cc: WDircks
JRoe
[redacted]
WKerr

NOTATION VOTE

RESPONSE SHEET

TO: SAMUEL J. CHILK, SECRETARY OF THE COMMISSION

FROM: COMMISSIONER BERNTHAL

SUBJECT: SECY-84-485 - PROPOSED REVISION OF 10 CFR PART 35 "MEDICAL USE OF BYPRODUCT MATERIAL"

APPROVED ✓ DISAPPROVED ______ ABSTAIN ______

NOT PARTICIPATING ______ REQUEST DISCUSSION ______

COMMENTS: See attached comments.

SIGNATURE

4/24/85
DATE

SECRETARIAT NOTE: PLEASE ALSO RESPOND TO AND/OR COMMENT ON MEMORANDUM IF ONE HAS BEEN ISSUED ON THI

Comments of Commissioner Bernthal, SECY 84-485:

1) Although I agree with the intended purpose of the proposed rule, I am troubled by the controversy in a general area that I have long considered to be a somewhat neglected backwater when it comes to serious Commission attention. In this particular case, a Commission request for comment on the proposed threshold defining "minor" changes requiring license amendments might assist in resolving the concerns of agreement states. Could a flexible threshold, within limits defined by the NRC, allow agreement States or licensees to select appropriate procedural or other license amendment criteria?

2) Diagnostic and therapeutic applications of ionizing radiation constitute by far the single largest source of non-natural radiation exposure to the general public. SECY 83-302 rationalized the threshold criteria for reporting medical misadministrations. But I confess I am somewhat surprised to be reminded that the Commission still has not defined its specific enforcement authority regarding misadministrations, beyond the mere requirement that such misadministrations be reported. I consider this circumstance to be inconsistent with the Commission's public health and safety responsibility. Although I recognize that the question was not proposed to be addressed within the context of this rulemaking, it did come up for discussion in the Commission's recent meeting, and I see no good reason to defer further Commission consideration of this significant policy issue.

In this regard, I generally agree with the suggestions of Commissioner Zech; along with publication of the proposed rule, the Commission should at least frame the issue by requesting comment on the adequacy of current medical misadministration requirements. However, if we intend to outline the issue at this time, as I believe we should, then I would be more direct in requesting comment on what the NRC's enforcement role and responsibilities should be in the area of medical misadministration. Medical administration is clearly a doctor-patient matter in which the Commission should be highly deferential. Informing the patient of misadministration may even fall within the same category, or at least require careful guidelines to avoid intrusion into the doctor-patient relationship. But misadministration is also the safety concern and responsibility of the NRC, and should be subject to sensible and effective enforcement. It would seem to me that "medical misadministration" implies, almost by definition, a procedural error.