SAINT PETER'S UNIVERSITY HOSPITAL

254 Easton Avenue, PO Box 591
New Brunswick, NJ 08903-0591
732-745-8600 • www.saintpetersuh.com

MS16

K-8

Licensee: St. Peter's University Hospital
License No.: 29-07566-01
Docket No.: 03002502
Control No.: 140559

July 16, 2007

To: Sandra Gabrielle
Senior Health Physicist
Nuclear Regulatory Commission

This is in response to your email requesting additional information regarding our amendment application for the use of GliaSite RTS.

1. Confirm that your request is for use of the Cytyc Surgical Products GliaSite Radiotherapy System (RTS) with the I-125 Iotrex liquid brachytherapy source. [Cytyc now provides a second GliaSite system called the GliaSite Spectrum System, however the NRC has not yet developed licensing guidance for the Spectrum System, as we have not received any requests.]

We confirm that this request is for use of the Cytyc Surgical Product GliaSite Radiotherapy System (RTS) with the I-125 Iotrex liquid brachytherapy source.

2. Specify the maximum possession limit of I-125 Iotrex that you wish to request. [1320 millicuries is the maximum activity permitted per device. Your requested possession limit should be sufficient to cover all I-125 Iotrex that may be in your possession at any one time, including waste.]

The maximum possession limit of I-125 Iotrex that we request is 2700 millicuries.

140559

NMSS/RGN1 MATERIALS-002

3. Name the authorized users (meeting the requirements for 35.400 AU) and confirm they will receive vendor training in the use of the GliaSite RTS system before performing any cases. Also confirm that you (as RSO) and other staff members directly involved in preparation and handling of I-125 Iotrex will receive the vendor training before performing any cases.

The authorized users (meeting the requirements for 35.400) will be as follows:

Gopal R. Desai, M.D.
Alexander Z. Haas, M.D.
Robert Knee, M.D.

We confirm that the Authorized Users will receive vendor training in the use of the GliaSite RTS system before performing any cases. The Radiation Safety Officer and other staff members involved in preparation and handling of I-125 Iotrex will receive the vendor training before performing any cases.

4. Provide the locations where the Iotrex will be prepared and administered. If patients are unable to be released from the hospital, identify the inpatient room(s) where the patients will be housed and confirm that these are private rooms with private baths. If you have not already provided to the NRC room diagrams of the locations where Iotrex will be prepared, administered, and inpatient rooms, please submit these.

The Iotrex will be prepared in the Nuclear Medicine Hot Lab and administered in one of the Radiation Oncology treatment rooms (see Attachment 1).

If patients are unable to be released from the hospital, the patients will be housed in one of the patient rooms on the 1G Oncology Nursing Unit. See Attachment 2. Each of these rooms either is a private room or will be converted to a private room. In addition, all of the rooms have a private bath.

5. 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. Also, confirm that an individual with experience in managing contamination from radiopharmaceutical therapy procedures will be on-site during all direct handling of Iotrex.

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. This will be one of the individuals authorized for 35.300. Additionally, an individual with experience in managing contamination from radiopharmaceutical therapy procedures will be on-site during all direct handling of Iotrex. This will be the RSO or his delegate who has experience managing contamination from radiopharmaceutical therapy procedures.

6. Confirm that, for brachytherapy using Cytyc Surgical Products GliaSite RTS, you will follow all of the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use, except where items a) through h), listed below, provide regulatory relief. Also confirm that you will follow items a) through h), listed below (you may repeat or paraphrase the text of each item):

a) "Prescribed dose" will mean the total dose documented in the written directive.

"Prescribed dose" will mean the total dose documented in the written directive.

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

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

c) Your procedures will specify how to confirm that the balloon does not leak before injection of the Iotrex or while the Iotrex is implanted in the patient.

Our procedures will specify how to confirm that the balloon does not leak before injection of the Iotrex or while the Iotrex is implanted in the patient.

d) 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.

We 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.

e) You will retain a record of the leak test for three years (the period that 10 CFR35.2067 requires for brachytherapy sources).

Diagnostic quality images will be obtained with the GliaSite catheter inflated, demonstrating the continued capability of the catheter to maintain its inflated fluid volume. The images used in this assessment will be kept in the patient's medical records as required by state regulations. The leak tests typically required of brachytherapy sources (e.g., removable contamination) are not possible as the GliaSite catheter is completely subcutaneous while the radioactive material resides within it. In addition, the SSDR document states leak tests are not applicable to the GliaSite system.

f) You will report a leaking source to the NRC within five days of the leakage test, providing the information described in 10 CFR 35.3067. You will send the report to the locations specified in 10 CFR 35.3067.

We will report a leaking source to the NRC within five days of identifying source leakage that results in a dose that exceeds 0.5Sv (50 rem) dose equivalent to any individual organ other than the treatment site.

g) 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."

We will provide instruction on how to safely handle contamination of unsealed material, in addition to the instructions required by 10 CFR35.410, "Safety Instruction."

h) 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).

If Iotrex is placed in vials, syringes, or radiation shields that are not labeled by the manufacturer, we 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).

7. Provide your procedure for ensuring that the balloon does not leak before injection of the Iotrex or while the Iotrex is implanted in the patient. It is unclear whether you are committing to follow the "Assessing Device Integrity Following Afterloading" section of the "Patient Release Justification" provided by Proxima Therapeutics and attached to your amendment request. Specify any differences in your procedure for inpatients vs. outpatients (for example, timing of surveys).

To ensure that the balloon is not leaking before injection of the Iotrex, the volume of solution extracted from the balloon will be measured and compared with the volume infused at the time balloon was surgically inserted.

Prior to the afterloading of the I-125 Iotrex solution, a survey of the patient will be performed using the appropriate gm survey meter. The results of the survey will be recorded. Within 15 minutes of the completion of the afterloading, a repeat survey will be performed with the same survey instrument at two hours following the afterloading of the Iotrex. The results will be recorded. It is expected that the exposure rate at the bladder will be less than 10% of the exposure rate at the injection site.

8. Provide your procedures or confirm that you will follow the manufacturer's procedures to assure that contrast medium does not inadvertently shield the dose.

We will follow the manufacturer's procedures to ensure that contrast medium does not inadvertently shield the dose.

9. How will you confirm that the prescribed dose was delivered? Will this be done by volumetric determination or some other method?

We will determine that the prescribed dose was delivered by volumetric determination.

10. Regarding your request to authorize outpatient GliaSite treatments:

a) Items 1 and 2 of your amendment request say that you will instruct patient the to stay within the confines of their home and yard during treatment, however your submitted patient instructions and patient release determination form do not include this specific instruction. Please add this specific instruction to your forms.

See attached instruction form.

b) How long will you require the patient to remain at the hospital following injection of the Iotrex before you release them?

The patient will be required to remain at the hospital for two hours following the injection of the Iotrex. Upon completion of the survey of the injection site and bladder, the patient will be released to go home.

c) What instructions for emergency medical care will you provide to patients?

The patient instruction form will list a contact name and phone number in the event of an emergency.

Instructions will state that the patient contains a radioactive substance in a balloon in the brain and to use universal precautions. Administer life-saving care as necessary.

d) How will you assure that the balloon catheter does not leak while the patient is at home?

The Authorized User will evaluate each patient for their ability and willingness to comply with outpatient release instructions for GliaSite. Patients approved for outpatient therapy will be given written and verbal instructions stressing radiation safety and contamination prevention precautions as well as the date and time for return to the hospital for retrieval of the Iotrex. In addition, we will call the patient and /or one of their caregivers or family members within 24 hours prior to the retrieval date and time, reminding the patient to return for the retrieval procedure.

There is no plan to routinely monitor with a survey meter the patients who are approved for outpatient therapy once they leave the hospital and prior to their return for the retrieval procedure.

e) Will you instruct patients to, if feasible, designate a toilet in their home for their sole use during the treatment?

We will instruct patients to designate a toilet in their home for their sole use during the treatment. This will not be a criteria for approval for outpatient therapy.

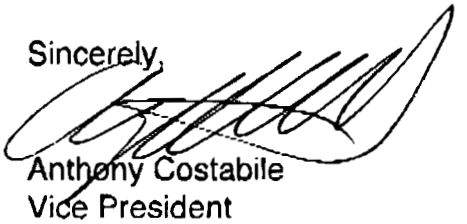
f) Item 3 of your amendment request says that the written instructions and patient evaluation form clearly state the date and time of return, and the patient signs to acknowledge this information. How will you assure that the patient will return to the hospital? (possible examples: reminder telephone calls, provision of transportation if needed, procedure to follow if patient does not return at the designated time)?

We will call the patient within 24 hours prior to the retrieval date and time, reminding the patient to return for the retrieval procedure. If the patient does not return for the retrieval procedure, we will first make contact with the patient immediately. If it appears that, the patient does not intend to return to the hospital for the retrieval procedure we will initiate a plan to go and bring the patient to the hospital for the retrieval procedure.

Because patients will be interviewed and selected based on their willingness to cooperate with the restrictions we believe it is unlikely that a patient will refuse to return to the hospital for the retrieval procedure.

Thank you for your assistance with this matter.

Sincerely,

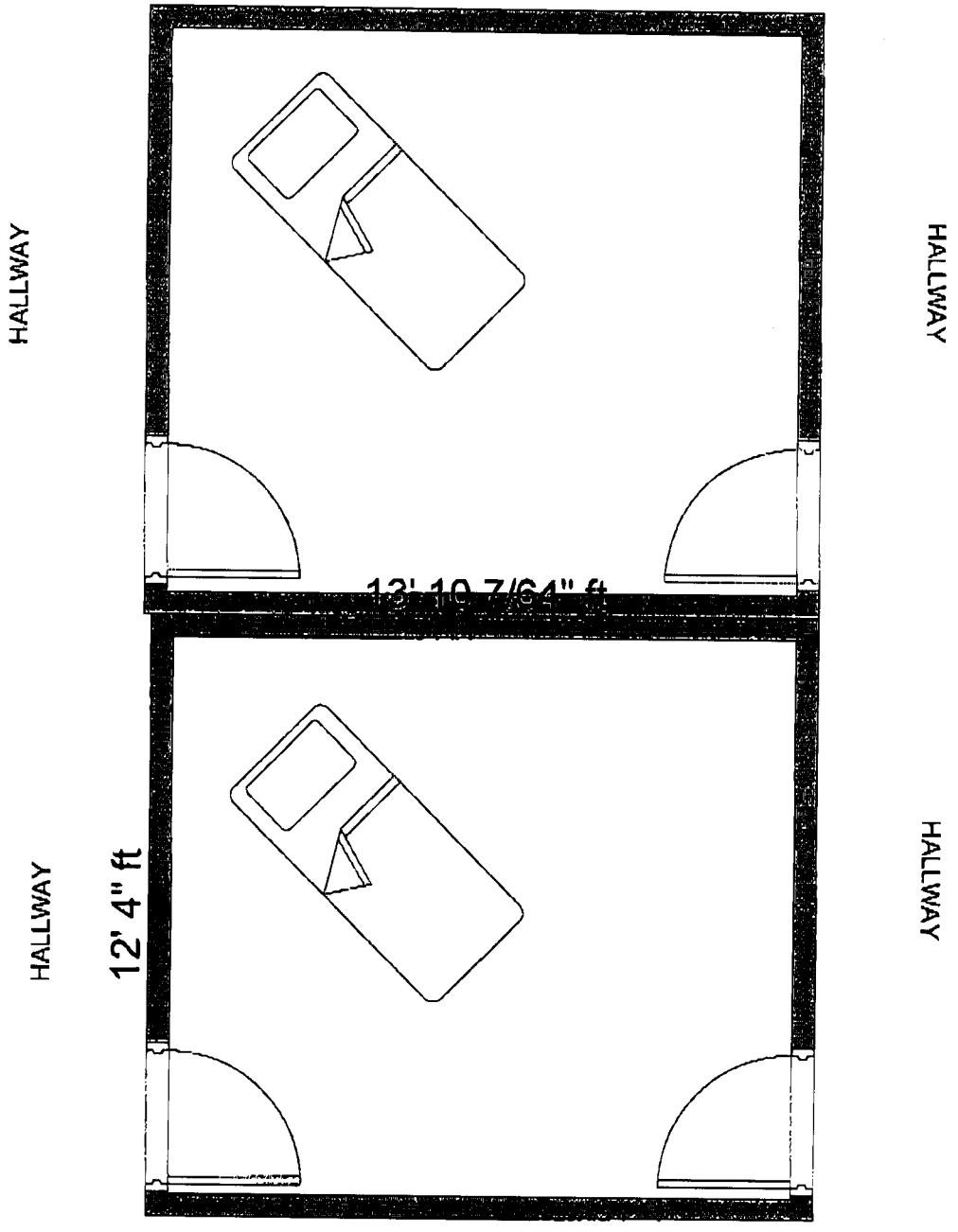


Anthony Costabile
Vice President
Professional Services

HALLWAY

RADIATION ONCOLOGY
TREATMENT ROOMS FOR
ADMINISTRATION

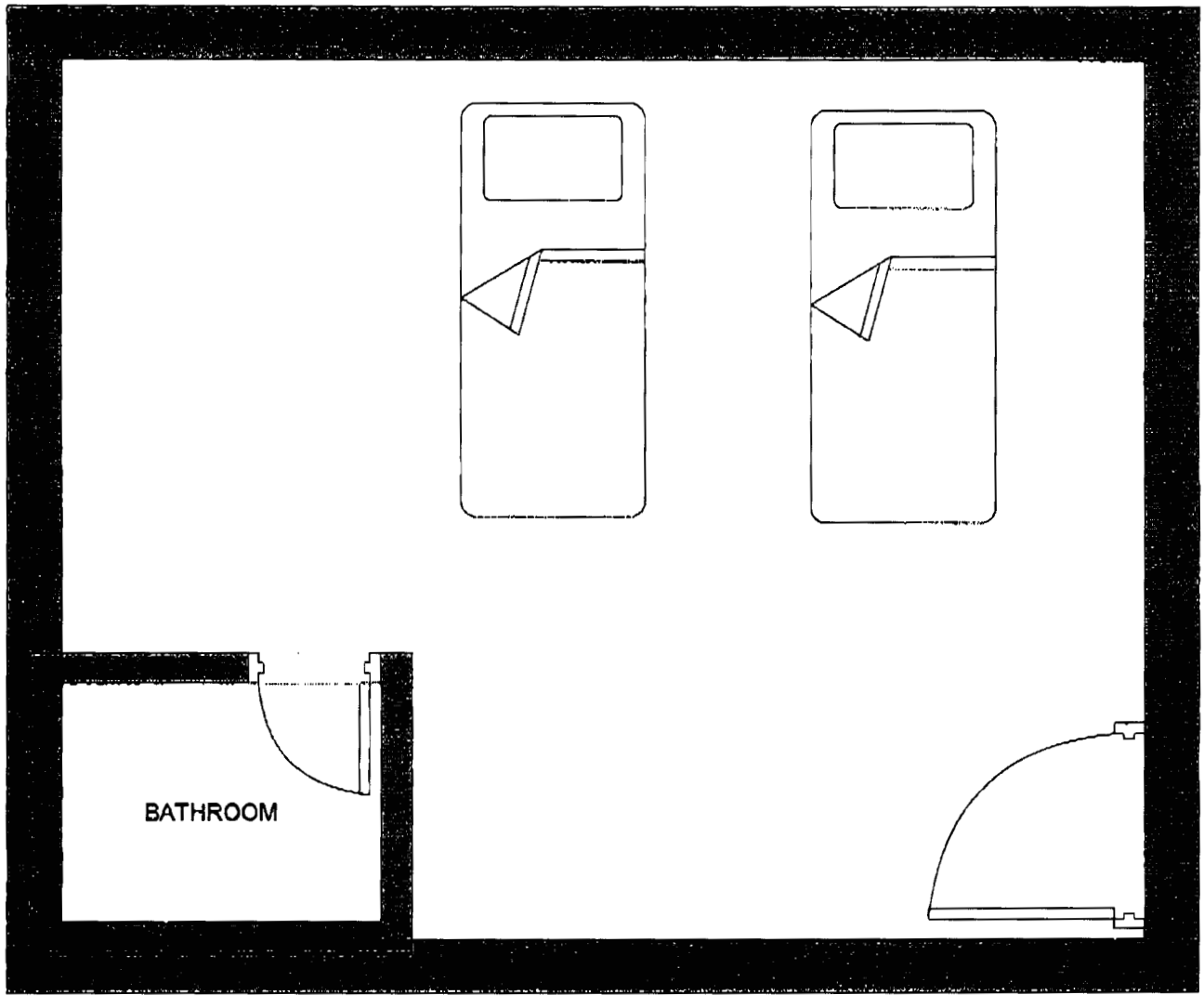
CONTROL 140559
ATTACHMENT 1



CONTROL 140559

ATTACHMENT 2

SAINT PETERS UNIVERSITY HOSPITAL
TYPICAL PATIENT ROOM ONCOLOGY NURSING UNIT



Patient Instructions: Outpatient Therapy with the GliaSite® RTS

In order to release a patient undergoing radiotherapy with the GliaSite RTS, written and verbal instructions should be given to the patient and understood by the patient. These instructions are meant to provide guidance in the good practices of radiation safety and contamination prevention for these patients.

For the duration of the outpatient therapy:

1. Sleep alone and keep a minimum distance of 10 feet from other people sleeping. If possible sleep in a room by yourself.
2. Do not return to work or participate in any volunteer activities away from home.
3. Maintain a prudent distance from other people as much as possible (e.g. > 3 feet).
4. Keep the toilet especially clean by flushing twice after use. Men should sit during urination. **Wash hands** thoroughly after using toilet.
5. Refrain from traveling by airplane or other mass transportation.
6. Refrain from traveling by automobile except for trips to and from doctor/hospital.
7. Stay within the confines of your home and yard during treatment.
8. Avoid contact with children (< 18 yrs. old) and pregnant women. Keep a minimum distance of 10 ft.
9. Terminate breast feeding (if applicable)
9. **Remember to return to hospital on scheduled Date and Time: _____ AM/PM _____**
   (circle one) (Date)
10. In case of emergency or if you have any questions, call _____ at _____

It is important to remember that these instructions are intended to keep yourself and others around you safe while you are at home during this radiation therapy treatment. Do not deviate from any of the above instructions.

I have received these instructions and fully understand them:

_____	_____	_____	_____
Patient signature	Date	Signature of responsible family member or guardian	Date

These instructions were given by:

_____	_____
Signature (Authorized User or their Representative)	Date