



JAMES B. HUNT JR.
GOVERNOR

WAYNE McDEVITT
SECRETARY

RICHARD M. FRY
DIRECTOR

May 8, 1998

DRP Information Notice 98-02

Memorandum

To: All North Carolina Medical Licensees
All NC Nuclear Pharmacy Licensees

From: J. Aaron Padgett, Chief
Radioactive Materials Section

Subject: Exemption of Capsules Containing Approximately One microcurie of C-14

Since the December 2, 1997 Federal Register that published an exemption by the Nuclear Regulatory Commission (NRC) for capsules containing approximately one microcurie of C-14 Urea, the NC Division of Radiation Protection (DRP) has been seeking a means to allow use of these capsules in NC for "in-vivo" diagnostic use without regard to the NC radiation protection regulations. We have been successful. Please note that other uses of the C-14 urea capsule will still require a license from either the NC Division of Radiation Protection or the Nuclear Regulatory Commission depending on the type of use. The policy that DRP plans to follow while a permanent rule change is being adopted is as follows:

1. Physicians may obtain capsules containing approximately one microcurie of C-14 Urea for the purpose of "in-vivo" diagnostic use for humans without obtaining a radioactive material license and without regard to the rules and regulations governing the use of radioactive materials in NC.
2. Item one above does not allow physicians to use the C-14 capsules for research. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific radioactive material license from the NC Division of Radiation Protection prior to receipt of C-14 Urea capsules.

3. 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 radioactive material license from the US Nuclear regulatory Commission.

4. Nothing in this policy relieves persons from complying with applicable FDA, other Federal and North Carolina requirements governing the receipt, administration, and use of drugs.

Please either write or call me if you have questions on the above policy.

Sincerely,

Original signed by

J. Aaron Padgett, Chief
Radioactive Materials Section