NOTATION VOTE

RESPONSE SHEET

TO: SAMUEL J. CHILK, SECRETARY OF THE COMMISSION

FROM: COMMISSIONER DE PLANQUE

SUBJECT: SECY-93-050 - PROPOSED AMENDMENTS ON PREPARATION, TRANSFER, AND USE OF BYPRODUCT MATERIAL FOR MEDICAL USE

APPROVED XX DISAPPROVED ____ ABSTAIN ____

NOT PARTICIPATING ____ REQUEST DISCUSSION ____

COMMENTS:

See attached edits to FR Notice.

The edit on Agreement State compatibility recognizes States' concerns over how to implement the requirements. The edit on research involving human subjects makes clear that any such research must be conducted under the Federal Policy for the Protection of Human Subjects.

This proposed rulemaking is the product of a considerable staff effort to resolve a number of difficult questions raised by the petition and the staff is commended for its work.

E. Gail de Planque
SIGNATURE

RELEASE VOTE /✓/

March 30, 1993
DATE

WITHHOLD VOTE /___/

150014

ENTERED ON "AS" YES ✓ NO ___

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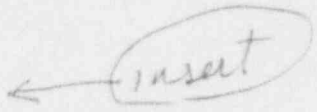
management rule and misadministrations in § 35.2 are Division 1 items of compatibility; §§ 35.32 and 35.33 are Division 2 items of compatibility; § 35.8 is a Division 4 item of compatibility; and all other sections of Part 35 are Division 3 items of compatibility.



Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the proposed amendments, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required. The proposed amendments would provide greater flexibility for physician authorized users to use byproduct material in the practice of medicine. The proposed amendments would also incorporate into the regulations the concept of authorized nuclear pharmacists to permit properly qualified pharmacists to prepare radioactive drugs containing byproduct material in the practice of pharmacy.

The proposed amendments would allow physician authorized users greater discretion to prepare and use radioactive drugs containing byproduct material. The proposed amendments would also allow authorized nuclear pharmacists greater discretion to prepare radioactive drugs containing byproduct material. It is expected that there will be no increase in radiation exposure to the public or to the environment beyond the exposures currently resulting from delivering the byproduct material or radiation from byproduct material to the patient. The draft environmental assessment and finding of no significant impact on which this determination is based is available for inspection at the

Insert

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NRC expects Agreement States to adopt rules required to maintain compatibility within 3 years after NRC's rules become effective. Some Agreement States, faced with administrative and resource constraints, may find the 3 year goal difficult to attain and may prefer that NRC extend flexibility in such cases to allow the States to implement the requirements through license conditions. Staff requests public comment on permitting Agreement States flexibility in this regard, and if permitted, under what conditions.

Pharmacist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

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9. Section 35.6 is added to read as follows:

§ 35.6 Provisions for research involving human subjects.

A licensee may conduct research involving human subjects using byproduct material provided that the research is conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. ~~Otherwise, a licensee shall apply for and receive approval of a specific amendment to its NRC license before conducting such research~~. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board."

10. Section 35.7 is added to read as follows:

§ 35.7 FDA, other Federal, and State requirements.

Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.