April 28, 1997 SECY-97-090

FOR: The Commissioners

FROM: L. Joseph Callan, Executive Director for Operations
/s/

SUBJECT: PROPOSED RULE: EXEMPT DISTRIBUTION AND USE OF A RADIOACTIVE DRUG CONTAINING ONE MICROCURIE OF CARBON 14 UREA (PARTS 30 AND 32)

PURPOSE:

To obtain the Commission's approval for the publication of the proposed rule.

BACKGROUND:

By negative consent, the Commission approved a rulemaking plan to amend Parts 30 and 32 to permit the exempt distribution and use of one micro-Curie (µCi) capsules of carbon-14-urea for in vivo diagnostic use. This rulemaking plan was submitted to the Commission on February 7, 1997 as SECY-97-031.

DISCUSSION:

Part 30 would be amended to add a new section (§ 30.21), to permit any person to receive, possess, use, transfer, own, or acquire carbon-14 urea capsules, not to exceed one microcurie of carbon-14, for "in vivo" diagnostic use, without a license. The proposed amendment would include a reminder that persons would not be relieved from complying with applicable FDA, other Federal, and State requirements governing drugs. Also, any person who desires to use the capsules for research involving human subjects still would be required to apply for and receive a specific license pursuant to Part 35.

CONTACT:
Sam Jones, RES/DRA
(301) 415-6198

Part 32 would be amended to add a new section (§ 32.21) to establish requirements for the manufacture and distribution of carbon-14 urea capsules to persons exempt from licensing. Currently, NRC requires licensees who manufacture, prepare, or commercially distribute radioactive drugs to meet the requirements in § 32.72(a)(2) (e.g., be registered or licensed with the FDA or a State as a drug manufacturer or be licensed as pharmacy by a State Board of Pharmacy). The proposed amendment would require licensees distributing these capsules under an exempt distribution license to meet this same requirement because the capsules will have widespread distribution for "in vivo" diagnostic use by persons who will be exempt from licensing. Also, this would provide high confidence that the carbon-14 urea capsules contain only one microcurie of carbon-14 and do not contain other radioactive contaminants.

COORDINATION:

The Office of the General Counsel has no legal objection to the proposed rulemaking. The Office of the Chief Financial Officer concurs in the resource impacts of this rulemaking. The Office of the Chief Information Officer concurs that there will be no information technology or management impacts.

RECOMMENDATION:

That the Commission:

1. Approve for publication in the Federal Register the proposed amendments to 10 CFR Parts 30 and 32 (Enclosure 1).

2. Note:

   a. That the proposed amendments will be published in the Federal Register allowing 30 days for public comment.

   b. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b).

   c. A regulatory analysis has been prepared for this rulemaking (Enclosure 2).

   d. An Environmental Assessment has been prepared for this rulemaking (Enclosure 3).

   e. The appropriate Congressional committees will be informed of this action (Enclosure 4).

   f. That a public announcement will be issued by the Office of Public Affairs when the proposed rulemaking is filed with the Office of the Federal Register (Enclosure 5).

g. This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule is being sent to the Office of Management and Budget for review and approval of the information collection requirements.

h. That resources to complete and implement this rulemaking are included in the current budget.

L. Joseph Callan
Executive Director
for Operations

Enclosures: As stated (5)

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30 and 32

RIN: AF70

Exempt Distribution of a Radioactive Drug

Containing One Microcurie of Carbon-14 Urea

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing an amendment to its regulations that would 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 radiation risk and, therefore, regulatory control of the drug for radiation safety is not necessary. If adopted, this amendment would make the drug more widely available, and reduce costs to patients. This action is being taken in response to a petition for rulemaking (PRM-35-12) submitted by Tri-Med Specialties, Inc.

DATES: Submit comments by (Insert date 30 days after publication date). Comments received after this date will be considered if it is practicable to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Docketing and Service Branch.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

The public may examine comments received, the environmental assessment and finding of no significant impact, and the regulatory analysis at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Sam Jones, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6198 or e-mail at SZJ@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Petition for Rulemaking

On October 6, 1994, the Commission docketed a petition for rulemaking (Docket No. PRM-35-12) from Tri-Med Specialties, Inc (Tri-Med). In a letter dated August 23, 1994, Tri-Med petitioned the NRC to amend its regulations "to allow for the general licensing and/or exemption for the commercial distribution by licensed pharmaceutical manufacturers of a capsule containing one micro-Curie (µCi) of ^{14}C-urea for in vivo diagnostic testing." The purpose of this diagnostic test is to detect the presence of the bacterium Helicobacter pylori (H. pylori), a cause of peptic ulcers.

"Peptic ulcer disease is 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. The disease has relatively low mortality, but it results in substantial human suffering and high economic costs." (Source: Article included as an appendix to the petition, from JAMA, July 6, 1994, Vol-272, No. 1, "H. pylori in Peptic Ulcer Disease-NIH Consensus Conference").

In the petition, the petitioner stated the following:

> Recent medical research has found that peptic ulcers are commonly caused by a bacterium called H. pylori. This bacterium lives in the stomach of most ulcer sufferers. By treating ulcer patients with antibiotics, doctors can now cure most ulcer problems.

It is therefore necessary to detect the presence of H. pylori bacteria in ulcer patients so that the new treatment can be given appropriately. In the past, this was done by a gastroenterologist who took biopsy samples of the stomach lining at endoscopy, a procedure which was uncomfortable and expensive ($1000).

With the new test, H. pylori can be detected non-invasively using a ^{14}C-urea tracer. ^{14}C-urea is broken down by H. pylori to form labeled CO_2 which is expired in the breath. To do the test, a doctor asks the patient to swallow the capsule with 30 mls of water. After 15 minutes the patient blows 2 liters of breath into a collection bag (a mylar balloon) which is mailed to a testing laboratory. If ^{14}C-CO_2 more than twice background is present in the breath sample, then the patient must be infected with H. pylori.

This proposed rule, should it become final, would grant the petition for rulemaking (PRM-35-12) from Tri-Med and complete action on the petition.

Public Comments on the Petition

Following the receipt of the petition, the NRC published for public comment a notice of receipt of petition for rulemaking in the Federal Register on December 2, 1994 (59 FR 61831). The comment period closed on February 15, 1995. The NRC received 315 public comment letters, of which 313 support the petition (they were mostly form letters) and 2 letters opposed the petition. The two letters opposing the petition stated that the product should not receive an

exempt status because the uncontrolled distribution and application of this product could lead to significant risk to the public and that the medical uses should be restricted to short-lived isotopes because of disposal problems presented by long-lived isotopes.

The NRC has considered the two opposing comments and has determined the following:

(1) The resulting radiation dose from the capsules to workers, patients, and the public is very low (see Regulatory Analysis).

(2) 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 (see Environmental Assessment). Similarly, the small doses from naturally occurring ^{14}C are of little significance to human health and the environment. Also, the Commission concludes that the potential long-term impacts from widespread releases of the long-lived ^{14}C (5,730-year radiological half-life) from breath tests are insignificant.

Comments from Advisory Committee on the Medical Uses of Isotopes

This petition was discussed with NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) at its October 1995 meeting. The ACMUI indicated that it endorsed the wide availability of this diagnostic test and that the radioactive drug could be used under a general license or an exemption, whichever the NRC may determine to be procedurally easier.

II. Discussion

Regulatory Issue

The regulatory issue is whether capsules containing one microcurie of carbon-14 urea present a sufficiently small radiation risk that they can be safely distributed to any person (including physicians who are not “authorized users” under Part 35).

Current NRC Regulations for the Manufacture and Commercial Distribution of Radioactive Drugs Containing Byproduct Material

NRC regulations in 10 CFR 32.72 address the manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material. This regulation requires manufacturers or preparers of radioactive drugs for commercial distribution to be:

(1) Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

(2) Registered or licensed with a state agency as a drug manufacturer; (3) Licensed as a pharmacy by a State Board of Pharmacy; or

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

These facilities have a specific license with the NRC. Under the specific license, the manufacturer or pharmacy can distribute radioactive drugs only to persons authorized pursuant to Part 35, "Medical Use of Byproduct Material."

Current NRC Regulations for the Medical Use of Radioactive Drugs Containing Byproduct Material

Currently, 10 CFR Part 35 only permits physicians who are authorized users (e.g., physicians who meet certain training and experience criteria regarding the safe use of radioactive drugs) or persons working under the supervision of an authorized user to use radioactive drugs for medical use. The Agreement States have similar requirements.

Current NRC Regulations on Exemptions from Licensing

Existing exemptions from licensing requirements for the use of byproduct material include exemptions for specific products (e.g., time pieces), exemption for classes of products (e.g., gas and aerosol detectors) and broader materials exemptions in § 30.14, "Exempt concentrations," and § 30.18, "Exempt quantities." These two broad materials exemptions specifically exclude the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or any product designed for ingestion or inhalation by, or application to, a human being. (In the case of exempt quantities, this prohibition is contained in § 32.18, "Manufacture, distribution and transfer of exempt quantities of byproduct material; Requirements for a license," § 32.18(b)).

Capsules containing one microcurie of carbon-14 urea would not qualify as an "exempt quantity" in accordance with § 30.18 because of their intended use (as a drug) even though they contain a smaller quantity than that set forth in § 30.71, Schedule B. This use is outside the intent of the exemption currently in § 30.18. It would introduce needless complexity to the regulations and confusion to accommodate this unique use under the aforementioned sections.

However, because the capsules present an insignificant radiological risk to the public and the environment, the NRC believes they could be distributed to persons exempt from licensing for "in vivo" diagnostic use.

Proposed Amendments for Permitting the Distribution of the Capsules to Persons Exempt from Licensing

Proposed Amendment to 10 CFR Part 32

The regulations in 10 CFR Part 32 would be amended to add a new § 32.21, to provide requirements for a specific license to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution capsules containing one microcurie of carbon-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 proposed regulation would include 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 NRC has decided that the manufacture or preparation of capsules containing one microcurie of carbon-14 urea should continue to 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 only one microcurie of carbon-14 urea and does not contain any other radioactive contaminants.

Proposed Amendment for Exempting "Any Person" from Licensing Requirements to Receive the Drug

Proposed Amendment to 10 CFR Part 30

The NRC has determined that the drug in capsule form presents no significant radiological safety or 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 would be 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 carbon-14 urea without a license. The proposed regulation would include 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 in order to protect human subjects.

The phrase "in vivo diagnostic use" is being used in § 30.21 instead of "medical use" for two reasons. First, the term "medical use" has a specific meaning and is defined in § 35.2 to mean "the intentional internal or external administration of byproduct material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user." This term would be inappropriate 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.

Effects of the Proposed Amendments

The effect of these proposed amendments would be to 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 would be exempt from NRC licensing, Agreement States would 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 would not regulate the use of the drug as long as its use was for "in vivo" diagnostic use. This means that, under NRC and Agreements State regulations, primary-care physicians would not need to be “authorized users” in order to administer the drug, and would not necessarily 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 would be left to determine and regulate who could receive

and use the drug for "in vivo" diagnostic use. NRC would regulate the use of the drug for research involving human subjects under a specific Part 35 license.

III. Summary of Proposed Amendments

Manufacturer and Distributors

A new section would be added to 10 CFR Part 32 to permit the distribution of the capsules to persons who are exempt from licensing.

§ 32.21 Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of carbon-14 urea capsules not exceeding one microcurie each for "in vivo" diagnostic use for humans to persons exempt from licensing; Requirements for a license

Paragraph (a)

This paragraph would establish the requirements for approval of a license application to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution carbon-14 urea capsules not exceeding one microcurie each for "in vivo" diagnostic use, to persons exempt from licensing.

Paragraph (a)(1)

This paragraph would limit 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 no more than one microcurie of carbon-14 and present no other radiological risks, this paragraph would require 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 would require applicants to provide evidence that each carbon-14 urea capsule will not exceed one microcurie. The NRC's evaluation that the capsules would not result in significant 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 will not exceed one microcurie.

Paragraph (a)(4)

This paragraph would prohibit carbon-14 urea from being contained in any food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by, or topical application to, a human being except for the capsules as described in this section, because exempt distribution of this drug has only been evaluated for "in vivo" diagnostic use in the form of a

capsule containing one microcurie of carbon-14 urea. Because of the capsule's "in vivo" diagnostic use, there is no prohibition against the capsule being combined with food or beverage at the time of administration so that the capsule can be ingested by the patient.

Paragraph (a)(5)

Because the exempt distribution of this drug has only been evaluated for "in vivo" diagnostic use in the form of a capsule containing one microcurie of carbon-14 urea, this paragraph would prohibit incorporation of the capsules into any manufactured or assembled commodity, product, or device intended for commercial distribution. Further, although the drug is being distributed to persons exempt from licensing, this paragraph would require the carbon-14 urea to be identified as radioactive because the drug is being used for its radioactive content; therefore, the end user must be provided with information that the drug contains a radioactive material.

Paragraph (a)(6)

As with any product approved for distribution to persons exempt from licensing, this paragraph would require persons who apply for a license to manufacture or commercially distribute these capsules to submit copies of prototype labels or brochures for NRC approval. This will allow the NRC to confirm that the labels or brochures meet the requirements of § 32.21a (a) and (b).

Paragraph (b)

This paragraph declares that the regulations do not relieve licensees or license applicants from complying with applicable FDA, other Federal, and State requirements governing the manufacture and distribution of drugs.

Section 32.21a Same: Conditions of license

This section would establish the conditions required for a license to commercially distribute the capsules to persons exempt from licensing.

Paragraph (a)

To inform the end user of the identity of the radioisotope, the physical and chemical form, and the dosage of radioactivity, this paragraph would establish that the immediate container of each capsule or capsules must bear a durable, legible label that:

(1) Identifies the radioisotope, the physical and chemical form of the radioisotope, the quantity of radioactivity contained in each container at a specific date; and

(2) Bears the words "Radioactive Material."

The date requirement is consistent with labeling requirements for other radioactive drugs with a half life of greater than 100 days.

Paragraph (b)

This paragraph would establish that, consistent with the intended use of the capsules, the label affixed to the immediate container, or an accompanying brochure, must:

(1) State that the contents are exempt from NRC or Agreement State licensing requirements;

(2) Bear the words "Radioactive Material. For "In Vivo" Diagnostic Use Only. This Material Is Not To Be Used for Research Involving Human Subjects, and Must Not Be Introduced into Foods, Beverages, Cosmetics, or Other Drugs or Medicinals, or into Products Manufactured for Commercial Distribution."

The intent of the requirement set out in (b)(2) is to make clear that the capsule must remain in the form of a capsule and is not to be combined with one of the listed items such as food or beverages which would result in a radioactive product other than in the form of a capsule for commercial distribution. Because of the capsule's "in vivo" diagnostic use, there is no prohibition against the capsule being combined with food or beverage at the time of administration so that the capsule can be ingested by the patient.

"In vivo" diagnostic use by persons exempt from licensing

A new section would be added to 10 CFR Part 30 to exempt any person from NRC or the Agreement State regulations to receive the drug for "in vivo" diagnostic use for humans.

Section 30.21 Radioactive drug: Capsules containing one microcurie of carbon-14 urea for "in vivo" diagnostic use for humans would be added to permit any person to receive the capsules.

Paragraph (a)

This paragraph would provide an exemption to any person from the requirements for a license to receive, possess, use, transfer, own, or acquire capsules containing one microcurie of carbon-14 urea for "in vivo" diagnostic purposes. It should be noted that the "transfer" in this paragraph does not include "transfer for commercial distribution," which is covered in paragraph (c) below.

Paragraph (b)

This paragraph would establish that persons exempt from licensing would be prohibited from using the drug for research involving humans subjects. A specific Part 35 license would be needed to use the drug in any research involving human subjects.

Paragraph (c)

This paragraph would specify that a specific license is needed to manufacture, prepare, process, produce, package, repackage or transfer such capsules for commercial distribution.

Paragraph (d)

This paragraph declares that the regulations do not relieve end users from complying with applicable FDA, other Federal, or State requirements governing the receipt, administration, and use of drugs.

IV. Agreement State Compatibility

Under the Atomic Energy Act, certain regulatory functions are reserved to the NRC. Among these are the distribution of products to persons exempt from licensing, as discussed in 10 CFR Part 150. Hence, the proposed rule, if adopted, would be a Division 4 item of compatibility, with regard to the manufacture and commercial distribution of the capsules (10 CFR Part 32). Due to the need for nationwide consistency in the use of products which are widely distributed, the proposed rule, if adopted, would be a Division 1 item of compatibility with regard to possession and use (10 CFR Part 30). Therefore, the Agreement States will need to make appropriate provisions in their regulations to allow any person to receive capsules containing one microcurie of carbon-14 urea for "in vivo" diagnostic use without need for a license.

V. Electronic Access

Comments may be submitted electronically, in either ASCII text or WordPerfect format (version 5.1 or later), by calling the NRC Electronic Bulletin Board on FedWorld or connecting to the NRC interactive rulemaking web site, “Rulemaking Forum.” The bulletin board may be accessed using a personal computer, a modem, and one of the commonly available communications software packages, or directly via Internet.

If using a personal computer and modem, the NRC subsystem on FedWorld can be accessed directly by dialing the toll free number: 1-800-303-9672. Communication software parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Using ANSI or VT-100 terminal emulation, the NRC NUREGs and Reg Guides for Comment

subsystem can then be accessed by selecting the "Rules Menu" option from the "NRC Main Menu." For further information about options available for NRC at FedWorld, consult the "Help/Information Center" from the "NRC Main Menu." Users will find the "FedWorld Online User's Guides" particularly helpful. Many NRC subsystems and databases also have a "Help/Information Center" option that is tailored to the particular subsystem.

The NRC subsystem on FedWorld can also be accessed by a direct-dial telephone number for the main FedWorld BBS, 703-321-3339, or by using Telnet via Internet, fedworld.gov. If using 703-321-3339 to contact FedWorld, the NRC subsystem will be accessed from the main FedWorld menu by selecting the "Regulatory, Government Administration and State Systems," then selecting "Regulatory Information Mall." At that point, a menu will be displayed that has an option "U.S. Nuclear Regulatory Commission" that will take you to the NRC Online main menu. The NRC Online area also can be accessed directly by typing "/go nrc" at a FedWorld command line. If you access NRC from FedWorld's main menu, you may return to FedWorld by selecting the "Return to FedWorld" option from the NRC Online Main Menu. However, if you access NRC at FedWorld by using NRC's toll-free number, you will have full access to all NRC systems but you will not have access to the main FedWorld system.

If you contact FedWorld using Telnet, you will see the NRC area and menus, including the Rules menu. Although you will be able to download documents and leave messages, you will not be able to write comments or upload files (comments). If you contact FedWorld using FTP, all files can be accessed and downloaded but uploads are not allowed; all you will see is a list of files without descriptions (normal Gopher look). An index file listing all files within a subdirectory, with descriptions, is included. There is a 15-minute time limit for FTP access.

Although FedWorld can be accessed through the World Wide Web, like FTP that mode only provides access for downloading files and does not display the NRC Rules menu.

You may also access the NRC's interactive rulemaking web site through the NRC home page (http://www.nrc.gov). This site provides the same access as the FedWorld bulletin board, including the facility to upload comments as files (any format), if your web browser supports that function.

For more information on NRC bulletin boards call Mr. Arthur Davis, Systems Integration and Development Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-5780; e-mail AXD3@nrc.gov. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, (301) 415 6215; e-mail CAG@nrc.gov.

VI. Finding of No Significant Environmental Impact: Availability

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 proposed amendments, if adopted, would not be a major Federal action significantly affecting the quality of the human environment; therefore, an environmental impact statement is not required. The proposed rule would establish requirements for the manufacture and commercial distribution of ^{14}C-urea capsules to persons exempt from licensing and establish 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 proposed rule, if adopted, would 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 would be no non-radiological impacts if the proposed rule is adopted.

The draft 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 draft environmental assessment and the finding of no significant impact are available from Sam Jones, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6198 or e-mail at SZJ@nrc.gov.

VII. Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

The public reporting burden for this collection of information is estimated to average 16 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The Nuclear Regulatory Commission is seeking public comment on the potential impact of the collection of information contained in the proposed rule and on the following issues:

1. Is the proposed collection of information necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of the burden correct?

3. Is there a way to enhance the quality, utility, and the clarity of the information to be collected?

4. How can the burden of the collection of information be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for reducing the burden, to the Information and Records Management Branch (T-6 F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0001, 3150-0017, and 3150-0120), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by (insert date 30 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VIII. Regulatory Analysis

The NRC has prepared a regulatory analysis for the proposed rule. The analysis examines the benefits and impacts considered by the NRC. The regulatory analysis is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the regulatory analysis are available from Sam Jones, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6198 or e-mail at SZJ@nrc.gov.

IX. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule does not have a significant economic impact upon a substantial number of small entities. The proposed rule would permit physicians to use an additional diagnostic test without having to obtain an NRC license, thus, would provide cost savings to physicians and patients. Any small entity subject to this regulation which
determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates the following:

(a) The licensee's size and how the regulation would result in a significant economic burden upon the licensee as compared to the economic burden on a larger licensee.

(b) How the regulations could be modified to take into account the licensee's differing needs or capabilities.

(c) The benefits that would accrue, or the detriments that would be avoided, if the regulations were modified as suggested by the licensee.

(d) How the regulation, as modified, would more closely equalize the impact of regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individual or group.

(e) How the regulation, as modified, would still adequately protect public health and safety.

X. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this rule, and therefore, a backfit analysis is not required because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

XI. List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalties, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and record keeping requirements.

10 CFR Part 32

Byproduct material, Criminal penalties, Labeling, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 30 and 32.

PART 30--RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for Part 30 continues to read as follows:

AUTHORITY: Sacs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); sacs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5841, 5846).

Section 30.7 also issued under Pub. L. 95-601, sec.10, 92 Stat. 2951 as amended by Pub. L. 102-486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. § 30.8(b) is revised to read as follows:

§ 30.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§30.9, 30.11, 30.15, 30.18, 30.19, 30.20, 30.21, 30.32, 30.34, 30.35, 30.36, 30.37, 30.38, 30.41, 30.50, 30.51, 30.55, appendices A and C to this part.

3. A new § 30.21 is added under the undesignated center heading "Exemptions" to read as follows:

§ 30.21 Radioactive drug: Capsules containing one microcurie of carbon-14 urea for "in vivo" diagnostic use for humans.

(a) Except as provided in paragraphs (b) and (c) of this section, any person is exempt from the requirements for a license set forth in Section 81 of the Act and from the regulations in this part and Part 35 of this chapter provided that such person receives, possesses, uses, transfers, owns, or acquires carbon-14 urea capsules, not exceeding one microcurie each, for "in vivo" diagnostic use for humans.

(b) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Part 35 of this chapter.

(c) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to § 32.21 of this chapter.

(d) Nothing in this section relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

PART 32--SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

4. The authority citation for Part 32 continues to read as follows:

AUTHORITY: Sacs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111,2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

5. § 32.8(b) is revised to read as follows:

§ 32.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§32.11, 32.12, 32.14, 32.15, 32.16, 32.17, 32.18, 32.19, 32.20, 32.21, 32.21a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.29, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.61, 32.62, 32.71, 32.72, 32.74, and 32.210.

6. A new § 32.21 is added to read as follows:

§ 32.21 Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of carbon-14 urea capsules not exceeding one microcurie each for "in vivo" diagnostic use for humans to persons exempt from licensing; Requirements for a license.

(a) An application for a specific license to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution carbon-14 urea capsules not exceeding one microcurie each for "in vivo" diagnostic use, to persons exempt from licensing under § 30.21 or the equivalent regulations of an Agreement State will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter, provided that the requirements of § 30.33(a)(2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, prepared, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(2) The applicant meets the requirements under § 32.72(a)(2);

(3) The applicant provides evidence that each carbon-14 urea capsule will not exceed one microcurie;

(4) The carbon-14 urea is not contained in any food, beverage, cosmetic, drug (except as described in this section) or other commodity designed for ingestion or inhalation by, or topical application to, a human being;

(5) The carbon-14 urea is in the form of a capsule, identified as radioactive, and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(6) The applicant submits copies of prototype labels and brochures and the NRC approves these labels and brochures.

(b) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing drugs.

7. A new § 32.21a is added to read as follows:

§ 32.21a Same: Conditions of license.

Each license issued under § 32.21 is subject to the following conditions:

(a) The immediate container of the capsule(s) must bear a durable, legible label which:

(1) Identifies the radioisotope, the physical and chemical form, the quantity of radioactivity of each capsule at a specific date; and

(2) Bears the words "Radioactive Material."

(b) In addition to the labeling information required by paragraph (a) of this section, the label affixed to the immediate container, or an accompanying brochure also must:

(1) State that the contents are exempt from NRC or Agreement State licensing requirements; and

(2) Bear the words "Radioactive Material. For "In Vivo" Diagnostic Use Only. This Material Is Not To Be Used for Research Involving Human Subjects and Must Not Be Introduced into Foods, Beverages, Cosmetics, or Other Drugs or Medicinals, or into Products Manufactured for Commercial Distribution."

Dated at Rockville, Maryland this ____ day of _____, 1997.

For the Nuclear Regulatory Commission.

_____
John C. Hoyle,
Secretary of the Commission.

REGULATORY ANALYSIS
FOR PROPOSED RULEMAKING
"EXEMPT DISTRIBUTION AND USE OF A RADIOACTIVE DRUG CONTAINING ONE MICROCURIE OF CARBON 14 UREA"
10 CFR PARTS 30 AND 32

1. Background

1.1 Statement of the Problem

On October 6, 1994, the Commission docketed a petition for rulemaking (Docket No. PRM-35-12) from Tri-Med Specialties, Inc (Tri-Med). In a letter dated August 23, 1994, Tri-Med petitioned the NRC to amend its regulations "to allow for the general licensing and/or exemption for the commercial distribution by licensed pharmaceutical manufacturers of a capsule containing one micro-Curie (µCi) of ^{14}C-urea for in vivo diagnostic testing." The purpose of this diagnostic test is to detect the presence of the bacterium Helicobacter pylori (H. pylori), a cause of peptic ulcers.

"Peptic ulcer disease is 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. The disease has relatively low mortality, but it results in substantial human suffering and high economic costs." (Source: Article included as an appendix to the petition, from JAMA, July 6, 1994-Vol 272, No. 1, "H. pylori in Peptic Ulcer Disease-NIH Consensus Conference").

In the petition dated August 23, 1994, the petitioner stated the following:

> Recent medical research has found that peptic ulcers are commonly caused by a bacterium called H. pylori. This bacterium lives in the stomach of most ulcer sufferers. By treating ulcer patients with antibiotics, doctors can now cure most ulcer problems.
>
> It is therefore necessary to detect the presence of H. pylori bacteria in ulcer patients so that the new treatment can be given appropriately. In the past, this was done by a gastroenterologist who took biopsy samples of the stomach lining at endoscopy, a procedure which was uncomfortable and expensive ($1000).
>
> With the new test, H. pylori can be detected non-invasively using a ^{14}C-urea tracer. ^{14}C-urea is broken down by H. pylori to form labeled CO_2 which is expired in the breath. To do the test, a doctor asks the patient to swallow the capsule with 30 mls of water. After 15 minutes the patient blows 2 liters of breath into a collection bag (a mylar balloon) which is mailed to a testing laboratory. If ^{14}C-CO_2 more than twice background is present in the breath sample, then the patient must be infected with H. pylori.

1.2 Current NRC Regulations

In 10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Materials," § 32.72, "Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35," provides for commercial distribution of radioactive drugs containing byproduct material for use by persons authorized pursuant to Part 35. Thus, the regulations currently would permit Part 32 licensees to commercially distribute capsules containing 1 µCi of ^{14}C-urea to persons authorized pursuant to Part 35.

In 10 CFR Part 35, "Medical Use of Byproduct Material," sets forth radiation safety requirements, including requirements for the training and experience of authorized user physicians to assure the safe possession and use of radioactive drugs containing byproduct material.

Existing exemptions for use of byproduct material in § 30.14, "Exemption concentrations" and § 32.18, "Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license," do not permit the exempt transfer of byproduct material contained in any food, beverage, cosmetic, drug, or any product designed for ingestion or inhalation by, or application to, a human being.

Therefore, under current regulations, the ^{14}C-urea capsules must be used under a Part 35 license.

1.3 Earlier NRC Actions

Following the receipt of the petition, 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 were received. Of these, 313 supported the petition (they were mostly form letters) and 2 letters opposed the petition. The two letters opposing the petition stated that (1) the product should not receive an exempt status because the uncontrolled distribution and application of this product could lead to significant risk to the public and (2) medical uses should be restricted to short-lived isotopes because of disposal problems presented by long-lived isotopes.

This petition was discussed with NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) at the October 1995 meeting. The ACMUI indicated that it endorsed the wide availability of this diagnostic test and that the radioactive drug could be used under a general license or an exemption, whichever the NRC may determine to be procedurally easier.

A rulemaking plan was prepared. After receiving comments from Agreement States on the draft rulemaking plan, the Commission approved a final rulemaking plan to develop a proposed rule to amend 10 CFR Parts 30 and 32 allowing the distribution of the Carbon-14 capsules as an exempt material to any person.

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 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. A additional burden could also be imposed on general licensees located in the Agreement State if the State charges a license or registration fee.

4. Value-Impact Analysis

4.1 The Petitioner's Assessment

In the letters dated August 23, 1994 and November 30, 1994, the petitioner stated, respectively:

> If exempted, the C-14 breath test could be done by most doctors for less than $100 cost to the patient. This is a considerable savings over endoscopy and biopsy ($1000).

> ... The test is 95 percent accurate and quite inexpensive because of its simplicity. The test would permit doctors to determine easily whether or not ulcer patients have been cured of their infection. By providing the public with an inexpensive, easily accessible diagnostic test, more individuals would be accurately diagnosed and treated for their H. pylori infection. This would save the United States an estimated $500 million per annum over conventional therapy.

The petitioner estimates annual benefits to be on the order of $500 million/year. This assumes approximately 600,000 ^{14}C-urea breath tests/year, at an average cost of $100, in lieu of performing endoscopy at an average cost of $1000/test. It assumes that the lower cost and greater availability of an unregulated breath test would result in a complete substitution for endoscopy. Tri-Med's benefit analysis provides a measure of the total benefits associated with the test and does not focus on the incremental benefits of administering the test pursuant to 10 CFR 35.100 regulation (status quo) versus releasing the test to all physicians (NRC licensed and non licensed alike). Implicit in Tri-Med's estimated annual benefits is the presumption that none of these ^{14}C tests and corresponding savings would accrue if the petition were denied. In reality, under the status quo, the test would be available and administered by physicians or clinics holding a license under NRC's Part 35 or an equivalent Agreement State regulations. Further, Tri-Med's estimate did not allow for the substitution of other non-invasive tests (e.g., serological test for IgG antibodies to H. pylori antigens) for both endoscopy and ^{14}C-urea tests.

4.2 The NRC's Assessment

(a) Cost Savings Associated with Amendments to 10 CFR Part 30

The value-impact analysis focuses on the incremental benefits of granting relief consistent with Alternative 2 or 3, as specified in Section 3 above. The analysis looks solely at changes relative to the base case or status quo. In this analysis, the comparison is between regulated and unregulated ^{14}C-urea breath tests, not unregulated ^{14}C-urea breath tests and endoscopies or other non-invasive tests. For the purposes of this regulatory analysis, the NRC assumes that the same number of breath tests (i.e., 600,000 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. This appears fully consistent with standard medical practice, whereby patients are referred routinely to laboratories and specialists for a wide array of tests and procedures.

The benefits of adopting the petition accrue as a result of reduced patient cost and reduced health-care cost resulting from the elimination of the need for referrals from a physician who is not an authorized user (e.g., gastrointestinal specialist). There would also be some regulatory savings because the NRC would not have to expend resources reviewing new applications for specific medical use licenses. However, these savings would be small because the NRC expects

that few physicians who are not authorized users would apply for a specific NRC license for use of this one product.

The benefit calculation is based on the assumption that as a result of the proposed action, a significant portion of the 600,000 patients would receive the ^{14}C breath test from physicians who are not authorized users (e.g., gastrointestinal specialists). The actual savings would be dependent on the number of tests ultimately administered by physicians who are not authorized users, thereby eliminating the need for a referral to physicians who are authorized users (e.g., nuclear medicine specialists).

The annual savings could be as high as approximately $20 million if there were a complete shift of the administration of the tests from physicians who are authorized users (i.e., base case) to physicians who are not authorized users.

The basis for this estimate is as follows.

Assuming adoption of the petition eliminates the need for up to 600,000 referrals, patient savings in averted travel expenses (transportation and personal time incurred with medical referral) would be:

> Assuming round trip of 20 miles @ $0.25/mile, and personal time of 0.5/hours/trip valued at $25.00/hour
>
> 600,000 trips/year x (20 miles/trip x $0.25/mile + 0.5 hours/trip x $25.00/hour) = $10.5 million/year

Health Care Savings in averted administrative expenses (administrative costs incurred with medical referral) would be:

> 600,000 patients/year x $19.00/patient = $11.4 million/year
>
> Assuming $19.00 (administrative cost/patient) as the differential between the cost of an office visit to a general family practice physician by an established patient ($45.90), and the cost to a new patient ($64.90 per visit) for completion of new patient paperwork, reviewing health history, maintaining medical records, etc. The patient who is referred to an authorized user (e.g., nuclear medicine specialist) for the ^{14}C-urea breath test would most likely be a new patient for the authorized user.

Total Savings:

> $10.5 million/year + $11.4 million/year = $ 21.9 million/year

Alternatively, if only 200,000 or 400,000 of the 600,000 tests were performed by a physician who is not an authorized user, the annual cost savings would be approximately $7 million per year and $15 million per year, respectively.

If Alternative 3 were adopted, it would permit any physician to receive and use capsules containing 1 µCi ^{14}C-urea for human use under a general license. The health and safety concerns for this alternative are the same as Alternative 2. However, the adoption of Alternative 3 could add unnecessary burden to those Agreement States and Agreement State licensees in States that assess licensing or registration fees for general license holders. Alternative 2 also imposes incremental cost burden for manufacturers or commercial distributors of the capsules because they would need to obtain an exempt distribution license. Each application is estimated to take up to 16 hours to prepare. Assuming 3 applicants per year, the total reporting burden would be 48 hours. For recordkeeping burden, assuming each of the 3 applicants in a year would need 2 hours to reprogram its computer to print additional words on the label or brochure, the one-time total recordkeeping burden would be 6 hours. Assuming a labor rate of $125 per hour, the total burden would be about $6,750 per year.

There would be costs for the Federal and State governments if Alternative 2 or 3 is adopted. Under both Alternatives 2 or 3, the NRC and some Agreement States would need to amend their regulations to permit the use of the capsules by persons other than physician who are authorized users.

(b) Health and Safety Effects

For the purposes of this regulatory analysis, the NRC assumes that the same number of breath tests (i.e., 600,000 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. In addition, the routine and accidental exposures per carbon-14 urea breath test is not expected to be affected by the level of NRC regulatory control. Thus, radiation exposures to the workers and members of the public would be the same regardless of which alternative is adopted.

The NRC has concluded that the human use of these capsules results in insignificant exposures as depicted below:

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 $^{14}C0_2$ 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, or 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 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.

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 adopting the proposed 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 proposing 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 and the savings to patients could be significant.

Environmental Assessment
For Proposed 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"

1. Introduction and Statement of the Proposed Action

The Nuclear Regulatory Commission (NRC) is proposing to amend 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 radiation risk and, therefore, regulatory control of the drug for radiation safety is not necessary. If adopted, this amendment would make the drug more widely available, thus reducing costs to patients. This action is being taken in response to a petition for rulemaking (PRM-35-12) submitted by Tri-Med Specialties, Inc.

2. Need for the Amendments

The proposed amendments have been developed to grant the petition for rulemaking. The proposed rule, if adopted, would permit manufacturers or commercial distributors to distribute Carbon-14 urea capsules as exempt material to any person. The Commission is proceeding with this rulemaking because it believes that the radiological risk from such distribution would be negligible 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.

3. 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 ^{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 such 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. Part 32 would be amended to establish requirements for the manufacture and distribution of ^{14}C-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 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. A 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 would avoid the unnecessary cost burden to some Agreement States and their licensees.

4. Impact on the Public and the Environment

The proposed amendments would have no significant 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, the proposed action would result in no change in radiation exposures to the workers and patients when compared with the status quo. Similarly, there would 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.

5. 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.

6. 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 proposed amendments, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required. The proposed rule would 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. The Commission believes that the radioactive component of this drug presents a minimal radiation risk and, therefore, regulatory control of the capsules for "in vivo" diagnostic use is not necessary. It is expected that this proposed rule, if adopted, would 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.

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

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee are copies of a public announcement and a Federal Register notice concerning a proposed 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 proposing to amend 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 radiation risk and, therefore, regulatory control of the drug for radiation safety is not necessary. If adopted, this amendment would make the drug more widely available, thus reducing costs to patients.

Sincerely,

Dennis K. Rathbun, Director

Office of Congressional Affairs

Enclosures:
1. Public Announcement
2. Federal Register Notice

cc: Representative Ralph Hall

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

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Sincerely,

Dennis K. Rathbun, Director

Office of Congressional Affairs

Enclosures:
1. Public Announcement
2. Federal Register Notice

cc: Representative Ralph Hall

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The Honorable James M. Inhofe, Chairman
Subcommittee on Clean Air, Wetlands,
Private Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Enclosed for the information of the Subcommittee are copies of a public announcement and a Federal Register notice concerning a proposed 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 proposing to amend 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 radiation risk and, therefore, regulatory control of the drug for radiation safety is not necessary. If adopted, this amendment would make the drug more widely available, thus reducing costs to patients.

Sincerely,

Dennis K. Rathbun, Director

Office of Congressional Affairs

Enclosures:
1. Public Announcement
2. Federal Register Notice

cc: Senator Bob Graham

The Honorable James M. Inhofe, Chairman
Subcommittee on Clean Air, Wetlands,
Private Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

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(RES File Code No.) 3A-3

Draft press release -- 4/23/97, 3:30 p.m.

NRC CONSIDERS CHANGING REGULATIONS TO PERMIT EXEMPT DISTRIBUTION OF RADIOACTIVE DIAGNOSTIC DRUG

The Nuclear Regulatory Commission is considering amending its regulations to allow a specific radioactive drug that can be used to diagnose stomach ulcers to be distributed to any person. Currently only licensed nuclear physicians may receive and use the drug.

The proposed change would 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 from Tri-Med Specialties, Inc. It would allow any person to receive, possess, use and transfer carbon-14 urea capsules, not exceeding one microcurie each, for diagnostic use in patients. The NRC has determined that the capsules present a minimal radiation risk, and therefore believes that regulatory control of the drug for radiation safety is not necessary.

Under the proposed revisions to NRC regulations, manufacturers of the capsules and commercial pharmacies that prepare the capsules would continue to need an NRC license, and the containers of the capsules would have to bear the words "radioactive material." In addition, only those persons who were licensed would 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.

The NRC's Advisory Committee on the Medical Uses of Isotopes discussed the petition at its October 1995 meeting. The committee endorsed making this diagnostic test widely available.

Currently Part 35 of the Commission's regulations permits only physicians who are authorized users (e.g., physicians who meet certain training and experience criteria regarding the safe use of radioactive drugs) or persons working under the supervision of an authorized user to administer radioactive drugs for medical purposes.

Under the proposed amendments, physicians would not need to be authorized users in order to administer the drug, and would not need to refer their patients to nuclear medicine physicians. This should result in cost savings to patients.

Interested persons are invited to submit comments on the proposed rule change by _____ (75 days after publication of a Federal Register notice on this subject on _____). They may be mailed to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff, or submitted electronically as described in the Federal Register notice.

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Mr. Robert P. Murphy
General Counsel
General Accounting Office
Room 7175
441 G. St., NW
Washington, DC 20548

Dear Mr. Murphy:

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801, the Nuclear Regulatory Commission (NRC) is submitting a proposed rule regarding distribution of a radioactive drug containing one microcurie of carbon-14 urea to any person for "in vivo" diagnostic use for humans. The proposed rule is intended to make the drug more widely available, and reduce costs to patients. The distribution of the drug in capsule form presents a minimal radiation risk and, therefore, regulatory control of the drug for radiation safety is not necessary. This action is being taken in

response to a petition for rulemaking (PRM-35-12) submitted by Tri-Med Specialties, Inc.

We have determined that this rule is not a "major rule" as defined in 5 U.S.C. 804(2). We have confirmed this determination with the Office of Management and Budget.

Enclosed is a copy of the proposed rule that is being transmitted to the Office of the Federal Register for publication with a 75-day public comment period. The Regulatory Flexibility Certification and a statement of the availability of the Regulatory Analysis are included in the proposed rule.

Sincerely,

Dennis K. Rathbun, Director

Office of Congressional Affairs

Enclosure: Proposed Rule

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RES#3A-3

The Honorable Al Gore
President of the United
States Senate
Washington, DC 20510

Dear Mr. President:

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801, the Nuclear Regulatory Commission (NRC) is submitting a proposed rule regarding distribution of a radioactive drug containing one microcurie of carbon-14 urea to any person for "in vivo" diagnostic use for humans. The proposed rule is intended to make the drug more widely available, and reduce costs to patients. The distribution of the drug in capsule form presents a minimal radiation risk and, therefore, regulatory control of the drug for radiation safety is not necessary. This action is being taken in response to a petition for rulemaking (PRM-35-12) submitted by Tri-Med Specialties, Inc.

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RES#3A-3

The Honorable Newt Gingrich
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Washington, DC 20515

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