

September 9, 1997

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle /s/

SUBJECT: STAFF REQUIREMENTS - SECY-97-177 - F

RULEMAKING PLAN: REVISION OF DOSE LIMIT FOR
MEMBERS OF THE PUBLIC EXPOSED TO HOSPITALIZED
PATIENTS (10 CFR PART 20 AND 35)

INAL

This is to advise you that the Commission has not objected to the staff's proposed rulemaking plan as described in Option 3 subject to the following comments.

The staff should justify on a public health and safety benefit basis the requirement for licensee documentation that it has provided instruction to the family members and that it has obtained informed consent from the family members in light of the fact that documentation of instruction to and informed consent from, released patients is not required under 10 CFR 35.75(a) or (b). If retained, this recordkeeping issue should be specifically discussed in the Federal Register notice accompanying the proposed rule and the staff should seek public comments and views on the need for these recordkeeping requirements. Should the consent form eventually be used, the staff should coordinate with ACMUI to draft a "plain English" informed consent form.

Any public notice of this rule should make it clear that family members admitted to the room of a patient treated with permanent implants, or administered radiopharmaceutical therapy, and subsequently released under 10 CFR 35.75 may, as a result of this rulemaking, actually receive a total dose of 1.0 rem.

The new compatibility categories described in the "Policy for Adequacy and Compatibility of Agreement State Programs" should be reflected in this rulemaking plan.

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
CIO

W, ASLBP

(via E-Mail)

CFO
OCA
OIG
Office Directors, Regions, ACRS, ACN

PDR
DCS