



DePaul Health Center

DEPAUL CANCER CARE

4-22-08

Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region (III)
2443 Warrenville Rd STE 210
Lisle, Ill 60532-4352

Re: License Amendment Application for License No. 24-02490-03 and fax dated 3-31-08

DePaul Health Center is submitting the requested changes outlined in the fax dated 3-31-08 (control number 316786) that your office sent. Attached to this letter you will find the modified documents specific to this request.

If you have any questions regarding this application, please contact me at (314) 344-6090. Thank you for your consideration.

A handwritten signature in black ink, appearing to read 'T. P. Bocchini'.

Thomas Philip Bocchini, M.D
Radiation Safety Officer

RECEIVED MAY 06 2008



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Request for Amendment of the DePaul Hospital

Radioactive Materials License

To Add the Cytoc Surgical Products' Gliasite® Brachytherapy Systems

Specifically, this licensee wishes to add the following line item to our license:

Material in 10CFR35.1000

- **Radionuclide:** I-125
- **Physical Form:** an aqueous solution containing Na-3-[I-125] Iodo-4-hydroxybenzenesulfonate (Iotrex)
- **Inventory Limit:** as needed (or 8 Ci)
- **Purpose:** Brachytherapy with the Gliasite catheter

This line item amendment request follows the format and content of the NRC guidance published on the NRC web page (<http://www.nrc.gov/materials/miau/med-use-toolkit/liquid-brach.html>).

Liquid Brachytherapy Sources and Devices

Licensing Guidance – I-125 Iotrex™ Liquid Brachytherapy Source in Cytoc Surgical Products' Gliasite® Radiation therapy System:

The licensee is requesting a line item amendment to use the Cytoc Surgical Products' Gliasite Catheters and Iotrex. Iotrex is a liquid brachytherapy radioactive source and the Gliasite catheters are used to temporarily contain the Iotrex during brachytherapy. The Gliasite catheters are listed on the U.S. NRC Sealed Source and Device Registry (GA-1148-D-101-S).

1. We will follow all radiation safety program elements previously committed to in our current license for the use of materials in 10 CFR 35.400 in the use of iodine-125 Iotrex in the Gliasite RTS system, except as specifically noted otherwise.
2. Cytoc Surgical Products will provide training for the authorized user(s), medical physicist, and nuclear medicine technologist prior to the licensee performing the first brachytherapy procedure using the Gliasite in patients.
3. All personnel will adhere to current procedures for the safe handling of unsealed radioactive material and techniques to minimize radioactive contamination. In addition instructions required by 10 CFR 35.410 will be given to the appropriate staff.



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4. The authorized user for this procedure will be Venkata Rao Devineni, M.D. The user is on our existing license and meets the training requirements outlined in 10 CFR 35.490.
5. The licensee will have an authorized physician user with experience in radiopharmaceutical therapy procedures available "on call" to provide guidance and assistance in case of actual or suspected leakage of the implanted device.
6. Our Written Directive for brachytherapy using Proxima Therapeutics Gliasite RTS, the "prescribed dose" means the total dose documented in the written directive in units of Gy.
7. Our Written Directive for brachytherapy using Proxima Therapeutics Gliasite RTS catheters will include:
 - a. Prior to implant
 - i. The treatment site
 - ii. the radionuclide (I-125)
 - iii. the chemical/physical form (Iotrex)
 - iv. prescribed radiation dose (Gy)
 - b. Post implantation but prior to completion of the procedure
 - i. The treatment site
 - ii. the nuclide (I-125)
 - iii. the chemical/physical form (Iotrex)
 - iv. administered dosage of Iotrex (mCi)
 - v. dwell time (hours)
 - vi. Total dose (Gy)
8. For patients treated during brachytherapy on an outpatient basis, we will follow the model guidance provided in US NRC NUREG – 1556, vol. 9, Appendix U in releasing these patients for the duration of their brachytherapy treatment, making only the minor changes necessary to satisfy 10 CFR 35.1000. Documentation demonstrating compliance with Section 35.75 requirements that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv is provided. Documentation includes forms describing the evaluation process for determining which patients are suitable for outpatient treatment, calculation for duration of outpatient release, patient release justification, and appropriate patient instructions (see attachments A-D).
9. The authorized user will evaluate each patient for their ability and willingness to comply with outpatient release instructions. Patients and/or their care givers will be given written

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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 lotrex.

10. Prior to afterloading the lotrex, the integrity of the GliaSite catheter will be determined by fluid inflation prior to implant in the operating room, fluid inflation under visual inspection in the surgical cavity at the time of implant, imaging using one of a variety of imaging modalities such as MRI, CT or radiographs several days post implant, and fluid retrieval immediately prior to afterloading lotrex. The images used in this assessment will be kept in the patient's medical records.
11. Upon completing the lotrex afterloading, radiation measurements will be performed at:
 - a. the injection site surface
 - b. 20-30 cm from the injection site
 - c. 1 meter from the injection site
 - d. Patient's bladder.

The patient will remain onsite for 1 hour and the measurements will be repeated. The patients will be asked to return to the hospital for daily measurements until the lotrex is retrieved. Any significant changes from the initial readings (greater than 30%) will be documented and evaluated for further action as appropriate.

12. The licensee will evaluate all events which occur involving the unexpected loss of retained radioactivity in the catheter. Source leakage for the lotrex implanted in the Gliasite RTS means leakage of I-125 that results in a dose of 0.5 Sv (50rem) dose equivalent to any individual organ other than the treatment site.
13. If it is determined that the balloon catheter leaked during brachytherapy, then it will be reported to the NRC within 5 days of the discovered leakage in accordance with 10 CFR 35.3067.
14. Licensee will retain a record of the leak test for three years in accordance with 10 CFR 35.2067.
15. Thyroid bioassays will not be performed. Data from other institutions using the GliaSite RTS system demonstrate that air concentrations of radioiodine are below minimum detectable levels. In addition, no radioiodine uptake has been observed on thyroid bioassay at these facilities or during the initial safety and performance clinical trial.
16. The licensee will label syringes, syringe shields, vials and vial shields with the form of the byproduct material (e.g., I-125 lotrex). Syringes and syringe shields will also include the procedure (e.g., GliaSite or brain brachytherapy).



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17. The licensee will follow Cytoc Surgical Products' instructions regarding limitations on x-ray contrast concentration (e.g., < 25% by volume). At the conclusion of brachytherapy, compliance with the Written Directive will be demonstrated by volumetric retrieval of the afterloaded Iotrex (and saline) volume to within 80% of the volume infused at the start of brachytherapy.

Cytoc Surgical Products has determined that when a radiopaque dye with 330 milligrams of iodine per millimole of solution is diluted to a 25% strength solution, the GliaSite Balloon can still be imaged and the diluted dye will absorb less than 20% of the I-125 dose from the Iotrex. Therefore, if the licensee follows Cytoc Surgical Products' Instruction Manual and dilutes the radiopaque dye prior to every time the GliaSite Balloon is imaged, the licensee will not have to measure the activity of the Iotrex upon its removal from the patient. In this case, the volumetric measurement of the removed Iotrex can be used to determine whether the administration was in accordance with the written directive.

18. The licensee will return the licensed material to authorized recipients. In accordance with 10 CFR 30.41(a)(5), we will confirm that persons are authorized to receive byproduct material prior to transfer and:

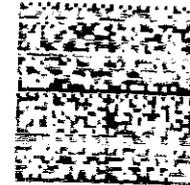
- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container
- Assemble the package in accordance with the manufacturer's instructions
- Perform the dose rate and removable contamination measurements;
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions
- Retain records of receipts and transfers in accordance with 10 CFR 30.51.

XX MAY-01-08 ST. LOUIS MO 631

SSM
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