

§ 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]

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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]

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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
- II. Discussion
- III. Summary of Proposed Amendments
- IV. Agreement State Compatibility
- V. Electronic Access
- VI. Finding of No Significant Environmental Impact: Availability
- VII. Paperwork Reduction Act Statement
- VIII. Regulatory Analysis
- IX. Regulatory Flexibility Certification
- X. Backfit Analysis
- XI. List of Subjects

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 (μ Ci) 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