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

July 26, 2005

Docket No. 03002522 License No. 29-09701-01
Control No. 137092

Tim Hogan
President
Riverview Medical Center
One Riverview Plaza
Red Bank, NJ 07701

SUBJECT: RIVERVIEW MEDICAL CENTER, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 137092

Dear Mr. Hogan:

This is in reference to your application dated May 18, 2005 requesting to renew Nuclear Regulatory Commission License No. 29-09701-01. In order to continue our review, we need the following information:

1. Please provide manufacturers and model numbers for all 35.400 manual brachytherapy sources that you currently possess or may use in the future. It is not necessary to submit information for palladium-103 sources, as currently available sources are produced in a cyclotron and are not licensed by NRC.

2. Item 7 of your application identifies Robert Wold, M.D. as “Acting” Radiation Safety Officer (RSO). Although 10 CFR 35.24 has a provision for a temporary RSO for up to 60 days each year, Dr. Wold has been Radiation Safety Officer on your license for over a year. NRC will regard Dr. Wold as the permanent RSO until you submit an amendment request to name a different RSO. No response to this item is necessary.

3. Item 7.1 of your application lists Frederick J. Zito, M.D. as an authorized user (AU) for 35.100, 35.200, and 35.300 and states that he is currently listed as an AU on your license. Please note that Dr. Zito is not currently listed as an AU on your license, however he is listed as AU for these uses on license 29-30606-01 issued to Central Jersey Radiologists. We will add Dr. Zito to your license as part of this renewal. If you need this to be done more quickly, please submit an expedited amendment request.

4. Item 7.1 of your application lists two authorized medical physicists (AMP’s) for high dose rate remote afterloading (HDR), however your license does not authorize you to perform HDR, nor have you requested to add this authorization. Your current license lists Satya Hirannaiah Narayana as AMP for your strontium-90 eye applicator, however your renewal application does not provide an AMP for the eye applicator. Please clarify

5. Item 9 of your application referred to an attached diagram of the nuclear medicine section, however no diagram was attached. Please submit this diagram as well as

diagrams of the locations of storage of your brachytherapy sources and strontium-90 eye applicator. Please indicate the position of each of the areas described below, including shielding. Exhibit 6 of NUREG-1556, Vol. 9 may be helpful in preparing your response and provides an example of a facility diagram that is acceptable to the NRC.

a. Use and storage of Tc-99m generators (if applicable).

b. Storage of radiopharmaceuticals (refrigerated and nonrefrigerated).

c. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. If this area is not located within your main department, describe how you will secure the material.

d. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block, etc.).

e. Storage of your 35.400 manual brachytherapy sources and strontium-90 eye applicator.

In addition, identify adjacent areas across the walls from use and storage locations and show that adequate steps have been taken to assure that radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301.

6. Item 9 of your application lists radiation monitoring instruments. If you perform iodine-125 prostate brachytherapy procedures, please specify the survey instrument used to identify dislodged sources. This instrument should be equipped with a thin sodium iodide crystal detector probe in order to maximize sensitivity for detection of iodine-125.

7. If you perform any radiopharmaceutical therapy or manual brachytherapy procedures for which the patient cannot be released under the provisions of 10 CFR 35.75, please provide a description of the inpatient rooms where they are housed, including any shielding. Confirm that patients undergoing iodine-131 treatments are housed in a private room with a private bathroom. Describe the emergency response equipment used for patients undergoing manual brachytherapy procedures.

8. Your application requests to continue your authorization to use Proxima Therapeutics GliaSite RTS system. Please review the current NRC licensing guidance for this modality at http://www.nrc.gov/materials/miau/med-use-toolkit/liquid-brach.html. Confirm that:

a. An authorized user with experience in radiopharmaceutical therapy procedures will be on call to provide guidance in case of leakage of the implanted device.

b. You will follow all of the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use, except where the following license conditions provide regulatory relief:

(1) For brachytherapy using Proxima Therapeutics' GliaSite® RTS, "prescribed dose" means the total dose documented in the written directive.

(2) The written directive will include (1) before implantation: the treatment site, the radionuclide (including the chemical/physical form [Iotrex™]), and dose; and (2) after implantation but before completion of the procedure: the radionuclide (including the chemical /physical form [Iotrex™]), treatment site, and the total dose.

(3) Your procedures will specify how to confirm that the balloon does not leak before injection of the Iotrex™ or while Iotrex™ is implanted in the patient or human research subject.

(4) You will define "Source leakage" for the Iotrex™ implanted in the GliaSite® RTS as leakage of I-125 that results in a dose that exceeds 0.5 Sv (50 rem) dose equivalent to any individual organ other than the treatment site (based on definition of a medical event).

(5) You will retain a record of the leak test for three years (the period that 10 CFR 35.2067 requires for brachytherapy sources).

(6) You will report a leaking source to the NRC within five days of the leakage test to the locations specified and provide the information identified in 10 CFR 35.3067.

(7) You will provide instructions on how to safely handle contamination of unsealed materials, in addition to the instructions required by 10 CFR 35.410, "Safety instructions."

(8) If Iotrex™ is placed in vials, syringes, or radiation shields that are not labeled by the manufacturer, you will label syringes and syringe radiation shields with the radioisotope, form, and therapeutic procedure (i.e., I-125 Iotrex™ for brain brachytherapy) and you will label vials and vial radiation shields with the radioisotope and form (i.e., I-125 Iotrex™).

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. 137092. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5182.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Original signed by Sandra Gabriel

Sandra Gabriel
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

cc:
Robert E. Wold, M.D., Radiation Safety Officer
Michael Cammarano, Radiology Manager

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SISP Review Complete: (SLG)
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