From: Sandra Gabriel
To: Robert Tokarz
Date: Fri, Jul 6, 2007 2:19 PM
Subject: Additional information for St. Peter's amendment request, mail control 140559

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

To: Bob Tokarz, RSO

This is in response to the amendment request to authorize outpatient use of GliaSite. Please provide the following additional information within 30 days, referencing mail control 140559.

Please note that you may not provide an official reply to this message by return e-mail. The reply must be signed by a member of senior management and submitted in writing by letter or fax (610-337-5269). If a fax is sent, you may wish to alert me by e-mail or voicemail so that I will know to retrieve it. If we do not receive a response within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue this request.

Please send an e-mail to confirm receipt of this message.

The NRC licenses GliaSite use under 10 CFR 35.1000. In order to consider your request to perform outpatient GliaSite treatments, it is necessary to also provide a complete GliaSite application. Many of the questions listed below are from the GliaSite licensing guidance on the NRC public website at http://www.nrc.gov/materials/miau/med-use-toolkit/liquid-brach.html .

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.]

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.]

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.

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.

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.

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.

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.

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.

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.

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

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.

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."

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).

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).

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.

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

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.

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

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

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

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

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)?

Thank you for your help. If you have any questions, you may e-mail me or call at 610-337-5182. I will be away from July 16-20.

Sandy Gabriel
Senior Health Physicist
Medical Branch
NRC Region I

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From: Sandra Gabriel

Created By: SLG2@nrc.gov

Recipients
verizon.net
robert.tokarz (Robert Tokarz)

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	verizon.net

Files	**Size**	**Date & Time**
MESSAGE	9808	Friday, July 6, 2007 2:19 PM

Options

Expiration Date:	None
Priority:	Standard
ReplyRequested:	No
Return Notification:	None
Concealed Subject:	No
Security:	Standard