



**Quality Management Program for
I¹²⁵ Radiotherapy Solution for IOTREX
for Intracavitary Therapy**

1. Written Directive

Prior to initiating radiation delivery using the I125 radiotherapy solution (IOTREX), a written directive shall be signed and dated by an Authorized User.

The Authorized User must be approved to administer radiation to patients and shall be listed on the facility's license or approved by the facility's Radiation Safety Committee. This treatment directive will be written for a specific patient.

If, in the authorized user's opinion, the patient may be harmed by the delayed treatment, treatment may proceed on the basis of:

- a) an *oral directive*, if documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive;
- b) an *oral modification to a written directive*, if documented immediately in the patient's record and a revised written directive is signed and dated by an authorized user within 48 hours of the oral directive.

A written modification to an existing written directive may be made provided the revision is dated and signed by an authorized user prior to completion of the existing brachytherapy dose prescription.

2. Verification of Patient Identity

Before administering (afterloading) the prescribed radiotherapy dosage (activity), the authorized user or a qualified person shall verbally ask the patient his or her name and confirm the response against the patient name on the written directive. The patient's identification will be verified by at least 2 means before the I125 radiotherapy solution (IOTREX) is loaded.

3. Verification of Written Directive by Administering Physician and/or Physicist

The authorized user, administering physician or physicist must verify, before administering, the prescribed radiotherapy dosage, that the details of the administration are in accordance with the written directive. Specifically, the radiotherapy solution, the activity, and route of administration should be confirmed by the person administering the radiotherapy solution to verify agreement with the written directive. That is, the activity should be measured in a dose calibrator and the results compared with the prescribed radiotherapy dosage in the written directive.

4. Seek Guidance

All personnel involved in delivery of the brachytherapy dose shall seek guidance if they do not understand how to carry out the written directive. Workers having any question or confusion about specific details of the treatment shall not administer the dosage until the question is resolved.

5. Radioactive Source Verification



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The authorized user, or a qualified person under the supervision of the authorized user, shall ensure that the treatment plan is in agreement with the signed written directive. Specifically, verify the radiotherapy solution, dosage and balloon size/volume are in agreement with the written directive before infusing the radiotherapy solution.

6. Recording Activity and Dose

As soon as practical after administration of the radiotherapy dosage, the authorized user shall record the actual activity infused, the corresponding dose rate, and the dwell time necessary to deliver the prescribed brachytherapy dose. This information shall be recorded in the patient's record and the authorized user shall sign or initial this record.

7. Dose Calculation Check

Before the brachytherapy treatment is completed, the authorized user or another qualified individual shall check the dose calculations. Calculations should be checked for arithmetic errors, accurate transcription and use of all dosimetry data and the proper use of formulas.

8. Routine Review of Written Directive

All written directives will be reviewed by a qualified physicist. The physicist shall review the written directive for any unintended deviation. If an unintended deviation from the written directive is found, the following shall occur as soon as is practical:

- a. Recalculate doses to the patient if necessary.
- b. Determine if any detriment to the patient has occurred.
- c. Conduct a review of the event to determine a root cause for the deviation
- d. Determine if the current practice is appropriate.
- e. Make changes as determined by c. and d. above.

10. Actions taken when a Recordable Event or Misadministration is Found during Routine Written Directive Reviews

All recordable events will be thoroughly reviewed and corrective actions devised. In doing this, the hospital will: a) assemble the relevant facts including the cause, b) identify what, if any, corrective actions may be required to prevent recurrence, and c) retain a record, in an auditable form, for 3 years, of the relevant facts and what corrective action was taken.

11. Annual Review

On a quarterly basis, all brachytherapy treatments shall be reviewed. The patients' records for the preceding year shall be reviewed for conformance of the given treatments to the corresponding written directives. A written summary of this review shall be transmitted to the Radiation Safety Committee.



**WRITTEN DIRECTIVE
FOR
THERAPEUTIC ADMINISTRATION OF I-125 RADIOTHERAPY SOLUTION (IOTREX)
FOR INTRACAVITARY RADIATION THERAPY**

Patient Name: _____ Date: _____

Double Identification of Patient:

In addition to verbally confirming the patient's name select at least one of the following methods of identification:
 verbal confirmation of : patient's address family member patient's SSN patient's birth date
 confirmation by wrist band
 confirmation by photograph
 other (*describe*): _____

Patient identified by: _____

Treatment Site: *Brain Resection Cavity*

Route of Administration: *Temporary implant using 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
- 3) Dose Prescription Point: _____ cm from inflated balloon surface.
- 4) Prescribed Brachytherapy Dose: _____ Gy/cGy
 - 5) a. Prescribed Radiotherapy Dosage: _____ mCi.
 - b. Assayed Radiotherapy Dosage: _____ mCi
- 6) Prescribed Dose Rate: _____ cGy/hr
- 7) Prescribed Dwell Time: _____ hours
- 8) Thyroid blocked with what thyroid blocking agent _____
- 9) If thyroid is not blocked, provide reason: _____

Authorized User

Date of Written Directive

Date of Administration

Revised Dose Prescription: _____ Gy/cGy at a treatment distance of _____ cm from the inflated balloon surface .

Authorized User

Date