

IN RESPONSE, PLEASE  
REFER TO: M100708B

July 21, 2010

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

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

SUBJECT: STAFF REQUIREMENTS – BRIEFING ON PROPOSED RULE  
ON PART 35 MEDICAL EVENTS DEFINITIONS – PERMANENT  
IMPLANT BRACHYTHERAPY, 1:30 P.M., THURSDAY, JULY 8,  
2010, COMMISSIONERS' CONFERENCE ROOM, ONE WHITE  
FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC  
ATTENDANCE)

The Commission was briefed by the NRC staff and the following list of stakeholders on the repropoed rule on Part 35 medical events definitions – permanent implant brachytherapy.

James Welsh, M.D., Member of the Advisory Committee on the Medical Uses of  
Isotopes (ACMUI), Subcommittee Chair on Medical Event Reporting for Prostate  
Brachytherapy, Radiation Oncologist  
Michael Hagan, M.D., Ph.D., National Director of the Radiation Oncology Program,  
Department of Veterans Affairs  
Douglas Pfeiffer, Chair of the Governmental and Regulatory Affairs Committee,  
American Association of Physicists in Medicine (AAPM)  
Brian Davis, M.D., Ph.D., Associate Professor of Radiation Oncology, Mayo Medical  
School, American Brachytherapy Society  
David Houchens, Ph.D., Treasurer, UsToo, International Board of Directors

The staff should develop internal guidance that requires that for all major medical policy issues that are submitted to the Commission, including proposed and final rules, the staff should include ACMUI recommendations and dissenting views along with staff's assessment of the ACMUI recommendation and dissenting views. This direction supersedes the direction to staff contained in the May 15, 2010, Staff Requirements Memorandum (M100511)

On a separate track, the staff should work with OGC to provide the Commission a paper outlining possible improved mechanisms for providing the Commission with the ACMUI's feedback regarding medical issues, including the pros and cons of restructuring ACMUI such that it reports to the Commission. This paper should provide an implementation plan that would be used to effect such a restructuring should the Commission decide to move forward.

Any additional direction will be provided via the Staff Requirements Memorandum for SECY-10-0062.

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