

September 9, 1997

MEMORANDUM TO: L. Joseph Callan  
Executive Director for Operations

FROM: John C. Hoyle /s/

SUBJECT: STAFF REQUIREMENTS - SECY-97-177 - FINAL  
RULEMAKING PLAN: REVISION OF DOSE LIMIT FOR  
MEMBERS OF THE PUBLIC EXPOSED TO HOSPITALIZED  
PATIENTS (10 CFR PART 20 AND 35)

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.

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SECY NOTE: THIS SRM AND SECY-97-177 WILL BE MADE PUBLICLY  
AVAILABLE 5 WORKING DAYS FROM THE DATE OF THIS  
SRM.

cc: Chairman Jackson  
Commissioner Dicus  
Commissioner Diaz  
Commissioner McGaffigan  
OGC  
CIO  
CFO  
OCA  
OIG  
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)  
PDR  
DCS