

June 30, 1997

MEMORANDUM TO: L. Joseph Callan  
Executive Director for Operations

FROM: John C. Hoyle, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - SECY-97-115 - PROGRAM FOR REVISION OF 10 CFR PART 35,  
"MEDICAL USES OF BYPRODUCT MATERIAL" AND ASSOCIATED FEDERAL REGISTER  
NOTICE

The Commission has approved the staff proposal to revise 10 CFR Part 35 consistent with the alternative program proposed in SECY-97-131 and subject to the following comments.

1. The staff should not only consider what regulations will be affected by the change to Part 35, but should also take a close look at existing guidance and draft guidance to determine what changes would be needed. To ensure that all regulatory rulemaking and guidance development potentially affecting medical uses will be consistent with the Commission's direction in DSI 7, the staff should identify in the public meetings and Federal Register notices all regulatory actions and proposed actions relating to or affecting Part 35 licensed activities. When appropriate, public comment should be invited.
2. The staff should continue to solicit input from members of the public to ensure, to the degree possible, that all interests are represented. The staff should include groups representing radiopharmacists and medical technologists, and other experts, as appropriate.
3. The staff should prepare alternatives with specific rule text to help focus the discussion during the first-round of facilitated meetings and assist the staff in developing draft rule language for publication and comment.
4. The staff should look for potential resource savings (FTE, consultants, and funds) that can be achieved through use of the internet, teleconferencing, etc. In making documents available over the internet, some caution should be exercised to ensure that the number of and versions of available documents for comment are not so large and varied that they will overwhelm commenters and lead to confusion on the part of the staff and management responsible for the rulemaking.

A Federal Register notice and press release should be issued reflecting the approach outlined in SECY-97-131, attachments 1 and 2, and published in time to support the facilitated public meetings.

(EDO)

(SECY Suspense: 9/5/97)

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

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SECY NOTE: SECY-97-115 WAS RELEASED TO THE PUBLIC ON JUNE 17, 1997. THIS SRM, SECY-97-131, AND THE COMMISSION VOTING RECORD CONTAINING THE VOTE SHEETS OF ALL COMMISSIONERS WILL BE MADE PUBLICLY AVAILABLE 5 WORKING DAYS FROM THE DATE OF THIS SRM.