



January 12, 2005

US Nuclear Regulatory Commission
Region 1
Allendale Rd.
King of Prussia, PA 19406

K-8
29-02234-02
03002448

Dear Ms Gabriel,

Enclosed is the additional information you requested concerning the use of the Gliasite brachytherapy System at Jersey Shore University Medical Center. Our license number is 29-~~2334~~-02 and the mail control number is 135945.

med *02234*

If you require any additional information, please contact Lynn DiPaola, M.S. at (732)776-4720. Thank you for your prompt attention to this request.

Sincerely,

Tim Foley,
Vice President, Service Line Manager

135945

NMSS/RGNI MATERIALS-002

T. 732.775.5500
Meridian Health Line 1.800.560.9990 - www.meridianhealth.com
1945 State Route 33 • P.O. Box 397 • Neptune, NJ 07754-0397

1) In addition to the commitments provided in your amendment request, please confirm that you will follow all of the requirements in 10 CFR Part 35 for brachytherapy and manual brachytherapy sources except where the items a-g listed below provide regulatory relief. Also confirm that you will follow items a-g listed below (you may repeat or paraphrase each of them):

- a. "Prescribed dose" means the total dose documented in the written directive.

Per our Written Directive for brachytherapy with the GliaSite RTS the "prescribed dose" will mean the total dose in units of Gy delivered as documented in the written directive.

- b. The written directive will include two sections:

(1) Prior to 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 treatment site, the radionuclide (including the chemical/physical form [Iotrex]), and the total dose.

Our Written Directive for brachytherapy with the GliaSite RTS includes the nuclide (I-125), the chemical/physical form (Iotrex), prescribed radiation dose (Gy), administered dosage of Iotrex (mCi) and dwell time (hours).

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

The design validation studies required for FDA clearance and sealed source device registration showed that the balloon can withstand more volume cyclings (inflation/deflation) than is seen clinically without adverse effects on the functionality of the catheter (personal communication – James B. Stubbs, Ph.D, Chief Technology Officer for Proxima Therapeutics). As per the device's instruction manual, several quality assurance steps are performed on the device's fluid integrity prior to brachytherapy to insure the GliaSite has not developed nor will develop a fluid integrity failure mode. Specifically, these QA steps are; fluid inflation prior to implant in the operating room, fluid inflation under visual inspection in the surgical cavity at time of implant, MRI (or other imaging modality) of the inflated catheter several days after surgery (prior to brachytherapy), and fluid retrieval and saline-rinsing of the balloon immediately prior to afterloading Iotrex. We will follow the above QA steps as defined by the manufacturer the images used in this assessment will be kept in the patient's medical records as required by state and NRC regulations.

Upon completing the Iotrex afterloading, radiation exposure rate measurements will be used to monitor for unexpected leakage of radioactive material from the GliaSite catheter. Radiation measurements will be performed at the injection site surface, 20 to 30 centimeters from the injection site, 1 meter from the injection site, and over the patient's bladder. These measurements will be repeated periodically until the radioactive material is retrieved. Any significant changes from the initial readings (e.g., large decrease in cranial exposure rates concomitant with large increases in bladder exposure rates) will be documented and evaluated for further action as appropriate.

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- d. Source leakage for Iotrex implanted in the GliaSite RTS means leakage of I-125 that results in a dose that exceeds 50 rem dose equivalent to any organ other than the treatment site (based on the definition of a medical event).

The licensee will evaluate all events which occur involving the unexpected loss of retained radioactivity in the catheter and assess the dose to the critical organ (bladder wall, per Iotrex Package Insert). If the dose to the critical organ exceeds 50 rem, the event will be handled and reported as a misadministration.

- e. You will retain a record of each leak test for 3 years (the period that 10 CFR 35.2067 requires for brachytherapy sources).

The leak tests typically required of brachytherapy sources are not possible for the GliaSite RTS as the GliaSite catheter is completely subcutaneous while the radioactive material resides within it. The Scaled Source and Device Registry, No. GA-1148-D-101-S, document states leak tests are not applicable to the GliaSite system. However, exposure readings taken during the therapy, and other QA tests, used to determine the integrity of the device will be retained for 3 years.

- f. You will report a leaking source to the NRC within 5 days of the leakage test to the locations specified and provide the information identified in 10 CFR 35.3067.

Any source found to be leaking will be reported to the NRC within 5 days of that determination to the locations specified and will include the information identified 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."

We will follow our policies and procedures for safe use of radioactive materials and provide instructions to the appropriate staff as required by 10 CFR 35.410.

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

At the conclusion of brachytherapy, compliance with the Written Directive will be demonstrated by the following: Volumetric retrieval of the afterloaded Iotrex (and saline) volume to within 80% of the volume infused at the start of brachytherapy and achieving the desired dwell time of the implant. If these conditions are not met, the patient, GliaSite catheter, and the recovered radioactive fluids will be further evaluated to ascertain whether the Written Directive was met. Corrective actions, as applicable, will be taken for unintended departures from the Written Directive.

- 3) Please confirm that you will follow the manufacturer's procedures or indicate your method for assuring that contrast medium will not inadvertently shield the dose.

The licensee agrees to follow the recommendations of the manufacturer concerning the concentration of contrast to be used in inflating the GliaSite device prior to brachytherapy.

- 4) Item 6 of your amendment request stated that one method you may use to assess GliaSite integrity during brachytherapy is periodic radiation exposure measurements (in the vicinity of the injection site and patient's bladder), but that this method will not be used exclusively. When using this method to assess catheter leakage, how

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often will you take radiation exposure measurements? Please specify the method you will use to assess catheter leakage in cases when you do not perform periodic radiation exposure measurements.

We will afterload the Iotrex in the patient while the patient is in the hospital. We propose, as an additional QA step, to keep the patient in the hospital for 2-4 hours following the afterloading and repeat the radiation surveys. Any significant changes from the initial readings (e.g., large decrease in cranial exposure rates [e.g., >35% drop] concomitant with large increases in bladder exposure rates [e.g., >30-fold increase]) will be documented and evaluated for further action as appropriate (e.g., patient not released from the hospital). Exposure rate surveys will be performed using survey meters appropriate for measuring exposure rates from low energy photon sources such as I-125. If the exposure rate surveys are consistent between baseline and the delayed set, the patient will be released upon meeting the evaluation and agreeing to the instructions.

5) Item 7 of your amendment request addressed outpatient GliSite treatment and stated that you will substantially follow the model guidance in NUREG-1556, Vol. 9, Appendix U, but that you will make minor changes necessary to satisfy 10 CFR 35.1000.

a. What minor changes will you make to the guidance in Appendix U?

a. Patient Instructions.

i. See attachment: Patient Instructions Outpatient Therapy with GliSite RTS.

b. Calculation for duration of outpatient release showing that the highest dose is ≤ 5 mSv to any individual in the general public.

i. See attachments:

“Calculation for Duration for Outpatient Release”

“GliSite Outpatient Therapy - NRC Justification of Patient Release”

b. What are your criteria to identify patients who are suitable candidates for outpatient treatment?

The criteria specified in the attachment: “Patient Information and Release Determination”

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

2-4 hours as stated in the attachment “GliSite Outpatient Therapy - NRC Justification of Patient Release” which we commit to following.

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

By committing to the QA steps as identified in the attachment “GliSite Outpatient Therapy - NRC Justification of Patient Release” which we commit to following.

e. What surveys will be done to provide reasonable assurance that no member of the general public will receive more than 0.5 rem?

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Exposure rate surveys will be taken at 1 meter from the patient's head, and used in the calculations defined in the "Calculation for Duration of Patient Release" form.

- f. What radiation safety instructions will you provide for outpatients receiving GliSite treatments? Will you require the patient to wear a lead skull cap? Will you instruct the patient to, when feasible, designate a toilet in their home for their sole use during the treatment? Do you intend to place any restrictions on patient mobility during GliSite treatment (i.e., remain at home and refrain from traveling by automobile except for trips to and from the doctor or hospital)? What emergency care instructions will you provide to the patient?

The patient will only be required to wear a lead cap if the exposure rates at one meter are such that any member of the general public could receive more than 0.5 rem. See attachments: "Calculation for Duration of Patient Release" and "Outpatient Patient Instructions". Emergency care instructions are included in the "Outpatient Patient Instructions".

- g. How will you assure that the patient will return to the hospital for removal of the Iotrex?

The patient will receive instructions at the time of release. They will be reminded via phone 24 hours prior to the retrieval.

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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.
2. Do not return to work.
3. Maintain a prudent distance from other people as much as possible (e.g. > 3 feet).
4. Do not go to public places (e.g. Grocery store, mall, bank, library, movie theater, museum, etc...)
5. Keep the toilet especially clean by flushing twice after use. Men should sit during urination. Wash thoroughly after using toilet. Where possible, identify a toilet to be used only by the patient during the therapy.
6. Refrain from traveling by airplane or other mass transportation.
7. Remain in the confines of your home during the therapy and refrain from traveling by automobile except for trips to and from doctor/hospital.
8. Avoid prolonged contact with children and pregnant women.
9. Terminate breast feeding (if applicable)
10. Remember to return to radiation oncology on scheduled Date and time: _____ AM/PM _____
(circle one) (Date)
11. In case of emergency or if you have any questions, call _____ at _____.

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 Date

Patient Information and Release Determination
(In conformance with US NRC NUREG-1556, Vol.9)
GliSite Therapy® with Iotrex®

I. Patient Information

- 1. Patient Name: 2. Date: 3. Net Afterloaded Activity: mCi
4. Sex: Male Female 5. Iotrex Afterloading date and time: AM/PM (circle one) (Date)
6. Iotrex Dwell Time: hr 7. Date and time for return to hospital: AM/PM (circle one) (Date)
8. Karnofsky Performance Status: (NOTE: if KPS less than 70, patient should remain hospitalized)
9. KPS evaluated by: MD

II. Household Information for Duration of Outpatient Therapy

- 1. Who will transport patient between hospital and residence?
2. Contact numbers:
3. Household Members: Age; a. b. c. d. e. Sex; a. b. c. d. e.

III. Patient Release Determination

Interview the patient to determine if the patient will adhere to the following instruction during the entire outpatient release.

Table with 3 columns: Action for Patient, YES, NO. Rows include: 1. Wear Flexible lead shielding (skull cap) measuring at least 10 HVL thickness... 2. Sleep alone. 3. Do not return to work. 4. Have sole use of toilet and maintain toilet cleanliness... 5. Refrain from traveling by airplane or other mass transportation. 6. Refrain from traveling by automobile... 7. Avoid prolonged contact with all individuals. 8. Terminate breast feeding (if applicable).

The patient is potentially releasable if their KPS score is at least 70 and they answer all questions with "YES". If any question is answered "NO" or the KPS is less than 70, the patient must be hospitalized (go to Section VI).

IV. Instructions

- 1. Ensure the patient receives, understands and is willing to follow instructions: Completed
2. Discuss procedures in case of emergency medical care: Completed

V. Release Record of Radiation Exposure Rate (should be maintained for 3 years per 10 CFR 35.75(c)).

Exposure Rate Measurement Data: Instrument Serial # Calibration date

Exposure rate: X' = mR/hr @ 1 meter Performed by:

If X' <= 1 mR/hr, then the patient is releasable. If X' > 1 mR/hr, then the skull cap should be reconstructed and reinforced with additional lead thickness until X' <= 1 mR/hr.

VI. Signature

- This patient was not releasable and therefore hospitalized.
This patient has reviewed all requirements for release, was given these written instructions and released.

Signature: (person completing this form) Date:

GliaSite Outpatient Therapy – NRC Patient Release Justification

1. Radiation Exposures to Family Members and Caregivers

According to the NRC regulations (10CFR35.75) for releasing patients administered radioactive material, the criteria for releasing the patient is "the effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem)." Specific guidance in evaluating patients for release is given in NUREG 1556 Volume 9, Appendix U (hereafter referred to as "Appendix U"). Thus, procedures will be implemented that achieve this requirement. There are two situations that may result in exposure of others to the radiation from the patient. First, exposures will result from the low energy photons emitted by the I-125 contained in the patient's body. Second, some level of exposure may occur from radioactivity excreted from the patient (urine is the only source of radioactivity excretion with the GliaSite and Iotrex).

The primary mode of radiation exposure will be from the low energy photons (photon energy <36 keV). Equation U.1 of Appendix U provides the basis for calculating the exposure of another person to radiation contained in the patient. However, instead of using an equation that has already been integrated over infinite time, and based upon the initially administered activity, in this case, one must integrate the exposure rate over the Iotrex dwell time (or duration of outpatient discharge, whichever is smaller). This total dose to an individual, based upon the measured initial exposure rate, is shown below:

The total dose for the most exposed person would be:

$$D = X' \text{ (mR/hr)} * 0.01 \text{ (mSv/mR)} * T \text{ (hr)} * OF$$

$$D = 0.0025 * X' \text{ (mR/hr)} * T \text{ (hr)}$$

Where:

D = dose to most exposed person (mSv)

X' = measured exposure rate at 1 meter (mR/hr)

T = outpatient duration (hr)

And we assume the following, per Appendix U:

- 1.0 R equals 10 mSv (or 1.0 mR equals 0.01 mSv)
- Occupancy Factor, OF = 0.25 (for nuclides with $T_p > 1$ day)

The maximum duration of outpatient release, T_{max} , that complies with this requirement is found by solving the equation above for T (hr):

$$T_{max} = 5 \text{ (mSv)} / [X' \text{ (mR/hr)} * 0.0025 \text{ (mSv/mR)}]$$

$$T_{max} = 2000 / X'$$

From this, it can be seen that the maximum outpatient release time interval (or the desired Iotrex dwell time) must be less than 2000 divided by the 1-meter exposure rate obtained following completion of the Iotrex afterloading procedure. Most Iotrex dwell times are 3-5 days (72-120 hours). Thus, based on the preceding dwell time range, patients can be released for this range of time provided the exposure rates are less than 27.8 mR/hr and 16.7 mR/hr at one meter, respectively. While these exposure rates are larger than those for permanent implants, recall that this is a short duration implant and higher exposure rates do not result in exposures above the regulatory limits. According to Proxima Therapeutics, typical exposure rates at 1 meter from the head are 2-3 mR/hr with the largest reported value less than 10 mR/hr. Thus, it is highly unlikely that exposures from GliaSite patients will exceed the regulatory limit. As an example, take a patient with a relatively long dwell time (144 hr) and high exposure rate (10 mR/hr). With the 0.25 occupancy factor, the exposure would be 3.6 mSv, a value below the regulatory limit.

The exposure one might receive from the slight amount of radioactivity excreted in the urine during normal operation of the device (<1% of the afterloaded activity) is negligible. Patients will be given explicit instructions on how to minimize potential for contamination. It is noted that the regulatory guidance in Appendix U explicitly disregards the potential radiation doses that might result from exposure or intakes of contamination activity, even for procedures that result in very large quantities of excreted activity (e.g., I-131 thyroid ablations with up to 200 mCi of I-131).

Therefore, we conclude that under normal operation of the device, radiation exposures to persons other than the family are unlikely to be above the regulatory limit. All patients who are to be released will undergo radiation exposure rate surveys and evaluation as to appropriateness for release (e.g., willingness to follow written and oral instructions) prior to release.

The other scenario to be evaluated is whether persons other than the patient might receive radiation exposures greater than 5 mSv in the event of a device failure during the outpatient time period. In this case, the majority of the radioactive material would be released from the GliSite into the patient's body within a few hours of the failure. The chemical form of the I-125 in Iotrex is largely organically bound (>80%) or in the iodide form. It has been demonstrated that the organic form of the iodide is very rapidly and completely cleared from the body via the renal pathway¹. In humans it is anticipated that clearance would be essentially complete in 24-48 hours. As to the small portion of I-125 in the iodide form, the patient's thyroid is blocked prior to therapy. Therefore, the iodide is not accumulated in the body and is excreted in the urine with a rapid biological removal half-time (~8 hr). Thus, essentially all iodide-form I-125 would also be excreted in 24-48 hours. The patient's written and verbal instructions include double flushing of toilets (and the patient should have sole use of that toilet) and that men should sit to urinate. These guidelines were employed by the I-131 Bexxar® radioimmunotherapy agent and should practically eliminate the radiation exposure from contamination due to I-125 in the patient's urine. It should be noted that the patient release evaluation criteria stipulates that to be releasable, a patient must have a Karnofsky Performance Status (KPS) of 70 or greater. This level of performance means that the patient is largely autonomous and needs little or no assistance in caring for themselves. This also means that the patient is competent to handle excretory functions autonomously. Therefore, the opportunity for family members or caregivers to come into contact with highly radioactive urine is minimal.

Therefore, under both normal operation and complete failure scenarios, radiation exposures to family members or caregivers, from radiation/radioactivity of a GliSite patient (temporary outpatient release) are unlikely to exceed the regulatory limit of 5 mSv. In all cases, patients released, as well as their caregivers, will be evaluated for appropriateness for release (performance status, willingness to follow instructions) and given the proper instructions to maintain radiation exposures to within regulatory limits.

2. Assessing Device Integrity Following Afterloading

It was noted that the NRC requests a methodology for assessing the GliSite's integrity for holding Iotrex during brachytherapy. In response, we note and propose the following. First, as shown above, regardless of whether the GliSite functions properly during brachytherapy, or undergoes a complete loss of radioactivity, the radiation exposures to the person most likely to receive the highest radiation exposure will be less than the regulatory limit of 5 mSv. Upon completing the Iotrex afterloading and during brachytherapy, radiation exposure rate measurements will be used to monitor for unexpected leakage of radioactive material from the GliSite catheter. Radiation measurements will be performed over the injection site surface (at 20 to 30 centimeters from the injection site), at 1 meter from the injection site, and over the patient's bladder. These measurements establish baseline, normal operational parameters for exposure rates.

The design validation studies required for FDA clearance and sealed source device registration showed that the balloon can withstand more volume cyclings (inflation/deflation) than is seen clinically without adverse effects on the functionality of the catheter (personal communication – James B. Stubbs, Ph.D. Chief Technology Officer for Proxima Therapeutics). As per the device's instruction manual, several quality assurance steps are performed on the device's fluid integrity prior to brachytherapy to insure the GliSite has not developed nor will develop a fluid

¹ Stubbs JB, Strickland AD, Frank RK, Simón J, McMillan K and Williams JA: Biodistribution and Dosimetry of an Aqueous Solution Containing Sodium 3-(¹²⁵I)iodo-4-hydroxybenzenesulfonate (Iotrex™) for Brachytherapy of Resected Malignant Brain Tumors. *Cancer Biotherapy and Radiopharmaceuticals* 15:645-656, 2000.

integrity failure mode. Specifically, these QA steps are; fluid inflation prior to implant in the operating room, fluid inflation under visual inspection in the surgical cavity at time of implant, MRI (or other imaging modality) of the inflated catheter several days after surgery (prior to brachytherapy), and fluid retrieval and saline-rinsing of the balloon immediately prior to afterloading Iotrex.

Thus, having successfully passed all pre-therapy QA tests, the patient proceeds to brachytherapy (obviously, if any QA step is failed, the device is not loaded with Iotrex). We will afterload the Iotrex in the patient while the patient is in the hospital. We propose, as an additional QA step, to keep the patient in the hospital for 2-4 hours following the afterloading and repeat the radiation surveys. Any significant changes from the initial readings (e.g., large decrease in cranial exposure rates [e.g., >35% drop] concomitant with large increases in bladder exposure rates [e.g., >30-fold increase]) will be documented and evaluated for further action as appropriate (e.g., patient not released from the hospital). Exposure rate surveys will be performed using survey meters appropriate for measuring exposure rates from low energy photon sources such as I-125. If the exposure rate surveys are consistent between baseline and the delayed set, the patient will be released upon meeting the evaluation and agreeing to the instructions.

Calculation for Duration of Outpatient Release
Using
U.S. NRC NUREG-1556, Vol. 9 Criteria

In NRC NUREG-1556, Vol. 9, a patient may be released if the radiation dose to the individual most likely to receive the highest dose is less than or equal to 5 mSv. For this patient, the duration of release will be determined by the exposure rate at 1 meter from the patient, using the acceptable assumptions from NUREG-1556, Vol. 9.

Assumptions:

- 1.0 R equals 10 mSv (or 1.0 mR equals 0.01 mSv)
- Occupancy Factor, OF = 0.25 (for nuclides with $T_p > 1$ day)

The total dose for the most exposed person would be:

$$D = X'(\text{mR/hr}) * 0.01 (\text{mSv/mR}) * T(\text{hr}) * \text{OF}$$

$$D = 0.0025 * X' (\text{mR/hr}) * T (\text{hr})$$

Where:

D = dose to most exposed person (mSv)

X' = measured exposure rate at 1 meter (mR/hr)

T = outpatient duration (hr)

To maintain compliance with NUREG 1556, Vol. 9, D must be less than 5 mSv. The duration of outpatient release that complies with this requirement is found by solving the equation above for "T":

$$T_{\text{max}} = 5 (\text{mSv}) / [X' (\text{mR/hr}) * 0.0025 (\text{mSv/mR})]$$

$$T_{\text{max}} = 2000 / X'$$

Patient Name: _____ X' = _____ mR/hr @ 1 meter Dwell time, T = _____ hr
Date: _____

$$T_{\text{max}} = 2000/(X') = 2000/(\text{_____ mR/hr})$$

This patient can be released for outpatient therapy for the following amount of time:

$$T_{\text{max}} = \text{_____ hours} \quad \text{Does } T_{\text{max}} \text{ exceed the desired dwell time? } \text{_____ Y/N}$$

$$D = 0.0025(X')(T) = .0025*(\text{_____ mR/hr})*(\text{_____ hr})$$

For the desired dwell time (_____ hours) of outpatient therapy, the dose to the most exposed person is estimated to be:

$$D = \text{_____ mSv}$$

Example:

The exposure rate at 1 meter from a patient was measured as 7 mR/h and the desired dwell time is 120 hours. What is the maximum amount of time this patient can be released from the hospital? What would the exposed person's dose be?

$$T_{\text{max}} = 2000/(X') = 2000 / 7 (\text{mR/hr})$$

$$T_{\text{max}} = 285 \text{ hours (more than the desired dwell time)}$$

$$D = 0.0025(X')(T) = .0025*(7)*(120)$$

$$D = 2.1 \text{ mSv (under the release limit of 5 mSv)}$$

WRITTEN DIRECTIVE FOR THERAPEUTIC ADMINISTRATION OF ¹²⁵I RADIOTHERAPY SOLUTION (IOTREX[™]) FOR INTRACAVITARY RADIATION THERAPY

Patient Name: _____ Diagnosis: _____

Patient I.D. No.: _____ Treatment Site: Brain Resection Cavity

Route of Administration: Temporary implant utilizing the GliaSite[®] RTS

Dose Assessment Data:

- 1) GliaSite[®] catheter implanted: 2.0 cm GliaSite Catheter [] 3.0 cm GliaSite Catheter [] 4.0 cm GliaSite Catheter []

2) GliaSite Balloon Fill Volume / Maximum Transverse Balloon Diameter of the Implanted GliaSite Catheter: _____ cc / cm (circle one)

3) Dose Prescription Point: _____ cm from inflated balloon surface

4) Prescribed Brachytherapy Dose: _____ Gy / cGy (circle one)

5) a. Prescribed Radiotherapy Dosage: _____ mCi

b. Assayed Radiotherapy Dosage: _____ mCi

6) Prescribed Dose Rate: _____ cGy/hour

7) Prescribed Dwell Time: _____ hours

8) Thyroid blocked with what thyroid blocking agent: _____

9) If thyroid is not blocked, provide reason: _____

Authorized Physician

Date of Written Directive

Date of Administration

Revised Dose Prescription: _____ Gy / cGy at a treatment distance of _____ cm from the inflated balloon surface (If required) (circle one)

Authorized Physician

Date

Reviewing Physicist's Signature: _____ Date: _____

Reviewing Physicist's Comments:

VERIFICATION OF WRITTEN DIRECTIVE

Name: _____ Patient ID No: _____

Does the radiotherapy solution agree with that listed in the written directive? _____

Does the dosage (activity) agree with that ordered in the written directive? _____

Does the planned route of administration agree with the one identified in the written directive? _____

Assayed radiotherapy dosage: _____ mCi Date and Time of Assay: _____

Has the patient's thyroid been blocked with a thyroid blocking agent prior to therapeutic administration of the radiotherapy solution? _____

Signature

Title

Date

VERIFICATION OF PATIENT IDENTITY

Name: _____ Patient ID #: _____ Date: _____

Before administering (afterloading) the prescribed radiotherapy dosage (activity), the authorized user shall verify the patient's identity by verbally addressing the patient, and by at least one other confirmatory method selected from the following:

Physician addresses patient by name and the patient confirms.

At least one of the below items must be checked off.

Date of Birth

Address

Social Security #

Signature

Name on patient's ID bracelet

Name on patient's medical insurance card

VERIFICATION OF RADIOACTIVE SOURCE AND BALLOON PLACEMENT

Is the information on the labeled syringe, i.e., the radiotherapy solution name, and either the patient's name or treatment procedure, consistent with the written directive? _____

Is the assayed radiotherapy dosage in agreement with the written directive? _____

Is the implanted balloon diameter in agreement with the written directive and has correct placement of the balloon into the resected cavity been verified by either radiographs or MR images? _____

Signature of Authorized User or qualified person

Date of Administration