

May 30, 1997

MEMORANDUM TO: L. Joseph Callan  
Executive Director for Operations

FROM: John C. Hoyle, Secretary /s/

SUBJECT: STAFF REQUIREMENTS - SECY-97-090 - PROPOSED  
RULE: EXEMPT DISTRIBUTION AND USE OF A  
RADIOACTIVE DRUG CONTAINING ONE MICROCURIE OF  
CARBON UREA (PARTS 30 AND 32)

The Commission has approved publication of the proposed rule in the Federal Register with incorporation of the changes to the Federal Register notice, Congressional letters, and press release noted in the attachments.

(EDO)

(SECY Suspense: 6/30/97)

Attachment:  
As stated

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

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SECY NOTE: THIS SRM, SECY-97-090, AND THE COMMISSION VOTING RECORD CONTAINING THE VOTE SHEETS OF ALL COMMISSIONERS WILL BE MADE PUBLICLY AVAILABLE 5 WORKING DAYS FROM THE DATE OF THIS SRM.

[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, **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.

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.

## 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~~ administer 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

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 Agreement 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

## 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 **and other health care providers** to use an additional diagnostic test without having to obtain an NRC license, thus, would provide cost savings to ~~physicians and patients,~~ **insurers, and the health care industry.** 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:

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. **The manufacture and distribution of the capsules would continue to require an NRC license.** If adopted, this amendment would make the drug more widely available, thus reducing costs to patients, **insurers, and the health care industry.**

[make same changes to the Schaefer letter]

Sincerely,

Dennis K. Rathbun, Director  
Office of Congressional Affairs

Enclosures:

1. Public Announcement
2. Federal Register Notice

cc: Senator Bob Graham

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 ~~for administration to humans~~. Currently, only ~~licensed nuclear physicians~~ ~~authorized by NRC or Agreement States~~ may receive and ~~use~~ ~~administer~~ the drug.

The proposed change would not relieve persons from the requirement to comply with applicable Food and Drug Administration or other ~~f~~Federal and ~~s~~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~~ ~~to provide high confidence of capsule contents~~. ~~t~~The containers of the capsules would have to bear the words "radioactive material" ~~and other specific information on the contents of the container~~. 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 **or other health care workers** would not need to be authorized users in order to administer the drug, and **physicians** would not need to refer their patients to nuclear medicine physicians. This should result in cost savings to patients, **insurers, and the health care industry**.

Interested persons are invited to submit comments on the

proposed rule change by \_\_\_\_\_ ( ~~75~~ 30 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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