

July 25, 2008

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

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

SUBJECT: STAFF REQUIREMENTS – SECY-08-0080 – PROPOSED
RULE: MEDICAL USE OF BYPRODUCT MATERIAL –
AMENDMENTS/MEDICAL EVENT DEFINITIONS (RIN 3150-
AI26)

The Commission has approved publication of a proposed rule in the *Federal Register* to amend 10 CFR Part 35 related to reporting and notification of medical events and to clarify requirements for permanent implant brachytherapy as recommended by the staff. The staff should continue its engagement with the ACMUI, Agreement States, and other interested stakeholders as it proceeds with finalizing this rule.

(EDO)

(SECY Suspense:

8/8/08)

In parallel with drafting the final rule, the staff should also work with the Agreement States to develop revised guidance documents that reflect the new requirements in order to ensure that they can be distributed to affected external stakeholders and be made publicly available prior to the effective date of the final rule.

cc: Chairman Klein
Commissioner Jaczko
Commissioner Lyons
Commissioner Svinicki
OGC
CFO
OCA
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR