August 13, 2012

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

FROM: Kenneth R. Hart, Acting Secretary ***/RA/***

SUBJECT: STAFF REQUIREMENTS – SECY-12-0053 – RECOMMENDATIONS ON REGULATORY CHANGES FOR PERMANENT IMPLANT BRACHYTHERAPY PROGRAMS

The Commission has approved the staff's recommendations for modifying the regulatory requirements that appear in 10 CFR 35.3045 for permanent implant brachytherapy medical event reporting, as outlined in the enclosure to SECY-12-0053, and conforming changes to the current written directive requirements in 10 CFR 35.40(b)(6). These modifications should be developed as part of the proposed rule for the expanded 10 CFR Part 35 rulemaking.

Ahead of the current schedule for the expanded 10 CFR Part 35 rulemaking, the staff should clarify medical event reporting for permanent implant brachytherapy under the existing rule as outlined in the May 23, 2012, Commissioners' Assistants Note, "Options to Clarify Medical Event Reporting for Permanent Implant Brachytherapy." Specifically, the staff should pursue Option 3, issuance of a Regulatory Issue Summary to NRC medical use licensees and to Agreement State regulatory programs to provide insights about compliance with the current NRC requirements related to permanent implant brachytherapy. The staff should also pursue Option 5, development of an interim enforcement policy for Commission approval that would allow the staff to exercise enforcement discretion for both existing and future violations of current Part 35 that do not result in the misapplication of byproduct material by those licensees that use total source strength and treatment time for determining the existence of a medical event. The interim enforcement policy should be shared with the Agreement States so that they may choose whether or not to use a similar interim policy.

The staff should replace the term "seeds" with "sources" in all 10 CFR Part 35 rulemaking documentation.

As the combined rulemaking proceeds, the staff should provide the Commission with a new paper at any time a substantive delay in the completion schedule for this rule becomes apparent. This paper should explain the schedule delay and the impact of separating a permanent implant brachytherapy rule from the combined rulemaking.

Where possible, the staff should leverage the significant outreach done during the development of the regulatory basis for the proposed rule to further streamline the rulemaking process.

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