March 9, 1999

MEMORANDUM TO: Jeffrey S. Merrifield

FROM: Edward McGaffigan, Jr. /S/

SUBJECT: COMJSM-99-001 - SCHEDULE FOR FINAL RULEMAKING CONCERNING 10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL

I have reviewed your proposal to revise the current schedule for submittal of the final rule on Part 35 to the Commission. I agree in part and disagree in part and offer the following comments for your consideration.

I agree with you that the staff needs additional time to propose a final rule to the Commission for approval. I also support the March 26 briefing by the staff and the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), which I originally proposed. But I do not believe that the staff will be ready in late March to give the Commission the united staff position concerning the finalization of rule language and to thoroughly lay out policy issues and options for the Commission. The staff will be ending an ACMUI meeting that same morning and thus will need an opportunity to consider the committee's input. Also, it is my understanding that the Part 35 Project Manager will attend the Conference of Radiation Control Program Director's SR-6 Committee meeting the week of March 15 to obtain input on Agreement State concerns on Part 35. Therefore, I would consider the March briefing to be the Commission's first taste of complex policy issues for subsequent discussion and consideration. So as not to delay the staff's iterative process, the March briefing SRM could be limited in scope to reiterate the schedule decided as a result of this COM, and possibly to identify policy issues where additional detailed discussions are needed as highlighted by the staff or Commission during the March briefing.

Then, I suggest a second Commission briefing be held in early to mid June preceded by a staff paper in late May of the sort the Commission just received on the final rule on 10 CFR 50.59 (SECY-99-054)--discussion of major issues and draft rule text without the statements of consideration, OMB package or guidance documents. The Commission would then issue an SRM on the May paper and give the staff three months from the date of the SRM to provide a final rule and OMB package to the Commission for approval. I also believe that the guidance should be submitted to the Commission with the final rule package to facilitate the Commission's review of the rule. More importantly, if we do not have the guidance available at the time of the final rule, the OMB review and clearance of the rule could be delayed. Finally, I agree that finalization of the Medical Use Policy Statement could be postponed for three or more months after the final rule and guidance are approved by the Commission, if necessary.

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
SECY
EDO
OGC