IN RESPONSE, PLEASE
REFER TO M990325B

April 23, 1999

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Annette Vietti-Cook, Secretary /s/

SUBJECT: STAFF REQUIREMENTS:BRIEFING ON PART 35 RULEMAKING, 1:30 P.M. THURSDAY, MARCH 25, 1999, COMMISSIONERS CONFERENCE ROOM, ONE WHITE FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

The Commission was briefed by the NRC staff and members of the Advisory Committee on Medical Uses of Isotopes on the status of proposed amendments to 10 CFR part 35, "Medical Use of Byproduct Material." The proposed rule, as contained in SECY-98-128 and modified by SRM S98-128, dated July 21, 1998, was issued for public comment from August 13, 1998 to November 12, 1998. SRM S98-263 extended the comment period 30 days.

At the meeting, there were no requirements identified for staff action. However, the Commission indicated that it would provide guidance on the schedule for the completion date of the revised final rule. This staff requirements memorandum (SRM) provides such guidance.

The staff should provide the Commission with a brief paper that provides a draft Federal Register notice (FRN) to include the draft final rule text and those portions of the statements of consideration (SOC) that discuss resolution of public comments and provide enough information to allow comparison of the changes from the current rule to the proposed rule and draft final rule. The staff should offer rule language options in either the draft FRN or as an attachment to the paper on any issues where the staff does not have a preferred approach.

(EDO) (Suspense Date: 07/23/99)

The Commission requests that in addition to the current patient notification language the staff consider and provide the pros and cons in the July paper of revising the Part 35 patient notification provisions to require: 1) verbal notification of the patient (or the individual's responsible relative or guardian) of the medical event while retaining the current caveat regarding referring physician discretion on patient notification; 2) written documentation of the medical event in the patient's file; and 3) a written certification by the referring physician to the NRC that the patient was notified, unless discretion was exercised, as part of the event report submitted to NRC.

The staff should plan to make the July paper publicly available two business days from the date of the paper unless directed otherwise by the Commission. The Commission may choose to conduct a public briefing on the draft final rule after receipt of the paper. An SRM would then be issued to require submittal of the complete final rulemaking package to the Commission approximately three months from the date of the SRM. The package should include the final FRN, the Office of Management and Budget package for clearance, related rule guidance and, if possible, the revised medical policy statement.

The staff is encouraged to keep the Commission informed on these important issues through informal briefings to the Commissioner Assistants previously designated for each office. Mr. John Thoma is designated as the contact for Commissioner Merrifield.

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
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