Trinitas Hospital
Williamson Campus
225 Williamson Street
Elizabeth, New Jersey 07207

J-1
MS-16

RECEIVED
'05 MAR 11 P 3:11

February 1, 2005

Michele Beardsley
Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406 –1415

RE: **Trinitas Hospital Radioactive Materials License Renewal**
 # 29 – 04333 – 01 Control # 135886 03002476

Dear Ms Beardsley,

This letter is in response to your request for additional information regarding our Radioactive Materials License Renewal Application:

1 The HDR Procedures are attached. (ATT 1)
2 The Emergency Procedures are attached. (ATT 2)
3 The facility diagram of the HDR Room is attached. (ATT 3)
4 The Gliasite Bracytherapy Procedures are attached. (ATT 4)

If you need any additional information please contact me at (908) 994 – 5226 or our consultant physicist Thomas Petrone, PhD. at (718) 815-6807.

Nancy DiLiegro

Nancy DiLiegro, Ph.D
Director of Clinical Services
Administration

135886
NMSS/RGNI MATERIALS-002

Trinitas Hospital
Williamson Campus
225 Williamson Street
Elizabeth, New Jersey 07207

March 4, 2005

Michele Beardsley
Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406 –1415

RE: **Trinitas Hospital Radioactive Materials License Renewal**
 # 29 – 04333 – 01 Control # 135886

Dear Ms Beardsley,

This letter is in response to your request for some additional clarification regarding our Radioactive Materials License Renewal Application:

Gliasite

1 We will report any leaking source to the NRC within 5 days of the leakage test to the locations specified and provide the information identified in 10 CFR 35.3067.

2 Please allow authorization to allow future changes to our radiation safety program, provided the following conditions are met:

(a) the revision is in compliance with the regulations;
(b) the revision is based upon NRC's current guidance for Proxima Therapeutics' GliaSite RTS 35.1000 use posts on the NRC Web site;
(c) the revision has been reviewed and approved by the licensee's radiation safety officer and licensee's management;
(d) the affected individuals are instructed on the revised program before the change is implemented;
(e) the licensee will retain a record of each change for five years; and
(f) the record will include a copy of the appropriate Web site guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

Patient Monitoring Procedures

We have attached the updated Proxima procedure (ATT 1)

HDR Q.C. Checks

1)The timer is checked by watch to make sure that the treatment time is within 1 second of the set time and that the travel time is within 2 seconds of the baseline travel time. The time used is 30 seconds for the treatment time.

2) For daily treatments, the treatment date and time is verified to be correct and matching on the treatment unit and plan. In addition, the source's activity on both is verified by an independent mathematical decay calculation.

3) In addition to the copy of the emergency procedures, If the unit malfunctions, the vendor is called and the door is locked. Signs are placed.

If you need any additional information please contact me.

Nancy Diliegro, Ph.D
Director of Clinical Services- Administrator

ATT. 1

Patient Monitoring

Introduction
The following information describes the recommended action for monitoring a patient during radiotherapy.

Radiation Survey of the patient's head and bladder
Upon completing the Iotrex afterloading and during radiotherapy, ambient radiation exposure rate measurements (with an appropriate survey meter) can be used to monitor for unexpected leakage of radioactive material from the GliaSite catheter. Radiation measurements should be performed at the injection site surface, 20 to 30 centimeters from the injection site, 1 meter from the injection site and over the patient's bladder. These measurements should be repeated daily until the radioactive material is retrieved. Any significant changes from the initial readings (e.g., large decrease in cranial exposure rates concomitant with large increases in bladder exposure rates) should be documented and evaluated for further action as appropriate.

Radiation Survey of Urine Collections
Another method for monitoring the function of the GliaSite catheter during radiotherapy is urine survey. This can be performed as surveys (with an appropriate survey meter) of 24-hour collections of individual urinations or of each urine collection. The action limit for 24-hour collections should be higher than that for an individual urine collection by a factor of approximately 5 (a typical person voids their bladder 5 times daily). This method applies equally well to urine collected in a foley catheter. Approximate calculations of the exposure rates at 1 foot from a large volume of urine containing ^{125}I (assumes inverse square law is valid) indicates that 1 mCi should give a meter reading of 1.6 mR/hr (assuming the meter is calibrated accurately). If the urine survey indicates proper function of the GliaSite, then the urine collected can be flushed down the toilet (verify this with the RSO). Detection of a high level of radiation should be documented and evaluated for further action as appropriate.

Detection of unexpected leakage of radioactive material from the GliaSite catheter (via either method) should be addressed as follows:

1. Notify the Radiation Safety Office and the Radiation Oncologist.
2. The remaining Iotrex should be retrieved.
3. Provide additional thyroid blocking to patient and hydrate orally or via intravenous line.
4. Monitor urine activity levels for 24-48 hours after retrieval of Iotrex.
5. When urine activity levels drop to acceptable levels, surgically remove GliaSite from patient, observing radioactive material precautions. (The external surfaces of the GliaSite and the resection cavity are most likely radioactive.)
6. Determine whether a misadministration has occurred. Upon discovery of a misadministration, follow all notification and reporting requirements as required by state and/or NRC regulations.