QUALITY MANAGEMENT PROGRAM FOR I-125 AND Pd-103 PERMANENT IMPLANT

I. Radiation Oncologist must date and sign the "WRITTEN DIRECTIVE" prior to the administration of any brachytherapy radiation dosage of Iodine 125 or Palladium 103 as required by 10 CFR 35.32 (a) (1). No one shall administer a therapeutic dose of radioactive isotope without a complete legible Written Directive.

II. WRITTEN DIRECTIVE.
The "WRITTEN DIRECTIVE" must contain:

- Patient's name
- Date
- The radio-isotope
- Number of sources
- Sources Strengths
- Authorized user's signature

III. The Radiation Oncologist shall identify the patient by more than one method before administering any brachytherapy radiation dose as required by 10 CFR 35.32 (a) (2), to confirm that the individual named in the "WRITTEN DIRECTIVE" is the individual who should receive the dose. Any of two procedures my be used to identify the patient:

- Ask the patient for his name
- Confirm patient's identity with person who accompanies the patient
- Match patient identification to the accompanying patient information to:
  - Face sheet
  - Birth date
  - Address
  - Social Security Number
  - Wrist Band
  - Photo of patient's face
  - Name on the medical insurance card

IV. The Radiation Oncologist and Physicist will review and verify that the dose to be administered and the plans of treatment are in accordance with the "WRITTEN DIRECTIVE' as required by 10 CFR 35.32 (a) (3) and (a) (4). Any deviation from the WRITTEN DIRECTIVE will be identified and evaluated, and appropriate action will be taken as require by 10 CFR 35.32 (a)(5). The appropriate action to be taken will be as defined by 10 CFR 35.32 (c). The treatment plan will be reviewed by an individual other than the individual who performed the calculations and computer generated treatment plan when possible. Both Radiation Oncologist and Physicist will sign and date the treatment plan.

Computer-generated dose calculation should be checked by examining the computer printout to verify that correct input data for the patient were used in the calculations (e.g., source, strength and positions). After reviewing the calculations the treatment plan will be initialed and dated by the Radiation Oncologist.

V. The Radiation Oncologist, Physicist or and appropriately trained individual will conduct an in-service on Radiation Safety for Permanent Implant Procedures. The in-service will cover the Quality Management Program as well as radiation safety for individuals involved with the procedure as well as the subject matter listed on the attached sheet labeled "Addendum A". Formal training will be conducted at the time of orientation, and at periodic intervals of no more than one calendar year. The Nursing Care Instruction sheet is attached as "Addendum B". Whenever a modification to the regular procedure occurs, those individuals specifically involved with the procedure will undergo re-orientation.

VI. All staff members rendering patient care will wear a film badge if they are assigned a badge. All persons directly handling the implant material will wear a ring badge. Staff who are pregnant will not be allowed to render care to any implant patient.

VII. Radioactive seeds will be received in the Nuclear Medicine Department and stored in the Hot Lab. The seeds will be transferred to the Operating Room when ready for use by the Physicist, Physician or an appropriately trained individual. The specific policy for receiving seeds, transferring seeds to the Operation Room, needle loading is attached as "Addendum C".

VIII. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.

After the procedure is completed, a survey of the Operating Room must be performed and documented. The survey should include operating instruments used for the procedure, linen, tubing used for aspiration, aspirant, operative table and floor. The survey results must be documented.

IX. POST WRITTEN DIRECTIVE FORM:
After administering any brachytherapy radiation dose, the Radiation Oncologist will date and sign written record that documents the administered brachytherapy radiation dose. Both the WRITTEN DIRECTIVE and the WRITTEN RECORD of administered dose will be retrained for no less than 3 years as required by 10 CFR 35.32. (d)

X. After the patient is transferred from the Operating Room to the Recovery room, a survey will be performed according tot he room layout plan and a proper radiation sign will be posted at the door/bedside.

While in the Recovery Room, the patient will be positioned so that no unrestricted area will have an exposure rate greater than 2 millirem per hour as required by 10 CFR 20.1301.

After the patient leaves the Recovery Room, a survey must be performed. The survey should include, but is not limited to, the patient's linen, bed, catheters, tubing, urine bag and garbage. A new patient will not be admitted to the room until the survey is completed and deemed safe by the Radiation Physicist, authorized user, or an appropriately trained individual.

XI. When the patient clears Recovery Room, he will be transferred to the Same Day Surgery Room or a Private Hospital Room. A survey will then be performed and documented according to the room layout/plan and a proper radiation sign will be posted at the door/bedside.

While in the Same Day Surgery Room and/or Private Hospital Room, the patient will be positioned so that no unrestricted area will have an exposure rate greater than 2 millirems per hour as required by 10 CFR 20.1301.

After the patient leaves the Same Day Surgery Room and/or Private Hospital Room a survey must be performed. The survey should include, but in not limited to, the patient's linen, bed, catheters, tubing, urine bag and garbage. A new patient will not be admitted to the room until the survey is completed and deemed safe by the Radiation Physicist, authorized user, or an appropriately trained individual.

The patient will be briefed on radiation safety procedures for visitor control and other items as applicable consistent with good medical care.

XII. Permanent implant patients cannot be released from the hospital until the exposure rate is less than the following at one meter (Regulatory Guide 8.39):
I-125 implant – 1 mrem/hr. (8.39-4 Table 1)
Pd-103 implant —3 mrem/hr. (8.39-4 Table 1)

XIII. As part of the periodic Radiation Protection Audit, the Quality Management Program will be reviewed for compliance as required by 10 CFR 35.32 (b) (1). This shall be performed at least annually, and should be performed quarterly when deemed necessary be the Radiation Safety Committee. The review will include:

a. A representative sample of patient administrations
b. All recordable events.
c. All misadministration.

The results of the review will be evaluated to determine the program's effectiveness as required by CFR 35.32(b) (2), and will be presented to the Radiation Safety Committee and documented in the minutes.

Records of each review including evaluations and findings of the review will be retained for no less than 3 years as required by 10 CFR 35:32 (b) (3).

XIV. Modifications to the Quality Management Program may be made as approved by the Radiation Safety Committee. Modifications will be submitted to the NRC within 30 days as specified in 10 CFR 35.32(e).

All documentation will be stored and maintained as are all other hospital records.

ADDENDUM A

IN-SERVICE REVIEW
NURSING STAFF AND ANCILLARY PERSONNEL
I-125 AND Pd-103 PERMANENT IMPLANTS

Radiation exposure is generally very low, less than a few millirems per hours.

The patients implanted with I-125 and Pd-103 seeds usually receive between 8000 to 16000 cGy to the prostate gland.

The activity and energy of these isotopes are very low.

The total activity of the implanted isotopes is between 15 mCi. And 170 mCi.

Background radiation is about 150 mrem per year form the sky and earth and it varies around the world. In some places in the Untied States it can be tow to three times greater.

All nurses and ancillary staff caring for radioactive implant patients who are assigned a badge will wear the film badge.

No pregnant nurses or ancillary staff are allowed to render care to the implanted patient.

Practice principles of time and distance inpatient care.

A proper radiation sign must be posted on the patient's door/bed.

After a patient enters and/or leaves his room/area, a survey is performed. This information is documented in the hospital records.

Radiation level in any unrestricted area (i.e. surrounding hallway, adjacent room or a non-implant patient's bed/chair in a general holding area) must be less than 2 mR/hr.

Incase of emergency surgery, death, or in the event of a cardiac code, proceed with the necessary life-saving techniques. Notify the RSO and the Radiation Oncologist immediately.

ADDENDUM B

NURSING CARE INSTRUCTIONS FOR I-125 AND Pd-103 PERMANENT IMPLANTS

All females nurses, ancillary staff and visitors should be asked if they are pregnant. Any pregnant individual is NOT to be permitted in the room of a permanent implant patient.

All nurses and ancillary staff caring for radioactive implant patients who are assigned a badge will wear the film badge.

Practice principles of time and distance

Notify Physicist or appropriate personnel when patient is brought to Recovery Room, or Same Day Surgery Room in order for a survey to be performed. Contact numbers are found on the patient's chart.

Bed, bath or perineal care should not be performed routinely on a permanent implant patient, but may be performed when necessary.

The patient must remain in their assigned room/area at all times

Bed linens, Foley, strainers, etc. will be stored in the patient's room/area so that they can be surveyed prior to removal/disposal.

All urine should be strained for dislodged seeds. If any seeds are found, use forceps to place seed (s) into lead container provided. Record number of seeds found on the patient's chart and notify physicist or appropriate personnel for instructions. Contact numbers are found on the patient's chart.

Permanent implant patients cannot be released from the hospital until the exposure rate is less than the following at one meter (Regulatory Guide 8.39):
I-125 implant - 1 mrem/hr. (8.39-4 Table 1)
Pd-103 implant —3 mrem/hr. (8.39-4 Table 1)

Radiation level in any unrestricted are (i.e. surrounding hallway, adjacent room or a non-implant patient's bed/chair in a general holding area) must be less than 2 mR/hr.

In case of emergency surgery, death, or in the event of a cardiac code, proceed with the necessary life-saving techniques. Notify the RSO and the Radiation Oncologist immediately.

ADDENDUM C

PRECAUTIONS TO BE EMPLOYED WHILE HANDLING I-125 AND Pd-103 SEEDS

The seeds will be received and stored in the Hot Lab. Appropriate personnel will inspect and survey the box in accordance with the licensee's policy for receiving packages.

The seeds will be counted and at least 10% of the loose seeds will be assayed prior to any implant procedure.

Preparation and loading of the needles should take place before the time of insertion of the seeds.

Load needles behind the L-block employing tongs or forceps. Do no pick up the seeds by hand.

Log the use of seeds as they leave the storage area.

Transport all seeds to and from storage room in a shielded container only.

After all implant procedures, return any unused seeds promptly to the storage room and log the return of the seeds.

In general, minimize your time spent handling sources and maximize your distance form source when possible.

All documentation will be stored and maintained as are all other hospital records.

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PERMANENT IMPLANT PRESCRIPTION

*PATIENT NAME:*_____

*PRESCRIPTION DATE:*_____

*SCHEDULED IMPLANT DATE:*_____

SEED SOURCE TYPE: *I-125* *Pd-103*

*NUMBER OF SEEDS:*_____

*ACTIVITY OF SEEDS:*_____ *mCi/seed*

*TOTAL ACTIVITY:*_____ *mCi*

_____

_____

_____

_____

_____

*SIGNATURE AUTHORIZED USER:*_____ *M.D.*

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Package Survey Report: I^{125} / Pd^{103}

Delivery Date:_____

Survey Date:_____ _____

Survey Instruments:

Serial Number:

Calibration Date:

1. Condition of the package: ☐ O.K. ☐ Damaged

2. Measured Radiation Level:

Background_____ **mR/hour**

At the surface_____ **mR/hour**

At one meter_____ **mR/hour**

3. Wiped Test Performed:

If more than 200 DPM - report to RSO

_____ **counts/minute**

Background_____ **counts/minute**

Net_____ **DPM**

Test Performed by _____

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I^{125}/Pd^{103} Seed assay

Patient Name:_____ Date:_____

Instrument:_____

Setting._____

Total number of seeds received_____ I-125 or Pd-103

Total number of seeds assayed with the dose calibrator_____ (> 10%)

1. _____mCi.	6. _____mCi.	11. _____mCi.
2. _____mCi.	7. _____mCi.	12. _____mCi.
3. _____mCi.	8. _____mCi.	13. _____mCi.
4. _____mCi.	9. _____mCi.	14. _____mCi.
5. _____mCi.	10. _____mCi.	Ave. _____mCi.

Manufacturer's stated range and average activity :_____
Manufacturer's reference date:_____

Activity correction factor based upon manufacturer's reference date compared to the assay date: _____

Corrected average activity on the assay date is _____ mCi/seed.

Did the average activity of the assayed seeds agree with the manufacturer's stated activity within 5%. Yes or No

Physicist:_____

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Survey Patient Room/Recovery/Operating Room

Patient Name_____

1

Survey Meter: _____
Serial Number:_____
Calibration Date:_____
Background: _____cpm

2

Survey Meter: _____
Serial Number:_____
Calibration Date:_____
Background: _____mR/hr

Location	Operating Room after patient departure	Recovery Room after patient arrival	Recovery Room after patient departure	Patient Room after patient arrival	Patient Room after patient departure
Survey meter used:	1	2	1	2	1
Surface above implant		mR/hr		mR/hr	
A. Bedside 3 ft		mR/hr		mR/hr	
B. Bedside 6 ft		mR/hr		mR/hr	
C. Door		mR/hr		mR/hr	
D. Adjacent room		mR/hr		mR/hr	
E. Toilet					cpm
F. Hallway		mR/hr		mR/hr	cpm
Operating room table	cpm				
Catheter/urine container	cpm		cpm		cpm
Patient's linen/bed	cpm		cpm		cpm
Floor	cpm		cpm		cpm
Garbage can/s	cpm		cpm		cpm
Cystoscopy fluid	cpm				
Equipment	cpm				
The general room	cpm		cpm		cpm
Surveyed by (name and date):					

At discharge:_____**mR/hr. at 1 meter**

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FINAL WRITTEN RECORD OF ADMINISTRATION PERMANENT IMPLANTS

*PATIENT NAME:*_____

*DATE ADMINISTERED:*_____ *TIME:*_____

PATIENT IDENTIFIED BY:

*1.*_____

*2.*_____

PLANS OF TREATMENT WERE IN ACCORDANCE WITH WRITTEN DIRECTIVE: *YES* *NO*

*TREATMENT SITE:*_____

SEED SOURCES IMPLANTED: *I-125* *Pd-103*

*ACTIVITY OF SEEDS:*_____ *mCi/seed*

*TOTAL NUMBER OF SEEDS COUNTED PRIOR TO PROCEDURE:*_____

*TOTAL NUMBER OF SEEDS IMPLANTED:*_____

*TOTAL NUMBER OF SEEDS RETURNED TO STORAGE:*_____

*TOTAL ACTIVITY OF IMPLANTED SEEDS:*_____ *mCi.*

*EXPOSURE TIME:*_____

_____

_____

*AUTHORIZED USER:*_____ *M.D.*

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MUST REPORT TO NURSE'S STATION BEFORE ENTERING THIS ROOM !!!

This is a controlled radiation area.

Please observe the following:

1. *No items are to be removed from room until surveyed by the physicist or approved personnel.*

2. *Pregnant women are prohibited from entering room.*

3. *Persons under the age of 18 are not permitted in room.*

*Patient Name:*_____
*Isotope:*_____
*Total Apparent Activity:*_____
*Emergency Number:*_____

*Date of implant.*_____
*Reading at 1 meter:*_____

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Union Hospital

I-125 Inventory

Date of delivery / Date of implant	Patient's name	Number of seeds ordered for the patient	Number of seeds implanted	Number of seeds returned to the hot lab	Activity per seed on the date of implant	Date, time and Signature of who returned the seed/s to hot lab		Elapsed days (t) (Storage to ship date)	$e^{-(.011552*t)}$ Activity correction	Remaining total apparent activity of seeds for this patient		Total number of seeds in storage to date
									Total amount being sent to Medi-Physics	Apparent Activity		Seeds