



**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

**MAR 03 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 Puget Sound Health Care System, Seattle, Washington.

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 05 2010**

EW

NRC Request for Information (February 16, 2010)  
*VA Puget Sound Health Care System, Seattle, Washington*

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: Dunn, David J

Sent: Wednesday, February 24, 2010 4:27 PM

To: Williams, Gary E

Cc: Leidholdt, Ed; Huston, Thomas E.; Offutt, Lisa M; Sutlief, Steven G.

Subject: RE: additional information for NRC inspection (Training)

Per your request dated February 17, 2010, the following information is provided regarding policies and procedures for prostate implants:

- a. Pdf copies of policies and procedures current at the time of the on-site NRC inspection for the prostate implant program on the 18th of November 2008.
- b. Pdf copies of policies and procedures revised after the on-site inspection or in response to NHPP recommendations with the effective date indicated.
- c. Pdf copies of training records for the calendar years 2007, 2008 and 2009 for medical physicists, dosimetrists, the physician authorized users, and radiation safety staff involved in prostate implants.

Regarding the specific NRC requested information items, the "Written Directive Procedure for Prostate Brachytherapy":

Version 2.2 dated September 23, 2008, is the revision based on recommendations from NHPP during their site visit.

Version 2.3 dated November 20, 2008, is the revision based on recommendations from NRC during their on-site inspection of our prostate brachytherapy program.

Version 2.4 dated April 6, 2009, the documents name was changed from "Quality Management Program for Permanent Implant Brachytherapy" to "Written Directive Procedure for Permanent Implant Brachytherapy".

All VHA standard procedures were adopted as required by VHA directive (March 2009 as revised), Clinical Procedures, Training, Training in Medical Events, and Written Directives.

<http://nhpp.med.va.gov/Top/2VAspecific/7ApprovedPubs/2009OncMeeting/RadiationOncologyMeetingWeb.htm>

They are not included as an attachment here.

David J. Dunn, Radiation Safety Officer  
VA Puget Sound Health Care System  
W 206 277-1789

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

From: Dunn, David J

Sent: Wednesday, February 24, 2010 4:22 PM

To: Williams, Gary E

Cc: Leidholdt, Ed; Huston, Thomas E.; Offutt, Lisa M; Sutlief, Steven G.

Subject: RE: additional information for NRC inspection

Per your request, the following information is provided regarding policies and procedures for prostate implants:

- a. PDF copies of policies and procedures current at the time of the on-site NRC inspection for the prostate implant program on the 18th of November 2008.
- b. PDF copies of policies and procedures revised after the on-site inspection or in response to NHPP recommendations with the effective date indicated.
- c. PDF copies of training records for the calendar years 2007, 2008 and 2009 for medical physicists, dosimetrists, the physician authorized users, and radiation safety staff involved in prostate implants.

Regarding the specific NRC requested information items:

The "Written Directive Procedure for Prostate Brachytherapy" Version 2.2 dated September 23, 2008, is the revision based on recommendations from NHPP during their site visit.

Version 2.3 dated November 20, 2008, is the revision based on recommendations from NRC during their on-site inspection of our prostate brachytherapy program.

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Attachments:

QMP for Permanent Implant Brachytherapy on 11/20/08  
Written Directive Procedure for Permanent Implant Brachytherapy v2.2 09/23/08  
Written Directive Procedure for Permanent Implant Brachytherapy v2.3 11/20/08  
Written Directive Procedure for Permanent Implant Brachytherapy v2.4 04/06/09  
Prostate Brachytherapy Standard Clinical Procedures 04/08/09  
Brachytherapy Emergency Procedures for Radioactive Material 10/14/08  
2007 Annual Training for Brachytherapy  
2008 Annual Training for Brachytherapy  
2009 Annual Training for Brachytherapy

The following procedures (available on the web and not included here) were adopted as mandated by VHA directive:

The NHPP Transperineal Permanent Implant Prostate Seed Brachytherapy - Audit Checklist as revised adopted 03/2009 The VHA Standard Procedures for Training, Training in Medical Events, Clinical Requirements, and Written Directives all adopted 03/2009 as revised.

<http://nhpp.med.va.gov/Top/2VAspecific/7ApprovedPubs/2009OncMeeting/RadiationOncologyMeetingWeb.htm>

David J. Dunn, Radiation Safety Officer

**Veteran's Administration, Puget Sound Health Care System (VA PSHCS)  
PROCEDURE: Brachytherapy Emergency Procedures for Radioactive Material**

**DATE: 14 October 2008**

**REVIEWED:**

**REVISED:**

**DEPARTMENT REPRESENTATIVE:** \_\_\_\_\_

**RADIATION SAFETY OFFICER:** \_\_\_\_\_

**MEDICAL PHYSICIST:** \_\_\_\_\_

**MEDICAL PHYSICIST:** \_\_\_\_\_

**POLICY/PURPOSE:**

It is the policy of this facility to provide guidelines for the safe operation and control of radioactive materials and to provide proper response to emergency and abnormal situations. The following emergency procedures will be followed as emergency situations arise involving radioactive materials.

**PROCEDURE:**

A lead shielded container, long-handled forceps, and a survey instrument shall be available during all radioactive implant procedures.

1. If a source (seed) becomes dispelled or dislodged from the patient:
  - a. All linens, draping, and objects that came into contact with the patient shall be surveyed for radioactivity prior to being released from the room.
  - b. Use long handled forceps to place the source(s) into a lead container.
  - c. Move the lead container or source holder away from the patient and other personnel and contact the Radiation Safety Officer (RSO), Medical Physicist and the Radiation Oncologist as soon as possible.
  
2. Loss of radioactive source or seed:
  - a. Contact the RSO and the Medical Physicist immediately.
  - b. Qualified staff will use a G.M. counter to search for the lost source/seed.
  - c. Do not remove any bandages, linen, bedding, trash, etc. from the area until they have been surveyed.
  - d. Once the source/seed is found, it should be placed in a lead container using long forceps.
  - e. If the source/seed is not found, the appropriate NHPP and federal agencies will be notified immediately by the RSO.
  
3. Visible damage to a radioactive source or seed:
  - a. If a source or seed has been damaged due to rough handling, high temperature or crushing, rupture and leakage could occur. The area should be closed off and the RSO should be notified immediately.
    - i. Shut off fans and ventilators.
    - ii. Drop damp towels on the suspect material.
    - iii. Do not throw anything away.

- b. The qualified medical physicist will place the seed into a lead container using long forceps.
  - c. The area should be surveyed and decontaminated, if necessary.
  - d. A wipe test will be performed to ensure the decontamination was successful.
4. Emergency procedures to be followed in the event of suspected leakage of seed in contact with patient:
- a. If internal contamination is suspected, contact the Radiation Oncologist immediately.
  - b. Radiation Oncologist order saturation of the patient's thyroid with stable iodine from the pharmacy: 0.5 mL Lugols solution or 5-6 drops of SSKI, Saturated Solution of Potassium Iodide (1 g/ml) in the case of an I-125 source rupture. \*\* See emergency numbers below.
  - c. Wipe the patient's skin surface and decontaminate the patient if indicated from wipe count (see Item 5).
  - d. Request patient urine sample for bioassay.
  - e. The patient will be counseled by the Authorized user, provided with a verbal summary of the event and any patient questions answered.
  - f. Ensure Patient follow-up should they not return for explanation, multiple attempts will be made to contact the patient and to perform a dose assessment.
  - g. The Radiation Safety Officer will contact VHA National Health Physics Program (NHPP) at 501-257-1571/1570 during normal working hours and 1(800) 815-1016 after normal working hours.
  - h. Advise the Chief Staff and Medical Center Director of the NHPP notification.
5. Emergency procedures to be followed in the event contamination is identified:
- a. Close off the area and post a "Radioactive Materials" sign. No one will be permitted in the area. Any fans, ventilators or air conditioners operating in the area should be turned off.
  - b. Contact the RSO.
  - c. Survey and decontaminate the patient and/or treatment area from a ruptured source as indicated.
  - d. RSO will perform skin decontamination.
  - e. Qualified staff (staff trained in this emergency Brachytherapy Checklist) will follow these instruction to remove contamination:
    - i. Confine any liquid spillage by dropping quantities of paper towels onto it and blotting.
    - ii. Put on protective gear (rubber gloves, protective gowns, safety eyewear, shoe covers).
    - iii. An uncontaminated person will obtain a survey meter and determine background reading in a non-contaminated area.
    - iv. Scrub the area with decontaminants and detergents
    - v. Blot the area dry with clean paper towels
    - vi. Perform a wipe test to confirm the decontamination.
    - vii. If the exposure is still above background, repeat the washing process
    - viii. If the exposure level cannot be reduced, mark the area with red tape, cover with absorbent paper and label as contaminated area (exposure level, time and isotope).

- ix. Notify personnel to stay clear of the area. Allow area to decay to background level before returning area to normal use.
  - x. Place all of the cleanup materials in the appropriate container, seal, label and take to the decay storage area.
  - xi. If shoes appear contaminated, remove before leaving the area. If feet are contaminated a washbowl and soap should be brought to the area for clean up.
- f. All personnel involved in the spill and the cleanup will survey their hands, feet and clothing for contamination. Gently wash skin with soap and water until background levels are reached. The cleanup area must be treated as contaminated until cleared by the RSO.
  - g. Document the spill incident, recording the date, isotope, amount spilled, final exposure and background readings and the name of personnel involved in the cleanup. A report should be given to the RSO.

6. In the event of the death of the patient, physicians (pathologist) shall:

- i. Remove the radioactive source(s)/organ, if possible; otherwise, survey the body prior to removal to the morgue. Notify the RSO (6-1433) that the patient has died and still contains radioactive material.
  - Sealed sources implanted in the prostate (or any other organ) do not release any radioactive material into the body fluids. As long as there is minimal contact with the organ itself the exposure will be small. If a post-mortem requires removal of the organ it should be handled as briefly as possible, preferably with tongs or forceps.
- ii. Ensure the morgue pack contains the form for "PATIENT CONTAINS RADIOACTIVE MATERIAL" is filled out by the appropriate radiation oncology attending physician or radiation safety. Keep one copy of the form in the chart. Send one copy of the form with the body to the morgue. Place a "radioactive material" label on the body bag.
- iii. If the radioactive source(s) has not been removed, and the external radiation dose rate is greater than 0.2 mR/hr, arrange transport of the patient so that hallways are cleared and elevators are free of other passengers when transporting the body to the Morgue.
- iv. In the Morgue, move the body into the cold storage area. Ensure the "RADIOACTIVE" Label on the body bag is clearly visible. Place the appropriate sign on the outside the door of the cold storage unit to indicate a radioactive source is inside. Place the form indicating the level of radioactivity in the holder just below the sign outside the door of the cold storage unit. Note: only take these precautions if the body still contains an active radioactive source.

**EMERGENCY PHONE NUMBERS:**

**Daytime:** 206-768-5356

**Evenings and weekends:**

<b>Kent Wallner, Radiation Oncologist:</b>	<b>65356</b>	<b>206-699-4478</b>
<b>Steven Sutlief, Medical Physicist:</b>	<b>66597</b>	<b>206-699-3167</b>
<b>Carl Bergsagel, Medical Physicist:</b>	<b>65333</b>	<b>206-699-4535</b>
<b>Sandy Arthurs-Cutshall, Supervisor:</b>	<b>66443</b>	<b>206-570-7304</b>
<b>David Dunn, Radiation Safety Officer:</b>	<b>61789</b>	<b>206-699-2179</b>
<b>Pharmacist on Duty/Manager:</b>	<b>6-1412</b>	<b>206-610-0305</b>
<b>Vendor: ONCURA Inc. (Marc Malloy)</b>	<b>1-800-228-0126</b>	

Key NHPP contact information for notifications or consultations is noted below.

- Normal business hours for Central Time Zone at telephone 501-257-1571
- After normal business hours for Central Time Zone at telephone 800-815-1016, and request the answering service to have NHPP staff to contact the caller

Recommended dosage if KI from Food and Drug Administration Guidance: **“Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies”**

<b>Threshold Thyroid Radioactive Exposures and Recommended Doses of KI for Different Risk Groups</b>				
	Predicted Thyroid exposure(cGy)	KI dose (mg)	# of 130 mg tablets	# of 65 mg tablets
Adults over 40 yrs	≥500	130	1	2
Adults over 18 through 40 yrs	≥10			
Pregnant or lactating women	≥ 5			
Adoles. over 12 through 18 yrs*		65	1/2	1
Children over 3 through 12 yrs				
Over 1 month through 3 years		32	1/4	1/2
Birth through 1 month		16	1/8	1/4

\*Adolescents approaching adult size (≥ 70 kg) should receive the full adult dose (130 mg).



VA Puget Sound Health Care System—Radiation Therapy

## **Policy: Prostate Brachytherapy Standard Clinical Procedures**

Creation date: 4/8/09

Revision Date: 4/8/09

Prepared by Steven Sutlief.

Revised by Steven Sutlief.

This Standard Operating Procedure establishes policy and procedures for technical quality assurance (QA), pre-implant and intraoperative treatment planning, post-implant treatment planning, post-treatment dose analysis, and seed placement and verification.

1. The facility shall have a QA program for each device used for planning, performing, and assessing the implant procedures. These devices include:
  - Transrectal ultrasound system (TRUS) including the stepper/stabilizer: QA for the TRUS should substantially conform to the AAPM TG 128 report. Mechanical accuracy will be evaluated in terms of the tests given in the AAPM TG 128 report.
  - Treatment planning system: Evaluations will be recorded to ensure that the seed definitions correctly represent the parameters given in AAPM TG 43 and subsequent reports.
  - CT system: For the CT system used for imaging for post-implant dose assessment, the QA program must address image quality, accuracy of the transfer of geometric parameters to the treatment planning system, and dose to the patient.

A therapeutic medical physicist experienced in prostate brachytherapy procedures must approve the QA program and annually review the program.

2. Computerized treatment planning system requirements are as follows:

a. Acceptance testing of the treatment planning system will be completed before the first patient treatment use and after software revisions or upgrades and commissioning other models of seeds. The acceptance testing methods and results will be reviewed and approved by a therapeutic medical physicist experienced in prostate brachytherapy procedures. The acceptance testing and seed commissioning will be documented in a written report describing references, methods, and results. The testing will assess:

- (1) Geometric accuracy of image information transferred from imaging modalities used for pre- and post-plans,
- (2) Source specific input parameters required by the dose calculation algorithm, and
- (3) Accuracy of calculated doses and displays of dose distributions, such as dose plots and graphical displays, at representative points.

*KEAT WARRICK 4/17/09*

b. Dose rate values from the planning system for applicable seed models will be compared to current values listed in the appropriate AAPM report: Report No. 51 (TG-43), Report No. 84, Report No. 84s, or its successor.

c. Medical physics staff shall be aware of and use technical guidelines in AAPM Report No. 68 (TG-64).

3. Seed strength calibrations.

a. The source output or activity of each seed will be determined before implantation and a record of each calibration will be maintained as required by 10 CFR 35.432.

b. The facility will measure the output or activity of every seed per AAPM Report No. 98 or maintain written documentation that the seed manufacturer or vendor assays every seed and the measurements conform to 10 CFR 35.432.

4. Pre-implant or intraoperative treatment planning. The facility will:

a. Complete treatment planning for each patient before or during seed implantation.

b. Use appropriate imaging modalities such as TRUS, CT scanning, or MRI to assist in the treatment planning process.

c. Check the treatment plan as required by 10 CFR 35.41(b) (3). This check is to be performed with respect to the Written Directive Procedure.

d. Before implantation of the first seed, complete the pre-implantation portion of the written directive, to include the NRC required information in 10 CFR 35.40 (treatment site, radionuclide, and dose).

e. 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 match those of the pre-plan. If they differ excessively, intra-operative measures will be taken to accommodate the changes.

5. At the end of each procedure, the facility will 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.

6. After completion of the implant procedure, the facility will 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").

7. Immediately after the completion of each implant, the facility will 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 will be made as required by 10 CFR 35.2404. The survey should include the feet of people leaving the room.

8. Before releasing the patient, the facility will perform a release survey as required by 10 CFR 35.75 and document the survey as required by 10 CFR 35.2075(a). The survey is to 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 will be made with a radiation survey meter calibrated for the energy of the radiation emitted from the seeds, or the measurement will be corrected for energy using the energy response curve of the meter and any attached detector. The patient will also be given instructions, both in writing and verbally, on actions recommended to keep doses to others as low as reasonably achievable. The instructions will include actions to take if a seed is passed in the urine.

9. Post-treatment planning. The facility will:

a. Complete post-implant imaging and dosimetric analysis for each implant procedure, unless the patient refuses post-implant imaging.

b. Complete post-treatment planning of each patient using post-implant CT or MRI imaging.

c. Determine the actual dose distribution delivered and identify any variances or deviations from the original treatment plan.

d. Evaluate the relationship of the implanted seeds to the prostate, rectum, and other extra prostatic tissues.

e. Establish a consistent post-implant image acquisition time frame by obtaining a post-implant CT images on the day of the procedure or during the next 2 days. If the post-implant dose distribution is unacceptably low, obtain repeat CT images at approximately 2 to 3 weeks post-implantation for Pd-103 and approximately 4 weeks post-implantation for I-125, and create another post-plan.

f. Report the following parameters in a reviewable document (either the dose analysis documentation or the Written Directive):

(1) Date of implant procedure and date of post-implant CT imaging. This is found in the Written Directive.

(2) Prescribed dose. This is found in the Written Directive.

(3) D90, defined as the minimum dose received by 90% of the target volume as delineated on the post-implant CT. This is found in the dose analysis documentation.

(4) V100, defined as the percentage of the target volume delineated on the post-implant CT receiving 100% of the prescribed dose. A V100 equal to 90% (of the prostate volume) is equivalent to a D90 equal to the prescription dose. This is found in the dose analysis documentation.

(5) Rectal dose index, such as the R100 (volume of the rectum in  $\text{cm}^3$  that receives 100% or more of the prescribed dose). This is found in the dose analysis documentation.

(6) Evaluate seeds outside the intended treatment volume. This is found in the dose analysis documentation.

10. Post-treatment dose analysis. The facility will:

a. Review dose indices including D90, V100, and rectal dose index, and evaluate seeds significantly outside the intended treatment volume. Note: Seeds may be deliberately implanted at the boundary of or just outside the prostate to provide adequate treatment margins.

b. Compare the results to the prescribed dose to determine if a medical event occurred, including whether the D90 is less than 80% of the prescription dose (10 CFR 35.3045(a)(1)(i)).

c. Notify the patient and determine whether corrective action, such as implantation of additional seeds, is warranted, if the dose distribution for a specific patient is inadequate.

11. The facility will perform physician peer review to reduce intra-observer variability in the contouring of prostate volumes from post-implant CT scans and definition of rectal volumes and to assess quality of care. This is to include ongoing within-department peer review. In addition, five cases each year will receive external peer review as specified by the Director, National Radiation Oncology Program, or as required by a VHA Handbook or Directive. The internal review will be comprised of the same number of cases as the external review and those five internal cases will be reviewed within the annum. This review will include assessment of the organ contours and the dosimetric parameters (D90, V100, and R100).

#### References

American College of Radiology *Practice Guideline for Transperineal Permanent Brachytherapy of Prostate Cancer*

AAPM Report No. 68 (TG-64), *Permanent Prostate Seed Implant Brachytherapy*, October 1999

AAPM Report No. 51 (TG-43), *Dosimetry of Interstitial Brachytherapy Sources*, March 1995

AAPM Report No. 84, *Update of AAPM Task Group No. 43 Report: A revised AAPM protocol for brachytherapy dose calculations*, February 2004

AAPM Report No. 84s, *Supplement to the 2004 update of the AAPM Task Group No. 43 Report*, June 2007

AAPM Report No. 89, *Recommendations of the American Association of Physicists in Medicine regarding the Impact of Implementing the 2004 Task Group 43 Report on Dose Specification for 103Pd and 125I Interstitial Brachytherapy*, April 2005

AAPM Report No. 98, *Third-party Brachytherapy Source Calibrations and Physicist Responsibilities*

AAPM TG 128, *Quality Assurance Tests for Prostate Brachytherapy Ultrasound Systems*

NRC Regulations – 10 CFR 35, *Medical Use of Byproduct Material*



## VA Puget Sound Health Care System Radiation Oncology Service

### Quality Management Program for Permanent Implant Brachytherapy

This document describes the quality management program instituted at the VA Puget Sound Health Care System, Radiation Oncology Service, for permanent implant brachytherapy treatments. These policies and procedures are designed to comply with 10 CFR Part 35.40, 10 CFR Part 35.41 and NRC NUREG-1556, Vol. 9, Rev. 2 in the context of permanent implant brachytherapy.

#### 1. Directives

Written directives signed and dated by an authorized physician user are required before the administration of any brachytherapy dose. An oral directive may be used only in the event that the delay in obtaining a written directive would jeopardize the patient's health in the opinion of the physician. In the event of use of an oral directive, a written directive must be obtained and placed in the patient's chart within 24 hours.

Before delivery of any brachytherapy dose, the radiation therapist/dosimetrist/ physicist will check that the written directive section of the brachytherapy form is filled out by an Authorized Physician User. The individual performing the procedure must sign and date the appropriate section of the form prior to loading.

#### 2. Patient Identification

Prior to delivery of treatment, each patient will be identified by two of the following methods:

- Asking patient his name and confirming that the name matches record.
- Social Security Number given by patient matches record.
- Date of birth given by patient matches record.
- Address given by patient matches record.
- Visual comparison to chart face photo.

After patient identification is confirmed by two of the methods described, the Authorized User will initial the appropriate section of the brachytherapy form.



3. Preliminary verification of brachytherapy pre-plan

Before preparation of sources for a brachytherapy treatment, a pre-implant treatment plan will be reviewed by a dosimetrist/physicist. He/she will initial the appropriate section of the brachytherapy form prior to preparation of the sources.

4. Obtaining guidance for carrying out written directives

Any worker having questions about carrying out a written directive should consult with the Authorized Physician User who created the written directive, rather than continuing a procedure when in doubt.

5. Verification of sources for pre-plan

Two individuals (dosimetrist/physicist/therapist/physician) will verify that the radioisotope, number of sources, and source strengths are in agreement with the written directive and the treatment pre-plan prior to implanting. After verification both individuals will initial the brachytherapy form in the appropriate section.

6. Verification of computer generated treatment plans

All treatment plans will be computer generated. Prior to delivery of total brachytherapy dose a dosimetrist/physicist/therapist, who whenever possible did not do the original plan, will double-check the treatment plan and dose calculations. Computer generated plans shall be examined for use of correct patient data. After the plan is verified, the appropriate section of the brachytherapy form shall be filled out and signed by the individual performing the double check.

7. Double check procedure for emergent patients

If the Authorized Physician User determines that performance of the double check procedure as defined in (6) above will cause an unacceptable delay and jeopardize a patient's health, the verification process may be performed within two working days of completion of the treatment. Reasonable attempt will be made to confirm visually that the dose distribution depicted in the computer plan conforms to the written directive.

When the verification is completed, the appropriate section of the brachytherapy form will be completed and signed by the individual performing the verification.

8. Recording of actual number of sources used

Promptly after insertion of the sources, the Authorized Physician User shall record the actual number of sources implanted on the brachytherapy form and sign the appropriate section.

9. CT image verification of source placement



Following the implant procedure, a CT scan will be performed and source placement reconstruction will be used to generate the final treatment plan and total dose calculation.

10. Acceptance testing for computer hardware/software used to generate treatment plans

Acceptance testing will be performed by a physicist for all computer hardware and software prior to use for treatment planning. The acceptance testing will validate the appropriateness of the software/hardware for the needs of the department and also to verify that a performance matches manufacturer specifications. Additionally, accuracy of data input and output devices and information will be confirmed.



**VA Puget Sound Health Care System  
Radiation Oncology Service**

**Quality Management Program for Permanent Implant Brachytherapy**

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When the verification is completed, the appropriate section of the brachytherapy form will be completed and signed by the individual performing the verification.

### 8. Recording of actual number of sources used

Promptly after insertion of the sources, the Authorized Physician User shall record the actual number of sources implanted on the brachytherapy form and sign the appropriate section.

### 9. CT image verification of source placement



Following the implant procedure, a CT scan will be performed and the CT images imported into the VariSeed™ prostate brachytherapy treatment planning program. Source placement reconstruction with the VariSeed™ program will be used to generate the final treatment plan and total dose calculation, to verify that the administration is in accordance with the written directive.

10. Acceptance testing for computer hardware/software used to generate treatment plans

Acceptance testing will be performed by a physicist for all computer hardware and software prior to use for treatment planning. The acceptance testing will validate the appropriateness of the software/hardware for the needs of the department and also to verify that a performance matches manufacturer specifications. Additionally, accuracy of data input and output devices and information will be confirmed.



## VA Puget Sound Health Care System Radiation Oncology Service

### Written Directive Procedure for Permanent Implant Brachytherapy

This document describes the written directive policies and procedures instituted at the VA Puget Sound Health Care System, Radiation Oncology Service, for permanent implant brachytherapy treatments. These policies and procedures are designed to comply with 10 CFR Part 35.40, 10 CFR Part 35.41 and NRC NUREG-1556, Vol. 9, Rev. 2 in the context of permanent implant brachytherapy.

#### 1. Directives

Written directives signed and dated by an authorized physician user are required before the administration of any brachytherapy dose. An oral directive may be used only in the event that the delay in obtaining a written directive would jeopardize the patient's health in the opinion of the physician. In the event of use of an oral directive, a written directive must be obtained and placed in the patient's chart within 24 hours.

Before delivery of any brachytherapy dose, the radiation therapist/dosimetrist/ physicist will check that the written directive section of the brachytherapy form is filled out by an Authorized Physician User. The individual performing the procedure must sign and date the appropriate section of the form prior to loading.

#### 2. Patient Identification

Prior to delivery of treatment, each patient will be identified by two of the following methods:

- Asking patient his name and confirming that the name matches record.
- Social Security Number given by patient matches record.
- Date of birth given by patient matches record.
- Address given by patient matches record.
- Visual comparison to chart face photo.

After patient identification is confirmed by two of the methods described, the Authorized User will initial the appropriate section of the brachytherapy form.



3. Preliminary verification of brachytherapy pre-plan

Before preparation of sources for a brachytherapy treatment, a pre-implant treatment plan will be reviewed by a dosimetrist/physicist. He/she will initial the appropriate section of the brachytherapy form prior to preparation of the sources.

4. Obtaining guidance for carrying out written directives

Any worker having questions about carrying out a written directive should consult with the Authorized Physician User who created the written directive, rather than continuing a procedure when in doubt.

5. Verification of sources for pre-plan

Two individuals (dosimetrist/physicist/therapist/physician) will verify that the radioisotope, number of sources, and source strengths are in agreement with the written directive and the treatment pre-plan prior to implanting. After verification both individuals will initial the brachytherapy form in the appropriate section.

6. Verification of computer generated treatment plans

All treatment plans will be computer generated. Prior to delivery of total brachytherapy dose a dosimetrist/physicist/therapist, who whenever possible did not do the original plan, will double-check the treatment plan and dose calculations. Computer generated plans shall be examined for use of correct patient data. After the plan is verified, the appropriate section of the brachytherapy form shall be filled out and signed by the individual performing the double check.

7. Double check procedure for emergent patients

If the Authorized Physician User determines that performance of the double check procedure as defined in (6) above will cause an unacceptable delay and jeopardize a patient's health, the verification process may be performed within two working days of completion of the treatment. Reasonable attempt will be made to confirm visually that the dose distribution depicted in the computer plan conforms to the written directive.

When the verification is completed, the appropriate section of the brachytherapy form will be completed and signed by the individual performing the verification.

8. Recording of actual number of sources used

Promptly after insertion of the sources, the Authorized Physician User shall record the actual number of sources implanted on the brachytherapy form and sign the appropriate section.

9. CT image verification of source placement



Following the implant procedure, a CT scan will be performed and the CT images imported into the VariSeed™ prostate brachytherapy treatment planning program. Source placement reconstruction with the VariSeed™ program will be used to generate the final treatment plan and total dose calculation, to verify that the administration is in accordance with the written directive.

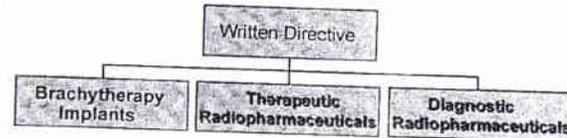
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## Brachytherapy WRITTEN DIRECTIVES Training

Radiation Safety  
VA Puget Sound Health  
Care System

- ◆ **10 CFR Part 35.40** mandates that each **Medical Radioactive Material Permit holder** establish **implement and maintain Written Procedures** for each **administration** requiring a **written directive**.



- ◆ **Written Directives Procedures** provide high confidence that **byproduct material or radiation** will be administered as directed by the **authorized user**.

NRC defines a written directive, in 10 CFR 35.2

- ◆ **Written directive** means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in 10 CFR 35.40.

NRC requirements for a written directive in Prostate Brachytherapy

- ◆ a. A written directive must be dated and signed by an authorized user before the administration any therapeutic dose of radiation from byproduct material.

NRC Requirements for Written Directives for Permanent Implant Prostate Brachytherapy

- ◆ b. The written directive must contain the patient or human research subject's name and the following information:
  - ◆ (1) Before implantation: treatment site, the radionuclide, and dose; and
  - ◆ (2) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

Written Directives for Permanent Implant Prostate Brachytherapy

- ◆ c. A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

Written Directives for Permanent Implant Prostate Brachytherapy

- ◆ d. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

### WD Record Retention Requirement

- ◆ A licensee shall retain a copy of each written directive as required by 10 CFR 35.40 for 3 years.

Audit Requirement: QUARTERLY

Records of each review and findings shall be maintained in an audible form for 3 years

### NHPP Requirements for Written Directives for Permanent Implant Prostate Brachytherapy

- ◆ Quarterly audits of written directives to ensure NRC and VHA requirements have been met.
- ◆ For the pre-implant portion of the written directive, provide the following information per 10 CFR 35.40: treatment site, the radionuclide, and dose.

### NHPP Requirements for Written Directives for Permanent Implant Prostate Brachytherapy

- ◆ For the post-implant part of the written directive, provide the following information per 10 CFR 35.40: radionuclide, treatment site, number of sources, total source strength, and the word "permanent."

### NHPP Requirements for Written Directives for Permanent Implant Prostate Brachytherapy

- ◆ At the bottom of the written directive, after the post-implant part, or on a separate review worksheet for written directives provide the following information:
- ◆ (1) Name, date, and signature for medical physicist review to determine if a medical event occurred. (If possible, the reviewing medical physicist should be a reviewer other than the medical physicist who prepared the treatment plan.)
- ◆ (2) Name, date, and signature for Radiation Safety Officer review to determine if a medical event occurred.

◆ The procedures must meet the following specific objectives:

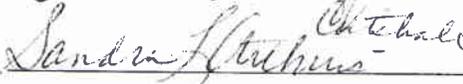
1. That a **WRITTEN DIRECTIVE** is dated and signed by an authorized user **PRIOR** to the administration:
2. That prior to each administration, the patient's identity is verified by more than one method as the individual named in the **WRITTEN DIRECTIVE**.
3. That each administration is in accordance with the Written Directive **AND** that any unintended deviation from the Written Directive is identified and evaluated **AND** the appropriate action is taken.

VA Puget Sound Health Care System  
Radiation Safety Training Report

I have received training and instruction regarding the radiation safety program at the VA Puget Sound Health Care System. The topics that were covered include: **Brachytherapy Emergency Procedures for Radioactive Material**; work rules specific to my position or service; my obligation to report unsafe conditions to the Radiation Safety Officer; my response to emergencies or unsafe conditions; and my right to be informed of my occupational exposure and bioassay results, if applicable.

I have received the following specialized training:

- Where Emergency Procedures are Located
- Response to Lost Seed (Danger to Public)
- Response to Leaking Seed (Patient)
- Retrieval and Securing of Seeds
- How to Obtain KI (During and After Hours)

Signature	Printed Name	Service	Date
	Steven Suther	PSMC	10/29/09
	Sandra Arthur	PSMC	10/29/09

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# ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

## Requirement:

Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials, during annual refresher training, and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Records of worker training will be maintained for at least 3 years.

Date of Instruction: 11/6/2008

Instructor: D.J. Dunn, RSO

Name: Dr. Kent Wallner

Signature



## Topical Issues

### USER RESPONSIBILITIES

Users of radioactive materials must be familiar with their responsibilities and obligations. Fundamental responsibilities include following all applicable regulations and safety protocols along with maintaining good documentation. Each user should also be familiar with the NRC Form - 3 "Notice to Employees" posted in each radioactive materials laboratory. That document describes and explains your legal rights as a worker using radioactive materials.

### SECURITY OF RADIOACTIVE MATERIAL

The NRC expects vigilant adherence to rules requiring security of radioactive materials. ***All radioactive material MUST be secured from unauthorized use, removal and vandalism at all times.*** Secure sealed/plated sources in a locked storage area and/or locked lab room when left unattended. Unsecured radioactive materials must **NEVER** be stored or used in an unrestricted and unposted room, area or facility. Unsecured material **MUST** never be left unattended.

### INVENTORY CONTROL

It is difficult if not impossible to identify missing radioactive material when users are unsure as to the proper amount that is supposed to be present. ***Maintain an accurate, documented inventory of materials received, used and disposed.***

### WARNING LABELS

NRC regulations require users of radioactive materials to affix labels to containers or items holding radioactive materials. The labels **MUST** be clearly visible and durable and **MUST** bear the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" The label must also provide sufficient information to permit individuals handling or using the containers or items to take

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

precautions to avoid or minimize exposures. Such information should include: 1) radionuclide(s), 2) estimated activity, and 3) date. [10 CFR 20.1904(a)]  
 Finally, labels on containers that are both empty AND uncontaminated *must* be fully defaced or removed prior to disposal of the containers. [10 CFR 20.1904(b)]

### EMERGENCIES & CONTAMINATION INCIDENTS

**ALWAYS** perform post-procedural contamination checks using a GM survey meter or other appropriate survey instrument

You **MUST** check:

- Yourself including your labcoat and clothing
- Your ungloved hands and your shoes (soles and tops)
- The immediate work areas where material was used or brought
- Floor areas near where material was handled or carried

**NOTIFY RSO immediately when CONTAMINATION has been identified:**

- On yourself, the patient
- On floors
- On other items or at areas not expected to become contaminated during routine use of radioactive materials, **OR**
- At levels exceeding 20 times background

### OCCUPATIONAL DOSE LIMITS

The Nuclear Regulatory Commission (NRC) has established Maximum Annual Occupational Radiation Dose Limits. These limits apply to exposure to radiation resulting from occupationally-related activities.

NRC MAXIMUM ANNUAL OCCUPATIONAL RADIATION DOSE LIMITS	
<b>ADULT</b>	
Whole Body ("TEDE")	5000 mrem / yr
Lens of the Eye	15,000 mrem / yr
Extremities	50,000 mrem / yr
Skin	50,000 mrem / yr
Individual Internal Organs ("TODE")	50,000 mrem / yr
<b>OTHER EMPLOYEE LIMITS</b>	
Embryo/Fetus of "Declared Pregnant Woman"	500 mrem over entire pregnancy
Minor (< 18 Yrs. of Age)	10% of Adult Limits

# ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

## AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)

The dose limits established by the NRC represent annual maximum limits and doses at those levels present a small risk of potential adverse health effects. However, that small risk will be reduced further by making the effort to keep occupational doses to as low as is reasonably achievable ("ALARA"). Doses must not only be below the regulatory limits, but they must be kept as much below those limits as is reasonably achievable. *The NRC mandates that all persons working with licensed radioactive materials must use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles in order to achieve occupational doses (internal & external) that are ALARA.*

## WRITTEN DIRECTIVES

**A written directive must be dated and signed by an authorized user before any therapeutic dose of radiation from byproduct material.**

- (1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.
- (b) The written directive must contain the patient or human research subject's name and the following information--
  - (1) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site; (2) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site; (3) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
  - (4) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:
    - (i) Before implantation: treatment site, the radionuclide, and dose; and
    - (ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).
- (c) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(d) The licensee shall retain a copy of the written directive for 3 years.

### MEDICAL EVENT

What is a "medical event"?

For all medical uses of NRC-licensed radioactive materials, a "medical event" occurs if **BOTH** of the following criteria are met:

(1) One or more of the following representative incidents occur:

- the dose administered to a patient differs from the prescribed dose by at least 20 percent, either too high or too low
- the wrong radioactive drug is administered
- the radioactive drug is administered by the wrong route
- the dose is administered to the wrong individual
- the patient receives a dose to a part of the body other than the intended treatment site that exceeds by 50 percent or more the dose expected by proper administration of the prescription
- a sealed source used in the treatment leaks;

**AND**

(2) The difference between the dose administered and the prescribed dose exceeds one of the reporting limits contained in the NRC's regulations at 10 CFR 35.3045, which correspond to the annual occupational dose limits at 10 CFR 20.1201.

**A "medical event" does not necessarily result in harm to the patient.**

The NRC requires licensees to report a medical event because it indicates that the licensee had technical or quality assurance problems in administering the physician's prescription. A dose error of 20 percent or more may indicate treatment delivery problems in the medical facility's operations that need correcting. However, there is no scientific basis to conclude that such an error necessarily results in harm to the patient.

Actual harm to a patient, whether injury (from overexposure) or inadequate treatment (due to underexposure) must be determined through a separate analysis done by the physician. In severe events (for example, rare occurrences when the dose error is well over 20 percent too high or too low), an independent medical consultant will assess the patient's risk of harm.

### REPORT AND NOTIFICATION OF A MEDICAL EVENT

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

Any event MUST be reported, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in--

- (1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
    - (i) The total dose delivered differs from the prescribed dose by 20 percent or more;
    - (ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
    - (iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
  - (2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following--
    - (i) An administration of a wrong radioactive drug containing byproduct material;
    - (ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;
    - (iii) An administration of a dose or dosage to the wrong individual or human research subject;
    - (iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or
    - (v) A leaking sealed source.
  - (3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).
- (b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.
- (c) The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the medical event.

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

(d) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event.

(1) The written report must include--

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(g) A licensee shall:

**ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in  
Sealed Sources**

- (1) Annotate a copy of the report provided to the NRC with the:
  - (i) Name of the individual who is the subject of the event; and
  - (ii) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and
- (2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

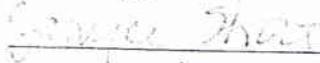
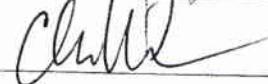
4/29/2008

VA Puget Sound Health Care System  
Radiation Safety Training Report

I have received training and instruction regarding the radiation safety program at the VA Puget Sound Health Care System. The topics that were covered include: Nuclear Regulatory Commission regulations, conditions of the license granted to this facility, and the location of required documents; a description of the areas in which isotopes are used or stored; the potential hazards of radioactive materials; appropriate radiation safety procedures for an individual in my service; work rules specific to my position or service; my obligation to report unsafe conditions to the Radiation Safety Officer; my response to emergencies or unsafe conditions; and my right to be informed of my occupational exposure and bioassay results, if applicable.

I have received the following specialized training:

ANNUAL UPDATE TRAINING FOR Medical Uses of Radionuclides (RADONC)

Signature	Printed Name	Service	Date
		Radiation Onc	4/29/2008
	T. Quang	Rad Onc	4/29/08
	JANCYE SAUER	"	4-29-08
	DONALD PUTMAN	"	4-29-08
	David J. Dunge	Rad Safety	4-29-08
	CHRIS KAHLE	Rad Safety	4-29-08

4/29/2008

VA Puget Sound Health Care System  
Radiation Safety Training Report

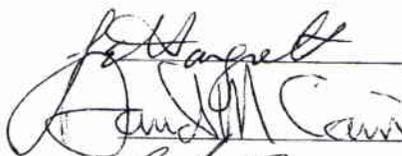
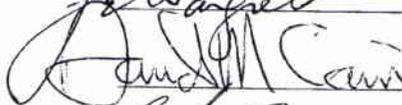
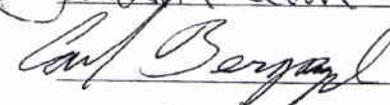
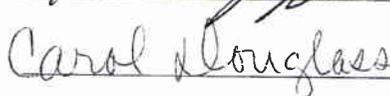
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I have received the following specialized training:

**ANNUAL UPDATE TRAINING FOR Medical Uses of Radionuclides (RADONC)**

\_\_\_\_\_  
\_\_\_\_\_

Signature	Printed Name	Service	Date
		Radiation Onc	4/29/2008

	Jean Hargrett		4/29/08
	DAVID CAIN		4-29-08
	Carl Bergsagel		4-29-08
	Carol Douglass		4-29-08

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4/29/2008

VA Puget Sound Health Care System  
Radiation Safety Training Report

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I have received the following specialized training:

**ANNUAL UPDATE TRAINING FOR Medical Uses of Radionuclides (RADONC)**

Signature	Printed Name	Service	Date
<i>Steve Sotlief</i>	Steve Sotlief	Radiation Onc	4/29/2008
<i>Sandra L. Arthur</i>	Sandra L. Arthur	Rad Onc	4/29/08
<i>Joe Walker</i>	Joseph B. Walker	Rad Onc	4/29/08



# Department of Veterans Affairs

VA Puget Sound Health Care System

Radiation Oncology Service 174

Radiation Therapy Chart Rounds, Physics Meeting, Staff Meeting, Therapist Meeting

Date 6/22/09

Radiation Safety Emergency Seeds Procedures

Name	Signature or Initials
Arthurs, Sandy	SA
Bergsagel, Carl	Carl Bergsagel
Bishop, Michael	
Borg, Chris	
Bowen, Wayne	W Bowen
Cain, David	David Cain
Check, Corey	C
Douglass, Carol	C
Fisher, Ana	
Gwinn, Micah	Micah Gwinn RTT
Hargrett, Jean	Jean Hargrett PA-C
Hauge, Winona	
Pritchard, Patti	
Putman, Don	
Quang, Tony	
Rosholt, Pegi	
Short, Janyce	Janyce Short
Simpson, Colleen	
Sutlief, Steve	Steve Sutlief
Walker, Joe	
Walker, Melinda	
Wallner, Kent	K. Wallner
*Resident*	WR

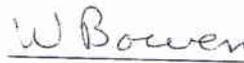
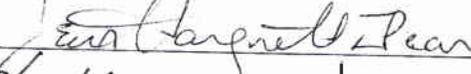
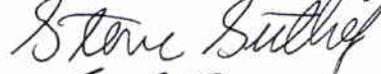
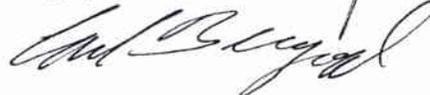
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I have received the following specialized training:

**Brachytherapy Emergency Procedures for Radioactive Material**

**Protecting the patient ;Assaying activity released into the patient;**  
**Protecting staff; Meeting Regulatory requirements; Contact information**

Signature	Printed Name	Service	Date
	Wayne Bowen	PMSC	6-22-09
	Carol Douglass	Rad Onc	6-22-09
	Janyce Short	PSMC	6-22-09
	Micah Guinn	PSMC	6-22-09
	Madhu Bathu	Rad Onc	6-22-09
	Sandra L. Arthurs- <sup>Cutshall</sup>	PSMC Rad Onc	6/22/09
	Jean Margaret	Rad Onc	6/22/09
	KENT WARNER	RAD ONC	6/22/09
	DAVID CAIN	RAD ONC	6-22-09
	Steve Sutrieb	Rad Onc	6/22/09
	Carl Bergsma	Rad Onc	6/22/09



**Veteran's Administration, Puget Sound Health Care System (VA PSHCS)**  
**PROCEDURE: Brachytherapy Emergency Procedures for Radioactive Material**

**DATE: 14 October 2008**

**REVIEWED:**

**REVISED:**

**DEPARTMENT REPRESENTATIVE:** \_\_\_\_\_

**RADIATION SAFETY OFFICER:** \_\_\_\_\_

**MEDICAL PHYSICIST:** \_\_\_\_\_

**MEDICAL PHYSICIST:** \_\_\_\_\_

**POLICY/PURPOSE:**

It is the policy of this facility to provide guidelines for the safe operation and control of radioactive materials and to provide proper response to emergency and abnormal situations. The following emergency procedures will be followed as emergency situations arise involving radioactive materials.

**PROCEDURE:**

A lead shielded container, long-handled forceps, and a survey instrument shall be available during all radioactive implant procedures.

1. If a source (seed) becomes dislodged or dislodged from the patient:
  - a. All linens, draping, and objects that came into contact with the patient shall be surveyed for radioactivity prior to being released from the room.
  - b. Use long handled forceps to place the source(s) into a lead container.
  - c. Move the lead container or source holder away from the patient and other personnel and contact the Radiation Safety Officer (RSO), Medical Physicist and the Radiation Oncologist as soon as possible.
2. Loss of radioactive source or seed:
  - a. Contact the RSO and the Medical Physicist immediately.
  - b. Qualified staff will use a G.M. counter to search for the lost source/seed.
  - c. Do not remove any bandages, linen, bedding, trash, etc. from the area until they have been surveyed.
  - d. Once the source/seed is found, it should be placed in a lead container using long forceps.
  - e. If the source/seed is not found, the appropriate NHPP and federal agencies will be notified immediately by the RSO.
3. Visible damage to a radioactive source or seed:
  - a. If a source or seed has been damaged due to rough handling, high temperature or crushing, rupture and leakage could occur. The area should be closed off and the RSO should be notified immediately.
    - i. Shut off fans and ventilators.
    - ii. Drop damp towels on the suspect material.
    - iii. Do not throw anything away.

- b. The qualified medical physicist will place the seed into a lead container using long forceps.
    - c. The area should be surveyed and decontaminated, if necessary.
    - d. A wipe test will be performed to ensure the decontamination was successful.
4. Emergency procedures to be followed in the event of suspected leakage of seed in contact with patient:
  - a. If internal contamination is suspected, contact the Radiation Oncologist immediately.
  - b. Radiation Oncologist order saturation of the patient's thyroid with stable iodine from the pharmacy: 0.5 mL Lugols solution or 5-6 drops of SSKI, Saturated Solution of Potassium Iodide (1 g/ml) in the case of an I-125 source rupture. \*\* See emergency numbers below.
  - c. Wipe the patient's skin surface and decontaminate the patient if indicated from wipe count (see Item 5).
  - d. Request patient urine sample for bioassay.
  - e. The patient will be counseled by the Authorized user, provided with a verbal summary of the event and any patient questions answered.
  - f. Ensure Patient follow-up should they not return for explanation, multiple attempts will be made to contact the patient and to perform a dose assessment.
  - g. The Radiation Safety Officer will contact VHA National Health Physics Program (NHPP) at 501-257-1571/1570 during normal working hours and 1(800) 815-1016 after normal working hours.
  - h. Advise the Chief Staff and Medical Center Director of the NHPP notification.
5. Emergency procedures to be followed in the event contamination is identified:
  - a. Close off the area and post a "Radioactive Materials" sign. No one will be permitted in the area. Any fans, ventilators or air conditioners operating in the area should be turned off.
  - b. Contact the RSO.
  - c. Survey and decontaminate the patient and/or treatment area from a ruptured source as indicated.
  - d. RSO will perform skin decontamination.
  - e. Qualified staff (staff trained in this emergency Brachytherapy Checklist) will follow these instruction to remove contamination:
    - i. Confine any liquid spillage by dropping quantities of paper towels onto it and blotting.
    - ii. Put on protective gear (rubber gloves, protective gowns, safety eyewear, shoe covers).
    - iii. An uncontaminated person will obtain a survey meter and determine background reading in a non-contaminated area.
    - iv. Scrub the area with decontaminants and detergents
    - v. Blot the area dry with clean paper towels
    - vi. Perform a wipe test to confirm the decontamination.
    - vii. If the exposure is still above background, repeat the washing process
    - viii. If the exposure level cannot be reduced, mark the area with red tape, cover with absorbent paper and label as contaminated area (exposure level, time and isotope).
    - ix. Notify personnel to stay clear of the area. Allow area to decay to background level before returning area to normal use.

- x. Place all of the cleanup materials in the appropriate container, seal, label and take to the decay storage area.
- xi. If shoes appear contaminated, remove before leaving the area. If feet are contaminated a washbowl and soap should be brought to the area for clean up.
- f. All personnel involved in the spill and the cleanup will survey their hands, feet and clothing for contamination. Gently wash skin with soap and water until background levels are reached. The cleanup area must be treated as contaminated until cleared by the RSO.
- g. Document the spill incident, recording the date, isotope, amount spilled, final exposure and background readings and the name of personnel involved in the cleanup. A report should be given to the RSO.

6. In the event of the death of the patient, physicians (pathologist) shall:

- i. Remove the radioactive source(s)/organ, if possible; otherwise, survey the body prior to removal to the morgue. Notify the RSO (6-1433) that the patient has died and still contains radioactive material.
  - Sealed sources implanted in the prostate (or any other organ) do not release any radioactive material into the body fluids. As long as there is minimal contact with the organ itself the exposure will be small. If a post-mortem requires removal of the organ it should be handled as briefly as possible, preferably with tongs or forceps.
- ii. Ensure the morgue pack contains the form for "PATIENT CONTAINS RADIOACTIVE MATERIAL" is filled out by the appropriate radiation oncology attending physician or radiation safety. Keep one copy of the form in the chart. Send one copy of the form with the body to the morgue. Place a "radioactive material" label on the body bag.
- iii. If the radioactive source(s) has not been removed, and the external radiation dose rate is greater than 0.2 mR/hr, arrange transport of the patient so that hallways are cleared and elevators are free of other passengers when transporting the body to the Morgue.
- iv. In the Morgue, move the body into the cold storage area. Ensure the "RADIOACTIVE" Label on the body bag is clearly visible. Place the appropriate sign on the outside the door of the cold storage unit to indicate a radioactive source is inside. Place the form indicating the level of radioactivity in the holder just below the sign outside the door of the cold storage unit. Note: only take these precautions if the body still contains an active radioactive source.

**EMERGENCY PHONE NUMBERS:**

**Daytime: 206-768-5356**

**Evenings and weekends:**

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<b>Kent Wallner, Radiation Oncologist:</b>	<b>65356</b>	<b>206-699-4478</b>
<b>Steven Sutlief, Medical Physicist:</b>	<b>66597</b>	<b>206-699-3167</b>
<b>Carl Bergsagel, Medical Physicist:</b>	<b>65333</b>	<b>206-699-4535</b>
<b>Sandy Arthurs-Cutshall, Supervisor:</b>	<b>66443</b>	<b>206-570-7304</b>
<b>David Dunn, Radiation Safety Officer:</b>	<b>61789</b>	<b>206-699-2179</b>
<b>Pharmacist on Duty/Manager:</b>	<b>6-1412</b>	<b>206-610-0305</b>

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DRAFT

## **Emergency Plans for Leaking Brachytherapy Seed Sources**

### **Training: Annual**

The brachytherapy team should be trained in procedures periodically.

#### **Protecting the patient**

If an implanted iodine-125 seed is leaking, administration of non-radioactive iodine to the patient can protect the patient's thyroid. The non-radioactive iodine should be prescribed by a physician. However, the RSO should be prepared to provide a guidance document on dosage ) to the physician and know how to quickly obtain pharmaceutical non-radioactive iodine.

#### **Assaying activity released into the patient**

In the case of leaking iodine-125 seeds, the RSO should be prepared to perform and evaluate both thyroid and urine bioassays. If it is suspected an implanted iodine-125 seed is leaking, nonradioactive iodine should be administered to the patient promptly; do not wait for a bioassay to confirm the leak. If leakage is confirmed, nonradioactive iodine should be administered daily.

#### **Protecting staff**

The plan should include safety precautions, such as those for handling unsealed radioactive material and bodily fluids, for staff.

#### **Meeting Regulatory requirements**

10 CFR 35.3045 defines a leaking brachytherapy source as a medical event if the dose exceeds 0.5 Sv to an organ or tissue, 0.05 Sv effective dose equivalent, or 0.5 Sv shallow dose equivalent to the skin. In this case, NHPP must be promptly notified so it can notify NRC by the end of the next day. 10 CFR 35.3045 requires notification of the referring physician and patient.

#### **Contact information**

Information for contacting key members of the brachytherapy team, during and after working hours, should be available.

References:

**NCRP Report No. 65**

(such as NCRP Report No. 65 or FDA's Guidance:

**Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies,**

<http://www.fda.gov/cder/guidance/4825fnl.htm>

## **Guidance Excerpted from Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies**

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)

**December 2001  
Procedural**

Rockville, MD 20857  
(Tel) 301-827-4573

Internet) <http://www.fda.gov/cder/guidance/index.htm>

The effectiveness of KI as a specific blocker of thyroid radioiodine uptake is well established as are the doses necessary for blocking uptake. As such, it is reasonable to conclude that KI will likewise be effective in reducing the risk of thyroid cancer in individuals contaminated with radioiodines.

Short-term administration of KI at thyroid blocking doses is safe and, in general, more so in children than adults. The risks of stable iodine administration include sialadenitis (an inflammation of the salivary gland, of which no cases were reported in Poland among users after the Chernobyl accident), gastrointestinal disturbances, allergic reactions and minor rashes. In addition, persons with known iodine sensitivity should avoid KI, as should individuals with dermatitis herpetiformis and hypocomplementemic vasculitis, extremely rare conditions associated with an increased risk of iodine hypersensitivity. Individuals with multinodular goiter, Graves' disease, and autoimmune thyroiditis should be treated with caution, especially if dosing extends beyond a few days.

**Recommended Doses of KI for Different Risk Groups**

	Predicted Thyroid exposure(cGy)	KI dose (mg)	# of 130 mg tablets	# of 65 mg tablets
Adults over 40 yrs	≥500	130	1	2
Adults over 18 through 40 yrs	≥10			

The protective effect of KI lasts approximately 24 hours. For optimal prophylaxis, KI should therefore be dosed daily, until a risk of significant exposure to radioiodines by either inhalation or ingestion no longer exists. KI may still have a substantial protective effect even if taken 3 or 4 hours after exposure. Furthermore, if the release of radioiodines into the body is protracted, then, of course, even delayed administration may reap benefits by reducing, if incompletely, the total radiation dose to the thyroid.

**FDA/Center for Drug Evaluation and Research**

VA Puget Sound Health Care System  
Radiation Safety Officer (11R)

Reporting Radiation Therapy Misadministrations and Recordable Events

1. Definitions.

a. *Recordable Event.*

(1) External Beam Therapy: When the calculated weekly administered dose exceeds the weekly prescribed dose by 15% or more of the prescribed dose.

(2) Brachytherapy: When the calculated administered dose differs from the prescribed dose by more than 10% of the prescribed dose.

b. *Misadministration.*

(1) External Beam Therapy:

(a) A radiation dose involving the wrong individual, wrong mode of treatment, or wrong treatment site;

(b) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose;

(c) When the calculated weekly administered dose exceeds the weekly prescribed dose by 30% or more of the weekly prescribed dose; or

(d) When the calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose.

(2) Brachytherapy (Permanent Implants): A radiation dose:

(a) Involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

(b) Involving a sealed source that is leaking;

(c) When the calculated administered dose differs from the prescribed dose by more than 20% of the prescribed dose.

c. *Prescribed Dose:*

(1) External Beam Therapy: The prescribed total dose and dose per fraction.

(2) Permanent Implant Brachytherapy: The total dose, as documented in the written directive.

d. *Written Directive* (required for all brachytherapy): An order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation. The written directive must include:

(1) Prior to implantation: The radioisotope, number of sources, and source strengths;

(2) After implantation: The radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

2. Reporting Requirements.

a. *Recordable Event.* Notify the Radiation Safety Officer (RSO) as soon as possible. The RSO will investigate to determine the cause of the recordable event and recommend corrective actions to prevent recurrence of this or a similar event. The investigation must be completed within 30 days after discovery of the recordable event.

b. *Misadministration.*

(1) Notify the Radiation Safety Officer (RSO) as soon as possible after the misadministration is discovered. For brachytherapy misadministrations, the RSO must notify the Nuclear Regulatory Commission (NRC) Operations Center by telephone no later than the next calendar day after discovery of the misadministration, and submit a written report to the NRC within 15 days.

(2) The referring physician and also the patient receiving the misadministration must be notified no later than 24 hours after discovery of the misadministration, unless the referring physician personally states that he or she will inform the patient, or that, based on medical judgment, telling the patient would be harmful. The patient does not have to be notified without first consulting the referring physician. If the referring physician or the patient receiving the misadministration cannot be reached within 24 hours, the individual must be notified as soon as possible thereafter.

### **VHA Standard Procedure - - Training for Medical Events**

1. VHA facilities performing permanent implant prostate brachytherapy must provide initial and periodic training to the staff involved in, or supporting, the prostate brachytherapy program. The training must be provided to physician authorized users, medical physicists, urologists participating in these procedures, dosimetrists, and the Radiation Safety Officer (RSO) and staff.
2. A specific training topic is medical events to include specific details for NRC definition of a medical event, how to recognize a medical event, and actions to be taken if a medical event is discovered. The training should be provided by the RSO or by a qualified person, such as a therapeutic medical physicist, designated by the facility Radiation Safety Committee or RSO.
3. The guidelines for this training are listed below and consist of questions and answers to be addressed at the facility level. Training must be commensurate with duties. Also, facilities must incorporate these guidelines into other facility procedures, as needed, to ensure requirements for medical events are made known to the staff.

#### **Training for Medical Events**

##### **What is the regulatory definition of a medical event?**

NRC defines a medical event in 10 CFR 35.3045. A link to the NRC Web site with the definition is:

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3045.html>

The definition of a medical event is listed below.

“A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in.

1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
  - a. The total dose delivered differs from the prescribed dose by 20% or more,
  - b. The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range, or
  - c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.
2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following.
  - a. An administration of a wrong radioactive drug containing byproduct material,
  - b. An administration of a radioactive drug containing byproduct material by the wrong route of administration,

### **VHA Standard Procedure - - Training Medical Events**

- c. An administration of a dose or dosage to the wrong individual or human research subject,
  - d. An administration of a dose or dosage delivered by the wrong mode of treatment, or
  - e. A leaking sealed source.
3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.”

#### **What are roles and responsibilities related to medical events?**

The Radiation Safety Committee provides oversight of the safe use of radioactive materials and requires initial and periodic training for staff commensurate with their duties.

The RSO or a designee normally provides or coordinates staff training, including the training for medical events, and maintains training records. The RSO has primary responsibility for identifying and reporting medical events. If a medical event is discovered, the RSO makes required notifications to NHPP (to be reported to the NRC Operations Center by the next calendar day after discovery) and prepares the 15-day written report to send to NHPP.

Physician authorized users, medical physicists, dosimetrists, and other staff involved in prostate brachytherapy procedures must be aware of patient circumstances that might be a medical event and the requirement to report those circumstances to the RSO promptly upon identification.

Staff must be aware of the significance of the written directive, both the pre-implant part, which documents the prescribed dose, and the post-implant part, which documents the administered activity.

#### **What is a medical event?**

A medical event is patient circumstances that are within the NRC definition in 10 CFR 35.3045.

For prostate brachytherapy procedures, the figure of merit to identify a medical event during the post-treatment dose analysis is D90. The D90 must be 80% or greater of the prescribed dose in the written directive.

A medical event may also result from an overly large dose to tissue outside the prostate. A cause would be a seed or seeds outside the prostate. Note: Some physicians deliberately implant seeds just outside the prostate to treat a margin around the prostate.

An implanted leaking seed is a medical event if the seed will cause a dose exceeding 0.5 gray (50 rad) to an organ or tissue. For I-125 seeds, the primary organ of concern is the thyroid.

## **VHA Standard Procedure - - Training Medical Events**

### **How to identify a medical event including the criteria for a medical event?**

A medical event is identified by comparing the results of the treatment, particularly the post-treatment images and dose indices such as the D90; the authorized user's intent, as defined in the written directive and approved pre-plan; and the NRC definition of a medical event. Deviations or discrepancies are determined to help identify if a medical event occurred.

The post-implant dose analysis produces the D90. The D90 is a figure of merit for determining whether the prescribed dose was achieved. The D90 must exceed 80% of the prescribed dose in the written directive or a medical event has occurred.

Identification of a medical event resulting from seed(s) outside of the prostate is determined on a case-by-case basis in consultation with NHPP. Circumstances to consider include: a seed or seeds distant from the prostate, unless the seed(s) migrated; a seed or seeds in the rectum or very close to the rectum; and a volume of the rectum exceeding 160 gray that is more than about 1.5 cc.

### **What are the notification and reporting requirements for a medical event?**

10 CFR 35.3045 requires:

- Notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a medical event.
- Submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the medical event.
- Notify the referring physician and the patient.

Under the master materials license issued to VHA, NHPP makes notifications to the NRC Operations Center. The facility must contact NHPP as soon as possible about any patient circumstances that might be a medical event. The telephone information is noted below.

- Normal business hours for Central Time Zone at 501-257-1571.
- After normal business hours for Central Time Zone at 800-815-1016.
- Intranet Web page for information to contact individual NHPP staff at the following URL.

<http://nhpp.med.va.gov/emergency.asp>

For notification of, or contact with, NHPP, voice mail or e-mail must NOT be substituted for a direct discussion with NHPP staff, preferably a technical staff member. This is particularly important if an immediate or next day notification is required to NRC.

The RSO must have a recall list with contact information for the physician authorized users, referring physicians if possible, and NHPP. The list should have the office and cellular telephone numbers so key staff can be contacted and consulted in a medical event situation, both during and outside normal working hours.

January 9, 2009

**VHA Standard Procedure - - Training Medical Events**

The after-hours recall information is especially important for a weekend recall when a patient therapy procedure or post-implant dose analysis might have been completed late in the week, such as on a Friday, and notification is required within a specific time period.

This recall list should also include vendor telephone numbers if sealed sources are used in the patient therapy procedure.

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

### Requirement:

Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials, during annual refresher training, and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Records of worker training will be maintained for at least 3 years.

Date of Instruction: 4/15/2009

Instructor: D.J. Dunn, RSO

Name:

K. W. A. L. W. A.

Signature

[Handwritten Signature]

### Topical Issues

#### USER RESPONSIBILITIES

Users of radioactive materials must be familiar with their responsibilities and obligations. Fundamental responsibilities include following all applicable regulations and safety protocols along with maintaining good documentation. Each user should also be familiar with the NRC Form - 3 "Notice to Employees" posted in each radioactive materials laboratory. That document describes and explains your legal rights as a worker using radioactive materials.

#### SECURITY OF RADIOACTIVE MATERIAL

The NRC expects vigilant adherence to rules requiring security of radioactive materials. *All radioactive material MUST be secured from unauthorized use, removal and vandalism at all times.* Secure sealed/plated sources in a locked storage area and/or locked lab room when left unattended. Unsecured radioactive materials must NEVER be stored or used in an unrestricted and unposted room, area or facility. Unsecured material MUST never be left unattended.

#### INVENTORY CONTROL

It is difficult if not impossible to identify missing radioactive material when users are unsure as to the proper amount that is supposed to be present. *Maintain an accurate, documented inventory of materials received, used and disposed.*

#### WARNING LABELS

NRC regulations require users of radioactive materials to affix labels to containers or items holding radioactive materials. The labels MUST be clearly visible and durable and MUST bear the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" The label must also provide sufficient information to permit individuals handling or using the containers or items to take

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

precautions to avoid or minimize exposures. Such information should include: 1) radionuclide(s), 2) estimated activity, and 3) date. [10 CFR 20.1904(a)]  
 Finally, labels on containers that are **both empty AND uncontaminated must be fully defaced or removed** prior to disposal of the containers. [10 CFR 20.1904(b)]

### EMERGENCIES & CONTAMINATION INCIDENTS

**ALWAYS** perform **post-procedural contamination checks** using a GM survey meter or other appropriate survey instrument

You **MUST** check:

- Yourself including your labcoat and clothing
- Your ungloved hands and your shoes (soles and tops)
- The immediate work areas where material was used or brought
- Floor areas near where material was handled or carried

**NOTIFY RSO immediately when CONTAMINATION has been identified:**

- On yourself, the patient
- On floors
- On other items or at areas not expected to become contaminated during routine use of radioactive materials, **OR**
- At levels exceeding 20 times background

### OCCUPATIONAL DOSE LIMITS

The Nuclear Regulatory Commission (NRC) has established Maximum Annual Occupational Radiation Dose Limits. These limits apply to exposure to radiation resulting from occupationally-related activities.

NRC MAXIMUM ANNUAL OCCUPATIONAL RADIATION DOSE LIMITS	
<b>ADULT</b>	
Whole Body ("TEDE")	5000 mrem / yr
Lens of the Eye	15,000 mrem / yr
Extremities	50,000 mrem / yr
Skin	50,000 mrem / yr
Individual Internal Organs ("TODE")	50,000 mrem / yr
<b>OTHER EMPLOYEE LIMITS</b>	
Embryo/Fetus of "Declared Pregnant Woman"	500 mrem over entire pregnancy
Minor (< 18 Yrs. of Age)	10% of Adult Limits

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

### AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)

The dose limits established by the NRC represent annual maximum limits and doses at those levels present a small risk of potential adverse health effects. However, that small risk will be reduced further by making the effort to keep occupational doses to as low as is reasonably achievable ("ALARA"). Doses must not only be below the regulatory limits, but they must be kept as much below those limits as is reasonably achievable. *The NRC mandates that all persons working with licensed radioactive materials must use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles in order to achieve occupational doses (internal & external) that are ALARA.*

### WRITTEN DIRECTIVES

A written directive must be dated and signed by an authorized user before any therapeutic dose of radiation from byproduct material.

- (1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.
- (b) The written directive must contain the patient or human research subject's name and the following information--
  - (1) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site; (2) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site; (3) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
  - (4) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:
    - (i) Before implantation: treatment site, the radionuclide, and dose; and
    - (ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).
- (c) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(d) The licensee shall retain a copy of the written directive for 3 years.

### MEDICAL EVENT

What is a "medical event"?

For all medical uses of NRC-licensed radioactive materials, a "medical event" occurs if **BOTH** of the following criteria are met:

(1) One or more of the following representative incidents occur:

- the dose administered to a patient differs from the prescribed dose by at least 20 percent, either too high or too low
- the wrong radioactive drug is administered
- the radioactive drug is administered by the wrong route
- the dose is administered to the wrong individual
- the patient receives a dose to a part of the body other than the intended treatment site that exceeds by 50 percent or more the dose expected by proper administration of the prescription
- a sealed source used in the treatment leaks;

**AND**

(2) The difference between the dose administered and the prescribed dose exceeds one of the reporting limits contained in the NRC's regulations at 10 CFR 35.3045, which correspond to the annual occupational dose limits at 10 CFR 20.1201.

A "medical event" does not necessarily result in harm to the patient.

The NRC requires licensees to report a medical event because it indicates that the licensee had technical or quality assurance problems in administering the physician's prescription. A dose error of 20 percent or more may indicate treatment delivery problems in the medical facility's operations that need correcting. However, there is no scientific basis to conclude that such an error necessarily results in harm to the patient.

Actual harm to a patient, whether injury (from overexposure) or inadequate treatment (due to underexposure) must be determined through a separate analysis done by the physician. In severe events (for example, rare occurrences when the dose error is well over 20 percent too high or too low), an independent medical consultant will assess the patient's risk of harm.

### REPORT AND NOTIFICATION OF A MEDICAL EVENT

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

Any event MUST be reported, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in--

- (1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
  - (i) The total dose delivered differs from the prescribed dose by 20 percent or more;
  - (ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
  - (iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
- (2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following--
  - (i) An administration of a wrong radioactive drug containing byproduct material;
  - (ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;
  - (iii) An administration of a dose or dosage to the wrong individual or human research subject;
  - (iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or
  - (v) A leaking sealed source.
- (3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).
  - (b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.
  - (c) The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the medical event.

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

(d) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event.

(1) The written report must include--

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(g) A licensee shall:

**ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in  
Sealed Sources**

- (1) Annotate a copy of the report provided to the NRC with the:
  - (i) Name of the individual who is the subject of the event; and
  - (ii) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and
- (2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

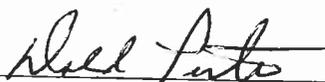
### Requirement:

Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials, during annual refresher training, and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Records of worker training will be maintained for at least 3 years.

Date of Instruction: 04/07/2009

Instructor: D.J. Dunn, RSO

Name: DONALD PUTMAN

Signature 

### Topical Issues

#### USER RESPONSIBILITIES

Users of radioactive materials must be familiar with their responsibilities and obligations. Fundamental responsibilities include following all applicable regulations and safety protocols along with maintaining good documentation. Each user should also be familiar with the NRC Form - 3 "Notice to Employees" posted in each radioactive materials laboratory. That document describes and explains your legal rights as a worker using radioactive materials.

#### SECURITY OF RADIOACTIVE MATERIAL

The NRC expects vigilant adherence to rules requiring security of radioactive materials. *All radioactive material MUST be secured from unauthorized use, removal and vandalism at all times.* Secure sealed/plated sources in a locked storage area and/or locked lab room when left unattended. Unsecured radioactive materials must **NEVER** be stored or used in an unrestricted and unposted room, area or facility. Unsecured material **MUST** never be left unattended.

#### INVENTORY CONTROL

It is difficult if not impossible to identify missing radioactive material when users are unsure as to the proper amount that is supposed to be present. *Maintain an accurate, documented inventory of materials received, used and disposed.*

#### WARNING LABELS

NRC regulations require users of radioactive materials to affix labels to containers or items holding radioactive materials. The labels **MUST** be clearly visible and durable and **MUST** bear the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" The label must also provide sufficient information to permit individuals handling or using the containers or items to take

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

precautions to avoid or minimize exposures. Such information should include: 1) radionuclide(s), 2) estimated activity, and 3) date. [10 CFR 20.1904(a)]

Finally, **labels on containers that are both empty AND uncontaminated must be fully defaced or removed** prior to disposal of the containers. [10 CFR 20.1904(b)]

### EMERGENCIES & CONTAMINATION INCIDENTS

**ALWAYS** perform **post-procedural contamination checks** using a GM survey meter or other appropriate survey instrument

You **MUST** check:

- ⇒ Yourself including your labcoat and clothing
- ⇒ Your ungloved hands and your shoes (soles and tops)
- ⇒ The immediate work areas where material was used or brought
- ⇒ Floor areas near where material was handled or carried

**NOTIFY RSO immediately when CONTAMINATION has been identified:**

- On yourself, the patient
- On floors
- On other items or at areas not expected to become contaminated during routine use of radioactive materials, **OR**
- At levels exceeding 20 times background

### OCCUPATIONAL DOSE LIMITS

The Nuclear Regulatory Commission (NRC) has established Maximum Annual Occupational Radiation Dose Limits. These limits apply to exposure to radiation resulting from occupationally-related activities.

NRC MAXIMUM ANNUAL OCCUPATIONAL RADIATION DOSE LIMITS	
<b>ADULT</b>	
Whole Body ("TEDE")	5000 mrem / yr
Lens of the Eye	15,000 mrem / yr
Extremities	50,000 mrem / yr
Skin	50,000 mrem / yr
Individual Internal Organs ("TODE")	50,000 mrem / yr
<b>OTHER EMPLOYEE LIMITS</b>	
Embryo/Fetus of "Declared Pregnant Woman"	500 mrem over entire pregnancy
Minor (< 18 Yrs. of Age)	10% of Adult Limits

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

### AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)

The dose limits established by the NRC represent annual maximum limits and doses at those levels present a small risk of potential adverse health effects. However, that small risk will be reduced further by making the effort to keep occupational doses to **as low as is reasonably achievable** ("ALARA"). Doses must not only be below the regulatory limits, but they must be kept as much below those limits as is reasonably achievable. *The NRC mandates that all persons working with licensed radioactive materials must use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles in order to achieve occupational doses (internal & external) that are ALARA.*

### WRITTEN DIRECTIVES

**A written directive must be dated and signed by an authorized user before any therapeutic dose of radiation from byproduct material.**

- (1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.
- (b) The written directive must contain the patient or human research subject's name and the following information--
  - (1) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site; (2) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site; (3) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
  - (4) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:
    - (i) Before implantation: treatment site, the radionuclide, and dose; and
    - (ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).
- (c) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(d) The licensee shall retain a copy of the written directive for 3 years.

### MEDICAL EVENT

What is a "medical event"?

For all medical uses of NRC-licensed radioactive materials, a "medical event" occurs if **BOTH** of the following criteria are met:

(1) One or more of the following representative incidents occur:

- the dose administered to a patient differs from the prescribed dose by at least 20 percent, either too high or too low
- the wrong radioactive drug is administered
- the radioactive drug is administered by the wrong route
- the dose is administered to the wrong individual
- the patient receives a dose to a part of the body other than the intended treatment site that exceeds by 50 percent or more the dose expected by proper administration of the prescription
- a sealed source used in the treatment leaks;

**AND**

(2) The difference between the dose administered and the prescribed dose exceeds one of the reporting limits contained in the NRC's regulations at 10 CFR 35.3045, which correspond to the annual occupational dose limits at 10 CFR 20.1201.

**A "medical event" does not necessarily result in harm to the patient.**

The NRC requires licensees to report a medical event because it indicates that the licensee had technical or quality assurance problems in administering the physician's prescription. A dose error of 20 percent or more may indicate treatment delivery problems in the medical facility's operations that need correcting. However, there is no scientific basis to conclude that such an error necessarily results in harm to the patient.

Actual harm to a patient, whether injury (from overexposure) or inadequate treatment (due to underexposure) must be determined through a separate analysis done by the physician. In severe events (for example, rare occurrences when the dose error is well over 20 percent too high or too low), an independent medical consultant will assess the patient's risk of harm.

### REPORT AND NOTIFICATION OF A MEDICAL EVENT

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

Any event MUST be reported, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in--

- (1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
  - (i) The total dose delivered differs from the prescribed dose by 20 percent or more;
  - (ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
  - (iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
- (2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following--
  - (i) An administration of a wrong radioactive drug containing byproduct material;
  - (ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;
  - (iii) An administration of a dose or dosage to the wrong individual or human research subject;
  - (iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or
  - (v) A leaking sealed source.
- (3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).
  - (b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.
  - (c) The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the medical event.

## ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in Sealed Sources

- (d) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event.
- (1) The written report must include--
- (i) The licensee's name;
  - (ii) The name of the prescribing physician;
  - (iii) A brief description of the event;
  - (iv) Why the event occurred;
  - (v) The effect, if any, on the individual(s) who received the administration;
  - (vi) What actions, if any, have been taken or are planned to prevent recurrence; and
  - (vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.
- (2) The report may not contain the individual's name or any other information that could lead to identification of the individual.
- (e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.
- (f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.
- (g) A licensee shall:

**ANNUAL REFRESHER TRAINING for Medical Uses of Radionuclides in  
Sealed Sources**

- (1) Annotate a copy of the report provided to the NRC with the:
  - (i) Name of the individual who is the subject of the event; and
  - (ii) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and
- (2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

January 9, 2009  
**VHA Standard Procedure --  
Training for Medical Events**



VHA facilities performing permanent implant prostate brachytherapy must provide initial and periodic training to the staff involved in, or supporting, the prostate brachytherapy program.



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**What is the regulatory  
definition of a medical event?**



A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in.:



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**What is the regulatory  
definition of a medical event?**



1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and



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**What is the regulatory  
definition of a medical event?**



- a. The total dose delivered differs from the prescribed dose by 20% or more,
- b. The total dosage delivered differs from the prescribed dosage by 20% or more or falls outside the prescribed dosage range, or
- c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.



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**What is the regulatory definition of a medical event?**



2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following.



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**What is the regulatory definition of a medical event?**



- a. An administration of a wrong radioactive drug containing byproduct material,
- b. An administration of a radioactive drug containing byproduct material by the wrong route of administration,



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**What is the regulatory definition of a medical event?**



- c. An administration of a dose or dosage to the wrong individual or human research subject,
- d. An administration of a dose or dosage delivered by the wrong mode of treatment, or
- e. A leaking sealed source.



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**What is the regulatory definition of a medical event?**



3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).



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### What is the regulatory definition of a medical event?



A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

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### What are roles and responsibilities related to medical events?



The Radiation Safety Committee provides oversight of the safe use of radioactive materials and requires initial and periodic training for staff commensurate with their duties.



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### What are roles and responsibilities related to medical events?



- The RSO or a designee normally provides or coordinates staff training, including the training for medical events, and maintains training records.
- The RSO has primary responsibility for identifying and reporting medical events.
- If a medical event is discovered, the RSO makes required notifications to NHPP (to be reported to the NRC Operations Center by the next calendar day after discovery) and prepares the 15-day written report to send to NHPP.

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### What are roles and responsibilities related to medical events?



- Physician authorized users, medical physicists, dosimetrists, and other staff involved in prostate brachytherapy procedures must be aware of patient circumstances that might be a medical event and the requirement to report those circumstances to the RSO promptly upon identification.



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### What are roles and responsibilities related to medical events?



- Staff must be aware of the significance of the written directive, both the pre-implant part, which documents the prescribed dose, and the post-implant part, which documents the administered activity



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### When has a Medical Event Occurred?



- For prostate brachytherapy procedures, the figure of merit to identify a medical event during the post-treatment dose analysis is D90. The D90 must be 80% or greater of the prescribed dose in the written directive.



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### When has a Medical Event Occurred?



- A medical event may also result from an overly large dose to tissue outside the prostate. A cause would be a seed or seeds outside the prostate. Note: Some physicians deliberately implant seeds just outside the prostate to treat a margin around the prostate.



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### When has a Medical Event Occurred?



- An implanted leaking seed is a medical event if the seed will cause a dose exceeding 0.5 gray (50 rad) to an organ or tissue. For I-125 seeds, the primary organ of concern is the thyroid.



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### How to Identify a Medical Event



- A medical event is identified by comparing the results of the treatment, particularly the post-treatment images and dose indices such as the D90; the authorized user's intent, as defined in the written directive and approved pre-plan; and the NRC definition of a medical event.



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### How to Identify a Medical Event



- Deviations or discrepancies are determined to help identify if a medical event occurred.



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### How to Identify a Medical Event



- The post-implant dose analysis produces the D90. The D90 is a figure of merit for determining whether the prescribed dose was achieved. The D90 must exceed 80% of the prescribed dose in the written directive or a medical event has occurred.



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### How to Identify a Medical Event



- Identification of a medical event resulting from seed(s) outside of the prostate is determined on a case-by-case basis in consultation with NHPP. Circumstances to consider include: a seed or seeds distant from the prostate, unless the seed(s) migrated; a seed or seeds in the rectum or very close to the rectum; and a volume of the rectum exceeding 160 gray that is more than about 1.5 cc.



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## NRC Notification Requirements



- Notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a medical event.
- Submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the medical event.
- Notify the referring physician and the patient.

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## NRC Notification Requirements



- Under the master materials license issued to VHA, NHPP makes notifications to the NRC Operations Center. The facility must contact NHPP as soon as possible about any patient circumstances that might be a medical event. The telephone information is noted below.



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## NRC Notification Requirements



- Normal business hours for Central Time Zone at:
  - 501-257-1571.
- After normal business hours for Central Time Zone at:
  - 800-815-1016.
- Intranet Web page for information to contact individual NHPP staff at the following URL.
  - <http://nhpp.med.va.gov/emergency.asp>



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## NRC Notification Requirements



- For notification of, or contact with, NHPP, voice mail or e-mail must NOT be substituted for a direct discussion with NHPP staff, preferably a technical staff member. This is particularly important if an immediate or next day notification is required to NRC.



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## NRC Notification Requirements



- **The RSO must have a recall list with contact information for the physician authorized users, referring physicians if possible, and NHPP. The list should have the office and cellular telephone numbers so key staff can be contacted and consulted in a medical event situation, both during and outside normal working hours.**



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## NRC Notification Requirements



- **The after-hours recall information is especially important for a weekend recall when a patient therapy procedure or post-implant dose analysis might have been completed late in the week, such as on a Friday, and notification is required within a specific time period.**



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## NRC Notification Requirements



- **This recall list should also include vendor telephone numbers if sealed sources are used in the patient therapy procedure.**



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Department of Veterans Affairs

VA Puget Sound Health Care System

Radiation Oncology Service 174

Radiation Therapy Chart Rounds, Physics Meeting, General/Staff Meeting

Date 2/27/07

Radiation Safety

Name	Signature
Arthurs, Sandy	(SA)
Bergsagel, Carl	<i>Carl Bergsagel</i>
Bowen, Wayne	<i>W Bowen</i>
Cain, David	<i>David Cain</i>
Check, Corey	
<del>Davenport, Sue</del>	
<del>Dickson, Barb</del>	
Douglass, Carol	SL today
Gwinn, Micah	SL today
Hargrett, Jean	<i>Jean Hargrett, RRT</i>
Lee, Jennifer	<i>Jennifer Lee</i>
Lenz, Hila	AL today
Putman, Don	<i>Don Putman</i>
Short, Janyce	<i>Janyce J. Short</i>
Simpson, Colleen	<i>Colleen Simpson</i>
Sutlief, Steve	<i>Steve Sutlief</i>
Walker, Joe	<i>Joe Walker</i>
Wallner, Kent	out today
*Resident*	
<del>Rob</del> Weaver, Rob	<i>Rob A. Weaver</i>



**VAMC  
Radiation Safety  
Oncology  
Radiation Safety Training**

VA Puget Sound Health  
Radiation Safety Office  
206-277-1433  
January 2007

### Course Information



Review of the following information and completion of the exam found at the end of this course fulfills the radiation safety training requirement for individuals participating in Radiation Oncology procedures.

For more information concerning radiation safety, call or visit Bldg 1/316 (206-277-1789).

### Getting Started

**Course Credit**  
To obtain credit for this course:

- Read the following material
- Complete the exam
- Print and mail a copy of the completed exam to RSO



### Training Requirements

**Initial Training is required for:**

- All Radiation Oncology personnel new hires.

**Annual Refresher Training is required for:**

- All individuals participating in radiopharmaceutical therapy patient care and/or who are likely to receive a whole body dose equivalent of greater than 100 mrem in one year.

For radiation safety assistance contact D. J. Dunn at 6-1789 / 6-1433 or David.Dunn3@VA.gov

### Radiation Safety Policies



Radiation safety use and enforcement policies are set by the VA PSHCS's Radiation Safety Committee. Dr. John D. Harley, Chief, Radiology Service, is the Chair of the RSC Committee.

Policies are based *both* on the VA's Master radioactive Materials License conditions and Nuclear Regulatory Commission (NRC) regulations.

### Radiation Safety Officer



**The Radiation Safety Officer (RSO) for The VA PSHCS is David Dunn.** You may address questions or concerns to by phone at 6-1789 or david.dunn3@va.gov.

The RSO is responsible for managing 's (VA PSHCS's) radiation protection program. He has authority from the Director VA PSHCS to stop any operation considered unsafe or immediately dangerous to life and health.

## VA Regulations & Medical Research



**VA PSHCS regulations** pertaining to the use of ionizing radiation-producing machines are found in the FDA Administrative Code.



**Research** involving the use of radioactive materials in or on human subjects must be approved by the Radiation Safety Committee. Submit to MS (S-002-RSO), along with an IRB submission.

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## Notice to Employees & WOCs



Radiation workers are required to comply with VA radiation protection policies and NRC regulations including completing required training, taking measures to avoid unnecessary radiation exposure and to wear dosimeters, where assigned.

VA MML requires that copies of the radiation safety regulations, license inspection reports, and your dosimetry reports are made available for review. You may examine copies of these documents by calling RSO at 6-1789. NRC regulations can also be viewed online.

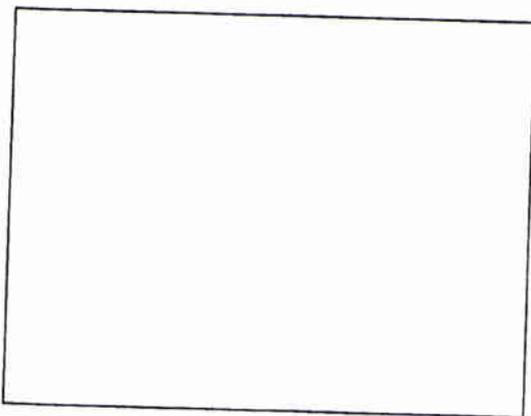
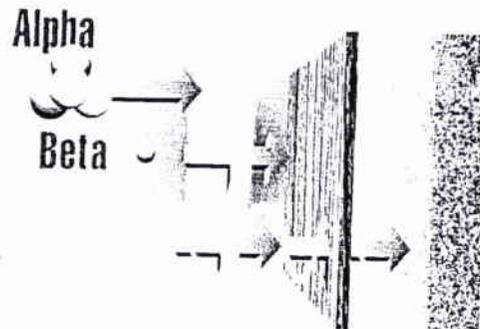
8



## Reporting Concerns or Violations

- If you suspect that a radiation safety violation has occurred, report the violation to your supervisor. If you believe that adequate corrective action has not been taken, notify D. J. Dunn, RSO, at 6-1789.
- If the violation has not been resolved this way, contact the NHPP. You have the right to contact NRC ( see NRC Form 3).
- VA and NRC regulations prohibit academic or job discrimination against individuals who report radiation safety concerns or violations.

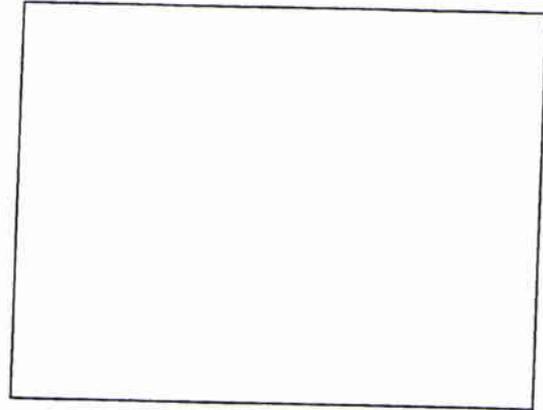
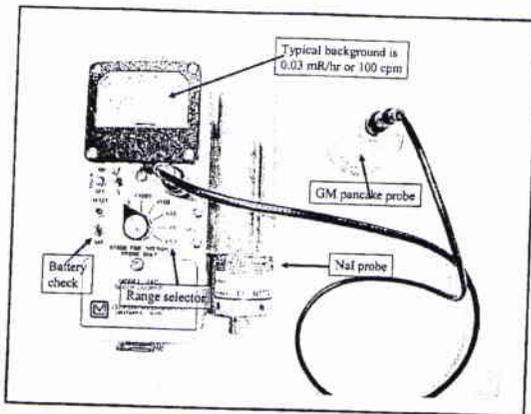
9



CAUTION



RADIOACTIVE  
MATERIAL



### Types of Biological Effects

Ionizing radiation exposure greater than permissible occupational levels may lead to:

#### Somatic Effects -

physical effects that occur in the exposed individual. The effects may be acute (immediate) or delayed.

#### Genetic Effects -

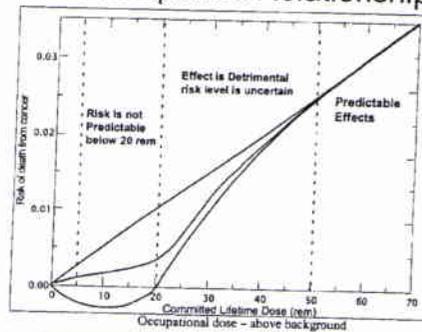
birth defects that occur as a result of irradiation of an individual's reproductive cells prior to conception.

#### Teratogenic Effects -

effects such as cancer or congenital malformation caused by radiation exposure to a fetus in utero.

15

### Dose Response Relationship

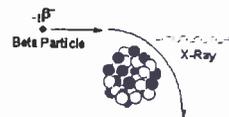


### Beta Emitters

- Beta particles cannot penetrate the body to irradiate internal organs, but the dead outer layer of skin can be penetrated resulting in a dose to basal skin cells.
- Beta particles have a limited range in air that is dependent upon their energy. The more energetic the beta particle, the farther it can travel unshielded in air.
- Some beta emitters used in Radiation Oncology include:
  - P-32
  - Sr90
  - Cs-137

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### Bremsstrahlung Radiation



Bremsstrahlung (or x-ray) radiation results when high energy  $\beta$  particles interact with materials of high density.

- The greatest bremsstrahlung production occurs when high energy beta particles interact with high density materials such as lead.
- However, the conversion yield to x-ray rays is low (1-10%) for beta energies under 10 MeV.

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## Shielding Beta Emitters

- Plastic or acrylic makes the best primary shielding material because the conversion of beta energy to x-radiation will be minimal. Shield high energy beta emitters with low Z materials such as Plexiglas surrounded on the outside with lead.

Ideally, shielding should be made of a thin layer of lead encapsulated in acrylic to attenuate any bremsstrahlung produced.

19

## Penetrating Radiation

X-rays and Gamma Rays are able to penetrate the body and irradiate internal organs.

Exposure can result in basal skin and lens of the eye dose.

20

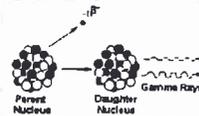
## X-Rays



X-rays are released when an atomic nucleus stabilizes itself by capturing an electron from the electron cloud. The captured electron combines with a proton creating a neutron. The captured electron creates a vacancy in the electron cloud and x-rays are emitted as the electrons rearrange themselves to fill the vacancy.

21

## Gamma Rays



Gamma rays are released when an atomic nucleus releases excess energy after a decay reaction.

Gamma rays have no mass or charge and are able to travel significant distances before their energy is dissipated.

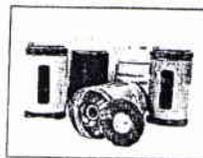
Most alpha and beta emitters also emit gamma rays -- there is no such thing as a "pure" gamma emitter.

22

## Shielding X-Rays and Gamma Rays

Lead shielding will reduce the intensity of gamma rays or x-rays being emitted from a source.

Lead shielding does not automatically reduce exposure by 100%.



Each gamma or x-ray emitter has a specific thickness needed to reduce exposure by some desired %.

Contact RSO at 6-1433 for more information.

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## Sealed Sources

- Use remote handling tools whenever you manipulate Sealed Sources because the intensity of exposure is greatly magnified by direct handling.
- Gamma Sealed Sources are tested by RSO for leakage every six months.
- However, each time a Sealed Source is used, the user should visually inspect it for damage.
- Do not use a source that appears corroded or otherwise damaged. Notify RSO (6-1789) at once.

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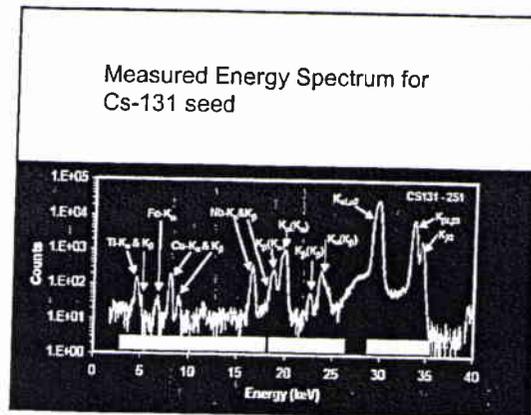
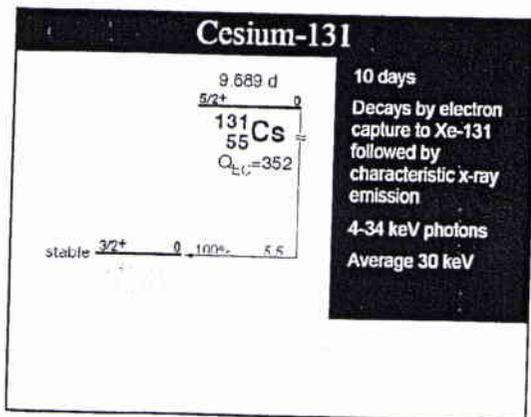
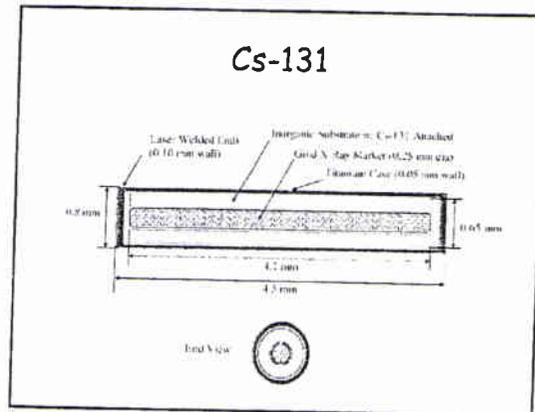
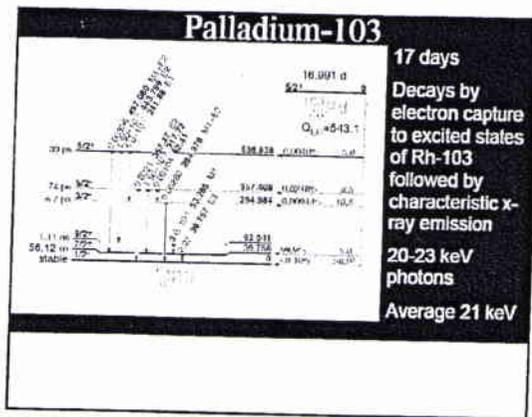
$^{125}_{53}\text{I}$   
 60.14 d  
 EC  
 $\gamma$  0.035  
 E 0.177

### Iodine - 125

#### Principal Radiation Emissions<sup>1)</sup>

Gamma: 0.035 MeV (6.5%)  
 K $\alpha$  X-ray: 0.027 MeV (11.5%)  
 K $\beta$  X-ray: 0.031 MeV (25.4%)

Unshielded Exposure Rate for 1 mCi Point Source at 1 cm: 1.4 R/h<sup>2)</sup>



## Ionizing Radiation

Alpha particles, beta particles, x-rays and gamma rays can cause the removal of electrons from the atoms of the object they interact with. This is called "ionization."

**Ions** (ionized atoms) are more reactive chemically than neutral atoms. They can form compounds that may interfere with cell division and metabolism and cause chemical changes in tissue.

There are two commonly used units used to describe the magnitude of interaction between ionizing radiation and matter - **rads** and **rems**.

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## Radiation Absorbed Dose - RAD

The **RAD** is a radiation unit used to describe the amount of energy transferred from a source of ionizing radiation to any material, including human tissue.

**As a unit of exposure**, 1 rad means that each gram of air at zero Centigrade and 1 atmosphere has absorbed 100 ergs of energy.

**As a unit of dose**, 1 rad means that each gram of exposed tissue has absorbed 100 ergs of energy.

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## Radiation Absorbed Dose

Radiation absorbed dose is sometimes referred to in units of R/hr instead of rad/hr. When measuring x-ray, gamma ray or beta dose either may be used, although rad/hr is preferred.



Use Only  
Calibrated Instruments

### Unit Conversions -

- 1 rad = 1,000 millirad (mrad)
- 1 mrad = 1,000 microrad (μrad)
- 1 gray (SI unit) = 100 rads

Background radiation dose measures ~0.1 mrad/hr using an ion chamber or ~0.05 mrad/hr using a Geiger counter.

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## Radiation Equivalent in Man - REM

Given the same amount of radiation energy transferred, different types of ionizing radiation can produce different degrees of biological effects in human tissue. To account for this, the "rad" is multiplied by a specific quality factor (QF) to determine the dose equivalent (DE) or **REM**.

**Question** - Is the DE for 1 rad of x-ray exposure the same as the DE for 1 rad of fast neutron exposure. The answer is "no" because the quality factor is different for x-rays and neutrons, as illustrated below:

- X-rays, (1 rad) x (1 QF) = 1 rem
- Fast Neutrons, (1 rad) x (10 QF) = 10 rem

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## Radiation Equivalent in Man



Dosimeters record DE  
and are reported in  
mrem or rem

Dose rate plays a role in determining biological harm. For example, a DE of 100 rem received in 1 hour will have a direct biological effect - lowering of the WBC count. In contrast, a dose equivalent of 100 rem received over a working lifetime is not expected to carry with it any adverse health risk.

### Unit Conversions -

- 1 rem = 1,000 millirem (mrem)
- 1 mrem = 1,000 microrem (μrem)
- 1 sievert (SI unit) = 100 rems

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## Curie

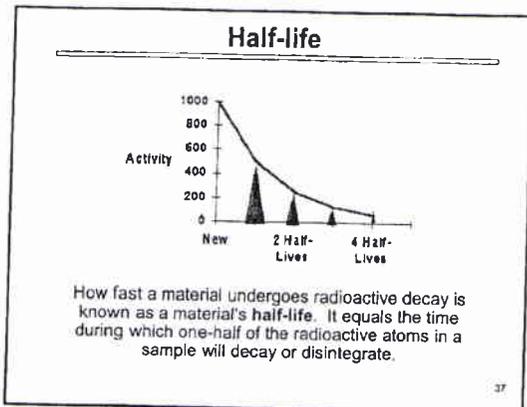


The **Curie** is a unit of activity describing the rate of nuclear decay as a function of time. It is named in honor of Marie Curie who discovered radium in 1898. In 1903, Marie and her husband Peter were awarded the Nobel Prize in Physics for their discovery of natural radioactivity.

A curie is equal to 3.7E10 decays per second (dps) which is the rate of decay for 1 gram of radium-226.

- 1 Becquerel (Bq) = 1 dps
- 1 Curie = 3.7E10 Bq = 3.7E10 dps

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### Maximum Permissible Dose Limits

Federal regulations have established yearly maximum permissible dose limits (MPDs) for radiation workers.

These limits have been created to prevent threshold effects and minimize chance effects. Yearly doses within these limits are not expected to cause adverse health effects even if the maximum is received each year for a total of 50 years.

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### Max. Permissible Exposures Radiation Workers

#### MPDs for Adult Radiation Workers

**Whole Body - Head, Neck Torso, Upper Arms & Legs**  
5,000 mrem/year

**Extremities, Skin and Internal Organs**  
50,000 mrem/year

**Lens of Eye**  
15,000 mrem/year

Minors are not generally permitted to work with sources of ionizing radiation. Contact David Dunn at 6-1789 or david.dunn3@va.gov with questions.

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### MPDs - Prenatal Radiation Exposure

- The maximum permissible dose limit of an embryo/fetus of a declared pregnant radiation worker is 500 mrem (0.5 rem) for the entire gestation period.
- To declare a pregnancy, the worker must submit a signed Pregnancy Declaration form.
- If a pregnant worker chooses not to declare her pregnancy to RSO then the maximum permissible dose limit remains the same as the limit for the adult radiation worker.
- Contact the RSO at 6-1789 or refer to the Radiation Policy and Procedures Manual for more information.

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### Whole Body Dosimeter

**A Luxel™ dosimeter is used to measure an individual's whole body dose equivalent (DE).**

It can detect x- and gamma radiation above 1 mrem and high energy beta radiation above 10 mrem. It cannot detect radiation emitted from low-energy beta emitters.

**A Luxel™ dosimeter is required to be worn by Radiation Oncology personnel.**

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### Ring Dosimeter

**A ring dosimeter is used to measure an individual's extremity dose equivalent.**

It can detect x- and gamma radiation above 30 mrem and high energy beta radiation above 40 mrem.

**A ring dosimeter is required if you routinely work with, prepare, and/or administer sealed source byproduct material.**

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## Dosimeter Adds and Changes

### Dosimeter Requests

Complete a "Dosimeter Add" form to request a dosimeter(s) if you have not previously been issued a dosimeter at the VAMC.

### Dosimeter Changes or Cancellations

If you are a current dosimeter participant complete, a "Dosimeter Change" form to make changes to or cancel your dosimeter(s).

### For Additional Information

For information regarding dosimeter requests, changes or cancellations contact RSO at 6-1789 / 6-1433.

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## Dosimeter Guidelines



Wear your whole body dosimeter on your upper torso in the area likely to receive the highest dose.

Wear your ring dosimeter with your name facing outwards on the hand likely to receive the highest dose.

Wear your ring dosimeter *underneath* your disposable glove.

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## To Avoid Inaccurate Dosimeter Readings

- Internal dosimeter elements should never be removed from the protective plastic dosimeter case.
- If your dosimeter becomes lost or damaged, notify the RSO at 6-1789 / 6-1433.
- Dosimeters should not be exposed to non-occupational radiation exposure such as medical or dental x-rays.
- Store your dosimeter(s) away from sources of ionizing radiation when not in use.

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## Dosimetry Reports

A report is generated showing the amount of DE received for each month your dosimeter was worn.

X-ray or gamma ray DE may be indicated by a "P" in the radiation quality column. DDE indicates whole body dose from penetrating radiation, LDE indicates lens of the eye dose, and SDE indicates skin or hand dose.

A whole body dosimeter exposure of <1 mrem for the month, will be indicated by an "M" for minimum reportable quantity. "M" for ring dosimeters is <30 mrem.

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## Dosimetry Reports

- Each person's monthly dosimeter report is sent to his or her supervisor.
- Contact your supervisor or RSO at 6-1789 for the location of your monthly dosimeter report.
- RSO investigates the cause of any exposure that exceeds a pre-established level as a means of reducing future radiation exposures.
- For more information contact the RSO at 6-1433 or David.Dunn3@VA.gov.

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## Returning Dosimeters

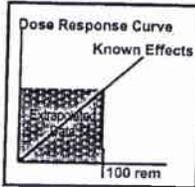
Return your dosimeters to RSO by the 10th of the month.



Dosimeters not returned cost the facility \$15 per dosimeter. A monetary penalty is will be assessed to your department if your dosimeter is lost and/or late 3 times within a 12 month period of time.

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## ALARA



**ALARA**, As Low As Reasonably Achievable, is a regulation requiring that every reasonable effort must be made to maintain radiation exposures as far below the MPDs as practical.

Currently, ALARA is based on the assumption that any exposure to ionizing radiation carries with it some risk. That risk is assumed to be linear. That is, as your exposure increases so does your risk of an adverse health affect due to that exposure.

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## The ALARA Program



A notification and investigational program exists to help keep occupational radiation doses ALARA (as low as reasonably achievable).

Notification and investigation are based on quarterly limits -

- 1,250 mrem for whole body exposure
- 3,750 mrem for the lens of the eye exposure, and
- 12,500 mrem for the skin whole body & extremity exposure

If any of these limits are exceeded by more than 10%, RSO will notify the individual and their supervisor. Corrective actions may be initiated to help reduce future exposures.

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## Radiation Safety Guidelines

### TIME

- ALARA can be implemented by limiting your time near sources of ionizing radiation.
- Radiation dose is directly proportional to the time an individual is exposed to a source of radiation.
- Minimize time whenever possible.



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## Radiation Safety Guidelines

### Distance

- **Point Source Exposure**  
Doubling your distance from a point source (such as a source vial) reduces your exposure by a factor of 4.
- **Patient Exposure**  
Doubling your distance from a therapy patient reduce your exposure by a factor of 2. Additionally, remain as far from the patient as possible during imaging.
- Use remote handling tools when required.

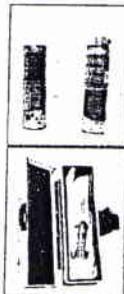


52

## Radiation Safety Guidelines

### Shielding

- Use lead shields, plastic/lucite shields, L-blocks, leaded glass, and/or lead-lined carriers to reduce radiation exposure.
- Each radionuclide has its own half-value layer (HVL). The HVL is dependent upon the density of the shielding material and the energy of the radiation. Using seven HVLs will reduce the incident exposure rate by about 100%.



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## Patient Release Criteria

Any patient administered a diagnostic or therapeutic radiopharmaceutical may be released if the total effective dose equivalent (TEDE) to any other person due to contact with the patient is not likely to exceed 500 mrem.



The released patient must be provided with written instructions on keeping exposure to others ALARA if the TEDE to any person coming into contact with the patient (including a breast-feeding child) is likely to exceed 100 mrem.

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## Patient Release Criteria

### Current Release Criteria

The patient exposure rate below which release is acceptable is different for each radionuclide.



Patients administered radiopharmaceuticals can be released if it can be calculated or demonstrated that no individual will receive more than 500 mrem as a result of exposure to the patient.

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## Patient Release Criteria

### Release Can Be Based on ANY of the Following



Activity administered

Actual measured exposure rate

Specific dose calculations



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## Written Instructions

Written Instructions must be given to the patient if the administered activity exceeds:

$$D(\infty) = \frac{34.6 \text{ l} \cdot Q_0 \cdot T_p (0.25)}{(100 \text{ cm})^2}$$



These are the administered activities that could result in an individual receiving a dose in excess of 100 mrem from exposure to a patient administered a radiopharmaceutical.

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## Records of Patient Release



Records are required if patient release is based on:

- A dose calculation that considered retained fraction
- Use of an occupancy factor <0.25
- Effective half-life
- Measured exposure rate at 1 meter from patient

$$< = 5.96 \text{ mR/hr}$$

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## Records of Patient Release

- Records for all releases must be recorded and retained.
- Records must include:
  - A patient identifier
  - The activity of the radionuclide administered
  - The identity of the radionuclide administered
  - All pertinent information concerning the basis for patient release

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## PATIENT RELEASE

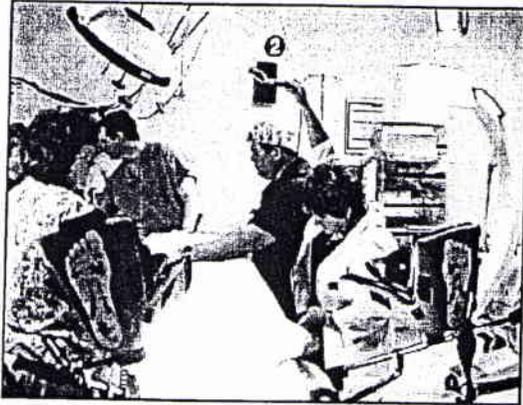
5 mrem/hr rule

NEW Rules 10 CFR35.75

< 500 mrem (lifetime) from release

> 100 mrem (lifetime) from release -  
provide written instructions

Ref: NRC Reguide 1556 Vol 9, Appdx U



For patients who have received implants, additional instructions may include the following:

A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/2 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for \_\_\_\_\_ days:

- Stay at a distance of \_\_\_\_\_ feet from \_\_\_\_\_
- Maintain separate sleeping arrangements.
- Minimize time with children and pregnant women.
- Do not hold or cuddle children.
- Avoid public transportation.
- Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.
- If you find a seed or pellet that falls out:
  - Do not handle it with your fingers. Use something like a spoon or tweezers to place it in a jar or other container that you can close with a lid.
  - Place the container with the seed or pellet in a location away from people.
  - Notify \_\_\_\_\_ or telephone number \_\_\_\_\_.

### Patient Isolation Precautions

**Notify RSO at least 1-2 hours prior to patient admission**

If a patient must be admitted for radiation safety isolation precautions.

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### Patient Isolation Precautions

- **Loss of Body Fluid.** Notify RSO if there is a loss of patient's body fluid such as a leaking catheter, blood, or vomit.
- **Laboratory procedures** should be performed as ordered. Label all specimens taken as "radioactive". The specimens should be returned to RSO for disposal.
- **Pregnant staff** should not attend patients.
- **Visitors** are not generally permitted to visit brachytherapy inpatients. Minors and pregnant visitors are not generally permitted to visit patients admitted for radiation safety precautions.

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### Medical Emergencies

- Notify medical staff providing patient care that the patient has been administered radioactive source material.
- **Begin emergency and lifesaving procedures immediately without regard for possible radiation exposure or contamination.**
- Notify RSO as soon as possible.
- Hold all dressings, linens, trash, and items used to treat or transport the patient. RSO must survey them prior to their being disposed of or returned to service.

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### Patient Death

- **Notify RSO immediately.**
- Notify the morgue that a body containing radiopharmaceutical is being sent to them.
- All post-mortem procedures should be approved by RSO prior to being performed.
- Hold all items associated with transport and post-mortem procedures. RSO must survey prior to release of the body and associated equipment.

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## Contact RSO About Radiation Safety Issues



**RSO Pager : 206-699-2179**  
Monday-Friday from 8 a.m. until 5 p.m.

**RSO Main Office : 277-1789**  
You should contact RSO directly (360-908-4145) if your pager is not answered within 10 minutes.

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## For More Information

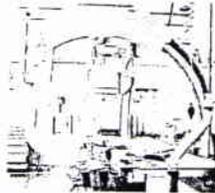
Additional radiation safety information is available at RSO Office: Bldg 1 Rm 316.

- Instruction Concerning Prenatal Radiation Exposure.
- Instruction Concerning Risks from Occupational Radiation Exposure
- NRC Form 3 Notice to Employees
- Instrument Calibration
- Pregnancy Declaration Program
- Radiation Exposure to Minors

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## Sources of Medical Radiation

- Each year about one-third of all individuals hospitalized undergo medical procedures that use radiation.
- The average radiation dose from man-made medical sources of radiation is about 53 mrem per year.
- A large percentage (75-80%) of present day biomedical research would not be possible without the use of radioactive materials.



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## Types of Biological Effects

### Threshold Effects

Certain biological effects are caused when a radiation dose greater than some threshold value is received. Below the threshold value no radiation effect is seen. Acute Radiation Syndrome and radiation-induced cataract formation are examples of threshold effects.

### Non-threshold Effects

Some radiation-induced biological effects are not thought to have a threshold. Instead, the chance of occurrence of the effect rather than the severity of the effect is assumed to be proportional to the dose received. Cancer and genetic effects are examples of chance effects.

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## Threshold Effects

Chernobyl  
Reactor #4



**Acute Radiation Syndrome** is a whole body effect with a threshold of 100,000 mrem. It occurs when the whole body receives a very large dose in a very short amount of time.

### Other thresholds -

Cataracts - 200,000 mrem (acute)  
Cataracts - 800,000 mrem (chronic)  
Severe skin injury - 1,500,000 mrem  
Teratogenic effects - 20,000 mrem

As a radiation worker your maximum allowable whole body occupational radiation exposure is 5,000 mrem per year and, therefore, acute radiation syndrome is not a possibility.

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## Non-Threshold Effects



**Cancer Risk** is estimated to be about 5 deaths per 10,000 persons each who received 1,000 mrem. However, research studies have not conclusively shown an increase in the cancer rate of populations receiving doses <10,000 mrem slowly, over long periods of time.

**Genetic Effects** are not considered a likely result of occupational radiation exposure. This is based on the observation that an increase in birth defects was not seen in 77,000 children born between 1948-1962 to Hiroshima and Nagasaki bomb survivors. Additionally, an increase in the number of inherited birth defects has not been found in populations living in high background radiation areas.

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# VA PSHCS Radiation Oncology Training Exam

Please select the best answer.

- |                                  |                                  |  |   |
|----------------------------------|----------------------------------|--|---|
| <input checked="" type="radio"/> | F                                |  | 1. Annual radiation safety training is required if you receive or are likely to receive a whole body yearly dose of more than 100 mrem.   |
| <input checked="" type="radio"/> | F                                |  | 2. NRC regulations prohibit job discrimination against individuals who report radiation safety concerns or violations.  |
| <input checked="" type="radio"/> | F                                |  | 3. Dosimeters record your radiation dose equivalent and are reported in units of rads or millirads.   |
| <input checked="" type="radio"/> | F                                |  | 4. The RSO automatically lowers the maximum permissible exposure to the embryo/fetus of any pregnant radiation worker from 5,000 mrem per year to 500 mrem for the entire pregnancy.                              |
| T                                | <input checked="" type="radio"/> |  | 5. Radiation safety training for Radiation Oncology Personnel is required only upon hiring and at no other time.  |
| T                                | <input checked="" type="radio"/> |  | 6. Radiation workers may comply with VAMC radiation protection policies and NRC regulations only if they wish to do so.   |
| <input checked="" type="radio"/> | F                                |  | 7. 1 curie is equal to 1 disintegration per second which is equal to 1 becquerel.   |
| <input checked="" type="radio"/> | F                                |  | 8. Radiation safety use and enforcement policies are set by the VA PSHCS's Radiation Safety Committee   |
| <input checked="" type="radio"/> | F                                |  | 9. ALARA is a <i>regulation</i> that requires that every reasonable effort be made to keep radiation exposures as far below the MPDs as is practical.   |
| T                                | <input checked="" type="radio"/> |  | 10. Beta-emitting radioactive materials can produce x-rays if shielded only with high density materials such as lead.   |
| <input checked="" type="radio"/> | F                                |  | 11. Doubling your distance from a radio-therapy implant patient reduces your exposure by a factor of 4.   |
| T                                | <input checked="" type="radio"/> |  | 12. Any radiopharmaceutical therapy patient can be released from radiation safety restrictions if the total effective dose to any other person due to contact with the patient is not likely to exceed 1000 mrem. |
| T                                | <input checked="" type="radio"/> |  | 13. If you suspect that a radiation safety violation has occurred, you should report the violation directly to the NRC.   |
| <input checked="" type="radio"/> | F                                |  | 14. Permanent Implant patients can be released when their exposure rate at 1 meter is less than 5 mrem/hour.  |
| <input checked="" type="radio"/> | F                                |  | 15. It is recommended that pregnant staff should not provide care for inpatient implant patients.   |
| <input checked="" type="radio"/> | F                                |  | 16. Written radiation safety instructions must be given to a permanent implant patient if the dose rate at 1 meters exceeds 2 mrem/hour.  |
| <input checked="" type="radio"/> | F                                |  | 17. You should contact The RSO directly at 6-1789 if your page is not answered within 10 minutes.   |
| <input checked="" type="radio"/> | F                                |  | 18. If a patient administered an radiotherapeutic implant has a medical emergency while at VA Puget Sound Health Care System, The RSO should be notified as soon as possible.                                     |
|                                  |                                  |  | 19. 100 rads equals:<br>A. 10 gray B. 100 gray C. 10 rems <input checked="" type="radio"/> D. 1 gray  |
|                                  |                                  |  | 20. Using seven HVLs will reduce the incident exposure rate by:<br><input checked="" type="radio"/> A. ~99% B. ~50% C. ~10% D. None of the above.   |

Name  
Job Title

W Bowen

Department  
VA PSHCS Radiation  
Oncology

# VA PSHCS Radiation Oncology Training Exam

Please select the best answer.

- T F 1. Annual radiation safety training is required if you receive or are likely to receive a whole body yearly dose of more than 100 mrem.
- T F 2. NRC regulations prohibit job discrimination against individuals who report radiation safety concerns or violations.
- T F 3. Dosimeters record your radiation dose equivalent and are reported in units of rads or millirads.
- T F 4. The RSO automatically lowers the maximum permissible exposure to the embryo/fetus of any pregnant radiation worker from 5,000 mrem per year to 500 mrem for the entire pregnancy.
- T F 5. Radiation safety training for Radiation Oncology Personnel is required only upon hiring and at no other time.
- T F 6. Radiation workers may comply with VAMC radiation protection policies and NRC regulations only if they wish to do so.
- T F 7. 1 curie is equal to 1 disintegration per second which is equal to 1 becquerel.
- T F 8. Radiation safety use and enforcement policies are set by the VA PSHCS's Radiation Safety Committee
- T F 9. ALARA is a *regulation* that requires that every reasonable effort be made to keep radiation exposures as far below the MPDs as is practical.
- T F 10. Beta-emitting radioactive materials can produce x-rays if shielded only with high density materials such as lead.
- T F 11. Doubling your distance from a radio-therapy implant patient reduces your exposure by a factor of 4.
- T F 12. Any radiopharmaceutical therapy patient can be released from radiation safety restrictions if the total effective dose to any other person due to contact with the patient is not likely to exceed 1000 mrem.
- T F 13. If you suspect that a radiation safety violation has occurred, you should report the violation directly to the NRC.
- T F 14. Permanent Implant patients can be released when their exposure rate at 1 meter is less than 5 mrem/hour.
- T F 15. It is recommended that pregnant staff should not provide care for inpatient implant patients.
- T F 16. Written radiation safety instructions must be given to a permanent implant patient if the dose rate at 1 meters exceeds 2 mrem/hour.
- T F 17. You should contact The RSO directly at 6-1789 if your page is not answered within 10 minutes.
- T F 18. If a patient administered an radiotherapeutic implant has a medical emergency while at VA Puget Sound Health Care System, The RSO should be notified as soon as possible.
19. 100 rads equals:  
A. 10 gray B. 100 gray C. 10 rems D. 1 gray
20. Using seven HVLs will reduce the incident exposure rate by:  $(\frac{1}{2})^7 = \frac{1}{128}$   
A. ~99% B. ~50% C. ~10% D. None of the above.

Name

Steve Suttel

Job Title

Medical Physicist

Department

VA PSHCS Radiation  
Oncology

# VA PSHCS Radiation Oncology Training Exam

Please select the best answer.

1. Annual radiation safety training is required if you receive or are likely to receive a whole body yearly dose of more than 100 mrem. (T) F
2. NRC regulations prohibit job discrimination against individuals who report radiation safety concerns or violations. (T) F
3. Dosimeters record your radiation dose equivalent and are reported in units of rads or millirads. T (B)
4. The RSO automatically lowers the maximum permissible exposure to the embryo/fetus of any pregnant radiation worker from 5,000 mrem per year to 500 mrem for the entire pregnancy. (B) F
5. Radiation safety training for Radiation Oncology Personnel is required only upon hiring and at no other time. T (F)
6. Radiation workers may comply with VAMC radiation protection policies and NRC regulations only if they wish to do so. T (F)
7. 1 curie is equal to 1 disintegration per second which is equal to 1 becquerel.  $3.7 \times 10^{10}$  T (F)
8. Radiation safety use and enforcement policies are set by the VA PSHCS's Radiation Safety Committee. (T) F
9. ALARA is a *regulation* that requires that every reasonable effort be made to keep radiation exposures as far below the MPDs as is practical. T (F)
10. Beta-emitting radioactive materials can produce x-rays if shielded only with high density materials such as lead. T (B)
11. Doubling your distance from a radio-therapy implant patient reduces your exposure by a factor of 4. (T) F
12. Any radiopharmaceutical therapy patient can be released from radiation safety restrictions if the total effective dose to any other person due to contact with the patient is not likely to exceed 1000 mrem. T (F)
13. If you suspect that a radiation safety violation has occurred, you should report the violation directly to the NRC. T (B)
14. Permanent Implant patients can be released when their exposure rate at 1 meter is less than 5 mrem/hour. (B) (F)
15. It is recommended that pregnant staff should not provide care for inpatient implant patients. (T) F
16. Written radiation safety instructions must be given to a permanent implant patient if the dose rate at 1 meters exceeds 2 mrem/hour. (T) F
17. You should contact The RSO directly at 6-1789 if your page is not answered within 10 minutes. (B) F
18. If a patient administered an radiotherapeutic implant has a medical emergency while at VA Puget Sound Health Care System, The RSO should be notified as soon as possible. (T) F
19. 100 rads equals:
  - A. 10 gray
  - B. 100 gray
  - C. 10 rems
  - (D) 1 gray
20. Using seven HVLs will reduce the incident exposure rate by:
  - A. ~99%
  - B. ~50%
  - (C) ~10%
  - None of the above.

Name  
Job Title

Janyce Short  
Radiation Therapist

Department  
VA PSHCS Radiation  
Oncology

# VA PSHCS Radiation Oncology Training Exam

Please select the best answer.

- T  F 1. Annual radiation safety training is required if you receive or are likely to receive a whole body yearly dose of more than 100 mrem.
- T  F 2. NRC regulations prohibit job discrimination against individuals who report radiation safety concerns or violations.
- T  F 3. Dosimeters record your radiation dose equivalent and are reported in units of rads or millirads.
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- T  F 6. Radiation workers may comply with VAMC radiation protection policies and NRC regulations only if they wish to do so.
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- T  F 8. Radiation safety use and enforcement policies are set by the VA PSHCS's Radiation Safety Committee
- T  F 9. ALARA is a *regulation* that requires that every reasonable effort be made to keep radiation exposures as far below the MPDs as is practical.
- T  F 10. Beta-emitting radioactive materials can produce x-rays if shielded only with high density materials such as lead.
- T  F 11. Doubling your distance from a radio-therapy implant patient reduces your exposure by a factor of 4.
- T  F 12. Any radiopharmaceutical therapy patient can be released from radiation safety restrictions if the total effective dose to any other person due to contact with the patient is not likely to exceed 1000 mrem.
- T  F 13. If you suspect that a radiation safety violation has occurred, you should report the violation directly to the NRC.
- T  F 14. Permanent Implant patients can be released when their exposure rate at 1 meter is less than 5 mrem/hour.
- T  F 15. It is recommended that pregnant staff should not provide care for inpatient implant patients.
- T  F 16. Written radiation safety instructions must be given to a permanent implant patient if the dose rate at 1 meters exceeds 2 mrem/hour.
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19. 100 rads equals:  
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20. Using seven HVLs will reduce the incident exposure rate by:  
A. ~99% B. ~50% C. ~10% D. None of the above.

Name  
Job Title

Robert Weaver PSA

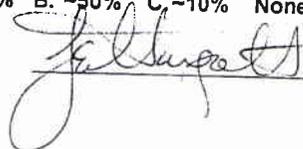
Department  
VA PSHCS Radiation  
Oncology

# VA PSHCS Radiation Oncology Training Exam

Please select the best answer.

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7. 1 curie is equal to 1 disintegration per second which is equal to 1 becquerel. T (E)
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9. ALARA is a *regulation* that requires that every reasonable effort be made to keep radiation exposures as far below the MPDs as is practical. (T) F
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11. Doubling your distance from a radio-therapy implant patient reduces your exposure by a factor of 4. (F)
12. Any radiopharmaceutical therapy patient can be released from radiation safety restrictions if the total effective dose to any other person due to contact with the patient is not likely to exceed 1000 mrem. (T) F
13. If you suspect that a radiation safety violation has occurred, you should report the violation directly to the NRC. T (F)
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Name  
Job Title



Department  
VA PSHCS Radiation  
Oncology

# VA PSHCS Radiation Oncology Training Exam

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Name  
Job Title

Sheld Pinto  
RADIATION THERAPIST

Department  
VA PSHCS Radiation  
Oncology

# VA PSHCS Radiation Oncology Training Exam

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Name  
Job Title

Carl Bergsagel  
Medical Physicist

Department  
VA PSHCS Radiation  
Oncology

# VA PSHCS Radiation Oncology Training Exam

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A. ~99%  B. ~50% C. ~10% D. None of the above.

Name  
Job Title

WALKER  
RT/I

Department  
VA PSHCS Radiation  
Oncology

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VHA National Health Physics Pr  
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NORTH LITTLE ROCK, AR 72114



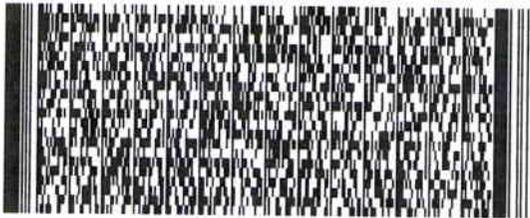
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