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 01 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 Boston Healthcare System, Boston, Massachusetts.

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 02 2010

NRC Request for Information (February 16, 2010)
VA Boston Healthcare System, Boston, Massachusetts

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.

02-25-10A11:09 RCVD

Drum, David

From: Williams, Gary E
Sent: Wednesday, February 17, 2010 3:43 PM
To: Drum, David
Cc: Leidholdt, Ed; Huston, Thomas E.; Offutt, Lisa M
Subject: additional information for NRC inspection
Attachments: NRC RFI Boston.doc

NRC requested additional information related to their on-site inspection at Boston for the prostate seed implant program.

I am attaching the specific questions for which NRC has requested a response be received from NHPP by February 24, 2010.

Please review the questions and provide to NHPP an e-mail or facsimile response with the best possible response for the requested information or documents as soon as possible.

Some of the questions might not be applicable based on the current or past status for your prostate seed implant program.

If so, you should indicate which information or documents are not applicable.

As an example, training records might not be applicable for calendar year 2009, if your program was inactive during that calendar year.

If you have any questions, please contact Ed Leidholdt.

Gary E. Williams
National Health Physics Program
Veterans Health Administration
North Little Rock, Arkansas
W 501-257-1572; C 501-256-5331

NRC Request for Information (February 16, 2010)
VA Boston Healthcare System, Boston, Massachusetts

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.

Drum, David

From: Naughton, John P VHABHS
Sent: Tuesday, February 23, 2010 5:47 AM
To: Drum, David
Cc: Williams, Tenita
Subject: RE: seed therapy training

Dr. Drum,

I did not mail the training package. I sent all my materials to you for review prior to shipment.

John

From: Drum, David
Sent: Monday, February 22, 2010 12:45 PM
To: Williams, Tenita
Cc: Naughton, John P VHABHS
Subject: seed therapy training

Tenita, thanks for your always cheerful help.
For tomorrow's fast FedX envelope,

Return address: David E. Drum, MD
Nuclear Medicine 115
VA Boston Healthcare System
1400 VFW Parkway
West Roxbury, MA 02132

Main addressee: Edwin M. Leidholdt, Jr. PhD
Program Manager, SW Services area
VHA National Health Physics Program
2200 Fort Roots Drive, Bldg 108, Room 206
North Little Rock, AR 72114

If we find that John mailed the package, I'll save these labels for another time.

Thanks, DED

CMS Interplant TPC is used for our Prostate Seed Implant Program. The treatment planning system is used to compute dose and dose distributions and is derived from a FDA approved software package. Since this software is FDA approved, it has already been through comprehensive testing and quality assurance from the manufacturer as well as the federal government. During acceptance testing and software upgrades, Physics will evaluate the following CMS TPC criterion prior to its use:

1. Source-specific input parameters
2. Accuracy of point dose at distance
3. Spatial accuracy of the graphics dose display
4. Accuracy of treatment planning tools

For software upgrades, a set of reference data will be established and a comparison will be made of subsequent software versions. Comparisons will agree with the reference data by ±2%.

Pre NRC Site Visit (Submitted to RSC)

E. <u>Brachytherapy Program QMP.</u>

The Brachytherapy Program at the Boston VAMC consists of permanent I-125 interstitial brachytherapy of the prostate and temporary I-125 eye plaque brachytherapy. Prostate brachytherapy permanently implants I-125 seeds according to an isodose plan to the prostate. Eye plaque brachytherapy is a temporary implant where the eye plaque is fixed to the eye for a planned duration of time. The Brachytherapy QMP will address the fore mentioned procedures separately and apply policies and procedures that promote safe and accurate brachytherapy practices. The Brachytherapy QMP will employ practices suggested in AAPM TG-40, TG-56 and other regulatory agencies.

1. Prostate Seed Implant Brachytherapy Procedures

The following policy and procedures are implemented for performing prostate brachytherapy at the Boston VAMC.

a. CT Prostate Volume and Pubic Arch Study

After the patient's initial consultation, the physician will order a CT to determine if the patient is a prostate implant candidate. The CT is imported into the Philips Pinnacle3 TPC and the physician will contour the prostate. Once the prostate is contoured, Pinnacle3 will calculate the prostate volume. An implant candidate will have a prostate volume between 20 and 60 cm^3. For the pubic arch study, Physics will set up a PIO (Posterior Inferior Oblique) beams eye view which

written directive will be maintained by the Radiation Therapy Service for a period of at least three years as per 10CFR35.2040.

Each patient's written directive will be reviewed and signed by the Radiation Oncology Physicist and the RSO. A signed peer review of the implant will be made by a Radiation Oncologist after the post implant dose analysis is complete during department chart rounds.

d. Ordering Sources

I-125 seeds are ordered on a specific implant patient basis. The quantity of seeds ordered is calculated based on the patient's prostate volume study and the prescription dose. When the seed order is place with the vender, one additional calibrated seed will be ordered for every I-125 prostate seed implant. The number of seeds required for each implant will be calculated by the Radiation Therapy Physicist and confirmed by the Dosimetrist and Physician. A "Prostate Seed Order Request Form" will be completed by Physics and submitted to the Chief Therapist for ordering. The "Prostate Seed Order Request Form" will contain the following:

1. Patient's Name.
2. Patient's ID.
3. Number of Seeds Needed Plus Calibrated Seed.
4. Isotope and Model.
5. Implant Date.
6. Desired Activity on Implant Date.
7. Activity Ordered and Reference Date.
8. Requested Delivery Date.
9. Physician, Physicist, and Dosimetrist Signatures.

The seed order calculation and the "Prostate Seed Order Request Form" will be maintained in the patient's chart.

e. Receiving and Securing Sources

I-125 seed shipments are delivered directly to the Radiation Therapy Department at the Boston VAMC by FedEx. Upon receipt, the Radiation Therapy Physicist or trained designee is contacted to pick-up the radioactive material package. Once an I-125 seed shipment is received, the package(s) will be moved to a secure radioactive materials storage area, DB-102. This storage area will posted with a "CAUTION: RADIOATIVE MATERIALS" sign and emergency contact numbers.

Within 3 hours of receipt, the package(s) must be surveyed to determine that there is no contamination or damage during shipping. Exposure readings at one meter from the package(s), at the package surface and at the source container(s) will be measured and recorded. A wipe test of the package(s) and source

with a NaI probe to detect surface contamination.

If a leaking seed is detected before, during or after the implant procedure, referred to the "Emergency Plan For Leaking I-125 Barchytherapy Seed Source." If the leaking seed is not detect in the OR follow the emergency plan in similar manner. The emergency plan is maintain in the Radiation Therapy Service

h. Pre-Implant Preparations

The RSO or Physicist will transport the I-125 seeds to the operating room in shielded containers. At all times the I-125 seeds shall be under constant surveillance and control of the RSO or Radiation Therapy Physicist.

In the sterilization area, the seeds are place in a shielded sterilization cup with cover and an autoclave bio-test package (Attest) is prepared. Prior to sterilization, the area is assayed with a survey meter to verify that there are no stray seeds. The seeds and test package are then sterilized. Note: The test package requires one hour after sterilization before it can be read.

All other implant equipment will be inspected for proper operation before the patient is put under anesthesia.

Prior to and during the implant the RSO and Radiation Oncology Physicist shall be present in the OR to assure that proper radiation safety procedures are followed.

No special precautions are required by the OR personnel while they are working under the supervision of the RSO.

i. Time Out

Once the patient enters the OR suite and prior to any activity a "Time Out" will be initiated. The "Time Out" will verify the identity of the patient using two forms of identification (full name, full social security number and/or date of birth). The procedure site and procedure that the patient is present for will also be identified by the patient. The AU Physician and procedural team will verify that the information provided is consistent with the informed consent.

j. Treatment Planning

After general anesthesia is administered and the patient is positioned properly on the OR couch, the Ultrasonographer utilizes the Transrectal US (TRUS) probe and the US measuring tool to determine a reference prostate volume. The TRUS probe is then fixed to the probe stepper and positioned to acquire prostate US images. The Radiation Oncologist and the Ultrasonographer collaborate to

The administration of the prostate seed implant shall be in accordance with the written directive. Prior to administration of the treatment plan, the Radiation Oncologist must verify that all the details specified in the written directive and in the treatment plan are in agreement. During seed implantation, the Radiation Oncologist will utilize fluoroscopic imaging to view seed deployment and to verify that seeds are not inadvertently place away from the intended target. At the conclusion of the seed implant, the Radiation Oncologist will verify the graphical isodose distribution delivered to the prostate and DVHs for the prostate, urethra and rectum. At the conclusion of the implant, the written directive will be completed as specified in 10CFR35.40. Any unintended deviation from the written directive shall be identified and the appropriate action taken. Any intended deviation will be documented in the written directive with the signature of the Radiation Oncologist.

m. Post Implant Procedures

After the implant is completed, an anterior-to-posterior (AP) Fluoro image of the implanted seeds must be obtained to verify and account for the number of seeds implanted into the patient. The AP Fluoro image is printed and maintained in the patient's chart.

The OR must be surveyed by the RSO or Radiation Oncology Physicist to ensure that there are no stray radioactive sources. Floors, tables, linens, waste materials, applicators, US probe, and all needles must be surveyed for misplaced sources. The survey must include a survey of the feet of all personnel associated with the implant prior to leaving the OR. This area survey reading is recorded in the patient's chart and maintained by the Radiation Therapy Service. In addition, the sum of the seeds implanted and not implanted must agree with the total number of seeds brought to the OR.

Finally, the seeds are returned to the radioactive materials storage area DB-102 and logged into the "I-125 Receipt, Removal and Storage Log". The "I-125 Receipt, Removal and Storage Log" will fulfill the requirements of 10CFR35.2406.

If a leaking seed is detect before, during or after the implant procedure, referred to the "Emergency Plan For Leaking I-125 Barchytherapy Seed Source." This emergency plan is maintained in the Radiation Therapy Service.

n. I-125 Seed Decay-In-Storage

All I-125 seeds not used during the prostate implant procedure will be decayed in storage as detailed in 10CFR35.92. At the end of each calendar year, all the seeds not used in the prostate seed implant procedures will be stored collectively and assigned a Batch #. The Batch # represents the calendar year the seeds

during the patient recovery period after the implant. It will also give instructions on the proper handling and management on the patient's recovery area.

The Post Implant Patient Instructions and Nursing Instructions will be maintained by the Radiation Therapy Service and reviewed annually by the RSO.

q. Documentation

The administered plan and all images (US and radiographic) will be printed and kept in the patient's chart and maintained by the Radiation Therapy Service. All documents will be reviewed and signed by the Physicist and Radiation Oncologist. A peer review by an intradepartmental Radiation Oncologist will be made during department chart rounds after the post implant evaluation is complete. The reviewing Radiation Oncologist will sign the written directive to signify a satisfactory implant.

r. Post Implant Evaluation

Within 4 to 6 weeks following the seed implant, every patient will be scheduled to receive a post-operative CT scan of the prostate. The post implant CT is used to evaluate the actual dose distribution to the prostate and critical structures and identify deviations from the originally planned implant. The post implant analysis also provides an opportunity for improving techniques, evaluating outcomes and identifying patients who might benefit from supplemental therapy.

The 3mm CT images of the prostate will be acquired and imported to the TPC. Using the images, the Physicist will generate a 3D dose distribution and DVHs to the prostate and critical structure. The Radiation Oncologist and Physicist will evaluate the following:

1) The dose received by 90% of the prostate volume (D90),
2) The percentage of the prostate volume receiving 100% of the prescribed dose (V100),
3) The volume of rectum in cm^3 receiving 100% or more of the prescribed dose (R100).
4) Seeds implanted outside the treatment volume.

The dosimetric evaluation of the implant will be as follows:

1) A D90 that is equal to or greater than the prescribed dose is considered a "good" implant.
2) A $V100_{prostate}$ of 75% is considered a "good" implant.
3) A R100 $\leq$ 1.3 cm^3 of rectal volume is adequate rectal dosimetry.

addition, at least five cases each year will receive an external physician peer review as required by the VHA Handbook.

At least annually, the Prostate Implant QMP will be reviewed by the Physicist of the Radiation Therapy Service. The review will determine the effectiveness of the QMP and make necessary modifications. The review will also include an audit of all prostate seed implant cases performed in the previous year and presented to the Chief Radiation Oncologist for evaluation.

Reviewed / Modified 2/28/09

Post NHPP Inspection Aug 2009

E. Brachytherapy Program QMP.

The Brachytherapy Program at the Boston VAMC consists of permanent I-125 interstitial brachytherapy of the prostate and temporary I-125 eye plaque brachytherapy. Prostate brachytherapy permanently implants I-125 seeds according to an isodose plan to the prostate. Eye plaque brachytherapy is a temporary implant where the eye plaque is fixed to the eye for a planned duration of time. The Brachytherapy QMP will address the fore mentioned procedures separately and apply policies and procedures that promote safe and accurate brachytherapy practices. The Brachytherapy QMP will employ practices suggested in AAPM TG-40, TG-56 and other regulatory agencies.

1. Prostate Seed Implant Brachytherapy Policy and Procedures

The following policy and procedures are implemented for performing prostate brachytherapy at the Boston VAMC.

a. CT Prostate Volume and Pubic Arch Study

After the patient's initial consultation, the physician will order a CT to determine if the patient is a prostate implant candidate. The CT is imported into the Philips Pinnacle3 TPC and the physician will contour the prostate. Once the prostate is contoured, Pinnacle3 will calculate the prostate volume. An implant candidate will have a prostate volume between 20 and 60 cm^3. For the pubic arch study, Physics will set up a PIO (Posterior Inferior Oblique) beams eye view which mimics the implant set up. With the contour 3-D view on, the physician will be able to determine whether there is pubic arch interference. Both criteria must be met in order to produce an implant candidate. If the patient's anatomy exceeds the limits of the implant criteria but not excessively, the physician and physicist will discuss the limitations of the case and determine if the patient is a prostate implant candidate. If it is decided that the patient is an implant candidate and the patient consents to the procedure, an implant will be schedule within a couple of months of the consult or at the discretion of patient.

The prostate volume and pubic arch study will be printed and maintained in the patient's chart. A record of the prostate volume will be maintained in the Brachytherapy QMP by Physics

b. Treatment Prescription

Two prescriptions are available for prostate implant brachytherapy: 1) 108Gy prescription is assigned to patients that have had 45Gy external beam radiation therapy to be followed by a prostate implant brachytherapy boost; and 2) 145Gy prescription is assigned to prostate implant brachytherapy when it is the sole course of treatment. The intent of the prescription is to cover the entire prostate and a margin of a few millimeters with the prescribed dose while limiting the dose to critical structures.

c. Written Directive

When an implant candidate is selected, the physician will discuss with Physics the treatment plan and prescription dose. The written directive for a specific brachytherapy patient must include:

1. Pre-Implant Written Directive: Treatment site, radionuclide, prescription dose, number of sources, total apparent activity, physician signature, and date. (The pre-implant written directive must be approved and signed before implantation of the first seed.)
2. Post-Implant Written Directive: Radionuclide, treatment site, activity per seed, prescription dose, number of sources, total source strength, physician signature, and date, and the word "permanent".

The "Pre-Implant Written Directive" will be completed prior to the implantation of the first seed. Oral revisions of the written directive are acceptable during the implant procedure because of the sterile restraints of the procedure and the patient's health considerations.

The "Post Implant Written Directive" section of the written directive will be completed in the OR when possible or within 24 hours of the procedure. The post implant written directive will be approved the Radiation Oncologist and verified by the physicians' signature and date after the implant. A patient's written directive will be maintained by the Radiation Therapy Service for a period of at least three years as per 10CFR35.2040.

Each patient's written directive will be reviewed and signed by the Radiation Oncology Physicist and the RSO. A signed peer review of the implant will be made by a Radiation Oncologist after the post implant dose analysis is complete during department chart rounds.

d. Ordering Sources

I-125 seeds are ordered on a specific implant patient basis. The quantity of seeds ordered is calculated based on the patient's prostate volume study and the prescription dose. When the seed order is place with the vender, one additional calibrated seed will be ordered for every I-125 prostate seed implant. The number of seeds required for each implant will be calculated by the Radiation Therapy Physicist and confirmed by the Dosimetrist and Physician. A "Prostate Seed Order Request Form" will be completed by Physics and submitted to the Chief Therapist for ordering. The "Prostate Seed Order Request Form" will contain the following:

1. Patient's Name.
2. Patient's ID.

3. Number of Seeds Needed Plus Calibrated Seed.
4. Isotope and Model.
5. Implant Date.
6. Desired Activity on Implant Date.
7. Activity Ordered and Reference Date.
8. Requested Delivery Date.
9. Physician, Physicist, and Dosimetrist Signatures.

The seed order calculation and the "Prostate Seed Order Request Form" will be maintained in the patient's chart.

e. Receiving, Securing and Recording Source Shipments

I-125 seed shipments are delivered directly to the Radiation Therapy Department at the Boston VAMC by FedEx. Upon arrival, the Radiation Therapy Physicist or trained designee is contacted to directly pick-up the radioactive material package. Once an I-125 seed shipment is received, the package(s) will be moved to a secure radioactive materials storage area, DB-102. This storage area will posted with a "CAUTION: RADIOATIVE MATERIALS" sign and emergency contact numbers.

Within 3 hours of receipt, the package(s) must be surveyed to determine that there is no contamination or damage during shipping (Note: No radioactive material packages will be received after hours). The package survey will be conducted as outline in the Boston VAMC Radiation Safety Plan. The number of sources, the isotope model number, the source strength and patient name shall be verified to be in agreement with the "Prostate Seed Order Request Form" and the receipt will be logged into the "I-125 Receipt, Removal, Storage and Inventory Log". Finally, the received I-125 containers will be dually secured in the labeled refrigerator in DB-102. All documentation will be maintained in the patient chart and the Radiation Therapy Service Physics Department.

f. Source Accountability and Inventory

When brachytherapy sources are in use or storage accountability will be maintained at all times. A record, the "I-125 Receipt, Removal, Storage and Inventory Log," will be maintained for at least three years which documents the following:

1. The number of sources received, the total activity received, the receiver of the shipment and the date
2. The number of sources removed from storage, the date they were removed, the name of the person who removed the sources from storage
3. The number and activity of the sources permanently implanted in the patient
4. The number of sources returned to storage, the activity of stored sources, the storage date, and the name of the person who stored the sources.

An inventory of all stored sources will be conducted every three months.

g. Radioactive Material Survey and Wipe Test

All packages containing radioactive materials shall be surveyed within 3 hours of receipt. If the Radiation Therapy Physicist is not available to survey or wipe test the package the RSO will be contacted.
Exposure readings at one meter from the package(s), at the package surface and at the source container(s) will be measured and recorded. Any reading detected above background will be assumed to be contaminated. A wipe test of all radioactive materials package(s) and source container(s) will also be performed and results documented. A NaI well counter will be utilized to detect surface contamination. Procedures for performing package surveys and wipe tests are as describe in the Boston VAMC Radiation Safety Plan.

h. I-125 Seed Calibration

The activity of each seed received will be assayed by the seed manufacturer/vender and the measurements will conform to 10CFR35.432. Documentation of the vender's assay for every seed will be maintained in the patient's record and the Radiation Therapy Service.
Prior to the day of implantation, Physics will verify the source strength provided by the manufacturer for each prostate implant patient. Source strength verification will follow the recommendations of AAPM Report #98. To achieve this, a certified secondary I-125 seed standard and a calibrated well chamber, which are NIST traceable, will be utilized to verify the stated manufacturer's source strength. To assure the well chamber has maintained its calibration, the certified secondary I-125 seed standard is measured and verified to be within a relative difference of ± 3%. Then a random batch of at least 10% of the total number of seeds ordered or 10 seeds, whichever is larger, will be assayed. The average activity of the batch will be verified to be within a relative difference of ± 3%. If an assay produces result outside the relative difference of ± 3%, the seeds will be sent back to the manufacturer and a new order will be placed. Documentation of each seed assay will be maintained in the patient's chart and the Radiation Therapy Service.

i. Evaluation for Possible Leaking Seeds

The seed manufacturer leak tests all seeds prior to shipment. The vendor certifies that a leak test showing <0.005 μCi of removable I-125 was passed. Other methods of evaluated for leaking seeds beyond the manufacturer's certification will be employed as follows:

1) When the seeds are removed from the vendor's sealed shipment container, the glass vial and lead container will be surveyed with a NaI probe to detect surface contamination.
2) As the seeds are assayed in the well chamber, a leaking seed will cross contaminate the chamber's seed holder. A well chamber

reading of the empty seed holder will be observed after the seed assay. A reading above background would indicate a leaking seed.

3) After the seed assay, the seed holder will be surveyed with a NaI probe to detect contamination.
4) After the implant, the empty shielded well container will be surveyed with a NaI probe to detect surface contamination.

If a leaking seed is detected before, during or after the implant procedure, referred to the "Emergency Plan For Leaking I-125 Brachytherapy Seed Source." If the leaking seed is not detected in the OR follow the emergency plan in similar manner. The emergency plan is maintain in the Radiation Therapy Service

j. Pre-Implant Preparations

The RSO or Physicist will transport the I-125 seeds to the operating room in shielded containers. At all times the I-125 seeds shall be under constant surveillance and control of the RSO or Radiation Therapy Physicist.

In the sterilization area, the seeds are place in a shielded sterilization cup with cover and an autoclave bio-test package (Attest) is prepared. Prior to sterilization, the area is assayed with a survey meter to verify that there are no stray seeds. The seeds and test package are then sterilized. Note: The test package requires one hour after sterilization before it can be read.

All other implant equipment will be inspected for proper operation before the patient is put under anesthesia. This includes: 1) examination of the stepper/stabilizer for mechanical integrity and functionality and 2) verification that the US images are of adequate quality to perform the implant and that connectivity to the TPC can be established.

Prior to and during the implant the Radiation Oncology Physicist shall be present in the OR to assure that proper radiation safety procedures are followed.

No special precautions are required by the OR personnel while they are working under the supervision of the RSO.

k. US Probe Cleaning and Sterilization

The US probe is cleaned and sterilized following the manufacturer's instruction. SOP 3802 BK Medical Transrectal Biplane Ultrasound Transducer Type 8848 contains all applicable pre-cleaning, cleaning and sterilization procedures.

l. Time Out

Once the patient enters the OR suite and prior to any activity a "Time Out" will be initiated. The "Time Out" will verify the identity of the patient using at least two forms of identification (full name, full social security number and/or date of birth). The procedure site and procedure that the patient is present for will also be identified by the patient. The AU Physician and procedural team will verify that the information provided is consistent with the informed consent. "Time Out" policy and procedures are available on the Boston VAMC website.

Once the "Time Out" is complete, the seeds to be used for the patient who was verified by the "Time Out" will be confirmed to be in agreement with the seed receipt. Specifically, the name appearing in the Special Instructions section of the receipt will be in agreement with the patient identified in the "Time Out". Furthermore, the number of seeds available to the procedure will be in agreement with the seed order receipt.

m. Treatment Plan Generation and Approval

After general anesthesia is administered and the patient is positioned properly on the OR couch, the Ultrasonographer utilizes the Transrectal US (TRUS) probe and the US measuring tool to determine a reference prostate volume. The TRUS probe is then fixed to the probe stepper and positioned to acquire prostate US images. The Radiation Oncologist and the Ultrasonographer collaborate to determine the ideal position for the TRUS probe with respect to the prostate, urethra and rectum. Once the prostate base position is selected and the stepper is fixed in position, US images at 5mm increments are captured by the CMS Interplant Treatment Planning Computer (TPC). Images from the base of the prostate to several images/slices past the apex of the prostate are captured on the TPC. At this time, the Radiation Oncologist contours the prostate, urethra, and rectum on the TPC.

Once all critical structures are defined, the Physicist generates a plan that will optimally deliver the dose indicated in the written directive to the prostate volume with a margin of several millimeters. During dose optimization of the treatment plan, dose sparing considerations are examined for the urethra and rectum. No percentage of urethral volume will exceed a dose of 250 Gy and the amount of rectal volume to receive the prescription dose will be kept to a minimum. After treatment plan optimization, the Radiation Oncologist will check all treatment parameters, which includes the seed activity, the isodose distribution and DVH for the prostate, urethra, and rectum. The isodose distribution and DVH values should conform to the following prior to treatment plan approval:

1) Prescription isodose distribution covers prostate volume with a margin of several millimeters.
2) $D90_{Prostate} \geq 145$ Gy or 108 Gy for boost implant.
3) $V150_{Urethra} \leq 10\%$: percentage of urethra receiving 150% of the prescribed dose (217Gy for brachytherapy only and 162 Gy for EBRT with brachytherapy boost.)
4) R100: rectal volume in cm^3 receiving 100% or more of the prescribed

dose. Volume not to exceed 1.5 cm^3; reviewed on a case by case basis.

After the final review, the treatment plan is approved at the discretion of the Radiation Oncologist. The completed treatment plan is approved with Radiation Oncologist's signature in the pre-implant written directive before the seed implant procedure is initiated.

n. Needle Loading

Upon plan approval, the RSO or designate is provided a printout of planned needle locations and their associated seed loading. The RSO or trained alternative, under sterile conditions, will be assisted by the Physicist or an OR Nurse when loading the seed implant needles. The Physicist or OR Nurse will support the RSO by indicating the seed loading configuration of each implant needle and its placement location in the needle holder. When all planned needles are loaded, the RSO will account for and secure the remaining seed.

o. Verification of the Implant Administration

The administration of the prostate seed implant shall be in accordance with the written directive. Prior to administration of the treatment plan, the Radiation Oncologist must verify that all the details specified in the written directive and in the treatment plan are in agreement. During seed implantation, the Radiation Oncologist will utilize fluoroscopic imaging to view seed deployment and to verify that seeds are not inadvertently place away from the intended target. In addition, an anterior to posterior view of the seed geometry generated during treatment planning will printed to allow comparison to fluoro images.

At the conclusion of the seed implant, the Radiation Oncologist will verify the graphical isodose distribution delivered to the prostate and DVHs for the prostate, urethra and rectum. At this time, the written directive will be completed as specified in 10CFR35.40. Any unintended deviation from the written directive shall be identified and the appropriate action taken. Any intended deviation will be documented in the Radiation Oncologist's treatment note.

p. Seed Accountability and Post Implant Imaging

After the implant is completed, an anterior-to-posterior (AP) Fluoro image of the implanted seeds must be obtained to verify and account for the number of seeds implanted into the patient. In addition, the sum of the seeds implanted and the seeds remaining will be in agreement with the total number of seeds brought to the OR. The AP Fluoro image is printed and maintained in the patient's chart. Finally, the seeds are returned to the radioactive materials storage area DB-102 and logged into the "I-125 Receipt, Removal and Storage Log". The "I-125 Receipt, Removal and Storage Log" will fulfill the requirements of 10CFR35.2406.

q. OR and PACU Area Survey

The OR must be surveyed by the RSO or Radiation Oncology Physicist to ensure that there are no stray radioactive sources. Floors, tables, linens, waste materials, applicators, US probe, and all needles must be surveyed for misplaced sources. The survey must include a survey of the feet of all personnel associated with the implant prior to leaving the OR. Likewise, after the patient is released from the PACU the patient's recovery area, linens, and waste materials are survey to ensure that no radioactive source are present. These area survey readings must include the date, the survey results, the survey instrument and name of the surveyor. A record of the surveys is maintained in the patient's chart by the Radiation Therapy Service.

r. Leaking Seed

If a leaking seed is detected before, during or after the implant procedure, referred to the "Emergency Plan For Leaking I-125 Brachytherapy Seed Source." This emergency plan is maintained in the Radiation Therapy Service.

s. I-125 Seed Decay-In-Storage

All I-125 seeds not used during the prostate implant procedure will be decayed in storage as detailed in 10CFR35.92. At the end of each calendar year, all the seeds not used in the prostate seed implant procedures will be stored collectively and assigned a Batch #. The Batch # represents the calendar year the seeds were received. When the Batch is created, it is logged into the "I-125 Receipt, Removal, Storage, and Inventor Log" and decayed for at least 10 half lives.

At the discretion of the RSO, the Batches will be disposed of when: at least ten half lives have past and the Inventory log indicates the activity is essentially zero. Before the Batch is disposed of it will be surveyed with an appropriate survey meter on its most sensitive scale and with no shielding. If the radioactivity from the seed Batch can not be distinguished from the background radiation level it may be disposed of in the trash. All radioactive labels will be removed prior to disposal and a record of the disposal, which will include the date of disposal, the survey meter used, the background radiation level, the radiation level measured at the surface of the I-125 seeds, and the name of the surveyor. The disposal record will be maintained for at least 3 years by the RSO and the Radiation Therapy Service.

Note: This disposal method is under review by the RSO. No sources will be disposed until final approval.

t. Patient Survey and Release

A prostate implant patient may be released after the implant procedure if the total effective dose equivalent to any other individual from exposure to the released patient individual is not likely to exceed 5 mSv. Since the I-125 total implanted activity always exceeds 9 mCi, the immediate release of the patient will be based on measured dose rate, as detailed in NUREG-1556, Vol. 9. A dose rate reading at one meter from the patient will be acquired by the RSO or Radiation Oncology Physicist immediately following the implant in the OR. If the dose rate reading at 1 meter is less than or equal to 1 mR/h (RG 8.39, Table 1, Column 2), the patient may be released. If the dose rate reading at 1 meter exceeds 1 mR/h, accommodation will be made for the patient to stay hospitalized until the dose rate meets the regulatory requirement. Dose rate, date and survey meter will be recorded in the patient chart and maintained by the Radiation Therapy Service.

It is to be noted that energy response for the Ludlum 44-9 probe utilized during the patient survey has an over-response to the decay energies of I-125. Since this will produce an exposure rate greater than the actual an energy correction is not necessary. Conservatively, the exposure reading observed will be recorded.

u. Post Implant Patient Instructions and Nursing Instructions

All prostate I-125 implant patients will receive verbal instructions and be provided written instructions by the Radiation Oncologists following the implant procedure. The Post Implant Patient Instructions will direct the patient on how to minimize radiation exposure to family member and the general public. It also instructs the patient on actions to be taken if an I-125 seed is discharged from the patient.

Nursing instructions will be provided to OR personnel. The instruction will direct the nursing staff of safety precautions needed for prostate seed implant patients during the patient recovery period after the implant. It will also give instructions on the proper handling and management of the patient's recovery area.

The Post Implant Patient Instructions and Nursing Instructions will be maintained by the Radiation Therapy Service and reviewed annually by the RSO.

v. Documentation

The administered plan and all images (US and radiographic) will be printed and kept in the patient's chart and maintained by the Radiation Therapy Service. All documents will be reviewed and signed by the Physicist and Radiation Oncologist. A peer review by an intradepartmental Radiation Oncologist will be made during department chart rounds after the post implant evaluation is complete. The reviewing Radiation Oncologist will sign the written directive to signify a satisfactory implant.

w. Post Implant Evaluation

Within 4 to 6 weeks following the seed implant, every patient will be scheduled to receive a post-operative CT scan of the prostate. The post implant CT is used to evaluate the actual dose distribution to the prostate and critical structures and identify deviations from the originally planned implant. The post implant analysis also provides an opportunity for improving techniques, evaluating outcomes and identifying patients who might benefit from supplemental therapy.

3mm CT images of the prostate will be acquired and imported to the TPC. Using the images, the Radiation Oncologist will draw the prostate and critical structures and the Physicist will generate a 3D dose distribution and DVHs for the critical structures. The Radiation Oncologist and Physicist will evaluate the following:

1) The dose received by 90% of the prostate volume (D90),
2) The percentage of the prostate volume receiving 100% of the prescribed dose (V100),
3) The volume of rectum in cm^3 receiving 100% or more of the prescribed dose (R100).
4) Seeds implanted outside the treatment volume.

The dosimetric evaluation of the implant will be as follows:

1) A D90 that is within 80% of the prescribed dose is considered a "good" implant.
2) A $V100_{prostate}$ of 75% is considered a "good" implant.
3) A R100 $\leq$ 1.5 cm^3 of rectal volume is adequate rectal dosimetry. Rectal dosimetry will be evaluated at the discretion of the Radiation Oncologist.
4) Dose considerations to critical structures, due to placement of seeds outside of the prostate, will be evaluated. The evaluation will be based on supplemental clinical judgment.

A record will maintained by the Radiation Therapy Service.

On a quarterly basis, an audit of: 1) D90, 2) V100, 3) R100 and 4) seeds placed outside the treatment volume will be performed for all post implant patients . The report will also include the implant date and prescribed dose. The report will be generated and submitted to the Radiation Therapy Service Chief and the RSC for review.

x. Medical Events/Incidents, Notification and Reporting

The method of determining whether a medical event has occurred will be based on the dose received by 90% of the prostate volume, (D90). A medical event has occurred if D90 is less than 80% of the prescribed dose specified in the written directive. A medical event can also occur as a result of seeds being placed outside of the prostate. In this instance, a medical event will be determined on a case by case basis in consultation

with the NHPP. If the dose distribution is determined to be inadequate, the patient will be notified and the possibility of the implantation of additional seeds, as a corrective action, will be assessed. If seeds are

If the post implant evaluation of D90 indicates a medical event has occurred, the medical event will be reported as defined in 10CFR35.3045. Specifically, within 24 hours after discovery of a medical event the NRC, RSO, referring physician and patient will be notified of the event. A written report will be also be submitted to the NRC, referring physician, and patient within 15 days after discovery of the event.

The NHPP reports medical events for the VHA to the NRC. The NHPP, RSO and after hours contact information are as follows:

1) Business hours central time zone: 501-257-1571.
2) NHPP after business hours central time zone: 800-815-1016.
3) RSO: 857-363-5939.
4) RSO after hours: pager #: 617-705-1195
5) Radiation Therapy Service: 857-364-5629.
6) Radiation Therapy After-hours On-call Service 617-323-7700
7) Seed Vender: 800-228-0126.

Note: The Radiation Therapy Physicist is contacted through the On-call Radiation Oncologist

y. Prostate Implant QA and Peer Review

Following the post implant evaluation, the completed implant is to be thoroughly reviewed by the Radiation Therapy Physicist and RSO. The review will assess the compliance of the prostate implant with the Prostate Brachytherapy QMP and VHA Standard Procedures. As a final check of the prostate implant, an intra-departmental physician peer review will be performed for each prostate implant. The RSO, Physicist and intradepartmental peer review Radiation Oncologist will sign the written directive, after review, to signify a satisfactory implant. In addition, at least five cases each year will receive an external physician peer review as required by the VHA Handbook.

At least annually, the Prostate Implant QMP will be reviewed by the Physicist of the Radiation Therapy Service. The review will determine the effectiveness of the QMP and make necessary modifications. The review will also include an audit of all prostate seed implant cases performed in the previous year and presented to the Chief Radiation Oncologist for evaluation.

z. Training

Initially and periodically, training of the authorized user physicians, medical physicists and other brachytherapy staff will be performed. Initially, all personnel will receive a review of the Prostate Brachytherapy QMP, associated federal regulations and VHA

standard procedures. As needed and at least annually, follow-up training for all prostate brachytherapy personnel will be conducted. This periodic training will be directed at federal regulations, VHA standard procedures, clinical requirements, medical events and radiation safety. The effectiveness of the training will be evaluated through group discussion on the training material. Training of personnel involved in prostate brachytherapy is the responsibility of the Radiation Therapy Service and the RSO.

Reviewed/Modified by: John Naughton, JN
8/21/09 Prostate Brachytherapy, JN
2/28/09 Prostate Brachytherapy, JN

( ) Workshop
( ) In-service

( ) Mandatory

DEPARTMENT OF VETERAN AFFAIRS
VA BOSTON HEALTHCARE SYSTEM

ATTENDANCE SHEET

( ) Entered In Computer

Program: Brachytherapy and Radiation Safety
Date: 11/30/07
Presentor(s): J Naughton
Length of Program: 1hr
Contact Hours:

Content:

PRINT NAME	TITLE	SIGNATURE	SERVICE	UNIT/ WARD	CAMPUS/ CLINIC	
1. AMOROSO, PATRICIA	RN		NSG	RAD	JP	
2. ANDERSON, JANICE	RN		NSG	RAD	JP	
3. BUOTE, NICOLE	RT(T)			RAD	JP	
4. DUGGAN, LINDA	RT(T)		RTT	RAD	JP	
5. ELSAYYAD, NAGY	MD					
6. FLAGG, NICOLE	DOS (contract)					
7. GOLSTON, CARL	RT (contract)			RAD	JP	
8. HANSEN, ROBERT	BLK		RT	RAD	JP	
9. LOCHIATTO, JOSEPH	RT(T)			RAD	JP	
10. MCALPINE, JAMES	RT		Rad Tx	RAD	JP	
11. MCKINZEY, MARY	PG.CLK			RAD	JP	
12. NAUGHTON, JOHN	PHYS (contract)					
13. PAGLIUCA, THERESA	MD (contract)			RAD	JP	
14. VARLOTTO, JOHN	MD			RAD	JP	

Prostate Brachytherapy Needle Loading
&
Radiation Safety Training

Syllabus

1. I-125 (Oncura Oncoseed)
2. Bard Needles
3. Steam Sterilization and Bio Test
4. Prostate Brachytherapy QMP
5. Implant Procedures
6. CMS Treatment Plan
7. Needle Loading
8. Radiation Survey Meter
9. Patient Survey
10. Seed Accountability
11. Seed Storage

Radioactive Materials Receipt and Package Survey

Syllabus

1. Brachytherapy QMP
2. Receipt and Log
3. Survey Meter
4. Exposure Reading
5. Wipe Test
6. Storage

ONCURA

OncoSeed™ (Iodine-125 Seeds)

Model 6711
Non-Sterile OncoSeed
Model 6715
Sterile Convenience Pack

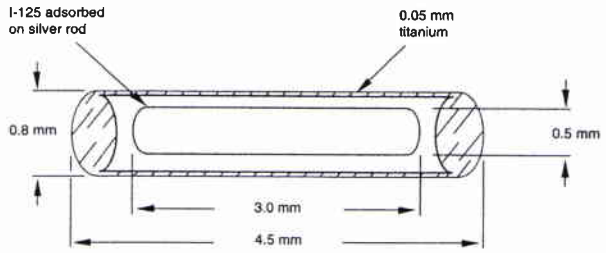
R_X ONLY

Device Description

Model No. 6711

OncoSeed seeds consists of a welded titanium capsule containing Iodine-125 adsorbed onto a silver rod.

ONCOSEED DIAGRAM



Model No. 6715

The OncoSeed Sterile Convenience Pack contains fifteen OncoSeed Seeds (Model 6711) loaded into a Mick® Disposable Cartridge and steam sterilized Ready to Use.

Physical Properties

- Principle Radionuclide: ^{125}I (Iodine)
- Radionuclide Purity: > 99.9% ^{125}I; < 0.005% ^{126}I
- Half-life of ^{125}I: 59.43 days
- Types of Radiation: X-ray and Gamma
- Energy Level:

Photon	27.4 keV
X-ray	31.4 keV
Gamma	35.5 keV
Fluorescent X-Rays from the Silver Rod	22.1 keV and 25.2 keV

- Decay Mode: ^{125}I decays by electron capture with the emission of characteristic photons and electrons. The electrons are absorbed by the titanium wall of an OncoSeed.

Shelf Life

The useful "shelf life" of the source and convenience pack can be calculated by considering the day of use after the assay date and corresponding value of decay factor. Unused seeds must be disposed of within six months of the leak test date shown on the certification form accompanied with the product.

Radiation Protection

The half value thickness of lead for Iodine-125 is 0.025 mm. Thus, a 0.25 mm lead sheet will provide > 99% reduction in exposure.

To correct for the physical decay of Iodine-125, the decay factors at selected days after the assay date are shown in the table below:

Iodine-125 Decay Chart (59.43 day Half-Life[1])

Days	Decay Factor	Days	Decay Factor
0	1.000	36	0.657
2	0.977	38	0.642
4	0.954	40	0.627
6	0.932	42	0.613
8	0.911	44	0.599
10	0.890	46	0.585
12	0.869	48	0.571
14	0.849	50	0.558
16	0.830	52	0.545
18	0.811	54	0.533
20	0.792	56	0.520
22	0.774	58	0.508
24	0.756	60	0.497
26	0.738	62	0.485
28	0.721	64	0.474
30	0.705	66	0.463
32	0.689	68	0.452
34	0.673	70	0.442

Intended Use/Indications

OncoSeed seeds with apparent activities from 0.191 to 1.01 mCi are indicated for permanent interstitial implantation of selected localized tumors which are of low to moderate radiosensitivity. They may be used either as primary treatment (such as for prostate cancer or unresectable tumors) or for treatment of residual disease after excision of the primary tumor. Seeds in this apparent activity range may be used to treat superficial, intraabdominal, and intrathoracic tumors. Tumors of the head, neck, lung, pancreas, and prostate (early stages) are commonly treated.

OncoSeed seeds with total apparent activities greater than 1.01 mCi are indicated for interstitial treatment of tumors which have the following characteristics: unresectable, localized, and moderate radiosensitivity. These seeds may be used for selected radiation applications as temporary implants.

OncoSeed seeds are indicated to treat residual tumors concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy. In addition, recurrent tumors may be implanted with OncoSeed seeds.[10, 11]

Contraindications

As with other brachytherapy sources, treatment of tumors in generally poor condition (e.g., ulcerated) is not recommended with OncoSeed seeds.

WARNINGS

1) Do not use visibly damaged seeds for implantation.
2) Do not apply excessive force during loading/removing of seeds.
3) Do not pick up seeds with the fingers, use forceps.
4) Do not use dry heat or chemical sterilization.
5) To minimize radiation exposure, use vented chemical hood and proper shielding in handling of seeds.
6) Caution should be exercised in performing Transurethral Resection (TURP) with electrocautery in patients who have undergone prostatic radioactive seed implantation. Because the integrity of the seed capsule can potentially be breeched by electrocautery, the patient and surgical personnel should be monitored for any possible radioactive contamination after the procedure. Additionally the radioactive half-life of the seed should be considered prior to the use of electrocautery.
7) Do not over tighten base in the Mick Cartridge.

PRECAUTIONS

1) Loading/Unloading of Seed

Sterile Convenience Pack (Model 6715) is loaded Ready to Use. No special loading/unloading is required.

Do not force an OncoSeed into (or from) any implant tube, needle, or cartridge; doing so may damage the wall or end welds of the seed, potentially causing release of I-125 into the environment and into body fluids should the seed be implanted. UNDER NO CIRCUMSTANCES SHOULD VISIBLY DAMAGED SEEDS BE IMPLANTED.

When loading or removing an OncoSeed from plastic or rubber afterloading catheters, it is advisable to use a vented chemical hood which has adequate air flow up the stack and a filtered exhaust. If a chemical hood is not available, a plastic glove box specifically designed for work with radioactive iodine may be substituted, provided it is properly vented.

If a razor blade, scalpel, or other sharp tool is used to remove an OncoSeed from the afterloading catheters, use extra care to avoid contacting or cutting a seed. A seed which has been damaged (nick, cut, slice, or other type of damage) will release I-125 into the environment.

To assure that seeds have not been damaged following removal from the afterloading catheters, a contamination survey should be conducted using a radiation monitor capable of detecting 30 keV photons. This survey should include wipe (or leak) tests of seeds and an overall area survey. For seed leak test details, contact Oncura Customer Care at (877) 639-8060.

2) Seed Corrosion

The titanium shell of an OncoSeed has excellent corrosion resistance under normal use. However, do not expose a seed to acid or alkaline solutions exceeding 1 molar. Seeds are not affected by common solvents such as acetone and alcohol or by mild detergents.

3) Personnel Monitoring

OncoSeed seeds are radioactive, and appropriate precautions must be taken when handling the sources. All steps of the implantation procedure should be planned in advance to minimize radiation exposure to personnel.

Personnel monitoring is required. Typically a film badge or TLD dosimeter worn on the body and a ring badge (during seed handling) is adequate.

4) Storage and Transportation

The lead seed container effectively shields >99.9% of the photons from I-125. The lead seed container may be used for storage and transport of seeds.

5) Seed Handling

OncoSeed seeds should be handled behind shielding of adequate thickness. Forceps, either reverse or normal action, should be used to maintain operator to seed distance. If normal action forceps are used, gentle pressure should be applied so that seeds are not damaged. ONCOSEED SEEDS SHOULD NOT BE PICKED UP WITH THE FINGERS.

OncoSeed Convenience Pack is loaded into the Mick Disposable Cartridge and steam sterilized Ready to Use. No special handling is required.

6) Seed Sterilization

OncoSeed seeds are not sterilized when shipped and must be sterilized prior to use. Before implantation, they must be sterilized using steam or ethylene oxide (EtO).

Sterile Convenience Pack is shipped sterilized. In the event resterilization is required, use a steam sterilization method with the following conditions: 120 - 122°C, 14 – 18 psi, 30 – 33 minutes. If a second resterilization is required, the seeds should be removed from the cartridge and sterilized as loose seeds (Model 6711) per the Directions for Use, Steam Sterilization (Autoclave) section on page 3 of this document. Multiple resterilization of the Mick® Disposable Cartridge is not recommended.

For Sterile Covnenience Pack: DO NOT USE DRY HEAT OR CHEMICAL STERILIZATION.

7) Accidental Damage to Seed

Although an OncoSeed has a high structural integrity, it is possible through rough handling, exposure to excessive temperature, or crushing to rupture a seed causing it to release "free" I-125. If this happens, the area of the accident should be closed off, the seeds should be sealed in a lead container; personnel movement should be controlled to avoid spread of any radioactive contamination; and the area and personnel should be decontaminated according to established procedures. Personnel working in or near the accident should also undergo a thyroid scan to determine if I-125 has accumulated in this organ through contact, ingestion, or inhalation of the radionuclide.

ADVERSE REACTIONS

General

Since I-125 seeds deliver radiation to the target tissue in order to provide therapy, any adverse effect associated with tissue radiation damage theoretically may be associated with their use. The potential for and symptoms of such damage will vary depending on the nature and location of the target tissue.

Prostate Brachytherapy

The following adverse event information has been derived from published articles listed in the reference section.

Immediately subsequent to transperineal seed implantation for prostate brachytherapy, there is often procedure-related bleeding or burning beneath the scrotum, or passage of blood in the urine.[12] These symptoms are usually treated supportively. Incidents of asymptomatic seed embolization to the lungs have been noted in the literature.[13]

Short-term irritative or obstructive urinary symptoms, such as frequent, urgent or uncomfortable urination, dribbling, or difficulty voiding, may be experienced after implantation, and may last for several weeks to a few months.[14-16] Generally, these are transient, mild effects which resolve spontaneously (as seed radiation levels decrease) or require minor intervention.

Impotence has been noted as a long-term adverse effect, with an incidence ranging from 6-30%, as published by some groups.[14, 16-20] The risk of impotence may be age-related.[16] Proctitis may occur, with several groups reporting a 2-6% incidence.[15, 18, 21,22] Long-term incontinence is uncommon,[14, 16, 21] although patients who have previously undergone transurethral resection of the prostate (TURP) are at a higher risk.[23,24] Urethral stricture has been reported in a small percentage of cases.[14, 15, 18]

Patient Counseling Informati

All patients should be informed of the nature of OncoSeed seed implants and the expected period of time during which radiation precautions will be necessary. Patients, their close associates and associated medical personnel should be instructed in the necessary radiation safety procedures required for someone who has received an OncoSeed seed implant. Guidelines for necessary precautions have been established.[25]

All patients should be advised of the possibility that, during a course of treatment, one or more OncoSeed seeds might slough off and become detached as a tumor regresses and becomes smaller. Under these circumstances, any bandages or linens which come into contact with the site of the implant should be scrutinized for small metallic seeds (1/4 of an inch long). Patients should be advised that whenever seeds are found, they should be picked up with a spoon and placed in a jar or other container, and placed in an inaccessible area in the home. The radiation center should be notified of such an event as soon as possible after its occurrence.

How Supplied

Model No. 6711 OncoSeed seeds are shipped in a shrink wrapped, screw-cap glass vial which is inside a sealed lead "securitainer" The lead securitainer can be opened by pulling off the plastic ring seal. OncoSeed seeds are supplied non-sterile and loose with apparent activities from 0.191 to 6.24 mCi per seed and, by special request, from 6.24 to 40 mCi per seed. Please contact Oncura Customer Care for further details.

Model No. 6715 OncoSeed seeds in the Sterile Convenience Pack contains fifteen Model 6711 OncoSeeds loaded into a Mick Disposable Cartridge and steam sterilized Ready to Use. Each Sterile Convenience Pack is placed in a primary sterility barrier and held in a lead container, which holds a maximum of ten convenience packs. OncoSeed Sterile Convenience Pack are available with apparent activities from 0.27 mCi to 0.673 mCi per seed. Please contact Oncura Customer Care for further details.

Both seed models are packaged with labeling information on air kerma strength and apparent activity per seed, total air kerma strength and apparent activity, reference date, number of seeds, and order I.D. number. Air kerma strength is specified in units of microGray meter squared per hour ($\mu Gym^2/h$), and apparent activity has units of milliCurie (mCi). The label contains precautionary regulatory statements pertaining to licensing of the seeds. Any discrepancies noted upon receipt of the product, from that which was ordered, must be reported immediately to Oncura Customer Care at (877) 639-8060.

Leak Testing

OncoSeed seeds are leak tested prior to shipment and have passed a leak test showing <0.005 µCi of removable I-125 as required by Illinois Emergency Management Agency 32 Ill. Adm. Code Part 335, Subpart C, 335.2050. This leak test value is printed on the Certification form that accompanies each shipment.

OncoSeed seeds that retain clinical utility for more than six months must be leak tested at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State, except for sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been leakage-tested within six months before the date of use or transfer, as prescribed in Illinois Emergency Management Agency 32 Ill. Adm. Code Part 335, Subpart C, 335.2050.

OncoSeed seeds intended for temporary implants (1 to 40 mCi) might fall into the above category and, if so, would need to be leak tested. Additionally, since the higher activity seeds are often reused, leak testing at more frequent intervals is recommended. For leak test details, contact Oncura Customer Care at (877) 639-8060.

Unused OncoSeed seeds intended for permanent implants (nominal strength of 0.50 mCi) will not require additional leak testing providing they are disposed of within six months of the date shown on the Seed Certification form.

Licensing

The Illinois Emergency Management Agency (IEMA) has approved this sealed source for distribution to persons licensed pursuant to 32 Ill. Adm. Code 330.260(a) and Part 335 Subpart H 335.7010 or under equivalent licenses of the USNRC or an Agreement State, and outside the United States, to persons authorized by the appropriate authority.

Directions for Use

General

OncoSeed seeds and Convenience Pack should be used only by individuals who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Radiation detection equipment, capable of detecting 30 keV photons, should be available whenever I-125 Seeds seeds are being handled. The seeds are quite small and it may be difficult to locate a dropped seed visually.

All practical physical protection should be provided during the implantation procedure. Frequently, however, protective barriers are not practical in the surgery. In this circumstance, operators must rely upon distance and speed to minimize radiation exposure.[28-31]

OncoSeed seeds can be implanted directly with an 18 or larger gauge needle or using a seed applicator attached to the needle. Common seed applicators are the Mick, Henschke and Scott. The Royal Marsden Gold Grain gun can be used to implant seeds provided a special modification is requested of the manufacturer.

For temporary implant, OncoSeed seeds are usually loaded into plastic tubing or other devices (e.g., gold eye plaques) to facilitate afterloading procedures and seed recovery.

OncoSeed seeds are shipped with a source output strength certificate. However, if verification of source output is considered necessary, the AAPM guidelines should be followed.[7]

OncoSeed Convenience Pack (Model 6715) is loaded into the Mick Disposable Cartridge and steam sterilized Ready to Use.

Steam Sterilization (autoclave):

Model 6711

Use the normal cycle (121 degrees C at 15 psi for 15 to 30 minutes) or the flash cycle (133 degrees C at 30 psi for about 3 minutes). DO NOT EXPOSE SEEDS TO TEMPERATURES AND PRESSURES IN EXCESS OF 138 DEGREES C and 35 PSI. Autoclaves should be equipped with traps or other means to prevent seed loss through the drain hole.

When in doubt about compatibility of steam heat with various seed containers, load them with non-radioactive seeds to determine the effect of steam on the container material and on seed recovery.

Model 6715

Sterile Convenience Pack is shipped sterilized Ready to Use. Refer to the Precautions section, item six, for resterilization.

Dosage and Administration

The total activity of OncoSeed seeds required for any given treatment depends upon the tumor volume and the previous radiation history of the tumor site. Established practice [5-9, 26, 27] should be followed for the calculation of the total activity to be implanted, the proper placement of the sources within the tissue, and the evaluation of the radiation dose distribution achieved.

Dose distribution around each individual seed is not isotropic.[2-9] This anisotropy should be considered in dose distribution calculations.

Titanium encapsulation assures good tissue compatibility, and together with the silver rod, results in a total self-absorption of approximately 35%.

Iodine-125 has a 59.43 day half-life. Decay corrections must be made in order to properly calculate the activity of the seeds on the day they are implanted.

Accountability/Disposal

Iodine-125 is an accountable radioactive material. OncoSeed seeds should, therefore, be strictly controlled and stored in a locked safe. If any significant material cannot be accounted for, the loss must be reported to the appropriate federal or state licensing agency.

When disposal is indicated, OncoSeed seeds should be transferred to an authorized radioactive waste disposal agency. OncoSeed seeds should never be disposed of in normal waste.

If a seed has been visibly damaged in any way, seal it in a container and discard it immediately to radioactive waste and check the area for contamination.

An OncoSeed disposal service is provided by GE Healthcare (Medi-Physics, Inc.). Customers wishing to dispose of OncoSeed seeds in this manner must contact Oncura Customer Care for approval and specific shipping container and forms.

Material approved for return must comply with Department of Transportation regulations (49 CFR Parts 171-177) regarding packaging and labeling,

Shipments are to be directed to: GE Healthcare (Medi-Physics, Inc.), 3350 N. Ridge Ave., Arlington Heights, IL 60004.

References

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Note: The NCRP (National Council on Radiation Protection and Measurements) documents are available from: NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814.

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43-6711J
Rev. June 2006

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VA Boston Healthcare System
Brachytherapy Order Form &
Written Directive for I-125 Seed Implant

Patient's Name:_____ **Patient's ID:** _____

Sources Ordered

Type of Implant:_____ Isotope/Activity:_____
Scheduled Implant Date:_____ No. of Seeds Ordered:_____
Sealed Source Prescription:_____
Physicians Signature/Date:_____

Sources Received

Date Received:_____ Batch/Lot#:_____
Received By:_____ Total number of Seeds:_____
Stated Activity:_____mCi/Seed Date of Calibration:_____

Prior to Implantation

Radioisotope:_____ Number of Sources:_____
Source Strength:_____
Physicians Signature/Date:_____

Sources Implanted

Patient ID: State Name( ) Wrist Band ( ) DOB ( ) SSN( )
Date/Time of Implantation:_____ Activity per Seed:_____mCi
Number of Seeds:_____
Number of Needles:_____ Total Activity
Prescription Dose:_____
Sources Administered By:_____

Patient Release Survey

Survey Instrument:_____ Model No:_____
Serial No:_____
Survey Performed By:_____

Patient: Exposure Rate @ 1 m:_____mR/hr

Room Release Survey

Operating Room: Exposure Rate :_____mR/hr
Recovery Room: Exposure Rate :_____mR/hr
Patient Room: Exposure Rate :_____mR/hr

Survey Performed By:_____

RECEIPT OF RADIOACTIVE PACKAGES (Staple to Invoice)

Date/Time
received:_____ Vendor:_____
P.O. or order #:_____ Package received by (print):_____
Principal Investigator:_____
Isotope:_____ Total Activity:_____ Physical and chemical form:_____
Label type (Exempt: or Radioactive I, II, or III):_____
Transportation index (TI), if applicable._____
Physical appearance of package (OK, or Describe):_____

Survey meter used:
Ludlum Model 3 S/N:_____ Probe Model 44-7 S/N:_____
Calibration due date:_____ Battery Check:_____
Background reading:_____(mR/hr) Attached check source reading:_____(mR/hr)

External exposure rate:
@1 meter from package reading:_____(mR/hr)
@Surface of package reading:_____(mR/hr)

Action Levels at Surface
Exempt > bkg
White Rad I > 0.5(mR/hr)
Yellow Rad II > 50(mR/hr)
Yellow Rad III > 200 (mR/hr)
(page RSO @ 617 705 5623, if exceeded)

Contamination Swipe test: Instrument used: LSC, GM (circle one), ***Must Use LSC for H-3***
For GM detector:
Instrument background:_____(mR/hr) Swipe reading:_____(mR/hr)
Net reading = Swipe - background = _____(mR/hr)
:net 0.01 mR/hr = 200 dpm for P-32, P-33 and 400 dpm for C-14 and S-35
Package surface: (Net Reading X (200 or 400))/.01=_____(dpm/100 cm. Sq.)
Final container: (Net Reading X (200 or 400))/.01=_____(dpm/100 cm. Sq.)

For LSC detector:
Instrument used:_____ Calibration date:_____
Background count:_____(cpm) Swipe count:_____(cpm)
Net reading = Swipe - background = _____(cpm)
:detection efficiency = 0.92 c/d, C-14: 0.86 c/d, H-3
Package Surface: (Net Reading)/efficiency=_____dpm/100 cm. Sq.)

Action Level: 1000 dpm
(page RSO @ 617 705 5623, if exceeded)

Person performing package survey:_____ Date_____
(Signature)
Possession transferred to:_____ Date:_____
(Print) (Signature)

Attachment III - G

AREA SURVEY PROCEDURES

1. All elution, preparation, and injection areas will be surveyed daily with an appropriate low-range survey meter and decontaminated if necessary.[1]

2. Laboratory areas where only small quantities of radioactive material are used (less than 200 uCi) will be surveyed monthly.

3. Waste storage areas and all other laboratory areas will be surveyed weekly.

4. The weekly and monthly surveys will consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 cm^2 for the contaminant involved. Wipes of elution and preparation areas or other "high background" areas will be removed to a low background area for measurement.

5. A permanent record will be kept of all survey results, including negative results. The record will include:

   a. Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies.

   b. Name of person conducting the survey.

   c. Drawing of the area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

   d. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

   e. Detected contamination levels, keyed to locations on drawing.

   f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

6. Area must be cleaned if the contamination level exceeds 2000 dpm/100 cm^2.

---

1. For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey results will be recorded.

PROCEDURE FOR SAFELY OPENING PACKAGES
CONTAINING RADIOACTIVE MATERIAL

1. Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in paragraph 20.205(b) of 10 CFR 20 (e.g., more than 20 curies of ^{99}Mo-^{99m}Tc, or more than 0.001 curies of ^{226}Ra: refer to Table A of Appendix A of part 71 of 10 CFR). Such packages must be monitored for external radiation levels and surface contamination within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). The NRC Regional Office must be notified if removable contamination exceeds 0.01 microcurie (22,000 dpm)/100cm^2.

2. For packages received containing specific licensable material, the following procedure for opening each package will be followed:

   a. Put on gloves to prevent hand contamination.

   b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).

   c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is higher than expected, stop and notify the RSO. (The "transport index" noted on packages with "Yellow II" or "Yellow III" labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface (see section 71.4 of 10 CFR Part 71); the surface dose rate for such packages should not exceed 200 millirem per hour. The dose rate from packages with "White I" labels should be less than 0.5 millirem per hour at the package surface. (See section 172.403 of 49 CFR Part 172.))

   d. Open the package with the following precautionary steps:

      (1) Remove the packing slip.

      (2) Open the outer package following the supplier's instructions, if provided.

      (3) Open the inner package and verify that the contents agree with the packing slip.

      (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

(5) If anything is other than expected, stop and notify the RSO.

e. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. A survey meter with a thin-window "pancake" probe for beta or gamma emitters, a NaI(Tl) crystal and scaler for gamma emitters, or a liquid scintillation counter for tritium, shall be used for these assays. The detection efficiency must be determined to convert wipe sample counts per minute to disintegrations per minute. Take precautions against the potential spread of contamination.

f. Check the user request to ensure that the material received is the material that was ordered.

g. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding.

(1) If contaminated, treat this material as radioactive waste.

(2) If not contaminated, remove or obliterate the radiation labels before discarding into in-house trash.

h. Make a record of the receipt.

3. For packages received containing generally licensable material under 10 CFR 31.11, the following procedure for opening each package will be followed:

a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.

b. Check to ensure that the material received is the material that was ordered.

c. Make a record of the receipt.

4. The record of receipt of these packages should contain the items in the following list: 1) date received; 2) purchase order number; 3) packing slip number; 4) activity (mCi); 5) isotope; 6) chemical; 7) supplier; 8) catalog number, if available; 9) verification that the package is OK; 10) for packages in #2. above, mR/hr at 1 meter and (11) at the package surface; 12) notes; and 13) initials of person monitoring; 14) RSO six digit number.

Attachment III-E

E. Brachytherapy Program QMP.

The Brachytherapy Program at the Boston VAMC consists of permanent I-125 interstitial brachytherapy of the prostate and temporary I-125 eye plaque brachytherapy. Prostate brachytherapy permanently implants I-125 seeds according to an isodose plan to the prostate. Eye plaque brachytherapy is a temporary implant where the eye plaque is fixed to the eye for a planned duration of time. The Brachytherapy QMP will address the fore mentioned procedures separately and apply policies and procedures that promote safe and accurate brachytherapy practices. The Brachytherapy QMP will employ practices suggested in AAPM TG-40 and TG-56.

1. Prostate Seed Implant Brachytherapy Procedures

The following serves as a step by step guide to performing a prostate brachytherapy at the Boston VAMC.

a. CT Prostate Volume and Pubic Arch Study

After the patient's initial consultation, the physician will order a CT to determine if the patient is a prostate implant candidate. The CT is imported into the ADAC TPC and the physician will contour the prostate. Once the prostate is contoured, ADAC will calculate the prostate volume. An implant candidate will have a prostate volume between 20 and 60 cm^3. For the pubic arch study, Physics will set up a PIO (Posterior Inferior Oblique) beams eye view which mimics the implant set up. With the contour 3-D view on, the physician will be able to determine whether there is pubic arch interference. Both criteria must be met in order to produce an implant candidate. If the patient's anatomy exceeds the limits of the implant criteria but not excessively, the physician and physicist will discuss the limitations of the case and determine if the patient is a prostate implant candidate.

The prostate volume and pubic arch study will be printed and maintained in the patient's chart. A record of the study will be maintained in the Brachytherapy QMP by Physics

b. Treatment Prescription

Two prescriptions are available for prostate implant brachytherapy: 1) 108Gy prescription is assigned to patients that have had 45Gy external beam radiation therapy to be followed by a prostate implant brachytherapy boost; and 2) 145Gy prescription is assigned to prostate implant brachytherapy when it is the sole course of treatment.

When an implant candidate is selected, the physician will discuss with Physics the treatment plan and prescription dose. The written directive for a specific brachytherapy patient must include:

1. Prior to Implantation: Radioisotope, prescription dose, number of sources, source strength, physician signature, and date.
2. After implantation and prior to treatment completion: Radioisotope, prescription dose, number of sources, source strength, physician signature, and date.

Oral revisions of the written directive are acceptable during the implant procedure because of the sterile restraints of the procedure and the patient's health. Oral revision will be documented in "Sources Implanted" section of the written directive and verified by the physicians' signature and date after the implant.

c. Ordering Sources

I-125 seeds are ordered on a specific implant patient basis. The quantity of seeds ordered is calculated based on the patient's prostate volume study and the prescription dose. When the seed order is place with the vender, one additional calibrated seed will bee ordered for every I-125 prostate seed implant. The number of seeds calculated for implant will be verified and signed off by the dosimetrist and physician. A "Prostate Seed Order Request Form" will be completed by Physics and submitted to the Chief Therapist for order. The "Prostate Seed Order Request Form" will contain the following:

1. Patient's Name.
2. Patient's ID.
3. Number of Seeds Needed Plus Calibrated Seed.
4. Isotope and Model.
5. Implant Date.
6. Desired Activity on Implant Date.
7. Activity Ordered and Reference Date.
8. Requested Delivery Date.
9. Physician, Physicist, and Dosimetrist Signatures.

The seed order calculation and the "Prostate Seed Order Request Form" will be maintained in the patient's chart.

d. Receiving Sources

I-125 seed shipments are delivered to the Receiving Department at the Boston VAMC. Upon receipt, the RSO is immediately paged for package pick-up. If the RSO is not available a designee from the Radiation Therapy Service will be contacted to pick-up the radioactive shipment. Once an I-125 seed shipment is

received, the package(s) will be moved to a secure radioactive materials storage area, DB-102. This storage area will posted with a "CAUTION: RADIOATIVE MATERIALS" sign and emergency contact numbers.

After receipt, the package(s) must be surveyed to determine that there is no contamination due to damage during shipping. Exposure readings at one meter from the package(s) and at the source container(s) will be measured and recorded. A wipe test of the package(s) and source container(s) will also be performed and results documented. Finally, the number of sources, the isotope model number, and source strength shall be verified to be in agreement with the "Prostate Seed Order Request Form." All documentation will be maintained in the patient chart, Physics Department, and the RSO office.

e. Calibrating Sources

Prior to implantation, Physics will verify the source strength provided by the manufacturer. To achieve this, a calibrated seed and a calibrated well chamber, which are NIST traceable, will be utilized to verify the stated manufacturer's source strength. To assure the well chamber has maintained its calibration, the calibrated seed is measured and verified to be within a tolerance of 2%. Then a random batch of at least 10% of the seeds ordered will be calibrated. The mean of the batch will be verified to be within a tolerance of 3%.

f. Pre-Implant Preparations

The RSO or physicist will transport the I-125 seeds to the operating room in lead shipment containers. In the sterilization area, the seeds are place in a sterilization cup with cover and an autoclave test package is prepared. Prior to sterilization, the area is assayed with a survey meter to verify that there are no stray seeds. The seeds and test package are then sterilized. Note: The test package requires one hour after sterilization before it can be read.

All other implant equipment will be inspected for proper operation before the patient is put under anesthesia.

g. Treatment Planning

After the patient is positioned properly on the OR couch, the US probe is positioned to acquire prostate images and fixed to the probe stepper. The Radiation Oncologist and the Ultrasonogragher collaborate and contour the prostate and urethra positions. After each 5mm image is contoured, it is sent to the CMS treatment planning computer. Once all prostate images are received, the Physicist generates a plan that will deliver the written directive dose distribution to the prostate volume. Prior to implantation the dose distribution is reviewed and orally approved by the Radiation Oncologist.

h. Needle Loading

Upon plan approval, the RSO is provided a printout of planned needles locations and their associated seed loading. The RSO, under sterile conditions, will be assisted by the Physicist or an OR Nurse when loading the seed implant needles. The Physicist or OR Nurse will support the RSO by indicating the seed loading configuration of each implant needle and its placement location in the needle holder. When all planned needles are loaded, the RSO will account for and secure the remaining seed.

i. Seed Implantation

The administration of the prostate seed implant shall be in accordance with the written directive. Prior to administration of the treatment plan, the Radiation Oncologist must verify that all the details specified in the written directive and the treatment plan are correct. At the conclusion of the seed implant, the Radiation Oncologist will verify the graphic dose distribution that is representative of the dose delivered to the prostate. Any unintended deviation from the written directive shall be identified and the appropriate action taken. Any intended deviation will be documented on the written directive with the signature of the Radiation Oncologist.

j. Post Implant Procedures

After the implant, an anterior-to-posterior (AP) image of the implanted seeds must be taken to verify and account for the number of seeds implanted into the patient. In addition, the number of seeds implanted and not implanted must agree with the total number of seeds brought to the OR. The OR must be surveyed by the RSO to ensure that all radioactive sources have been accounted for. Finally, the seeds are returned to the radioactive materials storage area DB-102 and logged into waste.

k. Documentation

The administered plan and all images (US and radiographic) will be printed and kept in the patient's chart. All documents will be reviewed and signed by the Radiation Oncologist.

l. Post Implant Evaluation

Within one month following the seed implant, every patient will be scheduled to receive a post-operative CT scan of the prostate. The CT scan will be imported to the TPC and a graphic dose distribution plan and DHV will be generated by Physics. The Radiation Oncologist and physicist will evaluate the implant and a

printout will be kept in the patient's chart. Any deviation from the written directive will be evaluated and the appropriate action taken.

m. Prostate Implant QMP Review

At least annually, the Prostate Implant QMP will be reviewed by the Physicist of the Radiation Therapy Service. The review will determine the effectiveness of the QMP and make necessary modifications. The review will also include an audit of a sampling of prostate seed implant cases performed in the previous year. At a minimum, a sampling of 20% of all prostate implant cases will be reviewed annually.

APPENDIX A

Table A–1. Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine

Radionuclide[1]	Half-Life (days)[2]	Exposure Rate Constant[3] (R/mCi–h at 1 cm)	Radionuclide[1]	Half-Life (days)[2]	Exposure Rate Constant[3] (R/mCi–h at 1 cm)
Ag–111	7.45	0.150	Pd–103 implant	16.96	0.86[5]
Au–198	2.696	2.3	Re–186	3.777	0.2
Cr–51	27.704	0.16	Re–188	0.708	0.26
Cu–64	0.529	1.2	Sc–47	3.351	0.56
Cu–67	2.578	0.58	Se–75	119.8	2.0
Ga–67	3.261	0.753	Sm–153	1.946	0.425
I–123	0.55	1.61	Sn–117m	13.61	1.48
I–125	60.14	1.42	Sr–89	50.5	NA[6]
I–125 implant	60.14	1.11[4]	Tc–99m	0.251	0.756
I–131	8.04	2.2	Tl–201	3.044	0.447
In–111	2.83	3.21	Y–90	2.67	NA[6]
Ir–192 implant	74.02	4.59[4]	Yb–169	32.01	1.83
P–32	14.29	NA[6]			

[1] Although non-byproduct materials are not regulated by the NRC, information on non-byproduct material is included in this regulatory guide for the convenience of the licensee.

[2] K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, "Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA–520/1–88–020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, 1988.

[3] Values for the exposure rate constant for Au–198, Cr–51, Cu–64, I–131, Sc–47, and Se–75 were taken from the *Radiological Health Handbook*, U.S. Department of Health, Education, and Welfare, pg. 135, 1970. For Cu–67, I–123, In–111, Re–186, and Re–188, the values for the exposure rate constant were taken from D.E. Barber, J.W. Baum, and C.B. Meinhold, "Radiation Safety Issues Related to Radiolabeled Antibodies," NUREG/CR–4444, U.S. NRC, Washington, DC, 1991. For Ag–111, Ga–67, I–125, Sm–153, Sn–117m, Tc–99m, Tl–201, and Yb–169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG–1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," U.S. NRC, February 1997.

[4] R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of ^{125}I and ^{192}Ir Interstitial Brachytherapy Sources," Medical Physics, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into account the attenuation of gamma rays within the implant capsule itself.

[5] A.S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," E*ndocurietherapy Hyperthermia Oncology*, Volume 6, April 1990. The exposure rate constant given is an "apparent" value (i.e., with respect to an apparent source activity) and takes into account the attenuation of gamma rays within the implant capsule itself.

[6] Not applicable (NA) because the release activity is not based on beta emissions.

U.S. NUCLEAR REGULATORY COMMISSION

Revision 1
February 1996

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 8.29

(Draft was issued as DG-8012)

INSTRUCTION CONCERNING RISKS FROM OCCUPATIONAL RADIATION EXPOSURE

A. INTRODUCTION

Section 19.12 of 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," requires that all individuals who in the course of their employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) be instructed in the health protection issues associated with exposure to radioactive materials or radiation. Section 20.1206 of 10 CFR Part 20, "Standards for Protection Against Radiation," requires that before a planned special exposure occurs the individuals involved are, among other things, to be informed of the estimated doses and associated risks.

This regulatory guide describes the information that should be provided to workers by licensees about health risks from occupational exposure. This revision conforms to the revision of 10 CFR Part 20 that became effective on June 20, 1991, to be implemented by licensees no later than January 1, 1994. The revision of 10 CFR Part 20 establishes new dose limits based on the effective dose equivalent (EDE), requires the summing of internal and external dose, establishes a requirement that licensees use procedures and engineering controls to the extent practicable to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA), provides for planned special exposures, establishes a dose limit for the embryo/fetus of an occupationally exposed declared pregnant woman, and explicitly states that Part 20 is not to be construed as limiting action that may be necessary to protect health and safety during emergencies.

Any information collection activities mentioned in this regulatory guide are contained as requirements in 10 CFR Part 19 or 10 CFR Part 20. These regulations provide the regulatory bases for this guide. The information collection requirements in 10 CFR Parts 19 and 20 have been cleared under OMB Clearance Nos. 3150-0044 and 3150-0014, respectively.

B. DISCUSSION

It is important to qualify the material presented in this guide with the following considerations.

The coefficient used in this guide for occupational radiation risk estimates, 4×10^{-4} health effects per rem, is based on data obtained at much higher doses and dose rates than those encountered by workers. The risk coefficient obtained at high doses and dose rates was reduced to account for the reduced effectiveness of lower doses and dose rates in producing the stochastic effects observed in studies of exposed humans.

The assumption of a linear extrapolation from the lowest doses at which effects are observable down to

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This guide was issued after consideration of comments received from the public. Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience.

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the occupational range has considerable uncertainty. The report of the Committee on the Biological Effects of Ionizing Radiation (Ref. 1) states that

> "... departure from linearity cannot be excluded at low doses below the range of observation. Such departures could be in the direction of either an increased or decreased risk. Moreover, epidemiologic data cannot rigorously exclude the existence of a threshold in the 100 mrem dose range. Thus, the possibility that there may be no risk from exposures comparable to external natural background radiation cannot be ruled out. At such low doses and dose rates, it must be acknowledged that the lower limit of the range of uncertainty in the risk estimates extends to zero."

The issue of beneficial effects from low doses, or hormesis, in cellular systems is addressed by the United Nations Scientific Committee on the Effects of Atomic Radiation (Ref. 2). UNSCEAR states that "... it would be premature to conclude that cellular adaptive responses could convey possible beneficial effects to the organism that would outweigh the detrimental effects of exposures to low doses of low-LET radiation."

In the absence of scientific certainty regarding the relationship between low doses and health effects, and as a conservative assumption for radiation protection purposes, the scientific community generally assumes that any exposure to ionizing radiation can cause biological effects that may be harmful to the exposed person and that the magnitude or probability of these effects is directly proportional to the dose. These effects may be classified into three categories:

Somatic Effects: Physical effects occurring in the exposed person. These effects may be observable after a large or acute dose (e.g., 100 rems[1] (1 Sv) or more to the whole body in a few hours); or they may be effects such as cancer that may occur years after exposure to radiation.

Genetic Effects: Abnormalities that may occur in the future children of exposed individuals and in subsequent generations (genetic effects exceeding normal incidence have not been observed in any of the studies of human populations).

Teratogenic Effects: Effects such as cancer or congenital malformation that may be observed in children who were exposed during the fetal and embryonic stages of development (these effects have been observed from high, i.e., above 20 rems (0.2 Sv), acute exposures).

The normal incidence of effects from natural and manmade causes is significant. For example, approximately 20% of people die from various forms of cancer whether or not they ever receive occupational exposure to radiation. To avoid increasing the incidence of such biological effects, regulatory controls are imposed on occupational doses to adults and minors and on doses to the embryo/fetus from occupational exposures of declared pregnant women.

Radiation protection training for workers who are occupationally exposed to ionizing radiation is an essential component of any program designed to ensure compliance with NRC regulations. A clear understanding of what is presently known about the biological risks associated with exposure to radiation will result in more effective radiation protection training and should generate more interest on the part of the workers in complying with radiation protection standards. In addition, pregnant women and other occupationally exposed workers should have available to them relevant information on radiation risks to enable them to make informed decisions regarding the acceptance of these risks. It is intended that workers who receive this instruction will develop respect for the risks involved, rather than excessive fear or indifference.

C. REGULATORY POSITION

Instruction to workers performed in compliance with 10 CFR 19.12 should be given prior to occupational exposure and periodically thereafter. The frequency of retraining might range from annually for licensees with complex operations such as nuclear power plants, to every three years for licensees who possess, for example, only low-activity sealed sources. If a worker is to participate in a planned special exposure, the worker should be informed of the associated risks in compliance with 10 CFR 20.1206.

In providing instruction concerning health protection problems associated with exposure to radiation, all occupationally exposed workers and their supervisors should be given specific instruction on the risk of biological effects resulting from exposure to radiation. The extent of these instructions should be commensurate with the radiological risks present in the workplace.

The instruction should be presented orally, in printed form, or in any other effective communication media to workers and supervisors. The appendix to this guide provides useful information for demonstrating compliance with the training requirements in 10 CFR Parts 19 and 20. Individuals should be given an opportunity to discuss the information and to ask questions. Testing is recommended, and each trainee should be asked to acknowledge in writing that the instruction has been received and understood.

[1] In the International System of Units (SI), the rem is replaced by the sievert; 100 rems is equal to 1 sievert (Sv).

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which an applicant or licensee proposes acceptable alternative methods for complying with specified portions of the Commission's regulations, the guidance and instructional materials in this guide will be used in the evaluation of applications for new licenses, license renewals, and license amendments and for evaluating compliance with 10 CFR 19.12 and 10 CFR Part 20.

REFERENCES

1. National Research Council, *Health Effects of Exposure to Low Levels of Ionizing Radiation*, Report of the Committee on the Biological Effects of Ionizing Radiation (BEIR V), National Academy Press, Washington, DC, 1990.
2. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), *Sources and Effects of Ionizing Radiation*, United Nations, New York, 1993.

APPENDIX

INSTRUCTION CONCERNING RISKS FROM OCCUPATIONAL RADIATION EXPOSURE

This instructional material is intended to provide the user with the best available information about the health risks from occupational exposure to ionizing radiation. Ionizing radiation consists of energy or small particles, such as gamma rays and beta and alpha particles, emitted from radioactive materials, which can cause chemical or physical damage when they deposit energy in living tissue. A question and answer format is used. Many of the questions or subjects were developed by the NRC staff in consultation with workers, union representatives, and licensee representatives experienced in radiation protection training.

This Revision 1 to Regulatory Guide 8.29 updates the material in the original guide on biological effects and risks and on typical occupational exposure. Additionally, it conforms to the revised 10 CFR Part 20, "Standards for Protection Against Radiation," which was required to be implemented by licensees no later than January 1, 1994. The information in this appendix is intended to help develop respect by workers for the risks associated with radiation, rather than unjustified fear or lack of concern. Additional guidance concerning other topics in radiation protection training is provided in other NRC regulatory guides.

1. What is meant by health risk?

A health risk is generally thought of as something that may endanger health. Scientists consider health risk to be the statistical probability or mathematical chance that personal injury, illness, or death may result from some action. Most people do not think about health risks in terms of mathematics. Instead, most of us consider the health risk of a particular action in terms of whether we believe that particular action will, or will not, cause us some harm. The intent of this appendix is to provide estimates of, and explain the bases for, the risk of injury, illness, or death from occupational radiation exposure. Risk can be quantified in terms of the probability of a health effect per unit of dose received.

When x-rays, gamma rays, and ionizing particles interact with living materials such as our bodies, they may deposit enough energy to cause biological damage. Radiation can cause several different types of events such as the very small physical displacement of molecules, changing a molecule to a different form, or ionization, which is the removal of electrons from atoms and molecules. When the quantity of radiation energy deposited in living tissue is high enough, biological damage can occur as a result of chemical bonds being broken and cells being damaged or killed. These effects can result in observable clinical symptoms.

The basic unit for measuring absorbed radiation is the rad. One rad (0.01 gray in the International System of units) equals the absorption of 100 ergs (a small but measurable amount of energy) in a gram of material such as tissue exposed to radiation. To reflect biological risk, rads must be converted to rems. The new international unit is the sievert (100 rems = 1 Sv). This conversion accounts for the differences in the effectiveness of different types of radiation in causing damage. The rem is used to estimate biological risk. For beta and gamma radiation, a rem is considered equal to a rad.

2. What are the possible health effects of exposure to radiation?

Health effects from exposure to radiation range from no effect at all to death, including diseases such as leukemia or bone, breast, and lung cancer. Very high (100s of rads), short-term doses of radiation have been known to cause prompt (or early) effects, such as vomiting and diarrhea,[1] skin burns, cataracts, and even death. It is suspected that radiation exposure may be linked to the potential for genetic effects in the children of exposed parents. Also, children who were exposed to high doses (20 or more rads) of radiation prior to birth (as an embryo/fetus) have shown an increased risk of mental retardation and other congenital malformations. These effects (with the exception of genetic effects) have been observed in various studies of medical radiologists, uranium miners, radium workers, radiotherapy patients, and the people exposed to radiation from atomic bombs dropped on Japan. In addition, radiation effects studies with laboratory animals, in which the animals were given relatively high doses, have provided extensive data on radiation-induced health effects, including genetic effects.

It is important to note that these kinds of health effects result from high doses, compared to occupational levels, delivered over a relatively short period of time.

Although studies have not shown a consistent cause-and-effect relationship between current levels of occupational radiation exposure and biological effects, it is prudent from a worker protection perspective to assume that some effects may occur.

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[1]These symptoms are early indicators of what is referred to as the acute radiation syndrome, caused by high doses delivered over a short time period, which includes damage to the blood-forming organs such as bone marrow, damage to the gastrointestinal system, and, at very high doses, can include damage to the central nervous system.

3. **What is meant by early effects and delayed or late effects?**

EARLY EFFECTS

Early effects, which are also called immediate or prompt effects, are those that occur shortly after a large exposure that is delivered within hours to a few days. They are observable after receiving a very large dose in a short period of time, for example, 300 rads (3 Gy) received within a few minutes to a few days. Early effects are not caused at the levels of radiation exposure allowed under the NRC's occupational limits.

Early effects occur when the radiation dose is large enough to cause extensive biological damage to cells so that large numbers of cells are killed. For early effects to occur, this radiation dose must be received within a short time period. This type of dose is called an acute dose or acute exposure. The same dose received over a long time period would not cause the same effect. Our body's natural biological processes are constantly repairing damaged cells and replacing dead cells; if the cell damage is spread over time, our body is capable of repairing or replacing some of the damaged cells, reducing the observable adverse conditions.

For example, a dose to the whole body of about 300–500 rads (3–5 Gy), more than 60 times the annual occupational dose limit, if received within a short time period (e.g., a few hours) will cause vomiting and diarrhea within a few hours; loss of hair, fever, and weight loss within a few weeks; and about a 50 percent chance of death if medical treatment is not provided. These effects would not occur if the same dose were accumulated gradually over many weeks or months (Refs. 1 and 2). Thus, one of the justifications for establishing annual dose limits is to ensure that occupational dose is spread out in time.

It is important to distinguish between whole body and partial body exposure. A localized dose to a small volume of the body would not produce the same effect as a whole body dose of the same magnitude. For example, if only the hand were exposed, the effect would mainly be limited to the skin and underlying tissue of the hand. An acute dose of 400 to 600 rads (4–6 Gy) to the hand would cause skin reddening; recovery would occur over the following months and no long-term damage would be expected. An acute dose of this magnitude to the whole body could cause death within a short time without medical treatment. Medical treatment would lessen the magnitude of the effects and the chance of death; however, it would not totally eliminate the effects or the chance of death.

DELAYED EFFECTS

Delayed effects may occur years after exposure. These effects are caused indirectly when the radiation changes parts of the cells in the body, which causes the normal function of the cell to change, for example, normal healthy cells turn into cancer cells. The potential for these delayed health effects is one of the main concerns addressed when setting limits on occupational doses.

A delayed effect of special interest is genetic effects. Genetic effects may occur if there is radiation damage to the cells of the gonads (sperm or eggs). These effects may show up as genetic defects in the children of the exposed individual and succeeding generations. However, if any genetic effects (i.e., effects in addition to the normal expected number) have been caused by radiation, the numbers are too small to have been observed in human populations exposed to radiation. For example, the atomic bomb survivors (from Hiroshima and Nagasaki) have not shown any significant radiation-related increases in genetic defects (Ref. 3). Effects have been observed in animal studies conducted at very high levels of exposure and it is known that radiation can cause changes in the genes in cells of the human body. However, it is believed that by maintaining worker exposures below the NRC limits and consistent with ALARA, a margin of safety is provided such that the risk of genetic effects is almost eliminated.

4. **What is the difference between acute and chronic radiation dose?**

Acute radiation dose usually refers to a large dose of radiation received in a short period of time. Chronic dose refers to the sum of small doses received repeatedly over long time periods, for example, 20 mrem (or millirem, which is 1-thousandth of a rem) (0.2 mSv) per week every week for several years. It is assumed for radiation protection purposes that any radiation dose, either acute or chronic, may cause delayed effects. However, only large acute doses cause early effects; chronic doses within the occupational dose limits do not cause early effects. Since the NRC limits do not permit large acute doses, concern with occupational radiation risk is primarily focused on controlling chronic exposure for which possible delayed effects, such as cancer, are of concern.

The difference between acute and chronic radiation exposure can be shown by using exposure to the sun's rays as an example. An intense exposure to the sun can result in painful burning, peeling, and growing of new skin. However, repeated short exposures provide time for the skin to be repaired between exposures. Whether exposure to the sun's rays is long term or spread over short periods, some of the injury may not be repaired and may eventually result in skin cancer.

Cataracts are an interesting case because they can be caused by both acute and chronic radiation. A certain threshold level of dose to the lens of the eye is required before there is any observable visual impairment, and the impairment remains after the exposure is stopped. The threshold for cataract development

from acute exposure is an acute dose on the order of 100 rads (1 Gy). Further, a cumulative dose of 800 rads (8 Gy) from protracted exposures over many years to the lens of the eye has been linked to some level of visual impairment (Refs. 1 and 4). These doses exceed the amount that may be accumulated by the lens from normal occupational exposure under the current regulations.

5. What is meant by external and internal exposure?

A worker's occupational dose may be caused by exposure to radiation that originates outside the body, called "external exposure," or by exposure to radiation from radioactive material that has been taken into the body, called "internal exposure." Most NRC-licensed activities involve little, if any, internal exposure. It is the current scientific consensus that a rem of radiation dose has the same biological risk regardless of whether it is from an external or an internal source. The NRC requires that dose from external exposure and dose from internal exposure be added together, if each exceeds 10% of the annual limit, and that the total be within occupational limits. The sum of external and internal dose is called the total effective dose equivalent (TEDE) and is expressed in units of rems (Sv).

Although unlikely, radioactive materials may enter the body through breathing, eating, drinking, or open wounds, or they may be absorbed through the skin. The intake of radioactive materials by workers is generally due to breathing contaminated air. Radioactive materials may be present as fine dust or gases in the workplace atmosphere. The surfaces of equipment and workbenches may be contaminated, and these materials can be resuspended in air during work activities.

If any radioactive material enters the body, the material goes to various organs or is excreted, depending on the biochemistry of the material. Most radioisotopes are excreted from the body in a few days. For example, a fraction of any uranium taken into the body will deposit in the bones, where it remains for a longer time. Uranium is slowly eliminated from the body, mostly by way of the kidneys. Most workers are not exposed to uranium. Radioactive iodine is preferentially deposited in the thyroid gland, which is located in the neck.

To limit risk to specific organs and the total body, an annual limit on intake (ALI) has been established for each radionuclide. When more than one radionuclide is involved, the intake amount of each radionuclide is reduced proportionally. NRC regulations specify the concentrations of radioactive material in the air to which a worker may be exposed for 2,000 working hours in a year. These concentrations are termed the derived air concentrations (DACs). These limits are the total amounts allowed if no external radiation is received. The resulting dose from the internal radiation sources (from breathing air at 1 DAC) is the maximum allowed to an organ or to the worker's whole body.

6. How does radiation cause cancer?

The mechanisms of radiation-induced cancer are not completely understood. When radiation interacts with the cells of our bodies, a number of events can occur. The damaged cells can repair themselves and permanent damage is not caused. The cells can die, much like the large numbers of cells that die every day in our bodies, and be replaced through the normal biological processes. Or a change can occur in the cell's reproductive structure, the cells can mutate and subsequently be repaired without effect, or they can form precancerous cells, which may become cancerous. Radiation is only one of many agents with the potential for causing cancer, and cancer caused by radiation cannot be distinguished from cancer attributable to any other cause.

Radiobiologists have studied the relationship between large doses of radiation and cancer (Refs. 5 and 6). These studies indicate that damage or change to genes in the cell nucleus is the main cause of radiation-induced cancer. This damage may occur directly through the interaction of the ionizing radiation in the cell or indirectly through the actions of chemical products produced by radiation interactions within cells. Cells are able to repair most damage within hours; however, some cells may not be repaired properly. Such misrepaired damage is thought to be the origin of cancer, but misrepair does not always cause cancer. Some cell changes are benign or the cell may die; these changes do not lead to cancer.

Many factors such as age, general health, inherited traits, sex, as well as exposure to other cancer-causing agents such as cigarette smoke can affect susceptibility to the cancer-causing effects of radiation. Many diseases are caused by the interaction of several factors, and these interactions appear to increase the susceptibility to cancer.

7. Who developed radiation risk estimates?

Radiation risk estimates were developed by several national and international scientific organizations over the last 40 years. These organizations include the National Academy of Sciences (which has issued several reports from the Committee on the Biological Effects of Ionizing Radiations, BEIR), the National Council on Radiation Protection and Measurements (NCRP), the International Commission on Radiological Protection (ICRP), and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). Each of these organizations continues to review new research findings on radiation health risks.

Several reports from these organizations present new findings on radiation risks based upon revised estimates of radiation dose to survivors of the atomic bombing at Hiroshima and Nagasaki. For example, UNSCEAR published risk estimates in 1988 and 1993 (Refs. 5 and 6). The NCRP also published a report in 1988, "New Dosimetry at Hiroshima and Nagasaki and Its Implications for Risk Estimates" (Ref. 7). In January 1990, the National Academy of Sciences released the fifth report of the BEIR Committee, "Health Effects of Exposure to Low Levels of Ionizing Radiation" (Ref. 4). Each of these publications also provides extensive bibliographies on other published studies concerning radiation health effects for those who may wish to read further on this subject.

8. What are the estimates of the risk of fatal cancer from radiation exposure?

We don't know exactly what the chances are of getting cancer from a low-level radiation dose, primarily because the few effects that may occur cannot be distinguished from normally occurring cancers. However, we can make estimates based on extrapolation from extensive knowledge from scientific research on high dose effects. The estimates of radiation effects at high doses are better known than are those of most chemical carcinogens (Ref. 8).

From currently available data, the NRC has adopted a risk value for an occupational dose of 1 rem (0.01 Sv) Total Effective Dose Equivalent (TEDE) of 4 in 10,000 of developing a fatal cancer, or approximately 1 chance in 2,500 of fatal cancer per rem of TEDE received. The uncertainty associated with this risk estimate does not rule out the possibility of higher risk, or the possibility that the risk may even be zero at low occupational doses and dose rates.

The radiation risk incurred by a worker depends on the amount of dose received. Under the linear model explained above, a worker who receives 5 rems (0.05 Sv) in a year incurs 10 times as much risk as another worker who receives only 0.5 rem (0.005 Sv). Only a very few workers receive doses near 5 rems (0.05 Sv) per year (Ref. 9).

According to the BEIR V report (Ref. 4), approximately one in five adults normally will die from cancer from all possible causes such as smoking, food, alcohol, drugs, air pollutants, natural background radiation, and inherited traits. Thus, in any group of 10,000 workers, we can estimate that about 2,000 (20%) will die from cancer without any occupational radiation exposure.

To explain the significance of these estimates, we will use as an example a group of 10,000 people, each exposed to 1 rem (0.01 Sv) of ionizing radiation. Using the risk factor of 4 effects per 10,000 rem of dose, we estimate that 4 of the 10,000 people might die from delayed cancer because of that 1-rem dose (although the actual number could be more or less than 4) in addition to the 2,000 normal cancer fatalities expected to occur in that group from all other causes. This means that a 1-rem (0.01 Sv) dose may increase an individual worker's chances of dying from cancer from 20 percent to 20.04 percent. If one's lifetime occupational dose is 10 rems, we could raise the estimate to 20.4 percent. A lifetime dose of 100 rems may increase chances of dying from cancer from 20 to 24 percent. The average measurable dose for radiation workers reported to the NRC was 0.31 rem (0.0031 Sv) for 1993 (Ref. 9). Today, very few workers ever accumulate 100 rems (1 Sv) in a working lifetime, and the average career dose of workers at NRC-licensed facilities is 1.5 rems (0.015 Sv), which represents an estimated increase from 20 to about 20.06 percent in the risk of dying from cancer.

It is important to understand the probability factors here. A similar question would be, "If you select one card from a full deck of cards, will you get the ace of spades?" This question cannot be answered with a simple yes or no. The best answer is that your chance is 1 in 52. However, if 1000 people each select one card from full decks, we can predict that about 20 of them will get an ace of spades. Each person will have 1 chance in 52 of drawing the ace of spades, but there is no way we can predict which persons will get that card. The issue is further complicated by the fact that in a drawing by 1000 people, we might get only 15 successes, and in another, perhaps 25 correct cards in 1000 draws. We can say that if you receive a radiation dose, you will have increased your chances of eventually developing cancer. It is assumed that the more radiation exposure you get, the more you increase your chances of cancer.

The normal chance of dying from cancer is about one in five for persons who have not received any occupational radiation dose. The additional chance of developing fatal cancer from an occupational exposure of 1 rem (0.01 Sv) is about the same as the chance of drawing any ace from a full deck of cards three times in a row. The additional chance of dying from cancer from an occupational exposure of 10 rem (0.1 Sv) is about equal to your chance of drawing two aces successively on the first two draws from a full deck of cards.

It is important to realize that these risk numbers are only estimates based on data for people and research animals exposed to high levels of radiation in short periods of time. There is still uncertainty with regard to estimates of radiation risk from low levels of exposure. Many difficulties are involved in designing research studies that can accurately measure the projected small increases in cancer cases that might be caused by low exposures to radiation as compared to the normal rate of cancer.

These estimates are considered by the NRC staff to be the best available for the worker to use to make an informed decision concerning acceptance of the risks associated with exposure to radiation. A worker who decides to accept this risk should try to keep exposure to radiation as low as is reasonably achievable (ALARA) to avoid unnecessary risk.

9. If I receive a radiation dose that is within occupational limits, will it cause me to get cancer?

Probably not. Based on the risk estimates previously discussed, the risk of cancer from doses below the occupational limits is believed to be small. Assessment of the cancer risks that may be associated with low doses of radiation are projected from data available at doses larger than 10 rems (0.1 Sv) (Ref. 3). For radiation protection purposes, these estimates are made using the straight line portion of the linear quadratic model (Curve 2 in Figure 1). We have data on cancer probabilities only for high doses, as shown by the solid line in Figure 1. Only in studies involving radiation doses above occupational limits are there dependable determinations of the risk of cancer, primarily because below the limits the effect is small compared to differences in the normal cancer incidence from year to year and place to place. The ICRP, NCRP, and other standards-setting organizations assume for radiation protection purposes that there is some risk, no matter how small the dose (Curves 1 and 2). Some scientists believe that the risk drops off to zero at some low dose (Curve 3), the threshold effect. The ICRP and NCRP endorse the linear quadratic model as a conservative means of assuring safety (Curve 2).

For regulatory purposes, the NRC uses the straight line portion of Curve 2, which shows the number of effects decreasing linearly as the dose decreases. Because the scientific evidence does not conclusively demonstrate whether there is or is not an effect at low doses, the NRC assumes for radiation protection purposes, that even small doses have some chance of causing cancer. Thus, a principle of radiation protection is to do more than merely meet the allowed regulatory limits; doses should be kept as low as is reasonably achievable (ALARA). This is as true for natural carcinogens such as sunlight and natural radiation as it is for those that are manmade, such as cigarette smoke, smog, and x-rays.

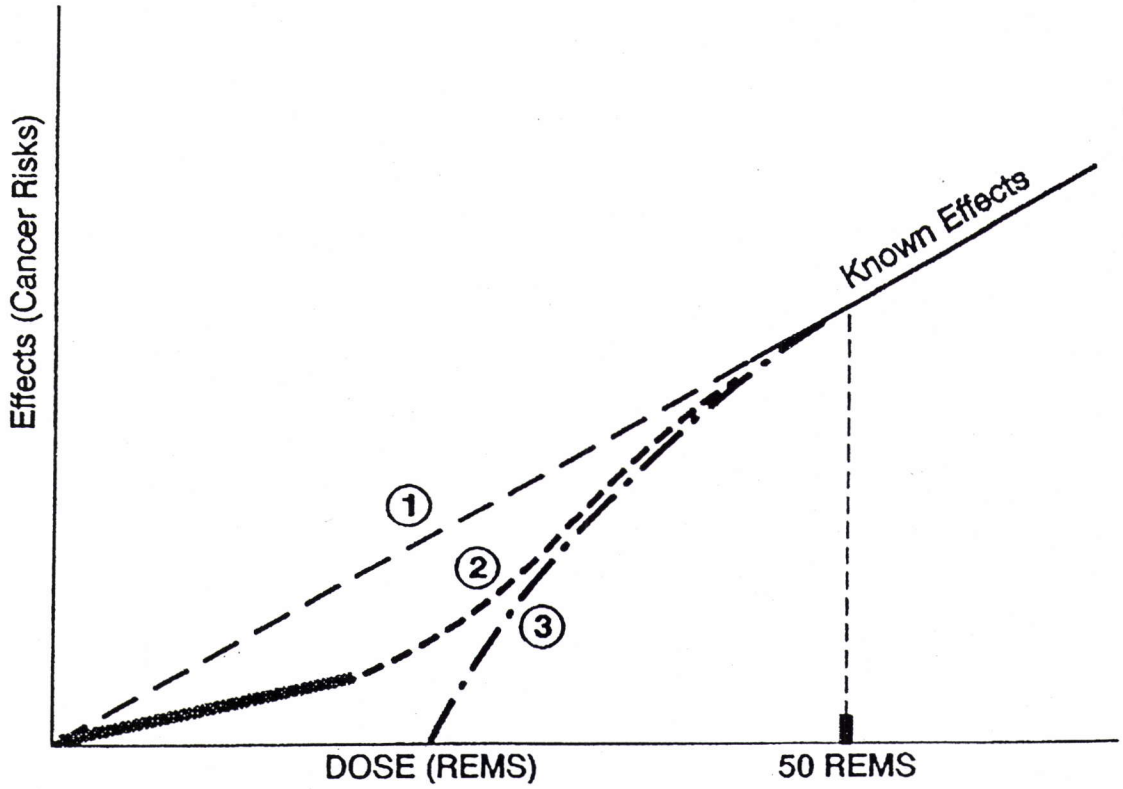

Figure 1. Some Proposed Models for How the Effects of Radiation Vary With Doses at Low Levels

10. How can we compare the risk of cancer from radiation to other kinds of health risks?

One way to make these comparisons is to compare the average number of days of life expectancy lost because of the effects associated with each particular health risk. Estimates are calculated by looking at a large number of persons, recording the age when death occurs from specific causes, and estimating the average number of days of life lost as a result of these early deaths. The total number of days of life lost is then averaged over the total observed group.

Several studies have compared the average days of life lost from exposure to radiation with the number of days lost as a result of being exposed to other health risks. The word "average" is important because an individual who gets cancer loses about 15 years of life expectancy, while his or her coworkers do not suffer any loss.

Some representative numbers are presented in Table 1. For categories of NRC-regulated industries with larger doses, the average measurable occupational dose in 1993 was 0.31 rem (0.0031 Sv). A simple calculation based on the article by Cohen and Lee (Ref. 10) shows that 0.3 rem (0.003 Sv) per year from age 18 to 65 results in an average loss of 15 days. These estimates indicate that the health risks from occupational radiation exposure are smaller than the risks associated with many other events or activities we encounter and accept in normal day-to-day activities.

It is also useful to compare the estimated average number of days of life lost from occupational exposure to radiation with the number of days lost as a result of working in several types of industries. Table 2 shows average days of life expectancy lost as a result of fatal work-related accidents. Table 2 does not include non-accident types of occupational risks such as occupational disease and stress because the data are not available.

These comparisons are not ideal because we are comparing the possible effects of chronic exposure to radiation to different kinds of risk such as accidental death, in which death is inevitable if the event occurs. This is the best we can do because good data are not available on chronic exposure to other workplace carcinogens. Also, the estimates of loss of life expectancy for workers from radiation-induced cancer do not take into consideration the competing effect on the life expectancy of the workers from industrial accidents.

11. What are the health risks from radiation exposure to the embryo/fetus?

During certain stages of development, the embryo/fetus is believed to be more sensitive to radiation damage than adults. Studies of atomic bomb survivors exposed to acute radiation doses exceeding 20 rads (0.2 Gy) during pregnancy show that children born after receiving these doses have a higher risk of mental retardation. Other studies suggest that an association exists between exposure to diagnostic x-rays before birth and carcinogenic effects in childhood and in adult life. Scientists are uncertain about the magnitude of the risk. Some studies show the embryo/fetus to be more sensitive to radiation-induced cancer than adults, but other studies do not. In recognition of the possibility of increased radiation sensitivity, and because dose to the

Table 1 Estimated Loss of Life Expectancy from Health Risks[a]

Health Risk		*Estimate of Life Expectancy Lost (average)*
Smoking 20 cigarettes a day		6 years
Overweight (by 15%)		2 years
Alcohol consumption (U.S. average)		1 year
All accidents combined		1 year
Motor vehicle accidents	207 days	
Home accidents	74 days	
Drowning	24 days	
All natural hazards (earthquake, lightning, flood, etc.)		7 days
Medical radiation		6 days
Occupational Exposure		
0.3 rem/y from age 18 to 65	15 days	
1 rem/y from age 18 to 65	51 days	

[a]Adapted from Reference 10.

Table 2 Estimated Loss of Life Expectancy from Industrial Accidents[a]

Industry Type	*Estimated Days of Life Expectancy Lost (Average)*
All industries	60
Agriculture	320
Construction	227
Mining and Quarrying	167
Transportation and Public Utilities	160
Government	60
Manufacturing	40
Trade	27
Services	27

[a]Adapted from Reference 10.

embryo/fetus is involuntary on the part of the embryo/fetus, a more restrictive dose limit has been established for the embryo/fetus of a declared pregnant radiation worker. See Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure."

If an occupationally exposed woman declares her pregnancy in writing, she is subject to the more restrictive dose limits for the embryo/fetus during the remainder of the pregnancy. The dose limit of 500 mrems (5 mSv) for the total gestation period applies to the embryo/fetus and is controlled by restricting the exposure to the declared pregnant woman. Restricting the woman's occupational exposure, if she declares her pregnancy, raises questions about individual privacy rights, equal employment opportunities, and the possible loss of income. Because of these concerns, the declaration of pregnancy by a female radiation worker is voluntary. Also, the declaration of pregnancy can be withdrawn for any reason, for example, if the woman believes that her benefits from receiving the occupational exposure would outweigh the risk to her embryo/fetus from the radiation exposure.

12. Can a worker become sterile or impotent from normal occupational radiation exposure?

No. Temporary or permanent sterility cannot be caused by radiation at the levels allowed under NRC's occupational limits. There is a threshold below which these effects do not occur. Acute doses on the order of 10 rems (0.1 Sv) to the testes can result in a measurable but temporary reduction in sperm count. Temporary sterility (suppression of ovulation) has been observed in women who have received acute doses of 150 rads (1.5 Gy). The estimated threshold (acute) radiation dose for induction of permanent sterility is about 200 rads (2 Gy) for men and about 350 rads (3.5 Gy) for women (Refs. 1 and 4). These doses are far greater than the NRC s occupational dose limits for workers.

Although acute doses can affect fertility by reducing sperm count or suppressing ovulation, they do not have any direct effect on one's ability to function sexually. No evidence exists to suggest that exposures within the NRC's occupational limits have any effect on the ability to function sexually.

13. What are the NRC occupational dose limits?

For adults, an annual limit that does not exceed:

- 5 rems (0.05 Sv) for the total effective dose equivalent (TEDE), which is the sum of the deep dose equivalent (DDE) from external exposure to the whole body and the committed effective dose equivalent (CEDE) from intakes of radioactive material.
- 50 rems (0.5 Sv) for the total organ dose equivalent (TODE), which is the sum of the DDE from external exposure to the whole body and the committed dose equivalent (CDE) from intakes of radioactive material to any individual organ or tissue, other than the lens of the eye.
- 15 rems (0.15 Sv) for the lens dose equivalent (LDE), which is the external dose to the lens of the eye.
- 50 rems (0.5 Sv) for the shallow dose equivalent (SDE), which is the external dose to the skin or to any extremity.

For minor workers, the annual occupational dose limits are 10 percent of the dose limits for adult workers.

For protection of the embryo/fetus of a declared pregnant woman, the dose limit is 0.5 rem (5 mSv) during the entire pregnancy.

The occupational dose limit for adult workers of 5 rems (0.05 Sv) TEDE is based on consideration of the potential for delayed biological effects. The 5-rem (0.05 Sv) limit, together with application of the concept of keeping occupational doses ALARA, provides a level of risk of delayed effects considered acceptable by the NRC. The limits for individual organs are below the dose levels at which early biological effects are observed in the individual organs.

The dose limit for the embryo/fetus of a declared pregnant woman is based on a consideration of the possibility of greater sensitivity to radiation of the embryo/fetus and the involuntary nature of the exposure.

14. What is meant by ALARA?

ALARA means "as low as is reasonably achievable." In addition to providing an upper limit on an individual's permissible radiation dose, the NRC requires that its licensees establish radiation protection

programs and use procedures and engineering controls to achieve occupational doses, and doses to the public, as far below the limits as is reasonably achievable. "Reasonably achievable" also means "to the extent practicable." What is practicable depends on the purpose of the job, the state of technology, the costs for averting doses, and the benefits. Although implementation of the ALARA principle is a required integral part of each licensee's radiation protection program, it does not mean that each radiation exposure must be kept to an absolute minimum, but rather that "reasonable" efforts must be made to avert dose. In practice, ALARA includes planning tasks involving radiation exposure so as to reduce dose to individual workers and the work group.

There are several ways to control radiation doses, e.g., limiting the time in radiation areas, maintaining distance from sources of radiation, and providing shielding of radiation sources to reduce dose. The use of engineering controls, from the design of facilities and equipment to the actual set-up and conduct of work activities, is also an important element of the ALARA concept.

An ALARA analysis should be used in determining whether the use of respiratory protection is advisable. In evaluating whether or not to use respirators, the goal should be to achieve the optimal sum of external and internal doses. For example, the use of respirators can lead to increased work time within radiation areas, which increases external dose. The advantage of using respirators to reduce internal exposure must be evaluated against the increased external exposure and related stresses caused by the use of respirators. Heat stress, reduced visibility, and reduced communication associated with the use of respirators could expose a worker to far greater risks than are associated with the internal dose avoided by use of the respirator. To the extent practical, engineering controls, such as containments and ventilation systems, should be used to reduce workplace airborne radioactive materials.

15. What are background radiation exposures?

The average person is constantly exposed to ionizing radiation from several sources. Our environment and even the human body contain naturally occurring radioactive materials (e.g., potassium-40) that contribute to the radiation dose that we receive. The largest source of natural background radiation exposure is terrestrial radon, a colorless, odorless, chemically inert gas, which causes about 55 percent of our average, nonoccupational exposure. Cosmic radiation originating in space contributes additional exposure. The use of x-rays and radioactive materials in medicine and dentistry adds to our population exposure. As shown below in Table 3, the average person receives an annual radiation dose of about 0.36 rem (3.6 mSv). By age 20, the average person will accumulate over 7 rems (70 mSv) of dose. By age 50, the total dose is up to 18 rems (180 mSv). After 70 years of exposure this dose is up to 25 rems (250 mSv).

Table 3 Average Annual Effective Dose Equivalent to Individuals in the U.S.[a]

Source	*Effective Dose Equivalent (mrems)*	
Natural		
Radon	200	
Other than Radon	100	
Total		300
Nuclear Fuel Cycle		0.05
Consumer Products[b]		9
Medical		
Diagnostic X-rays	39	
Nuclear Medicine	14	
Total		53
Total		about 360 mrems/year

[a]Adapted from Table 8.1, NCRP 93 (Ref. 11).

[b]Includes building material, television receivers, luminous watches, smoke detectors, etc. (from Table 5.1, NCRP 93, Ref. 11).

16. What are the typical radiation doses received by workers?

For 1993, the NRC received reports on about a quarter of a million people who were monitored for occupational exposure to radiation. Almost half of those monitored had no measurable doses. The other half had an average dose of about 310 mrem (3.1 mSv) for the year. Of these, 93 percent received an annual dose of less than 1 rem (10 mSv); 98.7 percent received less than 2 rems (20 mSv); and the highest reported dose was for two individuals who each received between 5 and 6 rems (50 and 60 mSv).

Table 4 lists average occupational doses for workers (persons who had measurable doses) in various occupations based on 1993 data. It is important to note that beginning in 1994, licensees have been required to sum external and internal doses and certain licensees are required to submit annual reports. Certain types of licensees such as nuclear fuel fabricators may report a significant increase in worker doses because of the exposure to long-lived airborne radionuclides and the requirement to add the resultant internal dose to the calculation of occupational doses.

Table 4 Reported Occupational Doses for 1993[a]

Occupational Subgroup	Average Measurable Dose per Worker (millirems)
Industrial Radiography	540
Commercial Nuclear Power Reactors	310
Manufacturing and Distribution of Radioactive Materials	300
Low-Level Radioactive Waste Disposal	270
Independent Spent Nuclear Fuel Storage	260
Nuclear Fuel Fabrication	130

[a]From Table 3.1 in NUREG–0713 (Ref. 9).

17. How do I know how much my occupational dose (exposure) is?

If you are likely to receive more than 10 percent of the annual dose limits, the NRC requires your employer, the NRC licensee, to monitor your dose, to maintain records of your dose, and, at least on an annual basis for the types of licensees listed in 10 CFR 20.2206, "Reports of Individual Monitoring," to inform both you and the NRC of your dose. The purpose of this monitoring and reporting is so that the NRC can be sure that licensees are complying with the occupational dose limits and the ALARA principle.

External exposures are monitored by using individual monitoring devices. These devices are required to be used if it appears likely that external exposure will exceed 10 percent of the allowed annual dose, i.e., 0.5 rem (5 mSv). The most commonly used monitoring devices are film badges, thermoluminescence dosimeters (TLDs), electronic dosimeters, and direct reading pocket dosimeters.

With respect to internal exposure, your employer is required to monitor your occupational intake of radioactive material and assess the resulting dose if it appears likely that you will receive greater than 10 percent of the annual limit on intake (ALI) from intakes in 1 year. Internal exposure can be estimated by measuring the radiation emitted from the body (for example, with a "whole body counter") or by measuring the radioactive materials contained in biological samples such as urine or feces. Dose estimates can also be made if one knows how much radioactive material was in the air and the length of time during which the air was breathed.

18. What happens if a worker exceeds the annual dose limit?

If a worker receives a dose in excess of any of the annual dose limits, the regulations prohibit any occupational exposure during the remainder of the year in which the limit is exceeded. The licensee is also required to file an overexposure report with the NRC and provide a copy to the individual who received the dose. The licensee may be subject to NRC enforcement action such as a fine (civil penalty), just as individuals are subject to a traffic fine for exceeding a speed limit. The fines and, in some serious or repetitive cases, suspension of a license are intended to encourage licensees to comply with the regulations.

Radiation protection limits do not define safe or unsafe levels of radiation exposure. Exceeding a limit does not mean that you will get cancer. For radiation protection purposes, it is assumed that risks are related to the size of the radiation dose. Therefore, when your dose is higher your risk is also considered to be higher. These limits are similar to highway speed limits. If you drive at 70 mph, your risk is higher than at 55 mph, even though you may not actually have an accident. Those who set speed limits have determined that the risks of driving in excess of the speed limit are not acceptable. In the same way, the revised 10 CFR Part 20 establishes a limit for normal occupational exposure of 5 rems (0.05 Sv) a year. Although you will not necessarily get cancer or some other radiation effect at doses above the limit, it does mean that the licensee's safety program has failed in some way. Investigation is warranted to determine the cause and correct the conditions leading to the dose in excess of the limit.

19. What is meant by a "planned special exposure"?

A "planned special exposure" (PSE) is an infrequent exposure to radiation, separate from and in addition to the radiation received under the annual occupational limits. The licensee can authorize additional dose in any one year that is equal to the annual occupational dose limit as long as the individual's total dose from PSEs does not exceed five times the annual dose limit during the individual's lifetime. For example, licensees may authorize PSEs for an adult radiation worker to receive doses up to an additional 5 rems (0.05 Sv) in a year above the 5-rem (0.05–Sv) annual TEDE occupational dose limit. Each worker is limited to no more than 25 rems (0.25 Sv) from planned special exposures in his or her lifetime. Such exposures are only allowed in exceptional situations when alternatives for avoiding the additional exposure are not available or are impractical.

Before the licensee authorizes a PSE, the licensee must ensure that the worker is informed of the purpose and circumstances of the planned operation, the estimated doses expected, and the procedures to keep the doses ALARA while considering other risks that may

be present. (See Regulatory Guide 8.35, "Planned Special Exposures.")

20. Why do some facilities establish administrative control levels that are below the NRC limits?

There are two reasons. First, the NRC regulations state that licensees must take steps to keep exposures to radiation ALARA. Specific approval from the licensee for workers to receive doses in excess of administrative limits usually results in more critical risk-benefit analyses as each additional increment of dose is approved for a worker. Secondly, an administrative control level that is set lower than the NRC limit provides a safety margin designed to help the licensee avoid doses to workers in excess of the limit.

21. Why aren't medical exposures considered as part of a worker's allowed dose?

NRC rules exempt medical exposure, but equal doses of medical and occupational radiation have equal risks. Medical exposure to radiation is justified for reasons that are quite different from the reasons for occupational exposure. A physician prescribing an x-ray, for example, makes a medical judgment that the benefit to the patient from the resulting medical information justifies the risk associated with the radiation. This judgment may or may not be accepted by the patient. Similarly, each worker must decide on the benefits and acceptability of occupational radiation risk, just as each worker must decide on the acceptability of any other occupational hazard.

Consider a worker who receives a dose of 3 rems (0.03 Sv) from a series of x-rays in connection with an injury or illness. This dose and any associated risk must be justified on medical grounds. If the worker had also received 2 rems (0.02 Sv) on the job, the combined dose of 5 rems (0.05 Sv) would in no way incapacitate the worker. Restricting the worker from additional job exposure during the remainder of the year would not have any effect on the risk from the 3 rems (0.03 Sv) already received from the medical exposure. If the individual worker accepts the risks associated with the x-rays on the basis of the medical benefits and accepts the risks associated with job-related exposure on the basis of employment benefits, it would be unreasonable to restrict the worker from employment involving exposure to radiation for the remainder of the year.

22. How should radiation risks be considered in an emergency?

Emergencies are "unplanned" events in which actions to save lives or property may warrant additional doses for which no particular limit applies. The revised 10 CFR Part 20 does not set any dose limits for emergency or lifesaving activities and states that nothing in Part 20 "shall be construed as limiting actions that may be necessary to protect health and safety."

Rare situations may occur in which a dose in excess of occupational limits would be unavoidable in order to carry out a lifesaving operation or to avoid a large dose to large populations. However, persons called upon to undertake any emergency operation should do so only on a voluntary basis and with full awareness of the risks involved.

For perspective, the Environmental Protection Agency (EPA) has published emergency dose guidelines (Ref. 2). These guidelines state that doses to all workers during emergencies should, to the extent practicable, be limited to 5 rems (0.05 Sv). The EPA further states that there are some emergency situations for which higher limits may be justified. The dose resulting from such emergency exposures should be limited to 10 rems (0.1 Sv) for protecting valuable property, and to 25 rems (0.25 Sv) for lifesaving activities and the protection of large populations. In the context of this guidance, the dose to workers that is incurred for the protection of large populations might be considered justified for situations in which the collective dose to others that is avoided as a result of the emergency operation is significantly larger than that incurred by the workers involved.

Table 5 presents the estimates of the fatal cancer risk for a group of 1,000 workers of various ages, assuming that each worker received an acute dose of 25 rems (0.25 Sv) in the course of assisting in an emergency. The estimates show that a 25-rem emergency dose might increase an individual's chances of developing fatal cancer from about 20% to about 21%.

Table 5
Risk of Premature Death from Exposure to 25-Rems (0.25-Sv) Acute Dose

Age at Exposure (years)	*Estimated Risk of Premature Death (Deaths per 1,000 Persons Exposed)*
20–30	9.1
30–40	7.2
40–50	5.3
50–60	3.5

Source: EPA-400-R-92-001 (Ref. 2).

23. How were radiation dose limits established?

The NRC radiation dose limits in 10 CFR Part 20 were established by the NRC based on the recommendations of the ICRP and NCRP as endorsed in Federal radiation protection guidance developed by the EPA

(Ref. 12). The limits were recommended by the ICRP and NCRP with the objective of ensuring that working in a radiation-related industry was as safe as working in other comparable industries. The dose limits and the principle of ALARA should ensure that risks to workers are maintained indistinguishable from risks from background radiation.

24. Several scientific reports have recommended that the NRC establish lower dose limits. Does the NRC plan to reduce the regulatory limits?

Since publication of the NRC's proposed rule in 1986, the ICRP in 1990 revised its recommendations for radiation protection based on newer studies of radiation risks (Ref. 13), and the NCRP followed with a revision to its recommendations in 1993. The ICRP recommended a limit of 10 rems (0.1 Sv) effective dose equivalent (from internal and external sources), over a 5-year period with no more than 5 rems (0.05 Sv) in 1 year (Ref. 13). The NCRP recommended a cumulative limit in rems, not to exceed the individual's age in years, with no more than 5 rems (0.05 Sv) in any year (Ref. 14).

The NRC does not believe that additional reductions in the dose limits are required at this time. Because of the practice of maintaining radiation exposures ALARA (as low as is reasonably achievable), the average radiation dose to occupationally exposed persons is well below the limits in the current Part 20 that became mandatory January 1, 1994, and the average doses to radiation workers are below the new limits recommended by the ICRP and the NCRP.

25. What are the options if a worker decides that the risks associated with occupational radiation exposure are too high?

If the risks from exposure to occupational radiation are unacceptable to a worker, he or she can request a transfer to a job that does not involve exposure to radiation. However, the risks associated with the exposure to radiation that workers, on the average, actually receive are comparable to risks in other industries and are considered acceptable by the scientific groups that have studied them. An employer is not obligated to guarantee a transfer if a worker decides not to accept an assignment that requires exposure to radiation.

Any worker has the option of seeking other employment in a nonradiation occupation. However, the studies that have compared occupational risks in the nuclear industry to those in other job areas indicate that nuclear work is relatively safe. Thus, a worker may find different kinds of risk but will not necessarily find significantly lower risks in another job.

26. Where can one get additional information on radiation risk?

The following list suggests sources of useful information on radiation risk:

- The employer—the radiation protection or health physics office where a worker is employed.
- Nuclear Regulatory Commission Regional Offices:

King of Prussia, Pennsylvania	(610) 337-5000
Atlanta, Georgia	(404) 331-4503
Lisle, Illinois	(708) 829-9500
Arlington, Texas	(817) 860-8100

- U.S. Nuclear Regulatory Commission
  Headquarters
  Radiation Protection & Health Effects Branch
  Office of Nuclear Regulatory Research
  Washington, DC 20555
  Telephone: (301) 415-6187
- Department of Health and Human Services
  Center for Devices and Radiological Health
  1390 Piccard Drive, MS HFZ-1
  Rockville, MD 20850
  Telephone: (301) 443-4690
- U.S. Environmental Protection Agency
  Office of Radiation and Indoor Air
  Criteria and Standards Division
  401 M Street NW.
  Washington, DC 20460
  Telephone: (202) 233-9290

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*Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202) 634-3273; fax (202) 634-3343. Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202) 512-2249); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.

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[2]Single copies of regulatory guides may be obtained free of charge by writing the Office of Administration, Attn: Distribution and Services Section, USNRC, Washington, DC 20555, or by fax at (301) 415-2260. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555-0001; telephone (202) 634-3273; fax (202) 634-3343.

NRC FORM 3
(5-2005)
Part 1

UNITED STATES NUCLEAR REGULATORY COMMISSION
Washington, DC 20555-0001

NOTICE TO EMPLOYEES

STANDARDS FOR PROTECTION AGAINST RADIATION (PART 20); NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS (PART 19); EMPLOYEE PROTECTION

WHAT IS THE NUCLEAR REGULATORY COMMISSION?

The Nuclear Regulatory Commission is an independent Federal regulatory agency responsible for licensing and inspecting nuclear power plants and other commercial uses of radioactive materials.

WHAT DOES THE NRC DO?

The NRC's primary responsibility is to ensure that workers and the public are protected from unnecessary or excessive exposure to radiation and that nuclear facilities, including power plants, are constructed to high quality standards and operated in a safe and secure manner. The NRC does this by establishing requirements in Title 10 of the Code of Federal Regulations (10 CFR) and in licenses issued to nuclear users.

WHAT RESPONSIBILITY DOES MY EMPLOYER HAVE?

Any company that conducts activities licensed by the NRC must comply with the NRC's requirements. If a company violates NRC requirements, it can be fined or have its license modified, suspended or revoked.

Your employer must tell you which NRC radiation requirements apply to your work and must post NRC Notices of Violation involving radiological working conditions.

WHAT IS MY RESPONSIBILITY?

For your own protection and the protection of your co-workers, you should know how NRC requirements relate to your work and should obey them. If you observe violations of the requirements or have a safety concern, you should report them.

WHAT IF I CAUSE A VIOLATION?

If you engaged in deliberate misconduct that may cause a violation of the NRC requirements or would have caused a violation if it had not been detected, or deliberately provided inaccurate or incomplete information to either the NRC or to your employer, you may be subject to enforcement action. If you report such a violation, the NRC will consider the circumstances surrounding your reporting in determining the appropriate enforcement action, if any.

HOW DO I REPORT VIOLATIONS AND SAFETY CONCERNS?

If you believe that violations of NRC rules or the terms of the license have occurred, or if you have a safety concern, you should report them immediately to your supervisor. You may report violations or safety concerns directly to the NRC. However, the NRC encourages you to raise your concerns with the licensee since it is the licensee who has the primary responsibility for, and is most able to ensure, safe operation of nuclear facilities. If you choose to report your concern directly to the NRC, you may report this to an NRC inspector or call or write to the NRC Regional Office serving your area. If you send your concern in writing, it will assist the NRC in protecting your identity if you clearly state in the beginning of your letter that you have a safety concern or that you are submitting an allegation. The NRC's toll-free SAFETY HOTLINE for reporting safety concerns is listed below. The addresses for the NRC Regional Offices and the toll-free telephone numbers are also listed below. You can also e-mail safety concerns to allegation@nrc.gov.

WHAT IF I WORK WITH RADIOACTIVE MATERIAL OR IN THE VICINITY OF A RADIOACTIVE SOURCE?

If you work with radioactive materials or near a radiation source, the amount of radiation exposure that you are permitted to receive may be limited by NRC regulations. The limits on exposure for workers at NRC licensed facilities whose duties involve exposure to radiation are contained in sections 20.1201, 20.1207, and 20.1208 of Title 10 of the Code of Federal Regulations (10 CFR 20) depending on the part of the regulations to which your employer is subject. While these are the maximum allowable limits, your employer should also keep your radiation exposure as far below those limits as is "reasonably achievable."

MAY I GET A RECORD OF MY RADIATION EXPOSURE?

Yes. Your employer is required to advise you of your dose annually if you are exposed to radiation for which monitoring was required by NRC. In addition, you may request a written report of your exposure when you leave your job.

HOW ARE VIOLATIONS OF NRC REQUIREMENTS IDENTIFIED?

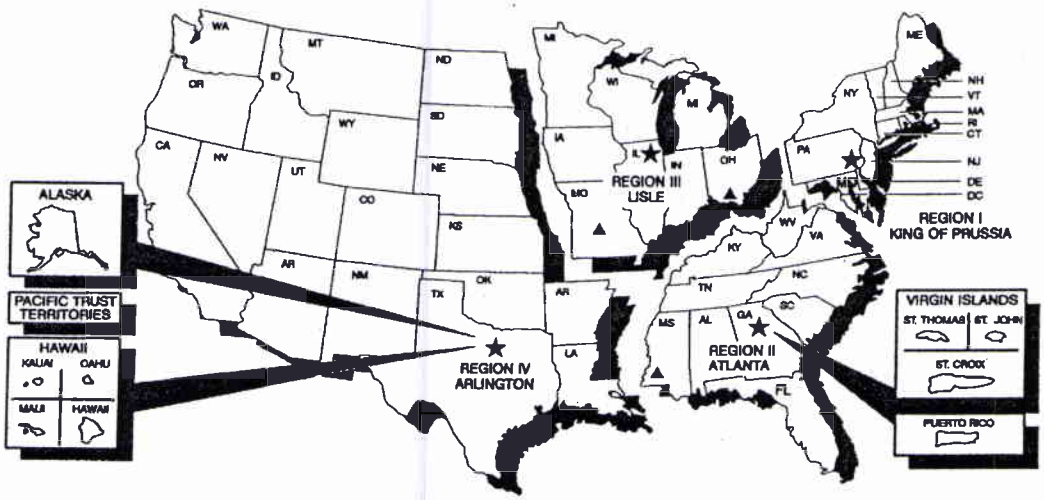
NRC conducts regular inspections at licensed facilities to assure compliance with NRC requirements. In addition, your employer and site contractors may conduct their own inspections to assure compliance. All inspectors are protected by Federal law. Interference with them may result in criminal prosecution for a Federal offense.

MAY I TALK WITH AN NRC INSPECTOR?

Yes. NRC inspectors want to talk to you if you are worried about radiation safety or have other safety concerns about licensed activities, such as the quality of construction or operations at your facility. Your employer may not prevent you from talking with an inspector. The NRC will make all reasonable efforts to protect your identity where appropriate and possible.

MAY I REQUEST AN INSPECTION?

Yes. If you believe that your employer has not corrected violations involving radiological working conditions, you may request an inspection. Your request should be addressed to the nearest NRC Regional Office and must describe the alleged violation in detail. It must be signed by you or your representative.



▲ - Callaway Plant Site in Missouri and Grand Gulf Plant Site in Mississippi are under the purview of Region IV. The Portsmouth Gaseous Diffusion Plant in Ohio is under the purview of Region II.

NRC FORM 3
5-2005)
Part 2

HOW DO I CONTACT THE NRC?

Talk to an NRC inspector on-site or call or write to the nearest NRC Regional Office in your geographical area (see map below). If you call the NRC's toll-free SAFETY HOTLINE during normal business hours, your call will automatically be directed to the NRC Regional Office for your geographical area. If you call after normal business hours, your call will be directed to the NRC's Headquarters Operations Center, which is manned 24 hours a day. You can also e-mail safety concerns to allegation@nrc.gov.

CAN I BE FIRED FOR RAISING A SAFETY CONCERN?

Federal law prohibits an employer from firing or otherwise discriminating against you for bringing safety concerns to the attention of your employer or the NRC. You may not be fired or discriminated against because you engage in certain protected activities, including but not limited to,

- ask the NRC to enforce its rules against your employer;
- refuse to engage in activities which violate NRC requirements:
- provide information or are about to provide information to the NRC or your employer about violations of requirements or safety concerns;
- are about to ask for, or testify, help, or take part in an NRC, Congressional, or any Federal or State proceeding.

WHAT FORMS OF DISCRIMINATION ARE PROHIBITED?

It is unlawful for an employer to fire you or discriminate against you with respect to pay, benefits, or working conditions because you help the NRC or raise a safety issue or otherwise engage in protected activities. Violations of Section 211 of the Energy Reorganization Act (ERA) of 1974 (42 U.S.C. 5851) include actions such as harassment, blacklisting, and intimidation by employers of (i) employees who bring safety concerns directly to their employers or to the NRC; (ii) employees who have refused to engage in an unlawful practice, provided that the employee has identified the illegality to the employer; (iii) employees who have testified or are about to testify before Congress or in any Federal or State proceeding regarding any provision (or proposed provision) of the ERA or the Atomic Energy Act (AEA) of 1954; (iv) employees who have commenced or caused to be commenced a proceeding for the administration or enforcement of any requirement imposed under the ERA or AEA or who have, or are about to, testify, assist, or participate in such a proceeding.

HOW DO I FILE A DISCRIMINATION COMPLAINT?

If you believe that you have been discriminated against for bringing violations or safety concerns to the NRC or your employer, you may file a complaint with the NRC, the U.S. Department of Labor (DOL), or appropriate state entities. If you desire a personal remedy, you must file a complaint with the DOL pursuant to Section 211 of the ERA or with appropriate state entities. Your complaint to the DOL must describe in detail the basis for your belief that the employer discriminated against you on the basis of your protected activity, and it must be filed in writing either in person or by mail within 180 days of the discriminatory occurrence. Additional information is available at the DOL web site at www.osha.gov. Filing an allegation, complaint, or request for action with the NRC does not extend the requirement to file a complaint with the DOL within 180 days. To do so, you may contact the Allegation Coordinator in the appropriate NRC Region, as listed below, who will provide you with the address and telephone number of the correct OSHA Regional office to receive your complaint. You may also check your local telephone directory under the U.S. Government listings for the address and telephone number of the appropriate OSHA Regional office.

WHAT CAN THE DEPARTMENT OF LABOR DO?

If your complaint involves a violation of Section 211 of the ERA by your employer, it is the DOL, NOT THE NRC, that provides the process for obtaining a personal remedy. The DOL will notify your employer that a complaint has been filed and will investigate your complaint.

If the DOL finds that your employer has unlawfully discriminated against you, it may order that you be reinstated, receive back pay, or be compensated for any injury suffered as a result of the discrimination and be paid attorney's fees and costs.

Relief will not be awarded to employees who engage in deliberate violations of the Energy Reorganization Act or the Atomic Energy Act.

WHAT WILL THE NRC DO?

The NRC will evaluate each allegation of harassment, intimidation, or discrimination to determine whether sufficient information exists to initiate an investigation. Following this evaluation, an investigator from the NRC's Office of Investigations may interview you and review available documentation. Based on the evaluation, and, if applicable, the interview, the NRC will assign a priority and a decision will be made whether to pursue the matter further through an investigation. The assigned priority is based on the specifics of the case. The NRC may not pursue an investigation of low priority cases to the point that a conclusion can be made whether the harassment, intimidation, or discrimination actually occurred. If you do not object, the NRC may refer lower priority cases to the involved licensee for a response and will request that the licensee independently review such issues. Even if NRC decides not to pursue an investigation, if you have filed a complaint with the DOL, the NRC will monitor the results of the DOL investigation.

If the NRC or the DOL finds that unlawful discrimination has occurred, the NRC may issue a Notice of Violation to your employer, impose a fine, or suspend, modify, or revoke your employer's NRC license.

UNITED STATES NUCLEAR REGULATORY COMMISSION REGIONAL OFFICE LOCATIONS

A representative of the Nuclear Regulatory Commission can be contacted by employees who wish to register complaints or concerns about radiological working conditions or other matters regarding compliance with Commission rules and regulations at the following addresses and telephone numbers.

REGIONAL OFFICES

REGION	ADDRESS	TELEPHONE
I	U.S. Nuclear Regulatory Commission, Region I 475 Allendale Road King of Prussia, PA 19406-1415	(800) 432-1156
II	U.S. Nuclear Regulatory Commission, Region II Sam Nunn Atlanta Federal Center 61 Forsyth Street, S.W., Suite 23T85 Atlanta, GA 30303-8931	(800) 577-8510
III	U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	(800) 522-3025
IV	U.S. Nuclear Regulatory Commission, Region IV 611 Ryan Plaza Drive, Suite 400 Arlington, TX 76011-4005	(800) 952-9677

To report safety concerns or violations of NRC requirements by your employer,

telephone:

NRC SAFETY HOTLINE

1-800-695-7403

To report incidents involving fraud, waste, or abuse by an NRC employee or NRC contractor,

telephone:

OFFICE OF THE INSPECTOR GENERAL

HOTLINE

1-800-233-3497

RADIONUCLIDE SAFETY DATA SHEET

NUCLIDE: I-125

FORMS: INORGANIC OR FREE IODINE

PHYSICAL CHARACTERISTICS:

HALF LIFE: 60 days

TYPE DECAY: e^- capture
Gamma rays: 0.035 MeV (7%)
X-rays: 0.027 – 0.031 MeV (140%)

Hazard Category: **C** - level (low hazard): 0.1 to 200 μ Ci
B - level (moderate hazard): >200 μ Ci to 10 mCi
A – level (high hazard): greater than 10 mCi

EXTERNAL RADIATION HAZARDS AND SHIELDING:

The exposure rate at 1 cm from a 1 mCi is 1.5 R/hr. (Exposure varies directly with activity and inversely with the square of the distance from the materials.)

Amount of lead required to reduce the exposure rate by a factor of 10 (1 TVL) is approximately 0.1 mm. 1/8 inch of glass would reduce the exposure rate by half. Leaded rubber gloves (0.1 mm lead = 1 TVL) are available from Health Physics.

HAZARDS IF INTERNALLY DEPOSITED:

Contamination on the skin or inhalation from air containing iodine vapors will result in internal deposition. Iodide solutions are easily oxidized and the elemental iodine will become airborne. About 70% of activity inhaled is deposited in the body and about 30% of that is deposited in the thyroid. Ingestion of 4 μ Ci, or inhalation of 6 μ Ci, would result in that glad's receiving Stanford's ALARA guideline, i.e., 5 rem.

Blocking the uptake of radioiodine with the stable nuclide is not permitted. WORK IN PROPER FUME HOODS. (See Radiation Safety Manual, Part III).

DOSIMETRY AND BIOASSAY REQUIREMENTS:

Film badges and dosimeter rings are usually required if 5 millicuries are handled at any one time or if millicurie levels are handled on a frequent (daily) basis.

Arrange for a thyroid survey within 24-48 hours after the first procedure; thereafter, every three months.

SPECIAL PROBLEMS AND PRECAUTIONS:

1. GM survey meters have a poor efficiency of detection for I^{125}. Survey by smear tests or use NaI (TI) Scintillation probes.
2. Segregate wastes to those with half-lives from 19 days to less than 65 days. Assume items in work areas are contaminated unless cleared with a NaI scintillation survey meter. Wrap all waste items in plastic bags prior to placing them in waste.
3. Limit of soluble wastes to the sewer is 100 μ Ci / month per lab.
4. Wear double gloves. Change gloves often.
5. See separate Radiation Safety Data Sheet for non-volatile or non-cleaving compounds.

ABNORMAL OCCURRENCES
IN FISCAL YEAR 2005

NUCLEAR POWER PLANTS

During this period, no events at U.S. nuclear power plants were significant enough to be reported as AOs.

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FUEL CYCLE FACILITIES
(Other Than Nuclear Power Plants)

During this period, no events at U.S. fuel cycle facilities were significant enough to be reported as AOs.

****

OTHER NRC LICENSEES
(Industrial Radiographers, Medical Institutions, etc.)

During this reporting period, three events at NRC-licensed or regulated facilities were significant enough to be reported as AOs based on the criteria in Appendix A to this report.

05-01 Medical Event at the University of Minnesota in Minneapolis, Minnesota

Criterion IV, "For Medical Licensees," of Appendix A to this report states, in part, that a medical event that results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and represents a prescribed dose or dosage that is delivered to the wrong treatment site will be considered for reporting as an AO.

Date and Place — January 24, 2005, Minneapolis, Minnesota

Nature and Probable Consequences — The licensee reported that a patient being treated for cervical cancer received an incorrect dose distribution. One area of the cervix received 8.21 Gy (821 rads) instead of the intended 16.43 Gy (1,643 rads). Another area of the cervix received 3.72 Gy (372 rads) instead of the intended 4.65 Gy (465 rads). Additionally, other locations received higher than intended doses. The intended doses to the bladder and the rectum were 11.47 Gy (1,147 rads) each, but they received 14.48 Gy (1,448 rads) and 20.12 Gy (2,012 rads), respectively. The treatment involved an applicator with an insert which contained low-dose radiotherapy sources. The licensee cut the insert 6 centimeters (cm) too short so that when the applicator was positioned in the patient's cervix, the three cesium-137 (Cs-137) sources were not extended the proper distance. The referring physician and patient were informed of this event. The licensee does not believe that this event will have any adverse health effects on the patient. The patient subsequently received a follow-up treatment to deliver the full intended dose to the treatment sites.

NHPP Frequently Asked Question 04-06
May 12, 2004

Question:

We plan to implement a permanent-implant prostate seed brachytherapy program at our medical center. What are the recommended guidelines?

Answer:

Background information

Permanent-implant prostate seed brachytherapy is used, alone or in conjunction with external beam radiation therapy to treat early stage cancer of the prostate. The goal for the brachytherapy is to achieve a specified dose to the prostate while avoiding excessive doses to nearby radiosensitive organs such as the rectum or the urethra, which pass through the prostate.

Permanent-implant prostate seed brachytherapy requires cooperation of the radiation oncology staff, including a radiation oncologist and a medical physicist, radiation safety staff, and usually an urologist. The radiation oncologist is usually the authorized user. Supporting staff includes anesthesiology and nursing.

The implantation procedure is typically performed in an operating room. The seeds are placed in the prostate, using long needles inserted through the perineum, under transrectal ultrasound (TRUS) guidance. In one common method, the seeds, separated by spacers, are loaded into needles before the procedure. A second method is to use a Mick Applicator® device to place seeds individually through a needle during the procedure. Fluoroscopy is often used in addition to TRUS to help determine needle and seed positions.

The dose prescribed by the authorized user is dependent upon whether the seed brachytherapy is to be used alone or in conjunction with external beam treatment. The prescribed dose is dependent upon the radionuclide as well, with a lower dose prescribed for ^{103}Pd, because of the shorter half-life and higher dose rate for ^{103}Pd. For a specific dose, the number of seeds and the total activity implanted vary with the volume of the prostate.

Radionuclides used

^{125}I $T_{1/2}$ = 60 days, electron capture decay, x and gamma rays from 27 to

35 keV, activity per seed 0.3 to 0.8 mCi

^{103}Pd $T_{1/2}$ = 17 days, electron capture decay, x rays from 20 to 23 keV,

activity per seed 1.0 to 1.5 mCi.

The strength of an individual seed can be specified by the quantity *air kerma strength*. The air kerma strength is the air kerma rate at a specified distance multiplied by the distance squared. The air kerma strength of a seed is determined by the total activity in the seed, the radionuclide, and attenuation by the seed itself. The common unit of strength is U = $\mu Gy\ m^2\ h^{-1} = cGy\ cm^2\ h^{-1}$. Alternatively, at least one vendor specifies the strength of an individual ^{125}I seed by the quantity *apparent activity*.

Regulatory requirements

The medical center permit must authorize the possession of ^{125}I and/or ^{103}Pd as sealed sources with a sufficient possession limit for the proposed brachytherapy procedures.

A broad-scope permit for medical uses usually has sufficient possession limits for ^{125}I and/or ^{103}Pd and does not require specific authorization listed in the permit for the radionuclides or for 35.400 uses. A limited-scope permit for medical uses must specifically authorize 35.400 uses and the authorized radionuclides by sealed source model and possession limits.

An authorized user for 35.400 uses must be approved. At a medical broad-scope permittee, the Radiation Safety Committee approves authorized users in writing. Otherwise, the authorized users must be named on the permit as authorized for 35.400 uses. For all permittees, 10 CFR 35.40 and 35.41 requires written directive procedures. These procedures are developed by the permittee and not submitted to the NHPP for approval.

An amendment request to add seed brachytherapy must provide the information specified in NUREG-1556, Volume 9.

When approved for seed brachytherapy, the medical center must comply with commitments and conditions in the medical center's permit and the Nuclear Regulatory Commission (NRC) regulations for ordering, receipt, use, storage, and disposal of the seeds. The medical center must comply with 10 CFR 35.75 for patient release. The medical center must dispose excess seeds by returning the seeds to the vendor, by decay-in-storage and discarding the seeds through an appropriate waste stream, or by

shipment to an authorized waste disposal site.

The medical center staff must recognize that non-VA personnel such as consultants and affiliated university staff physicians are not likely to be as familiar with permit or NRC requirements as the medical center staff. The medical center Radiation Safety Officer, Radiation Safety Committee, and executive management are responsible for oversight of seed brachytherapy.

Typical steps in permanent-implant prostate seed brachytherapy

1. Trans-rectal ultrasound (TRUS) imaging ("volume study") and preparation of the initial treatment plan and preparation of a seed loading worksheet. Note: The volume study is usually obtained no earlier than 2 or 3 weeks before the implantation procedure to minimize changes in the anatomy of the prostate. The authorized user physician must approve the initial treatment plan.

2. Seed ordering and receipt, with survey of the package per 10 CFR 20.1906.

3. Seed assay. Note: Assaying 10% of seeds recommended by the AAPM. Note: If seeds are obtained in pre-loaded, pre-sterilized needles, it may not be possible for the medical center to assay the seeds. In this case, records of the calibration of the seeds by the vendor must be obtained. These records must contain the information specified by 10 CFR 35.2432. Furthermore, documents must be obtained from the vendor to demonstrate the vendor's seed calibration complies with 10 CFR 35.432 and the vendor's calibration system complies with 10 CFR 35.630(a).

4. Seed and needle preparation and sterilization. Note: Seeds can be loaded into needles by the medical center or, alternatively, pre-loaded, pre-sterilized needles can be purchased. Needles are not loaded if a Mick Applicator® is used.

5. Patient preparation in operating room. Note: The patient's identity must be verified.

6. TRUS and treatment planning just before seed implantation are performed at some institutions.

7. Comparison of prostate anatomy on TRUS images with initial treatment plan.

8. Preparation of first part of the written directive.

9. Seed implantation under TRUS guidance. Note: Intraoperative (real time) dosimetric calculations may be done. Fluoroscopy is used at many institutions to help verify needle position.

10. Cystoscopy for seeds misplaced into the bladder. Note: Some facilities, with experience, achieve a level of competence whereby they do not find seeds in the bladder and discontinue routine cystoscopy.

11. Acquisition of a radiographic image to document the position of the seeds.

12. Completion of second part of written directive.

13. Operating room radiation survey including trash and linens for misplaced seeds and count of excess seeds. All persons leaving the room should be surveyed for misplaced seeds.

14. Patient release radiation survey and patient instructions per 10 CFR 35.75 and NUREG-1556, Volume 9, Appendix U.

15. Recording the number of unused and recovered seeds returned to storage. Note: The individual seeds should be counted.

16. Shipping excess seeds or storing for decay. Note: If excess seeds are shipped, they are typically not shipped after each procedure. Instead, excess seeds are collected from several procedures and shipped back to the vendor together.

17. CT scan of patient and post plan, with dose volume histogram.

Manufacturers and models of prostate seeds

The *Joint AAPM/RPC Registry of Low-Energy Brachytherapy Seeds* lists models of seeds meeting the AAPM dosimetric prerequisites. The list is located at the URL: http://rpc.mdanderson.org/rpc/htm/Home_htm/Low-energy.htm.

Guidelines, standards, and textbooks

ACR Practice Guideline for Transperineal Permanent Brachytherapy of Prostate Cancer

AAPM Report No. 68, *Permanent Prostate Seed Implant Brachytherapy* (TG64)

Khan FM. *Prostate Implants*, in The Physics of Radiation Therapy, 3rd Ed, 2003, Lippincott Williams and Wilkins, 539-547

NRC regulations for prostate brachytherapy:

10 CFR 35.40 (written directives) Note: The written directive has two parts, one written

before seed implantation and the other written after seed implantation, but before completion of the procedure.

10 CFR 35.40 (written procedures for written directives, check of manual and computer-generated dose calculations, patient identity verification, and verification that the administration is in accordance with treatment plan and written directive).

10 CFR 35.75, 35.2075(a) (patient release). NUREG-1556, Vol. 9, Appendix U, contains guidance on patient release. If patient release is based upon the measured radiation level at a specified distance from the patient, the energy response of the survey instrument must be taken into account. Survey instruments are commonly calibrated with ^{137}Cs (662 keV gamma rays) and may significantly under-respond to the low energy photons emitted by ^{125}I and ^{103}Pd seeds.

10 CFR 35.400 (sources that may be used).

10 CFR 35.404, 2404 (surveys after source implantation).

10 CFR 35.406, 2046 (source accountability).

10 CFR 35.432, 2432 (calibration measurements of sources). A system used to calibrate sources (seeds) must meet the requirements of 35.630(a).

10 CFR 35.457 (testing of treatment planning computer system).

10 CFR 35.490, 35.59 (training and experience requirements for authorized user physicians).

rcl — CJA

return to JM for Filing

U.S. NUCLEAR REGULATORY COMMISSION

April 1997

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 8.39

(Draft was DG–8015)

RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS

A. INTRODUCTION

Section 35.75, "Release of Individuals Containing Radiopharmaceuticals or Permanent Implants," in 10 CFR Part 35, "Medical Use of Byproduct Material," permits licensees to "authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem)."

Further, 10 CFR 35.75(b) requires that the licensee "provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include (1) guidance on the interruption or discontinuation of breast-feeding and (2) information on the consequences of failure to follow the guidance."

In addition, 10 CFR 35.75(c) requires that the licensee "maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the total effective dose equivalent is calculated by (1) using the retained activity rather than the activity administered, (2) using an occupancy factor less than 0.25 at 1 meter, (3) using the biological or effective half-life, or (4) considering the shielding by tissue."

In 10 CFR 35.75(d), the licensee is required to "maintain a record, for 3 years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem)."

In this guide, the individual to whom the radioactive material has been administered is called the "patient."

This guide provides guidance to the licensee on determining (1) when the licensee may authorize the release of a patient who has been administered radiopharmaceuticals or permanent implants containing radioactive material, (2) when instructions to the patient are required by 10 CFR 35.75(b), and (3) when records are required by 10 CFR 35.75(c) and (d) to be generated and maintained. The guide lists activities for commonly used radionuclides and their corresponding dose rates with which a patient may be released in compliance with the dose limits in 10 CFR 35.75.

USNRC REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the Commission's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the NRC staff in its review of applications for permits and licenses. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public. Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience.

Written comments may be submitted to the Rules Review and Directives Branch, DFIPS, ADM, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

The guides are issued in the following ten broad divisions:

1. Power Reactors
2. Research and Test Reactors
3. Fuels and Materials Facilities
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5. Materials and Plant Protection
6. Products
7. Transportation
8. Occupational Health
9. Antitrust and Financial Review
10. General

Single copies of regulatory guides may be obtained free of charge by writing the Office of Administration, Attention: Distribution and Mail Services Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; or by fax at (301)415–2260.

Issued guides may also be purchased from the National Technical Information Service on a standing order basis. Details on this service may be obtained by writing NTIS, 5285 Port Royal Road, Springfield, VA 22161.

The information collections contained in this regulatory guide are covered by the requirements in 10 CFR Part 35, which were approved by the Office of Management and Budget, approval number 3150-0010. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

B. DISCUSSION

The activities at which patients could be released were calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides" (Ref. 1).

NCRP Report No. 37 uses the following equation to calculate the exposure until time t at a distance r from the patient:

$$D(t) = \frac{34.6\,\Gamma\,Q_0\,T_p\,(1 - e^{-0.693t/T_p})}{r^2} \qquad \text{(Equation 1)}$$

Where $D(t)$ = Accumulated exposure at time t, in roentgens,

34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44),

Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm,

Q_0 = Initial activity of the point source in millicuries, at the time of the release,

T_p = Physical half-life in days,

r = Distance from the point source to the point of interest in centimeters,

t = Exposure time in days.

This guide uses the NCRP equation (Equation 1) in the following manner to calculate the activities at which patients may be released.

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, $(1-e^{-0.693t/T_p})$ is set equal to 1.
- It is assumed that 1 roentgen is equal to 10 millisieverts (1 rem).
- The exposure rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in Appendix A to this guide.
- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the radionuclides.
- When release is based on biological elimination (i.e., the effective half-life) rather than just the physical half-life of the radionuclide, Equation 1 is modified to account for the uptake and retention of the radionuclide by the patient as discussed in Appendix B.
- For radionuclides with a physical half-life greater than 1 day and no consideration of biological elimination, it is assumed that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25 percent of the dose to total decay (0.25 in Equation 2) at a distance of 1 meter. Selection of 25 percent of the dose to total decay at 1 meter for estimating the dose is based on measurements discussed in the supporting regulatory analysis (Ref. 2) that indicate the dose calculated using an occupancy factor, E, of 25 percent at 1 meter is conservative in most normal situations.
- For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25 because relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate.

Thus, for radionuclides with a physical half-life greater than 1 day:

$$D(\infty) = \frac{34.6\,\Gamma\,Q_0\,T_p\,(0.25)}{100\ \text{cm}^2} \qquad \text{(Equation 2)}$$

For radionuclides with a physical half-life less than or equal to 1 day and if an occupancy factor of 1.0 is used:

$$D(\infty) = \frac{34.6\,\Gamma\,Q_0\,T_p\,(1)}{100\ \text{cm}^2} \qquad \text{(Equation 3)}$$

Equations 2 and 3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of the public because the dose from intake by other individuals is expected to be small

for most radiopharmaceuticals (less than a few percent) relative to the external gamma dose (see Section B.3, "Internal Dose," of Appendix B). Further, the equations above do not apply to the dose to breast-feeding infants or children who continue to breast-feed. Patients who are breast-feeding an infant or child must be considered separately, as discussed in Regulatory Position 1.1, "Release of Patients Based on Administered Activity."

C. REGULATORY POSITION

1. RELEASE CRITERIA

Licensees should use one of the following options to release a patient who has been administered radiopharmaceuticals or permanent implants containing radioactive material in accordance with regulatory requirements.

1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in 10 CFR 35.75(a), licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table 1. The activities in Table 1 are based on a total effective dose equivalent of 5 millisieverts (0.5 rem) to an individual using conservative assumptions of (1) administered activity, (2) physical half-life, (3) occupancy factor of 0.25 at 1 meter for physical half-lives greater than 1 day, and, for conservatism, an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day, and (4) no shielding by tissue. The total effective dose equivalent is approximately equal to external dose because the internal dose is a small fraction of the external dose (see Section B.3, "Internal Dose," of Appendix B). In this case, no record of the release of the patient is required unless the patient is breast-feeding an infant or child as discussed in Regulatory Position 3.2, "Records of Instructions for Breast-Feeding Patients." The licensee may demonstrate compliance by using the records of activity that are already required by 10 CFR 35.32 and 35.53.

If the activity administered exceeds the activity in Column 1 of Table 1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table 1. In this case, a record is required by 10 CFR 35.75(c) because the patient's release is based on the retained activity rather than the administered activity. The activities in Column 1 of Table 1 were calculated using either Equation 2 or 3, depending on the physical half-life of the radionuclide.

If a radionuclide not listed in Table 1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for NRC inspection, a calculation of the release activity that corresponds to the dose limit of 5 millisieverts (0.5 rem). Equation 2 or 3 may be used, as appropriate, to calculate the activity Q corresponding to 5 millisieverts (0.5 rem).

The release activities in Column 1 of Table 1 do not include consideration of the dose to a breast-feeding infant or child from ingestion of radiopharmaceuticals contained in a patient's breast milk. When the patient is breast-feeding an infant or child, the activities in Column 1 of Table 1 are not applicable to the infant or child. In this case, it may be necessary to give instructions as described in Regulatory Positions 2.2 and 2.3 as a condition for release. If failure to interrupt or discontinue could result in a dose to the breast-feeding infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 10 CFR 35.75(d).

1.2 Release of Patients Based on Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table 1 provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table 1 for that radionuclide. In this case, however, 10 CFR 35.75(c) requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in Table 1 is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 5-millisievert (0.5-rem) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required by 10 CFR 35.75(c). The dose rate at 1 meter may be calculated from Equation 2 or 3, as appropriate, because the dose rate at 1 meter is equal to $\Gamma Q/10{,}000\ cm^2$.

1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, based on 10 CFR 35.75(a), the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 5 millisieverts (0.5 rem), the patient may be released. Using this method, licensees may be able

Table 1. Activities and Dose Rates for Authorizing Patient Release†

Radionuclide	COLUMN 1 Activity at or Below Which Patients May Be Released		COLUMN 2 Dose Rate at 1 Meter, at or Below Which Patients May Be Released*	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag–111	19	520	0.08	8
Au–198	3.5	93	0.21	21
Cr–51	4.8	130	0.02	2
Cu–64	8.4	230	0.27	27
Cu–67	14	390	0.22	22
Ga–67	8.7	240	0.18	18
I–123	6.0	160	0.26	26
I–125	0.25	7	0.01	1
I–125 implant	0.33	9	0.01	1
I–131	1.2	33	0.07	7
In–111	2.4	64	0.2	20
Ir–192 implant	0.074	2	0.008	0.8
P–32	**	**	**	**
Pd–103 implant	1.5	40	0.03	3
Re–186	28	770	0.15	15
Re–188	29	790	0.20	20
Sc–47	11	310	0.17	17
Se–75	0.089	2	0.005	0.5
Sm–153	26	700	0.3	30
Sn–117m	1.1	29	0.04	4
Sr–89	**	**	**	**
Tc–99m	28	760	0.58	58
Tl–201	16	430	0.19	19
Y–90	**	**	**	**
Yb–169	0.37	10	0.02	2

† The activity values were computed based on 5 millisieverts (0.5 rem) total effective dose equivalent.

* If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by 10 CFR 35.75(c) because the measurement includes shielding by tissue. See Regulatory Position 3.1, "Records of Release," for information on records.

** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

NOTES: The millicurie values were calculated using Equations 2 or 3 and the physical half-life. The gigabecquerel values were calculated based on the millicurie values and the conversion factor from millicuries to gigabecquerels. The dose rate values are calculated based on the millicurie values and the exposure rate constants.

In general, the values are rounded to two significant figures. However, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG–1492 (Ref. 2).

Although non-byproduct materials are not regulated by the NRC, information on non-byproduct material is included in this regulatory guide for the convenience of the licensee.

Agreement State regulations may vary. Agreement State licensees should check with their State regulations prior to using these values.

to release patients with activities greater than those listed in Column 1 of Table 1 by taking into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case. If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c).

Appendix B contains procedures for performing patient-specific dose calculations, and it describes how various factors may be considered in the calculations.

2. INSTRUCTIONS

2.1 Activities and Dose Rates Requiring Instructions

Based on 10 CFR 35.75(b), for some administrations the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals as low as is reasonably achievable after the patients are released.[1] Licensees may use Column 1 of Table 2 to determine the activity above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter, based on the activities in Column 1. If the patient is breast-feeding an infant or child, additional instructions may be necessary (see Regulatory Position 2.2, "Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release").

The activities or dose rates in Table 2 may be used for determining when instructions must be given. When patient-specific calculations (as described in Appendix B) are used, instructions must be provided if the calculation indicates a dose that is greater than 1 millisievert (0.1 rem).

If a radionuclide not listed in Table 2 is administered, the licensee may calculate the activity or dose rate that corresponds to 1 millisievert (0.1 rem). Equation 2 or 3, as appropriate, may be used.

2.2 Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release

The requirement in 10 CFR 35.75(b) that a licensee provide instructions on the discontinuation or the interruption period of breast-feeding, and the consequences of failing to follow the recommendation, presumes that the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient.[1] The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breast-feeding an infant or child when the dose to the infant or child could exceed 5 millisieverts (0.5 rem) if there is no interruption of breast-feeding.

If the patient could be breast-feeding an infant or child after release, and if the patient was administered a radiopharmaceutical with an activity above the value stated in Column 1 of Table 3, instructions on discontinuation or on the interruption period for breast-feeding and the consequences of failing to follow the recommendation must be provided. The patient should also be informed if there would be no consequences to the breast-feeding infant or child. Table 3 also provides recommendations for interrupting or discontinuing breast-feeding to minimize the dose to below 1 millisievert (0.1 rem) if the patient has received certain radiopharmaceutical doses. The radiopharmaceuticals listed in Table 3 are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in Table 3 is administered to a patient who could be breast-feeding, the licensee should evaluate whether instructions or records (or both) are required. If information on the excretion of the radiopharmaceutical is not available, an acceptable method is to assume that 50 percent of the administered activity is excreted in the breast milk (Ref. 2). The dose to the infant or child can be calculated by using the dose conversion factors given for a newborn infant by Stabin (Ref. 3).

2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations. However, the instructions should not interfere with or contradict the best medical judgment of physicians. The instructions may include the name of a knowledgeable person to contact and that person's telephone number in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided.

2.3.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following.

[1]The NRC does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility to do so.

Table 2. Activities and Dose Rates Above Which Instructions Should be Given When Authorizing Patient Release*

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Dose Rate at 1 Meter Above Which Instructions Are Required	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag–111	3.8	100	0.02	2
Au–198	0.69	19	0.04	4
Cr–51	0.96	26	0.004	0.4
Cu–64	1.7	45	0.05	5
Cu–67	2.9	77	0.04	4
Ga–67	1.7	47	0.04	4
I–123	1.2	33	0.05	5
I–125	0.05	1	0.002	0.2
I–125 implant	0.074	2	0.002	0.2
I–131	0.24	7	0.02	2
In–111	0.47	13	0.04	4
Ir–192 implant	0.011	0.3	0.002	0.2
P–32	**	**	**	**
Pd–103 implant	0.3	8	0.007	0.7
Re–186	5.7	150	0.03	3
Re–188	5.8	160	0.04	4
Sc–47	2.3	62	0.03	3
Se–75	0.018	0.5	0.001	0.1
Sm–153	5.2	140	0.06	6
Sn–117m	0.21	6	0.009	0.9
Sr–89	**	**	**	**
Tc–99m	5.6	150	0.12	12
Tl–201	3.1	85	0.04	4
Y–90	**	**	**	**
Yb–169	0.073	2	0.004	0.4

* The activity values were computed based on 1 millisievert (0.1 rem) total effective dose equivalent.

** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

NOTES: The millicurie values were calculated using Equations 2 or 3 and the physical half-life. The gigabecquerel values were calculated based on millicurie values and the conversion factor from millicuries to gigabecquerels. The dose rate values were calculated based on millicurie values and exposure rate constants.

In general, values are rounded to two significant figures. However, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG–1492 (Ref. 2).

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Agreement State regulations may vary. Agreement State licensees should check with their State regulations prior to using these values.

breast-feeding. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breast-feeding an infant or child, the pamphlet should be supplemented with information specified in 10 CFR 35.75(b)(1) and (2).

The requirement of 10 CFR 35.75(b) regarding written instructions to patients who could be breast-feeding an infant or child does not in any way interfere with the discretion and judgment of the physician in specifying the detailed instructions and recommendations.

2.3.2 Instructions Regarding Permanent Implants

For patients who have received permanent 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 1/3 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 one of the persons listed in this instruction.

3. RECORDS

3.1 Records of Release

There is no requirement for recordkeeping on the release of patients who were released in accordance with Column 1 of Table 1. However, if the release of the patient is based on a dose calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by 10 CFR 35.75(c). This record should include the patient identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration. In addition, depending on the basis for release, records should include the following information.

(1) For Immediate Release of a Patient Based on a Patient-Specific Calculation: The equation used, including the patient-specific factors and their bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose. The patient-specific factors (see Appendix B of this guide) include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical half-life was assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record.

(2) For Immediate Release of a Patient Based on Measured Dose Rate: The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.

(3) For Delayed Release of a Patient Based on Radioactive Decay Calculation: The time of the administration, date and time of release, and the results of the decay calculation.

(4) For Delayed Release of a Patient Based on Measured Dose Rate: The results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

In some situations, a calculation may be case-specific for a class of patients who all have the same patient-specific factors. In this case, the record for a particular patient's release may reference the calculation for the class of patients.

Records, as required by 10 CFR 35.75(c), should be kept in a manner that ensures the patient's confidentiality, that is, the records should not contain the patient's name or any other information that could lead to identification of the patient. These recordkeeping re-

( ) Workshop
( ) In-service

( ) Mandatory

DEPARTMENT OF VETERAN AFFAIRS
VA BOSTON HEALTHCARE SYSTEM

ATTENDANCE SHEET

( ) Entered In Computer

Program: Radiation Receipt, Survey + Storage
Date: MAR-09
Presentor(s): John Naughton
Length of Program:
Contact Hours:

Content:

PRINT NAME	TITLE	SIGNATURE	SERVICE	UNIT/ WARD	CAMPUS/ CLINIC	
1. AMOROSO, PATRICIA	RN		NSG	RAD	JP	
2. ANDERSON, JANICE	RN		NSG	RAD	JP	
3. BUOTE, NICOLE	RT(T)			RAD	JP	
4. DUGGAN, LINDA	RT(T)		RTT	RAD	JP	
5. ELSAYYAD, NAGY	MD					
6. FLAGG, NICOLE	DOS (contract)	Nicole Flagg RTT	DOS	RAD	JP	
7. GOLSTON, CARL	RT (contract)			RAD	JP	
8. HANSEN, ROBERT	BLK		RT	RAD	JP	
9. LOCHIATTO, JOSEPH	RT(T)			RAD	JP	
10. MCALPINE, JAMES	RT			RAD	JP	
11. MCKINZEY, MARY	PG.CLK			RAD	JP	
12. NAUGHTON, JOHN	PHYS (contract)					
13. PAGLIUCA, THERESA	MD (contract)			RAD	JP	
14. VARLOTTO, JOHN	MD			RAD	JP	

§ 20.1906 Procedures for receiving and opening packages.

(a) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a quantity, as defined in § 71.4 and appendix A to part 71 of this chapter, shall make arrangements to receive-

(1) The package when the carrier offers it for delivery; or

(2) Notification of the arrival of the package at the carrier's terminal and to take possession of the package ex

(b) Each licensee shall--

(1) Monitor the external surfaces of a labeled[3a] package for radioactive contamination unless the package con radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4;

(2) Monitor the external surfaces of a labeled[3a] package for radiation levels unless the package contains quan radioactive material that are less than or equal to the Type A quantity, as defined in § 71.4 and appendix A to this chapter; and

(3) Monitor all packages known to contain radioactive material for radioactive contamination and radiation lev evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

(c) The licensee shall perform the monitoring required by paragraph (b) of this section as soon as practical af the package, but not later than 3 hours after the package is received at the licensee's facility if it is received c licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is r working hours.

(d) The licensee shall immediately notify the final delivery carrier and the NRC Operations Center (301-816-5 telephone, when--

(1) Removable radioactive surface contamination exceeds the limits of § 71.87(i) of this chapter; or

(2) External radiation levels exceed the limits of § 71.47 of this chapter.

(e) Each licensee shall--

(1) Establish, maintain, and retain written procedures for safely opening packages in which radioactive materi and

(2) Ensure that the procedures are followed and that due consideration is given to special instructions for the package being opened.

(f) Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a exempt from the contamination monitoring requirements of paragraph (b) of this section, but are not exempt survey requirement in paragraph (b) of this section for measuring radiation levels that is required to ensure tl is still properly lodged in its shield.

[56 FR 23401, May 21, 1991, as amended at 57 FR 39357, Aug. 31, 1992; 60 FR 20185, Apr. 25, 1995; 63 F 23, 1998]

[3a] Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transpo regulations, 49 CFR 172.403 and 172.436-440.

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Subpart I--Storage and Control of Licensed Material

Source: 56 FR 23401, May 21, 1991, unless otherwise noted.

§ 20.1801 Security of stored material.

The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled unrestricted areas.

§ 20.1802 Control of material not in storage.

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

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§ 35.2406 Records of brachytherapy source accountability.

(a) A licensee shall maintain a record of brachytherapy source accountability required by § 35.406 for 3 years

(b) For temporary implants, the record must include--

(1) The number and activity of sources removed from storage, the time and date they were removed from st name of the individual who removed them from storage, and the location of use; and

(2) The number and activity of sources returned to storage, the time and date they were returned to storage, of the individual who returned them to storage.

(c) For permanent implants, the record must include--

(1) The number and activity of sources removed from storage, the date they were removed from storage, an the individual who removed them from storage;

(2) The number and activity of sources not implanted, the date they were returned to storage, and the name individual who returned them to storage; and

(3) The number and activity of sources permanently implanted in the patient or human research subject.

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§ 35.406 Brachytherapy sources accountability.

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall r brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with § 35.240

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§ 35.2092 Records of decay-in-storage.

A licensee shall maintain records of the disposal of licensed materials, as required by § 35.92, for 3 years. Th include the date of the disposal, the survey instrument used, the background radiation level, the radiation lev at the surface of each waste container, and the name of the individual who performed the survey.

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§ 35.40 Written directives.

(a) A written directive must be dated and signed by an authorized user before the administration of I-131 soc greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byprodu any therapeutic dose of radiation from byproduct material.

(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directiv jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive documented as soon as possible in writing in the patient's record. A written directive must be prepared within the oral directive.

(b) The written directive must contain the patient or human research subject's name and the following inform

(1) For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;

(2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-: radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate treatment for each anatomically distinct treatment site;

(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, fractions, and total dose; or

(6) 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 sou 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 au before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma radiosurgery dose, the teletherapy dose, or the next fractional dose.

(1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written c jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision documented as soon as possible in the patient's record. A revised written directive must be signed by the autl within 48 hours of the oral revision.

(d) The licensee shall retain a copy of the written directive in accordance with § 35.2040.

[67 FR 20370, Apr. 24, 2002 as amended at 68 FR 75389, Dec. 31, 2003]

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§ 35.41 Procedures for administrations requiring a written dire

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain v procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

(b) At a minimum, the procedures required by paragraph (a) of this section must address the following items applicable to the licensee's use of byproduct material--

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written di

(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of the medical units authorized by §§ 35.600 or 35.1000.

(c) A licensee shall retain a copy of the procedures required under paragraph (a) in accordance with § 35.204

[72 FR 45151, Aug. 13, 2007]

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§ 35.404 Surveys after source implant and removal.

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a locate and account for all sources that have not been implanted.

(b) Immediately after removing the last temporary implant source from a patient or a human research subjec shall make a survey of the patient or the human research subject with a radiation detection survey instrumen that all sources have been removed.

(c) A licensee shall retain a record of the surveys required by paragraphs (a) and (b) of this section in accord 35.2404.

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§ 35.2404 Records of surveys after source implant and removal

A licensee shall maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years. Each record r
the date and results of the survey, the survey instrument used, and the name of the individual who made the

§ 35.75 Release of individuals containing unsealed byproduct m or implants containing byproduct material.

(a) A licensee may authorize the release from its control of any individual who has been administered unseale material or implants containing byproduct material if the total effective dose equivalent to any other individua exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[1]

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, in written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably a the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effe equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of t the instructions must also include--

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance wi (a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance witt (b).

[67 FR 20370, Apr. 24, 2002 as amended at 70 FR 16363, Mar. 30, 2005; 72 FR 45151, Aug. 13, 2007]

[1] The current revision of NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Sp Guidance About Medical Licenses" describes methods for calculating doses to other individuals and contains ta activities not likely to cause doses exceeding 5 mSv (0.5 rem).

§ 35.432 Calibration measurements of brachytherapy sources.

(a) Before the first medical use of a brachytherapy source on or after October 24, 2002, a licensee shall have

(1) Determined the source output or activity using a dosimetry system that meets the requirements of § 35.6

(2) Determined source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of (1) and (a)(2) of this section.

(b) Instead of a licensee making its own measurements as required in paragraph (a) of this section, the licens measurements provided by the source manufacturer or by a calibration laboratory accredited by the Americar of Physicists in Medicine that are made in accordance with paragraph (a) of this section.

(c) A licensee shall mathematically correct the outputs or activities determined in paragraph (a) of this sectio decay at intervals consistent with 1 percent physical decay.

(d) A licensee shall retain a record of each calibration in accordance with § 35.2432.

[67 FR 20370, Apr. 24, 2002, as amended at 68 FR 19325, Apr. 21, 2003]

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E. Brachytherapy Program QMP.

The Brachytherapy Program at the Boston VAMC consists of permanent I-125 interstitial brachytherapy of the prostate and temporary I-125 eye plaque brachytherapy. Prostate brachytherapy permanently implants I-125 seeds according to an isodose plan to the prostate. Eye plaque brachytherapy is a temporary implant where the eye plaque is fixed to the eye for a planned duration of time. The Brachytherapy QMP will address the fore mentioned procedures separately and apply policies and procedures that promote safe and accurate brachytherapy practices. The Brachytherapy QMP will employ practices suggested in AAPM TG-40 and TG-56.

1. Prostate Seed Implant Brachytherapy Procedures

The following serves as a step by step guide to performing a prostate brachytherapy at the Boston VAMC.

a. CT Prostate Volume and Pubic Arch Study

After the patient's initial consultation, the physician will order a CT to determine if the patient is a prostate implant candidate. The CT is imported into the ADAC TPC and the physician will contour the prostate. Once the prostate is contoured, ADAC will calculate the prostate volume. An implant candidate will have a prostate volume between 20 and 60 cm^3. For the pubic arch study, Physics will set up a PIO (Posterior Inferior Oblique) beams eye view which mimics the implant set up. With the contour 3-D view on, the physician will be able to determine whether there is pubic arch interference. Both criteria must be met in order to produce an implant candidate. If the patient's anatomy exceeds the limits of the implant criteria but not excessively, the physician and physicist will discuss the limitations of the case and determine if the patient is a prostate implant candidate.

The prostate volume and pubic arch study will be printed and maintained in the patient's chart. A record of the study will be maintained in the Brachytherapy QMP by Physics

b. Treatment Prescription

Two prescriptions are available for prostate implant brachytherapy: 1) 108Gy prescription is assigned to patients that have had 45Gy external beam radiation therapy to be followed by a prostate implant brachytherapy boost; and 2) 145Gy prescription is assigned to prostate implant brachytherapy when it is the sole course of treatment.

When an implant candidate is selected, the physician will discuss with Physics the treatment plan and prescription dose. The written directive for a specific brachytherapy patient must include:

1. Prior to Implantation: Radioisotope, prescription dose, number of sources, source strength, physician signature, and date.
2. After implantation and prior to treatment completion: Radioisotope, prescription dose, number of sources, source strength, physician signature, and date.

Oral revisions of the written directive are acceptable during the implant procedure because of the sterile restraints of the procedure and the patient's health. Oral revision will be documented in "Sources Implanted" section of the written directive and verified by the physicians' signature and date after the implant.

c. Ordering Sources

I-125 seeds are ordered on a specific implant patient basis. The quantity of seeds ordered is calculated based on the patient's prostate volume study and the prescription dose. When the seed order is place with the vender, one additional calibrated seed will be ordered for every I-125 prostate seed implant. The number of seeds required for each implant will be calculated by the Radiation Therapy Physicist and confirmed by the Dosimetrist and Physician. A "Prostate Seed Order Request Form" will be completed by Physics and submitted to the Chief Therapist for ordering. The "Prostate Seed Order Request Form" will contain the following:

1. Patient's Name.
2. Patient's ID.
3. Number of Seeds Needed Plus Calibrated Seed.
4. Isotope and Model.
5. Implant Date.
6. Desired Activity on Implant Date.
7. Activity Ordered and Reference Date.
8. Requested Delivery Date.
9. Physician, Physicist, and Dosimetrist Signatures.

The seed order calculation and the "Prostate Seed Order Request Form" will be maintained in the patient's chart.

d. Receiving and Securing Sources

I-125 seed shipments are delivered directly to the Radiation Therapy Department at the Boston VAMC by FecEx. Upon receipt, the Radiation Therapy Physicist or trained designee is contacted to pick-up the radioactive material package. Once

an I-125 seed shipment is received, the package(s) will be moved to a secure radioactive materials storage area, DB-102. This storage area will posted with a "CAUTION: RADIOATIVE MATERIALS" sign and emergency contact numbers.

Within 3 hours of receipt, the package(s) must be surveyed to determine that there is no contamination or damage during shipping. Exposure readings at one meter from the package(s), at the package surface and at the source container(s) will be measured and recorded. A wipe test of the package(s) and source container(s) will also be performed and results documented. The number of sources, the isotope model number, and source strength shall be verified to be in agreement with the "Prostate Seed Order Request Form" and the receipt will be logged into the "I-125 Receipt, Removal and Storage Log". Finally, the received I-125 containers will be secured in the labeled refrigerator in DB-102. All documentation will be maintained in the patient chart and the Radiation Therapy Service Physics Department.

e. Calibrating Sources

Prior to the day of implantation, Physics will verify the source strength provided by the manufacturer. To achieve this, a calibrated seed and a calibrated well chamber, which are NIST traceable, will be utilized to verify the stated manufacturer's source strength. To assure the well chamber has maintained its calibration, the calibrated seed is measured and verified to be within a tolerance of 2%. Then a random batch of at least 10% of the seeds ordered will be calibrated. The mean of the batch will be verified to be within a tolerance of 3%.

f. Pre-Implant Preparations

The RSO or physicist will transport the I-125 seeds to the operating room in shielded shipment containers. At all times the I-125 seeds shall be under constant surveillance and control of the RSO or Radiation Therapy Physicist.

In the sterilization area, the seeds are place in a sterilization cup with cover and an autoclave test package is prepared. Prior to sterilization, the area is assayed with a survey meter to verify that there are no stray seeds. The seeds and test package are then sterilized. Note: The test package requires one hour after sterilization before it can be read.

All other implant equipment will be inspected for proper operation before the patient is put under anesthesia.

Prior to and during the implant the RSO and Radiation Oncology Physicist shall be present in the OR to assure that proper radiation safety procedures are followed.

No special precautions are required by the OR personnel while they are working under the supervision of the RSO.

g. Treatment Planning

After the patient is positioned properly on the OR couch, the US probe is positioned to acquire prostate images and fixed to the probe stepper. The Radiation Oncologist and the Ultrasonogragher collaborate and contour the prostate and urethra positions. After each 5mm image is contoured, it is sent to the CMS treatment planning computer. Once all prostate images are received, the Physicist generates a plan that will deliver the written directive dose distribution to the prostate volume. Prior to implantation the dose distribution is reviewed and orally approved by the Radiation Oncologist.

h. Needle Loading

Upon plan approval, the RSO is provided a printout of planned needles locations and their associated seed loading. The RSO, under sterile conditions, will be assisted by the Physicist or an OR Nurse when loading the seed implant needles. The Physicist or OR Nurse will support the RSO by indicating the seed loading configuration of each implant needle and its placement location in the needle holder. When all planned needles are loaded, the RSO will account for and secure the remaining seed.

i. Seed Implantation

The administration of the prostate seed implant shall be in accordance with the written directive. Prior to administration of the treatment plan, the Radiation Oncologist must verify that all the details specified in the written directive and in the treatment plan are in agreement. At the conclusion of the seed implant, the Radiation Oncologist will verify the graphic dose distribution that is representative of the dose delivered to the prostate. Any unintended deviation from the written directive shall be identified and the appropriate action taken. Any intended deviation will be documented on the written directive with the signature of the Radiation Oncologist.

j. Post Implant Procedures

After the implant, an anterior-to-posterior (AP) image of the implanted seeds must be taken to verify and account for the number of seeds implanted into the patient. In addition, the sum of the seeds implanted and not implanted must agree with the total number of seeds brought to the OR. The OR must be surveyed by the RSO or Radiation Oncology Physicist to ensure that there are no stay radioactive sources. Finally, the seeds are returned to the radioactive materials storage area DB-102 and logged into decay in storage.

k. I-125 Seed Decay-In-Storage

All I-125 seeds not used during the prostate implant procedure will be decayed in storage as detailed in 10CFR35.92. At the end of each calendar year, all the seeds not used in the prostate seed implant procedures will be stored collectively and assigned a Batch #. The Batch # represents the calendar year the seeds were received. When the Batch is created, it is logged into the "I-125 Receipt, Removal, Storage, and Inventor Log" and decayed for at least 10 half lives.

At the discretion of the RSO, the Batches will be disposed of when: at least ten half lives have past and the Inventory log indicates the activity is essentially zero. Before the Batch is disposed of it will be surveyed with an appropriate survey meter on its most sensitive scale and with no shielding. If the radioactivity from the seed Batch can not be distinguished from the background radiation level it may be disposed of in the trash. All radioactive labels will be removed prior to disposal and a record of the disposal, which will include the date of disposal, the survey meter used, the background radiation level, the radiation level measured at the surface of the of the I-125 seeds, and the name of the surveyor. The disposal record will be maintained for at least 3 years by the RSO and the Radiation Therapy Service.

l. Patient Release

Since the I-125 implanted activity always exceeds 9 mCi, the immediate release of the patient will be based on measured dose rate, as detailed in RG 8.39. A dose rate reading at one meter from the patient will be acquired by the RSO or Radiation Oncology Physicist immediately following the implant in the OR. If the dose rate reading at 1 meter is less than 1 mR/h (RG 8.39, Table 1, Column 2), the patient may be released. If the dose rate reading at 1 meter exceeds 1 mR/h, accommodation will be made for the patient to stay hospitalized until the dose rate meets the regulatory requirement. Patient reading will be recorded in the patient chart and maintained by the Radiation Therapy Service.

m. Post Implant Patient Instructions and Nursing Instructions

All prostate I-125 implant patients will be provided written instructions by the Radiation Oncologists following the implant procedure. The Post Implant Patient Instructions will direct the patient on how to minimize radiation exposure to family member and the general public. It also instructs the patient on actions to be taken if an I-125 seed is discharged from the patient.

Nursing instructions will be provided to OR personnel. The instruction will direct the nursing staff of safety precautions needed for prostate seed implant patients during the patient recovery period after the implant. It will also give instructions on the proper handling and management on the patient's recovery area.

The Post Implant Patient Instructions and Nursing Instructions will be maintained by the Radiation Therapy Service and reviewed annually by the RSO.

n. Documentation

The administered plan and all images (US and radiographic) will be printed and kept in the patient's chart. All documents will be reviewed and signed by the Radiation Oncologist.

o. Post Implant Evaluation

Within one month following the seed implant, every patient will be scheduled to receive a post-operative CT scan of the prostate. The CT scan will be imported to the TPC and a graphic dose distribution plan and DHV will be generated by Physics. The Radiation Oncologist and physicist will evaluate the dose received by 90% of the prostate volume (D90) and a printout will be kept in the patient's chart. Any deviation from the written directive will be evaluated and the appropriate action taken.

p. Prostate Implant QMP Review

At least annually, the Prostate Implant QMP will be reviewed by the Physicist of the Radiation Therapy Service. The review will determine the effectiveness of the QMP and make necessary modifications. The review will also include an audit of all prostate seed implant cases performed in the previous year and presented to the Chief Radiation Oncologist for evaluation.

( ) Workshop
( ) In-service

( ) Mandatory

DEPARTMENT OF VETERAN AFFAIRS
VA BOSTON HEALTHCARE SYSTEM

ATTENDANCE SHEET

( ) Entered In Computer

Program: Prostate Brachy Seed Load + Rad Safety * Package Survey
Date: 7/07
Presentor(s): Dr. A. Drum, John Naughton
Length of Program:
Contact Hours:

Content:

PRINT NAME	TITLE	SIGNATURE	SERVICE	UNIT/ WARD	CAMPUS/ CLINIC	
1. AMOROSO, PATRICIA	RN		NSG	RAD	JP	
2. ANDERSON, JANICE	RN		NSG	RAD	JP	
3. BUOTE, NICOLE	RT(T)			RAD	JP	
4. DUGGAN, LINDA	RT(T)		RTT	RAD	JP	
5. FLAGG, NICOLE	DOS	Nicole Flagg	RTT	RAD	JP	
6. GOLSTON, CARL	RT(TEMP)			RAD	JP	
7. HANSEN, ROBERT	BLK		RT	RAD	JP	
8. LOCHIATTO, JOSEPH	RT(T)			RAD	JP	
9. MCALPINE, JAMES	RT			RAD	JP	
10. MCKINZEY, MARY	PG.CLK			RAD	JP	
11. NAUGHTON, JOHN	PHYS	John Naughton	Physicist		JP	
12. USAS, CRAIG	MD			RAD	JP	
13. VARLOTTO, JOHN	MD			RAD	JP	
14. WALSH, MARK	RSO					

APPENDIX O

Model Procedures for Ordering and Receiving Packages

Model Procedures for Ordering and Receiving Packages

This model provides acceptable procedures for ordering and receiving packages containing licensed material. Applicants may either adopt this model or develop alternative procedures.

Model Guidance

- Authorize, through a designee (e.g., RSO), each order of radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting AU and that possession limits are not exceeded.

- Establish and maintain a system for ordering and receiving radioactive material; include the following information:

  - Records that identify the AU or department, radionuclide, physical and/or chemical form, activity, and supplier;

  - Confirmation, through the above records, that material received was ordered through proper channels.

- For deliveries during normal working hours, inform carriers to deliver radioactive packages directly to a specified area.

- For deliveries during off-duty hours, inform security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum for delivery of packages to the Nuclear Medicine Division, provided below. Develop a similar memorandum for delivery of packages to other divisions.

Sample Memorandum

MEMO TO: Chief of Security
FROM: Radiation Safety Officer
SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty will accept delivery of radioactive material that arrives outside normal working hours. Packages will be taken immediately to the Nuclear Medicine Division, Room ___. Unlock the door, place the package on top of the counter, and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer, at extension _____.

	Name	**Home Telephone**
Radiation Safety Officer:		
Director of Nuclear Medicine:		
Nuclear Medicine Technologist Supervisor:		
Nuclear Medicine Technologist on call (call page operator at extension _____)		
Nuclear Medicine Physician on call (call page operator at extension _____)		

APPENDIX P

Model Procedure for Safely Opening Packages Containing Radioactive Material

Model Procedure for Safely Opening Packages Containing Radioactive Material

This model provides acceptable procedures for opening packages containing radioactive material. Applicants may either adopt this model procedure or develop an alternative procedure to meet the requirements of 10 CFR 20.1906.

Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in Table A.1 of 10 CFR Part 71 (e.g., 13.5 curies of Mo-99 [20 curies for domestic use], Cs-137, Ir-192; 54.1 curies of I-125; 541 curies of Xe-133, or 216 curies of Tc-99m). Such packages must be received expeditiously when the carrier offers it for delivery or when the carrier notifies the licensee that the package has arrived at the carrier's terminal. For these and other packages for which monitoring is required, check for external radiation levels and surface contamination within 3 hours of receipt (if received during working hours) or no later than 3 hours from the beginning of the next working day (if received after working hours), in accordance with the requirements of 10 CFR 20.1906(c). NRC Regional Office and the final delivery carrier must be notified if the following conditions apply:

- Removable radioactive surface contamination exceeds the limits of 10 CFR 71.87(i); and
- External radiation levels exceed the limits of 10 CFR 71.47.

Model Procedure

1. Put on gloves to prevent hand contamination.
2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO or the designee of the RSO if the RSO is not present immediately.
3. Monitor the external surfaces of a labeled[1] package for radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form, as defined in 10 CFR 71.4.
4. Monitor the external surfaces of a labeled[1] package for radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Table A to 10 CFR Part 71.
5. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels, if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
6. Remove the packing slip.
7. Open the outer package, following any instructions that may be provided by the supplier.

---

[1] Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations.

8. Open the inner package and verify that the contents agree with the packing slip.

9. Check the integrity of the final source container. Notify the RSO (or the RSO's designee) of any broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.

10. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. An appropriate instrument with sufficient sensitivity will be used to assay the sample. For example, a NaI(T1) crystal and rate meter, a liquid scintillation counter, or a proportional flow counter may be used for these assays. The detection efficiency will be determined to convert wipe sample counts per minute to disintegrations per minute. *Note: a dose calibrator is not sufficiently sensitive for this measurement.* Take precautions against the potential spread of contamination.

11. Check the user request to ensure that the material received is the material that was ordered.

12. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding. If contaminated, treat this material as radioactive waste. If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.

13. Make a record of the receipt.

For packages received under the general license in 10 CFR 31.11, implement the following procedure for opening each package:

1. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO (or the RSO's designee) immediately.

2. Check to ensure that the material received is the material that was ordered.

APPENDIX Q

Model Leak Test Program

Model Leak Test Program

This model provides acceptable procedures for sealed source leak testing and analysis. Applicants may either adopt these model procedures or develop alternative procedures.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests should be analyzed in a low-background area.
- Consider using a NaI(Tl) well counter system with a single or multichannel analyzer to analyze samples obtained from gamma-emitting sources (e.g., Cs-137).
- Consider using a liquid scintillation or gas-flow proportional counting system to analyze samples obtained from beta-emitting sources (e.g., Sr-90).
- Instrumentation used to analyze leak test samples must be capable of detecting 185 Bq (0.005 μCi) of radioactivity.

Model Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as sealed source serial number, radionuclide, and activity.
- Use a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate identifying information for each source.
- Wear gloves.
- Obtain samples at the most accessible area where contamination would accumulate if the sealed source were leaking.
- Measure the background count rate and record.
- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within ± 5% of the stated value and traceable to a primary radiation standard, such as those maintained by NIST.

- Calculate efficiency of the instrument.

  For example,

$$Eff = \frac{[(cpm\ from\ std) - (cpm\ from\ bkg)]}{(activity\ of\ std\ in\ microcurie)}$$

  where:

Eff	= efficiency, in cpm / microcurie,
cpm	= counts per minute,
std	= standard, and
bkg	= background.

- Analyze each wipe sample to determine net count rate.

- For each sample, calculate the activity in microcurie and record.

- The activity on the wipe sample is given by:

$$\frac{[(cpm\ from\ wipe\ sample) - (cpm\ from\ bkg)]}{(Eff\ in\ cpm/microcurie)}$$

$$= activity\ on\ wipe\ sample\ in\ microcurie$$

- Leak test records will be retained in accordance with 10 CFR 35.2067 for 3 years. Licensees should include the following in records:

  - The model number and serial number (if assigned) of each source tested;
  - The identity of each source radionuclide and its estimated activity;
  - The measured activity of each test sample expressed in microcurie;
  - A description of the method used to measure each test sample;
  - The date of the test; and
  - The name of the individual who performed the test.

- If the wipe test reveals 185 Bq (0.005 μCi) or greater:

  - Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in 10 CFR Parts 20 and 30 [10 CFR 35.67].
  - File a report within 5 days of the leak test in accordance with 10 CFR 35.3067.

APPENDIX R

Model Procedure for Area Surveys

Model Procedure for Area Surveys

This model provides acceptable procedures for area surveys. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 20.1101,10 CFR 20.1501, and 10 CFR 35.70. Guidance for developing alternate trigger levels for contamination in restricted areas is included below.

Ambient Radiation Level Surveys

Procedures for ambient radiation level surveys (reference 10 CFR 20.1101, 10 CFR 20.1501, and 10 CFR 35.70):

- Perform surveys of dose rates in locations where:
  - Workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits; or
  - An individual is working in an environment with a dose rate of 2.5 mrem/hour or more (5 rem/year divided by 2,000 hour/year).
- 10 CFR 20.1301 requires that the TEDE to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year, and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Appropriate surveys will be conducted to assure that the requirements of 10 CFR 20.1301 are met.
- Perform radiation level surveys with a survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR) per hour in the following areas, at the frequency specified:
  - Survey at the end of each day of use all radiopharmaceutical elution, preparation, assay and administration areas (except patient rooms, which will be surveyed at the end of the therapy instead of on the day of administration) when using radiopharmaceuticals requiring a written directive (e.g., all therapy dosages and any iodine-131 dosage exceeding 30 μCi).
  - Survey monthly all laboratory areas where only small quantities of gamma-emitting radioactive material are used (< 200 μCi at a time).
  - Survey weekly all radionuclide use, storage, and waste storage areas. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99m heart agents) and special care is taken to remove all paraphernalia, those rooms need not be surveyed.
  - Survey quarterly all sealed source and brachytherapy source storage areas.
- If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Example trigger levels for restricted and unrestricted areas are presented in Table R.1.

Table R.1 Ambient Dose Rate Trigger Levels		
Type of Survey	Area Surveyed	Trigger Level
Ambient Dose Rate	Unrestricted	0.1 mR/hr
Ambient Dose Rate	Restricted	5.0 mR/hr

Contamination Surveys

Facilities and equipment for contamination surveys:

To ensure achieving the required sensitivity of measurements, analyze survey samples in a low-background area. Table K-1 entitled "Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples" in Appendix K provides examples of appropriate instruments.

Perform contamination surveys using instruments suitable for removable and fixed contamination to identify areas of contamination that might result in doses to workers or to the public. Removable contamination can be detected and measured by conducting a wipe test of the surface, counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Procedures for contamination surveys:

- Contamination surveys are performed in areas where unsealed forms of materials are used:
  - To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
  - After any spill or contamination event;
  - When procedures or processes have changed;
  - To evaluate contamination of users and the immediate work area, at the end of the day, when licensed material is used;
  - In unrestricted areas at frequencies consistent with the types and quantities of materials in use, but not less frequently than monthly;
  - In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.
- Use methods for conducting surveys for removable contamination that are sufficiently sensitive to detect contamination for those radionuclides in use and for which the most restrictive limits apply, as listed in Tables R.2 for restricted areas and R.3 for unrestricted areas (e.g., 200 dpm/100 cm^2 for isotopes of iodine-131 in unrestricted areas). Removable contamination survey samples should be measured in a low-background area. The following areas and frequencies should be followed:

- Removable contamination surveys weekly for radiopharmaceutical elution, preparation, assay, and administration areas. If diagnostic administrations are occasionally made in patients' rooms (i.e., bone scan injections, Tc-99m heart agents, etc.), with special care taken to remove all paraphernalia, those rooms need not be surveyed.

- Removable contamination surveys monthly of laboratory areas where only small quantities of photon-emitting radioactive material are used (<200 microcuries at a time).

- Removable contamination surveys weekly for radionuclide storage and radionuclide waste storage areas.

- A radioactive source with a known amount of activity should be used to convert sample measurements (usually in cpm) to dpm.

- The area should be either decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated.

- If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Example trigger levels for restricted areas are presented in Table R.2. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels.

Table R.2 Surface Contamination Levels in Restricted Areas (dpm/100 cm^2)

Area, clothing	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
Restricted areas, protective clothing used only in restricted areas	2000	20000

Table R.3 Surface Contamination Levels in Unrestricted Areas (dpm/100 cm^2)			
Nuclide[1]	Average[2,3,6]	Maximum[2,4,6]	Removable[2,5,6]
I-125, I-126, I-131, I-133, Sr-90	1000	3000	200
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	5000	15000	1000

1 Where surface contamination by multiple nuclides exists, the limits established for each nuclide should apply independently.

2 As used in this table, dpm means the rate of emission by radioactive material, as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

3 Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

4 The maximum contamination level applies to an area of not more than 100 cm^2.

5 The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

6 The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad/hour at 1 centimeter and 1.0 millirad/hour at 1 centimeter, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

Establishing Alternate Trigger Levels for Restricted Areas

The following guidance is provided for those applicants who plan to develop procedures for surveying and controlling contamination using action levels for controlling contamination that differ from those provided in Tables R.1 and R.2:

Alternate action levels for cleanup of contamination restricted areas may be developed without prior NRC approval if

- acceptable unrestricted area trigger levels are implemented (e.g., Tables R.1 and R.3);
- the action levels maintain occupation doses ALARA;
- the action levels meet all other regulatory requirements (e.g., they should also be designed to minimize, to the extent practicable, contamination of the facility, and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste).

Alternate Survey Frequency

An example alternate survey frequency is described below. The objective is to determine how often to survey the laboratory. To do this, multiply the activity range for the appropriate group under LOW, MEDIUM, and HIGH survey frequency by the appropriate Modifying Factor to construct a new set of mCi ranges for LOW, MEDIUM, and HIGH survey frequency. For instance, if 30 millicuries of iodine-131 is used in the hot laboratory, the survey frequency for the hot laboratory would be daily; since the group for iodine-131 is Group 2, the survey frequency category for an activity of greater than 10 millicuries is high, and the modifying factor is 1.

Table R.4 Grouping of Radioisotopes for Alternate Survey Frequency

Group 1	Group 1, excerpted from IAEA Safety Series 115, does not include radioisotopes traditionally used in medicine.
Group 2	Co-60 Sr-90 I-125 I-126 I-131 I-133 Cs-134 Cs-137 Eu-152 (13 y) Eu-154 Ir-192 T1-204
Group 3	C-14 F-18 Na-24 P-32 S-35 Cr-51 Fe-59 Co-57 Co-58 Se-75 Sr-85 Y-90 Mo-99 Tc-99 Rh-105 Pd-103 In-115m Sn-113 Sm-153 Eu-152 Eu-155 Gd-153 Dy-165 Yb-175 Lu-177 Au-198 Hg-197 Tl-201
Group 4	H-3 0-15 Rb-87 Tc-99m Rh-103m In-113m Xe-133 Cs-134m

Table R.5 Classification of Laboratories for Alternate Survey Frequency

	Survey Frequency Category		
Group	Low	Medium	High
1	<0.1 mCi	0.1 mCi to 1 mCi	>1 mCi
2	<1 mCi	1 mCi to 10 mCi	>10 mCi
3	<100 mCi	100 mCi to 1 Ci	>1 Ci
4	<10 Ci	10 Ci to 100 Ci	>100 Ci

Survey Frequency:

- Low – Not less than once a month;
- Medium – Not less than once per week;
- High – Not less than once per normal working day.

Proportional fractions are to be used for more than one isotope.

Table R.6 Modifying Factors for Alternate Survey Frequency	
Modifying Factors	Factors
Simple storage	x 100
Very simple wet operations (e.g., preparation of aliquots of stock solutions)	x 10
Normal chemical operations (e.g., analysis, simple chemical preparations)	x 1
Complex wet operations (e.g., multiple operations, or operations with complex glass apparatus)	x 0.1
Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds	x 0.1
Exposure of non-occupational persons (including patients)	x 0.1
Dry and dusty operations (e.g., grinding)	x 0.01

Contents of Survey Records

- A diagram of the area surveyed;
- A list of items and equipment surveyed;
- Specific locations on the survey diagram where wipe tests were taken;
- Ambient radiation levels with appropriate units;
- Contamination levels with appropriate units;
- Make and model number of instruments used;
- Background levels;
- Name of the person making the evaluation and recording the results and date.

Record contamination levels observed and procedures followed for incidents involving contamination of individuals. Include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER
BROCKTON/WEST ROXBURY/WOPC, MASSACHUSETTS

Inservice Education Record Form
Medical Center Education Department

Title of Inservice Education Class: QUALITY IMPROVEMENT COMMITTEE

Description of Class: RADIATION ONCOLOGY 7/29/09

Length of Class: 60 min **Instructor:** GOODNER — STAFF

Teaching Methods: (Circle all that apply)

1. Lecture 2. Lecture/discussion 3. Lecture/demonstration 4. Videotape 5. Audio tape
6. Reading material 7. Learning module 8. Computer Assisted Instruction 9. Other

Date	Name - PRINT	Title	Service	Social	Security	Number
7/29/09	DAVID DROM.	RSO	NUCLEAR	228	42	5205
7/29	Lisa Bradley	BME	ClinEng			
7/29	Paul Cavanaugh	BMET	ClinEng			
7/29	DONALD MORGE	BME	CLINENG			
7/29/09	David Taylor	NSA	RT			
7/29/09	TENITA WILLIAMS	AO	RT			
7/29/09	Patricia AMOROSO	RN	Nursing			
7/29/09	Nicole Flagg	RTT/DOS	RT			
7/29/09	JUAN GODINEZ	RT/MD	RT			
7/29/09	John Naughton	Physicist	RT			
7/29/09	JASON MACNEAU	RT(T)	RT			
7/29/09	Susan Sheppard	RT(T)	RAD THR.			3519

Education Department (#11B-insvform)
April, 1992
Revised March, 1997
Revised September, 1998

VA Medical Center Department of Radiation Therapy
QUALITY IMPROVEMENT COMMITTEE

Wednesday, July 29, 2009, 2:00pm, Radiation Therapy Break room.

1. Update on Patient Chart Rounds Conference:
   Results of the weekly Patient Care Conference reveal that at the VA from 05/01/2009 07/21/2009, 100% of the charts were complete at the time of the first chart review.

2. Bio Engineering (Cavanaugh, Byrne)
   - **a)** Backing up the LANTIS and Pinnacle systems to the network.(Naughton IRM)
   - **b)** What equipment BIO-med will be taking care of for calibration, need for PO's.
   - **c)** Old LANTIS drives being sent to get worked on to see if anything is recoverable/update.
   - **d)** Computer in PRIMUS hooked up to the PRIMEVIEW.
     - **a)** Either with the BlackBox ServSwitch KVM unit or the PC anywhere program. Getting a quote from Siemens/update.
   - **e)** Contact FUJI to find out how to fix the non-RT image problem we are having with the new CR machine/update.
   - **f)** Update from Siemens meeting.
   - **g)** Fan for the CT Computer

3. Physics update: (Naughton)
   - a) Treatment Machine down-time log review (Naughton)
   - b) IMRT updates (Naughton)
   - c) Fiducial Placement update.(Dr. Godinez)
   - d) New starts the day after implants.(Flagg)

4. Nursing/Please add too if needed.
   - a) Patient Surveys
   - b) Patient Stats Mortality and Morbidity
   - c) Unplanned interruptions during treatment

5. Policies/Procedures/Guidelines/Forms (Morneau)
   - a) Filming Policy
   - b) ACR accreditation what we need to review and update.

6. Projects
   - a) ACR update
   - b) Endo-rectal coil for MRI of prostate
   - c) Going Paperless, going chartless. Using LANTIS

7. Review of incident and discrepancy reports

8. Facility Patient-Related Outcome Data

9. Information Only:
   - a) Dr. Drum: audit checklist and the safety culture

NHPP Scatterings

January/February 2009

Oversight for use of radioactive materials

Facility oversight for use of radioactive materials is a planned key review item for inspections in 2009. The inspection review will include the following.

- Organization and reporting for Radiation Safety Committee and Radiation Safety Officer.
- Possible undue reliance on affiliate universities or outside consultants.
- Reporting options for concerns or allegations.
- Focus to a safety culture and willingness to stop work to ensure regulatory compliance.

Tritium exit signs

NRC has requested 61 organizations including VHA to check tritium exit signs in their possession against their records and to report any lost or missing signs.

In a "demand for information" issued January 16, 2009, NRC has asked organizations possessing 500 or more tritium exit signs to report in writing to NRC within 60 days the following information:

- An explanation of how the organization ensures compliance with regulatory requirements for the possession, transfer, and disposal of tritium exit signs the organization has acquired;
- A confirmation of the total number of signs in possession and whether this matches the number in the organization's records;
- The reasons for any discrepancies, and actions taken or planned to locate any missing signs; and
- Actions taken or planned to prevent future losses.

Policy statement on safety culture

NRC encourages licensees to establish and maintain a strong safety culture which is a work environment where management and employees are dedicated to putting safety first. NRC is holding a public workshop to discuss safety culture in January 2009.

NRC plans to develop a draft policy statement about a safety culture by April 2009. The policy statement is to outline considerations both for safety and security culture in materials programs such as VHA.

NHPP inspections - - contractors

NHPP completes performance-based inspections with a focus on outcomes that demonstrate compliance to applicable regulations and permit conditions.

A person working under a facility permit is evaluated for regulatory compliance irrespective of whether the person is from an affiliate university, a consultant, or a contractor.

NRC inspections

NRC continues to complete independent inspections as oversight for the master materials license. They have completed 20 independent inspections in the current inspection cycle that began in April 2008.

NRC has completed other focused inspections for seed implant programs.

NRC inspected NHPP during December 8-12, 2008, and noted one apparent violation related to timing for National Radiation Safety Committee approval for escalated enforcement actions.

The committee has normally approved actions at the next quarterly meeting after the action was issued by NHPP. NRC questioned whether SOP #3 implies that committee approval should be before the report is issued.

NRC inspection concern

NRC inspected a seed implant program and discussed a concern about program oversight at the exit meeting. The specific issues noted by NRC included the following.

- Quality of internal quarterly audits in identifying and reporting program deficiencies,
- Follow-up by Radiation Safety Committee such as evaluation of annual program reviews, and
- Failure to have a safety conscious work environment (i.e., medical events identified by radiation worker not being reported to Radiation Safety Officer).

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NHPP Scatterings

March/April 2009

Safety culture defined

NRC plans to develop a draft policy statement about a safety culture by April 2009. The policy statement is to outline considerations both for safety and security culture in materials programs such as VHA.

FAQ 09-01 has an initial definition for safety culture as a work environment where both management and employees are dedicated to putting safety first. For medical institutions, "safety" includes both patient safety and occupational safety.

A safety culture involves a questioning attitude and alertness for errors and vulnerabilities by all staff; staff at all levels working together to avoid errors and accidents; managers and leaders welcoming safety concerns and suggestions from workers; and a willingness to stop work, if needed, to avoid accidents and achieve regulatory compliance.

Closeout surveys

NHPP Internal Procedure No. 16 has basic guidelines for amendment requests to release a location of use. Specific radiation survey requirements are described in the attachment to the procedure. In addition, FAQ 02-03 has suggested best practices and templates for closeout survey documentation.

Closeout survey requirements in the procedure are consistent with NUREG-1757, Volume 1, Figure 8.1, and involve three types of measurements.

Surface scans for contamination.

Surface scans must be performed for contamination using an appropriate detector. Scans should cover 100% of affected floors, lower walls, and bench tops. Stationary surface activity measurements should be reported at each survey location. The results of measurements should be reported in dpm/100 cm^2.

Swipe surveys for removable contamination.

A swipe survey for removable contamination must be performed at each survey location. Results should be reported in dpm/100 cm^2.

Exposure rate measurements.

An exposure rate measurement is required at 1 meter above/from surfaces at each survey location. The results should be reported in mR/hr.

A closeout survey normally should include at least 30 survey or measurement locations for each room, or area to be released. Measurement locations must be keyed to a facility diagram, drawing, or survey grid.

The NHPP Intranet Web site has a page for issues related to footprint management. A separate page specific to closeout surveys is under development.

Tritium exit signs

In a "demand for information" issued January 16, 2009, NRC has asked organizations possessing 500 or more tritium exit signs to report to NRC information about the location and status of the signs.

The NRC database indicates around 1,400 signs were distributed to VHA facilities. Initial information about tritium exit signs is on the NHPP Intranet Web site.

NHPP is providing health physics input to VHA central office for a plan to respond to NRC and establish a program to track tritium exit signs.

NRC inspections

NRC has completed more than 20 inspections in the current inspection cycle that began in April 2008 for the biannual inspection. The status of the NRC on-site inspection at North Little Rock, Arkansas, is unclear as is the overall biannual inspection.

NRC inspected NHPP during December 8-12, 2008, and noted one apparent violation related to timing for National Radiation Safety Committee approval for escalated enforcement actions. This inspection is for seed implant programs and will include separate NRC on-site inspections at all seed implant programs.

The status for this NRC inspection of NHPP and other inspections specific to the seed implant programs is unclear.

No FEAR Act commitment

The No FEAR Act ensures all Department of Veterans Affairs (VA) workers have the right to raise legitimate concerns about possible regulatory violations without fear of reprisal.

The new VA Secretary stated commitment to the No FEAR Act in a memorandum dated February 27, 2009.

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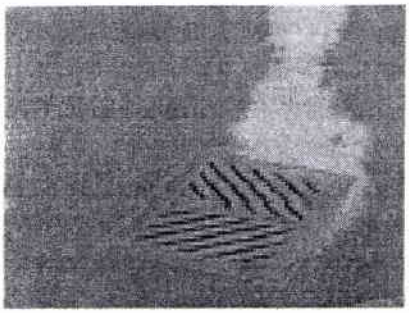
Boston Healthcare System
The Information source for Boston HCS employees

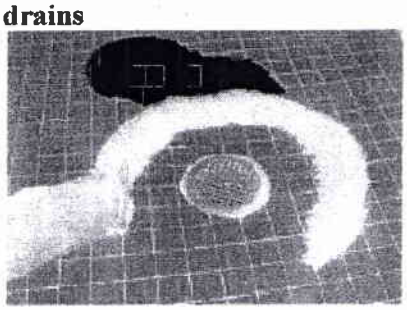
Date: 03/12/2009

SPILL RESPONSE

All Boston Healthcare System employees having a role in managing or maintaining hazardous materials and oil containing devices must be able to initiate an appropriate spill response.



Storm Drains- Frequently check hydraulic lines for trash compacters that are near storm drains



Upon discovery of a spill: ASSESS the severity of the situation.

- **Determine if the situation is immediately hazardous to your well being, evacuate if in danger.**
- **For large spills that can reach a drain or catch basin, immediately call the telephone operators at 33333.**
- **If situation allows, quickly cover/block the floor drain/catch basin with a drain cover, boom, speedy dry, etc.**

For small (incidental) spills:

- **CONTAIN spill without endangering yourself or others.**
- **Block storm or floor drains or floor openings to prevent the spilled material from reaching the environment.**
- **Ensure the area is properly ventilated.**

Small Spill Clean Up:

- **Wear appropriate protection equipment (safety glasses, gloves, etc.).**
- **Use absorbent material (pads, speedy dry, etc.).**
- **Store in a covered bucket or drum with secure lid.**
- **Affix a Hazardous Waste label.**
- **Contact the Safety Office at 774-826-1158 for disposal.**

Oil Spill Prevention:

- All waste containers need to be placed in/on secondary containment that has a storage capacity of 110% of the container size.
- Perform monthly inspections on all oil containing devices that have a capacity of 55 gallons or greater.
- Know where all spill kits are located in you facility and take time to ensure they are properly stocked.

Group Discussion Topics:

- Identify any past spill situations and how they were handled.
- Are there any oil containing equipment and/or hazardous materials that pose a greater risk than others for a potential spill/release?

RADIATION AT VA BOSTON HEALTHCARE

Radiation is energy emitted from the nuclei of radioactive atoms or produced by machines. Radioactive sources emit radiation in several forms. Gamma rays and x-rays are able to penetrate the body; they differ only by their source, i.e., radioactive atoms or x-ray machines.

We measure radiation exposure in terms of the roentgen, R, a measure of radiation exposure in air. The terms Gray (= 100 rads) or Sievert (= 100 rem) are used to measure the dose of radiation deposited in the body.

In Diagnostic Radiology, x-ray machines emit radiation at the instant a single picture is taken. In contrast, radiation may be continuous during fluoroscopy, as in the cardiac cath lab. Nuclear Medicine uses radiopharmaceuticals (a pharmaceutical with radioisotope tag attached) for diagnostic studies. Injected intravenously, the radiopharmaceutical seeks out its target organ, permitting pictures to be made from the emitted gamma rays. The patient remains slightly radioactive for up to 24 hours.

Radiation is also used therapeutically. Two linear accelerators in Radiation Oncology provide high energy x-rays to destroy cancer cells. Patients do not become radioactive. For other patients, therapy may be done with radioisotopes, such as Iodine-131 for thyroid conditions, or Iodine-125 for prostate cancer. These patients become a temporary source of radiation, and may need to be kept in the hospital until they are no longer any hazard to family and friends.

Research laboratories use radioisotopes for their analyses. Warning signs should indicate the presence and location of radioisotopes in a laboratory.

When radiation penetrates the body, it may go right through or may injure some or many cells, depending upon the uses described above. Most sensitive to radiation are those cells that multiply most rapidly, such as bone marrow, intestinal lining, or embryonic cells. The chromosomal DNA in cell nuclei may be affected, but in most cases any damage is rapidly repaired by the body. Only when many cells are exposed to high radiation doses is there an increased risk of later cancer.

We are exposed to some background radiation all the time, in addition to that we may receive for medical management. Cosmic radiation, radioisotopes in the earth and in building materials, foodstuffs, and in fallout from weapons tests all contribute to our annual dose.

A GI series, for example, may deliver 2 to 3 times the annual background dose. We accept this dose, and that from CT scans and fluoroscopy, in anticipation of the benefit to medical diagnosis. High doses may be needed to kill cancer cells.

Facility Response for Implementation of VHA Standard Procedures

Facility name: VA Boston

Implementation of VHA standard procedures:

Training	(✓) Yes	( ) No
Training for medical events	(✓) Yes	( ) No
Written directives	(✓) Yes	( ) No
Clinical requirements	(✓) Yes	( ) No

Signature and date
Director or Chief of Staff

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER
BROCKTON/WEST ROXBURY/WOPC, MASSACHUSETTS

Inservice Education Record Form
Medical Center Education Department

Title of Inservice Education Class: MANUAL BRACHYTHERAPY

Description of Class: REVIEW KEY REQUIREMENTS OF NHPP

Length of Class: 60 MIN **Instructor:** DR DRUM RSO; J NAUGHTON

Teaching Methods: (Circle all that apply) 3/24/09 JP Conf. Room

1. Lecture 2. Lecture/discussion 3. Lecture/demonstration 4. Videotape 5. Audio tape
6. Reading material 7. Learning module 8. Computer Assisted Instruction 9. Other

Date	Name - PRINT	Title	Service	Social	Security	Number
3/24/09	DAVID E. DRUM	RSO	NUCLEAR	228	42	5205
3/24/09	JUAN GODINEZ	Rad Onc MD	Rad onc	049	86	1212
3/24/09	KAPLAN, Jerry	Rad onc	Rad onc	122	52	8440.
03-24-09	KARASIEWICZ, CAROL	ULTRASOUND TECH	RAD ONC	030	90	1854
3/24/09	John Naughton	Physicist	Rad Onc	012	62	1548
3/24/09	Nicole Flagey	RTI Dosimetrist	RADONC	004	82	3484

Notice to all

(1) Purpose these meetings

(2) recent NRC inspection comments

(3) 2006 scattering

(4) Events - - ?D

(5) written directive

(6) audit check list

(7) wipes

(8) chemical requirements

$2 \times 10^6 = 1 \mu C$

$2000 = 0.1 \mu C$

$= .001 \mu C$

REPORT

None Entered

January 9, 2009

VHA Standard Procedure - - Clinical Requirements

1. This VHA standard procedure has requirements for technical quality assurance (QA), pre-implant or intraoperative treatment planning, post-implant treatment planning, post-treatment dose analysis, and seed placement and verification.

2. VHA facilities performing permanent implant prostate brachytherapy must develop, maintain, and implement written procedures for the clinical requirements listed above. The facilities must also develop, maintain, and implement written procedures for written directives per 10 CFR 35.41. A facility has the option to combine written procedures into a single document. The items below are specific guidelines to be followed by VHA facilities performing permanent implant prostate brachytherapy.

3. The guidelines are based on the American College of Radiology *Practice Guideline for Transperineal Permanent Brachytherapy of Prostate Cancer* and publications by the American Association of Physicists in Medicine (AAPM).

4. The facility must have a QA program for each device used for planning, performing, and assessing the implant procedures; these devices include the stepper/stabilizer, transrectal ultrasound system (TRUS), treatment planning system, and CT or MRI system. A therapeutic medical physicist experienced in prostate brachytherapy procedures must approve the QA program and periodically review the program. QA for the TRUS should substantially conform to the AAPM TG 128 report. Medical physicists and physicians should pay attention to spatial resolution, grey scale contrast, geometric accuracy, and distance measurement. The correspondence between the electronic grid pattern on the ultrasound image and the template grid pattern should be verified. 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.

5. Computerized treatment planning system requirements are as follows.

a. Complete acceptance testing of the treatment planning system per 10 CFR 35.457 before the first patient treatment use and after software revisions or upgrades and commissioning other models of seeds. The acceptance testing methods and results should be reviewed and approved by a therapeutic medical physicist experienced in prostate brachytherapy procedures. The acceptance testing and seed commissioning must be documented in a written report describing references, methods, and results. The testing must 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.

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

c. Ensure medical physics staff is aware of and uses technical guidelines in AAPM Report No. 68 (TG-64).

6. Seed strength calibration requirements are as follows.

January 9, 2009

VHA Standard Procedure - - Clinical Requirements

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

b. The output or activity of the seeds may be determined by a commercial vendor such as the seed manufacturer or a vendor that loads the seeds into needles or cartridges or places them in suture material. If the facility does not measure every seed, the facility must maintain written documentation that the seed manufacturer or vendor assays every seed and the measurements conform to 10 CFR 35.432.

c. In addition to the above, the facility may choose to assay seeds from each shipment on site. AAPM Report No. 98 provides guidance on such assays and should be followed.

7. Pre-implant or intraoperative treatment planning requirements are as follows.

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. Checking of the treatment plan must be performed as required by 10 CFR 35.41(b)(3). The written procedures should specify how this check is to be performed.

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

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, another pre-plan should be created.

8. At the end of each procedure, obtain a radiographic or fluorographic image depicting seed positions in the patient. Fluoroscopic imaging should be immediately available during the procedure, to serve as a check that seeds are not being inadvertently placed away from the intended region.

9. After completion of the implant procedure, complete the post-implant portion of the written directive to record the information required in 10 CFR 35.40 (treatment site, radionuclide, number of sources implanted, total source strength implanted, and the word "permanent").

10. Immediately after the completion of each implant, perform a survey of the room using a portable radiation survey meter to locate any misplaced sources, as required by 10 CFR 35.404. The survey should include the floor, linens, waste material, applicators, and empty needles and cartridges. A record of the survey must be made as required by 10 CFR 35.2404. The survey should include the feet of people leaving the room.

11. Before releasing the patient, perform a release survey as required by 10 CFR 35.75 and document the survey as required by 10 CFR 35.2075(a). The survey should include measurement of the exposure rate, air kerma rate, dose rate, or dose equivalent rate at a distance of 1 meter from the patient. The survey must be made with a radiation survey meter calibrated for the energy of the radiation emitted from the seeds, or the measurement must be corrected for energy using the energy response curve of the meter and any attached detector. The patient must also be given instructions, both in writing and verbally, on

actions recommended to keep doses to others as low as reasonably achievable. The instructions must include actions to take if a seed is passed in the urine.

12. Post-treatment planning requirements are as follows.

a. Post-implant imaging and dosimetric analysis is mandatory and must be completed 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. The post-treatment planning must evaluate the relationship of the implanted seeds to the prostate, rectum, and other extra prostatic tissues.

e. Establishment of a consistent post-implant image acquisition time frame. Examples:

(1) Obtain CT images at approximately 2 to 3 weeks post-implantation for Pd-103 and approximately 4 weeks post-implantation for I-125, or

(2) Obtain 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, such as a quarterly report:

(1) Date of implant procedure and date of post-implant CT imaging.

(2) Prescribed dose.

(3) D90, defined as the minimum dose received by 90% of the target volume as delineated on the post-implant CT. According to AAPM Report No. 68 (TG-64), "An implant with good coverage is characterized by D90 equal to or greater than the prescribed dose."

(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.

(5) Rectal dose index, such as the R100 (volume of the rectum in cm^3 that receives 100% or more of the prescribed dose).

(6) Evaluation of seeds outside the intended treatment volume.

13. Post-treatment dose analysis requirements are as follows.

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.

January 9, 2009

VHA Standard Procedure - - Clinical Requirements

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.

14. 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 should include ongoing within-department peer review. In addition, five cases each year should receive external peer review as specified by the Director, National Radiation Oncology Program, or as required by a VHA Handbook or Directive.

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*

December 19, 2008

VHA Standard Procedure - - Training

1. VHA facilities with prostate brachytherapy programs must complete initial and periodic training for the staff involved in, or supporting, the prostate brachytherapy program.

2. Training must be provided to physician authorized users, medical physicists, dosimetrists, participating urologists, and Radiation Safety Officers and staff. Other workers who participate in the procedures (e.g., anesthesiologists or anesthetists, nursing staff, and resident physicians) must receive training, as needed.

3. The training must be commensurate with duties. A separate VHA standard procedure has more details for training for medical events.

4. The training topics to consider are listed below. The facility must document training completion and evaluate effectiveness of training by various methods such as group and one-on-one discussions, written or computer-based tests, and during audits.

Training Topics

1. Basic radiation biology, including risk estimates.
2. Radiation protection to include concepts of time, distance, and shielding.
3. Concept of maintaining radiation exposure ALARA (10 CFR 20.1101).
4. Posting requirements (10 CFR 20.1902).
5. Proper use of dosimetry (if applicable).
6. Access control procedures and security (10 CFR 20.1601 and 20.1801/.1802) and two delay methods if stored.
7. Proper use of radiation shielding, if used.
8. Patient release instructions, procedures, surveys, and records (10 CFR 35.75 and 35.2075).
9. Instruction in procedures for notification of the Radiation Safety Officer and physician authorized user, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. Note: The intent of these procedures should not interfere with or be in lieu of appropriate patient care (10 CFR 19.12, 35.310, 35.410, and 35.610).
10. Occupational dose limits (10 CFR 20.1201).
11. Worker's right to be informed of occupational radiation exposure (10 CFR 19.13).
12. Worker's obligation to report unsafe conditions to the Radiation Safety Officer (10 CFR 19.12) and have a safety focus to ensure regulatory compliance. Methods and procedures for management oversight for use of radioactive materials.
13. Applicable regulations, licenses, permits, and notices (10 CFR 19.12).

14. Location and availability of applicable regulations, licenses, permits, notices, and Web sites (10 CFR 19.12).

15. Recordkeeping requirements (10 CFR 19.12), and documents and records for prostate brachytherapy procedures.

16. Radiation surveys to be completed (10 CFR 20.1501).

17. Proper calibration of survey instruments (10 CFR 20.1501).

18. Emergency procedures such as for a damaged or leaking seed, a leaking or damaged seed implanted in a patient, and a lost seed or seeds.

19. Decontamination and release of facilities and equipment (10 CFR 20.1406).

20. Dose to members of the public (10 CFR 20.1301).

21. Facility written procedures, protocols, and practices for prostate brachytherapy procedures.

Handling and security of sealed sources

a. Radioactive material package receipt surveys and records (10 CFR 20.1906).

b. Source accountability (10 CFR 35.406) and records of accountability (10 CFR 35.2406).

c. Physical inventory (10 CFR 35.67(g)).

d. Source disposal (i.e., ship to vendor or decay on site) (10 CFR 35.92 and 35.3092).

Preparations for seed implant procedures

e. Written procedures and checklists (10 CFR 35.40 and 35.41).

f. Patient identity verification, written directive, and treatment plan checking procedures (10 CFR 35.40 and 35.41).

g. Pre-implant imaging (volume study), modality (TRUS, CT)

h. Pre-plan preparation.

i. Written directive, pre-implant part preparation, including prescribed dose.

j. Surveys after source implant for misplaced seeds and records (10 CFR 35.404 and 35.2404).

k. Calibration measurements of sources (10 CFR 35.432).

l. Acceptance testing of treatment planning system (10 CFR 35.457).

m. Quality assurance of imaging (i.e., TRUS, CT, and accuracy of image transfer).

VHA Standard Procedure - - Training

n. Possible problems, precautions to prevent, and follow-up actions for the following:

(1) Lost seeds,

(2) Seeds damaged during procedure,

(3) Leaking seeds, including leaking seeds implanted in patient

22. Medical event definitions and roles and responsibilities to include what is a medical event, how to identify a medical event, criteria to determine if specific patient circumstances are a medical event, and reporting requirements for a medical event. Procedures for after-hours recall or notifications (10 CFR 35.3045).

23. Methods and procedures to verify seed placement is correct and determine proper needle placements during prostate brachytherapy procedures, including appropriate imaging modality verifications.

24. Preparation and completion of written directives (pre- and post-implant parts).

25. Methods and procedures for pre-implant treatment planning, post-implant treatment planning, and post-treatment dose analysis.

December 19, 2008

VHA Standard Procedure - - Training

1. VHA facilities with prostate brachytherapy programs must complete initial and periodic training for the staff involved in, or supporting, the prostate brachytherapy program.

2. Training must be provided to physician authorized users, medical physicists, dosimetrists, participating urologists, and Radiation Safety Officers and staff. Other workers who participate in the procedures (e.g., anesthesiologists or anesthetists, nursing staff, and resident physicians) must receive training, as needed.

3. The training must be commensurate with duties. A separate VHA standard procedure has more details for training for medical events.

4. The training topics to consider are listed below. The facility must document training completion and evaluate effectiveness of training by various methods such as group and one-on-one discussions, written or computer-based tests, and during audits.

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12. Worker's obligation to report unsafe conditions to the Radiation Safety Officer (10 CFR 19.12) and have a safety focus to ensure regulatory compliance. Methods and procedures for management oversight for use of radioactive materials.
13. Applicable regulations, licenses, permits, and notices (10 CFR 19.12).

VHA Standard Procedure - - Training

14. Location and availability of applicable regulations, licenses, permits, notices, and Web sites (10 CFR 19.12).

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c. Physical inventory (10 CFR 35.67(g)).

d. Source disposal (i.e., ship to vendor or decay on site) (10 CFR 35.92 and 35.3092).

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g. Pre-implant imaging (volume study), modality (TRUS, CT)

h. Pre-plan preparation.

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24. Preparation and completion of written directives (pre- and post-implant parts).

25. Methods and procedures for pre-implant treatment planning, post-implant treatment planning, and post-treatment dose analysis.

Drum, David

From: Williams, Gary E

Sent: Thursday, February 26, 2009 9:58 AM

To: Bergsagel, Carl E.; Boyd, Katherine R; Bravenec III, Joseph S; 'Breslow, Richard'; Cipperley, Kristine; Drum, David; Dunn, David J; Funkhouser, Michael,D; Furr, Walter L. (Buddy) DURVAMC; Germes, Arnulfo; Giri, Shankar; Hensch, Thomas; Huang, Shawn; Krutoff, Bradford M.; Lowe, John D. (VHAJAC); Mirell, Stuart .; Moore, Mary E.; Naughton, John P VHABHS; Patel, Indravadan; Phillips, Roland; 'ppfatouros@vcu.edu'; Qin, Lihong; Rauf, Chris, VHACIN; Rutan, James H.; Sarfaraz, Esfandiar; Sitek, Mark A.; Smith, Mike (VHAJAC); Song, Haijun DURVAMC; Sutlief, Steven G.; Phillips, Roland; Hershatter, Bruce MD; iris@radonc.emory.org; Kemp, Wendy H. RICVAMC; Saleh, Habeeb RICVAMC; Balog, John P; Mokadam, Alka; Chacko, Koruth K. (VHAJAC); Guerrero, Mariana

Cc: Anderson, Charles M.; McGuire, Lynn (VACO); Yurko, Paul; Wissing, Joseph; Huston, Thomas E.; Leidholdt, Ed; Offutt, Lisa M; Williamson, Sandra; MHagan@mcvh-vcu.edu; Hagan, Michael P., M.D., Ph.D. RICVAMC

Subject: audit checklist list - - revised for standard procedures

Attachments: seed implant checklist 25 Feb 09.doc

I am sending for your information a draft revision to the audit checklist for seed implant programs.

The revision incorporates questions related to the standard procedures.

The implementation date for the standard procedures is approaching.

NHPP will use a version of this checklist for future audits or inspections at seed implant programs.

Facilities with seed implant programs will be required to complete periodic audits using the checklis

The revisions in this draft are shown in yellow highlight.

Gary E. Williams
National Health Physics Program
Veterans Health Administration
North Little Rock, Arkansas
(501) 257-1572

Transperineal Permanent Implant Prostate Seed Brachytherapy - - Audit Checklist

(insert facility name and dates for audit)

The audit checklist should be used to determine overall status for the seed implant program and to ensure compliance with specific regulatory requirements and best clinical practices. The issues or categories to evaluate and review are in the ten major sections below.

1. Handling and security of sealed sources

   a. Radioactive material package receipt surveys and records (10 CFR 20.1906).

   b. Security requirements (10 CFR 20.1801 and 20.1802) and two delay methods if stored.

   c. Source accountability (10 CFR 35.406) and records of accountability (10 CFR 35.2406).

   d. Physical inventory (10 CFR 35.67(g)).

   e. Source disposal (i.e., ship to vendor or decay on site) (10 CFR 35.92 and 35.3092).

2. Preparations for seed implant procedures

   a. Written procedures and checklists (10 CFR 35.40 and 35.41).

   b. Patient identity verification, written directive, and treatment plan checking procedures (10 CFR 35.40 and 35.41).

   c. Pre-implant imaging (volume study), modality (TRUS, CT), how long before implant?

   d. Pre-plan preparation. Who draws the contours of the prostate and other organs?

   e. Written directive, pre-implant part preparation, including prescribed dose.

   f. Surveys after source implant for misplaced seeds and records (10 CFR 35.404 and 35.2404).

   g. Patient release procedures, surveys, and records (10 CFR 35.75 and 35.2075).

   h. Patient release measurements after source implantation with a survey meter capable of accurately measuring exposure rate, air kerma rate, or dose rate for photons of the energy emitted or a method to correct the measurements for the energy response of the meter.

   i. Patient instructions (10 CFR 35.75).

   j. Calibration measurements of sources (10 CFR 35.432).

   k. Acceptance testing of treatment planning system (10 CFR 35.457).

   l. Quality assurance of imaging (i.e., TRUS, CT, and accuracy of image transfer to TPS).

m. Requirements for a medical event or other incident circumstances including after-hours recall or notifications (10 CFR 35.3045).

n. Radiation Safety Committee approval of physician authorized users (broad-scope) or named on the permit (limited-scope).

o. Procedures to evaluate for possible leaking seeds and follow-up actions.

p. Training (i.e., initial and periodic) for authorized user physicians, medical physicists, and other staff.

q. Usual type of anesthesia?

r. Prescribed dose for each radionuclide used?

s. How are images (TRUS, radiographs, and CT) used for prostate brachytherapy stored (e.g., film, PACS, server in radiation oncology), are backup copies maintained, how long are the images retained?

t. Do any issues with digital information transfer hinder the preparation of pre- and post-plans?

3. Performance-based interviews and observations (includes requirements in VHA standard procedures)

a. Authorized user physicians.

b. Medical physicists and dosimetrists.

c. Other physicians including urologists and/or residents.

d. Radiation Safety Officer.

e. Support staff.

4. Performance-based tours and observations

a. Radiation oncology areas.

b. Package receipt areas.

c. Seed implant preparation areas.

d. Seed storage areas.

5. Evaluation of patient treatment results

a. Methods and procedures to determine if all seeds were implanted properly.

b. Fluoroscopy used to supplement TRUS during procedure (yes or no).

c. Radiograph acquired after implant (yes or no).

d. Written directive, post-implant part: when completed and how.

e. Post-implant CT scans: when completed?

f. Post-plans: when completed, who draws the contours of the prostate and other organs, are the seed locations found by software manually corrected, how to verify complies with written directive. Are any indices of rectal dose calculated?

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

h. Clinical quality assurance, including peer review.

6. Workload data

a. Method of implantation (preloaded needles, Mick applicator, needles loaded at facility).

b. Date of program inception.

c. Number of patients implanted per year.

d. Radionuclides (I-125, Pd-103, Cs-131) and seed models currently in use.

7. Implementation of standard procedure for training

a. Periodicity of training and how completed.

b. Review of training records.

c. Methods used to evaluate effectiveness of training.

d. Groups receiving training and evaluation of training topics used for each group.

(1) VHA standard procedures with emphasis on medical event identification and reporting

(2) NRC regulatory requirements

(3) Focus to a safety culture

e. Results for performance-based interviews (if different from #3 above).

8. Implementation of standard procedure for training for medical events

a. Overall review of training for medical events (if different from #7 above).

b. Overall review of written procedures and written directives for medical events.

c. Results for performance-based interviews for medical events.

(1) Regulatory definition of medical event.

(2) Permittee roles and responsibilities for medical event evaluation and reporting.

(3) Permittee definition of medical event.

(4) How to identify a medical event and criteria to use.

(5) Notification and reporting requirements for medical events.

9. Implementation of standard procedure for written directives

a. Overall review of training for written directives (if different from #7 above).

b. Overall review of written procedures and forms for written directives.

c. Overall review of completed written directives including results for quarterly audits.

d. Results for performance-based interviews for written directives.

(1) Regulatory definition of written directives.

(2) Record retention requirements for written directives.

(3) Permittee specific requirements for written directives.

10. Implementation of standard procedure for clinical requirements

a. Overall review of training for clinical requirements (if different from #7 above).

b. Overall review of written procedures and forms to incorporate clinical requirements.

c. Overall review of completed records that incorporate clinical requirements.

(1) Computerized treatment planning systems.

(2) Seed strength calibration.

(3) Pre-implant or intraoperative treatment planning.

(4) Images acquired at end of patient procedure.

(5) Completion of post-implant port of written directives

(6) Release surveys.

(7) Post-implant planning.

(8) Post-treatment dose analysis.

(9). Clinical peer reviews.

VA Boston Healthcare System Brachytherapy Order Form &
Written Directive for I-125 Seed Implant

Patient's Name:_____**Patient's ID:** _____

Sources Ordered

Type of Implant:_____Isotope/Activity:_____
Scheduled Implant Date:_____No. of Seeds Ordered:_____
Sealed Source Prescription:_____Physicians Signature/Date:_____

Sources Received

Date/Time Received:_____Vendor /PO#:_____
Received By:_____Radionuclide_____
Total Number of Seeds:_____Activity/Seed:_____mCi/Seed
AU:_____Total Apparent Activity:_____mCi
Label Type and Transportation Index:_____
Date of Calibration:_____Package Survey Signature/Date:_____

Pre-Implant Written Directive

Type of Implant:____Permanent Prostate Implant_____
Treatment Site:_____Radionuclide:_____
Number of Sources:_____Activity per Seed:_____mCi
Number of Needles:_____Total Apparent Activity:_____mCi
Prescription Dose:_____Physicians Signature/Date:_____

Time Out

Patient ID: State Name( ) Wrist Band ( ) DOB ( ) SSN( )

Post-Implant Written Directive

Type of Implant:____Permanent Prostate Implant_____
Radionuclide:_____Treatment Site:_____
Activity per Seed:_____mCi Number of Seeds:_____
Number of Needles:_____Prescription Dose:_____Gy
Total Source Strength:_____mCi Physicians Signature/Date:_____

Patient Release Survey and Room Release Survey

Survey Instrument:_____Model #:_____Serial #:_____
Probe:_____ Model #:_____Serial #:_____

Patient: Exposure Rate @ 1 m:_____mR/hr
Operating Room: Exposure Rate :_____mR/hr
Recovery Room: Exposure Rate :_____mR/hr
Patient Room: Exposure Rate :_____mR/hr
Survey Performed By:_____

Radiation Oncology Physics Review_____

RSO Review_____

Physician Peer Review_____

NHPP Scatterings

Special Edition, June 28, 2006

Current Issues in Permanent-Implant Prostate Seed Brachytherapy

NRC recently reviewed the definition of a medical event in NRC regulations. NRC concluded the definition of a medical event was satisfactory, except for permanent-implant brachytherapy. NRC plans to change the medical event definition for permanent-implant brachytherapy to base it upon the total source strength implanted in the treatment site instead of the dose imparted to the treatment site. Please note the regulations have NOT yet been changed. NHPP will notify permittees when the rulemaking occurs.

NRC also will take action to improve the public's understanding of the risks associated with medical events. NRC intends to publicize (1) NRC's definitions of a medical event "provide thresholds for identifying events indicative of technical or QA problems in accurately realizing the clinical intentions (prescriptions)" of authorized user physicians, and (2) thresholds in NRC's medical event definitions, if exceeded, are not necessarily indicative of patient harm.

FAQ 06-01, recently posted on the NHPP Web site, contains information for permittees performing permanent-implant prostate brachytherapy. It lists two medical events and two other events in which there were significant errors in seed placement and describes several possible contributing causes. This FAQ also notes, in some cases of prostate seed misplacement in the patient, it may be possible to revise the written directive immediately after the procedure and avoid the misplacement being a medical event.

The American College of Radiology (ACR) publishes *ACR Practice Guidelines and Technical Standards* on its Web site at the URL http://www.acr.org/s_acr/sec.asp?CID=1848&DID=16053**. We recommend use of the ACR Practice Guideline for Transperineal Permanent Brachytherapy of Prostate Cancer as a best practice.**

VA National Health Physics Program; Lisa M. Offutt, Administrative Officer
Telephone: (501) 257-1571; Fax: (501) 257-1570; Website: nhpp.med.va.gov
E-mail: vhconhpp@med.va.gov; Outlook global address: VACO NHPP

Attention Radiation Therapy Employees:

If any employee of the Radiation Therapy Department is interested in viewing our monthly Radiation Dosimetry Report, there is a copy located in the following areas:

1. ***Physics Office***
2. ***The Radiation Safety Officer (Dr. Drum)***
3. ***Chief Radiation Therapist (Jason Morneau)***

NRC Regulations, the NRC License and the operating procedures applicable to the licensed activities may be found in the Radiation Safety Office. Please contact Dr. Drum at 617-705-1195 for more information.

Name_____

PROSTATE BRACHYTHERAPY EXAM

Circle the correct answer

1. Written documentation on seed activity must be maintained for:
   A) All seeds
   B) 10% of seeds
   C) None
2. When is the pre-implantation portion of the written directive completed?
   A) During planning
   B) After the implant
   C) Before the first needle/seed
3. The operating room survey performed immediately after the implant procedure should include:
   A) Floor
   B) Linen
   C) Waste
   D) Feet of OR personnel
   E) All of the above
4. For I-125, a patient may be release if his exposure rate at 1 meter is:
   A) Less than 1mR/h
   B) Less than 2mR/h
   C) Less than 5mR/h
   D) None of the above
5. Upon receipt of a radioactive materials shipment, a package must be surveyed:
   A) Within 24hrs
   B) Within 3hrs
   C) Within 5hrs
6. For a prescribed dose of 145Gy, which qualifies as a medical event:
   A) D90 = 130Gy
   B) V100 = 87%
   C) R100 = 1.3cm^3
   D) D90 = 110Gy
7. Who is notified if a medical event is notified?
   A) NRC
   B) Referring physician
   C) Patient

D) NHPP
E) All of the above

8. When should the NRC and NHPP be notified when a medical event is discovered?
   A) Within 15 days
   B) Within 2 days
   C) No later than the next calendar day

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER
BROCKTON/WEST ROXBURY/WOPC, MASSACHUSETTS

Inservice Education Record Form
Medical Center Education Department

Title of Inservice Education Class: MANUAL BRACHYTHERAPY

Description of Class: LECTURE

Length of Class: 60 min 3/11/09 **Instructor:** DAVID DROM RSO

Teaching Methods: (Circle all that apply)

1. Lecture 2. Lecture/discussion 3. Lecture/demonstration 4. Videotape 5. Audio tape
6. Reading material 7. Learning module 8. Computer Assisted Instruction 9. Other

Date	Name - PRINT	Title	Service	Social	Security	Number
3/6/09	DAVID E. DROM	RSO	NUCLEAR	225	42	5205
3/6/09	JUAN GODINEZ	MD.	RAD ONC	049	86	1212
3/11/09	Jerry Kudlow	MD	RADONC	122	52	8440.
3/11/09	John Naughton	Physicist	Radonc	015	65	1542
3/11/09	Nicole Flagg	RTT/DOS	RADONC	004	82	3484
3/11/09	JASON HOFMANN	RTT	Radonc	003	56	4233

( ) Workshop
( ) In-service

DEPARTMENT OF VETERAN AFFAIRS
VA BOSTON HEALTHCARE SYSTEM

Program: **VERIFICATION OF PATIENT IDENTIFICATION**

Date: 6-30-08

PRINT NAME	TITLE	SERVICE	CAMPUS	SIGNATURE/DATE
1. AMOROSO, PATRICIA	RN	NSG	JP	
2. ANDERSON, JANICE	RN	NSG	JP	
3. BUOTE, NICOLE	RT(T)	RT	JP	
4. CLANCY, MARIE	RT(T)	RT	JP	Marie Clancy RT(T) 6/30/08
5. ELSAYYAD, NAGY	MD	RT	JP	
6. FLAGG, NICOLE	DOS	CONTRACT	JP	Nicole B Flagg RTT 6/30/08
7. HANSEN, ROBERT	BLK	RT	JP	Robert Hansen
8. KNOLL, MEGAN	SEC	RT	JP	
9. LOCHIATTO, JOSEPH	RT(T)	FEE BASIS	JP	
10. MCALPINE, JAMES	RT(T)	RT	JP	
11. NAUGHTON, JOHN	PHYS	CONTRACT	JP	
12. NORTON, JUNE	SEC	RT	JP	30 Jun 08
13. WILLIAMS, TENITA	OA	RT	JP	
14. WALSH SUE	RT(T)	RT.	JP.	RT(T)
USAS, CRAIG	MD	RT		

KAPLAN, IRVING		MD	CONTRACT	JP	
KARASIEWICZ, CAROL		RT®	CONTRACT	JP	Carol Karasiewicz

08/04/2009 12:46 FAX 617 667 4990 002

VA MEDICAL CENTER
PROVIDENCE, RHODE ISLAND

POLICY MEMORANDUM CBO- 12
October 5, 2006
(CBO-1)

VERIFICATION OF PATIENT IDENTIFICATION

1. PURPOSE

To establish policy, procedure, and responsibility for verification of patient identification, and define a minimum standard of practice within the Providence VA Medical Center.

2. POLICY

It is the policy of the VA Medical Center to promote a safe environment for the care of patients by minimizing clinical risks where possible. The verification of patient identification is a critical aspect of patient safety in every patient care encounter.

3. DEFINITIONS

a. For the purpose of this policy, "verification of patient identification" includes confirmation of the patient's full name and full social security number. For blood transfusion, this definition is expanded to include blood type and group, and the use of new scanning technology, as available; and, for operative and other procedures, confirmation of the correct procedure to be performed.

b. All patients being treated in the ER (Emergency Department), ADTU (Ambulatory Diagnostic Treatment Unit), and scheduled admissions must be issued a patient identification wristband that contains the patient's full name and social security number. Review of any known allergies or adverse reactions to drugs should also be included in procedures that involve the dispensing or administration of medications. At a minimum, procedures for the verification process must include:

(1) verbal confirmation of patient identification by asking the patient to state full name and full social security number, if feasible, and;

(2) review of patient identification bracelet, VA hospital card or other documented forms of identification;

(3) if patient is confused, comatose, or otherwise unable to participate in the verbal verification of their identity, a member of the staff, relative, or other individual that may be accompanying the patient must be able to accurately verify their identification.

c. In other ambulatory care settings, each service/service line is responsible for establishing and maintaining processes to assure the verification of patient identification, especially in the absence of identification wristbands. The standard process is to ASK the patient

to state his or her full name and full social security number. It is important to use two unique identifiers in verifying patient identification. Comparing the individual's stated full name with the name on the requisition would be one identifier. In the event that a patient does not know their social security number, another acceptable second identifier can be date of birth, address, or phone number. In any situation of continuing one-on-one care where the provider "knows" the individual, one of the identifiers can be direct facial recognition.

4. MEMBERSHIP

None.

5. PROCEDURES

a. Identification of inpatients is verified during admission processing and an identification wristband is placed on the patient's upper extremity. The wristband contains the patient's full name and social security number.

b. At a minimim, all inpatients and patients in the ADTU, or other procedural units, i.e., GI suite, Bronchoscopy Suite, Invasive Radiology, Nuclear Medicine, the ER area, must have an identification wristband on at all times.

c. The Administrative Officer of the Day (AOD), ER clerks and Admission clerks will verify patient identifications via the VA Identification Card by verbally asking the patient their full name, and full social security number at the time of application of the ID bracelet.

(1) Emergency Department Patients:

a. The AOD's and ER clerks will apply ID bracelets on all patients being treated in the ER area.

b. In those instances when a clinical situation precludes the AOD/ER clerks from physically applying the ID bracelet, the AOD/ER clerks will ensure the placement of the bracelet. They may delegate the task of applying the ID bracelet to a clinician at the bedside and visualize the application as taking place.

(2) Scheduled Admissions:

The Admission Clerks, AOD's and/or ER clerk will apply the ID bracelet on all patients presenting for scheduled admission.

(3) Scheduled ADTU Patients:

a. Admission clerks and/or AOD's will apply the ID bracelets on all patients scheduled for surgery through the ADTU.

b. The ADTU staff will apply the ID bracelets on all other ADTU patients upon arrival to the ADTU Unit.

c. Upon arrival to the ADTU or an Inpatient Unit, Nursing personnel will verify that the correct ID bracelet is in place, in accordance with Nursing Procedure 0010, Admission of Patient.

6. RESPONSIBILITY

a. It is the responsibility of all members of the staff to accurately verify the identification of patients at every patient encounter, including, but not limited to prior to the dispensing or administration of medication and the performance of treatments or operative and other procedures within the scope of their job functions.

b. All Service Line Managers and Service Chiefs are responsible for assuring that procedures are in place to accomplish the accurate verification of patient identification, as appropriate, within the scope of authority.

c. AOD's, ER Clerks and Admission Clerks are responsible for issuing the proper ID bracelet and placing it on the patient's wrist.

d. Any clinical staff removing a patient's ID bracelet to perform a procedure (blood drawing, etc). will immediately notify the nurse and/or Medical Support Assistant so that a replacement ID bracelet can be prepared and placed on the patient's wrist.

7. REFERENCES

VISN 1 Memorandum No. 10N1-33.
M-1, Part I, Chapter 4.
M-2, Part I, Chapter 17, Change 27.
Nursing Service Procedure No. 0010, Admission of Patient.
JCAHO Manual 2006.

8. RESCISSIONS

Policy Memorandum 136-23, Identification Bracelets, dated September 5, 2003.

VINCENT NG
Medical Center Director

Attachments: None

DISTRIBUTION: D

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER
BROCKTON/WEST ROXBURY/WOPC, MASSACHUSETTS

Inservice Education Record Form
Medical Center Education Department

Title of Inservice Education Class: PROSTATE BRACHYTHERAPY TRAINING I

Description of Class: INTERACTIVE LECTURE – DISCUSSION (WASHINGTON DC MEETING ITEMS) 2/3/09

Length of Class: 1 hour **Instructor:** DAVID DRUM RSO

Teaching Methods: (Circle all that apply)

(1.) Lecture (2.) Lecture/discussion 3. Lecture/demonstration 4. Videotape 5. Audio tape
(6.) Reading material 7. Learning module 8. Computer Assisted Instruction 9. Other

Date	Name - PRINT	Title	Service	Social	Security	Number
2/3/09	DAVID DRUM	MD	RSO			5205
2/3/09	Irving Kaplan	MD	XRT.			
02-03-09	CAROL KARASIEWICZ	ULTRASOUND TECH	XRT			1854
2/3/09	JUAN GODINEZ	MD	XRT			1212
2/3/09	JASON MORRAY	Chief RT	XRT			4233
2/3/09	John Naughton	Physicist	XRT			
2/3/09	Nicole B Hacyg	Dosimetrist	XRT			

Education Department (#11B-insvform)
April, 1992
Revised March, 1997
Revised September, 1998

RADIATION ONCOLOGY SAFETY TRAINING
DC Guidance Conference, 1/8-9/09
VHA Standard Procedures, 12/19/08

Four basic segments:

1. Basic VHA guidelines
2. Medical events
3. Written directives
4. Start-stop

General
Basic biology. Risk of late cancer 5E-02 Sv^{-1}

Occupational dose limits – NRC vs OSHA
Radiation Protection 7 items
ALARA program: ALARA I = 10% of annual limit; ALARA II = 30% of limit
Posting: warnings, RSO, form 3
Security: two delay locks
Release instructions Reg Guide 8 .39
Emergency procedures
Copies of NHPP permit; NRC/NHPP regs at nrc.gov ; most local regs in hospital server
Package receipt and testing and documents

Medical events 10CFR35.3045
Dose over 50mSv whole body; 500mGy in organ or skin
And
Dose off by 20% or
Fraction off by 50% or
Wrong drug, wrong patient, wrong route, wrong route or
LEAKING SEED

The Radiation Safety Committee provides oversight of radioactive materials and radiation producing machines and requires periodic training for staff commensurate with their duties and responsibilities.

The Radiation Safety Officer must notify NHPP of a medical event within 24 hours.
Awareness is keyed to the written directive.
For brachytherapy, the figure of merit to identify a medical event during the posttreatment dose analysis is D90, which must be 80% of the prescribed target dose in the written directive..

Authorized user status – handouts and discussion.

David E. Drum,MD, RSO

RADIATION UNITS

	WORLD	USA
ACTIVITY, dps	Becquerel, Bq	Curie, Ci
ABSORBED DOSE, J/Kg	Gray, Gy	rad
EFFECTIVE DOSE, J/Kg	Sievert, Sv	rem
EXPOSURE, C/Kg	Roentgen, R	Roentgen, R

ANNUAL WORKER DOSE LIMITS

NCRP-116 1993

EFFECTIVE DOSE	
ANNUAL	50 mSv
CUMULATIVE	age x 10 mSv
LENS OF EYE	150 mSv
SKIN, HANDS, FEET	500 mSv
FETUS, MONTHLY	0.5 mSv

OCCUPATIONAL DOSE LIMITS
OSHA 29 CFR 1910.1096(b)(1)
quarterly

	rems
Whole body, head, trunk, marrow, lens, gonads, thyroid	1.25
Hands, forearm, feet, ankles	18.75
Skin, other organs	7.5

NRC vs OSHA

annualized dose limits

	dose, mSv	
	NRC	OSHA
Whole body, gonads, marrow	50	50
Lens	150	750
Skin, other organs	500	300

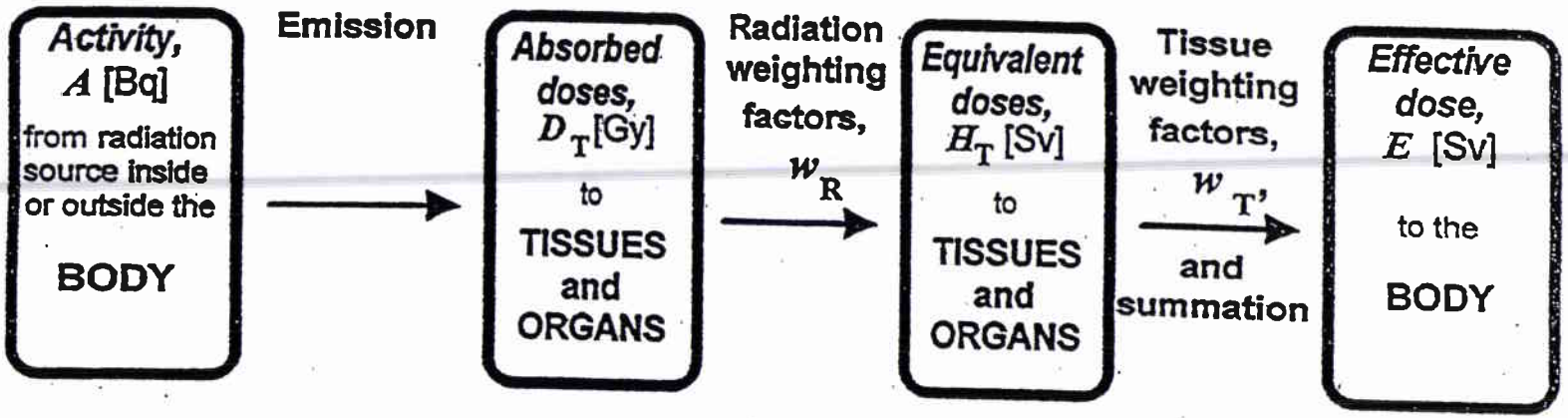


Fig. B.1. The relationship between activity, A, absorbed dose, D_T equivalent dose, H_T, and effective dose, E.

NRC FORM 3
(10-2008)

The VHA MML, amendments and the supporting applications are maintained by NHPP at their headquarters office. These documents are available for examination by contacting VHA NHPP (115HP), 2200 Fort Roots Drive, North Little Rock, AR 72114

UNITED STATES NUCLEAR REGULATORY COMMISSION
Washington, DC 20555-0001

NOTICE TO EMPLOYEES

STANDARDS FOR PROTECTION AGAINST RADIATION (PART 20); NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS (PART 19); EMPLOYEE PROTECTION

WHAT IS THE NUCLEAR REGULATORY COMMISSION?

The Nuclear Regulatory Commission is an independent Federal regulatory agency responsible for licensing and inspecting nuclear power plants and other commercial uses of radioactive materials.

WHAT DOES THE NRC DO?

The NRC's primary responsibility is to ensure that workers and the public are protected from unnecessary or excessive exposure to radiation and that nuclear facilities, including power plants, are constructed to high quality standards and operated in a safe and secure manner. The NRC does this by establishing requirements in Title 10 of the Code of Federal Regulations (10 CFR) and in licenses issued to nuclear users.

WHAT RESPONSIBILITY DOES MY EMPLOYER HAVE?

Any company that conducts activities licensed by the NRC must comply with the NRC's requirements. If a company violates NRC requirements, it can be fined or have its license modified, suspended or revoked.

Your employer must tell you which NRC radiation requirements apply to your work and must post NRC Notices of Violation involving radiological working conditions.

WHAT IS MY RESPONSIBILITY?

For your own protection and the protection of your co-workers, you should know how NRC requirements relate to your work and should follow them. If you observe violations of the requirements or have a safety concern, you should report them.

WHAT IF I CAUSE A VIOLATION?

If you engaged in deliberate misconduct that may cause a violation of the NRC requirements, or would have caused a violation if it had not been detected, or deliberately provided inaccurate or incomplete information to either the NRC or to your employer, you may be subject to enforcement action. If you report such a violation, the NRC will consider the circumstances surrounding your reporting in determining the appropriate enforcement action, if any.

HOW DO I REPORT VIOLATIONS AND SAFETY CONCERNS?

If you believe that violations of NRC rules or the terms of the license have occurred, or if you have a safety concern, you should report them immediately to your supervisor. You may report violations or safety concerns directly to the NRC. However, the NRC encourages you to raise your concerns with the licensee since the licensee has the primary responsibility for, and is most able to ensure, safe operation of nuclear facilities. If you choose to report your concern directly to the NRC, you may report it to an NRC inspector or call or write to the NRC Regional Office serving your area. If you send your concern in writing, it will assist the NRC in protecting your identity if you clearly state in the beginning of your letter that you have a safety concern. The NRC's toll-free SAFETY HOTLINE for reporting safety concerns is listed below. The addresses for the NRC Regional Offices and the toll-free telephone numbers are also listed below. You can also e-mail safety concerns to NRC.Allegation@nrc.gov.

WHAT IF I WORK WITH RADIOACTIVE MATERIAL OR IN THE VICINITY OF A RADIOACTIVE SOURCE?

If you work with radioactive materials or near a radiation source, the amount of radiation exposure that you are permitted to receive may be limited by NRC regulations. The limits on exposure for workers at NRC licensed facilities whose duties involve exposure to radiation are contained in sections 20.1201, 20.1207, and 20.1208 of Title 10 of the Code of Federal Regulations (10 CFR 20) depending on the part of the regulations to which your employer is subject. While these are the maximum allowable limits, your employer should also keep your radiation exposure as far below those limits as is "reasonably achievable."

MAY I GET A RECORD OF MY RADIATION EXPOSURE?

Yes. Your employer is required to make available to you the information in your dose records (as maintained under the provisions of 10 CFR 20.2106). In addition your employer is required to provide you with an annual report of the dose you received in that monitoring year if the dose exceeds 100 millirem, or if you request an annual report.

HOW ARE VIOLATIONS OF NRC REQUIREMENTS IDENTIFIED?

NRC conducts regular inspections at licensed facilities to assure compliance with NRC requirements. In addition, your employer and site contractors may conduct their own inspections to assure compliance. All inspectors are protected by Federal law. Interference with them may result in criminal prosecution for a Federal offense.

MAY I TALK WITH AN NRC INSPECTOR?

Yes. NRC inspectors want to talk to you if you are worried about radiation safety or have other safety concerns about licensed activities, such as the quality of construction or operations at your facility. Your employer may not prevent you from talking with an inspector. The NRC will make all reasonable efforts to protect your identity where appropriate and possible.

MAY I REQUEST AN INSPECTION?

Yes. If you believe that your employer has not corrected violations involving radiological working conditions, you may request an inspection. Your request should be addressed to the nearest NRC Regional Office and must describe the alleged violation in detail. It must be signed by you or your representative.

HOW DO I CONTACT THE NRC?

Talk to an NRC inspector on-site or call or write to the nearest NRC Regional Office in your geographical area (see map below). If you call the NRC's toll-free SAFETY HOTLINE during normal business hours, your call will automatically be directed to the NRC Regional Office for your geographical area. If you call after normal business hours, your call will be directed to the NRC's Headquarters Operations Center, which is manned 24 hours a day. You can also e-mail safety concerns to NRC.Allegation@nrc.gov.

CAN I BE FIRED FOR RAISING A SAFETY CONCERN?

Federal law prohibits an employer from firing or otherwise discriminating against you for bringing safety concerns to the attention of your employer or the NRC. You may not be fired or discriminated against because you engage in certain protected activities, including but not limited to,

- asking the NRC to enforce its rules against your employer;
- refusing to engage in activities which violate NRC requirements;
- providing information or preparing to provide information to the NRC or your employer about violations of requirements or safety concerns; or
- asking for, or testifying, helping, or taking part in an NRC, Congressional, or any Federal or State proceeding.

WHAT FORMS OF DISCRIMINATION ARE PROHIBITED?

It is unlawful for an employer to fire you or discriminate against you with respect to pay, benefits, or working conditions because you help the NRC or raise a safety issue or otherwise engage in protected activities. Violations of Section 211 of the Energy Reorganization Act (ERA) of 1974 (42 U.S.C. 5851) include actions such as harassment, blacklisting, and intimidation by employers of (i) employees who bring safety concerns directly to their employers or to the NRC; (ii) employees who have refused to engage in an unlawful practice, provided that the employee has identified the illegality to the employer; (iii) employees who have testified or are about to testify before Congress or in any Federal or State proceeding regarding any provision (or proposed provision) of the ERA or the Atomic Energy Act (AEA) of 1954; or (iv) employees who have commenced or caused to be commenced a proceeding for the administration or enforcement of any requirement imposed under the ERA or AEA or who have, or are about to, testify, assist, or participate in such a proceeding.

HOW DO I FILE A DISCRIMINATION COMPLAINT?

If you believe that you have been discriminated against for bringing violations or safety concerns to the NRC or your employer, you may file a complaint with the NRC, the U.S. Department of Labor (DOL), or appropriate state entities. If you desire a personal remedy, a complaint may be filed with the DOL pursuant to Section 211 of the ERA or with appropriate state entities. Your complaint to the DOL must describe in detail the basis for your belief that the employer discriminated against you on the basis of your protected activity, and it must be filed in writing either in person or by mail within 180 days of the date of the alleged discriminatory action or the date you received any notice, in writing or otherwise, of an adverse personnel action, whichever occured first. Additional information is available at the DOL web site at www.osha.gov. Filing an allegation, complaint, or request for action with the NRC does not extend the requirement to file a complaint with the DOL within 180 days. To do so, you may contact the Allegation Coordinator in the appropriate NRC Region, as listed below, who will provide you with the address and telephone number of the correct OSHA Regional office to receive your complaint. You may also check your local telephone directory under the U.S. Government listings for the address and telephone number of the appropriate OSHA Regional office.

WHAT CAN THE DEPARTMENT OF LABOR DO?

If your complaint involves a violation of Section 211 of the ERA by your employer, the DOL provides a process for obtaining a personal remedy. The DOL will notify your employer that a complaint has been filed and will investigate your complaint.

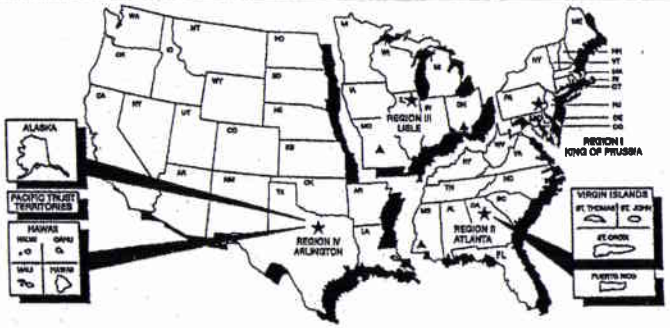
If the DOL finds that your employer has unlawfully discriminated against you, it may order that you be reinstated, receive back pay, or be compensated for any injury suffered as a result of the discrimination and be paid attorney's fees and costs.

Relief will not be awarded to employees who engage in deliberate violations of the Energy Reorganization Act or the Atomic Energy Act.

WHAT WILL THE NRC DO?

The NRC will evaluate each allegation of harassment, intimidation, or discrimination to determine whether sufficient information exists to initiate an investigation. Following this evaluation, an investigator from the NRC's Office of Investigations may interview you and review available documentation. Based on the evaluation, and, if applicable, the interview, the NRC will assign a priority and a decision will be made whether to pursue the matter further through an investigation. The assigned priority is based on the specifics of the case. The NRC may not pursue an investigation of low priority cases to the point that a conclusion can be made whether the harassment, intimidation, or discrimination actually occurred. Even if NRC decides not to pursue an investigation, if you have filed a complaint with the DOL, the NRC will monitor the results of the DOL investigation.

If the NRC or the DOL finds that unlawful discrimination has occurred, the NRC may issue a Notice of Violation to your employer, impose a fine, or suspend, modify, or revoke your employer's NRC license.



▲ - Callaway Plant Site in Missouri and Grand Gulf Plant Site in Mississippi are under the purview of Region IV. The Portsmouth Gaseous Diffusion Plant in Ohio is under the purview of Region II.

UNITED STATES NUCLEAR REGULATORY COMMISSION REGIONAL OFFICE LOCATIONS

A representative of the Nuclear Regulatory Commission can be contacted by employees who wish to register complaints or concerns about radiological working conditions or other matters regarding compliance with Commission rules and regulations at the following addresses and telephone numbers.

REGIONAL OFFICES

REGION	ADDRESS	TELEPHONE
I	U.S. Nuclear Regulatory Commission, Region I 475 Allendale Road King of Prussia, PA 19406-1415	(800) 432-1156
II	U.S. Nuclear Regulatory Commission, Region II Sam Nunn Atlanta Federal Center 61 Forsyth Street, S.W., Suite 23T85 Atlanta, GA 30303-8931	(800) 577-8510
III	U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	(800) 522-3025
IV	U.S. Nuclear Regulatory Commission, Region IV 612 East Lamar Blvd., Suite 400 Arlington, TX 76011-4125	(800) 952-9677

To report safety concerns or violations of NRC requirements by your employer,

telephone:

NRC SAFETY HOTLINE

1-800-695-7403

To report incidents involving fraud, waste, or abuse by an NRC employee or NRC contractor,

telephone:

OFFICE OF THE INSPECTOR GENERAL HOTLINE

1-800-233-3497

NHPP After Hours Emergency Number: 1-800-815-1016. During Work Hours Call: 1-501-257-1571.

Department of Veterans Affairs

MATERIALS PERMIT

Amendment No. **67**

In accordance with VHA Directive 1105.1 and reliance on statements made by the applicant, permission is hereby granted to receive, possess, transfer, and store radioactive materials listed below, and to use this material for the purpose and at the places listed below.

Permittee

1. VA Boston Healthcare System
2. 150 South Huntington Avenue
   Boston, Massachusetts 02130-4893

3. In accordance with **NRSC meeting of August 8, 2007,** Permit Number 20-00671-02 is amended to read as follows:
4. Expiration date: December 31, 2013
5. Docket or Reference Number: 030-01815

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount permittee may possess at any one time under this permit
A. Any byproduct material with Atomic Numbers 1-83	A. Any	A. 200 millicuries per radionuclide and 15 curies total
B. Fluorine 18	**B. Any**	**B. 10 curies**
C. Technetium 99m	C. Any	C. 10 curies
D. Molybdenum 99	D. Any	D. 10 curies
E. Iodine 131	E. Any	E. 1 curie
F. Xenon 133	F. Any	F. 500 millicuries
G. Any byproduct material with Atomic Numbers 3-83	G. Sealed sources	G. 1.5 curies per radionuclide and 15 curies total
H. Gadolinium 153 permitted by 10 CFR 35.500	H. Sealed sources (North American Scientific Model MED3601; and Isotope Products Laboratories Model NES 8412)	H. 300 millicuries per source and 3 curies total
I. Depleted uranium	I. Solid metal	I. 55 kilograms

9. Authorized use:

A. through **G.** Medical diagnosis, therapy, and research in humans. Research and development as defined in 10 CFR 30.4, including animal studies, instrument calibration, student instruction, and *in vitro* studies.

H. For use in ADAC Laboratories Model Vantage device for patient attenuation correction during SPECT Imaging.

I. Radiation shielding.

CONDITIONS

10. Permitted material may be used at the permittee's facilities located at 150 South Huntington Avenue, Boston, Massachusetts; 1400 Veterans of Foreign Wars Parkway, West Roxbury, Massachusetts; and 940 Belmont Street, Brockton, Massachusetts.

MATERIALS PERMIT
SUPPLEMENTARY SHEET

Permit Number: 20-00671-02
Docket or Reference Number: 030-01815
Amendment No. **67**

11. A. The Radiation Safety Officer for this permit is David E. Drum, M.D.

    B. The use of permitted material in or on humans shall be by an authorized user as defined in 10 CFR 35.2.

    C. Individuals designated to work as authorized users, authorized nuclear pharmacists, or authorized medical physicists as defined in 10 CFR 35 shall meet the training, experience, and recentness of training criteria established in 10 CFR 35, and shall be designated, in writing, by the permittee's Radiation Safety Committee.

    D. Permitted material for other than human use shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee.

12. Permitted material shall not be used in field applications where activity is released except as provided otherwise by specific condition of this permit.

13. Experimental animals, or the products from experimental animals, that have been administered permitted material shall not be used for human consumption.

14. This permit does not authorize commercial distribution of permitted material.

15. For sealed sources not associated with 10 CFR 35 use, the following conditions apply:

    A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

    B. Notwithstanding Paragraph A of this permit condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.

    C. Each sealed source fabricated by the permittee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

    D. In the absence of a certificate from a transferor indicating a leak test has been made within the intervals specified in the certificate of registration issued by the Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

    E. Sealed sources need not be tested if they contain only hydrogen 3, or they contain only a radioactive gas, or the half-life of the isotope is 30 days or less, or they contain not more than 100 microcuries of beta- and/or gamma-emitting material, or not more than 10 microcuries of alpha-emitting material.

    F. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transfer to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

    G. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the National Health Physics Program in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Nuclear Regulatory Commission regulations.

    H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the permittee or by other persons specifically licensed by the Nuclear Regulatory Commission or an Agreement State to perform such services.

16. Sealed sources containing permitted material shall not be opened or sources removed from source holders by the permittee.

17. A. The permittee shall conduct physical inventories to account for all sealed sources and/or devices received and possessed under this permit.

    (1) Quarterly, for sealed sources with either current activity greater than one millicurie or current activity greater than 1000 times the quantities in 10 CFR 20, Appendix C.

    (2) Semiannually, for all other sealed sources, except sources specifically exempted by 10 CFR 30.

    B. The permittee shall maintain records for five years from the date of each inventory and include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

    C. The permittee shall classify sealed sources, not in active use for their intended clinical or research purpose for a period of 24 months, as disused sources and evaluate the disused sources for disposal as expeditiously as possible.

    D. The permittee shall provide oversight for security of radioactive materials by:

    (1) Compliance with regulations per 10 CFR 20.1801 and 10 CFR 20.1802.

    (2) Prevention of adversary or unauthorized removal of, or access to, radioactive materials.

    (3) Use of two delay methods for sealed sources not in use.

    (4) Focus to security commensurate with possible risks of radioactive materials unauthorized use.

18. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by the Nuclear Regulatory Commission.

    B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

19. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Nuclear Regulatory Commission or an Agreement State to perform such services.

20. For radioactive material held for decay in storage other than that held in accordance with 10 CFR 35.92, the permittee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay in storage before disposal in ordinary trash, provided:

    A. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    B. A record of each disposal permitted under this permit condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

21. The permittee is authorized to transport permitted material only in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."

MATERIALS PERMIT
SUPPLEMENTARY SHEET

Permit Number: 20-00671-02
Docket or Reference Number: 030-01815
Amendment No. **67**

22. In addition to the possession limits in Item 8, the permittee shall further restrict the possession of unsealed byproduct material to quantities less than 10^5 times the applicable limits in Appendix B of 10 CFR 30, as specified in 10 CFR 30.35(d).

23. Incineration of permitted material for the purpose of disposal may be performed only as authorized by 10 CFR 20.2004(a)(2).

24. Except as specifically provided otherwise in this permit, the permittee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This permit condition applies only to those procedures required to be submitted in accordance with the regulations. Additionally, this permit condition does not limit the permittee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The Nuclear Regulatory Commission regulations shall govern unless the statements, representations, and procedures in the permittee's application and correspondence are more restrictive than the regulations.

    A. Application dated September 26, 2003
    B. Letter dated November 14, 2003 [additional information for renewal]
    C. Letter dated May 19, 2004 [add additional source]
    D. Telephone call with K. Acerra of June 6, 2007 [change Radiation Safety Officer]
    E. Memorandum dated October 26, 2007 [NOV response, except attachments to memorandum]

FOR THE DEPARTMENT OF VETERANS AFFAIRS

Date APR 29 2008

By E. Lynn McGuire
Director, National Health Physics Program
North Little Rock, Arkansas

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

FedEx Express

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CAD: 5250401/INET3010

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SHIP TO: (501) 257-1571 BILL SENDER

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

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