



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

In Reply Refer To: 598/115HP/NLR

FEB 25 2010

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, Cincinnati, Ohio.

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

Sincerely,


Lisa Maloy Offutt
Administrative Officer, National Health Physics Program

Enclosure

RECEIVED MAR 01 2010

GW

NRC Request for Information (February 16, 2010)
VA Medical Center, Cincinnati, Ohio

1. Provide copies of policies and procedures for prostate implants to include the following:
 - a. Copies of policies and procedures current at the time of the on-site NRC inspection for the prostate implant program with the effective date indicated.
 - b. Copies of policies and procedures that were revised after the on-site NRC inspection or in response to NHPP recommendations with the effective date indicated.
2. 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.

-----Original Message-----

From: Richards, Diane, VHACIN
Sent: Wednesday, February 24, 2010 2:42 PM
To: Williams, Gary E
Cc: Rauf, Chris, VHACIN; Alder, Marlene, VHAV10; Staten, Johnna Lacey, VHAV10; VISN 10 SUSPENSE - CINTI
Subject: FW: additional information for NRC inspection
Importance: High

Attached are the documents requested as well as comment from Mr.Rauf in regard to the Brachytherapy program users and improvements.

Diane Richards
Administrative Assistant
Chief of Staff Office
Tel: 513-487-6065
Fax: 513-475-6525

-----Original Message-----

From: Smith, Linda (SES) (VHACIN)
Sent: Wednesday, February 24, 2010 10:35 AM
To: Richards, Diane, VHACIN; Ninneman, David, VHACIN; Steinberg, Sidney R., VHACIN
Cc: VISN 10 SUSPENSE - CINTI; Rauf, Chris, VHACIN
Subject: RE: additional information for NRC inspection

Approved

-----Original Message-----

From: Richards, Diane, VHACIN
Sent: Wednesday, February 24, 2010 8:11 AM
To: Smith, Linda (SES) (VHACIN); Ninneman, David, VHACIN; Steinberg, Sidney R., VHACIN
Cc: VISN 10 SUSPENSE - CINTI; Rauf, Chris, VHACIN
Subject: FW: additional information for NRC inspection
Importance: High

This response is due today, 2-24-10. Your review and approval is requested to send the documentation along with the comments listed below from Chris.

Diane Richards
Administrative Assistant
Chief of Staff Office
Tel: 513-487-6065

Fax: 513-475-6525

-----Original Message-----

From: Rauf, Chris, VHACIN

Sent: Tuesday, February 23, 2010 4:43 PM

To: Richards, Diane, VHACIN

Cc: Rauf, Chris, VHACIN

Subject: FW: additional information for NRC inspection

Gary

The attachments will provide all the information the NRC requested.

Two of the Authorized Users did not perform any Prostate Brachytherapy during this period.

1. William Barrett, M.D.
2. David Grisell, M.D.

We made the following changes to improve the Brachytherapy Program.

1. We purchased a new Varian VariSeed system to be used at the VAMC.
2. An Isolader was purchased, which will allow more accurate loading and better record keeping of patient data.
3. We will have a physicist working at the VAMC with the Brachytherapy Program.

NRC Request for Information (February 16, 2010)
VA Medical Center, Cincinnati, Ohio

1. Provide copies of policies and procedures for prostate implants to include the following:
 - a. Copies of policies and procedures current at the time of the on-site NRC inspection for the prostate implant program with the effective date indicated.
 - b. Copies of policies and procedures that were revised after the on-site NRC inspection or in response to NHPP recommendations with the effective date indicated.
2. 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.

BRACHYTHERAPY PROCEDURE MANUAL
VA MEDICAL CENTER
CINCINNATI, OHIO

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OVERVIEW

Radiation Oncology Physicians from the Barrett Center and the VA Medical Center have developed a program to treat veterans from many VISN's in the eastern part of the United States.

This program uses radioactive seeds implanted into the prostate which will deliver high doses of radiation directly to the tumor. In this outpatient procedure, physicians use ultrasound images of the prostate to determine the most effective placement of the seeds which are permanently implanted in the prostate through thin needles. The seeds are small (about the size of a grain of rice), cause little to no discomfort, and their radioactivity diminishes over time. Brachytherapy can be effective in treating men with early stage prostate cancer. Possible side effects include impotence, urinary urgency and frequency, and occasional rectal discomfort.

OBJECTIVE

To comply with regulatory requirements in regard to administration of permanent implant brachytherapy treatment at Cincinnati VAMC. These policies and procedures are designed to comply with the requirements of the VA Master Material License (03-23853-01VA) and VAMC Cincinnati Permit # (34-00799-03).

The brachytherapy procedure protocol is part of the Written Directive Program at the VAMC and is prepared in accordance with 10CFR Part 34 requirements with the main purpose of avoiding medical events.

AUTHORITY

The Authorized User (AU) will work under the authority of the VA Master Material License #03-23853-01VA and VAMC Cincinnati Permit #34-00799-03. The Radiation Safety Officer will be responsible for ensuring that audits occur as required in 10CFR Part 35.

The program will be responsive to the VACO, JCAHO, NHPP directives and NRC directives, standards, and guidelines.

POLICIES AND PROCEDURES

This procedure will be incorporated into the Radiation Oncology Procedure and remains responsive to the VACO, JCAHO, NHPP Program Directives and NRC Directives, standards and guidelines.

Policies and Procedures for the Use of Brachytherapy Sources:

- A. Prior to administration of any dose from a Brachytherapy source, a “Written Directive” will be dated and signed by an “Authorized User”. With regard to therapeutic Brachytherapy doses a “written directive” is defined as an order, in writing, for a specific patient, dated and signed by an “Authorized User” prior to the administration of a Brachytherapy dose and contains the following information:

- Patient Name
- Patient Identification Number
- Brachytherapy source / isotope
- Dose / number of sources / total strength
- Area of implantation / treatment site

A “written directive” may be revised by the Authorized User, but the revision(s) must be recorded and signed prior to the administration of the dosage.

Except in emergent situation, as defined in subsection D, no personnel shall administer any brachytherapy source in the absence of a signed “written directive” with the above elements.

- B. Prior to administration, the patient’s identity must be verified as the patient named in the “written directive”. The person responsible for the administration of the brachytherapy source will complete the verification. Verification of the patient’s identity **MUST** be by **two** of the following methods:

- Positive identification by employee.
- Requesting and confirming name from patient
- Requesting from patient and confirming from DOB, SS#, address, or signature
- Requesting from patient and confirming name with companion
- Confirming name using I.D. bracelet, hospital card, or medical insurance card
- Confirming with photograph or patient’s face with proper identification.

- Confirming that the name on the tray matches the patient's I.D. **(MUST BE COMPLETED)**.

If the information obtained from this identity check does not correspond to the information on the "written directive", the brachytherapy procedure will not be administered until conclusive verification is obtained. (10CFR 35.41(a))

C. Ensure each administration is in accordance with the "written directive"

The brachytherapy dose and treatment site shall be confirmed prior to administration of the dose to verify its agreement with the treatment plan and the "written directive". A check of both the manual and computer-generated dose calculations will be performed prior to administration of the prescribed dose. (10CFR35.41 (b)) by the authorized user.

Written documentation of the seed strength verification will be kept in the appropriate records.

D. Oral Directives are permissible under the following conditions (10CFR35.40(a)(1)):

- When a patient's medical condition is such that his health would be jeopardized by the delay needed for origination or revising a "written directive".
- When "oral directives" are employed, the information contained in the original "written directive" is prepared within 24 hours of the "oral directive".
- In the situation of an oral revision of an existing "written directive", it must be revised, dated and signed by the Authorized User within 48 hours of the oral revision.

E. In the case of a "Medical Event", as described in 10 CFR Part 35.3045, the Authorized User and the RSO will be notified immediately. They will take appropriate actions. Reports will be filed as required.

F. Policies for all Workers:

All radiation workers in the Nuclear Medicine area will receive appropriate instructions for the current Brachytherapy Procedure Protocols or of any of its modifications.

It is required that every worker who does not understand how to carry out any procedures described herein or does not understand the "written directive", seek guidance. He/she must ask the supervisor or Authorized User about what

to do or how it should be done before continuing a procedure when there is any doubt.

All personnel involved in the Brachytherapy procedures, to include O.R. and Recovery Room personnel, will receive training, as appropriate. This instruction will include:

- Demonstrations, using a “dummy” seed/ribbon of permanent implant seeds and a discussion of how a seed/ribbon might be released from the patient (urine, wound, etc.)
- Precautions in the event of a seed/ribbon dislodging.
 - Never handle radioactive sources directly with your fingers. Use a long-handled forceps to pick-up the seed and return to a shielded lead container.
 - Immediately notify the RSO or Authorized User (Radiation Oncologist) if a seed/ribbon is found.
- Use standard radiation protection principles of time, distance and shielding to keep occupational radiation doses As Low As Reasonably Achievable (ALARA). Employees involved in these brachytherapy procedures will be issued appropriate Dosimetry badges. The type of badge(s) assigned will be according to the employee’s assigned duties.

G. Radiation Surveys:

- Procedure areas (to include any medical instruments and devices) will be surveyed with an appropriate survey instruments to identify any areas that might harbor a stray sealed source and brachytherapy form must be completed by the technologist at the time of the survey.
- The patient will be surveyed with an appropriate radiation survey instrument when moved to PACU, or patient room to confirm acceptable dose rate around the patient. The brachytherapy survey form must be completed by the technologist at the time of the survey.

Patient Release and Instructions:

Permanent Implant Patients will be provided from the Authorized User oral instructions, and written instructions will be given by the technologist when appropriate and recorded in patient survey record. Instructions will include radiation safety guidance on methods to keep radiation doses to household members and the public ALARA, and radiation precautions in the event a seed is dislodged.

Annual Review:

Frequency: An audit of the Brachytherapy Procedure Protocols shall be conducted periodically, with a written summary report filed annually. Using pre-established criteria, the review shall determine the effectiveness of the Brachytherapy Program. Review will include, but not limited to, written directive, number dislodged seeds, and proper completion of patient survey records.

Responsibility: Individuals, other than Authorized Users, shall conduct the annual review. For example, the Radiation Safety Officer or Chairman of the Radiation Safety Committee.

Scope: The audit shall evaluate 100% compliance with the following criteria:

1. Having a “written directive” prior to administration of a brachytherapy dose.
2. Oral directives are reserved for emergent situations where delay would jeopardize the patient’s health.
3. The content of the “written directive” is as required by the policy.
4. All individuals involved in the preparation/administration of brachytherapy sources have received instructions in the requirements of the Prostate Brachytherapy Procedure Protocol and documentation of this fact is available.
5. Verification of the patient’s identity is performed prior to administration of the brachytherapy source by one of the accepted methods.
6. Brachytherapy administration is in accordance with the specific information contained in the “written directive”.
7. Unintended deviations from the “written directive” are identified, evaluated and appropriate corrective actions are instituted.
8. Each “medical event” evoked appropriate response and notified to proper individuals (i.e. RSO, Attending physician).
9. Appropriate records are kept in file, including the annual review, “written directives”, Brachytherapy dosages, and “medical events”.

Modification can be made to this program at any time to increase its effectiveness and to meet the objectives of the program as required by 10 CFR Part 35. A copy of any modifications will be approved by the Radiation Safety Committee (RSC) and be kept on file with the RSC’s minutes in the Radiation Safety Office.

VA MEDICAL CENTER
BRACHYTHERAPY PROCEDURE
IODINE-125 SEEDS (LOW ACTIVITY)

1. Treatment sites: Prostate, chest cavity, abdominal cavity, extremities, head and neck, brain, and other sites as deemed necessary by the radiation oncologist.
2. Source strength: Approximately 0.4 mCi (individual seeds), range from 0.3 mCi – 0.80 mCi.
3. Chemical and physical form of the radioisotope: I-125 absorbed on silver rod 0.5 mm diameter, 3.0 mm length.
4. Source description: A welded titanium capsule 0.8 mm diameter, 4.5 mm length, 0.05 mm wall thickness.
5. Provider of sealed source to VAMC: Oncura Inc, Arlington Heights, IL 60004.
6. Procedure on receipt of source to detect leakage: None on site—supplier certifies less than 0.005 microCi of removable I-125 activity. Wipe test (using cotton-tipped applicators) of package is taken for removable contamination and recorded in the hot lab. Cotton applicator is counted in caprac counter and recorded in the incoming package log or RAM.
7. Source calibration technique on site: Supplier furnishes certification of calibration—See attachment.
8. Temporary location of source storage (room) and description of shielding: Will be placed in room C217 in locked cabinet and kept in shielded containers.
9. Techniques for handling of source, including loading, shielding, etc., for technologists and user: I-125 seeds are permanently implanted. The I-125 seed can be implanted with loose seeds or rapid strand by using a sterile biopsy needle. Seeds are loaded in Room C217 by the Nuclear Medicine Technologist. If sterilization is required, Oncura Model 6711 (or

comparable seed), the method is the choice of the brachytherapist (Authorized User). After loading, the instruments used to handle seeds and the table will be monitored to detect contamination, which would indicate any mechanical damage to a seed causing release of I-125. For ultrasonically guided implant, pre-loaded biopsy needles are inserted through a template into tissue and withdrawn over stylet to deposit seeds. Upon completion of the insertion, the Nuclear Medicine Technologist will monitor suction apparatus, tubing trap, Foley bags, and all materials in which a loose source may become lodged. Any unused seeds are returned to Nuclear Medicine, Room C217 by the Authorized User or the Nuclear Medicine Technologist for return to manufacturer. All instruments which have been used to load seeds will be surveyed for contamination to detect any mechanical damage to a seed which may result in any discharge of I-125. If at background level, they will be sent to SPD for cleaning and sterilization. If any leakage is discovered, the nuclear medicine technologist will notify the Radiation Safety Officer and Authorized User performing the implant. If leakage is detected, the following procedure will be followed: All patients and personnel involved will undergo thyroid counting. Area surveys and wipes will be taken to determine the extent of decontamination necessary. The use of SSKI as a thyroid blocking agent will be the judgment of the physician. The patient will be transferred from the O.R. to PACU, before being discharged, the Nuclear Medicine Technologist will survey the patient and urine bag and record that the survey has been completed in the chart at the bedside and on survey form.

10. Survey performed after handling? Yes: X No:

11. Sterilization technique: Model 6715, 7000 presterilized. Model 6711 (See package for sterilization instruction).

12. Is this a permanent implant? Yes: X No:

13. Do technologists wear finger badges? Yes: X No:

14. Room location for use: Fisher House, 5 North, O.R., PACU, seed loading area.

15. Monitoring for lost source after implant: Operating Room, Foley bag, urine bag are monitored for lost sources.

16. Method of accountability for source location use: Seed log kept.
17. Equipment involved in handling source: Sent for cleaning and sterilization.
18. Nursing instructions: See Training Sheets.
19. Instructions to patient before, during, and after implant: Given by Authorized User or nuclear medicine technologist.

SEED LOADING

1. The technologist receives two treatment planning forms from the Barrett Center (must receive one day prior to implant date)

a. Template coordinate form must include the following:

1. Seed activity
2. Date of calibration
3. Reference (#clicks)
4. Hole location
5. Number of seeds at each activity
6. Initial of dosimeter performing treatment plan.
7. Physician's checking plan.
8. Brachytherapist's approval plan
9. Date of implant
10. Name of patient

If any of the above elements are missing, the technologist should return the form to the Barrett Center for confirmation.

b. Needle loading configuration form (must include the following):

1. Needle location parameters (For example: bb3.5)
2. Type of seed (For example: NR, NL)
3. Name of patient

If any of the above elements are missing, the technologist should return the form to the Barrett Center for confirmation

NEEDLE LOADING

- a. Rapid and loose seeds will be placed into sterile needles to exactly conform to the treatment and placed into correctly labeled holes on the needle tray.
- b. Each tray will be x-rayed. The technologist will check each needle to insure that it conforms to the proper numbered hole location and the proper number of seeds.
- c. After seed confirmation, the technologist will sign the loading configuration form (X-ray must be kept for a record).

- d. Seed tray will be placed in drawer of locked cabinet with the name of the patient and the last four numbers of the social security number firmly attached.

TRANSPORT

- a. Seed trays will be placed in locked cabinet for transportation to the O.R.
- b. Appropriate radiation signs will be attached.
- c. Only the following personnel can transport I-125 seeds to the O.R:
 1. Brachytherapist (Authorized User)
 2. Nuclear Medicine Technologist
 3. Oncology Fellow (Under supervision of the Authorized User).

BRACHYTHERAPY (PATIENT RECORDS)

The patient chart in Nuclear Medicine must include the following. The technologist who performed the loading procedure is responsible for ensuring the information is in the patient's record:

- a. Original treatment plan from the Barrett Cancer Center
- b. Post treatment plan from Barrett Cancer Center
- c. X-ray from O.R.
- d. Completed written directive
- e. Seed certification form
- f. Completed template form
- g. Completed seed loading configuration form
- h. Completed patient survey form
- i. Certification Form 43-67081 (from all lots used)

Cincinnati VA Medical Center

Brachytherapy Policies and Procedures



Cincinnati VA Medical Center Brachytherapy Policies and Procedures

The Department of Veteran Affairs Memorandum of January 28, 2009 details the requirements for VA medical centers approved by the VHA National Health Physics Program for transperineal permanent implant prostate brachytherapy. This document, the *Cincinnati VA Medical Center Brachytherapy Policies and Procedures*, contains the standard procedures and quality assurance designed to meet these standards. It is based in part on the following documents:

Memorandum: Veterans Health Administration (VHA) Facilities Approved for Transperineal Permanent Implant Prostate Brachytherapy, From Director, VHA National Health Physics Program (NHPP) (115HP/NLR), January 28, 2009

Practice guideline for transperineal permanent brachytherapy of prostate cancer,. American College of Radiology (ACR). Reston (VA): American College of Radiology (ACR); 2005.

Permanent prostate seed implant brachytherapy: Report of the American Association of Physicists in Medicine Task Group No. 64, Med. Phys. 26(10), October 1999.

AAPM Task Group 128: Quality assurance tests for prostate brachytherapy ultrasound systems, Med. Phys. 35(12), December 2008.

Supplement to the 2004 update of the AAPM Task Group No. 43 Report, Med. Phys. 34(6), June 2007.

10CFR35.41, .75, .404, .432, .2075, .457, 3045

Policies and procedures for additional brachytherapy procedures are also included. These include

- 1) Lung Brachytherapy (added 7/14/09)

Modification can be made to this program at any time to increase its effectiveness and to meet the objectives of the program as required by 10 CFR Part 35. A copy of any modifications will be approved by the Radiation Safety Committee (RSC) and be kept on file with the RSC's minutes in the Radiation Safety Office.

Cincinnati VA Medical Center
Brachytherapy Policies and Procedures

Cincinnati VA Medical Center Brachytherapy Policies and Procedures

1. Overview

- a. Radiation Oncology Physicians from the Barrett Center and the VA Medical Center have developed a program to treat veterans from many VISN's in the eastern part of the United States.
- b. This program uses radioactive seeds implanted into the prostate, which will deliver high doses of radiation directly to the tumor. In this outpatient procedure, physicians use ultrasound images of the prostate to determine the most effective placement of the seeds which are permanently implanted in the prostate through thin needles. The seeds are small (about the size of a grain of rice), cause little to no discomfort, and their radioactivity diminishes over time. Brachytherapy can be effective in treating men with early stage prostate cancer. Possible side effects include impotence, urinary urgency and frequency, and occasional rectal discomfort.

2. Objective

- a. It is the objective of this program to provide the highest quality prostate implants and to comply with regulatory requirements in regard to administration of permanent implant brachytherapy treatment at Cincinnati VAMC. These policies and procedures are designed to comply with the requirements of the VA Master Material License (03-23853-01VA) and VAMC Cincinnati Permit # (34-00799-03).
- b. The brachytherapy procedure protocol is part of the Written Directive Program at the VAMC and is prepared in accordance with 10CFR Part 34 requirements with the main purpose of avoiding medical events.

3. Authority

- a. The Authorized User (AU) will work under the authority of the VA Master Material License #03-23853-01VA and VAMC Cincinnati Permit #34-00799-03. The Radiation Safety Officer will be responsible for ensuring that audits occur as required in 10CFR Part 35.
- b. The program will be responsive to the VACO, JCAHO, NHPP directives and NRC directives, standards, and guidelines.

4. General Procedures for low activity I125 Seeds for permanent implants

- a. Treatment sites: Prostate, chest cavity, abdominal cavity, extremities, head and neck, brain, and other sites as deemed necessary by the radiation oncologist.

Cincinnati VA Medical Center
Brachytherapy Policies and Procedures

- b. Source strength: Approximately 0.4 mCi (individual seeds), range from 0.3 mCi – 0.80 mCi.
- c. Chemical and physical form of the radioisotope: I-125 absorbed on silver rod
- d. Source description: A welded titanium capsule 0.8 mm diameter, 4.5 mm length, 0.05 mm wall thickness.
- e. Provider of sealed source to VAMC: Oncura Inc, Arlington Heights, IL 60004.
- f. Procedure on receipt of source to detect leakage: None on site—supplier certifies less than 0.005 microCi of removable I-125 activity. Wipe test (using cotton-tipped applicators) of package is taken for removable contamination and recorded in the hot lab. Cotton applicator is counted in caprac counter and recorded in the incoming package log or RAM.
- g. Source calibration technique on site: Supplier furnishes certification of calibration—See attachment.
- h. In addition to the supplier furnished source calibration, 10% of seeds will be assayed with a NIST traceable instrument prior to implant.
- i. Temporary location of source storage (room) and description of shielding: Will be placed in room C217 in locked cabinet and kept in shielded containers.
- j. Techniques for handling of source, including loading, shielding, etc., for technologists and user: I-125 seeds are permanently implanted. The I-125 seed can be implanted with loose seeds or rapid strand by using a sterile biopsy needle. Seeds are loaded in Room C217 by the Nuclear Medicine Technologist. If sterilization is required, Oncura Model 6711 (or comparable seed), the method is the choice of the brachytherapist (Authorized User). After loading, the instruments used to handle seeds and the table will be monitored to detect contamination, which would indicate any mechanical damage to a seed causing release of I-125. For ultrasonically guided implant, pre-loaded biopsy needles are inserted through a template into tissue and withdrawn over stylet to deposit seeds. Upon completion of the insertion, the Nuclear Medicine Technologist will monitor suction apparatus, tubing trap, Foley bags, and all materials in which a loose source may become lodged. Any unused seeds are returned to Nuclear Medicine, Room C217 by the Authorized User or the Nuclear Medicine Technologist for return to manufacturer. All instruments which have been used to load seeds will be surveyed for contamination to detect any mechanical damage to a seed which may result in any discharge of I-125. If at background level, they will be sent to SPD for cleaning and sterilization. If any leakage is discovered, the nuclear medicine technologist will notify the Radiation Safety Officer and Authorized User performing the implant. If leakage is detected, the following procedure will be followed: All patients and personnel involved will undergo thyroid counting. Area surveys and wipes will be taken to determine the extent of decontamination necessary. The use of SSKI as a thyroid blocking agent will be the judgment of the physician. The patient will be transferred from the O.R. to PACU, before being discharged, the Nuclear Medicine Technologist

Cincinnati VA Medical Center
Brachytherapy Policies and Procedures

will survey the patient and urine bag and record that the survey has been completed in the chart at the bedside and on survey form.

- k. Survey performed after handling? Yes: X No: __
- l. Sterilization technique: presterilized.
- m. Is this a permanent implant? Yes: X No: __
- n. Do technologists wear finger badges? Yes: X No: __
- o. Room location for use: Fisher House, 5 North, O.R., PACU, seed loading area.
- p. Monitoring for lost source after implant: Operating Room, Foley bag, urine bag are monitored for lost sources.
- q. Method of accountability for source location use: Seed log kept.
- r. Equipment involved in handling source: Sent for cleaning and sterilization.
- s. Nursing instructions: See Training Sheets
- t. Instructions to patient before, during, and after implant: Given by Authorized User or nuclear medicine technologist.
- u. Seed Loading
 - i. The technologist receives two treatment planning forms from the Barrett Center (must receive one day prior to implant date)
 - ii. Template coordinate form must include the following:
 - 1. Seed activity
 - 2. Date of calibration
 - 3. Reference (#clicks)
 - 4. Hole location
 - 5. Number of seeds at each activity
 - 6. Initial of dosimeter performing treatment plan.
 - 7. Physician's checking plan.
 - 8. Brachytherapist's approval plan
 - 9. Date of implant
 - 10. Name of patient
 - 11. If any of the above elements are missing, the technologist should return the form to the Barrett Center for confirmation.
- v. Needle loading configuration form (must include the following):
 - i. Needle location parameters (For example: bb3.5)
 - ii. Type of seed (For example: NR, NL)
 - iii. Name of patient
 - iv. If any of the above elements are missing, the technologist should return the form to the Barrett Center for confirmation
- w. Needle Loading
 - i. The Core Oncology Isoloder will be used to load the needles.
 - ii. The electronic needle loading chart will transferred from the treatment planning system to the Isoloder system
 - iii. The needles will be loaded in accordance with the plan.
 - iv. The needles will be placed on an tray labeled with the patient's name with needles clearly numbered.

Cincinnati VA Medical Center
Brachytherapy Policies and Procedures

- v. Each tray will be x-rayed and kept for record. The technologist will check each needle to insure that it conforms to the proper numbered hole location and proper number and spacing of seeds.
 - vi. After seed confirmation, the technologist will sign the loading configuration form.
 - vii. Seed tray will be placed in drawer of locked cabinet with the name of the patient and the last four numbers of the social security number firmly attached
- x. Transport
- i. Seed trays will be placed in locked cabinet for transportation to the O.R.
 - ii. Appropriate radiation signs will be attached.
 - iii. Only the following personnel can transport I-125 seeds to the O.R:
 - 1. Brachytherapist (Authorized User)
 - 2. Nuclear Medicine Technologist
 - 3. Oncology Fellow (Under supervision of the Authorized User).
 - 4. Medical physicist

5. Training

- a. Training will be provided for physician authorized users, medical physicists, dosimetrists, and residents. Urologists, if they are to be substantively involved in the implants, will be trained appropriately at the time of involvement.
 - i. Training regarding Medical Events
 - 1. [See VHA Standard Procedure - - Training Medical Events]
 - ii. Training regarding Written Directive
 - 1. [See VHA Standard Procedure - - Preparation and Completion of Written Directives for Permanent Implant Prostate Brachytherapy]
- b. All personnel involved in the Brachytherapy procedures, to include O.R. and Recovery Room personnel, will receive standard radiation safety training, as appropriate. This instruction will include:
 - i. Demonstrations, using a “dummy” seed/ribbon of permanent implant seeds and a discussion of how a seed/ribbon might be released from the patient (urine, wound, etc.)
 - ii. Precautions in the event of a seed/ribbon dislodging.

Cincinnati VA Medical Center
Brachytherapy Policies and Procedures

1. Never handle radioactive sources directly with your fingers. Use a long-handled forceps to pick-up the seed and return to a shielded lead container.
 2. Immediately notify the RSO or Authorized User (Radiation Oncologist) if a seed/ribbon is found.
 - iii. Use standard radiation protection principles of time, distance and shielding to keep occupational radiation doses As Low As Reasonably Achievable (ALARA). Employees involved in these brachytherapy procedures will be issued appropriate Dosimetry badges. The type of badge(s) assigned will be according to the employee's assigned duties
- c. Training will be evaluated by interviewing trainees at the completion of training.

6. Written Directive and Chart Documentation

- a. Prior to administration of any dose from a Brachytherapy source, a "Written Directive" will be dated and signed by an "Authorized User Physician". With regard to therapeutic Brachytherapy doses a "written directive" is defined as an order, in writing, for a specific patient, dated and signed by an "Authorized User" prior to the administration of a Brachytherapy dose and contains the following information:
 - i. Patient Name
 - ii. Patient Identification Number
 - iii. Brachytherapy source and isotope
 - iv. Dose, number of sources, and source activity
 - v. Area of implantation or treatment site
- b. A "written directive" may be revised by the Authorized User, but the revision(s) must be recorded and signed prior to the administration of the dosage.
- c. Except in emergent situation, as defined in subsection D, no personnel shall administer any brachytherapy source in the absence of a signed "written directive" with the above elements.
- d. Prior to administration, the patient's identity must be verified as the patient named in the "written directive". The person responsible for the administration of the brachytherapy source will complete the verification. Verification of the patient's identity MUST be by **two** of the following methods:
 - i. Requesting and confirming name from patient
 - ii. Requesting from patient and confirming from DOB, SS#, address, or signature

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- iii. Requesting from patient and confirming name with companion
 - iv. Confirming name using I.D. bracelet, hospital card, or medical insurance card
 - v. Confirming with photograph or patient's face with proper identification.
- e. It will be confirmed that the patient identification on the tray containing the needles and sources matches the patient's I.D. prior to the implant start.
- f. If the information obtained from this identity check does not correspond to the information on the "written directive", the brachytherapy procedure will not be administered until conclusive verification is obtained. (10CFR 35.41(a)).
- g. Oral Directives are permissible under the following conditions (10CFR35.40(a)(1)):
- i. When a patient's medical condition is such that his health would be jeopardized by the delay needed for origination or revising a "written directive".
 - ii. When "oral directives" are employed, the information contained in the original "written directive" is prepared within 24 hours of the "oral directive".
 - iii. In the situation of an oral revision of an existing "written directive", it must be revised, dated and signed by the Authorized User within 48 hours of the oral revision.
- h. Upon the completion of the implant and post-implant dosimetry, the medical physicist will confirm that the implant was performed in conformance with the written directive. The check will include
- i. Brachytherapy source and isotope
 - ii. Dose, number of sources, and source activity
 - iii. Area of implantation or treatment site
- i. The medical physicist will review the post implant dose analysis. The medical physicist and RSO will confirm that the post implant dose analysis has been performed and evaluated to determine whether a medical event has occurred.
- j. In the event that, after the procedure followed in Post-Implant Dose Analysis, the implant is deemed a medical event, the Authorized User and RSO will be informed immediately. All appropriate actions will be taken, including informing NHPP within 24 hours, and a written report within 15 days
- k. Documentation of the implant will remain in the patient chart for a minimum of 3 years, including
- i. Pre-implant treatment plan

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- ii. Written directive
- iii. Needle loading printout
- iv. Needle loading verification x-ray
- v. Seed calibration from manufacturer
- vi. Seed calibration
- vii. Post-implant x-ray confirming seed location
- viii. Post-implant treatment plan
- ix. Room and patient survey forms
- x. Documentation that patient received post-implant instructions

7. Implant procedure

- a. Patient selection criteria
[insert Cincinnati VAMC patient selection criteria]
- b. Pre-implant treatment planning will be performed using appropriate imaging.
 - i. Complete treatment planning will be performed for each patient before or during seed implantation.
 - ii. Appropriate imaging modalities, specifically TRUS, will be performed to define the prostate in the treatment planning process.
 - iii. The treatment plan dose calculations will be checked by a medical physicist for dose and seed activity in conformance with the written directive. When possible, this check will be performed by an individual different than the treatment planner.
 - iv. Implants will be performed with a single seed activity to allow meaningful post-implant dosimetry.
- c. Before implantation of the first seed, complete the pre-implantation portion of the written directive, which must include the NRC required information in 10 CFR 35.40 (treatment site, radionuclide, and dose).
- d. Before implantation of the first seed, verify the ultrasound images of the prostate are of adequate quality to perform the implant. Verify the prostate dimensions and template match those of the pre-plan. If they differ excessively, another pre-plan should be created.
- e. At the completion of the implant, an x-ray will be taken to confirm the location of the seeds in the prostate.
- f. Post-implant treatment planning
 - i. At the end of each procedure, obtain a radiographic or fluorographic image depicting seed positions in the patient. Fluoroscopic imaging should be immediately available during the procedure, to serve as a check that seeds are not being inadvertently placed away from the intended region

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- ii. After completion of the implant procedure, complete the post-implant portion of the written directive to record the information required in 10 CFR 35.40 (treatment site, radionuclide, number of sources implanted, total source strength implanted, and the word "permanent").
 - iii. Immediately after the completion of each implant, perform a survey of the room using a portable radiation survey meter to locate any misplaced sources, as required by 10 CFR 35.404. The survey should include the floor, linens, waste material, applicators, and empty needles and cartridges. A record of the survey must be made as required by 10 CFR 35.2404. The survey should include the feet of people leaving the room.
 - iv. Before releasing the patient, perform a release survey as required by 10 CFR 35.75 and document the survey as required by 10 CFR 35.2075(a). This will be performed when the patient is moved to PACU, or to a patient room. The survey should include measurement of the exposure rate, air kerma rate, dose rate, or dose equivalent rate at a distance of 1 meter from the patient. The survey must be made with a radiation survey meter calibrated for the energy of the radiation emitted from the seeds, or the measurement must be corrected for energy using the energy response curve of the meter and any attached detector.
 - v. The patient will be given instructions, both in writing and verbally, on actions recommended to keep doses to others as low as reasonably achievable. The instructions must include actions to take if a seed is passed in the urine.
- g. Post-Implant Dose Analysis
- i. Post-implant imaging and dosimetric analysis is mandatory and must be completed for each implant procedure, unless the patient refuses post-implant imaging
 - ii. Complete post-treatment planning of each patient using post-implant CT or MRI imaging
 - iii. Determine the actual dose distribution delivered and identify any variances or deviations from the original treatment plan
 - iv. A post-implant CT will be acquired on the day of implant, or as soon as medically capable, for patients who travel to Cincinnati for the procedure. Contours will be generated of the prostate and rectum, and post-implant dosimetry will be performed before the patient leaves Cincinnati. For patients who live in the Cincinnati area, post-implant dosimetry will be performed within 5 days.
 - v. The following parameters will be calculated
 - 1. D_{90} , defined as the minimum dose received by 90% of the target volume as delineated on the post-implant CT
 - 2. V_{100} , the percentage of the target volume delineated on the CT receiving 100% of the prescribed dose.

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3. R_{145Gy} , Rectal Dose Index, the volume of the rectum receiving 145 Gy or more of the prescribed dose.
 4. The number of seeds implanted but not contributing meaningful dose to the target organ. For the purposes of this determination, this will include seeds more than 1 cm from the volume defined as prostate on the post-implant CT.
- vi. The implant will be evaluated based upon the above parameters.
1. The implant will be acceptable if all the of the following criteria are met:
 - a. 80% Prescribed Dose $\leq D_{90}$
 - b. seeds more than 1 cm from the prostate.
 - c. $R_{145Gy} < 1.0 \text{ cm}^3$.
 2. If $D_{90} < 80\%$ of prescribed dose, the following procedure will be followed
 - a. The patient will be counseled that the results of the post-implant dosimetry suggest that the dose delivered to the prostate may be low. The dosimetry may be low in part due to swelling of the prostate. The Authorized User will suggest options to address the low D_{90} . Options include
 - i. Immediately (before the patient leaves Cincinnati) implanting more seeds as deemed appropriate based on the post-implant dosimetry.
 - ii. Obtain a CT in 30 days and evaluate the dosimetry again. If D_{90} is again less than 80% of the prescribed dose, advise the patient to return to implant more seeds as deemed appropriate based on the 30 day CT post-implant dosimetry. If $D_{90} < 80\%$ at 30 days the implant will be reported as a medical event.
 - b. If D_{90} is less than or equal to 80% of the prescription dose and the patient refuses 30 day CT and/or implanting more seeds, the implant will be declared a medical event and all appropriate investigational and reporting requirements will be followed.
 3. If seeds are >1 cm from the prostate contoured on CT, or if R_{145Gy} is greater than 1.0 cm^3 , then the implant will be evaluated to determine whether it is a medical event. If it is determined to be a medical event, all appropriate reporting and investigation procedures will be performed.

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Brachytherapy Policies and Procedures

8. Quarterly Quality Assurance, Audit and Review

- a. An audit of the brachytherapy procedure shall be conducted quarterly, with a written summary report filed with the Radiation Safety Committee. Using pre-established criteria, the review shall determine the effectiveness of the Brachytherapy Program.
- b. The audit will be performed by individuals other than the authorized user, for example the Radiation Safety Officer, medical physicist, or Chairman of the Radiation Safety Committee.
- c. The audit will evaluate
 - i. Having a “written directive” prior to administration of a brachytherapy dose.
 - ii. Oral directives are reserved for emergent situations where delay would jeopardize the patient’s health.
 - iii. The content of the “written directive” is as required by the policy.
 - iv. All individuals involved in the preparation/administration of brachytherapy sources have received instructions in the requirements of the Prostate Brachytherapy Procedure Protocol and documentation of this fact is available.
 - v. Verification of the patient’s identity is performed prior to administration of the brachytherapy source by one of the accepted methods.
 - vi. Brachytherapy administration is in accordance with the specific information contained in the “written directive”.
 - vii. Unintended deviations from the “written directive” are identified, evaluated and appropriate corrective actions are instituted.
 - viii. Each “medical event” evoked appropriate response and notified to proper individuals (i.e. RSO, Attending physician).
 - ix. Appropriate records are kept in file, including the annual review, “written directives”, Brachytherapy dosages, and “medical events”.
 - x. Review of any changes in equipment or software
 - xi. Dosimetric analysis of implants performed during quarter, including
 1. Date of implant procedure
 2. date of post-implant CT imaging
 3. Prescribed dose
 4. D_{90} , defined as the minimum dose received by 90% of the target volume as delineated on the post-implant CT.
 5. V_{100} , defined as the percentage of the target volume delineated on the post-implant CT receiving 100% of the prescribed dose
 6. R_{145Gy} , the volume of rectum receiving more than 145 Gy.
 7. Evaluation of seeds outside the prostate treatment volume.

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9. Annual Clinical Quality Assurance

- a. Physician peer review will be performed to assess variability in the contouring of prostate volumes from post-implant CT scans and definition of rectal volumes and to assess quality of care. This should include ongoing within-department peer review.
 - i. An second authorized user at the University of Cincinnati Radiation Oncology, experienced with trans-rectal ultrasound guided prostate implants, will review 10 cases of pre-implant and post-implant dosimetry. The review will include
 1. Appropriateness of the pre-treatment plan.
 2. Contouring of prostate and rectum.
 3. Appropriateness of the post-implant plan.
 4. Evaluation of the quality of care.
 - ii. Further review of patients will be performed as required by the Director of the National VHA Radiation Oncology Program.
- b. The medical physicist will review the quality assurance program annually.

10. Technical Quality Assurance

- a. Treatment planning acceptance and QA
 - i. The acceptance testing procedure for the vendor-specific FDA-cleared treatment planning system will be followed and documented before the first patient treatment is performed and after software revisions. The results will be reviewed and approved by a therapeutic medical physicist experienced in TeIT will include, at a minimum, include
 1. Geometric accuracy of image information transferred from the ultrasound unit used during implants and CTs used for post-implant dosimetry.
 2. The source specification parameters will be evaluated.
 3. Display of dose calculations
 4. Dose accuracy
 - a. Point dose
 - b. Isodose level
 - c. Dose volume
 - ii. The dose rate values from the planning system will be evaluated for the applicable seed model relative to the Supplement to the 2004 update of the of the AAPM Task Group No. 43 Report (2007), or its successor.
 - iii. Ensure that the medical physics staff is aware and conforms with the guidelines the AAPM Report No. 68 (TG-64) – Permanent prostate

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seed implant brachytherapy: Report of the American Association of Physicists in Medicine.

- iv. Treatment planning systems will retain backward compatibility after upgrades.
 - v. Patient data from the treatment planning system, including pre- and post-plans, will be backed up to CD and placed in the patient chart.
- b. Trans-rectal ultrasound QA
- i. TRUS QA will be performed at acceptance and annually in conformance with *AAPM Task Group 128: Quality assurance tests for prostate brachytherapy ultrasound systems*, Med. Phys. 35(12), December 2008.
- c. CT QA
- i. The CT used for post-implant dosimetry will be tested for spatial fidelity before first use and annually thereafter. Post-implant patient CTs will be evaluated to with respect to the image quality being sufficient to identify seed locations and prostate/rectum volumes.
 - ii. Annual diagnostic QA will be performed and documented.
- d. Image transfer
- i. Prior to first use of a new imaging system or treatment planning system, a phantom will be scanned to assess spatial fidelity and the overall data transfer process.
- e. Seed Activity
- i. Isolader radiation response
 - 1. The Isolader system will be sent for NIST traceable calibration for I125 and Pd103 sources every two years.
 - ii. Written documentation of the calibration of the instrument used to measure the activity of seeds provided by the vendor will be maintained.

11. Lung Brachytherapy

- a. Protocol

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- i. Permanent implants using a mesh I-125 seeds are performed as part of the Z4032 Protocol of the American College of Surgeons Oncology Group. This is a randomized phase III study of sublobar resection versus sublobar resection plus brachytherapy in high risk patients with non-small cell lung cancer (NSCLC), 3 cm or smaller, or a similar clinical protocol.
- ii. In this study, or a similar clinical protocol, if the patients are randomized to resection plus brachytherapy, an implant is performed either with a mesh of seeds with 1 cm spacing, or with strands of 10 seeds with 1 cm spacing (double suture technique). The seeds with the mesh implant should be in the range of 0.4 – 0.6 mCi, and in the double suture technique should be in the range of 0.7 – 0.8 mCi. The intent of the implant is to provide a dose of 100 Gy to 5 mm depth with the mesh implant, or 100 Gy to 7 mm depth with the double suture technique.
- iii. Post implant imaging is to be performed at least 3 and no more than 6 weeks post-procedure, after complete re-inflation of the lung.

b. Written Directive

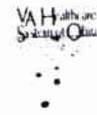
- i. Prior to performing the implant, the Written Directive will be signed and dated by the Authorized User as described in the pertinent portions of Section 6 above.
- ii. For lung implants, the Planned Activity portion of the Written Directive will include
 1. The isotope
 2. The number of sources and source activity
 3. The treatment site
 4. Permanent implant
- iii. Upon the completion of the implant the Authorized User will confirm by signing and dating in the Administered Dose portion of the Written Directive that the implant was performed in conformance with the written directive. The check will include
 1. Area of implantation or treatment site, confirmed at the time of surgery by direct visualization of the mesh sutured to the resection site.
 2. The isotope
 3. Number of sources and source activity.

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- iv. If the treatment site, or the total activity of the implanted sources differs by more than 20% from the Planned Activity, the implant will be deemed a medical event.
 - c. Post-implant dosimetry will be performed based on the CT acquired as described in the protocol above.
 - i. Seeds will be individually identified to verify that all seeds are maintained in the mesh.
 - ii. Seeds that are found to more than 3 cm from the mesh will be evaluated. The evaluation will determine whether dose to tissue other than the treatment site differed by more than 50% from the dose that would have occurred without the seed migration.
 - iii. For the purposes of the evaluation, the average dose to a spherical volume of tissue 1 cm in radius centered on the seed will be determined.
 - iv. If the dose is found to have differed to tissue other than the treatment site by more than 50% then it will be deemed a medical event.
 - v. If the seed is determined to have been implanted in the correct treatment site, but migrated after implantation, it will not be deemed a medical event.
 - d. The Medical Physicist and RSO will confirm by signing and dating the Written Directive in the Post-Implant Dose Analysis section that the isotope, number of sources, source activity, treatment site, and the post-implant dose analysis has been performed and evaluated to determine whether a medical event has occurred.
 - e. In the event that the implant is deemed a medical event, the Authorized User and RSO will be informed immediately. All appropriate actions will be taken, including informing NHPP within 24 hours, and a written report within 15 days.
 - f. Documentation of the implant will remain in the patient chart for a minimum of 3 years, including
 - i. Written directive
 - ii. Seed calibration from manufacturer
 - iii. Post-implant CT and dosimetry
 - iv. Room and patient survey forms
 - v. Documentation that patient received post-implant instructions.



Cincinnati VAMC
Brachytherapy Written Directive (Authorized Users Only)
 () Permanent Implant () Temporary Implant



Patient Name: Place Patient's Label here SS#: _____
 Date of Birth: _____

Planned Activity
 () Iodine 125 # of sources _____ strength/source _____ mCi
 () Other # of sources _____ strength/source _____ mCi

Prescribed Total Dose _____ cGy () Iodine 125 () Other
 Treatment Site: _____

Authorized User's Signature: _____ Date: _____

Patient Identification confirmation (Check two below/Do not use A and B together)

- () A. Positive identification by employee
- () B. Requesting and confirming name from patient
- () C. Requesting from patient and confirming from DOB, SS#, address, or signature
- () D. Requesting from patient and confirming name with companion
- () E. Confirming name using ID bracelet, hospital card, or medical insurance card
- () F. Confirming with photograph of patient's face with proper identification
- () G. Confirming that the name on the tray matches the patient's ID (**MUST BE COMPLETED**)

Confirmed by: _____

Administered Dose

Radiograph taken for treatment site: _____ Date: _____

() Iodine 125 # of sources _____ strength/source _____ mCi
 () Other # of sources _____ strength/source _____ mCi

Delivered Total Dose _____ cGy () Iodine 125 () Other

This administration was performed in accordance with this written directive and its final plan and related calculations

Prior to release patient was provided with radiation safety guidance or written instructions per NUREG 1556, Vol. 9, Rev. 2, Appendix U.

Authorized User's Signature _____ Date: _____

Record of Source Use

Storage Location _____
 Storage removed from storage Date/Time _____ / _____ am/pm
 Initials: _____

Source returned to storage Date/Time _____ / _____ am/pm None Returned

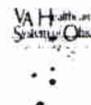
See source log book for further information

Reviewed by: _____ / Medical Physicist _____ Date

_____ / Radiation Safety Officer _____ Date



Cincinnati VAMC
Brachytherapy Patient Survey Records



Patient Name _____ Patient Label Here _____ Bldg/Room #: _____
 Medical Record #: _____ Radionuclide: _____

IMMEDIATELY AFTER IMPLANT "PATIENT AND AREA OF USE"

Date: _____ Time: _____ Instrument used: _____ Correction Factor _____
 Surveyor Initials: _____ Bldg/Room# _____
 Seeds found? () Yes () No

PROMPTLY AFTER IMPLANT "AREA RADIATION DOSE RATES"

Time survey completed: _____ am/pm _____ Surveyor Initials: _____
 Instrument used (if different from above): _____

1. Draw a plan of the patient's room and all immediate adjacent areas.
2. List dose rate readings in mR/hr for several points in each area. Use the table below to key the locations on the map.

- | | |
|----------|-----------|
| 1. _____ | 9. _____ |
| 2. _____ | 10. _____ |
| 3. _____ | 11. _____ |
| 4. _____ | 12. _____ |
| 5. _____ | 13. _____ |
| 6. _____ | 14. _____ |
| 7. _____ | 15. _____ |
| 8. _____ | 16. _____ |

IMMEDIATELY AFTER REMOVAL "SOURCE REMOVAL CONFIRMATION"

Date: _____ Time: _____ Instrument used: _____ Correction Factor _____
 Surveyor initials: _____ Bldg/Room#: _____
 Dose rate at 1 meter from patient _____ mR/hr

PERMANENT IMPLANT PATIENT "PRIOR TO RELEASE"

Date: _____ Time: _____ Instrument used: _____ Correction Factor _____
 Surveyor Name: _____ Dose rate at 1 meter from patient _____ mR/hr
 Release criteria: ($I^{125} \leq 1$ mR/hr) ($Ir^{192} \leq 0.8$ mR/hr) ($Pd^{103} \leq 3$ mR/hr)
 Required if dose rate at 1 meter exceeds 0.2 mR/hr for I^{125} & Ir^{192} or 0.7 mR/hr for Pd^{103}
 Release instructions provided to patient: () Yes () No



**Cincinnati VAMC
Brachytherapy Patient Survey Records**



Patient Name _____ Patient Label Here _____ Bldg/Room #: _____
 Medical Record #: _____ Radionuclide: I¹²⁵

IMMEDIATELY AFTER IMPLANT "PATIENT AND AREA OF USE"

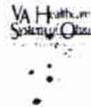
Date: _____ Time: _____ Instrument used: _____ Correction Factor _____
 Surveyor Initials: _____ Bldg/Room# _____
 Seeds found? () Yes () No

PERMANENT IMPLANT PATIENT "PRIOR TO RELEASE"

Date: _____ Time: _____ Instrument used: _____ Correction Factor _____
 Surveyor Name: _____ Dose rate at 1 meter from patient _____ mR/hr
 Release criteria: (I¹²⁵ ≤ 1 mR/hr) (Ir¹⁹² ≤ 0.8 mR/hr) (Pd¹⁰³ ≤ 3 mR/hr)
 Required if dose rate at 1 meter exceeds 0.2 mR/hr for I¹²⁵ & Ir¹⁹² or 0.7 mR/hr for Pd¹⁰³
 Release instructions provided to patient: () Yes () No



**Cincinnati VAMC
Brachytherapy Room Survey**



Patient: _____ Physician: _____

Hospital _____ Room _____ Single/Double Room Occupancy _____

Implant Site: _____

Applied Radionuclide: _____ Seeds _____

Number of Sealed Sources: _____ Ribbons _____

Activity: _____ (mg Ra equiv.) Tubes _____

_____ mCi Other _____

Unshielded exposure rate Hallway _____ = _____ mR/hr

At bedside = _____ mR/hr

Shielded exposure rate Room _____ = _____ mR/hr

At bedside = _____ mR/hr

Unshielded exposure rate Room _____ = _____ mR/hr

At 1 meter = _____ mR/hr

Maximum time for each worker at bedside without shielding is _____ minutes/week

Maximum time each worker at 1 meter without shielding is _____ minutes/week

Survey by: _____

Time of Implant: _____ am/pm on _____ 20 _____

Temporary Implant:

Expected time of removal _____ am/pm on _____ 20 _____

Expected time of discharge _____ am/pm on _____ 20 _____

Brachytherapy Source Removal Certification

I certify that patient _____ has had his/her entire Brachytherapy loading removed, and that all sources used in the loading are accounted for. These determinations were made by a survey of the patient and a source count, performed following the removal of the sources from the patient.

_____ M.D.

**CINCINNATI VAMC
INVENTORY**

Date Received	Patient/Other ID	Radionuclide	Number Seeds	Activity/Seed (mCi)			
Date Removed	Number Removed	Person Removing	Number Implanted	Number Returned	Person Returning	Date Disposed	How Disposed
Date Received	Patient/Other ID	Radionuclide	Number Seeds	Activity/Seed (mCi)			
Date Removed	Number Removed	Person Removing	Number Implanted	Number Returned	Person Returning	Date Disposed	How Disposed
Date Received	Patient/Other ID	Radionuclide	Number Seeds	Activity/Seed (mCi)			
Date Removed	Number Removed	Person Removing	Number Implanted	Number Returned	Person Returning	Date Disposed	How Disposed
Date Received	Patient/Other ID	Radionuclide	Number Seeds	Activity/Seed (mCi)			
Date Removed	Number Removed	Person Removing	Number Implanted	Number Returned	Person Returning	Date Disposed	How Disposed
Date Received	Patient/Other ID	Radionuclide	Number Seeds	Activity/Seed (mCi)			
Date Removed	Number Removed	Person Removing	Number Implanted	Number Returned	Person Returning	Date Disposed	How Disposed
Date Received	Patient/Other ID	Radionuclide	Number Seeds	Activity/Seed (mCi)			
Date Removed	Number Removed	Person Removing	Number Implanted	Number Returned	Person Returning	Date Disposed	How Disposed
Date Received	Patient/Other ID	Radionuclide	Number Seeds	Activity/Seed (mCi)			
Date Removed	Number Removed	Person Removing	Number Implanted	Number Returned	Person Returning	Date Disposed	How Disposed
Date Received	Patient/Other ID	Radionuclide	Number Seeds	Activity/Seed (mCi)			
Date Removed	Number Removed	Person Removing	Number Implanted	Number Returned	Person Returning	Date Disposed	How Disposed
Date Received	Patient/Other ID	Radionuclide	Number Seeds	Activity/Seed (mCi)			
Date Removed	Number Removed	Person Removing	Number Implanted	Number Returned	Person Returning	Date Disposed	How Disposed



Department of Veterans Affairs Medical Center
Cincinnati



DISCHARGE INSTRUCTIONS FOLLOWING IODINE-125 PROSTATE IMPLANTS

Small radioactive seeds have been implanted inside your prostate gland. The seeds consist of radioactive material Iodine-125. These radioactive seeds give off low energy radiation and lose their radioactivity over time. The low energy of the seeds means that the radiation is mostly contained within the prostate gland. Some amount of radiation is given off to structures very close to the prostate, such as the bladder and rectum.

The radioactive material is contained within the seeds implanted into your body. Objects that you touch or items that you use do not become radioactive. The seeds are similar in size and shape to a grain of rice and are less than 1/2 inch long (5mm).

To minimize radiation exposure to others from the radioactive seeds in your body, the precautions listed below should be followed for six months if you receive Iodine-125 seeds:

1. Any pregnant or possibly pregnant woman should avoid prolonged close contact with you. She can greet you briefly and move to a distance of 6 feet. At this distance, there is no measurable radiation exposure and no limit to the length of time that she can be in the same room with you.



2. Children should not be allowed to sit in your lap for a prolonged period of time during the first 6 months following the implant. You may affectionately greet (kiss/hug) a child for a short period of time and then move several feet or more away.

3. Sexual intercourse using a condom may be resumed after the implant. On very rare occasions, a seed can be passed with the ejaculate during intercourse. For this reason, we recommend the use of condoms for the first 2 or 3 encounters. The semen may be red, dark brown, or black. This is a normal result of bleeding that may have occurred during the implant and is not dangerous.

4. If you find a seed (small metal pellet at right), contact Nuclear Medicine Service 513-475-6319 or Kevin Redmond M.D. 513-861-3100

5. If you find a small seed in your bed, pick it up with tweezers or a spoon and flush it down your toilet and inform your physician at your next clinic appointment.

6. If you return to the Medical Center, clinic, or any other medical facility during the next 6 months, inform the medical staff that you have a radiation implant.

7. If you have any questions or concerns about this information, please contact: Kevin Redmond M.D. 513-861-3100



Seed size compared to dime



**Department of Veterans Affairs Medical Center
Cincinnati**



Seed Certification Slip/ Written Directive

Patient's Name:

Place Patient Label Here

Date:

Number of seeds brought up:

Lot#

Lot#

Number of seeds implanted:

Lot#

Lot#

Number of seeds brought back:

Lot#

Number of seeds excreted:

Technologist

Must be placed on seed tray

Place Patient Label Here

Seed Identification:

Lot#

Date:

Number of seeds present:

**QA BRACHYTHERAPY PROGRAM
CONTENTS**

1. **CT QC TESTING**
Required annually
2. **ISOLOADER**
Recertification required every two years
3. **CIRS BRACHYTHERAPY PHANTOM**
Certified annually by the manufacturer
4. **VARIAN SYSTEM**
Commission when installed and each new software install
5. **SEED CALIBRATION**
Attached data sheets

Emergency Plan Leaking Seeds

Purpose and Scope - This plan describes the procedure to be implemented in the event an implant source is leaking or suspected of leaking.

1. **Procedure-** As part of all Brachytherapy implant procedures, the radioactive material permit, the NHPP, and the NRC require surveys and wipe test of all incoming packs and surveys of the OR room and used needles at the completion of the implant procedure. Wipes of seed packaging will be taken at the end of loading procedure. If the wipes indicate the possibility of radioactive contamination from a leaking implant source (seed), the following steps will be taken to limit patient and personnel radiation exposure:
2. **Notification-**
 - A. The radiation oncologist will be notified immediately of the possibility of a leaking source (seed) who will notify the referring physician and the patient or patient's representative.
 - B. The Technologist will notify the Radiation Oncologist and the Radiation Safety Officer (RSO) in the event of a positive wipe test post loading.
 - C. The Radiation Safety Officer (RSO) will notify the Chairman of The Radiation Safety Committee, NHPP, and hospital administration of the possibility of a leaking source (seed).
 - D. The RSO will notify the NHPP of the final results to ensure that regulatory requirement were followed.
3. **Thyroid Blocking Agent-**
 - A. Patient will be offered a thyroid blocking agent by the Radiation Oncologist utilizing the recommendations found in the table on page 6 of *Guidance Potassium Iodine as a Thyroid Blocking Agent in Radiation Emergencies December 2001*.
 - a. The adult patient will be questioned by medical staff to ensure that there are no complications from iodine sensitivity.
 - b. The facility Pharmacy will be contacted to provide the SSKI compound
 - c. The adult patient will be administered 130 mg of SSKI per day for a period of 7 to 14 days depending on bioassay results.
 - B. Hospital personnel who were possibly exposed to leaking sources (seeds) will be offered a blocking agent through the Personnel Health Physician or Radiation Oncologist.
4. **Bioassays**
 - A. Thyroid burden will be measured on any patient or personnel who have possibly received exposure from Brachytherapy implant sources (seeds). Time of monitoring will be determined by the Radiation Safety Officer (RSO) with guidance from the consulting medical physicist.
 - B. Urine Bioassays

- a. Patients and personnel will be provided sample containers and instructions to provide daily urine samples for analysis with name, date, and time clearly marked on each sample. Number of samples will be determined by the Radiation Safety Officer with the guidance from the consulting Medical Physicists.
 - b. Administration of SSKI will continue until a clinical assessment is made by the Radiation Oncologist utilizing data provided by the Radiation Safety Officer (RSO) and the consulting Medical Health Physicist.
5. Review- The full Radiation Safety Committee will review the event at the next Radiation Safety meeting.

Kevin Redmond M.D.
Radiation-Oncologist

Chris Rauf
Radiation Safety Officer

RE: Variseed Prostate Implant Program
V8.0.1 Build 4512, SN H622112-VE

Date: October 22, 2009

From: Michael Lamba, Ph.D.



Acceptance testing and commissioning has been performed on Variseed v8.6 SN H622112-VE.
The items tested include

- 1) Source specific parameters for I-125SL and MED3631 seeds.
- 2) Point dose calculations.
- 3) 2D dose calculations and display.
- 4) Data integrity and spatial accuracy of ultrasound and CT images used for determining seed locations and resulting dose distributions, including data transfer.

The specifics of individual tests can be found on pages 2-15.

All results are found to be acceptable for clinical brachytherapy use.

Variseed Seed Modeling and Dose Calculation Test

Source Seed Commissioning:

Source type: I125-SL.

- **Equipment:**

Variseed Laptop, Version 8.0.1, SN H622112-VE

- **Date: 10/1/2009**

The I125-SL seed data was confirmed as from the update of AAPM Task Group No. 43 Report: A revised AAPM protocol for brachytherapy dose calculation, the supplement to the 2004 update of the AAPM Task Group No. 43 Report.

The point, isodose level, dose volume and anisotropy tests were performed (see attached) and the results were found to be acceptable.


Michael Lamba, Ph.D.

Test 1: Dose Point Calculation test:

- Source activity: 100 U.
- Dose calculation model: point source.
- Anisotropy correction: $g_{\text{point}}(r)$.

Procedure:

- Add one source seed to the first image.
- Add a dose calculation point on a template grid location that has the same X or Y coordinate as the seed 1 cm away from source.
- Record dose at calc. point.
- Compare to table one.
- Add a second dose calc. point on a template grid location that has the same X or Y coordinate as the seed 1 cm away from source.
- Record dose at calc. point.
- Compare to table one
- Sum doses at the two calculation points.
- Sum doses provided in table one for both locations.
- Compare the two Sums.

Results for I125-SL:

Dose at 1 cm (given)	1760.74
Doses at 1 cm (Variseed)	1760.7
Dose at .5 cm (given)	7696.76
Doses at .5 cm (Variseed)	7696.8
Dose Sum (given)	9457.5
Dose Sum (Variseed)	9457.5

Test 2: Isodose Level Test:

This test is to verify the display of isodose levels.

Procedure:

- Create a new pre-operative plan
- Use the B&K standard template
- Have at least 10 images.
- Use distance between images of .5 cm.
- Chose anisotropy factor(Point Model).
- Add 9 isodose levels in Gy, corresponding to those listed in table 2.
- On image one place a 100 U seed.

Results:

- On, image #1, the distance from the seed to each isodose contour should be within +/- 2 mm of the distance value that appears in the first column of table 2.

- Successive image should show one less isodose contour so that image #9 has only one contour for the lowest isodose level.
- Please check the attached printouts.
-

Test 3: Dose Volume Test:

This test uses the DVH values to verify the dose volume calculation of the VariSeed system.

Procedure:

- Create a new pre-operative plan.
- At least 13 images.
- 0.5 cm as the distance between images.
- Create a 6 cm X 6 cm square structure on the first and last image, and interpolate.
- Select point model.
- Set X-Y resolution to .5 mm/pixel.
- Set the Z resolution option to “Match Distance Between Images”.
- Set dose matrix extent value to 80 mm.
- DVH settings:
 - Minimum value= 0 Gy.
 - Maximum value= 100 Gy.
 - Increment=10 Gy.
- Select the activity level per table 3.
- Select DVH tab
- Select the created structure.

- The volume data of the 100 Gy isodose level should match those provided in table 3.

Results:

Radius (cm)	Dose Volume From Table 3 (cc)	Dose Volume From test 3 (cc)
1	3.52	3.52
1.5	13.04	13.05
2	31.96	31.98
2.5	63.43	63.49
3	110.59	110.63

Test 4: Anisotropy Function/Line Source Calculation test:

Procedure:

- Create a new-preoperative study with at least 10 images at 0.5 cm spacing, using the standard B&K template.
- Select anisotropy Function (line Model).
- Add the activity listed in table 4 (100U typically).
- Place one source on image 3, template position D, 4.0
- Enter dose calculation points at positions listed in table 4.
- Verify that doses to the dose points match the doses listed in table 4.
- Add a second source on image 4, position c, 3.0 with +2.5 mm.

- Verify that doses to the dose points match the doses listed in table 4.
- Remove the sources and dose points.
- Add a 100 U source on image 1, then add dose points on each subsequent image at the same template position. (All dose points will be located at a 0 degree angle from the source)
- Verify dose point values with those in table 5.

Source Seed Commissioning:

Source type: MED 3631.

- **Equipment:**

Variseed Laptop, Version 8.0.1, SN H622112-VE

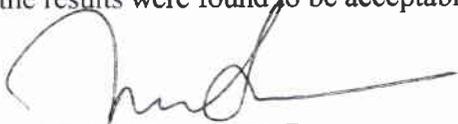
- **Date: 10/1/2009**

The MED 3631 seed data was confirmed as from the update of AAPM Task Group No.

43 Report: A revised AAPM protocol for brachytherapy dose calculation

The point, isodose level, dose volume and anisotropy tests were performed (see attached)

and the results were found to be acceptable.



Michael Lamba, Ph.D.

Test 1: Dose Point Calculation test:

- Source activity: 100 U.
- Dose calculation model: point source.
- Anisotropy correction: $g_{\text{point}}(r)$.

Procedure:

- Add one source seed to the first image.
- Add a dose calculation point on a template grid location that has the same X or Y coordinate as the seed 1 cm away from source.
- Record dose at calc. point.
- Compare to table one.
- Add a second dose calc. point on a template grid location that has the same X or Y coordinate as the seed 1 cm away from source.
- Record dose at calc. point.
- Compare to table one
- Sum doses at the two calculation points.
- Sum doses provided in table one for both locations.
- Compare the two Sums.

Results for I125-SL:

Dose at 1 cm (given)	2024.68
Doses at 1 cm (Variseed)	2024.7
Dose at .5 cm (given)	8446.50
Doses at .5 cm (Variseed)	8446.5
Dose Sum (given)	10471.18
Dose Sum (Variseed)	10471.2

Test 2: Isodose Level Test:

This test is to verify the display of isodose levels.

Procedure:

- Create a new pre-operative plan
- Use the B&K standard template
- Have at least 10 images.
- Use distance between images of .5 cm.
- Chose anisotropy factor(Point Model).
- Add 9 isodose levels in Gy, corresponding to those listed in table 2.
- On image one place a 100 U seed.

Results:

- On, image #1, the distance from the seed to each isodose contour should be within +/- 2 mm of the distance value that appears in the first column of table 2.

- Successive image should show one less isodose contour so that image #9 has only one contour for the lowest isodose level.
- Please check the attached printouts.
-

Test 3: Dose Volume Test:

This test uses the DVH values to verify the dose volume calculation of the VariSeed system.

Procedure:

- Create a new pre-operative plan.
- At least 13 images.
- 0.5 cm as the distance between images.
- Create a 6 cm X 6 cm square structure on the first and last image, and interpolate.
- Select point model.
- Set X-Y resolution to .5 mm/pixel.
- Set the Z resolution option to “Match Distance Between Images”.
- Set dose matrix extent value to 80 mm.
- DVH settings:
 - Minimum value= 0 Gy.
 - Maximum value= 100 Gy.
 - Increment=10 Gy.
- Select the activity level per table 3.
- Select DVH tab
- Select the created structure.

- The volume data of the 100 Gy isodose level should match those provided in table 3.

Results:

Radius (cm)	Dose Volume From Table 3 (cc)	Dose Volume From test 3 (cc)
1	3.52	3.52
1.5	13.04	13.04
2	31.96	31.98
2.5	63.43	63.46
3	110.59	110.61

Test 4: Anisotropy Function/Line Source Calculation test:

Procedure:

- Create a new-preoperative study with at least 10 images at 0.5 cm spacing, using the standard B&K template.
- Select anisotropy Function (line Model).
- Add the activity listed in table 4 (100U typically).
- Place one source on image 3, template position D, 4.0
- Enter dose calculation points at positions listed in table 4.
- Verify that doses to the dose points match the doses listed in table 4.
- Add a second source on image 4, position c, 3.0 with +2.5 mm.
- Verify that doses to the dose points match the doses listed in table 4.
- Remove the sources and dose points.

- Add a 100 U source on image 1, then add dose points on each subsequent image at the same template position. (All dose points will be located at a 0 degree angle from the source)
- Verify dose point values with those in table 5.

Variseed – CT Data Transfer Integrity Test

- Equipment:
 - Toshiba Aquilon, Model TSX-101A, SN HDA0813089
 - Variseed Laptop, Version 8.0.1, SN H622112-VE
 - CIRS Brachytherapy Phantom, Model 45, SN 8387

The CT of the brachytherapy phantom was acquired 5/4/09 in anticipation of the Variseed delivery. The CT was imported in the standard DICOM fashion and measurements of the phantom dimensions acquired and compared to specifications. All measurements and image characteristics were acceptable. See attached sheet.

The CT to Variseed data transfer is acceptable.



Michael Lamba, Ph.D.

Variseed – Ultrasound Data Transfer Integrity Test

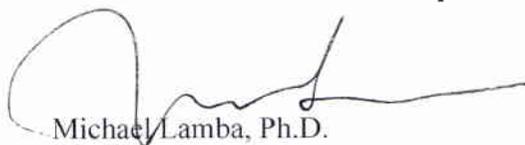
- Equipment:
 - Variseed Laptop, Version 8.0.1, SN H622112-VE
 - CIRS Brachytherapy Phantom, Model 45, SN 8387
 - BK PRO Focus Ultrasound SN 1890451, US Probe SN 1890217

- Date: October 14, 2009

The ultrasound unit was set up to acquire images of the brachytherapy phantom. The video capture card and driver were installed on the Variseed laptop and connected to the ultrasound. An image was acquired of the “N” object as well as contiguous 5 mm cuts of the egg shaped object. The Variseed Grid Calibration routine was performed. It was confirmed that the grid and measurement tool agreed with the physical dimensions. Calculation of the egg shaped volume was acceptable.

The pre-implant ultrasound images are currently transferred to the Variseed computer via video capture. While no data transfer issues currently hinder the process, improvement and flexibility will be sought by enabling a DICOM transfer capability of ultrasound images. It should be noted that CT data transfer via DICOM images is currently operational.

Variseed – ultrasound video capture is acceptable.



Michael Lamba, Ph.D.

**Cincinnati VA Medical Center
Radiation Safety Training**

The attached training was provided to the following individuals.

see attachments:

1. VHA Standard Procedure - Training for Medical Events;
2. VHA Standard Procedure - Training;
3. VHA Standard Procedure - Preparation and Completion of Written Directives for Permanent Implant Prostate Brachytherapy
4. VHA Standard Procedure -- Clinical Requirements

The clinical procedures were discussed in detail at this training and previous training discussions. M/L 6/1/09

Name	Signature	SS# (last 4)	Date
Kevin Redmond, MD	<i>[Signature]</i>	7595	6/23/09
William Barrett, MD	<i>[Signature]</i>	9688	6/24/09
Michael Lamba	<i>[Signature]</i>	8804	6/25/09
Howard Elson	<i>[Signature]</i>	8503	6/25/09
Chris Rauf	<i>[Signature]</i>	2281	6/25/09

Instructor: *Lamba* (6/23/09), *Elson* (6/24/09), *Rauf* (6/25/09)

Radiation Safety Officer: *[Signature]* 6/25/09

BRACHYTHERAPY TRAINING (5 NORTH)
RADIATION SAFETY TRAINING
SIGN IN SHEET

The licensee has provided radiation safety instructions to all personnel caring for the patient, undergoing implant therapy. The instruction has included the following:

- (1) Size and appearance of the brachytherapy sources;
- (2) Safe handling and shielding instructions in case of dislodged source;
- (3) Procedures for patient control;
- (4) Procedures for visitor control; and
- (5) Procedures for notification of the Radiation Safety Officer if the patient dies or has a medical emergency.

Pursuant to 10CFR 35.410, the safety instructions described above were given to the following personnel by CHRIS RAUF RSO on 5/18/09 and must have received training within past twelve months before caring for a patient receiving radioactive material.

DATE	NAME	NAME (PLEASE PRINT)	SS#
5/18/09	Patricia Jackson	Patricia A. Jackson	1059
5/18/09	Jennifer Brummett	Jennifer Brummett	2324
5/18/09	KAREN ANN MC CULL	KAREN ANN MC CULL	0352
5/18/09	EMMA J. LEWIS UPD	EMMA J. LEWIS UPD	3604
5/18/09	ERICA STOKES	ERICA STOKES	6883
5/18/09	Danielle Rizzo	Danielle Rizzo	0079
5/19/09	Diana Kirby	Diana Kirby	7807
5/19/09	Heather Slayter	Heather Slayter	4330
5-19-09	Mackie L. Bess	MACKIE L. BESS	4254
5/19/09	Donna M. Ford	Donna M. Ford	7247
5/29/09	KATHY McBRIDE	Kathy McBride	0465
6/2/09	Erica Hummons RN	Erica Hummons	2544
6-2-09	TISHA SPARROW	Tisha Sparrow	7127
6-2-09	Tiffany Bell	Tiffany Bell	0299
6/2/09	Carmen Chambers	Carmen Chambers	7058
6-2-09	Hazel Bowman	HAZEL BOWMAN	4939
6-2-09	TONIA EVANS, RN	TONIA EVANS	3140

V. Maddin

**ANNUAL RADIATION SAFETY TRAINING
BRACHYTHERAPY
NUCLEAR MEDICINE TECHNOLOGISTS**

The licensee has provided Radiation Safety Training for the following individuals.

1. Radiation Safety handout
2. Potential risks of radiation exposure
3. ALARA
4. Diagnostic Nuclear Medicine
5. Therapeutic Nuclear Medicine (I-131)
6. Brachytherapy (I-125)
7. General safety measures
8. Specific safety measures
9. Each day safety measures
10. Waste handling
11. Safety measures for hotlab
12. Pregnancy Policy
13. Posting
14. Patient release 10 CFR 20.1406
15. Workers rights
16. Access Control
17. Location permit (10CFR19.12)
18. Recordkeeping 10 CFR19.12
19. Radiation survey 10 CFR 20.1501
20. Calibration of survey meters 10 CFR 20.1501
21. Emergency Procedures
22. Public dose 10 CFR 20.1301
23. Medical event
24. Seed placement (c-arm)
25. Written directive
26. Pre-post treatment planning
27. Post- treatment analysis

NAME	SS#	DATE
<i>Victoria Maddin</i>	<i>5311</i>	<i>3/3/09</i>
<i>Michael Tase</i>	<i>6681</i>	<i>3/3/09</i>
<i>Michael Tase</i>	<i>4827</i>	<i>4/27/09</i>
<i>Jahan Tase</i>	<i>0964</i>	<i>4/27/09</i>
<i>Michelle Tase</i>	<i>3171</i>	<i>5/4/09</i>

Instructor
Ann Raso
G. ORCA Raso

Radiation Safety Officer

**ANNUAL RADIATION SAFETY TRAINING
BRACHYTHERAPY
MEDICAL EVENT TRAINING**

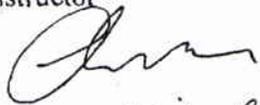
The licensee has provided Radiation Safety Training for the following individuals.

- | | |
|--|---|
| 1. Radiation risks | 11. Safety measures for hotlab |
| 2. Potential risks of radiation exposure | 12. Pregnancy policy |
| 3. ALARA dose limits | 13. Posting |
| 4. Diagnostic Nuclear Medicine | 14. Patient release |
| 5. Therapeutic Nuclear Medicine (I-131) | 15. Workers rights |
| 6. Brachytherapy (I-125) | 16. Regulatory definition of medical event |
| 7. General safety measures | 17. Responsibilities related to medical event |
| 8. Specific safety measures | 18. How to identify a medical event (c# 090) |
| 9. Each day safety measures | 19. Notification requirement for a medical event |
| 10. Waste handling | 20. How to address after hours recall and notification requirements |

NAME	SS#	DATE
<i>Distina Maddu</i>	5311	3/3/09
<i>Michelle Tarsce</i>	6681	3/3/09
<i>Michael A...</i>	4827	4/27/09
<i>Patricia V...</i>	0964	4/27/09
<i>Walter H...</i>	3171	5/14/09

CHRIS RAUF

Instructor



CHRIS RAUF

Radiation Safety Officer

**ANNUAL RADIATION SAFETY TRAINING
BRACHYTHERAPY
MEDICAL EVENT TRAINING**

The licensee has provided Radiation Safety Training for the following individuals.

- | | |
|--|---|
| 1. Radiation risks | 11. Safety measures for hotlab |
| 2. Potential risks of radiation exposure | 12. Pregnancy policy |
| 3. ALARA dose limits | 13. Posting |
| 4. Diagnostic Nuclear Medicine | 14. Patient release |
| 5. Therapeutic Nuclear Medicine (I-131) | 15. Workers rights |
| 6. Brachytherapy (I-125) | 16. Regulatory definition of medical event |
| 7. General safety measures | 17. Responsibilities related to medical event |
| 8. Specific safety measures | 18. How to identify a medical event (cX 090) |
| 9. Each day safety measures | 19. Notification requirement for a medical event |
| 10. Waste handling | 20. How to address after hours recall and notification requirements |

NAME	SS#	DATE
<i>Debra Maddux</i>	5311	3/3/09
<i>Michelle Arce</i>	6681	3/3/09

Instructor

Radiation Safety Officer

ANNUAL RADIATION SAFETY TRAINING

The licensee has provided Radiation Safety Training for the following individuals.

1. Radiation Safety handout
2. Potential risks of radiation exposure
3. ALARA
4. Diagnostic Nuclear Medicine
5. Therapeutic Nuclear Medicine (I-131)
6. Brachytherapy (I-125)
7. General safety measures
8. Specific safety measures
9. Each day safety measures
10. Waste handling
11. Safety measures for hotlab
12. PREGNACY POLICY

	NAME	SS#	DATE
	Takana Fryer	0964	09-05-08
	V. J. J. J.	3171	9/5/08
AU	J. J. J. J.	8309	9-5-08
AU	J. J. J. J.	7595	9-16-08
	Bruce Mahoney	3744	9-16-08
AU	J. J. J. J.	4949	10/9/08
AU	J. J. J. J.	-4216	10/10/08
AU	J. J. J. J.	-9688	10/10/08
	DIVAKAR CHOUBEY	-3081	10/18/08
	Kenneth R. Winger	-5416	12/22/08

The following Nuclear Medicine Technologists read and understand Brachytherapy Seed Loading Procedure May 20, 2008:

NAME	SIGNATURE	DATE
MICHAEL FASCE	<i>Michael Fasce</i>	6/24/08
MICHAEL GRANNEN	<i>Michael Grannen</i>	6/27/08
VICTORIA MADDEN	<i>Victoria Madden</i>	6/24/08
CHRIS RAUF	<i>Chris Rauf</i>	6/30/08

**The following Nuclear Medicine Technologists read and understand Brachytherapy
Emergency Plan for Leaking Seeds:**

NAME	SIGNATURE	DATE
MICHAEL FASCE	<i>Michael Fasce</i>	6/24/08
MICHAEL GRANNEN	<i>Michael Grannen</i>	6/27/08
VICTORIA MADDEN	<i>Victoria Madden</i>	6/24/08
CHRIS RAUF	<i>Chris Rauf</i>	6/30/08

**BRACHYTHERAPY TRAINING (5 NORTH)
RADIATION SAFETY TRAINING
SIGN IN SHEET**

The licensee has provided radiation safety instructions to all personnel caring for the patient, undergoing implant therapy. The instruction has included the following:

- (1) Size and appearance of the brachytherapy sources;
- (2) Safe handling and shielding instructions in case of dislodged source;
- (3) Procedures for patient control;
- (4) Procedures for visitor control; and
- (5) Procedures for notification of the Radiation Safety Officer if the patient dies or has a medical emergency.

Pursuant to 10CFR 35.410, the safety instructions described above were given to the following personnel by _____ on _____.

DATE	NAME (PLEASE PRINT)	SS#
3/4/07	Robert Gord RN	4715
3/6/07	Casey Brown RN	6489
3/6/07	Deborah A. USNEAL RN	6012
3-6-07	EARL PARKER	9004
3-6-07	Heather Stawler LPN	4330
3-6-07	MACKIE L BESS	4254
3-7-07	Marie A. Collier	4969
3/7/07	LORENA WHITE-WATTS	5069
3/7/07	Amanda Calhoun	9503
3/7/07	KATHY McBRIDE	0465
3/7/07	Dorothy Drain	

2007

**BRACHYTHERAPY TRAINING (5 NORTH)
RADIATION SAFETY TRAINING
SIGN IN SHEET**

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- (2) Safe handling and shielding instructions in case of dislodged source;
- (3) Procedures for patient control;
- (4) Procedures for visitor control; and
- (5) Procedures for notification of the Radiation Safety Officer if the patient dies or has a medical emergency.

Pursuant to 10CFR 35.410, the safety instructions described above were given to the following personnel by _____ on _____.

DATE	NAME (PLEASE PRINT)	SS#
3/4/07	ROBERT GOZD RN	4715
3/6/07	Casey Brown RN	6489
3/6/07	Deborah A. McNEAL RN	6012
3-6-07	EARL PARKER	9009
3-6-07	Heather Stawter LPN	4330
3-6-07	MACKIE L. BOSS	4254
3-7-07	Marie A. Collier	4969
3/7/07	LAVONIA WHITE-WATTS	5069
3/7/07	Amanda Calhoun	9503
3/7/07	KATHY McBRIDE	0465
3/7/07	Dorothy Drain	

INDIVIDUAL TRAINING REPORT

for

William Barrett

between

1/1/2007

--

2/22/2010

DATE	CLASS	TYPE
03/18/09	RADIATION ONCOLOGY RETRAINING	RAM Retraining
03/12/08	RADIATION ONCOLOGY RETRAINING	RAM Retraining
01/24/07	RADIATION ONCOLOGY RETRAINING	RAM Retraining

Monday, February 22, 2010

INDIVIDUAL TRAINING REPORT

for

Howard Elson

between

1/1/2007

—

2/22/2010

DATE	CLASS	TYPE
03/18/09	RADIATION ONCOLOGY RETRAINING	RAM Retraining
03/12/08	RADIATION ONCOLOGY RETRAINING	RAM Retraining
01/24/07	RADIATION ONCOLOGY RETRAINING	RAM Retraining

Monday, February 22, 2010

INDIVIDUAL TRAINING REPORT

for

David Grisell

between

1/1/2007

—

2/22/2010

DATE	CLASS	TYPE
04/10/09	RADIATION ONCOLOGY RETRAINING	RAM Retraining
03/12/08	RADIATION ONCOLOGY RETRAINING	RAM Retraining
02/05/07	RADIATION ONCOLOGY RETRAINING	RAM Retraining

Monday, February 22, 2010

INDIVIDUAL TRAINING REPORT

for

Michael Lamba

between

1/1/2007 -- 2/22/2010

DATE	CLASS	TYPE
03/18/09	RADIATION ONCOLOGY RETRAINING	RAM Retraining
03/12/08	RADIATION ONCOLOGY RETRAINING	RAM Retraining
01/24/07	RADIATION ONCOLOGY RETRAINING	RAM Retraining

Monday, February 22, 2010

INDIVIDUAL TRAINING REPORT

for

Kevin Redmond

between

1/1/2007

—

2/22/2010

DATE	CLASS	TYPE
05/31/09	RADIATION ONCOLOGY RETRAINING	RAM Retraining
06/06/08	RAD ONC AUDIT REVIEW VIDEO	RAM Retraining
01/24/07	RADIATION ONCOLOGY RETRAINING	RAM Retraining

Monday, February 22, 2010

VA HOSPITAL
BRACHYTHERAPY WRITTEN DIRECTIVE (Authorized User Only)
() PERMANENT IMPLANT () TEMPORARY IMPLANT

PATIENT NAME: _____ SS#: _____
DATE OF BIRTH: _____

PLANNED ACTIVITY

() Iodine 125 # of sources _____ strength/source _____ mCi
() Other # of sources _____ strength/source _____ mCi

PRESCRIBED TOTAL DOSE _____ cGy () Iodine 125 () Other
Treatment Site: _____

Authorized User's Signature _____ Date: _____

PATIENT IDENTIFICATION CONFIRMATION (Check two below. Do not use
A and B together)

- () A. Positive identification by employee
- () B. Requesting and confirming name from patient
- () C. Requesting from patient and conforming from DOB, SS#, address, or signature
- () D. Requesting from patient and confirming name with companion
- () E. Confirming name using I.D. bracelet, hospital card, or medical insurance card
- () F. Confirming with photograph of patient's face with proper identification
- () G. Confirming that the name on the tray matches the patient's I.D. (MUST BE COMPLETED)

Confirmed by: _____

ADMINISTERED DOSE

Radiograph taken for treatment site: _____ Date: _____

() Iodine 125 # of sources _____ strength/source _____ mCi
() Other # of sources _____ strength/source _____ mCi

Delivered Total Dose _____ cGy () Iodine () Other

This administration was performed in accordance with this written directive and its final plan and related calculations.

Prior to release patient provided with radiation safety guidance or written instructions per Reg. Guide 8.39.

Authorized User's Signature _____ Date: _____

RECORD OF SOURCE USE

Storage Location: _____

Sources removed from storage Date/Time _____ / _____ am/pm
Initials: _____

Sources returned to storage Date/Time _____ / _____ am/pm
Initials: _____

See source log book for further information.

9/2003

PATIENT LABEL HERE

MUST BE COMPLETED FOR EACH REFERENCE NUMBER AND MODEL NUMBER

1. PROSTHESIS ITEM: RADIOACTIVE SEEDS I-125
2. IMPLANT STERILITY CHECKED: YES
3. STERILITY EXPIRATION DATE:
4. VENDOR: MEDI-PHYSICS, INC
5. MODEL: 7000 OR 6715 (CIRCLE ONE)
6. LOT/SERIEAL NO:
7. STERILE RESP: MEDI-PHYSICS, INC.
8. SIZE: 0.5 mm
9. QUANTITY:

1. PROSTHESIS ITEM: RADIOACTIVE SEEDS I-125
2. IMPLANT STERILITY CHECKED: YES
3. STERILITY EXPIRATION DATE:
4. VENDOR: MEDI-PHYSICS, INC
5. MODEL: 7000 OR 6715 (CIRCLE ONE)
6. LOT/SERIEAL NO:
7. STERILE RESP: MEDI-PHYSICS, INC.
8. SIZE: 0.5 mm
9. QUANTITY:

1. PROSTHESIS ITEM: RADIOACTIVE SEEDS I-125
2. IMPLANT STERILITY CHECKED: YES
3. STERILITY EXPIRATION DATE:
4. VENDOR: MEDI-PHYSICS, INC
5. MODEL: 7000 OR 6715 (CIRCLE ONE)
6. LOT/SERIEAL NO:
7. STERILE RESP: MEDI-PHYSICS, INC.
8. SIZE: 0.5 mm
9. QUANTITY:

1. PROSTHESIS ITEM: RADIOACTIVE SEEDS I-125
2. IMPLANT STERILITY CHECKED: YES
3. STERILITY EXPIRATION DATE:
4. VENDOR: MEDI-PHYSICS, INC
5. MODEL: 7000 OR 6715 (CIRCLE ONE)
6. LOT/SERIEAL NO:
7. STERILE RESP: MEDI-PHYSICS, INC.
8. SIZE: 0.5 mm
9. QUANTITY:

MUST BE PLACED IN PATIENT CHART
NUCLEAR MEDICINE TECHNOLOGIST

UNIVERSITY OF CINCINNATI
BRACHYTHERAPY PATIENT SURVEY RECORDS

Patient Name: _____ Bldg/Room#: _____

Medical Record #: _____ Radionuclide: _____

IMMEDIATELY AFTER IMPLANT "PATIENT AND AREA OF USE"

Date: _____ Time: _____ Instrument used: _____

Surveyor Initials: _____ Bldg/Room#: _____

Seeds found? Yes ___ No ___

PROMPTLY AFTER IMPLANT "CONTIGUOUS AREA RADIATION DOSE RATES"

Time survey completed: _____ AM PM Surveyor Initials: _____

Instrument used (if different from above): _____

1. Draw a plan of the patient's room and all immediate adjacent areas.

2. List dose rate readings in mR/hr for several points in each area. Use the table below to key the locations on the map.

- 9. _____
- 10. _____
- 11. _____
- 12. _____
- 13. _____
- 14. _____
- 15. _____
- 16. _____

IMMEDIATELY AFTER REMOVAL "SOURCE REMOVAL CONFIRMATION"

Date: _____ Time: _____ Instrument used: _____

Surveyor Initials: _____ Bldg/Room#: _____

Dose rate at 1 meter from patient _____ mR/hr.

PERMANENT IMPLANT PATIENT "PRIOR TO RELEASE"

Date: _____ Time: _____ Instrument used: _____

Surveyor Name: _____ Dose rate at 1 meter from patient _____ mR/hr

Release criteria: [¹²⁵I ≤ 1 mR/hr] [¹⁹²Ir ≤ 0.8 mR/hr] [¹⁰³Pd ≤ 3 mR/hr]

_____ mR/hr

Written release instructions provided to patient: [] Yes [] No

Used if dose rate at 1 meter exceeds 0.2 mR/hr for ¹²⁵I & ¹⁹²Ir or 0.7 mR/hr for ¹⁰³Pd

Seed Certification Slip / Written Directive:

Patient's Name:

Date:

Number of seeds brought up:

Lot #

Lot #

Number of seeds implanted:

Lot #

Lot #

Number of seeds brought back:

Lot #

Number of seeds excreted:

Technologist:

Seed Identification:

Lot Number:

Date:

Number of seeds present:

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



J10101062050224

Ship Date: 25FEB10
ActWgt: 0.2 LB
CAD: 5250401/INET3010

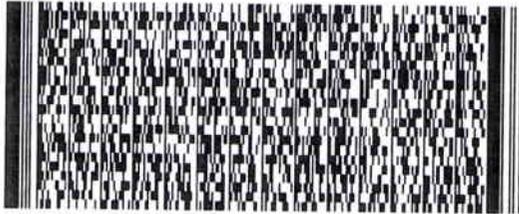
Delivery Address Bar Code



Ref #
Invoice #
PO #
Dept #

SHIP TO: (501) 257-1571 **BILL SENDER**

Cassandra Frazier
Nuclear Regulatory Commission
2443 Warrenville Road
Suite 210
Lisle, IL 60532



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