UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 27, 2005

Docket No. 03002466 License No. 29-03089-01
Control Nos. 136983
136909

Michael A. Medina
Assistant Vice President of Operations
Somerset Medical Center
110 Rehill Avenue
Somerville, NJ 08876-2598

SUBJECT: SOMERSET MEDICAL CENTER, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATIONS FOR AMENDMENT TO LICENSE, CONTROL NOS. 136983 and 136909

Dear Mr. Medina:

This is in reference to your letters dated April 18 and 26, 2005, requesting to amend Nuclear Regulatory Commission License No. 29-03089-01. In order to continue our review, we need the following additional information:

1. You have requested that Mr. Vincent Immerso be named Radiation Safety Officer (RSO) on your license. Mr. Immerso is listed on 2 other NRC licenses as RSO. In addition, it appears that this individual may be an outside consultant\contractor. If this is so, in support of this request, please address the following:

   a. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.

   b. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.

   c. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).

   d. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.

e. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.

2. With regard to your request to use the GliaSite device, please address the following:

a. Confirm that you will follow all of the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use except as described in Items 5-12 of your letter dated April 18, 2005.

b. Indicate which authorized users will use the GliaSite device and confirm that they will receive the vendor training in use of the Proxima Therapeutics GliaSite RTS prior to use of the device.

c. Confirm that the written directive will include the treatment site prior to implantation.

d. Item 7 of your amendment request states that one method you may use to assess GliaSite integrity during brachytherapy is periodic radiation exposure measurements (in the vicinity of the injection site and patient's bladder), but that this method will not be used exclusively. When using this method to assess catheter leakage, how often will you take radiation exposure measurements? In addition, please specify the method you will use to assess catheter leakage in cases when you do not perform radiation exposure measurements.

e. Item 7 of your amendment request addressed outpatient GliaSite treatment and stated that you will substantially follow the model guidance in NUREG-1556, Vol. 9, Appendix U, but that you will make minor changes necessary to satisfy 10 CFR 35.1000. With regard to outpatient treatments with the GliaSite device, please address the following:

i. Describe your minor changes to the guidance in Appendix U.

ii. Describe criteria for identifying patients who are suitable candidates for outpatient treatment.

iii. Provide the maximum hospital stay time following injection of the Iotrex before release as an outpatient.

iv. Provide procedures for assuring that the balloon catheter does not leak while the patient is at home.

v. Describe surveys to provide reasonable assurance that no member of the general public will receive more than 0.5 rem pursuant to 10 CFR 35.75.

vi. Provide a copy of the radiation safety instructions provided for outpatients receiving GliaSite treatments that address shielding and contamination control (e.g., lead skull cap, toilet in their home for their sole use during the treatment, any restrictions on patient mobility during GliaSite treatment such as remaining at home and refraining from traveling by automobile except for trips to and from the doctor or hospital). In addition provide a copy of the emergency instructions that you will provide to the patient.

vii. Describe how you assure that the patient will return to the hospital for removal of the Iotrex.

f. Item 8 of your letter describes "off-label" use where the drained GliaSite device will be left in place within the patient. Please confirm that no radioactivity will be left in place.

g. Confirm that balloon leakage (i.e., leaking source), as determined by imaging and/or radiation surveys, will be reported to the NRC within 5 days of the leakage test and that the information described in 10 CFR 35.3067 will be provided.

h. Your "Patient Monitoring" procedure is marked "Proprietary and Confidential to Proxima Therapeutics, Inc." This information may be placed in the public record unless information to support withholding pursuant to 10 CFR 2.790 is submitted and approved.

Current NRC regulations and guidance are available at the NRC web site at http://www.nrc.gov/materials/miau/mat-toolkits.html and http://www.nrc.gov/who-we-are/governing-laws.html or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 136983. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5169.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
Robert M. Jaffe, M.D., Radiation Safety Officer

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