

August 10, 2010

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

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

SUBJECT: STAFF REQUIREMENTS – SECY-10-0062 – REPROPOSED  
RULE: MEDICAL USE OF BYPRODUCT MATERIAL –  
AMENDMENTS/MEDICAL EVENT DEFINITIONS  
(RIN 3150- A126)

The Commission has disapproved the staff's recommendation to publish the repropoed amendments to Part 35 in the *Federal Register*.

The staff should work closely with the Advisory Committee on the Medical Uses of Isotopes and the broader medical and stakeholder community to develop event definitions that will protect the interests of patients, allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the agency to detect failures in process, procedure, and training as well as any misapplication of byproduct materials by authorized users. The staff should hold a series of stakeholder workshops to discuss issues associated with the medical event definition. Areas for discussion should include, but not limited to, methods for defining medical events which continue to ensure the safe use of radioactive materials while providing flexibility to account for medically necessary adjustments and the terms and thresholds for reporting medical events to the NRC and patients.

Given the array of pending activities in the medical area, the staff should provide the Commission with an integrated plan denoting schedule and Agreement States participation, for completing this rulemaking along with other activities in the medical area such as developing guidance for incorporating ACMUI input into major medical policy issues and for licensing and inspection programs.

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