United States Nuclear Regulatory Commission
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# 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 used to diagnose stomach ulcers to be distributed to any person for administration to humans. Currently only physicians authorized by the NRC or Agreement States may receive and administer 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 to provide high confidence of capsule contents. 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 within 30 days after publication of a Federal Register notice on this subject (expected about June 16). 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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