

IN RESPONSE, PLEASE
REFER TO: M971105B

November 5, 1997

MEMORANDUM FOR: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - AFFIRMATION SESSION,
11:30 A.M., AND 3:00 P.M., WEDNESDAY,
NOVEMBER 5, 1997, COMMISSIONERS' CONFERENCE
ROOM, ONE WHITE FLINT NORTH, ROCKVILLE,
MARYLAND (OPEN TO PUBLIC ATTENDANCE)

A. 11:30 A.M. Session

I. SECY-97-232 - Final Rule on Exempt Distribution and Use of a
Radioactive Drug Containing One Microcurie of Carbon 14 Urea
(Parts 30 and 32)

The Commission approved a final rule amending 10 CFR Parts 30 and 32 to permit the exempt distribution and use of capsules containing one microcurie carbon-14 urea for "in vivo" diagnostic use. The staff should incorporate the following comments and the editorial changes provided in the attachment.

The staff response to comment 3 should be reviewed and revised by a staff Health Physicist with expertise in radiological assessments to ensure it accurately and clearly responds to the comment.

The Health and Safety Effects section of the Regulatory Analysis should be revised to clarify that individual and collective dose estimates do not consider the radiation dose received by the patient, and that the collective dose of 5 person-rem over a 50 year period discussed in paragraph 4 is not an annual dose.

Following incorporation of these comments and the editorial changes provided in the attachment, the Federal Register notice should be reviewed by the Rules Review and Directives Branch in the Office of Administration and forwarded to the Office of the Secretary for signature and publication.

(EDO)

(SECY Suspense:

12/5/97)

B. 3:00 P.M. Session

I. SECY-97-228 - Final Amendments to 10 CFR Part 73, "Changes to Nuclear Power Plant Security Requirements"

The Commission approved a final rule amending 10 CFR Part 73 to change certain physical security requirements associated with an internal threat. The staff should coordinate the finalization of the public announcement with the Office of Public Affairs and issue a press release related to this rulemaking.

Following incorporation of the editorial changes provided in the attachment, the Federal Register notice should be reviewed by the Rules Review and Directives Branch in the Office of Administration and forwarded to the Office of the Secretary for signature and publication.

(EDO)

(SECY Suspense:

12/5/97)

Attachments:

As stated

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
EDO
OGC
CIO
CFO
OCAA
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR - Advance
DCS - P1-17

Editorial Changes to the Final Rule in SECY-97-232

Changes to the Federal Register Notice

1. On page 1, line 4, replace 'a minimal' with 'an insignificant.'
2. On page 9, paragraph 2, line 8, delete the 's' on 'procedures.'
3. On page 12, paragraph 1, line 6, delete 'nothing will prevent' and insert 'are not required to' after 'manufacturers.' Also, delete 'from' and replace 'indicating' with 'indicate.'
4. On page 13, paragraph 2, line 1, replace 'no significant' with 'an insignificant.' In line 2, replace 'or' with 'and.'
5. On page 14, item (2), line 2, replace 'be prohibited by this rulemaking' with 'continue to require a specific license pursuant to Part 35 under this rulemaking.'
6. On page 14, last paragraph, line 5, delete the comma.
7. On page 16, last paragraph, line 2, delete 'not' and in line 3, replace 'significant' with 'insignificant.'
8. On page 22, paragraph 1, line 4, replace 'no significant' with 'an insignificant.'

Changes to the Regulatory Analysis

1. On page 3, paragraph 5, line 6, replace 'a minimal' with 'an insignificant.'
2. On page 7, first full paragraph, line 13, replace 'or' with 'and.' Also, add at the end of the paragraph: The routine exposure of patients was not considered when calculating the individual or collective doses resulting from the diagnostic tests.
3. On page 7, last paragraph, line 5, delete 'annual' and in line 6, delete 'next.' Also in line 6, delete the 's' on 'years' and insert 'period' after 'year.'
4. On page 8, last paragraph, last line, replace 'negligible' with 'insignificant.'

Changes to the Environmental Assessment

1. On page 1, paragraph 1, line 4, replace 'a minimal' with 'an insignificant.'

2. On page 1, paragraph 2, line 4, replace 'negligible' with 'insignificant.'
3. On page 2, paragraph 2, line 7, replace 'a minimal' with 'an insignificant.'
4. On page 2, last paragraph, line 1, replace 'no significant' with 'an insignificant.'
5. On page 3, paragraph 2, add at the end of the paragraph:
This is far below the EPA reporting level of 1 mrem/year required under the Clean Air Act for routine exposures to a member of the public, and the 4 mrem/year EPA limit for public drinking water.
6. On page 4, last paragraph, line 9, replace 'a minimal' with 'an insignificant.'

Changes to the Congressional Letters

1. In paragraph 2, line 5, replace 'a minimal' with 'an insignificant.'

Changes to the Public Announcement

1. On page 1, paragraph 3, lines 4 and 5, replace 'a minimal' with 'an insignificant' and insert 'diagnostic use of the' before 'drug.'
2. On page 2, paragraph 1, line 5, the 'C' in 'carbon-14' should be lower case.

Editorial Changes to the Final Rule in SECY-97-228

Changes to the Federal Register notice:

1. On page 2, paragraph 1, line 2, replace 'revising' with 'that would revise.' In line 6, replace 'are as follows' with 'involve changes to.'
2. On page 5, paragraph 2, line 4, insert 'who are cleared for unescorted access' after 'employees.' In paragraph 3, line 4, replace 'discriminate' with 'distinguish.' In the last paragraph, line 3, replace 'of these' with 'commenter.'
3. On page 8, paragraph 2 under item 5, line 2, replace 'making' with 'make' and in line 4, insert a comma after 'been.'
4. On page 11, last line, replace 'assume' with 'assuming.'

Changes to the Congressional letters:

1. In line 1, replace the last 'the' with 'an' so that it reads '... copy of an amendment to'