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NRC CHANGES REGULATIONS TO PERMIT EXEMPT DISTRIBUTION OF RADIOACTIVE DIAGNOSTIC DRUG

The Nuclear Regulatory Commission is amending its regulations to allow a specific radioactive drug used to diagnose stomach ulcers to be distributed to any person for administration to humans. Before this change, only physicians authorized by the NRC or Agreement States could receive and administer the drug.

The change does 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 for rulemaking from Tri-Med Specialties, Inc. The revised regulation allows any person to receive, possess, use and transfer capsules containing one microcurie carbon-14 urea each for diagnostic use in patients. The NRC has determined that the capsules present an insignificant radiation risk, and therefore believes that regulatory control of the diagnostic use of the drug for radiation safety is not necessary.

Under the amendments, manufacturers of the capsules and commercial pharmacies that prepare the capsules will continue to need an NRC license to provide high confidence of capsule contents. The containers of the capsules must bear the words "radioactive material" and other specific information on the contents of the container. In addition, only those persons who are licensed will 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.

Before the change, only physicians who were authorized users (e.g., physicians who met certain training and experience criteria regarding the safe use of radioactive drugs) or persons working under the supervision of an authorized user could administer radioactive drugs for medical purposes.

Under the amendments, physicians or other health care workers will not need to be authorized users in order to administer the drug, and physicians will not need to refer their patients to nuclear medicine physicians. This should result in cost savings to patients, insurers, and the health care industry.

A proposed rule on this subject was published in the Federal Register for public comment on June 16. Minor changes made to the rule as a result of comments received are discussed in a Federal Register notice that will be published shortly.

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