



July 21, 2006

Sandy Gabriel
Senior Health Physicist
Medical Branch; NRC Region 1
U.S.N.R.C.
475 Allendale Road
King of Prussia, PA 19406-1415

K-8
MS-16

Re: Request for Information 03003011
License # 37-01873-01
Mail Control No.: 138885

Dear Ms. Gabriel:

The following are the responses to the questions posed in your request for additional information dated 7/14/06 and are listed in the order offered

1. Patients will be housed on our main campus location at 1086 Franklin Street. Patients will be housed in private rooms with private baths.
2. We would like to request a maximum possession limit for the GliaSite Therapy system of 8 curies.
3. Yes, we also request to authorize Dr. Harmon (letter dated June 13) for use of the GliaSite RTS system.
4. We confirm that an authorized user with experience in radiopharmaceutical therapy procedures will be on call to provide guidance in case of leakage of the implanted device.
5. a) We agree that the "prescribed dose" will mean the total dose recorded on the written directive.
b) We confirm that the written directive will include (1) before implantation: the treatment site, radionuclide chemical/physical form, dose and (2) after implantation but before completion of the procedure: the radionuclide including the chemical form, treatment site and total dose.
c) The balloon and catheter system will be tested for leakage prior to insertion in the operating room using sterile normal saline injected into the catheter and balloon and inspected for leakage.
d) We will define "source leakage" for Iotrex implanted in the GliaSite RTS as a leakage of I-125 that results in a dose that exceeds 0.5 Sv or 50 rem dose equivalent to any individual organ other than the targeted treatment site.

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NMSS/RGN MATERIALS-002



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- e) Records of GliaSite RTS leakage testing will be kept for three years.
 - f) "Safety Instructions" will provide instructions on how to safely handle contaminated unsealed materials, in addition to the instructions required by 10 CFR 35.410.
 - g) If Iotrex is placed in vials, syringes or radiation shields not labeled by the manufacturer, we will label these vessels with the radioisotope, form, and therapeutic procedure and we will label vials and vial radiation shields with the radioisotope and form.
6. We confirm that we will follow the manufacturer's procedures to assure that contrast medium will not inadvertently shield the dose
7. We withdraw our request for "exemption" made in Item 9 of our original submission. Instead, we provide this statement: Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose excess of 10% of allowable limits in 10 CFR Part 20 or we will provide radiation dosimetry that meets the requirements listed under "criteria" in NUREG-1556, Vol.9, Rev. 1, "Consolidated Guidance About Medical Use Licensees."

It is hoped that the following responses meet your concerns. If you have any additional questions concerning our initial application or this response, please feel free to contact our medical physics consultant, Keith Ostrom, Associates in Medical Physics, LLC at 1-800-709-4855 Ext. 31 or Randy Kutchman, Operations Manager – Radiology/Nuclear Medicine at 1-814-534-6032.

Sincerely,

Richard M. Sukenik
Vice-President
Conemaugh Valley Memorial Hospital

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