NOTATION VOTE

RESPONSE SHEET

TO: John C. Hoyle, Secretary

FROM: COMMISSIONER MCGAFFIGAN

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

(as modified by SECY-97-131)

Approved X Disapproved _____ Abstain _____

Not Participating _____ Request Discussion _____

COMMENTS: See attached.

Edward McGaffigan Jr.
SIGNATURE

Release Vote /X/

6/26/97
DATE

Withhold Vote /___/

Entered on "AS" Yes X No ____

COMMISSIONER McGAFFIGAN'S COMMENTS ON SECY-97-115 AS SUPPLEMENTED BY SECY-97-131:

I approve of the staff's plan (including the modality approach) and proposed time line for revising Part 35 as described in SECY-97-131 since it meets the time line and goals established by the Commission in the SRM on DSI 7 while providing enhanced opportunities for participation by licensees, professional organizations, the Agreement and non-Agreement States, the public, and the ACMUI. Indeed, the new staff plan provides more meaningful opportunities for public comments than the previous plan despite saving nine months because it will focus the process earlier on real issues as opposed to general discussion which has already gone on for years.

I agree with Commissioner Dicus' comments, but I disagree with those of Commissioner Rogers. During the facilitated public meetings, I believe that specific rule text and alternatives, couched to encourage a free flow of ideas, will help focus the discussion and assist the staff in developing draft rule language. We should not postpone rule language options until after these meetings.

I also believe that we need to go forward with a Federal Register notice and press release modified to reflect the SECY-97-131 approach. The heart of these documents would be attachments 1 and 2 to SECY-97-131.

The staff should continue to try and to identify sources of input from members of the public to ensure, to the degree possible, that all interests are represented. As I have noted previously, I found the candid remarks of Robert Adler, a member of the National Academy of Sciences committee that conducted the medical program study, useful and worthwhile for the Commission as it considered the NAS findings. I suggest that we include Mr. Adler among the individuals from whom we will specifically solicit comments.

I commend the staff for identifying non-traditional methods to solicit public comments such as making documents available over the Internet. However, 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 staff and management responsible for the rulemaking.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICE OF THE
SECRETARY

June 30, 1997

- Dupe out -

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary

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.

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.

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
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Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS