[7590-01-P]

U. S. NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: U. S. Nuclear Regulatory Commission (NRC)

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

1. Type of submission, new, revision, or extension: Revision.

2. The title of the information collection: Proposed rule, 10 CFR Parts 30 and 32 - Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea.

3. The form number if applicable: NRC Form 313.

C&R-8
X BAF-4A

110007

DF03

4. How often the collection is required: On occasion.

5. Who will be required or asked to report: Manufacturers and distributors of the radioactive drug containing Carbon-14 urea.

6. An estimate of the number of responses: 3.

7. The estimated number of annual respondents: 3.

8. An estimate of the total number of hours needed annually to complete the requirement or request: 54 hours initially; thereafter 48 hours annually - 16 hours for each of 3 respondents (48 hours per year reporting burden and a one-time 6-hour recordkeeping burden, 2 hours for each of 3 respondents)

9. An indication of whether Section 3507(d), Pub. L. 104-13 applies: Applicable.

10. Abstract: In response to a petition for rulemaking submitted by Tri-Med Specialties, Inc., the 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 adoption of this amendment would make the drug more widely available, thus reducing costs to patients.

Submit, by (insert date 30 days after publication in the Federal Register), comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

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

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

A copy of the submittal may be viewed free of charge at the NRC Public Document Room, 2120 L Street NW, (Lower Level), Washington, DC. The proposed rule indicated in "The title of the information collection" is or has been published in the Federal Register within several days of the publication date of this Federal Register Notice. Instructions for accessing the electronic OMB clearance package for the rulemaking have been appended to the electronic rulemaking. Members of the public may access the electronic OMB clearance package by following the directions for electronic access provided in the preamble to the titled rulemaking.

Comments and questions should be directed to the OMB reviewer by (insert date 30 days after publication in the Federal Register):

Edward Michlovich
Office of Information and Regulatory Affairs (3150-0001)
NEOB-10202
Office of Management and Budget
Washington DC 20503

Comments can also be submitted by telephone at (202) 395-3084.

The NRC Clearance Officer is Brenda Jo. Shelton, (301) 415-7233.

Dated at Rockville, Maryland, this 5th day of June, 1997.

For the Nuclear Regulatory Commission.

Arnold E. Levin, Acting Designated Senior
Official for Information Resources
Management

PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the Supporting Statement, and any additional documentation to: **Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503**

1. Agency/Subagency originating request
U.S. Nuclear Regulatory Commission

2. OMB control number
[X] a. 3150 - 0120 [ ] b. None

3. Type of information collection *(check one)*
[ ] a. New collection
[X] b. Revision of a currently approved collection
[ ] c. Extension of a currently approved collection
[ ] d. Reinstatement, **without change**, of a previously approved collection for which approval has expired
[ ] e. Reinstatement, **with change**, of a previously approved collection for which approval has expired
[ ] f. Existing collection in use without an OMB control number

4. Type of review requested *(check one)*
[Y] a. Regular submission [ ] c. Delegated
[ ] b. Emergency - Approval requested by (date)

5. Will this information collection have a significant economic impact on a substantial number of small entities?
[ ] a. Yes [X] b. No

6. Requested expiration date
[X] a. Three years from approval date
[ ] b. Other (Specify):

7. Title
Application for Material License

8. Agency form number(s) *(if applicable)*
NRC Form 313

9. Keywords
Byproduct material, Nuclear material

10. Abstract
The proposed rule, "Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon 14-urea," will amend Parts 30 and 32 to permit the exempt distribution and use of Carbon-14 capsules for in vivo diagnosis.

11. Affected public *(Mark primary with "P" and all others that apply with "X")*
[ ] a. Individuals or households
[P] b. Business or other for-profit
[X] c. Not-for-profit institutions
[ ] d. Farms
[X] e. Federal Government
[X] f. State, Local, or Tribal Government

12. Obligation to respond *(Mark primary with "P" and all others that apply with "X")*
[ ] a. Voluntary
[ ] b. Required to obtain or retain benefits
[P] c. Mandatory

13. Annual reporting and recordkeeping hour burden

a. Number of respondents	18,600
b. Total annual responses	11,841
1. Percentage of these responses collected electronically	0 %
c. Total annual hours requested	72,987
d. Current OMB inventory	72,987
e. Difference	0
f. Explanation of difference	
1. Program change	
2. Adjustment	

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*

a. Total annualized capital/startup costs	0
b. Total annual costs (O&M)	0
c. Total annualized cost requested	0
d. Current OMB inventory	0
e. Difference	0
f. Explanation of difference	
1. Program change	
2. Adjustment	

15. Purpose of information collection
(Mark primary with "P" and all others that apply with "X")
[ ] a. Application for benefits
[ ] b. Program evaluation
[ ] c. General purpose statistics
[ ] d. Audit
[ ] e. Program planning or management
[ ] f. Research
[P] g. Regulatory or compliance

16. Frequency of recordkeeping or reporting *(Check all that apply)*
[ ] a. Recordkeeping [ ] b. Third-party disclosure
[X] c. Reporting
[X] 1. On occasion [ ] 2. Weekly [ ] 3. Monthly
[ ] 4. Quarterly [ ] 5. Semi-annually [ ] 6. Annually
[ ] 7. Biennially [X] 8. Other (describe) 5 yr renewal

17. Statistical methods
Does this information collection employ statistical methods?
[ ] Yes [X] No

18. Agency contact *(person who can best answer questions regarding the content of this submission)*
Name: Anthony N. Tse
Phone: (301)415-6233

19. Certification for Paperwork Reduction Act Submissions

On behalf of this Federal agency, I certify that the collection of information encompassed by this request complies with 5 CFR 1320.9.

NOTE: The text of 5 CFR 1320.9, and the related provisions of 5 CFR 1320.8(b)(3), appear at the end of the instructions. *The certification is to be made with reference to those regulatory provisions as set forth in the instructions.*

The following is a summary of the topics, regarding the proposed collection of information, that the certification covers:

(a) It is necessary for the proper performance of agency functions;

(b) It avoids unnecessary duplication;

(c) It reduces burden on small entities;

(d) It uses plain, coherent, and unambiguous terminology that is understandable to respondents;

(e) Its implementation will be consistent and compatible with current reporting and recordkeeping practices;

(f) It indicates the retention periods for recordkeeping requirements;

(g) It informs respondents of the information called for under 5 CFR 1320.8(b)(3):

(i) Why the information is being collected;

(ii) Use of information;

(iii) Burden estimate;

(iv) Nature of response (voluntary, required for a benefit, or mandatory);

(v) Nature and extent of confidentiality; and

(vi) Need to display currently valid OMB control number;

(h) It was developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected (see note in Item 19 of the instructions).

(i) It uses effective and efficient statistical survey methodology; and

(j) It makes appropriate use of information technology.

If you are unable to certify compliance with any of these provisions, identify the item below and explain the reason in Item 18 of the Supporting Statement.

Signature of Senior Official or designee	Date
[signature]	6/5/97

OMB SUPPORTING STATEMENT FOR PROPOSED RULE 10 CFR PARTS 30 AND 32,

"Exempt Distribution of a Radioactive Drug

Containing One Microcurie of Carbon-14 Urea"

(3150-0001, 3150-0017, 3150-0120)

Description of Information Collection

This clearance package covers certain recordkeeping and reporting requirements in 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material." Two new sections would be added to Part 32: § 32.21, "Radioactive drug: Manufacture, distribution, and transfer of carbon-14 urea capsules not exceeding one microcurie each for "in vivo" diagnostic use; Requirements for a license" and § 32.21a, "Same: Conditions of license." Both sections would contain information collection requirements as described below. Because the distribution of items exempt from licensing and regulatory control is reserved under NRC's jurisdiction, Agreement State licensees would not be affected under the proposed amendments.

A. JUSTIFICATION

The regulations in 10 CFR Part 32 would be amended to add two new sections, §§ 32.21 and 32.21a, to provide requirements for a specific license to manufacture, process, produce, package, repackage, or transfer capsules containing one microcurie of carbon-14 urea, as a radioactive drug, to be distributed to any person for "in vivo" diagnostic use. A person who intends to manufacture or commercially distribute the capsules should submit a license application to describe how the person would meet applicable NRC requirements

pertaining to the radioactive drug. All burdens associated with application requirements are covered under NRC Form 313, "Application for Material License" (OMB Clearance No. 3150-0120).

1. Need for and Practical Utility of the Collection of Information

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

Paragraph (a) of this section would allow any person to receive, possess, use, transfer, own, or acquire capsules containing one microcurie carbon-14 urea for "in vivo" diagnostic testing without having to apply for and receive a license from the NRC or an Agreement State. There are no information collection requirements.

Paragraph (b) of this section would provide a reminder that any person who desires to use the capsules for research involving human subjects needs to apply for and receive a specific license pursuant to Part 35 of this chapter. The burden associated with application requirements is covered under NRC Form 313, "Application for Material License" (OMB Clearance No. 3150-0120).

Paragraph (c) of this section would provide a reminder that an NRC specific license would be required for any person who desired to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution carbon-14 capsules for in vivo diagnostic testing. The burden associated with application

requirements is covered under NRC Form 313, "Application for Material License" (OMB Clearance No. 3150-0120).

The information collection requirements of the amendments to 10 CFR Part 32 are described below.

§ 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) of this section would require an applicant to submit 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. The application should contain information sufficient for the NRC to make a decision that the applicant would meet NRC requirements. The burden associated with application requirements is covered under NRC Form 313, "Application for Material License" (OMB Clearance No. 3150-0120). Section 32.21(a)(6) would require the applicant to submit copies of prototype labels and brochures with the application for NRC approval.

Paragraph (b) of this section would provide a reminder that nothing in this section would relieve the licensees from complying with applicable FDA, other Federal, and

State requirements governing drugs. However, this section would not contain information collection requirements.

§ 32.21a Same: Conditions of license.

Paragraph (a) of this section would require that the container holding the capsules bear a label that specifies the radioisotope, its physical and chemical form, the quantity of radioactivity of each capsule at a specific date, and the words "Radioactive Material." The assumptions are that: (1) this requirement would impose a one-time burden because the Part 32 applicant generates labels using computers and would need to reprogram its computer to print additional words on the label or the brochure; and (2) the label will remain on the container until it no longer contains radioactive material.

Paragraph (b) of this section would require that the label or an accompanying brochure must state that the contents are exempt from NRC or Agreement State licensing requirements; 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."

2. Agency Use of Information

The NRC would review the information submitted in order to determine whether the capsules are manufactured with appropriate quantities of carbon-14 and without contamination of other radioactive material. Also, the NRC would review prototype labels and brochures to ensure that they contain necessary information such as the identity of the radioisotope, the physical and chemical form, and the dosage. The NRC considers that this information is necessary to inform any individual that the capsules contain radioactive material, the name of the radioisotope, its radioactivity, and intended use.

3. Reduction of Burden Through Information Technology

There are no known legal obstacles to reducing the burden associated with this information collection through information technology. Moreover, NRC encourages its use.

4. Effort to Identify Duplication and Use Similar Information

The information requested in the proposed rule does not duplicate information currently submitted to the NRC. The Information Requirements Control Automated System (IRCAS) was searched for duplication, and none was found.

5. Effort to Reduce Small Business Burden

The NRC believes that there is no way to reduce the burden on small businesses by less frequent or less complete records while maintaining the required level of safety.

6. Consequences of Federal Program or Policy Activities if the Collection Is Not Conducted or Is Conducted Less Frequently

There would be no basis for demonstrating compliance with the required level of safety through the NRC licensing program.

7. Circumstances That Justify Variation from OMB Guidelines

There are no variations from OMB guidelines.

8. Consultation Outside the NRC

The NRC published in the Federal Register on December 2, 1994 (59 FR 61831), a notice of receipt of the petition for rulemaking for public comment. A total of 315 public comment letters, 313 supporting (mostly form letters) and 2 opposing letters, were received. The NRC consulted with its Advisory Committee on the Medical Uses of Isotopes (ACMUI) at the October 1995 meeting. A draft rulemaking plan was forwarded to 29 Agreement States for comments. In addition, the proposed rule will be published in the Federal Register for public comment.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

NRC provides no pledge of confidentiality for this collection of information.

11. Justification for Sensitive Questions

No sensitive questions would be involved under the proposed amendments.

12. Estimated Burden and Burden Hour Cost

The burden for applicants can be estimated as follows:

(a) Burden for Reporting Requirements

Whereas a new applicant (non-licensee) who manufactures and distributes the capsule would be required to have two licenses, one to manufacture and one to distribute to persons exempt from NRC regulations, we do not anticipate any new applications for manufacturing only carbon-14 capsules. Therefore, the burden only addresses the licensees who already have licenses to manufacture radioactive drugs but require a new license to distribute the capsules to persons exempt from NRC regulations.

The application requirements of § 32.21(a) are covered by the NRC Form 313 (OMB Clearance No. 3150-0120). The annual increase in burden for the NRC Form 313 is estimated to be 48 hours, or 3 responses at 16 hours per response. At a cost of $125 per hour, the cost to licensees would be about $6,000 per year. There is no information collection burden for § 32.21(b).

(b) Burden for Recordkeeping Requirements

For § 32.21a(a) and (b), assuming annually each of 3 applicants would need 2 hours to reprogram their computers to print additional words on the label or the brochure, the one-time burden would be 6 hours. At a cost of $125 per hour, the annual cost to applicants would be $750.

(c) Total Burden

The annual burden to affected applicants would be 18 hours per applicant: 16 hours reporting and 2 hours recordkeeping, or 54 hours total. At a cost of $125 per hour, the total cost would be $6,750 per year.

13. Estimate of Other Additional Costs

None.

14. Estimated Annualized Cost to the Federal Government

The estimated burden on the NRC to review applications is estimated to be 8 hours per application, or 24 hours for an estimated 3 applicants per year. At a cost of $125 per hour, the estimated cost to NRC is $3,000 per year. This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170, or 171, or both.

15. Reasons for Changes in Burden or Cost

The existing regulations in 10 CFR Part 35, "Medical Use of Byproduct Material," require physicians who meet the training and experience requirements (i.e., authorized users) to administer radioactive drugs, including the capsules containing one microcurie of carbon-14. Thus, under the current rule, physicians who are not authorized users must refer patients to authorized users to undergo the diagnostic test.

The proposed amendments would allow the capsules to be distributed and used by any person (e.g., gastrointestinal specialist) who is permitted to receive and use the drug under an appropriate Federal or State law governing the drug. If the proposed amendments were adopted, there would be a slight increase in information collection burden for the manufacturers or distributors (estimated to be an annual cost of $6,750). However, the estimated annual savings to patients, insurers, and the health care industry could be as high as $20 million.

16. Publication for Statistical Use

There is no application to statistics in the information collected. There is no publication of this information.

17. Reasons for Not Displaying the Expiration Date

The expiration date is displayed on the NRC Form 313.

18. Exceptions to the Certification Statement

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.