of “e-reviewer” software began in March. More firms volunteered to participate in the pilot test in the spring, and OIVD hopes to have 9 by June.

OSB

15. Conditions of Approval

The official transfer of conditions of approval studies to OSB took place on schedule January 1. OSB submitted a guidance on schedule to OCD, and OCD just returned comments. There have been delays in developing a tracking system, which is now scheduled for the third quarter.

16. e-MAUDE

The purpose of this project is to receive adverse event reports from device firms electronically. OSB met with firms at an ADVAMED meeting on this project, and the firms were enthusiastic. OSB has the lead to define project requirements, and the funds for this project will be spent on time.

OSEL

17. Beowulf Cluster Research Network (COMPLETED)

The purpose of this project is to install software in OSEL's medical imaging and diagnostics laboratory that will serve as the computational platform for ongoing OSEL work like internal review consults, guidance development, and international standards.

18. Science Infrastructure Priorities

This project involves funding support for OSEL laboratories, and it is on schedule.

OMO

19. (OITCDRH) Cyclical replacement of PC/lap-tops

The purpose of this project is to do regular replacement of CDRH personal computers. Paul Fisher confirmed that there are about 1,800 PC/lap-tops that need replacement. Stu Carlow and Paul Fisher have the lead to identify what mix of PC/lap-tops to buy, get priorities on PC/laptop replacement, and then purchase the equipment.

20. (OITCDRH) IT Contract Support

At the March 9 meeting, Paul Fisher explained that although some contractor-related IT delays had occurred in the second quarter to COATS and IMAGE, the delays were less than anticipated. Stu Carlow, Paul Fisher, and Tim Ulatowski have the lead to decide if future Center-wide IT contractor delays could be reduced by accelerating the development of the OC tracking system ahead of schedule.