April 21, 2011

MEMORANDUM TO: R. W. Borchardt
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary **/RA/**

SUBJECT: STAFF REQUIREMENTS – SECY-11-0035 – INTEGRATED PLAN, TITLE 10 OF THE CODE OF FEDERAL REGULATIONS PART 35, MEDICAL USE OF BYPRODUCT MATERIAL, ACTIVITIES AND OPTIONS FOR STREAMLINING THE MEDICAL RULEMAKING PETITION AND RULEMAKING PROCESSES

The Commission has approved the staff's recommendation to decrease the petition resolution time to 9 months. (Option 2)

The Commission has approved the staff's recommendation of adherence to the existing rulemaking process and full implementation of existing flexibilities regarding stakeholder interactions. (Option 1)

The staff should, where possible, develop innovative approaches to further streamline the rulemaking process through more efficient means of obtaining ACMUI input on major policy issues, risk informing the medical regulations, and completing rulemaking activities in parallel. For example, the staff should work with ACMUI to develop approaches, such as less formal interaction outside of regularly scheduled ACMUI meetings, to shorten the staff's process for obtaining ACMUI input on less controversial or more fully vetted policy issues.

The staff should continue to place first priority on those petitions, whether medical or otherwise, that require immediate attention as a result of their health and safety implications.

After conducting stakeholder workshops, the staff should inform the Commission of its estimate of the overall schedule to complete this rulemaking and inform the Commission of any potential impacts this schedule could have on the medical industry at large.

The staff should, during the comprehensive rulemaking, consider whether there are areas of the regulations which could be further risk informed without a significant expenditure of resources or delay in the rulemaking, taking into consideration issues such as the safety significance and transboundary nature of the regulated activity. The staff should evaluate the possibility of further streamlining the comprehensive rulemaking by completing actions in parallel within existing resources.

cc: Chairman Jaczko
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
CFO
OCA
OPA
Office Directors, Regions, ACRS, ASLBP (via E-Mail)
PDR