§ 927.33 [Amended]

7. In § 927.33, paragraph (a) is amended by removing the word ''ten'' in the first sentence and adding in its place the word ''nine''; and adding the words ''telecopier or other electronic means,'' and a comma after the word ''mail'' in paragraph (b) first sentence.

Dated: June 9, 1997.

Lon Hatamiya,

Administrator, Agricultural Marketing Service.

[FR Doc. 97–15663 Filed 6–13–97; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1753

Acceptance Test Policy

AGENCY: Rural Utilities Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Rural Utilities Service (RUS) is proposing a minor amendment to its test acceptance procedures to correct 7 CFR part 1753.39, paragraph (c), to reflect new acceptance tests guidelines covered under RUS Bulletin 1753E–201, Acceptance Tests for Digital, Stored Program Controlled Central Office Equipment.

In the final rules section of this **Federal Register**, RUS is publishing this action as a direct final rule without prior proposal because RUS views this as a noncontroversial action and anticipates no adverse comments. If no adverse comments are received in response to the direct final rule, no further action will be taken on this proposed rule and the action will become effective at the time specified in the direct final rule. If RUS receives adverse comments, a document will be published withdrawing the effective date of the direct final rule and all public comments received will be addressed in a subsequent final rule based on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Comments on this proposed action must be received July 16, 1997.

ADDRESSES: Written comments should be sent to Orren E. Cameron III, Director, Telecommunications Standards Division, Rural Utilities Service, STOP 1598, United States Department of Agriculture, 1400 Independence Ave., SW, Washington, DC, 20250–1598. RUS requires, in hard copy, a signed original and three copies of all comments (7 CFR part 1700.30(e)). All comments received will be available for public inspection at room 2835 (address as above) during regular business hours (7 CFR part 1.27(b)).

FOR FURTHER INFORMATION CONTACT: John J. Schell, Chief, Central Office Equipment Branch, Telecommunications Standards Division, Rural Utilities Service, United States Department of Agriculture, STOP 1598, 1400 Independence Avenue, SW, Washington, DC 20250–1598, telephone number (202) 720–0671.

SUPPLEMENTARY INFORMATION: See the Supplementary Information provided in the direct final rule located in the final rules section of this **Federal Register** for the applicable supplementary information on this section.

Dated: June 9, 1997.

Jill Long Thompson,

Under Secretary, Rural Development.

[FR Doc. 97–15756 Filed 6–13–97; 8:45 am]

BILLING CODE 3410–15–P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30 and 32

RIN 3150–AF70

Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule; request for comments.

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 July 16, 1997. 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: Rulemakings and Adjudications Staff.

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: Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6233 or e-mail at ANT@nrc.gov.

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 ($1,000).

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 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 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 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 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.

Section 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). Because of 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 Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6233 or e-mail at ANT@nrc.gov.

VII. Paperwork Reduction Act Statement

This 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 July 16, 1997. 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 Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6233 or e-mail at ANT@nrc.gov.

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 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:

(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).

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: Secs. 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); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 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. In § 30.8, paragraph (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: Secs. 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. In § 32.8, paragraph (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 10th day of June, 1997.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 97–15697 Filed 6–13–97; 8:45 am]

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DEPARTMENT OF STATE

Bureau of Consular Affairs

22 CFR Part 22

[Public Notice 2555]

Schedule of Fees for Consular Services, Department of State and Overseas Embassies and Consulates, Diversity Lottery Fee

AGENCY: Bureau of Consular Affairs, State.

ACTION: Proposed rule.

SUMMARY: On September 30, 1996, the Immigration and Nationality Act (INA) was amended by section 636 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, (IIRIRA) to authorize the collection of a fee for administering the diversity immigrant visa lottery. The Department is, therefore, amending their regulations accordingly by instituting a $75.00 fee, in the nature of a surcharge, to be paid by applicants issued diversity immigrant visas. Collection of the fee would commence as of October 1, 1997.

DATES: Written comments should be received by July 16, 1997. The anticipated effective date of the final rule is October 1, 1997.

ADDRESSES: Interested persons are invited to submit comments to: Office of the Executive Director, Bureau of Consular Affairs, Room 4820A, Department of State, Washington, D.C. 20520.

FOR FURTHER INFORMATION CONTACT: Sally Light, Office of the Executive Director, Bureau of Consular Affairs, telephone (202) 647–1148; telefax (202) 647–3677.

SUPPLEMENTARY INFORMATION: The Department is instituting a new fee, in the nature of a surcharge, to be paid by applicants for diversity immigrant visas. This additional fee will recover the full costs of the visa lottery conducted pursuant to INA 203 and 222, 8 U.S.C. 1153, 1202, from those successful lottery entrants who actually apply for diversity visas. The fee was authorized by section 636 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, Pub. L. 104–208, 110 Stat. 3009–703–704 (Sept. 30, 1996). A single fee imposed on actual diversity visa applicants will ensure that the costs of administering the lottery and allocating diversity visas are recovered from actual users of the lottery, while avoiding the impracticable imposition of a fee on all visa lottery entrants (technically, visa ''petitioners''). The imposition of a fee on all entrants rather than actual applicants is not feasible, given the millions of entrants, the problems of collecting a uniform fee from individuals all over the world (who will have varying access to U.S. or other international currency), and the burden of having to collect and account for what would be a very small fee from a large number of persons. Roughly seven million entrants have entered the 1998 diversity lottery. Approximately 100,000 of those will be invited to apply for a visa, and of those, approximately 87,000 will apply and pay the fee. The Department's projected cost to administer the 1998 diversity lottery is about $6,500,000, which will be covered by the diversity visa surcharge of $75.00

Provision has already been made in the visa regulations (22 CFR 42.33(i)) governing the diversity visa lottery for a fee of this nature. (See 61 FR 1523.) Thus no regulatory amendments other than an addition of the Schedule of Fees for Consular Services published at 22 CFR 22.1 are required to establish this fee. The new fee is being added as item number 19 on the Schedule of Fees. This will locate it immediately before the other fees for immigrant visas, which diversity visa applicants will also be required to pay (i.e., before the fees for immigrant visa application and issuance).

With the exception of nonimmigrant visa reciprocity fees, which are established based on the practices of other countries, all consular fees are established on a basis of cost recovery and in a manner consistent with general user charges principles, regardless of the specific statutory authority under which they are promulgated. The proposed fee is consistent with these principles and the guidance in OMB Circular A–25, which addressed the establishment of user charges. The fee is based on a cost-of-service study using fiscal year 1995 data that documented and projected into fiscal year 1998 the direct and indirect costs associated with administration of the diversity visa lottery, so as to capture the full cost of service.

Proposed Rule

This rule is not considered to be a major rule for purposes of E.O. 12291, nor is it expected to have a significant impact on a substantial number of small entities under the criteria of the regulatory Flexibility Act, 5 U.S.C. 605(b). This rule does not impose information collection requirements under the provisions of the Paperwork Reduction Act, 44 U.S.C. Chapter 35. This rule has been reviewed as required by E.O. 12988 and determined to be in compliance therewith. This rule is exempt from review under E.O. 12866, but has been reviewed internally by the Department to ensure consistency with the objectives thereof.

List of Subjects in 22 CFR Part 22

Fees, Foreign Service, Passports and visas, Schedule of fees for consular services.

In view of the foregoing, 22 CFR is proposed to be amended as follows:

PART 22—[AMENDED]

1. The authority citation for Part 22 is revised to read: