Southeast Missouri Hospital
Regional Cancer Center

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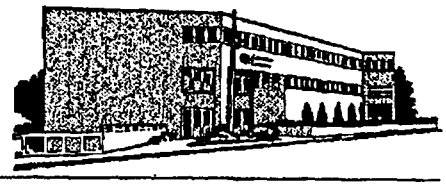
030-0226



www.southeastmissourihospital.com

September 23, 2003

United States Nuclear Regulatory Commission
Region III
ATTN: Colleen Casey
801 Warrenville Road
Lisle, Illinois 60532-4351

Dear Ms. Casey,

This letter is in reference to the Southeast Missouri Hospital materials license #24-00128-03. The license was amended recently to include Iodine-125 as permitted by 10 CFR, 35.1000, to utilize liquid as Iotrex in the GliaSite radiotherapy catheter system by Proxima Therapeutics.

Our intention was for this to be utilized on an outpatient basis at our institution. I believed this was mentioned in our letters that were dated either August 5, 2003 or September 5, 2003. However, based on conversation that you and I had on September 22, 2003, the license is not specifically amended for outpatient use of this therapy.

Therefore, I would like to request an additional amendment on the license to be expedited as soon as possible in that we have a patient with a catheter in place and needs this treatment sometime within the next two or three weeks. She has completed her external beam radiation for a mixed oligoastrocytoma that was recurrent after her first surgery. With her second surgery, the GliaSite catheter was placed in June 2003 and she has now completed her external beam radiation on September 10, 2003 and I am hoping to have the Iotrex administered sometime before October 10, 2003.

We will follow the guidance as specified in NUREG 1556, Vol. 9, Final, appendix U, for release of patients who are released from the hospital prior to GliaSite RTS treatment completion.

RECEIVED
SEP 23 2003
REGION III

1701 Lacey Street • Cape Girardeau, MO 63701 • 1-800-455-4636
Radiation Oncology 573/651-5544 • Outpatient Chemotherapy 573/651-5550

312561

When the patients are discharged with the GliaSite RTS system with Iodine-125 Iotrex, we plan to have the patient return every other day for the duration of the implant to survey the patient to determine whether there has been an unintended leakage of the Iotrex. This will allow the patient to be at home for the four to six days required for this treatment and as stated above, we will have the patient come to the hospital every other day to check for any unintended leakage.

We will inform and educate the patient and responsible family members and care givers for appropriate radiation precautions to take place at the patients home or patients location prior to the GliaSite RTS treatment completion. These instructions will be given to the patient and family in writing.

I appreciate your assistance in this matter and appreciate the promptness with which you are seeking to help us finalize this outpatient treatment amendment.

Please contact me if any further information is needed or required.

Sincerely yours,

Joseph P. Miller, M.D. 9/23/03
Director Radiation Oncology
Radiation Safety Officer
Southeast MO Hospital
JPM/pr

Patrick Bira
Assistant Administrator
Southeast MO Hospital
PB/pr

NOT IN SCOPE

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02230
Status Code: 0
Fee Category: 7C 2B
Exp. Date: 20101130
Fee Comments: _____
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: SOUTHEAST MISSOURI HOSPITAL
   Received Date: 20030923
   Docket No: 3002264
   Control No.: 312561
   License No.: 24-00128-03
   Action Type: Amendment

2. FEE ATTACHED
   Amount: Ø
   Check No.: _____

3. COMMENTS

Signed D. A. Hersey
Date 9-24-2003

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:
   Amendment _____
   Renewal _____
   License _____

3. OTHER _____
   _____

Signed _____
Date _____