AFFIRMATION VOTE

RESPONSE SHEET

TO: John C. Hoyle, Secretary

FROM: COMMISSIONER MCGAFFIGAN

SUBJECT: **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)**

Approved X Disapproved _____ Abstain _____

Not Participating _____ Request Discussion _____

COMMENTS:

See attached comments and edited pages.

Edward McGaffigan Jr.
SIGNATURE

Release Vote /X/

10/23/97
DATE

Withhold Vote /___/

Entered on "AS" Yes X No ____

Commissioner McGaffigan's comments on SECY-97-232:

I approve publication of the final rule to amend Parts 30 and 32 to permit the exempt distribution and use of carbon-14 capsules for human use as described by the staff. I commend the staff for expeditiously developing the final rule after review of public comments received on the proposed rule and offer the following comments for the staff's consideration.

1) The radiation risk associated with the diagnostic use of the carbon-14 capsules should be consistently characterized as "insignificant." Edits to achieve this purpose are indicated on the attached pages.

2) 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 (suggested edits are attached).

3) Other edits for clarification and consistency are indicated on the attached pages.

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30 and 32

RIN: 3150-AF70

Exempt Distribution of a Radioactive Drug

Containing One Microcurie of Carbon-14 Urea

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to permit NRC licensees to distribute a radioactive drug containing one microcurie of carbon-14 urea to any person for "in vivo" diagnostic use. The NRC has determined that the radioactive component of such a drug in capsule form presents ~~a minimal~~ an insignificant radiation risk and, therefore, regulatory control of the drug for radiation safety is not necessary. This amendment makes the drug more widely available and reduces costs to patients, insurers, and the health care industry. This action grants a petition for rulemaking (PRM-35-12) from Tri-Med Specialties, Inc. and completes action on the petition.

EFFECTIVE DATE: (30 days from date of publication in the Federal Register).

and provides a comparable alternative to the C-14 test. The apparent assumption underlying the environmental assessment is that in the absence of the C-14 test, the only alternative for the detection of H. pylori is invasive gastroendoscopy.

Response: Because the C-14 urea capsules are already available to authorized user physicians, the only regulatory issue in this rulemaking is whether the C-14 method should be made available to individuals who are not authorized users. The purpose of the environmental assessment is to consider and document whetner the subject rule is expected to have any significant impact to the environment. In this environment assessment, the NRC has determined that the environmental impact is expected to be insignificant because of the extremely low radiological hazards associated with the use of capsules containing one microcurie C-14 urea. The presence of an additional non-invasive alternative procedures does not affect NRC's determination of no significant environmental impact.

Comment 10: NRC's policy in the past has been not to exempt byproduct material that is ingested. Any change in this policy would be a significant departure from existing NRC regulations.

Response: This change is a departure from existing NRC regulations. In the statement of consideration for the proposed rule, under the heading "Current NRC Regulations on Exemptions From Licensing," the NRC stated that, although two broad material exemptions (§ 30.14, "Exempt concentrations," and § 30.18, "Exempt quantities") exclude the transfer of byproduct material contained in any product designed for ingestion or inhalation by a human being, the C-14 capsules manufactured or prepared as a radioactive drug can be distributed to persons exempt from licensing for "in vivo" diagnostic use because the capsules present an insignificant radiological risk to the public and the environment. This exemption only applies to

capsules may be disposed of by users as ordinary trash. Paragraph(a)(6) of § 32.21 requires that applicants submit copies of prototype labels and brochures for NRC approval. The NRC will ensure that the labels meet the requirements of § 32.21a before they are approved. Since paragraph (a) of § 32.21a specifies that the [illegible] must be durable and legible, the use of an additional phrase such as "conspicuously and prominently" is unnecessary. Promotional brochures are for information only, ~~nothing will prevent~~ or are not required to manufacturers ~~from~~ indicating on the promotional brochures that C-14 is a radioactive material.

III. Summary of the Final Amendments

Final Amendment to 10 CFR Part 32

The regulations in 10 CFR Part 32 are amended to add new §§ 32.21 and 32.21a, to provide requirements for a specific license to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution, capsules containing one microcurie of C-14 urea, as a radioactive drug, to be distributed to any person for "in vivo" diagnostic use. These requirements are consistent with the existing requirements on other items under the heading "Exemptions" in 10 CFR Part 30. The amendment includes a reminder that licensees distributing the radioactive drug to persons exempt from licensing would not be relieved from other applicable Federal (e.g., FDA) or State requirements governing the manufacture and distribution of drugs.

The amendment requires that the manufacture or preparation of capsules containing one microcurie of C-14 urea be prepared by persons who meet the current NRC regulations to manufacture and commercially distribute radioactive drugs. The NRC believes regulatory

control is needed to provide high confidence that the drug contains one microcurie of C-14 urea and does not contain any other radioactive contaminants.

Final Amendment to 10 CFR Part 30

The NRC has determined that the drug in capsule form presents ~~no significant~~ an insignificant radiological safety ~~or~~ and environmental risk, and that it is not necessary to regulate the use of this drug for its radioactive component. Therefore, the NRC can not justify requiring physicians, or any other person, to meet NRC training and experience criteria directed at the safe use of radioactive drugs, or to become an "authorized user." Hence, the capsules can be distributed to any person. However, other Federal or State agencies may limit the receipt and use of the capsules in accordance with their own requirements.

The regulations in 10 CFR Part 30 are amended to add a new § 30.21, to permit any person to receive, possess, use, transfer, own, or acquire for "in vivo" diagnostic use, capsules containing one microcurie of C-14 urea without a license. The final regulation includes a reminder that persons receiving the capsules would not be relieved from other Federal or State law governing drugs. Further, in accordance with the NRC's provisions for research involving human subjects (10 CFR 35.6), the exemption permitting receipt and use of the capsules for "in vivo" diagnostic use does not extend to use of the capsules for research involving human subjects. Any person desiring to use the capsules for human research would still be required to submit an application for a specific license under Part 35. The phrase "in vivo diagnostic use" was selected to describe the activity authorized in §30.21 to differentiate it from the term "medical use" because:

(1) "Medical use" limits administration to authorized users; use of this drug would not be so limited; and

(2) "Medical use" includes the administration of the drug to a human research subject, which would ~~be prohibited by this rulemaking~~ continue to require a specific license pursuant to Part 35 under this rulemaking.

Effects of the Final Amendments

The final amendments make the drug available to any person, for "in vivo" diagnostic use, without need for an NRC or Agreement State license. Because the receipt and use of the drug are exempt from NRC licensing, Agreement States need to make appropriate provisions in their regulations to recognize the exempt distribution of the drug, for "in vivo" diagnostic use. Thus, after the manufacture and distribution of the drug, the NRC and the Agreement States will not regulate the use of the drug as long as its use is for "in vivo" diagnostic use. This means that, under NRC and Agreement State regulations, primary-care physicians do not need to be "authorized users" in order to administer the drug, and do not need to refer their patients to nuclear medicine physicians. This should result in cost savings to patients. Other Federal and State organizations with responsibilities for regulating drugs will determine and regulate who can receive and use the drug for "in vivo" diagnostic use. NRC will continue to regulate the use of the drug for research involving human subjects under a specific Part 35 license.

distribution, capsules containing one microcurie carbon-14 urea each for "in vivo" diagnostic use, to persons exempt from licensing.

Paragraph (a)(1)

This paragraph limits issuance of an "exempt distribution license" for distribution of the capsules to persons exempt from licensing to only those who possess either a NRC or Agreement State "specific license" for possession and use of byproduct material.

Paragraph (a)(2)

To assure that the capsules contain one microcurie of carbon-14 and present no other radiological risks, this paragraph requires that the persons manufacturing and/or commercially distributing the capsules for "in vivo" diagnostic use must also meet the requirements of § 32.72(a)(2). Specifically, these persons must be:

(1) Registered with or licensed by the FDA as a drug manufacturer; or

(2) Registered with or licensed by a state agency as a drug manufacturer; or

(3) Licensed as a pharmacy by a State Board of Pharmacy; or

(4) Operating as a nuclear pharmacy within a Federal medical institution.

Paragraph (a)(3)

This paragraph requires applicants to provide evidence that each carbon-14 urea capsule contains one microcurie. The NRC's evaluation that the capsules would ~~not~~ result in insignificant radiation risks was based on the capsules containing one microcurie of carbon-14 urea. Therefore, applicants must demonstrate that the activity of each carbon-14 capsule

requirements for the manufacture and commercial distribution of carbon-14 urea capsules to persons exempt from licensing and establishes regulations to permit any person to receive the capsules without an NRC license. The Commission believes that the radioactive component of this drug presents no significant radiation risk and, therefore, regulatory control of the "in vivo" diagnostic use of the capsules for radiation safety is not necessary. It is expected that this final rule will not cause any significant increase in radiation exposure to the public or radiation release to the environment beyond the exposures or releases resulting from the use of the carbon-14 capsules under the current regulations. Also, it is expected that there will be no non-radiological impacts. One public comment on the draft environmental assessment has been received (See Comment 9 under the heading "Proposed Rule, Public Comments, and NRC Responses").

The environmental assessment and finding of no significant impact on which this determination is based is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the environmental assessment and the finding of no significant impact are available from Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6233 or e-mail at ANT@nrc.gov.

VII. Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval numbers 3150-0001, 3150-0017, and 3150-0120.

1.4 Proposed Rule and Public Comments

The proposed rule was published in the Federal Register (62 FR 32552, June 16, 1997) for a 30-day public comment period. The NRC received seven public comment letters. Four commenters supported the rule, one opposed the rule, and two provided comments without explicitly stating whether they support or oppose the rule. A summary of public comments and NRC's responses are presented in the preamble of the Federal Register notice. Except a minor change in wording, the final amendments are the same as the proposed amendments. No comments related to the draft Regulatory Guide has been received.

2. Objective

The objective of the rulemaking is to amend 10 CFR Part 32 to permit the manufacture and commercial distribution of ^{14}C-urea capsules to any person (including physicians who are not "authorized users" under Part 35) and to amend 10 CFR Part 30 to permit any person, without an NRC license, to receive and use the capsules for in vivo diagnostic use for humans.

3. Alternatives

Three alternatives have been considered in the regulatory analysis: deny the petition, i.e., maintain the status quo, permit the distribution of the capsules to persons exempt from licensing, and permit the distribution of the capsules to general licensees.

Under the first alternative, only physicians who are authorized users under Part 35 would be allowed to possess and administer the ^{14}C-urea test. Any physician could apply to become an authorized user. However, the NRC expects few physicians would apply for a Part 35 license for the sole purpose of using the capsules because of the requirement for training and experience and the associated costs of obtaining and maintaining a Part 35 license. Alternatively, physicians who are not authorized users can continue to refer their patients to physicians who are authorized users to undergo the diagnostic test. However this would not relieve the current expense, inconvenience, and delay encountered in an otherwise straight-forward procedure.

Under the second alternative, 10 CFR Parts 32 and 30 would be amended. 10 CFR Part 32 would be amended to permit the manufacture and commercial distribution of ^{14}C-urea capsules to any person (including physicians who are not "authorized users" under Part 35); 10 CFR Part 30 would be amended to permit the manufacture and commercial distribution of the capsules to any person, for in vivo diagnostic use for humans. The NRC has determined that the radioactive component of this drug presents ~~a minimal~~ an insignificant radiation risk and, therefore, regulatory control of the capsules is not necessary.

Under the third alternative, 10 CFR Part 35 would be amended to permit any physician to receive and use the capsules under a general license. The health and safety concerns for this alternative are the same as the Alternative 2. However, if this alternative were adopted, there could be a burden to those Agreement States that normally require registration of general

Scenario	Maximum Exposed Individual	Routine Exposure
Worker administering ^{14}C-urea breath tests	Full-time worker, 8,000 patients/yr	Less than 0.7 mrem/yr
Routine exposure of patients from ^{14}C-urea breath tests	Patient tests negative Patient tests positive	0.38 mrem/capsule 0.18 mrem/capsule
Release of 150 µCi of $^{14}CO_2$ into administration facility from fire	Member of public in the administration area	Less than 0.0002 mrem
Rupture of a capsule causing skin contamination of worker or patient	Skin (100 cm^2) exposed for one hour prior to washing; 0.075 µCi skin absorption	5.8 mrad skin dose, 0.029 mrem (CEDE)

Furthermore, the NRC concluded that the impacts associated with any releases of ^{14}C to the surrounding environment are expected to be very small and the expected risks are minimal. The earth's atmosphere contains an inventory of naturally occurring ^{14}C of about 3.8 million curies (equivalent to the activity in 3.8 trillion breath tests), which is in addition to the huge inventory of about 240 million curies in the world's oceans. The ^{14}C released into the atmosphere from the use of this test would mix with the global inventory and expose the public and other biotic components of the environment to ^{14}C intakes from inhalation, drinking water, and all possible food pathways in the same manner as naturally occurring ^{14}C. The current world inventory of naturally occurring ^{14}C results in an average dose to the public of about 1.25 mrem/year, and the release of 0.6 curies of ^{14}C from the total of 600,000 tests assumed to be administered annually would result in an additional average annual dose of 2×10^{-7} mrem. 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. In a total population of about 260 million people in the U.S., the collective annual dose from the breath tests would be about 0.051 person-rem. In addition, the doses from normal use of breath tests, or from any accidental release of ^{14}C to the environment also are expected to be very small because the concentration of CO_2 released is very low and it would mix immediately with the atmosphere. The routine exposure of patients was not considered when calculating the individual or collective doses resulting from the diagnostic tests.

The small doses from naturally occurring ^{14}C are of little significance to human health and the environment. Potential long-term impacts from widespread releases of the long-lived ^{14}C (5,730-year radiological half-life) from breath tests were concluded to be insignificant. Assuming that the testing in the U.S. would increase over a period of time to an average of a million tests per year for 50 years, the collective annual dose to the U.S. population would be about 5 person-rem over the next 50 years. This dose is very small when compared to the annual collective dose to the U.S. population from naturally occurring ^{14}C of over 300,000 person-rem, and about 78,000,000 person-rem from all naturally occurring radiation. Clearly, an increase of a few person-rem will not significantly change these exposures, and thus there is no expected impact from the widespread use of the breath test on the entire U.S. population.

period.

As a result of this analysis, the NRC concludes that Alternatives 2 and 3 are clearly preferable to the no action alternative. This is because either of the two alternatives will result in significant cost savings with no measurable adverse effect on health and safety. Furthermore, the NRC's recommended option is Alternative 2 because it would avoid the unnecessary cost burden to some Agreement States and their general licensees.

Therefore, by promulgating the final rule, the cost savings would be maximized without any measurable adverse effect on public health and safety.

5. Decision Rationale

Based on the above analysis, the NRC is amending its regulations to permit the manufacture and commercial distribution of Carbon-14 urea capsules to any person (including physicians who are not "authorized users" under Part 35) and permit any person, without an NRC license, to receive and use the capsules for in vivo diagnostic use for humans because the radiological risk from such distribution would be ~~negligible~~ insignificant and the savings to patients could be significant.

Environmental Assessment

For Final Amendments to 10 CFR Parts 30 and 32

"Distribution of a Radioactive Drug Containing One Microcurie of

Carbon-14 Urea as Exempt Material for "In Vivo" Diagnostic Testing"

Statement of the Final Action

The Nuclear Regulatory Commission (NRC) is amending its regulations to allow NRC licensees to distribute a radioactive drug containing one microcurie of carbon-14 urea to any person for "in vivo" diagnostic use. The NRC has determined that the radioactive component of such capsules presents ~~a minimal~~ an insignificant radiation risk and, therefore, regulatory control of the drug for radiation safety is not necessary. This amendment makes the drug more widely available, thus reducing costs to patients, insurers, and the health care industry. This action is being taken in response to a petition for rulemaking (PRM-35-12) submitted by Tri-Med Specialties, Inc.

Need for the Amendments

The amendments have been developed to grant the petition for rulemaking. The final rule permits manufacturers or commercial distributors to distribute carbon-14 urea capsules as exempt material to any person. The Commission is promulgating this rulemaking because it believes that the radiological risk from such distribution would be ~~negligible~~ insignificant and the savings to patients could be significant. In addition, the Commission recognizes that other Federal and State agencies (e.g., Food and Drug Administration and the State Boards of Pharmacy) are responsible for the receipt and use of drugs that do not contain byproduct materials, and would provide necessary oversight for the safe use of these carbon-14 urea capsules as drugs.

Alternatives Considered

Three alternatives have been considered regarding the petition: deny the petition, i.e., maintain the status quo, permit the distribution of the capsules as exempt material, and permit the distribution of the capsules to general licensees.

Under the first alternative, the current situation would continue: only physicians who are authorized users under Part 35 would be allowed to possess and administer the C-14 urea test.

Any physician could apply to become an authorized user. However, the NRC expects few physicians would apply for a Part 35 license for the sole purpose of using such capsules because of the requirement for training and experience and the associated cost of obtaining and maintaining a Part 35 license. Alternatively, physicians who are not authorized users can continue to refer their patients to physicians who are authorized users to undergo the diagnostic test. However this would not relieve the current expense, inconvenience, and delay encountered in an otherwise straight-forward procedure.

Under the second alternative, 10 CFR Parts 32 and 30 would be amended. Part 32 would be amended to establish requirements for the manufacture and distribution of C-14 urea capsules to persons exempt from licensing, i.e., any person (including physicians who are not "authorized users" under Part 35); Part 30 would be amended to permit any person to receive, possess, use, transfer, own, or acquire the capsules for in vivo diagnostic use for humans without a license. The NRC has determined that the radioactive component of this drug presents ~~a minimal~~ an insignificant radiation risk and, therefore, regulatory control of the capsules is not necessary.

Under the third alternative, 10 CFR Part 35 would be amended to permit any physician to receive and use the capsules under a general license. The health and safety concerns for this alternative are the same as the Alternative 2. However, if this alternative were adopted, there could be a burden to those Agreement States that normally require registration of general license holders. An additional burden could also be imposed on general licensees located in the Agreement State if the State charges a license or registration fee.

Based on the Draft Regulatory Analysis prepared for this proposed rule, the Commission concludes that Alternatives 2 and 3 are clearly preferable to the no action alternative. This is because either of the two alternatives will result in significant cost savings with no measurable adverse effect on health and safety. Furthermore, the NRC's recommended option is Alternative 2 because it avoids the unnecessary cost burden to some Agreement States and their licensees.

Impact on the Public and the Environment

The amendments are expected to have ~~no~~ an insignificant impact on the public and the environment. The NRC assumes that the same number of breath tests will be administered regardless of the level of NRC regulatory control. This view is predicated on the belief that

each physician's primary motivation is to provide the best possible care to his or her patients. If the breath test is judged preferable to endoscopy, or other procedure, any physician not authorized to use the test will refer his or her patient to authorized users who could perform the test under existing NRC regulations. Under this assumption, this rulemaking action is expected to result in no change in radiation exposures to the workers and patients when compared with the status quo. Similarly, it is expected that there will be no change in impact to the environment because the Commission assumes that the same number of tests will be administered regardless of which alternative is adopted.

The earth's atmosphere contains an inventory of naturally occurring C-14 of about 3.8 million curies which is in addition to the huge inventory of about 240 million curies in the world's oceans. The small amount of C-14 released into the atmosphere from the use of this test would mix with the global inventory and would have no impact on public health. The current world inventory of naturally occurring C-14 results in an average dose to the public of about 1.25 mrem per year, and the release of 0.6 curies of C-14 from the total of 600,000 tests assumed to be administered annually would result in an additional average annual dose of 2×10^{-7} mrem. 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.

List of Agencies and Persons Consulted and Identification of Sources Used

Following the receipt of the petition for rulemaking, a "Notice of receipt of petition for rulemaking" was published for public comment in the Federal Register on December 2, 1994, (59 FR 61831). A total of 315 public comment letters, 313 supporting (mostly form letters) and 2 opposing letters, were received. This petition was discussed with NRC's Advisory Committee on the Medical Uses of Isotopes ACMUI) at the October 1995 meeting. Furthermore, the draft rulemaking plan was forwarded to 29 Agreement States for comments.

A proposed rule was published in the Federal Register (62 FR 32552, June 16, 1997) for a 30-day public comment period. The NRC received seven public comment letters. Four commenters supported the rule, one opposed the rule, and two provided comments without explicitly stating support of or opposition to the rule. A summary of public comments and NRC's responses are presented in the preamble of the Federal Register notice. Except a minor change in wording, the final amendments are the same as the proposed amendments.

One commentor addressed the draft environmental Assessment. The commenter stated that the environmental Assessment fails to consider the fact that another equally non-invasive,

but non-radiological, diagnostic procedure (such as C-13 test) is available and provides a comparable alternative to the C-14 test. The commenter apparently concluded that the assumption underlying the environmental assessment is that in the absence of the C-14 test, the only alternative for the detection of H. pylori is invasive gastroendoscopy.

The purpose of the environmental assessment is to address and document the expected impact to the environment of subject rule. As presented in the regulatory analysis prepared for this rule, the NRC has determined that the environmental impact is expected to be insignificant because of the extremely low radiological hazards associated with the use of capsules containing one microcurie C-14 urea.

If the environmental impact had been significant, then the existence of a non-radioactive alternative would have been a factor in assessing the cost-benefit of this rulemaking. However, the impact is not significant. Hence, the regulatory issue in this rulemaking is whether the C-14 method should be made available to physicians who are not authorized users, and not whether there exists a non-radioactive alternative.

Finding of No Significant Impacts

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the amendments will not be a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required. The final rule amends 10 CFR Part 32 to permit the manufacture and commercial distribution of C-14 urea capsules to any person (including physicians who are not "authorized users" under Part 35) and to amend 10 CFR Part 30 to permit any person, without an NRC license, to receive and use the capsules for in vivo diagnostic use for humans. The Commission believes that the radioactive component of this drug presents ~~a minimal~~ an insignificant radiation risk and, therefore, regulatory control of the capsules for "in vivo" diagnostic use is not necessary. It is expected that this final rule will not cause any significant increase in radiation exposure to the public or radiation release to the environment beyond the exposures or releases resulting from the use of the carbon-14 capsules under the current regulations.

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

The Honorable Dan Schaefer, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington, DC 20515

* Identical changes should be made to each letter.

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee are copies of a public announcement and a Federal Register notice concerning a final amendment to 10 CFR Parts 30 and 32. This rulemaking is being taken in response to a petition for rulemaking submitted by Tri-Med Specialties, Inc.

The Nuclear Regulatory Commission (NRC) is amending its regulations to allow NRC licensees to distribute a radioactive drug containing one microcurie of carbon-14 urea to any person for "in vivo" diagnostic use. The purpose of this diagnostic test is to detect the presence of the bacterium Helicobacter pylori (H. pylori), a cause of peptic ulcers. The NRC has determined that the radioactive component of such capsules presents ~~a minimal~~ an insignificant * radiation risk and, therefore, regulatory control of the drug for radiation safety is not necessary. The manufacture and distribution of the capsules will continue to require an NRC license. This amendment makes the drug more widely available, thus reduces costs to patients, insurers, and the health care industry.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosures:
1. Public Announcement
2. Federal Register Notice

cc: Representative Ralph Hall

Draft press release -- 9/3/97

NRC CHANGES REGULATIONS TO PERMIT EXEMPT DISTRIBUTION OF RADIOACTIVE DIAGNOSTIC DRUG

The Nuclear Regulatory Commission is amending its regulations to allow a specific radioactive drug used to diagnose stomach ulcers to be distributed to any person for administration to humans. Before this change, only physicians authorized by the NRC or Agreement States could receive and administer the drug.

The change does not relieve persons from the requirement to comply with applicable Food and Drug Administration or other Federal and State requirements governing receipt, administration and use of drugs.

The change is in response to a 1994 petition for rulemaking from Tri-Med Specialties, Inc. The revised regulation allows any person to receive, possess, use and transfer capsules containing one microcurie carbon-14 urea each for diagnostic use in patients. The NRC has determined that the capsules present ~~a~~ an insignificant ~~minimal~~ radiation risk, and therefore believes that regulatory control of the diagnostic use of the drug for radiation safety is not necessary.

Under the amendments, manufacturers of the capsules and commercial pharmacies that prepare the capsules will continue to need an NRC license to provide high confidence of capsule contents. The containers of the capsules must bear the words "radioactive material" and other specific information on the contents of the container. In addition, only those persons who are licensed will be permitted to use the capsules for research involving human subjects.

The Tri-Med petition stated that Carbon-14 urea can be used to detect the presence of a bacterium that causes peptic ulcers, a chronic inflammatory condition of the stomach and duodenum that affects as many as 10 percent of

people in the United States at some time in their lives. According to a July 1994 article in the Journal of the American Medical Association, the disease has relatively low mortality, but results in substantial human suffering and high economic costs. Doctors can now cure most ulcer problems with antibiotics. The test using Carbon-14 urea is non-invasive. A doctor asks the patient to swallow the capsule with water. After 15 minutes the patient blows into a collection bag, which is mailed to a testing laboratory for analysis.

Before the change, only physicians who were authorized users (e.g., physicians who met certain training and experience criteria regarding the safe use of radioactive drugs) or persons working under the supervision of an authorized user could administer radioactive drugs for medical purposes.

Under the amendments, physicians or other health care workers will not need to be authorized users in order to administer the drug, and physicians will not need to refer their patients to nuclear medicine physicians. This should result in cost savings to patients, insurers, and the health care industry.

A proposed rule on this subject was published in the Federal Register for public comment on June 16. Minor changes made to the rule as a result of comments received are discussed in a Federal Register notice that will be published shortly.

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

SECRETARY

November 5, 1997

IN RESPONSE, PLEASE
REFER TO: M971105B

MEMORANDUM FOR: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary

Dupe out

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)

9711210267

B. 3:00 P.M. Session

1. 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 [illegible] 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 ....'