

March 1998

RADIOACTIVE MATERIALS PROGRAM
Bureau of Radiation Control
Information Notice 98-02

NOTICE OF EXEMPTION -- Carbon 14 Urea Breath Test to Detect Presence of H. Pylori Bacteria

NOTICE OF EXEMPTION: Effective Date: March 20, 1998.

In an effort to be consistent with 10 CFR 30.21, the Department of Health exempts from regulation the receipt and use of radioactive material to allow unlicensed persons to receive capsules of one microcurie of carbon 14 urea for "in vivo" diagnostic tests.

Carbon 14 urea capsules are used in breath tests to detect the presence of H. pylori bacteria, which causes stomach ulcers. The small doses of carbon 14 from these tests are of little significance to human health and the environment and the potential long-term impacts from any releases of carbon 14 as a result of these tests are insignificant. This exemption is effective from the date of publication in the Florida Administrative Weekly, March 20, 1998, Volume 24, No. 12, Part XII, (<http://election2.dos.state.fl.us/folio.cgi/2412.nfo?>). The Department is promulgating rules addressing this statement in accordance with s. 120.54(1)(a)1., Florida Statutes.

Attachment 1 is an excerpt from the U.S. Nuclear Regulatory Commission Final Rule 10 CFR 30.21 as published in the Federal Register, Volume 62, No. 231, December 2, 1997. This and other Federal Registers are available at http://www.access.gpo.gov/su_docs/aces/aces140.html.

Attachment 2 is an excerpt of the U.S. Nuclear Regulatory Commission Information Notice Number 97-176 that provides additional information regarding the exemption (<http://www.nrc.gov/OPA/gmo/nrarcv/nr97/97-176.htm>).

This information notice is generally distributed through the Bureau of Radiation Control's Internet Home Page located at www.state.fl.us/health/radiation. If you would like a hard copy of this document, phone or write the department at:

State of Florida
Department of Health
Bureau of Radiation Control
Radioactive Materials Program
1317 Winewood Boulevard
Tallahassee, FL 32399-0700

No specific actions nor written response is required. If you have any questions or need additional information, please contact us at (850) 487-2437.

[Federal Register: December 2, 1997 (Volume 62, Number 231)]
[Rules and Regulations]
[Page 63634-63640]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr02de97-6]

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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: Final rule.

Sec. 30.21 Radioactive drug: Capsules containing 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 capsules containing 37 kBq (1 micro Ci)
carbon-14 urea (allowing for nominal variation that may occur during
the manufacturing process) 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 Sec. 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.

Nuclear Regulatory Commission

Office of Public Affairs

Washington DC 20555

Telephone: 301/415-8200 -- E-mail: opa@nrc.gov

No. 97-176

November 26, 1997

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.

