KANSAS
DEPARTMENT OF HEALTH & ENVIRONMENT
BILL GRAVES, GOVERNOR
Clyde D. Graeber, Secretary

February 22, 2001

KANSAS INFORMATIONAL NOTICE 01-01 LICENSURE OF FLUORINE-18 IN THE FORM OF FLUORODEOXYGLUCOSE (FDG) USED IN POSITRON EMISSION TOMOGRAPHY (PET) STUDIES.

Addressees

All Kansas Medical Radioactive Material Licensees, Kansas Radiopharmacies, PET-NET (Omaha)

Purpose

The Kansas Radiation Control Program is issuing this notice to clarify the manner in which Fluorine-18 will be licensed in the State of Kansas when used in the form of Fluorodeoxyglucose (FDG) for Positron Emission Tomography (PET) studies.

Description of Circumstances

The Kansas Radiation Control Program has been operating under the premise that FDG, being an approved radiopharmaceutical, was allowed to be licensed under the Kansas Medical Groups II or III. Upon closer investigation this has been determined to not be in the best interest of the citizens of Kansas.

Discussion

Under the Modernization Act of 1997, the FDA is directed to establish appropriate procedures for the approval of PET drugs and to establish current good manufacturing practice (CGMP) requirements for PET drugs.

The FDA cannot require the submission of NDA's or abbreviated new drug applications (ANDA's) for compounded PET drugs that comply with United States Pharmacopeia (USP) PET compounding standards and monographs for a period of 4 years after the date of enactment or 2 years after the date that the agency adopts special approval procedures and CGMP requirements for PET drugs, whichever is longer. However, the act does not prohibit the voluntary submission and FDA review of applications before these time periods expire.

Traditionally, drugs for human use are produced by a manufacturer at a single location and transported to

pharmacies for distribution to hospitals and patients. The manufacturing process and location is approved by the Food and Drug Administration (FDA) through the New Drug Application (NDA) process. Because of the short half-life of PET radiopharmaceuticals, PET drug production for distribution must be accomplished by regional cyclotrons, many of which are located in hospitals or universities. Most of these facilities are not equipped to go through the difficult process of obtaining an NDA.

The main reason why PET drugs are new drugs and not generally recognized as safe and effective is that approximately 70 PET centers differ considerably in the way they formulate and manufacture these drugs. Such variations in drug constituents and in manufacturing procedures can significantly affect the identity, strength, quality, and purity of the drugs in a manner that may well adversely affect their safety and effectiveness.

In response to this problem, the PET community, represented by the Institute for Clinical PET, obtained a New Drug Application (NDA) for FDG at the Methodist Medical Center in Peoria, Illinois in August of 1994. Since then, there has been significant controversy over the method to obtain approval for other PET centers.

Some states have already included FDG as an approved drug and do not require specific license conditions for its possession and use. The State of Kansas previously considered FDG to be FDA approved, and therefore covered by the medical groups, but failed to take into consideration that each production site needed a NDA or ANDA. Beginning May 1, 2001 The State of Kansas will require a specific line item in the radioactive material license for Fluorine-18 in the form of Fluorodeoxyglucose (FDG).

Each licensee who possess FDG must amend their radioactive material license prior to May 1, 2001 to add Fluorine-18 in the form of Fluorodeoxyglucose (FDG). Licensees who fail to amend their radioactive material license must cease the use of FDG on May 1, 2001.

Because the State of Kansas previously considered FDG to fall under the medical groups, those licensees who have previously applied for Fluorine-18 in the form of Fluorodeoxyglucose (FDG) to be added to their license and who specifically request their license to be corrected, such correction will be provided at no charge to the licensee.

Licensing Considerations

The addition of Fluorine-18 (FDG) to the radiopharmaceuticals available for use by a nuclear imaging program brings increased risk and, therefore, the need for increased awareness and radiological controls.

- Describe the procurement of shielded equipment designed for the high energy 511 KeV gamma. L-block shields, syringe shields, dose calibrator well.

- Describe an increased awareness in the training provided by the RSO or Medical Physicist which should include:

  Technologists and staff minimizing patient contact time after dose administration, maximizing distance from high radiation sources, and the proper use of available shielding.

Technologists should practice PET receiving, calibrating, and injecting procedures with saline prior to handling PET radiopharmaceuticals.

Stress the wearing of hand and body dosimetry badges

- Describe shielding evaluations performed for the following:

  Storage location for sources, dose receiving and storage areas, dose calibration area, radioactive waste storage area, patient waiting area, injection and uptake area, scanner area and adjacent unrestricted areas.

- Radioactive material - Fluorine-18, Form - FDG, the possession limit and use.

This informational notice does not require any specific action or written response. If you have any questions about the information in this notice, please do not hesitate to contact this office.