

April 15, 1993

MEMORANDUM FOR: James M. Taylor
Executive Director for Operations

FROM: Samuel J. Chilk, Secretary /s/

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

The Commission (with all Commissioners agreeing) has approved publication of the Notice of Proposed Rulemaking enclosed in the subject paper with the changes described below and indicated in the attachment.

(EDO)

(SECY Suspense: 5/21/93)

The format of Table 1 on page 10 of Enclosure 1 is an effective way of summarizing the main points of the ACNP-SNM petition and the NRC's response to those points. However, several of the entries which describe NRC responses speak of permitting "greater discretion," but do not describe the nature of the discretion, and therefore do not respond directly to the points raised by the petition. The staff should revise the table to be more clearly responsive to the petition.

The staff should revise the definition of "patient" so as to distinguish between medical patients in the conventional sense and research subjects, which should be referred to as such in the proposed rule.

The Supplementary Information in the Federal Register notice should tell readers how they can acquire a copy of the Federal Policy for the Protection of Human Subjects so they can more easily comment on the proposed text of § 35.6.

Attachment:
As stated

SECY NOTE: THIS SRM, SECY-93-050, AND THE VOTE SHEETS OF ALL COMMISSIONERS WILL BE MADE PUBLICLY AVAILABLE 10 WORKING DAYS FROM THE DATE OF THIS SRM

cc: The Chairman
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
Commissioner de Planque
OGC
OIG
Office Directors, Regions, ACRS, ACNW (via E-Mail)
OP, SDBU/CR, ASLBP (via FAX)

Insert for page 47 of FRN

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.