



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
National Health Physics Program
2200 Fort Roots Drive
North Little Rock, AR 72114

MAR 03 2010

In Reply Refer To: 598/115HP/NLR

Cassandra F. Frazier
Division of Nuclear Materials Safety
Region III, Nuclear Regulatory Commission (NRC)
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: NRC License 03-23853-01VA

Dear Ms Frazier:

Per your request for information regarding the prostate seed implant program, I am enclosing documents from the VA Medical Center, Washington, DC.

Please contact Gary E. Williams at 501-257-1572, if you have any questions or comments.

Sincerely,

A handwritten signature in cursive script that reads "Lisa Maloy Offutt".

Lisa Maloy Offutt
Administrative Officer, National Health Physics Program

Enclosure

RECEIVED MAR 05 2010

rw

NRC Request for Information (February 16, 2010)
VA Medical Center, Washington, District of Columbia

1. Provide copies of any training records for calendar years 2007, 2008, and 2009 for medical physicists, dosimetrists, physician authorized users, and radiation safety staff involved in prostate implants.

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
50 Irving Street NW
Washington DC 20422



02-24-10A09:40 RCVD

February 22, 2010

Gary Williams, Interim NHPP Director
VA National Health Physics Program (115HP/NLR)
2200 Fort Roots Drive
North Little Rock, AR 72114

RE: Request for Training Information

Dear Mr. Williams:

1. Subject Training was conducted on April 13, 2009. See Memorandum, subject: Radiation Safety Training: Brachytherapy, dated April 13, 2009, enclosure 1, with sign-in sheet.
2. Memorandum, subject: Radiation Safety Training: Radioactive ^{103}Pd Permanent Seed Implant, dated November 5, 2008, enclosure 2. This included Emergency Response, enclosure 3; Instructions to Nursing Service, enclosure 4; Medical Events; NHPP Audit Checklist, enclosure 5; NHPP Inspections, Plan NRC Insp. Procedure 87132, "Brachytherapy Programs, Policy and Procedures," (online), 10 CFR 35.27 Supervision, and Policy and Procedures Quality Management Program, signed November 7, 2008, enclosure 6, including 10 CFR 10 CFR 35.41 Procedures for administrations requiring a written directive, and 10 CFR 35.3045 Report and notification of a medical event.
3. Attendance included Jo Ann Manning, M.D. Chief, Radiation Therapy, and Authorized User 10 CFR 35.400; William B. Jackson, M.D., Authorized User (10 CFR 400), I.S. Patel, Ph.D., Medical Physicist, and Mariana Guerrero, Ph.D., Dosimetrist. I regret that I can't locate a sign-in sheet, except for a blank page as submitted, enclosure 7. Nevertheless, training was documented in the Radiation Safety Minutes, dated November 7, 2008.
4. Subject training was not provided in 2007 as $^{103}\text{palladium}$ seeds were in the constant presents of the RSO and/or Medical Physicist, who preformed all radiation safety services until patients were released from same day surgery with instructions as provided by the Medical Physicist. Exposure rate from patients at one meter typically measured 0.1 mR/h.

Michael Funkhouser

MICHAEL FUNKHOUSER (RSO)
Radiation Safety Officer

Training and Education Management Program Sign-in Sheet

Course/Class Title: ON SITE NURSING TRAINING/Radiation Safety

Instructor: Funkhouser, Michael

Sponsor: NURSING SERVICE

Date: Mon. Apr 13, 2009

Start/End Time: /

Hours Credited: 1

CME/CEU Hours: 0

Last Name, First Name (Please Print)	INI	Organization	Phone Ext.
SYLVESTER PHYLLIS		NURSING/OR	8292
ASHTON, ELLEN		OR	8292
Fernal, Karen		OR	8292
Mendoza, Amelia		OR	8292
Cottman, Sharr		OR	8292
Washington, Mona		OR	8292
Griff Green		OR	8292
LOUISE HAURA Lewis		SPD	4113
Junious, Theresa		SPD	7529
Tsegu, Ukchah		SPD	6975
JEAN HENDERSON		OR	8292
Shackelford BARY		OR	8292
Shadow, Wayne		OR	8292
Joan Davenport		OR	8292
Soma Hall-Anderson		OR	8292
Ji Sheffell-Cuffie		OR	8292
Joseph A Braun		OR	

**Department of
Veterans Affairs**

Memorandum

Date: April 13, 2009
From: Radiation Safety Office (115)
Subj: Radiation Safety Training: brachytherapy
To: Nursing Services

1. Brachytherapy consists of the interstitial implantation of 50 to 100 ¹⁰³palladium seeds into the prostate by an Authorized User IAW 10 CFR 35.400.
2. Each seed encapsulates approximately 1.5 millicuries of activity with an unshielded dose rate constant of 0.865 R/h at 1 centimeter per millicurie.
3. Maximally exposed individuals wear radiation film badge monitors to ensure that exposures are less than 100 millrems.
4. The Radiation Physicist and the Radiation Safety Officer deliver ¹⁰³palladium seeds for autoclave, which are secured inside manufacturer's shielded container.
5. The Radiation Physicist and the Radiation Safety Officer initiate the Written Directive including identification of the patient, name of the patient, social security number, and date of birth.
6. The Authorized User completes and signs Part 1 and Part 2 of the Written Directive, including the number of sources implanted, the source strength, and the total dose in centigray.
7. The Radiation Physicist and the Radiation Safety Officer ensure security, storage, and surveillance of each seed. The Radiation Safety Officer maintains a written account and disposition of each seed to ensure accurate accountability and total inventory. Seeds not implanted are returned to the manufacturer, typically within seventy-two hours.
8. During operating room procedures, healthcare professionals shall remain no closer than necessary to the seeds yet provide proper and customary care. The Radiation Physicist will retrieve any misplaced seeds using a NaI scintillation probe.
9. The Authorized User completes the Written Directive.

VAMC DC

April 13, 2009

Subject: Radiation Safety Training: brachytherapy

10. After implantation, the patient is moved to PACU for recovery from anesthesia. The Radiation Safety Officer surveys for displaced seeds and exposure rate from implant-site as a function of distance. At bedside, exposure rates are typically five times the ambient background at one meter or less than 50 micro-roentgens per hour. Therefore, the "Declared Pregnant Worker" may wish not to render patient care.

11. The Radiation Physicist and the Radiation Safety Officer make bedside measurements with Ludlum, Micro-R-Meter on patient contact, 6 inches, 12 inches, 18 inches, 24, inches, and one meter. Measurements may vary from 3,000 μ R/h on contact to 50 μ R/h at one meter, which is about five times the ambient background.

12. The Radiation Physicist calculates optimal time and distance permissible to family members from medically administered 103 palladium permanent implant seeds, which lose their activity at a rate of 50 per cent every 17 days or three orders of magnitude every 170 days.

13. The Radiation Physicist counsels patient and provides written "Instructions for Family of Patient with Permanent Implant."



MICHAEL FUNKHOUSER (RSO)
Radiation Safety Officer

Ref: Instructions to Nursing and Staff Before Palladium-103 Seed Implant Therapy

8. Instructions to Nursing and Staff Before Palladium-103 Seed Implant Therapy:

- a. Wear radiation safety monitors.
- b. The Radiation Physicist and the Radiation Safety Office deliver Pd-103 seeds for autoclave inside manufacturer's shielded container.
- c. Individual seeds measure 4.5 mm long and 1 mm diameter, no larger than a grain of rice.
- d. Individual seeds are preloaded in MICK® magazines and secured in manufacturer's shielded carrying pig inside manufacturer's shielded carrying case.
- e. Individual seeds are handled by an Authorized User or one supervised by an Authorized User. Avoid direct contact with a seed. If necessary use forceps, tweezers, or spoon to secure seed in shielded carrying case.
- f. The Radiation Physicist and the Radiation Safety Officer initiate the Written Directive including identification of the patient.
- g. The Radiation Physicist, the Radiation Safety Officer, and Nursing staff ensure security, storage, and surveillance of each seed. The Radiation Physicist maintains a written account and disposition of each seed to ensure accurate accountability and total inventory. Seeds not implanted are returned to the manufacturer, typically within seventy-two hours.
- h. During operating room procedures, healthcare professionals shall remain no closer than necessary to the seeds yet provide proper and customary care. The Radiation Physicist will retrieve any misplaced seeds using a scintillation counter.
- i. After implantation, the patient is moved to PACU for recovery from anesthesia. The Radiation Safety Officer surveys for displaced seeds and exposure rate from implant site as a function of distance. At bedside, exposure rates are typically ten times the ambient background at one meter or less than 100 micro-roentgens per hour. Therefore, the "Declared Pregnant Worker" may wish not to render patient care.
- j. Visitation is limited to not more than 10 minutes, initially, not to exceed 0.002 rem in any one hour or 0.1 rem in one year.
- k. Be alert to any sealed source seeds that may have moved from their original position. Notify the Radiation Therapy immediately if an implant has become separated from a patient. Call the RSO for survey. Do not pick up the source by hands, but use long forceps; place source in a lead receptacle.

l. The Radiation Physicist completes the Written Directive and provides the patient with "Instructions for Family of Patient With Permanent Implant."

m. Perform close-out survey after the patient has been discharged. If survey is less than 0.1 mR/h and all seeds have been accounted, the room may be released for unrestricted use.

Department of
Veterans Affairs

Memorandum

Date: November 5, 2008
From: Radiation Safety Office (115)
Subj: Radiation Safety Training: Radioactive ¹⁰³Pd Permanent Seed Implant
To: C, Radiation Therapy

1. Handling and security of sealed sources.

a. Radioactive material package receipt surveys and records.

10 CFR 20.1906, Procedures for receiving and opening packages

(1) The Radiation Physicist orders seeds on a Thursday or Friday and notifies the RSO, who alerts Walter Henley at the Mailroom to expect a large bright yellow stripped box from BARD Theraseed®, Buford, Georgia, after 10 a.m. Monday for scheduled implantation on Wednesday.

(2) The RSO typically arrives at the Mailroom before noon on Monday to secure the package after signing a receipt of transfer.

(3) The RSO carries the package to GD-213.

(a) The RSO monitors the external surfaces of the package IAW Memorandum, subject: Survey of DOT Packaged Radioactive Material.

i. MDA is calculated using Performance Standard reference rod with 24 nCi of ¹²⁹iodine (40 keV), using a NaI well counter.

ii. Radiation levels do not exceed 0.05 mR/h at one meter.

(b) The RSO notifies the final carrier and the VHA-NHPP 501.257.1571; after-hours and emergencies 888.887.0079, if removable activity exceeds 10 CFR 71.87(i); i.e. 49CFR 173.443 or radiation levels exceed 10 CFR 71.47.

(1) Removable contamination may not exceed 22 dpm/cm².

(2) Radiation levels may not exceed 200 mrem/h at any point of contact on the external surface of the package; and the transportation index does not exceed 10.

(c) The Radiation Physicist initials receipt of package after survey by the RSO for removable contamination and radiation levels.

b. Security requirements and two delay methods if stored.

10 CFR 20.1801, Security of stored material

(a) Seeds are stored in GD-213 after hours.

(b) Seeds are stored in lock-box after hours.

10 CFR 20.1802, Control of material not in storage

(a) Seeds are under continuous surveillance when not in storage.

(b) Seeds are autoclaved before implantation.

c. Source accountability and records of accountability.

10 CFR 35.406, Brachytherapy sources accountability

(a) Accountability is maintained at all times.

(b) Seeds not implanted on Wednesday are returned by the RSO on Friday IAW manufacturer's instructions.

10 CFR 35.2406, Records of brachytherapy source accountability

(a) Initial seed count and activity are kept for three years at Form: RADIOACTIVE SHIPMENT RECEIPT REPORT and Packing Slip.

(b) Initial seed count and activity removed are initialed by Radiation Physicist at Form: RADIOACTIVE SHIPMENT RECEIPT REPORT.

(c) Seed count implanted and activity are recorded, dated, and signed at Written Directive by Authorized User/Physician.

(d) Seed count implanted and seed count not implanted are dated, recorded, and signed by the Radiation Safety Officer at Memorandum, subject: Radiation Survey: Baseline/Close-out.

(e) Seed count implanted and seed count not implanted are dated, recorded, and signed by the Radiation Safety Officer at Memorandum, subject: Radiation Survey: Brachytherapy.

(f) Seed count not implanted is dated, recorded, and signed by the Radiation Safety Officer at Form: BARD Return TheraSeed[®] Pd-103 Implant Packing List.

d. Physical inventory.

10 CFR 35.67 (g) Requirements for possession of sealed sources and brachytherapy sources

(1) Semiannual physical inventory at Form: QUARTERLY INVENTORY and SEALED SOURCE LEAK TEST REPORT; SEMI-ANNUAL DECAY CORRECTED ACTIVITY.

Subject: Radiation Safety Training: ^{103}Pd Permanent Seed Implant

(2) Records of leak tests and inventory of sealed sources and brachytherapy sources, including model number; serial number, activity, date of test, and individual who performed the test are maintained for three years.

e. Source disposal.

(1) 10 CFR 35.92, Decay in storage

(2) 10 CFR 35.2092, Records of Decay-in-Storage

(3) Return seeds not implanted to vendor IAW Theragenics Corporation's Form: BARD Return TheraSeed® Pd-103 Implant Packing List.

(4) Call for Return Authorization TS-####.

(5) Decay-in-Storage IAW Form: QUARTERLY INVENTORY and SEALED SOURCE LEAK TEST REPORT; SEMI-ANNUAL DECAY CORRECTED ACTIVITY.

(6) Records of Decay-in-Storage maintained for three years.

2. Preparation for seed implantation procedures.

a. Written procedures and checklists.

10 CFR 35.40, Written directive

(1) Name, SSN, DOB; treatment site, radionuclide, and dose before implantation.

(2) Before completion: treatment site, radionuclide, number of sources, source strength, total dose (cGy).

(3) Written directives are maintain for three years.

b. Patient identity verification, written directive, and treatment plan checking procedures.

10 CFR 35.41: Procedures for administrations requiring a written directive

(1) Patient identification, verification, written directive, treatment plan, checking treatment plan, including manual and/or computer-generated dose calculations.

(2) Quality Management Program: ^{103}Pd Permanent Seed Implant.

(3) Quality Management Program is maintain for the duration of the VHA Radioactive Material's Permit.

c. Pre-implantation imaging and volume studies are completed _____ days/weeks before permanent implantation.

d. Preplanning preparation.

e. Written directive, Part I: Preparation and prescribed dose

f. Surveys after source implant for misplaced seeds and records

10 CFR 35.404, Surveys after source implantation and removal

(1) The Radiation Physicist accounts for seeds implanted and for seeds not implanted. Radiation Physicist surveys operating room, stretcher, equipment, floor, linen, trash, and personnel to ensure exposure rate does not exceed ambient background with portable NaI detector, which is less than 100 cpm.

(2) The RSO documents the report of the Radiation Physicist at Memorandum, subject: Radiation Survey: Baseline/Close-out for seeds implanted and for seeds not implanted.

10 CFR 35.2404, Records of surveys after source implant and removal

(1) Surveys include date, results, survey meter used, and name of individual making survey.

(2) Surveys are maintained for three years.

g. Patient release procedures, surveys, and records.

10 CFR 35.75, Release of individuals containing . . . implants

(1) Patients may be released if the TEDE to another individual does not exceed 500 millirem. See NUREG-1556, Vol.9, Rev 2, Appendix U.

(2) Patients or family members are provided instructions to ensure TEDE is ALARA should the TEDE exceed 100 millirems.

(3) Additional instructions provided patients or family members should TMDE to nursing infant or child exceed 100 millirems.

(a) Guidance on interruption or discontinuation of breast-feeding provided as required.

(b) Information on potential, if any, of failure to follow the guidance provided as required.

10 CFR 35.2075, Records of release of individuals . . . implants

(1) TEDE is calculated IAW NUREG-1556, Vol.9.Rev 2, Appendix U.

(2) Records are maintained for three years.

h. Patient release records following calibrated measurements for $^{103}\text{palladium}$.

(1) Ludlum, Model 9, ion chamber is calibrated to $^{137}\text{cesium}$ standard. Manufacturer provides no log-log energy response, correction curve for exposure rate, air kerma rate, or dose rate for high yield $K\alpha$ and $K\beta$ cascade x-rays of 20-22 keV indicative of $^{103}\text{palladium}$.

Subject: Radiation Safety Training: ^{103}Pd Permanent Seed Implant

(2) Ludlum, Model 12S, NaI, Micro-R-Meter is calibrated to $^{137}\text{cesium}$ standard. Manufacturer provides log-log energy response, correction curve of 0.6 at 40 keV for exposure rate to $^{129}\text{iodine}$. See enclosure xx.

(3) Ludlum, Model 19, NaI, Micro-R-Meter is calibrated to $^{137}\text{cesium}$ standard. Manufacturer provides log-log energy response, correction curve of 7 at 59.9 keV for exposure rate to $^{241}\text{americium}$. See enclosure xx.

i. Patient instruction

10 CFR 35.75, Release of individual containing . . . implants containing byproduct material.

(1) Outpatient's Instruction Following Permanent Seed Implantation of Radioactive Medicine. See enclosure xx.

(2) Instructions for Family of Patient with Permanent Implant.

j. Calibration measurements of sources

10 CFR 35.432, Calibration measurements of brachytherapy sources

(1) Measurements are provided by manufacturer.

(2) Records of calibration are maintained for three years.

k. Acceptance testing of treatment planning system

10 CFR 35.457, Therapy-related computer systems. (pg. 586)

l. Quality assurance of imaging (ie TRUS, CT; accuracy of image transfer)

m. Requirements for a medical event or incident, including after hours recall or notification (10 CFR 35.3045) Report and notification of a medical event. (pg. 606)

(1) Dose differs from prescribed dose by more than 5 rem and TEDE delivered differs by 20 percent or more.

(2) The RSO shall notify the VHA-NHPP NLT than the next calendar day after discovery of a medical event.

n. RSC approval of Authorized Users: See VHA Permit as amended.

o. Procedures to evaluate possible leaking seeds and follow-up; 10 CFR 35.3067 Report of a leaking source. See enclosure xx.

(1) The RSO monitors the external surfaces of the package IAW Memorandum: subject: Survey of DOT Packaged Radioactive Material.

(2) Form: QUARTERLY INVENTORY and SEALED SOURCE LEAK TEST REPORT; SEMI-ANNUAL DECAY CORRECTED ACTIVITY ensures that sealed source leakage does not exceed 0.005 uCi

p. Training of AU, medical physicist, and staff.

q. Unusual type of anesthesia?

3. Performance-based interviews and observations.
 - a. Joan Collier-Manning, M.D. Chief, Radiation Therapy
 - b. William B. Jackson, M.D.
 - c. I.S. Patel, PhD, Medical Physicist.
 - d. Mariana Guerrero, Dosimetrist.
 - e. Urologist.
 - f. Michael Funkhouser (RSO)
 - g. Indira Santiago, RN.

4. Performance-based tours and observations.
 - a. Radiation Therapy (oncology), Room GG-101.
 - b. Package receipt, Room GD-213.
 - c. Seed implant preparation, Room GD-211.
 - d. Seed storage, lock-box, Room GD-213.

5. Evaluation of patient treatment results.
 - a. **Methods and procedures to determine if all seeds implanted properly.**
 - b. **Fluoroscopy used to supplement TRUS during procedure?**
 - c. **Is radiography acquired after implant?**
 - c. **Written Directive, Part 2: When completed and how?**
 - d. **Post implantation CT scans; when completed?**
 - e. **Post plans: when completed, how to verify compliance with Written Directive.**
 - f. **Review treatment plans and dose criteria i.e. V100 and D90.**
 - g. **Clinical quality assurance, including peer review.**

6. Workload data.
 - a. Method of implantation (preloaded needles, Mick applicator, needles loaded at facility)
 - b. Date of program inception. 1999
 - c. Number of patient-implantations per year

1998	one
1999	eighteen
2000	seventeen
2001	eighteen
2002	seven
2003	twelve
2004	seven
2005	four
2006	four
2007	six
2008	five, 20 Aug'08: 99 patient-implants to date

VAMC DC

November 5, 2008

Subject: Radiation Safety Training: ^{103}Pd Permanent Seed Implant

d. Radionuclide, Pd-103 only.

Handwritten signature of Michael Funkhouser in cursive.

MICHAEL FUNKHOUSER (RSO)
Radiation Safety Officer

DEPARTMENT OF VETERANS AFFAIRS

Medical Center
50 Irving Street NW
Washington DC 20422



EMERGENCY RADIOLOGICAL RESPONSE INFORMATION

CALLS from off-campus

DOSE to patients

EXPOSURES to personnel

LEAKING Source

LOST Source

MEDICAL Event

RELATED Equipment failure

RELEASE of activity

SECURITY breach

SPILLS in the lab

THEFT of source

CONTACT YOUR:

Authorized Supervisors
Authorized Physicians
Authorized Users

Michael Funkhouser

RADIATION SAFETY OFFICER: 202.745.8000
Michael Funkhouser (RSO) ext.7546
HNP 703.256.1287: After Hours Emergencies
Cell 703.201.5378: After Hours Emergencies

OCCUPATIONAL HEALTH CLINC: 202.745.8254
DEPARTMENT OF NUCLEAR MEDICINE: 202.745.8390

NATIONAL HEALTH PHYSICS PROGRAM 501.257.1571
AFTER HOURS EMERGENCIES NHPP 800.815.1016

8. Instructions to Nursing and Staff Before Palladium-103 Seed Implant Therapy:

- a. Wear radiation safety monitors.
- b. The Radiation Physicist and the Radiation Safety Office deliver Pd-103 seeds for autoclave inside manufacturer's shielded container.
- c. Individual seeds measure 4.5 mm long and 1 mm diameter, no larger than a grain of rice.
- d. Individual seeds are preloaded in MICK® magazines and secured in manufacturer's shielded carrying pig inside manufacturer's shielded carrying case.
- e. Individual seeds are handled by an Authorized User or one supervised by an Authorized User. Avoid direct contact with a seed. If necessary use forceps, tweezers, or spoon to secure seed in shielded carrying case.
- f. The Radiation Physicist and the Radiation Safety Officer initiate the Written Directive including identification of the patient.
- g. The Radiation Physicist, the Radiation Safety Officer, and Nursing staff ensure security, storage, and surveillance of each seed. The Radiation Physicist maintains a written account and disposition of each seed to ensure accurate accountability and total inventory. Seeds not implanted are returned to the manufacturer, typically within seventy-two hours.
- h. During operating room procedures, healthcare professionals shall remain no closer than necessary to the seeds yet provide proper and customary care. The Radiation Physicist will retrieve any misplaced seeds using a scintillation counter.
- i. After implantation, the patient is moved to PACU for recovery from anesthesia. The Radiation Safety Officer surveys for displaced seeds and exposure rate from implant site as a function of distance. At bedside, exposure rates are typically ten times the ambient background at one meter or less than 100 micro-roentgens per hour. Therefore, the "Declared Pregnant Worker" may wish not to render patient care.
- j. Visitation is limited to not more than 10 minutes, initially, not to exceed 0.002 rem in any one hour or 0.1 rem in one year.
- k. Be alert to any sealed source seeds that may have moved from their original position. Notify the Radiation Therapy immediately if an implant has become separated from a patient. Call the RSO for survey. Do not pick up the source by hands, but use long forceps; place source in a lead receptacle.

1. The Radiation Physicist completes the Written Directive and provides the patient with "Instructions for Family of Patient With Permanent Implant."

m. Perform close-out survey after the patient has been discharged. If survey is less than 0.1 mR/h and all seeds have been accounted, the room may be released for unrestricted use.

Transperineal Permanent Implant Prostrate Seed Brachytherapy

Check List

1. Handling and security

a. Radioactive material package receipt and records

10 CFR 20.1906 Procedures for receiving and opening packages

- (i) Notify Mail Room
- (ii) Monitor labeled package for contamination
- (iii) Monitor package for contamination
- (iv) Monitor ASAP but not later than 3 hours
- (v) Notify VHA-NHPP
 - If external radiation exceeds 200 mR/h
 - If leak test swipe exceeds 0.005 μ Ci
 - If removable activity exceeds 220 dpm/cm²
averaged over 300 cm²
 - If TI exceeds 10

b. Security requirements

10 CFR 20.1801 Security of stored material

The licensee shall secure from unauthorized removal or access to licensed material that is stored in controlled or unrestricted areas.

10 CFR 20.1802 Control of material not in storage

The licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area that is not in storage.

c. Source accountability

10 CFR 35.406 Brachytherapy sources accountability

Accountability shall be maintained at all times in storage & use ASAP after removing sources from a patient, a licensee shall return brachytherapy sources to a secure storage area

10 CFR 35.2406 Records of brachytherapy source accountability

- (i) Maintain a record of accountability for 3 years
- (ii) Record the number and activity of sources removed, the date they were removed from storage, the name of the individual who removed them from storage
- (iii) Record the number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage, and
- (iv) Record the number and activity of sources permanently implanted in the patient

d. Physical Inventory

10 CFR 35.67(g) The licensee shall conduct a semi-annual physical inventory of all such source in its possession and shall be maintained IAW Part 35.2067(b) for 3 years; records must include model number of each source, serial number if assigned, identity of each source by radionuclide, its nominal activity, location of the source, and name of individual who performed the inventory.

e. Source disposal

Ship to vendor

Decay-in-Storage

2. Preparation for seed implant procedures

a. Written procedures and checklists

10 CFR 35.40 Written directive

(i) **Appendix S: Model procedures for developing, maintaining, and implementing Written Directives**

10 CFR 34.41 Procedures for administrations requiring a written directive

(i) **Appendix S Model Procedures for developing, maintaining, and implementing Written Procedures**

b. Patient identification, written directive, treatment plan checking procedures

10 CFR 35.40 Written directive

10 CFR 35.41 Procedures for administrations requiring a written directive

c. Pre-implanting

Volume Study _____

How long before implant _____

d. Preplan preparation

e. Written directive, Part 1, preparation including prescribed dose.

f. Surveys after source implant for misplaced seeds and records

10 CFR 35.404 Surveys after source implant and removal
Immediately after implanting sources in a patient or human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted

10 CFR 35.2404 Records of survey after source implant and removal

(i) Records shall be maintained for 3 years; each record must include the date and results of the survey, instrument used, and the name of the individual who made the survey

g. Patient release procedures, surveys, and records

10 CFR 35.75 Release of individuals containing unsealed licensed material or implants containing licensed material

(i) The TEDE to another individual is not likely to exceed 0.5 rem

(ii) Instructions to ensure that TEDE to another individual is not likely to exceed 0.1 rem.

(iii) Appendix U: Model procedure for release of patients or human research subjects administered radioactive materials

(iv) Instructions For Family With Permanent Implant

10 CFR 35.2075 Records of the release of individuals containing unsealed licensed material or implants containing licensed material

h. Patient release measurement, including response correction to energy dependence of the survey meter

i. Patient instruction

10 CFR 35.75 Release of individuals containing unsealed licensed material or implants containing licensed material

(i) Using retained activity rather than activity administered

(ii) Using occupancy factor less than 0.25 at one meter.

(iii) Using biological or effective half-life; or

(iv) Considering the shielding by tissue

(v) Records shall be maintained for three years

j. Calibration measurements of sources

10 CFR 35.432 Calibration measurements of brachytherapy sources

(i) Determine the source output or activity using a dosimetry system that meets the requirements of Part 35.630(a) that includes a system accredited by the American Association of Physicists in Medicine (AAPM). . . [pg 590].

(ii) A system for spot-checking output measurement, if applicable.

(iii) Maintain records IAW Part 35.2630 Records of dosimetry equipment . . . for the duration of the license [pg 604].

c. Post implant CT scans: When completed

d. Post plans: When completed, How to verify with written directive

e. Review of treatment results to dose criteria e.g. V100 and D90

f. Clinical quality assurance, including peer review

6. Workload data

a. Method of implantation: Preloaded needles, Mick applicator, needles loaded at facility

b. Date of program inception

c. Number of patients implanted per year

d. Radionuclides

e. Is fluoroscopy used to supplement TRUS during procedures?

f. Is a radiograph acquired after implant?

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
50 Irving Street NW
Washington DC 20422



POLICY AND PROCEDURES
QUALITY MANAGEMENT PROGRAM (QMP)

VHA Permit No. 08-00942-05

1. This QMP includes written policies and procedures to ensure that a "written directive" is prepared before administration of ¹⁰³palladium permanent seed implant to the prostate.

2. A signed and dated "written directive" by the Authorized User will accompany each authorized implantation.

a. Before implantation, the Authorized User administering brachytherapy will verify that the specific details of the administration are in accordance with the written directive and the treatment plan.

b. Before implantation, the Authorized User administering brachytherapy will confirm that the radionuclide, treatment site, number of sources, source strength, and total dose is in accordance with the written directive and the treatment plan.

c. Before implantation in the operating room, the Medical Physicist under the supervision of the Authorized User will perform the dose calculations using the VeriSeed Treatment Planning System. Dose calculations will be checked for the following:

(1) Appropriate transfer of data from the written directive to the Veriseed Planning System,

(2) Appropriate use of all pertinent equipment including but not limited to phantoms, ultrasound, and related hardware and software,

(3) Appropriate use and configuration of peripherals and application of all pertinent data in the calculations,

(3) Appropriate use of computer-generated dose calculations.

d. Revisions to the "written directive" may be made for any therapeutic procedure, provided that the revision is dated and signed by the Authorized User before implantation or after implantation but before the completion of the procedure.

g. After implantation, the Authorized User will confirm the following:

(1) Date of implantation,

(2) Name of radionuclide,

(3) Number of sources,

(4) Source strength.

3. A "written directive" is an order for a specific patient, dated, and signed by the Authorized User before implanting brachytherapy sources.

a. The "written directive" will include the following information. See Attachment 1, "Brachytherapy Quality Management Form."

- (1) Date of implantation,
- (2) Patient's name and social security number,
- (3) Name of radionuclide,
- (4) Number of sources,
- (5) Source strength,
- (6) Total dose (cGy),
- (7) Signed by Authorized User.

b. Before implantation, the Authorized User will confirm the patient's identity by at least two of the following methods. Confirmation will be initialed by a second person under the supervision of the Authorized User at paragraph "c" below:

- (1) Patient's name,
- (2) Patient's address,
- (3) Patient's photograph,
- (4) Patient's date of birth,
- (5) Patient's social security number,
- (6) Patient's identification bracelet,
- (7) Patient's hospital identification card, and
- (8) For unresponsive patients, an accompanying relative or friend may attest to the patient's identity. The name and relationship of the relative or friend will be recorded.

c. If the information obtained from these two methods does not correspond to the "written directive," the implantation shall not be performed until conclusive verification is obtained.

4. A medical event following brachytherapy permanent seed-implant:

a. A wrong patient, a wrong radionuclide, a wrong treatment site, a leaking source, an unintended organ or tissue dose greater than 50 rem, or an administered dosage that differs from a prescribed dosage by more than plus or minus 20% of the prescribed dosage.

b. A figure of merit of D90 i.e. dose to 90% of the volume is equal to or less than 80% or equal to or greater than 120% of the prescribed dose.

c. Medical events trigger actions specified at 10 CFR 35.3045 Report and notification of a medical event.

d. Medical events are reported to the RSO, the Medical Center Director, and the VHA-NHPP Director, no later than the next calendar day.

5. Following implantation and discovery of a medical event by post CT evaluation, the Authorized User will:

- a. Initiate a reactive investigation:
 - (1) Assemble the relevant facts,
 - (2) Identify the cause,
 - (3) Specify actions and to prevent recurrence,
 - (4) Retain report for three years.
- b. By the next calendar day the Authorized User will notify:
 - (1) Attending physician,
 - (2) Medical Center Director,
 - (3) Radiation Safety Officer,
 - (4) Patient notification,
 - (5) VHA-NHPP Director.

6. An annual review will be conducted by the Radiation Safety Officer and the Radiation Physicist within 12 months of the of the previous annual review.

- a. A representative sampling may consist of:
 - (1) 000-020 patients; all cases will be reviewed.
 - (2) 021-100 patients; at least 20 cases will be reviewed.
 - (3) > 100 patients; at least 20 per cent be reviewed.
- b. Records of each review will be saved for at least three years, including evaluations and findings.
- c. An audit of the QMP shall be conducted at twelve months' intervals with written summary report filed by the first week of March. Attachment 2 contains a blank summary report.
- d. The audit shall be conducted by the Radiation Safety Officer and attached to the Radiation Safety Minutes, annually.
- e. The audit shall evaluate 100% compliance with the following criteria:
 - (1) Have "written directive" before implanting brachytherapy sources.
 - (2) Oral directive is reserved for emergency situations only where delay would jeopardize the patient's health.
 - (3) All individuals preparing and/or implanting brachytherapy sources of brachytherapy will be instructed in the requirements of this QMP.
 - (4) More than one method of confirmation/verification of patient's identity is required before implanting brachytherapy sources.
 - (5) Implantation is performed in accordance with specific information contained in the "written directive."
 - (6) Unintended deviations from the "written directive" are identified and evaluated followed by appropriate, corrective actions.

(7) Records of annual reviews, written directives, treatment plans, dosages, and implantation will be retained for three years.

7. Before release of patient following implantation, the patient is surveyed with a calibrated ion chamber on contact with the patient and at 0.5 ft, 1.0 ft, 1.5 ft, 2.0 ft and one meter. A manufacturer's energy dependent calibration factor is applied. Patient may release if dose rate at one meter is less than 3 mrem/h. Instructions are provided for activity greater than 8 mCi and a dose rate greater than 0.7 mrem/h.

8. The Radiation Safety Office will implement this QMP.

9. Radiation Safety Training shall be conducted before using brachytherapy sources. All workers will be instructed to seek guidance if they do not understand how to carry out the written directive. Workers will be asked if they have any questions about what they are to do, and how they are to do it rather than continuing the procedure when there is doubt.

10. This Quality Management policy and procedure shall be review annually.

11. Approved modifications will be submitted within 30 days to the VHA-NHPP.

ORIGINALS SIGNED

MICHAEL FUNKHOUSER (RSO)
Radiation Safety Officer

November 7, 2008
Date

ORIGINALS SIGNED

RAJ LAKSHMAN, Ph.D.
C, Radiation Safety Committee

November 7, 2008
Date

ATTACHMENT 1

QUALITY MANAGEMENT FORM
BRACHYTHERAPY TREATMENT FOR THE PROSTATE

VETERANS AFFAIRS MEDICAL CENTER
 QUALITY MANAGEMENT FORM
BRACHYTHERAPY TREATMENT OF THE PROSTATE
 (Permanent Implant)

Social Security Number _____

Patient's Name _____

WRITTEN DIRECTIVE	Inpatient	Outpatient
Date		
Radionuclide		¹⁰³ Palladium Prostate
Number of Sources		
Source Strength		
Total Dose (cGy)		
Signature & Date Authorized User (ONLY)		
Patient Confirmation	Check Two	Check Two
Name		
Date of Birth		
Hospital I.D.		
Relative/Friend		
Wrist Band		
Before implantation, Confirm:		
Followed Directive	Yes ___; No ___	Yes ___; No ___
After implantation, Confirm:		
Radionuclide		¹⁰³ Palladium Prostate
Number of Sources		
Source Strength		
Total Dose (cGy)		
Signature & Date Authorized User (ONLY)		

Annual Summary of Quality Management Program

Administrative therapeutic doses from sources of brachytherapy.

Period of audit from NOVEMBER 30, 2007 to DECEMBER 31, 2008 .
 Date of audit _____ JANUARY 29, 2009 _____ .
 Audit's name _____ MICHAEL FUNKHOUSER (RSO) _____ .
 Auditor is the Authorized User (check) Y _____ NO _____ .
 Auditor is the Radiation Safety Officer (check) YES _____ N _____ .

Number of patient doses administered:

a. ¹⁰³Palladium Ten (10)

b. Number of cases reviewed Ten (10).

1. Criteria	Yes	No	% Comp.
-------------	-----	----	---------

a. "Written Directive" prepared before implantation.	YES	_____	100%.
--	-----	-------	-------

b. "Oral Directive" only if patient's health is otherwise in jeopardy.	YES	_____	100%.
--	-----	-------	-------

c. The "written directive" Includes:	YES	_____	100%.
--------------------------------------	-----	-------	-------

- (1) Date of administration,
- (2) Patient's name and social security number,
- (3) Date of birth or address,
- (4) Patient's photograph,
- (5) Name of radioisotope,
- (6) Number of sources,
- (7) Source strength,
- (8) Total dose,
- (9) Plan of treatment,
- (10) Signed by Authorized User.

d. All individuals involved in brachytherapy procedures have been instructed in this program.	YES	_____	100%.
---	-----	-------	-------

e. Use of two (2) or more methods of verifying patient's identity before implantation.	YES	_____	100%.
--	-----	-------	-------

f. Implanting brachytherapy sources conducted IAW "written directive."	YES	_____	100%.
--	-----	-------	-------

1. Criteria - continued	Yes	No	% Comp.
g. Unintended deviations from "written directive."	"YES"	_____	_____.
(1) No. identified,	THREE	_____	_____.
(2) No. evaluated,	THREE	_____	_____.
(3) No. of corrective actions taken.	THREE	_____	_____.

h. Each medical event evoked proper response: (YES, AS APPLICABLE).

i. "Proposed" Medical Event(s) > +/- 20% of a prescribed dose reported as required to:
Total: YES.

- (1) Attending physician,
- (2) Medical Center Director,
- (3) Patient notification,
- (4) Radiation Safety Officer,
- (5) VHA-NHPP Director.
- (6) "Proposed" Medical Events retracted effective December 2, 2008.

j. Maintain adequate records including:

- (1) Annual review,
- (2) Clinical Requirement,
- (3) Treatment planning system,
- (4) Training for medical event,
- (5) Written Directive,
- (6) Written Procedure.

2. Recommendations:

(1) Request VHA-NHPP for approval for Transperineal Permanent Implant Prostate Brachytherapy IAW Memorandum, SAB, dated January 28, 2009, as attached.

(2) Create signature cards for Authorized Users.

3. Summary prepared by:

MICHAEL FUNKHOUSER (RSO) and INDRAVADAN S. PATEL, Ph.D.
Radiation Safety Officer Radiation Physicist

4. Summary reviewed by:

JOANN COLLIER-MANNING, M.D.
Chief, Radiation Therapy

From: Origin ID: LITA (501) 257-1571
 Kelly Mayo
 VHA National Health Physics Pr
 2200 FORT ROOTS DR
 B101 R208D
 NORTH LITTLE ROCK, AR 72114



J10101082220224

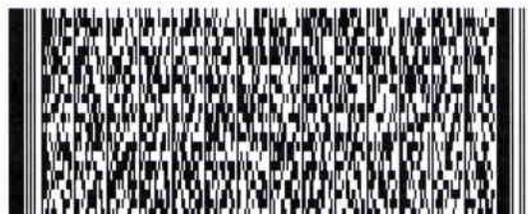
Ship Date: 03MAR10
 ActWgt: 5.0 LB
 CAD: 5250401/INET3010

Delivery Address Bar Code



Ref #
 Invoice #
 PO #
 Dept #

SHIP TO: (501) 257-1571 **BILL SENDER**
Cassandra Frazier
Nuclear Regulatory Commission
2443 Warrenville Road
Suite 210
Lisle, IL 60532



TRK# 7984 4178 6118
 0201

THU - 04 MAR A1
STANDARD OVERNIGHT
 DSR

60532
 IL-US
 ORD

XH ENLA



585G1F635FE8

After printing this label:

1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.