January 13, 2022

MEMORANDUM TO:  Daniel H. Dorman  
Executive Director for Operations

FROM:  Annette L. Vietti-Cook, Secretary

SUBJECT:  STAFF REQUIREMENTS – SECY-21-0013 – RULEMAKING PLAN TO ESTABLISH REQUIREMENTS FOR RUBIDIUM-82 GENERATORS AND EMERGING MEDICAL TECHNOLOGIES

The Commission has approved the staff’s recommended Option 3, to initiate a rulemaking that would address rubidium-82 generators along with all current, well-established emerging medical technologies (EMTs), plus create added flexibility throughout Title 10 of the Code of Federal Regulations Part 35, “Medical Use of Byproduct Material,” to accommodate future EMTs.

If the staff finds that the complexity of this approach would result in a timeframe substantially longer than the current estimate, the staff should notify the Commission and provide a recommendation about whether to proceed with a more targeted rulemaking to address only Rb-82 generators, gamma stereotactic radiosurgery units, and yttrium-90 microspheres, as envisioned in Option 2

cc:  Chairman Hanson  
Commissioner Baran  
Commissioner Wright  
OGC  
CFO  
OCA  
OPA